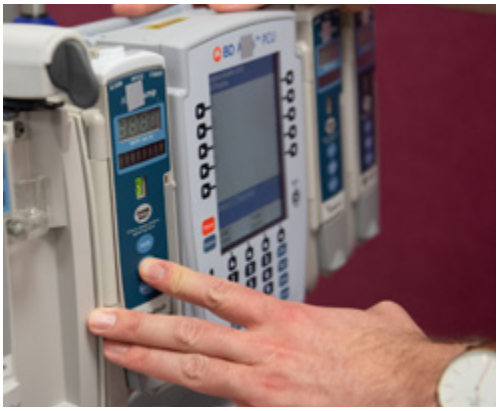
Australian Government
National Health and Medical Research Council





Ethical guidelines for cell, tissue and organ donation and transplantation in Australia

NHMRC

BUILDING
A HEALTHY
AUSTRALIA

This document is created by the National Health and Medical Research Council, in partnership with the Australian Organ and Tissue Authority

Publication details

Publication title:	Ethical guidelines for cell, tissue and organ donation and transplantation in Australia
Published:	2025
Publisher:	National Health and Medical Research Council (NHMRC)
Publication reference:	NH208
Online version:	www.nhmrc.gov.au/about-us/publications/ethical-guidelines-cell-tissue-and-organ-donation-and-transplantation
ISBN print:	978-0-6484644-6-4
ISBN online:	978-0-6484644-7-1
Suggested citation:	National Health and Medical Research Council (2025) Ethical guidelines for cell, tissue and organ donation and transplantation in Australia. Canberra: National Health and Medical Research Council
Cover images:	iStock Photos supplied by the Organ and Tissue Authority (OTA)

Copyright

Attribution

Use of images

Contact us

To obtain information regarding NHMRC publications or submit a copyright request, contact:

E: communications@nhmrc.gov.au
P: (02) 6217 9000

Ethical guidelines for cell, tissue and organ donation and transplantation in Australia

NHMRC

BUILDING
A HEALTHY
AUSTRALIA

Table of contents

Acronyms and abbreviations

Acronym	Definition
ABMDR	Australian Bone Marrow Donor Registry
ACGR	Australian Corneal Graft Registry
AHPRA	Australian Health Practitioner Regulatory Agency
ANZDATA	Australian and New Zealand Dialysis and Transplant Registry
ANZEDT	Australian and New Zealand Eye and Tissue Donation Registry
ANZOD	Australian and New Zealand Organ Donation Registry
ANZICS	Australian and New Zealand Intensive Care Society
ANZTCT	Australia and New Zealand Transplant and Cellular Therapies Ltd
AODR	Australian Organ Donor Register
ARTG	Australian Register of Therapeutic Goods
BMTSANZ	Bone Marrow Transplantation Society of Australia and New Zealand
COVID-19	Coronavirus disease 2019
Cth	Commonwealth
DCDD	Donation after circulatory determination of death
DNDD	Donation after neurological determination of death
EBAANZ	Eye Bank Association of Australia and New Zealand
ECD	Expanded criteria donor
GAEBA	Global Alliance of Eye Banking Associations
HIV	Human immunodeficiency virus
HSC	Haematopoietic stem cell
HSANZ	Haematology Society of Australia and New Zealand
NHMRC	National Health and Medical Research Council
NRP	Normothermic regional perfusion
OTA	Organ and Tissue Authority
SANOK	Senior Available Next of Kin
TGA	Therapeutic Goods Administration
TSANZ	Transplantation Society of Australia and New Zealand
VAD	Voluntary assisted dying
WHO	World Health Organization
WMA	World Medical Association
WMDA	World Marrow Donor Association

Acknowledgements

We acknowledge the sovereignty of Aboriginal and Torres Strait Islander Peoples as the original custodians of Australia and acknowledge and pay respect to Elders past, present and future.

1. Introduction

Transplantation is a highly effective treatment for advanced organ failure and other conditions associated with damaged or diseased cells and tissues, including blood and immune system disorders, burns, eye or musculoskeletal injuries, and disorders of genetic origin. Thousands of Australians benefit from transplants each year; however the need for donated cells, tissues and organs for transplantation often exceeds their availability. Many tissues and organs required for transplantation can only be donated after someone has died. Cells such as haematopoietic stem cells (HSCs) are generally renewable, and these and some non-renewable organs such as kidneys can be donated by individuals during life. People may also donate some tissues when these are removed as part of therapeutic surgery, such as femoral heads removed during hip replacement surgery. (See Chapter 2 for a summary of the organs, tissues and cells that can be donated and transplanted in Australia). All donations depend on the willingness of individuals or their families to donate in order to help others. Altruism and solidarity underpin Australia's donation programs, meaning the willingness to act for the benefit of others and the commitment to working together to achieve common goals. Ensuring ethical policy and practice in donation and transplantation activities within Australia is essential to maintain public trust and willingness to participate in donation, thus enabling more Australians to benefit from transplantation.

As discussed in Chapter 3, human cells, tissues, and organs may hold special value, or have cultural, social, and ethical significance for individuals, their families, and communities. Human cells, tissues and organs that are used in transplantation have thus been described by the World Health Organization (WHO) as 'exceptional medical products'.[1] In addition to the customary ethical concerns and considerations associated with delivery of health care, clinical decision-making, and allocation of healthcare resources in Australia, donation and transplantation activities may therefore be associated with specific and complex ethical considerations.

These guidelines aim to support understanding of ethical considerations and guide ethical decision-making in a range of donation and transplantation settings.

1.1 Role and purpose of the ethical guidelines

These guidelines have been developed with advice from many experts working in cell, tissue and organ donation and transplantation in Australia (see Appendix 2). They are intended to provide an overarching framework to guide ethical practice and inform decision-making by everyone involved in donation, transplantation and custodianship of human cells, tissues, and organs in Australia.

The ethical principles in this document are aligned with community expectations that altruistic donations of human cells, tissues and organs are treated respectfully, shared equitably, and used effectively for the benefit of all. They are consistent with established ethical and legal norms governing healthcare practice in Australia, and with respect for human rights and the rights of all individuals as patients receiving healthcare.[2–5]

These guidelines are also consistent with the guidance provided by the WHO and by donation and transplantation professional organisations, such as:

- *The World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation*,[1] endorsed by the Commonwealth of Australia.

- *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*,[6] supported by the National Health and Medical Research Council (NHMRC) and the Transplantation Society of Australia and New Zealand (TSANZ).
- The Global Alliance of Eye Bank Associations (GAEBA) Barcelona Principles on eye banking,[7] endorsed by the Eye Bank Association of Australia and New Zealand (EBAANZ).
- The World Marrow Donor Association (WMDA) International standards for non-directed HSC donor registries,[8] endorsed by the Australian Bone Marrow Donor Registry (ABMDR), and the WMDA ethical recommendations concerning 'donor commitment and patient needs'.[9]
- *The World Medical Association (WMA) Statement on Organ and Tissue Donation*.[10]

Other documents also provide guidance on donation and transplantation practice, including several ethics guidelines used within Australia as outlined in Chapter 3, and resources such as:

- *Clinical guidelines*, e.g., those developed by members of professional societies including the Haematology Society of Australia and New Zealand (HSANZ) and the Bone Marrow Transplantation Society of Australia and New Zealand (BMTSANZ) to provide guidance on management of haematology and oncology patients during the coronavirus disease 2019 (COVID-19) pandemic;11 those developed by TSANZ, to provide guidance for decision-making in organ transplantation based on clinical criteria and predicted transplantation outcomes;[12] those developed by the Australian and New Zealand Intensive Care Society (ANZICS), to provide guidance on the determination of death and deceased donation,[13] and those developed by EBAANZ, which articulate standards for quality and safety in eye banking.[14]
- *Implementation guidelines*, which describe detailed procedures and protocols at the local level, e.g., concerning tissue typing to allow matching of donor cells, tissues, or organs with potential recipients.
- *Information guidelines*, which provide information for potential donors, recipients and their families, carers and friends, e.g., those developed by transplantation units and hospitals, by the Australian Organ and Tissue Authority (OTA) and state and territory bodies, by various eye and tissue banking organisations,[15] and by the ABMDR.[16]

These ethics guidelines provide a framework to support ethical practice and inform decision-making by all those involved in Australia's donation and transplantation system, including:

- health professionals and others involved in the donation, transplantation, manufacture, allocation, distribution, and custodianship of human cells, tissues and organs
- potential donors and recipients of transplanted cells, tissues and organs, and their families, carers, and communities
- public and private institutions, such as hospitals, donation services, eye banks, umbilical cord blood banks, tissue banks, tissue manufacturers, and donor or transplant recipient registries
- governments and regulatory bodies.

1.2 Scope of the guidelines

The various types of cells, tissues and organs that are covered by these guidelines are described in detail in Chapter 2. They include HSCs obtained from bone marrow, peripheral or umbilical cord blood; tissues such as corneas, sclera, heart valves, skin and bones; and solid organs such as kidneys, hearts, and livers.

It is not always possible to clearly and consistently distinguish between donated and transplanted human biological materials that are cells, tissues, or organs; some tissues may be described as cells, and some tissues may be considered organs. In these guidelines, we refer simply to 'donation and transplantation' wherever ethical guidance may be considered generalisable to the broad categories of cells, tissues, and organs. In some instances, specific categories or types of materials are identified where these may be associated with specific ethical considerations.

The guidelines are focused on donation of cells, tissues, and organs for allogeneic transplantation, which means a donation from one individual that is transplanted in another individual(s).

These ethical guidelines are **not intended** to provide clinical advice for cell, tissue or organ donation or transplantation, nor do they apply to:

- blood donation or transfusion of blood or blood-related products
- gametes, ovarian or testicular tissue, or embryos
- faecal microbiota donation or transplantation
- autologous transplantation of cells or tissues
- xenotransplantation
- research activities involving human cells, tissues, organs; information collected from donors or transplant recipients; or cell lines derived from these sources, except where specified (see Chapter 12.7).

For information on these issues, readers are referred to specific guidelines, e.g., those developed by the NHMRC,[17–19] TSANZ, the ABMDR, the OTA, state or territory departments, or relevant professional or healthcare organisations and institutions.

All activities referred to in these guidelines must be carried out in compliance with existing law, legislation, and regulatory frameworks (see Chapter 3.5). The activities must also comply with relevant professional and accreditation standards and the maintenance of appropriate quality management systems.

1.3 Development of the guidelines

The process by which these guidelines were developed is outlined in detail in Appendix 2. Individuals and organisations that have contributed in a range of ways to the guidelines are also identified in Appendix 2.

1.4 Structure, use, limitations and content of the guidelines

The ethical guidelines provide explanation and discussion of a range of potential ethical considerations in donation and transplantation of cells, tissues, and organs.

Chapters 3-12 are arranged to focus on specific ethical considerations or sets of related ethical issues in donation or transplantation. They provide detailed explanations of ethical concepts and principles for those requiring nuanced guidance on a particular topic. They include links to further readings and resources curated in Appendix 1. In some chapters, examples illustrating particular points and summarised recommendations for ethical practice are presented in boxed text.

Some case studies are included to help readers reflect on ethical considerations in the context of hypothetical scenarios and consider how to apply the principles outlined in the guidelines. The case studies highlight the complex ethical issues involved in decision-making about donation and transplantation and the way in which the ethical principles and guidance can assist decision-making. In some instances, the case studies illustrate how ethical issues may be resolved.

Each chapter and the various Appendices are briefly described below in Chapter 1.4.3.

In addition, a Glossary comprises a list of key terms used in these ethical guidelines with brief explanations of their meaning, and a Reference list provides details of all the sources cited throughout the guidelines.

1.4.1 Using the guidelines

The guidelines are designed for use in a range of ways according to the needs and preferences of individuals. Some may choose to read the entire text, such as health professionals seeking to become familiar with a broad range of ethical issues in donation and transplantation. Others may prefer to read specific chapters to deepen their understanding of specific aspects of ethical practice in donation and transplantation or specific issues.

Individuals with experience in donation and transplantation may simply refer to relevant ethical recommendations at the end of each chapter when needed, for example if they encounter an ethical dilemma that is rare or new to them. Consulting the main text will help readers to understand the considerations underpinning specific ethical recommendations and thus assist them in interpreting and applying recommendations in the context of specific clinical situations.

The cases included in the guidelines are intended to help readers to reflect on ethical considerations in the context of hypothetical scenarios. Reviewing relevant cases will assist readers in understanding the potential significance of specific ethical considerations or issues and allow them to practice applying their knowledge and understanding of the relevant ethical recommendations. Some analysis of the cases is provided to support learning and reflection.

As many ethical considerations discussed in these guidelines are relevant in several chapters, hyperlinks are used to facilitate cross-referencing within the document. Readers can identify and access relevant sections of the guidelines by using the Table of Contents, or by searching for specific words within the document.

1.4.2 Limitations of the guidelines

These guidelines provide explanations of key ethical concepts and principles of relevance to decision-making in donation and transplantation, and brief discussion of important ethical considerations of relevance to specific issues that may arise in the context of donation and transplantation activities in Australia. Readers are encouraged to use the guidelines to help inform their evaluation of potential issues or ethically complex situations they may encounter.

Although some ethical recommendations are provided to assist in guiding decision-making in practice, this guidance does not provide definitive advice on specific actions that should be taken in any specific case. In clinical settings, decisions about the range of potential, clinically appropriate options for action and about the best course of action are the responsibility of health professionals providing care for patients. As discussed in Chapter 3.4 and Chapter 4, ultimate decisions regarding which course of action to pursue will depend on the values and preferences of the person(s) responsible for providing consent to treatment.

Ethical views and perspectives that are considered and recommendations that are included in these guidelines are not intended to represent the opinions or position of any contributor to these guidelines nor of any stakeholder. Several new and emerging issues are notably explored in these guidelines on which professional consensus may be lacking, or on which laws or regulations may be unclear or currently evolving.

1.4.3 Summary of chapters and appendices

- Chapter 1 provides an overview of the guidelines and their intended use.
- Chapter 2 describes the current system for cell, tissue and organ donation and transplantation in Australia and specific types of activities in donation and transplantation.
- Chapter 3 outlines the ethical principles and values that underpin policy and practice in donation and transplantation in Australia and provides a brief overview of relevant legislation. It also outlines an approach to ethical decision-making and management of issues such as conflicts of interest and conscientious objection.
- Chapter 4 explores ethical considerations in obtaining valid consent for donation and transplantation from adults and in decision-making about deceased donation.
- Chapter 5 explores special ethical considerations in the context of donation and transplantation involving children or adults who lack decision-making capacity.
- Chapter 6 discusses ethical considerations with regards to evaluation of risks and benefits in the context of donation and transplantation and how such evaluations guide decision-making about donation and transplantation.
- Chapter 7 provides information about key considerations with regards to respect for privacy and confidentiality in donation and transplantation activities, including anonymity requirements in non-directed donation, and ethical management of registries and of misattributed genetic relationships revealed during donor evaluation.
- Chapter 8 examines ethical concerns relating to equity in access to the benefits of donation and transplantation and in the distribution of burdens and risks that may be associated with donation and transplantation.

- Chapter 9 discusses the concept of self-sufficiency in organ and tissue donation and transplantation, as well as ethical considerations with regards to import or export of cells, tissues and organs and international travel for transplantation.
- Chapter 10 explores ethical concerns relating to commodification of human cells, tissues, and organs, such as use of financial incentives for donation, generation of profits, and trafficking in organs and tissues for transplantation.
- Chapter 11 examines a number of ethical issues that may arise in the context of deceased donation, including concerns relating to the determination of death and potential conflicts of interest in decision-making about end-of-life care, use of ante-mortem interventions to preserve opportunities for donation of tissues and organs, and donation following voluntary assisted dying or a conscious person's decision to cease life sustaining treatment.
- Chapter 12 examines several ethical issues that may arise in the context of donation and transplantation, including public solicitation of living organ donors, restricted or conditional non-directed donation, umbilical cord blood donation, and ethical considerations relating to innovative research in deceased donation and transplantation.
- Appendix 1 provides a summary of recommended readings and resources for each of the chapters in these guidelines.
- Appendix 2 outlines the process by which these guidelines were developed and identifies the various individuals and organisations that have contributed to them.

2. Overview of cell, tissue and organ donation and transplantation in Australia

Cell, tissue and organ donation and transplantation are made possible in Australia through State and Territory legislation and clinical guidelines which provide a governance framework and guidance for many important practices and procedures.

Many organisations and individuals play vital roles in supporting Australia's donation and transplantation systems. Conducting cell, tissue, and organ donation for transplantation in a safe, ethical, and medically appropriate way is the collective responsibility of government, professional organisations and the community.

2.1 Types of cell, tissue and organ transplantation

2.1.1 Cells for transplantation

Blood or marrow stem cells – known as haematopoietic stem cells (HSCs) - are donated by living donors and are used for treatment of a variety of blood disorders and other diseases, including blood cancers such as leukaemia and lymphoma. Human leucocyte antigen (HLA) matching between the donor and the intended recipient is ideally complete although degrees of mismatch are acceptable in certain circumstances. Many Australian recipients will find a suitable donor within their family, however the majority find matching donors within volunteer donor registries in Australia or around the world.

Table 2.1: Types of cells for transplantation and conditions leading to transplant

Cell type and source	Typical conditions leading to transplant
• Umbilical cord blood • Bone marrow • Peripheral blood stem cells	Blood or marrow stem cell transplants are potentially curative treatments for patients with a variety of blood and bone marrow diseases and syndromes. This includes blood cancers such as leukaemia and lymphoma, bone marrow failure syndrome (when the bone marrow doesn't produce the cells it should), blood disorders such as the haemoglobinopathies sickle cell anaemia or thalassemia, immunodeficiencies when the immune system doesn't work properly or inherited metabolic disorders.

More information about HSC donation and transplantation is available here: https://abmdr.org.au

2.1.2 Tissues for transplantation

Tissues used for transplantation include eye tissue, bone, other musculoskeletal tissue, cardiovascular tissue such as heart valves and blood vessels, and skin. Many of these tissues can only be donated after death. The main exception is bone, where the major source is from living donors who donate bone removed as part of hip joint replacement surgery.

Table 2.2 Types of tissue for transplantation and conditions leading to tissue transplants

Tissue type and source	Typical conditions leading to need for tissue transplant
Eye tissue e.g. cornea, sclera (from deceased donors)	Corneal transplants restore vision in people who have a damaged cornea. This damage can occur through infection, injury or diseases like keratoconus and Fuchs dystrophy. Scleral tissue can be used for surgical reconstruction or patch grafts to the eye and operations to treat glaucoma.
Heart valves, pericardium, blood vessels (majority from deceased donors)	Heart valves and pericardium are used in children born with heart defects and in adults with diseased heart valves. Blood vessels may be used to bridge vascular gaps or patch damaged vascular segments (aneurysms or strictures). Pericardium patches can be used to repair congenital paediatric heart defects and can also be used in ocular surgery in combination with glaucoma drainage devices.
Skin (from deceased donors)	Skin grafts are used as a critical lifesaving substitute in extensive burns as well as chronic and acute wounds.
Bone and other musculoskeletal tissue (living and deceased donors)	Bone grafts can be limb saving and restore function when used to replace bone that has been lost because of cancer or trauma. Bone can also be used to heal fractures, strengthen hip and knee joint replacements, repair curvatures of the spine (scoliosis) and in dental procedures. Tendons, ligaments and cartilage can be used to rebuild damaged joints.
Amnion (from living donors)	The amnion component of the placenta donated at birth can be utilised to treat a range of conditions such as burns, wounds, and ocular injuries, and for other purposes such as reconstructive surgery.

More information about eye tissue donation and transplantation is available here: Donation and Transplantation - EBAANZ

More information about other types of tissue donation and transplantation is available here: Donatelife - all about donation

2.1.3 Organs for transplantation

Organs that may be transplanted include the kidneys, heart, lungs, liver, pancreas, and the small intestine (see **Table 2.3**). Most organ transplantation is contingent on organs being donated after death, which is only feasible in limited circumstances. Living donation of some organs is also possible, most commonly the kidney.

Table 2.3 Types of organs for transplantation and conditions leading to organ transplants

Organ type and source	Typical conditions leading to need for organ transplant
Kidney (living or deceased donors)	Kidney failure is commonly caused by diabetes, chronic uncontrolled hypertension, chronic glomerulonephritis or polycystic kidney disease.
Liver (deceased donors and rarely partial liver from a living donor, usually parent to child)	Causes of liver failure include hepatitis B and C, alcoholic liver disease, and fatty liver disease. In children congenital biliary atresia is the most common cause leading to transplantation.
Lungs (deceased donor)	Chronic obstructive pulmonary disease (e.g., emphysema), cystic fibrosis, pulmonary fibrosis or pulmonary hypertension.
Heart (deceased donor)	Heart failure may be caused by ischemic heart disease, cardiomyopathy, congenital heart disease and valvular disease. Less commonly (<5%) heart transplantation is performed for acute heart failure due to cardiogenic shock complicating acute myocardial infarction or myocarditis.
Pancreas and pancreas Islets (deceased donor)	Type 1 diabetes, transplant usually requires a simultaneous kidney transplant, to treat diabetic kidney failure.
Intestine/multivisceral (deceased donor)	Short gut syndrome can lead to complications that require a segment or a whole intestine transplant. Bowel complications, e.g., malrotation and volvulus, adhesions, bowel necrosis due to blood clots, inflammation or tumours can also lead to transplantation.
Other combined transplants (deceased donors)	When there is more than a single organ failure, a combined transplant may be required. These commonly include heart/liver, heart/kidney, liver/kidney, kidney/pancreas and heart/lung transplant.

More information about organ donation and transplant is available here: https://transplant.org.au/types-of-transplant/

2.1.3.1 Other novel transplants – Vascularised composite allotransplantation

Vascularised composite allotransplantation (VCAs) involves the transplantation of a vascularised body part that functions as an anatomical or structural unit. The part may contain multiple tissue types such as skin, bone, muscles, blood vessels, nerves, and connective tissue. Examples include limbs, face, larynx, and abdominal wall. VCA is fundamentally more like organ transplant than tissue transplantation. Unlike internal organs, VCAs are usually also matched for size, skin colour, and gender, sex, and age range.

The need for a vascular composite allograft such as a face or hand/upper limb transplant is rare. There have been a limited number of VCA transplants performed world-wide and only one in Australia, a hand transplant in 2011.[20]

2.2 Legislation and clinical guidelines

Knowledge and application of relevant Commonwealth and State or Territory legislation is critical for appropriate decision-making in donation and transplantation.

2.2.1 Human Tissue Legislation

Legislation in each State and Territory governs donation and transplantation for clinical purposes (see Chapter 3.5.1). Although referred to as 'human tissue legislation' in accordance with the terminology used in much of this legislation, this is also inclusive of cells and organs.

Common features across all Australian jurisdictions include provision of a legal mechanism for authorising living and deceased donation of organs and tissues (see Chapter 4.3.1 and Chapter 4.4.1), disclosure of identity of donors and recipients (see Chapter 7.1.1.1), and prohibition against trading in human tissues with some limited exceptions (see Chapter 10.2).

2.2.2 Clinical guidelines

A number of the organisations described in Chapter 2.3 below are responsible for and involved in the development of clinical guidelines. Ownership of any document that is intended to guide clinical practice is determined by the professional group it applies to, the area of practice, and whether the document is a guideline, protocol, or standard operating procedure. Any changes to standards or policies undergoes a process of consultation, approval, and implementation. This can include endorsement by TSANZ, the Australian Donation & Transplant Coordinators Association (ADTCA), the OTA and any other relevant professional bodies.

2.3 Organisations and agencies involved in donation and transplantation in Australia

There are many different organisations and groups that play important roles and are integral to the success and safety of donation and transplantation in Australia. These include government and non-government organisations and agencies, hospitals, professional associations and societies, and community groups. There is a significant voluntary contribution of time and effort in both the professional and community areas. The following sections outline some key functions and features of some of these organisations.

2.3.1 Organ and Tissue Authority and organ donation agencies

The Australian Organ and Tissue Donation and Transplantation Authority, known as the Organ and Tissue Authority (OTA), was established in 2009 to manage the implementation of the national reform program. The goal of the national reform program is to implement a world's best practice approach to organ and tissue donation for transplantation. The OTA undertakes a leadership and coordinating role, working with state and territory governments, eye and tissue banks, clinicians, and the community, to develop and lead the implementation of initiatives to increase and improve the safety and efficiency of donation and transplantation.

The OTA contributes funding for the employment of donation specialist staff within hospitals and in each state and territory DonateLife Agency, which together comprise the DonateLife Network.

The DonateLife Network includes more than 90 hospitals across the country that cover more than 95% of deceased organ donation activity. The Network includes donation specialist nursing and medical roles, based both within hospitals, as well as in the DonateLife Agencies. Agencies include medical and nursing leadership and management roles, as well as staff with responsibility for health professional education, donor family follow-up and support, data and auditing, and community engagement and donation promotion. The DonateLife Network has responsibility for implementing clinical best practice, identifying and removing barriers to donation, managing donor referrals, undertaking donor assessment, providing family support and communication, coordinating the donation and retrieval processes as well as contributing to professional and community education.

DonateLife staff work closely with intensive care staff, emergency department staff, eye and tissue bank staff, hospital executives, and other key personnel to ensure all the steps for supporting donation are optimised. This includes ensuring all potential donation opportunities are recognised, that families of potential donors receive excellent care and communication, and that the process of donation is undertaken to a high medical and ethical standard.

For more information about the OTA and the role of DonateLife see: https://www.donatelife.gov.au

2.3.2 State and territory governments

The governance and financial resourcing of the donation and transplantation sector is complex with contributions at both a national and state/territory level. Much of the clinical activity around donation and transplantation happens in the public hospital system, regardless of the jurisdiction. Although state and territory governments are responsible for running and managing public hospitals, the federal government shares responsibility for paying for them, and also funds healthcare in the community or primary care via Medicare.

2.3.3 Organ transplant hospitals and surgical retrieval services

In Australia there are currently five states that provide organ transplant services. They are based in major public hospitals and known generally as 'transplant units'. There are differing organ transplant services available in each state, which are outlined in **Table 2.4**.

Table 2.4 Transplant units identified by jurisdiction (note these may change over time)

Transplant unit	Jurisdictions
Heart	NSW (including paediatric), QLD, VIC (including paediatric), and WA
Lungs	NSW, QLD, VIC (including paediatric), and WA
Liver adult	NSW QLD, SA, VIC, WA
Liver paediatric	NSW, QLD, VIC
Kidneys (adult and paediatric)	NSW, QLD, SA, VIC, WA
Intestinal and multivisceral	VIC
Pancreas including islets	NSW, SA, VIC

Deceased organ retrieval surgical teams are coordinated from every jurisdiction where transplant services are facilitated. The retrieval teams are comprised of specialised surgeons and other dedicated healthcare staff who travel from their respective hospitals to the donor hospital to perform the organ retrieval surgery. There are dedicated thoracic and abdominal retrieval teams that are dispatched depending on organs being retrieved and to which jurisdiction the organ will be transplanted. Jurisdictions without a surgical retrieval service rely on interstate retrieval services.

2.3.4 Immunogenetics, pathology and microbiology laboratories

There are five tissue typing laboratories in Australia located in the states with transplant units. The tissue typing laboratories have several functions:

- providing all HLA and immunogenetics testing for transplant compatibility between recipients and their donors for all deceased and living donor solid organ transplants and related and unrelated stem cell transplants
- providing pre and post transplantation testing for organ recipients
- every organ, eye and tissue donor undergoes infectious disease screening as part of routine workup processes. When required, microbiology testing of samples for the donor and/or the recipient are collected and tested. These samples are processed by the laboratories that have Therapeutic Goods Administration accreditation (see Chapter 2.3.5).

2.3.5 Therapeutics Goods Administration

The Therapeutic Goods Administration (TGA) has the remit to ensure the adequate level of safety and quality in biologicals used as therapeutic goods in Australia within the legislated Biologicals Framework.

This includes tissues (as Class II or Class III biologicals) but not whole organs which are excluded from TGA regulation. The TGA licences domestic facilities, such as eye and tissue banks, and assesses compliance to national quality and safety standards. These standards include requirements for donor risk assessment and exclusion criteria, graft processing, and storage conditions.

The TGA also verifies that imported tissue grafts distributed in Australia by tissue banks or intermediated by commercial distributors meet the same nationally required levels of quality and safety. Tissue transplants either donated and manufactured in Australia or imported must usually be approved by the TGA, in a process that includes inclusion on the Australian Registry of Therapeutic Goods (ARTG) before supply to end-users and use in transplantation.

The TGA also oversees tissue banks' responses to reports of non-compliance and leads investigations and responses to adverse events or reactions following transplantation, including effective product re-call where required.

For more information about the TGA, please see: https://www.tga.gov.au

2.3.6 Eye and tissue banks

Australia's eye and tissue sector comprises:

- public and private not-for-profit eye and tissue banks funded from a range of private and state government resources
- charitable organisations promoting and facilitating eye and tissue donation and
- commercial service providers.

The sector consists of banks that may focus on both eye and tissue grafts or tissue-derived products, only eye, or a single tissue, or they may collect and process different types of donated tissue. Collected tissues from a single donor are processed into numerous grafts. Processed grafts are stored and distributed for transplantation within their own jurisdiction or nationally.

Working closely with DonateLife Agencies, hospitals, and coronial services, eye and tissue banks cover all aspects of donation including the suitability assessment of potential eye and tissue donors, obtaining consent, the surgical retrieval of eye and other tissue, and the processing, manufacturing, storage and supply or distribution of eye and other tissue for use in transplantation.

Eye and tissue banks are required to operate under the regulatory and licensing system of the TGA. They are audited for compliance with the Code of Good Manufacturing Practice, Human Blood and Tissues.[21]

2.3.7 Blood and marrow stem cell donation and transplantation organisations

The Australian Bone Marrow Donor Registry (ABMDR) is the only organisation in Australia responsible for arranging blood or marrow stem cell donations for patients in need of an HSC transplant, who have not found a suitable match among relatives. The ABMDR recruits volunteer prospective HSC donors within Australia, facilitates the local or global search for suitably matched candidate donors or umbilical cord blood units for Australian patients and coordinates cell collection from selected donors and delivery to transplant centres. The ABMDR is accredited by the World Marrow Donor Association and sets local standards for collection and transplantation from unrelated blood and marrow stem cell donors.

Designated Australian 'transplant centres', such as major public hospitals within each state, are responsible for the selection of the most suitable cell source for their patient (i.e., blood or marrow stem cells from their selected related or unrelated donor, or umbilical cord blood); the clinical workup and collection of cells from donors related to

the patient; and the transplantation of cells. The clinical workup and collection of blood or marrow stem cells from an Australian donor unrelated to the intended recipient is performed at designated 'collection centres' – also major public hospitals. The collection, cryopreservation, storage, and release of cord blood within Australia is undertaken by public cord blood banks in New South Wales, Queensland, and Victoria.

The Commonwealth, State and Territory governments funds the ABMDR and the public cord blood banks.

2.3.8 Professional societies, colleges, and associations in Australia

There are several professional organisations that have a role in donation and transplantation in Australia. These are listed and briefly described below in **Table 2.5**.

Table 2.5 Professional societies, colleges and associations involved in donation and transplantation in Australia.

The **Australian and New Zealand Intensive Care Society (ANZICS)** seeks to advance all aspects of intensive care medicine including research, education, and resourcing. The ANZICS Death and Organ Donation Committee is responsible for the Statement on Death and Organ Donation which guides health professionals on death determination and other processes related to organ donation.[13] https://www.anzics.com.au/

Australian and New Zealand Transplant and Cellular Therapies Ltd (ANZTCT) is a society of clinicians, advanced trainees, scientists, medical graduates, nurses and pharmacists involved in the clinical or laboratory management of patients undergoing blood or marrow stem cell transplantation or with an interest in the field of blood or marrow or stem cell transplantation and cellular therapies research. https://anztct.org.au/

The **Australasian Donation & Transplant Coordinators Association (ADTCA)** seeks to promote collaboration amongst organ and tissue donor coordinators and transplant professionals and contributes to the development of best practice in organ donation through guidelines and Standard Operating Procedures. https://www.atca.org.au/

The **Biotherapeutics Association of Australia (BAA)** is the peak body representing cellular therapy and tissue bankers in Australia and New Zealand. Its mission is to be a forum to promote the exchange of information towards best practice, to issue guidelines and recommended practices, to formally represent the interests of its members nationally and internationally and provide expert advice where required.

The **College of Intensive Care Medicine of Australia and New Zealand (CICM)** is the body responsible for the intensive care medicine specialist training and education. Specialist training requirements include modules related to death determination, donation and communication. https://cicm.org.au/Home

The **Eye Bank Association of Australia & New Zealand (EBAANZ)** is the peak body for sight restoring tissue donation and transplantation within Australia and New Zealand. Through its Medical Advisory Committee EBAANZ articulates national standards for quality and safety in eye banking. https://ebaanz.org

The **Transplant Nurses Association (TNA)** represents nurses working in transplantation and seeks to advance opportunities for education, research and networking for its members. https://transplantnurses.org.au/

The **Transplantation Society of Australia and New Zealand (TSANZ)** aims to promote research, best clinical practice and advocacy to improve outcomes for transplant recipients and increase access to organ transplantation in Australia and New Zealand. https://tsanz.com.au/

Other organisations with an interest in organ donation and transplantation in Australia include:

- the Australian College of Critical Care Nurses Ltd (ACCCN) representing critical care nurses, https://acccn.com.au/
- the Australasian College for Emergency Medicine (ACEM) representing emergency medicine physicians, https://acem.org.au/
- the Australian and New Zealand Society of Nephrology (ANZSN) for health professionals committed to the prevention and treatment of kidney disease, https://nephrology.edu.au/
- the College of Emergency Nursing Australasia (CENA) representing emergency nurses, https://www.cena.org.au/about/about-cena/
- the Royal Australasian College of Surgeons (RACS) for training surgeons and maintaining surgical standards, https://www.surgeons.org/en

2.3.9 Community, special interest, and advocacy groups

Community, special interest, and advocacy groups play an important role in supporting donor families, transplant recipients and their families, or those with a chronic illness awaiting a transplant. These groups provide a forum for people who have or are experiencing a similar situation. Community groups are often strong advocates in promoting the importance of organ and tissue donation for transplantation. In most instances community groups are created and run by volunteers, with little monetary support other than through grants, sponsorship, and charitable donations.

Transplant Australia is a key community group supporting donors and recipients and their families: https://transplant.org.au. **Kidney Health Australia**, the peak body for kidney health provides education and support for those impacted by kidney disease: https://kidney.org.au/.

2.4 Pathways to deceased donation and determination of death

Donor organs and tissues need to be medically suitable for transplantation. This means being both of sufficient quality to perform the function required and free of diseases that pose a risk to the recipient.

The processes of organ and tissue donation after death share common key steps, including assessment of medical suitability and consent of family, the Coroner (when required), and the Designated Officer authorisation. The precise details for each of these steps, including their timing in relation to death determination may differ, and additional steps may be involved, according to the setting and nature of the donation.

Key steps in the deceased donation of organs are outlined in Chapter 2.5, and of tissues in Chapter 2.7.

2.4.1 Determination of death

In deceased donation the law and ethical practice require that organs and tissues only be removed after death has occurred, which is colloquially known as the 'dead donor rule' (see Chapter 11.1).

Death is determined using clinical criteria that focus either on the circulation of blood in a person's body (see Chapter 2.4.1.2), or on the functions of a person's brain (see Chapter 2.4.1.1).

Australia has a statutory definition of death that is specified in state and territory legislation (see Chapter 3.5.1.1) as:

- irreversible cessation of all function of the brain of the person; or
- irreversible cessation of circulation of blood in the body of the person.

The precise criteria and procedures for diagnosing death are determined by the medical profession, in accordance with this definition.[13]

Organ donation is possible following death in a limited number of circumstances, estimated to be about 2% of people dying in hospitals. This is primarily due to few deaths occurring in a manner whereby organs are in a condition suitable for transplantation.

2.4.1.1 Neurological determination of death

A small number of people die in hospital due to severe brain injury that culminates in irreversible cessation of all function of the brain while circulatory functions in the body are maintained artificially with the support of machines and medications. Death is diagnosed in these circumstances through clinical assessment that determines there has been irreversible cessation of all brain functions.

Commonly referred to as 'brain death', its diagnosis is more precisely referred to as the 'neurological determination of death' (see **Box 2.1**). Donation after the neurological determination of death (DNDD) comprises approximately 70% of deceased organ donation in Australia.

Box 2.1 The neurological determination of death

The permanent loss of all brain function and neurological determination of death follows certain types of extensive damage to the brain. It can result from a severe traumatic head injury, a stroke from bleeding (haemorrhage) or blockage of blood flow to the brain, brain infection, brain tumour, or following a period of prolonged lack of oxygen or blood flow to the brain.

When the brain is injured, it swells, and pressure builds up due to the constraint of the surrounding rigid skull. The pressure can reach a point where blood is unable to flow to the brain. If the entire brain dies, the person's brain will never function again – there is permanent loss of all brain and brainstem function. This includes loss of vital brain stem functions such as the ability to breathe and maintain blood pressure and body temperature. The condition differs from lesser forms of brain injury, including coma, post-coma unresponsiveness (vegetative state) and the minimally responsive state.[22]

Neurological death is only possible when a person is maintained on a mechanical ventilator, usually whilst receiving treatment in an intensive care unit (ICU). There are strict criteria and procedures for the neurological determination of death in Australia, which are outlined in the clinical guidelines of the Australian and New Zealand Intensive Care Society.[13] These include undertaking a careful neurological examination that confirms loss of crucial brainstem functions such as the ability to cough, blink, pupil constriction to light, and to breathe when temporarily disconnected from the ventilator.

It is a legal requirement if donation is to proceed, that two suitably qualified medical practitioners each undertake a clinical examination and independently determine that there is no brain function. In some circumstances the neurological examination cannot be solely relied upon for the determination of death and medical imaging tests demonstrating loss of blood flow to the brain are required.

Although death has been confirmed, the person's heart is still beating due to provision of medication supporting the circulation and the respiratory support provided by the ventilator and the person will feel warm and skin look pink due to blood flowing through the body. It is important that treating medical staff take time to explain the concept of neurological death to the family as the person does not have the usual appearance commonly associated with death.

DNDD provides the best conditions for organ donation as the surgical procedure can begin in the operating theatre whilst the heart is beating and blood flow continues to the organs, resulting in better transplant outcomes for some organs, particularly the liver and heart. The DNDD process is also more predictable with only a small proportion of initiated cases not proceeding to the surgical retrieval of transplantable organs.

The number of DNDD donors is limited by the low and decreasing incidence of brain trauma, stroke and other causes of neurological death observed in many developed countries including Australia.

2.4.1.2 Circulatory determination of death

The vast majority of deaths that occur in hospitals and in the community are determined using circulatory criteria. The 'irreversible' or permanent cessation of circulation in the body of a person is indicated by signs such as absent breathing, absent pulse, and absent heart sounds, in a context where efforts to restore circulation have been unsuccessful or are not planned.

Organ donation is feasible in only a very small number of such deaths (see **Box 2.2** below). In Australia, donation after circulatory determination of death (DCDD) accounts for approximately 30% of deceased organ donation.

Box 2.2 Determination of death using circulatory criteria in the context of organ donation

The determination of death using circulatory criteria requires certainty that cessation of the circulation is 'irreversible'. The term 'irreversible' used in the legislation is not ideal and in practice is taken to mean 'permanent', with it either being not possible to reverse the absence of the circulation or understood that no attempt will be made to reverse it.

When death is anticipated following withdrawal of supportive treatments, there will be no attempt to restart the circulation and so certainty of permanence is assured when the duration of cessation of circulation has extended beyond the possibility of its spontaneous resumption, known as autoresuscitation.[13]

Current evidence concludes that the circulatory determination of death requires absence of circulation for five minutes, with autoresuscitation not having been observed beyond this duration following withdrawal of supportive treatments. Given the risk of warm ischaemic damage to organs in DCDD, it is important to determine death as soon as possible and so no more than five minutes of circulatory arrest is recommended in clinical practice.[13]

The five-minute timeframe only applies in the context of controlled DCDD following withdrawal of supportive treatments. It does not apply following cardiopulmonary resuscitative attempts where there are reports of spontaneous resumption of the circulation up to 10 minutes post cessation of cardiopulmonary resuscitation. This phenomenon may occur as a consequence of the complex effect of the resuscitative efforts on the cardio-respiratory system.[13]

2.5 Key steps in the process of deceased donation of organs

Key steps in the process of deceased organ donation include:

- donor identification and referral (see Chapter 2.5.1)
- obtaining formal consents (see Chapter 2.5.2)
- assessment of medical suitability (see Chapter 2.5.3) and donor management (see Chapter 2.5.4)
- matching and allocation of organs to recipients (Chapter 2.5.5)
- donor management and end-of-life care
- the organ retrieval surgery, packaging and transportation (see Chapter 2.5.6).

The order of some of these steps and clinical practice details will vary depending on whether donation is occurring following death determined using neurological or circulatory criteria, and the specific circumstances of the donor. Some of these steps are detailed below.

2.5.1 Organ donor identification and referral

It is important that all potential deceased organ donors are identified and referred to donation services. To support this outcome and prevent missed donor opportunities, a process of routine 'notification' or 'referral' at end-of-life to donation services has been introduced in many parts of the world. In Australia this typically occurs in intensive care units and hospital emergency departments, when there is medical consensus that a patient is approaching the end of their life.[23]

This broad approach ensures all organ donation opportunities are identified and offered to the family. It also ensures that eye and tissue donation are considered and offered where appropriate.

Because of the complexities involved in deceased donation of organs, this process is time critical if organ donation is a possibility. Referral should occur directly after there is consensus about the patient's clinical situation, to allow assessment of suitability, time for family approach to offer donation and, where appropriate, for the donation coordination process to occur.

2.5.2 Obtaining formal consent

At the time of referral, Donation Specialists and Tissue Bank staff access the Australian Organ Donor Registration (AODR) to check the registration status of the patient. This information can be shared with the family to support the decision-making process if organ and/or eye and tissue donation is feasible. Even if donation is not possible, sharing this information with families has become standard practice in many hospitals to avoid families later questioning whether the opportunity to donate may have been overlooked, particularly if the person had registered to donate.

Box 2.3 The Australian Organ Donor Register (AODR)

The Australian Organ Donor Register (AODR) is the national register for people to record their decision about becoming an organ and tissue donor for transplantation after death. It is administered by the federal government through Services Australia.

There are several ways that people can register to be a donor on the AODR, including registration via www.donatelife.gov.au or via their myGov account linked to a Medicare online account. South Australian residents can also register on the AODR via their driver's licence application or renewal.

Registering on the AODR is voluntary. A list of organs and tissues is provided with the option to donate all or just those selected. It is also possible to use the AODR to register the decision to not be a donor.

To register, a person must be 16 years or older.

People are encouraged to register their decision on the AODR and to tell their family about their decision about being an organ and tissue donor. The AODR is checked by authorised clinical personnel, usually donation specialist staff, and the patient's registration status is shared with the family as part of the donation discussion seeking informed consent. It is practice in Australia to not proceed with donation if the family maintain an objection, even when the person has registered to donate. Families are more likely to follow a person's decision or preferences if they know about them from prior conversations.

See Chapter 4.4.2 for a discussion of ethical considerations relating to donor registration and consent for deceased donation.

The context in which organ, eye and tissue donation is possible is most often where a death has occurred suddenly and unexpectedly. Family members are experiencing enormous stress and grief and require support, compassion, and care. The donation process takes time and alters the family's experience of the end-of-life of their loved one. The participation and assistance of family members is required for providing vital health and lifestyle information that is important for improving the safety of the donation and transplantation. Guidelines and professional education are available to ensure clinicians and donation specialists have the knowledge and skills to best support and communicate with potential donor families at this time.[23]

The timing and approach to decision making about deceased organ donation may vary depending on the relevant donation pathway, as discussed below, as well as the preferences of the potential donor or donation decision-makers.

Further authorisation is also required from the coroner for coroner reportable cases and a Designated Officer (see Chapter 2.5.2.3).

2.5.2.1 Timing of decision making in DNDD

In the context of DNDD, it is usual practice for attending staff, including the Donation Specialist, to raise donation with family only once the person has been confirmed deceased, as the certainty of death may assist families in subsequent decision-making about donation. If the family consent to donation, the assessment for donation suitability and organisation of the surgical donation procedure occurs after death and many families use this time to undertake end-of-life rituals and to spend time with

their relative. The donor is taken to the operating theatre attached to the mechanical ventilator with their heart beating and circulation present.

Donation is sometimes raised by family prior to neurological death developing, often to express interest in donation and sometimes to indicate a lack of support. Staff may also raise donation prior to neurological death developing when it is necessary to decide whether to continue supportive treatments that are deemed no longer medically beneficial to the patient.

In these situations, continuation of supportive treatments may be offered to see if loss of brain function will occur for the purpose of subsequently facilitating donation, with a mutually agreed time for review of this plan, for example, in 12 to 24 hours. This discussion should include an explanation of the differences in donation and recipient outcomes that might occur under DNDD and DCDD conditions if both options are possible. (See Chapter 11.4 for discussion of ethical considerations relating to intensive care efforts aimed at preserving opportunities for organ donation).

2.5.2.2 Timing and decision making in DCDD

When DCDD is considered feasible, it is only raised with family once there has been agreement to withdraw treatments because they no longer offer medical benefits for the patient, given the patient's prognosis. This separation of decision-making is important to avoid any perceived conflict of interest regarding the decision-making for proceeding to withdrawal of treatment, end-of-life care, and about donation.

If the family (or rarely the conscious, competent patient - see Chapter 11.6) agrees to donation, the assessment for donation suitability and organisation of the surgical donation procedure occurs prior to death. Families often use this time to undertake end-of-life rituals and to spend time with their relative. The family may be with their relative at the time that treatment is withdrawn and during the dying process.

It is explained to family that organ donation procedures and retrieval surgery need to begin with minimal delay following death to limit any deterioration of organs due to lack of blood flow, so they will have limited time with their relative after the circulation has ceased and death has been confirmed. It is also explained to families that if death does not occur within the required timeframe, organ donation will not occur, although eye and tissue donation may still be possible.

2.5.2.3 Authorisation of deceased donation

There are several agreements required before donation can proceed after death. These are undertaken according to law and current best clinical practice guidance.[23] In all Australian jurisdictions there is a legal basis for the removal of organs (and tissues) after death, for the purpose of transplantation (see Chapter 3.5.1).

Ethical considerations in deceased donation decision-making, including discussion of the implications of donor registration, and the requirements for consent for donation are explored in detail in Chapter 4.4.

From a procedural perspective, authorisation for donation from a designated officer (see **Box 2.4**) is required before donation can proceed. If the circumstances of death meet criteria for it to be reported to the coroner, consent from the coroner for donation to proceed is required (see Chapter 4.4.1.1). In Australia, approximately 50% of all organ donors have a cause of death that is reportable to the coroner and, in the vast majority, the coroner places no limitations on donation.

Box 2.4 Role of the Designated Officer

All Australian state and territory laws recognise the specific role within a hospital of a designated officer responsible for authorising the removal of organs and tissue for the purpose of transplantation, or other therapeutic, medical, or scientific purposes. The designated officer has the responsibility to ensure that the removal of organ and tissues is in accordance with the law.

The designated officer needs to determine that the requirements of the legislation are met, which include those related to death determination, individual or family consent or lack of objection and, where relevant, coronial agreement to donation.

The officer must ensure that the deceased patient had no objection to donation, and a senior available next-of-kin consents to or has no objection to donation occurring for the deceased patient (according to state/territory legislation). For reportable deaths they must also determine that the coroner has provided consent or conditional approval to donation of organs and/or tissues, or the coroner has advised that consent is not required (as permitted by jurisdictional legislation).

2.5.3 Assessment of medical suitability for deceased organ donation

Donor medical suitability assessment includes individual organ assessment for transplant suitability as well as determining whether there are disease risks that may preclude donation of organs or tissues. Different medical criteria may apply depending on which organs are being considered for donation, and the characteristics of individuals awaiting transplantation at a particular time.

Criteria for donor suitability have evolved over time, including those relating to age (young and old), chronic health conditions, and other conditions that may pose an increased risk of disease transmission to recipients. Advances in organ transplantation medicine, for example, have led to improved survival and quality of life for organ recipients, even when proceeding with the transplantation of non-ideal organs. There are very few absolute medical exclusions to organ and tissue donation.

A careful evaluation of the potential donor is important to the quality, safety, and efficacy of donation. This information gathering is undertaken by a donation specialist nurse and involves obtaining health, lifestyle, and travel history of the donor from the next-of-kin, performing a clinical examination, and undertaking additional tests including blood testing for infectious diseases and radiological investigations. The potential donor's medical records may be accessed and reviewed, and additional health information may be sought from the patient's general practitioner and other healthcare providers, if necessary, to ensure that a sound determination can be made of donor suitability. Liaison with transplant specialists, and other experts may occur if advice on specific disease risks is required.

Any tests are conducted with the agreement of the family after suitable explanations and may occur after (in DNDD) or before (in DCDD) death is certified.

The organ 'donor work-up' process that includes all these steps can take many hours. There must be a reasonable prospect of at least one organ being transplantable before the decision is made to proceed to organ retrieval surgery. The scheduling of the organ donation operation is influenced by access to the operating theatre at the donor hospital, and the availability of the surgical retrieval team(s) who usually travel from the

transplant hospital(s). This can typically mean a 24 hour or longer period between the family approach to offer donation and the donation surgery.

2.5.4 Donor management and end-of-life care

The development and sequelae of neurological death can be associated with physiological changes that require careful monitoring and supportive treatment. It is usual for treatments to be maintained or even increased in order to preserve the possibility of donation. Where donation will occur following the circulatory determination of death, it is equally important that careful and expert intensive care treatment continue up until the time of withdrawal of treatment for planned DCDD.

This approach continues until it is appropriate for donation to be raised with the family. If the family decline donation, supportive treatments are ceased at a time agreed with the family, who may choose to be present. If the family agree to donation, treatment will continue in intensive care until the donor assessment and work up is complete and the organ donation surgery can be commenced.

Treatments that are continued or procedures undertaken before death for the specific purpose of facilitating organ donation, may be described as 'ante-mortem interventions' for donation. These treatments include mechanical ventilation, the use of intravenous fluids and medications to support blood pressure and circulation, as well as other general treatments that are standard in intensive care.

In DCDD cases, ante-mortem interventions are sometimes viewed more narrowly as those targeted at limiting ischaemic damage to transplantable organs, such as the administration of a blood thinner medication just prior to death to reduce blood clots forming in organs for transplantation.

Laws relevant to consent for ante-mortem interventions are not uniform in Australia (see Chapter 11.4.1). Clinicians must ensure that ante-mortem interventions comply with jurisdictional legislation, guidelines, and hospital protocols. See Chapter 11.4 for a discussion of ethical considerations relating to ante-mortem interventions for donation.

When treatment is withdrawn (ceased) in DCDD cases, it is usual practice for there to be simultaneous cessation of mechanical ventilatory support, usually with removal of the breathing tube, along with ceasing any intravenous infusions being administered to support the circulation. Retrieval teams and/or transplant units have no role in guiding any aspects of this care. Donation and treating healthcare staff continue to monitor and observe the patient and provide support to the family if they have chosen to be present.

Once circulatory arrest has been observed for five minutes, an attending doctor formally examines the patient and declares death, and the deceased patient is moved to the operating theatre. If death does not occur within the timeframe required for successful organ donation and transplantation, the family are informed, and end-of-life care continues to be provided by attending staff. Eye and tissue donation may still be possible.

2.5.5 Matching and allocation of organs to recipients

The organ allocation process is designed to provide the greatest benefit from available organs while also considering equity of access to transplantation. The allocation process is a complex and time-critical process influenced by a range of factors including characteristics of potential transplant recipients – 'transplant candidates' – such as medical need, urgency, wait list time; donor/recipient suitability; and logistics.

Organ allocation takes no account of race, religion, sex, gender, social status, disability or age (unless age is relevant to the organ matching criteria).

Specific criteria for the allocation of organs have been developed by professional groups to ensure an equitable and transparent access to transplantation.[12] Organs such as the heart, lungs, liver and pancreas are matched to recipients by blood group, size, compatibility and urgency. There is a national allocation mechanism that prioritises 'urgent' listed patients with a high risk of imminent death.

Kidneys are matched according to blood group and immunological compatibility, urgency, wait list time and more recently, 'survival matching'. Survival matching involves preferentially allocating better quality donor kidneys to recipients predicted to have a longer life-expectancy after transplantation, and donor kidneys with shorter estimated survival to recipients predicted to have a shorter life expectancy. (See Chapter 8.4.3.1).

OrganMatch® is a recently developed electronic system in Australia that manages transplant waiting lists and enables optimal matching and allocation of organs according to the agreed criteria.[12]

2.5.6 Organ retrieval surgery, organ packaging and transplantation

There are processes in place within each state and territory for the mobilisation of surgical retrieval teams who attend the donor hospital operating theatre to undertake the donation surgical procedure. Key staff who attend from transplant units include surgeons, anaesthetists, perfusion technicians and transplant coordinators. Team members from the local donation hospital include theatre nursing staff, operating theatre technicians, anaesthetists and surgical assistants. The donation specialist nurse also attends the retrieval surgery to coordinate the retrieval surgery, including managing logistical arrangements, documenting the process, and patient advocacy.

During the retrieval surgery, organs are further assessed for suitability by retrieval surgeons in consultation with transplant surgeons and physicians. Arrangements for the transportation of organs are made according to the organ type and whether organs are for local use or for transport interstate or between Australia and New Zealand (see Chapter 9.1.2).

At completion of the retrieval surgery the operating theatre staff and donation specialist nurses will ensure the deceased has appropriate dressings in place and prepare the deceased for transfer to the mortuary or another suitable viewing area where the family can spend time with their relative if they have elected to do so. The family are advised about the donor's appearance, which is minimally affected by the donation procedure, and provided with support at the time of the viewing by hospital or donation staff.

After donation, family follow up and support is offered by the DonateLife agency Family Support Service.

2.6 Assessment for organ transplant waiting list

To be wait-listed for organ transplantation from a deceased donor, patients must be referred to a transplant unit for assessment and meet the relevant eligibility criteria. Patients are usually referred for assessment for transplant suitability when they have end-stage organ failure, optimal alternative treatments have been provided, and their medical specialist believes they will benefit from a transplant.

The process of determining eligibility for transplantation involves assessment against eligibility criteria by a multidisciplinary team at the transplant unit — this takes into consideration medical history and other relevant factors (such as the ability to adhere to medical therapy) that affect transplantation outcomes.[12]

While they are waiting for a transplant, potential recipients receive support from a multidisciplinary team who keep them and their family informed of developments and timelines. Waiting times for transplantation vary according to organ type, the availability of an organ suitable to the individual and the urgency of the potential recipient's need for transplantation. In some circumstances it may be several years before the potential recipient is offered an organ.

The transplant team regularly reviews potential recipients to ensure that they remain suitable for transplantation. Individuals may be assessed as no longer eligible for organ transplantation if their condition changes, either because their organ function improves to a point that transplantation no longer offers a benefit or because their condition deteriorates to the point where they no longer meet the eligibility criteria.[12] Some transplant candidates may also receive a transplant from a living donor and therefore leave the waiting list.

If a potential recipient or their physician disagrees with an assessment made by the transplanting team regarding eligibility for transplantation, processes are in place to enable provision of a second opinion. (See Chapter 6.5.1 for a discussion of ethical considerations in evaluation of candidates for organ transplantation).

2.6.1 Acceptance of a deceased donor organ offer

When patients are being assessed and waitlisted for organ transplantation, a process of education and information provision is required so that they become informed about the potential benefits and risks of transplantation. This information sharing can occur at individual appointments, at group education sessions and through written information.

The conversation with the patient regarding consent to receive organs of differing quality or increased risk of disease transmission should occur early, ideally at the time of consent to waitlisting, and should be revisited periodically to consider changes in patient priorities and health status.[12]

Some transplant units have a specific program whereby recipients may choose in advance whether they wish to be offered donor organs with certain characteristics (e.g., increased viral risk donor organs). This prior information sharing, and 'pre-consent' is important because, at the point of an actual donor organ offer, there is limited time for the transplant team and waitlist patient to confer and decide whether to accept the offered organ (e.g., 60 minutes for decision-making about kidney offers and 30 minutes for other organs). Some patients may be reliant on surrogate decision makers if they are unable to consent due to decision making impairment arising from illness, such as acute liver failure, or for other reasons.

Decision-making is particularly complex when the organ being offered may have a lower likelihood of providing optimal outcomes. Characteristics of the donor organ and recipient factors all need to be weighed, including the likely benefit from transplantation of the organ on offer, urgency of need and likelihood of subsequent organ offers, and deterioration of health status while waiting for transplantation. For example, potential recipients who are stable on medical therapy may find the expected outcomes associated with transplantation of such an organ less acceptable than would

potential recipients who are advanced in age or extremely unwell who might see this as increasing their survival prospects. Thus, organs that may carry an unacceptable risk for some individuals may provide benefit for others. This balance must be decided on a case-by-case basis by the transplant team and the potential recipient (see Chapter 6.6).

Occasionally the recipient may not be able to accept an offered organ due to acute health issues (e.g., current infection) or logistic factors (e.g., unable to get to the transplant centre in time).

2.6.2 Transplantation

Once an organ offer is accepted there is a short time for preparation for the transplant surgical procedure. The potential recipient will need to travel to the transplanting hospital if they are not already an inpatient. Some waitlist patients who live in remote areas or interstate relative to the transplant centre may need to relocate to be within accessible distance to the hospital if a suitable organ offer becomes available.

Certain tests and treatments may be required prior to the transplant surgery. These may include routine pre-surgery tests such as standard blood tests and blood cross matching in case a transfusion is required as part of the surgery and routine pre-surgery medications. Specific treatments related to transplantation may also be required such as a dialysis treatment for renal failure patients, or other specific treatments to help reduce rejection.

2.6.3 Post transplant care

Heart, lung, and liver transplant patients are routinely admitted to the intensive care unit immediately after transplant surgery. Many require a period of mechanical ventilation and other support because of the complexity of the surgery and their underlying health state.

Most kidney and kidney-pancreas transplant recipients do not require intensive care support post-transplant surgery, although a proportion of kidney transplant recipients may require support with dialysis until the transplanted kidney is adequately functioning.

Careful assessment of transplant organ function and the overall health status requires close monitoring of vital signs, regular blood, and other tests. Immunosuppression medications are administered to prevent rejection of the transplanted organ.

After sufficient recovery, which may include a period of rehabilitation in a dedicated facility, recipients are discharged home with initially frequent follow up by the transplant centre. For some kidney transplant patients, follow up is undertaken by referring satellite renal units to enable their return home. A careful handover of any concerns and specific surveillance issues is required. Life-long medical review, monitoring of organ function and general health, fine-tuning of immunosuppression, and surveillance for complications that transplant recipients are at risk of such as infection and malignancy, or other organ specific complications, is also required.

2.7 Key steps in the process of deceased donation of tissues

More people are eligible to donate eyes and tissue compared to organs due to the tissue remaining suitable up to 24 hours after circulation permanently ceases.

Key steps in the process of deceased donation of tissues are outlined below. They include:

- donor identification and referral (see Chapter 2.7.1)
- assessment of medical suitability (see Chapter 2.7.2)
- family approach and authorisation (see Chapter 2.7.3)
- the tissue retrieval surgery and donor management (see Chapter 2.7.4)
- storage and allocation of tissues (see Chapter 2.7.5)
- processing, manufacture and use of tissues (see Chapter 2.7.6).

2.7.1 Identification and referral of potential tissue donors

The method of donor identification and referral practices varies between jurisdictions, some with direct referrals from hospitals and others through direct electronic notifications to eye and tissue banks through the hospital medical records systems once a person is identified as deceased.

Some jurisdictions also have a close relationship with the coronial service, such that deaths reported to the coroner and admitted to the forensic mortuary are routinely identified and referred, other relationships include funeral homes and aged care facilities.

2.7.2 Medical suitability for tissue donation

Staff from eye and tissue banks undertake a thorough medical suitability assessment to ensure the safety of donation for transplantation. A donor suitability assessment and health questionnaire are undertaken with the family by eye or tissue banking staff by telephone, if not already completed by nurse donation specialists as a part of potential solid organ donor work-up (see Chapter 2.5.3). Further medical suitability information is obtained from sources including hospital personnel, the patient's general practitioner or other health providers. Donors are tested for blood borne viruses and transmissible infectious diseases.

2.7.2.1 Eye tissue suitability

Medical suitability for eye donation is broad with only a few contraindications, such as human Immunodeficiency virus (HIV) and hepatitis. Active cancer (other than haematological cancer and metastatic melanoma) is not an absolute contraindication. Donor age is not as important as it is for organ donation with most eye donors aged in their 70s. Having impaired vision does not prevent eye donation.

2.7.2.2 Tissue suitability

A single deceased donor can provide tissue that may be transplanted into many different individuals. Medical suitability criteria for deceased tissue donation are often narrower because donors risk transmitting disease to many recipients and there are alternative therapeutic options for many types of tissue transplant. Cancer, most infections, and many immunological and degenerative conditions are contraindications to tissue donation.

2.7.3 Family approach and authorisation

Deceased donation of tissues usually does not involve any changes to end-of-life care before death.

Once medical suitability has been established by the relevant eye and tissue bank and the AODR has been checked for registration status, the family approach may be undertaken by hospital staff (when the person has died in hospital) or by the eye and tissue bank staff, usually by telephone contact in the hours after death.

When death and eye and/or tissue donation is to occur in a hospital, authorisation from the designated officer of the hospital must be provided. Reportable deaths require consent from the coroner for eye and /or tissue donation to occur (see Chapter 4.4.1.1).

2.7.4 Eye and tissue donation surgery

The eye donation procedure can take place in the hospital ward, mortuary, operating theatre if organ donation is also occurring, funeral home, coronial services, or donor tissue bank facility. Procedures for donation of other tissues may occur in the hospital operating theatre, mortuary or a dedicated tissue banking facility, depending on local processes, availability, and access to a suitable environment.

At the completion of retrieval procedures, depending on which tissues have been donated and according to the preferences of the donor and their family, the deceased is prepared for transfer to the mortuary or funeral services.

The family are advised about the donor's appearance and steps may be taken to preserve the donor's appearance. For example, eye donation, whether whole or in-situ retrieval occurs, prostheses are used to maintain the shape and appearance of the eye. Similarly, when long bones are donated, these may be replaced with protheses to maintain the shape of the donor's limbs.

2.7.5 Storage and allocation of tissues

In contrast to organs, tissues can be stored for longer periods of time before being distributed for transplantation. While corneal tissue must be transplanted within 6 – 30 days following the donor's death, other tissues may sometimes be stored for up to 10 years.

Most eye banks work closely with ophthalmologists who perform corneal transplants and align availability of eye tissue as surgeries are scheduled. Tissue banks may also follow 'in house' distribution protocols, where the close interaction between the tissue banks and the community of end-users such as surgeons who use tissue grafts establishes the priorities of access where needed and in scenarios of undersupply or emergencies (e.g., skin for burns).

Tissues can be packaged and transported under controlled conditions across national and international borders. Thus, not uncommonly, tissues donated and processed in one Australian jurisdiction may be delivered for transplantation to a recipient residing in another state or territory.

Exportation of tissues is not a frequent event and over time has been mostly limited to corneal tissue (when local availability was deemed sufficient and in a formal international collaboration) or in emergency situations. (See Chapter 9.3 for a discussion of ethical considerations relating to movement of tissues and organs across borders.)

2.7.6 Processing, manufacture and use of tissues

Tissues collected from a single donor can be processed into numerous grafts. Work must take place in TGA-licenced tissue banking or manufacturing facilities where controlled environments and audited processes ensure resulting transplants retain unique biological quality and efficacy and remain safe to recipients.

Like medicines, eye and tissue donations are processed in accordance with TGA approved technical dossiers and must be listed in the Australian Registry of Therapeutic Goods (ARTG). Listing in the ARTG is a pre-requisite for distribution in Australia (see Chapter 2.3.5).

Processing may range from cleaning and trimming through to processes where tissues are cut or ground into specialised formats to cater for specific surgical needs. Furthermore, changes in the biological response post transplantation can be enhanced by effecting changes in the original components, such as removing cells from the skin dermis, the demineralisation of bone, chemical enhancement and the addition of delivery media.

2.8 Living donation of cells, tissues and organs

Living kidney donation is the most common type of living organ donation in Australia (see Chapter 2.8.1). Living partial liver donation, usually from a parent to their infant child, is also undertaken in Australia, although infrequently. The living donation of organs such as lung, pancreas, and intestine is also possible; however, procedures for donation of these organs can be associated with significant risks, and at this time these procedures are not conducted in Australia.

Living tissue donation typically occurs as part of a therapeutic procedure whereby tissue removed as part of the procedure can be used for transplantation (see Chapter 2.8.2), except for most haematopoietic stem cell donations (see Chapter 2.8.3).

2.8.1 Living organ donation

Living organ donors go through extensive testing to check their suitability to donate. The donor must be in good physical and psychological health. The ethical implications of evaluating risks and benefits of living donation are discussed in Chapter 6.3.

Financial support to offset the financial costs of being a living donor is provided by the Australian Government Supporting Living Organ Donors Program.[24]

2.8.1.1 Living kidney donation

Short term risks of living kidney donation mostly relate to the surgical procedure, which is usually performed as laparoscopic (keyhole) surgery but occasionally requires open surgery. Pain, reduced mobility, and time required off work are typical. More serious complications are infrequent and include bleeding, infection, thrombo-embolism (blood clots), and, rarely, death. Longer term risks include a small increase in the likelihood of chronic kidney disease and requirement for dialysis. Assessment of donors seeks to exclude individuals at greater life-time risk of renal failure, although donors with co-morbidities are not excluded.

Box 2.5 Categories of living kidney donation

Directed donation	Living kidney donation is most commonly 'directed' to a known individual, often a family member or close friend. This person may be a relative who is genetically related or not related by blood, a partner or close friend, or another person known to them.
Non-directed donation	Non-directed living kidney donation also occurs, whereby an individual donates a kidney to an unknown individual who is determined by agreed local or national guidelines. Non-directed donation is sometimes also called 'Good Samaritan' donation, because they are volunteering to help a stranger, or 'altruistic' donation because it is assumed the donation is for purely altruistic reasons. Most donations of organs and tissues are altruistic. Kidneys from non-directed donors may be allocated to the paired kidney exchange program (see Chapter 2.8.1.2) which can lead to the transplantation of multiple people in a chain and thereby maximise the benefit from the donation.

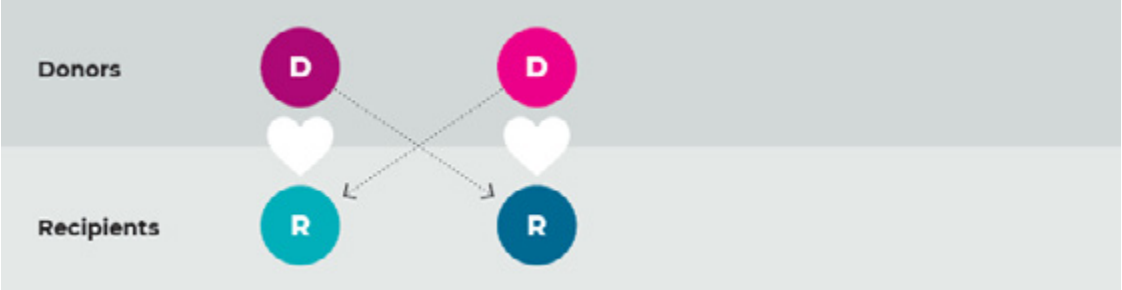
2.8.1.2 Paired kidney exchange

The paired kidney exchange program in Australia has increased the opportunity for kidney donation and transplantation for some individuals. Paired kidney exchange programs provide a mechanism to 'swap' kidneys between prospective living kidney donors and their intended transplant recipients. This is most used when the individual pairs are biologically incompatible although compatible pairs can also enter kidney exchange programs to improve their tissue type matching and thereby the long-term outcome of the transplant.

The Australian paired kidney exchange program commenced in 2010 and, following collaboration with an existing New Zealand paired kidney exchange program, the combined Australian New Zealand paired kidney exchange program was formed in 2019.

The Australian and New Zealand Paired Kidney Exchange program identifies matches for patients who are eligible for a kidney transplant and have a living donor who is willing, but unable to donate directly, because of an incompatible blood or tissue type or donor-recipient pairs who have been entered to improve their tissue type matching. The program matches two or more donor-recipient pairs, which when combined result in organ matches as shown in **Figure 2.1**.

Figure 2.1 Paired kidney exchange program example

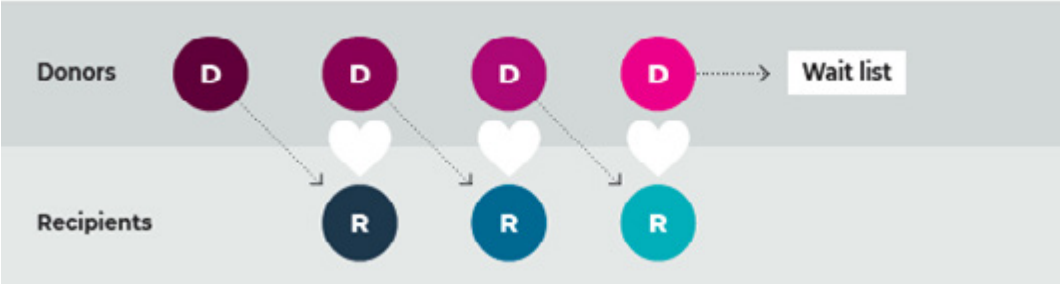


Paired kidney exchanges can involve two or more donor-recipient pairs.

If a kidney becomes available from a non-directed donor (see Chapter 2.8.1.1), this may enable a 'kidney donor chain' to form; this helps to facilitate a series of swaps between pairs as shown in the **Figure 2.2**.

The donor chain begins with the non-directed kidney donor donating their kidney to a matched recipient unknown to them, and the recipient's willing but incompatible donor donates their kidney to another person waiting, and so on. This is also known as a cascade. The final donor in the sequence has their kidney allocated to a suitable recipient on the waiting list.

Figure 2.2 Kidney chain program example



2.8.1.3 Domino donation from living donors

Rarely, whole vital organs can be donated as part of a domino transplant. Occasionally a combined heart and lung transplant is the best option for an individual with predominantly lung disease. In this case, during transplant surgery the recipient's own heart can be donated and transplanted into a person requiring a heart transplant.

Rarely, liver transplantation can be used to treat a form of amyloidosis in which an inherited gene abnormality causes the liver to produce abnormal amyloid proteins that are deposited around nerves and other organs causing damage. Liver transplantation can ameliorate this process and because the liver is otherwise functionally normal, it can be transplanted into another individual. As there is a risk of the recipient also developing amyloidosis, which takes some years to develop, careful recipient selection is required, for example, those with a lower post-transplant survival life expectancy.

2.8.2 Tissue donation following a therapeutic procedure and childbirth

Individuals undergoing surgery as a treatment for a medical condition may have tissue removed that can be used for transplantation. This most commonly occurs in hip joint replacement surgery. Very infrequently, a person who is undergoing heart

transplantation may have suitable heart valves for transplantation such that the explanted heart can be donated.

Placental tissue can also be donated at birth, with the amnion component used to treat burns, wounds and for other purposes such as reconstructive eye surgery. Umbilical cord blood can also be donated following childbirth for use in blood stem cell transplants see below (see Chapter 12.4).

2.8.2.1 Bone donation from hip joint replacement surgery

Individuals undergoing a primary hip joint replacement surgery for arthritis or other conditions may be able to donate the removed femoral head bone for transplantation. At assessment, a medical and social behaviour questionnaire requires completion to determine suitability. At the hip surgery the removed hip bone is transferred to the tissue bank for processing, rather than being discarded.

2.8.2.2 Placental tissue donation

Placental tissue consists of the amniotic membrane, chorion membrane, amniotic fluid, and the umbilical cord (see Chapter 2.8.3), that surround and protect the fetus during pregnancy. The amnion is the innermost lining of the placenta closest to the fetus where it acts as a barrier to the outside environment. The amnion component of the donated placenta can be used in a variety of ways, including for burns and wound healing and for reconstructive eye surgery. Donation is usually only possible when birth occurs via elective caesarean section.

For the purposes of the safety of donation and transplantation, a suitability assessment involves obtaining medical history and a blood sample for infectious disease screening from the mother.

2.8.3 Blood and marrow stem cell donation

For a stem cell transplant from a related or unrelated donor to be successful, the patient and donor must have a closely matched tissue type or human leukocyte antigen (HLA). Since tissue types are inherited and tend to cluster in ethnic groups, patients are likely to find a matched donor within their own family or ethnic group.

Early in the patient's treatment, transplant centres will test the tissue type of suitable family members and conduct a preliminary global search of the tissue type 'screening' results (and other key data) of approx. 40 million prospective unrelated cell donors (aged between 18-60 years) and approx. 800,000 stored umbilical cord blood units, through ABMDR (see Chapter 2.3.7).

Where potential related or unrelated donors are identified, a detailed clinical process is commenced to verify the candidate(s) HLA and medical history, test them for a suite of infectious and other relevant diseases and physically assess them to ensure that a) the transplant centre selects the most suitable donor for their patient and b) the selected donor is fit to donate. During these processes, the donor is educated on the risk and requirements of donation, and their consent is obtained (see Chapter 4.3.4.2).

ABMDR facilitates the evaluation and selection of Australian unrelated donors, to ensure that strict donor welfare standards are met and that donor-patient anonymity is observed (see Chapter 7.3.2.2). The physical examination, education, consenting and attestation that an unrelated donor is fit to donate (i.e. 'clinical workup') is performed by the nominated collection centre. Wherever possible, this collection centre is different to

the patient's transplant centre – if this cannot be avoided, a clinician other than the one caring for the patient is responsible for the donor's welfare. The majority of unrelated donors to Australian patients are located overseas, in which case ABMDR coordinates the process with the relevant international donor registry.

Where umbilical cord blood is selected by the transplant centre, the cord blood bank will be requested to perform additional verification tests on the stored unit/s in preparation for release. This process is also facilitated by ABMDR.

2.8.3.1 Collection of HSCs from donors

The method of collecting the cells from the donor depends on whether blood stem cells, bone marrow or umbilical cord blood stem cells are requested.

Peripheral **blood stem cell donation** involves a course of injections of a medication that stimulates the production of stem cells within the donor's bone marrow, releasing these into the donor's blood stream. These cells are then removed by apheresis over several hours. Around 90% of donations made in Australia are through this method.

Bone marrow donation is a surgical procedure in which liquid marrow is withdrawn from the back of the donor's pelvis using special needles and syringes. General anaesthesia is usually used for this procedure.

Umbilical cord blood is collected immediately following birth, and after a suitability assessment has been completed (which involves obtaining the mother's medical history and a blood sample for infectious disease screening). No blood is required from the baby. Donations that have sufficient stem cells for use in transplantation are then processed and cryopreserved by the cord blood bank and, after a quarantine period, 'published' through ABMDR for searches by transplant centres. Public cord blood banks in Australia are licensed by the TGA. See Chapter 12.4.2 for discussion of the implications of public and private cord blood banking.

2.9 Monitoring and evaluation of donation and transplantation activities and outcomes

Monitoring and evaluation of donation and transplantation processes and outcomes are vital for assuring the quality, efficiency, and transparency of the system. Data related to donation and transplantation play an important role in guiding and governing ethical practice (see Chapter 7.4) and in maintaining safety (see Chapter 2.9.1). Data are commonly collected via registries as outlined in Chapter 2.9.2.

The monitoring and evaluation activities include auditing donation processes such as deceased donor detection and family approach to offer donation, processes for transplant waitlisting and organ allocation, reporting and assessing adverse events, and tracking transplantation outcomes.

The OTA undertakes an audit of hospital deaths to ensure all potential organ donation opportunities are identified and families are approached to consider donation according to best practice. The TSANZ clinical guidelines outline the requirement to audit waitlisting processes and organ allocation to ensure that access to transplantation occurs according to agreed protocols.[25]

2.9.1 Vigilance and surveillance

Vigilance and surveillance processes exist to facilitate the detection, evaluation and reporting of adverse events to improve the quality and safety of donation and transplantation. Maintenance of donation and transplant registries (see Chapter 2.9.2) is vital for vigilance and surveillance, which enables the tracing of organs and tissues in the event that diseases are transmitted to transplant recipients, so that further transmission can be prevented, and steps can be taken to prevent or address harm.

The eye and tissue sector is regulated by the TGA through legislation (see Chapter 2.3.5) and is required to have robust processes in place which are reviewed as part of the TGA audit process. Adverse events related to tissues are reported to and monitored by the TGA.

Adverse events related to organ donation and transplantation are detected and managed through jurisdictional processes, with national notification and review also occurring through the Organ and Tissue Authority's Vigilance and Surveillance Framework and associated Vigilance and Surveillance Expert Advisory Committee (VSEAC). The VSEAC issues regular communiques to the sector that highlight key reported events and learnings and produces an annual report that provides an overview and analysis of reported events.

2.9.2 Data collection and reporting in donation and transplantation registries

In addition to personal data contained in medical records, which health authorities are permitted to audit for quality and safety purposes, or use in public health research in specific circumstances, data pertaining to donation and transplantation are also routinely collected and stored in registries. Outcome and activity registries for donation and transplantation in Australia are listed in **Table 2.6**. See Chapter 7.4 for discussion of ethical considerations relating to registry data collection and reporting.

Table 2.6 Outcome and activity registries for donation and transplantation in Australia

The **Australian and New Zealand Organ Donation Registry (ANZOD)** collects and records data on all organ donors after death, and it also collects a wide range of statistics that relate to organ donation. This website provides access to the ANZOD annual reports, monthly data collection and downloadable forms for organ donation.

https://www.anzdata.org.au/anzod/

The **Australia and New Zealand Dialysis and Transplant Registry (ANZDATA)** is a clinical quality registry that collects and produces a wide range of statistics relating to the outcomes of treatment of those with end stage renal failure. The Registry's fundamental purpose is to report on the incidence, prevalence and outcomes of dialysis and transplant treatment for patients with end stage renal disease across Australia and New Zealand.

https://www.anzdata.org.au/anzdata/

The **Australia and New Zealand Live Kidney Donor Registry (ANZLKD)** was established to provide information about the long-term health and well-being of people who donated a kidney for transplantation.

https://www.anzdata.org.au/anzlkd/

The **Australia and New Zealand Islet and Pancreas Transplant Registry (ANZIPTR)** is based at Westmead Hospital in NSW and records information about whole pancreas and pancreas islet cell transplantation in Australia and New Zealand.

http://anziptr.org/

The **Australia & New Zealand Liver and Intestinal Transplant Registry (ANZLITR)** contains data on all liver and intestinal transplants performed in Australia and New Zealand since establishment of first liver transplant unit in 1985. An annual report is produced and contains information on numbers of transplants performed, waiting list flows and patient and graft outcomes.

https://www.anzlitr.org/

The **Australia and New Zealand Eye & Tissue Donation (ANZETD)** gathers information from all eye and tissue banks across Australia and New Zealand. Data is analysed and reported to inform on eye and tissue donation and transplantation activity, performance measures and outcomes in the sector.

https://www.anzdata.org.au/anzetd/

The **Australia and New Zealand Transplant and Cellular Therapies Registry (ANZTCTR)** (formerly known as the Australian Bone Marrow Transplant Recipient Registry) was established in 1992 under the auspices of the Bone Marrow Transplant Society of Australia and New Zealand (BMTSANZ). It records details of bone marrow, peripheral blood and cord blood stem cell transplants throughout Australia and New Zealand.

https://anztct.org.au/registry/

The **Australian Corneal Graft Registry (ACGR)** is operated out of Flinders University and is an Australia-wide register of human corneal transplants. The purpose of the ACGR is to collect information to inform clinical practice and identify risk factors for poor patient outcomes.

https://www.flinders.edu.au/fhmri/research/fhmri-eye-vision/corneal-graft-registry

2.9.3 Monitoring and evaluation of blood and marrow stem cells

ABMDR monitors and evaluates donation processes and outcomes for Australian unrelated donors under its WMDA accreditation (see Chapter 2.3.7). WMDA operates a global 'serious (product) events and adverse reactions' (SPEAR) reporting and evaluation process, to gain insights into performance issues relating to a) blood stem cell donation by unrelated donors and b) blood stem cell collection, processing and transplantation from unrelated donors. WMDA's SPEAR Committee reviews all reported incidents on a weekly basis and has a global rapid-alert system in the event of donor death, product recall or any product prohibition or restriction issued by a nation's competent health authority. ABMDR submits reports on behalf of Australia following review by its Scientific and Expert Advisory Committee (SEAC), that reports on behalf of the sector to ABMDR's Board. It is also possible to report adverse events related to family member donation to this committee.

Cord blood banks are regulated by the TGA through legislation. Each cord blood bank is required to have robust processes in place which are reviewed as part of the TGA audit process.

The Australia and New Zealand Transplant and Cellular Therapies Ltd (ANZTCT) tracks blood and marrow transplant activity and outcomes reported by the Australasian Bone Marrow Transplant Recipient Registry, to improve outcomes for Australians and New Zealanders of all ages undergoing transplantation of blood or marrow stem cells (or other blood or marrow derived cells) through innovation and improvements in clinical care.

Jurisdictional oversight is provided by the Jurisdictional Haemopoietic Progenitor Cell Committee, which was established to oversee the implementation of a review commissioned by all governments in 2017,[26] and the subsequent response by governments via the *National Haemopoietic Progenitor Cell (HPC) Framework*.[27]

3. Ethical foundations of donation and transplantation in Australia

People have different languages and ways of communicating, different cultural practices, personal goals and priorities, and different types of social relationships. They also share common interests and values including being able to pursue their own goals freely and having control over their own lives and bodies. At times, people also depend on other members of their communities and societies to help them in meeting individual or collective needs, or to protect them from harm.

These shared interests and experiences are reflected in the ethical values embedded in international statements and guidelines such as the United Nations *Universal Declaration of Human Rights*,[4] the *United Nations Declaration on the Rights of Indigenous Peoples*,[2] the United Nations *Convention on the Rights of Persons with Disabilities*,[5] and the *United Nations Convention on the Rights of the Child*.[3] In Australia, these values are reflected in the ethical values and principles that underpin healthcare policy and practice, as well as the conduct of research involving human participants.

The ethical foundations of healthcare policy and practice in Australia include respect for human beings (respect for human dignity), for the rights of individuals to govern their own lives (respect for autonomy), and for justice, as well as obligations to help and avoid causing harm to others (beneficence and nonmaleficence).

These principles are all applicable in the context of donation and transplantation policies and practices. This requires decision-making that

- respects the human rights, dignity, and autonomy of all members of the Australian community
- promotes the wellbeing and broader interests of donors and recipients and their families and communities
- safeguards equity in the distribution of and access to the benefits of donation and transplantation of cells, tissues, and organs.

In this chapter we present a set of core values and ethical principles that should underpin policy and practice in donation and transplantation in Australia. These principles are consistent with the core values of healthcare policy and practice in Australia, with international guiding principles for donation and transplantation, and with existing Australian ethical guidelines and position statements of relevance. We briefly review Australian legislation that is or may be relevant to ethical decision-making in donation and transplantation. Finally, we outline a general approach to ethical decision-making and discuss some of the concerns that may arise when making ethically significant decisions, including concerns about conflicts of interest.

For further resources related to this chapter, please see Appendix 1.

3.1 Ethical values and principles guiding cell, tissue and organ donation and transplantation in Australia

The values and principles outlined below support decision-making by all those involved in donation and transplantation activities, particularly health professionals and policy makers. Use of an ethics framework helps to ensure that decision-making is rigorous,

consistent, transparent, and supported by the community. In most situations, more than one value or principle may need to be considered. Each value and principle is explained in more detail in the following sections.

The five values at the foundation of the ethics framework are:

- Respect for the dignity and autonomy of donors, recipients, and their families and communities (see Chapter 3.2.1)
- Promotion of the wellbeing of potential and actual donors, recipients, and their families and communities (see Chapter 3.2.2)
- Promotion of justice in donation and transplantation of organs and tissues (see Chapter 3.2.3)
- Promotion of solidarity and community reciprocity (see Chapter 3.2.4)
- Stewardship of the common good (see Chapter 3.2.5).

Eleven principles derived from these values are listed below. The principles aim to support decision-making by all those involved in donation and transplantation activities, particularly health professionals and policy makers. More than one principle may need to be considered in a specific situation.

- **Principle 1** Decision-making about donation and transplantation should seek out and take account of expressed preferences of donors, recipients, their families and communities, and facilitate self-determination. (See Chapter 3.3.1)
- **Principle 2** Decision-making about donation and transplantation should promote cultural safety, demonstrating cultural humility, critical reflection, and awareness of power dynamics. (See Chapter 3.3.2)
- **Principle 3** Decision-making about donation and transplantation should be free from bias or discrimination based on clinically irrelevant factors such as disability, cultural identity, or social or economic circumstances. (See Chapter 3.3.3)
- **Principle 4** In donation and transplantation activities, potential conflicts of interest should be avoided and, where unavoidable, should be appropriately managed. (See Chapter 3.3.4)
- **Principle 5** Donation and transplantation activities and associated decision-making should be transparent and open to scrutiny. (See Chapter 3.3.5)
- **Principle 6** Donation and transplantation activities and associated decision-making should protect the privacy of individuals and their families and the confidentiality of information related to donation and transplantation activities. (See Chapter 3.3.6)
- **Principle 7** Donation and transplantation activities should provide benefit and minimise burdens and risk of harm: where burdens or risks are unavoidable, they should be proportionate to the benefits that are anticipated. (See Chapter 3.3.7)
- **Principle 8** Donation and transplantation activities should promote equity in the distribution of and access to donation and transplantation of organs and tissues. (See Chapter 3.3.8)
- **Principle 9** Donation and transplantation activities should foster solidarity, efficiency, and sustainability, and support progress towards self-sufficiency with regional and international collaboration where necessary. (See Chapter 3.3.9)

- **Principle 10** Human organs, tissues and cells should not be treated as ordinary commodities that can be sold or exchanged for profit: any profits arising from the removal, processing, distribution, storage, transfer or use of donated cells, tissues or organs should be used to enhance quality, safety, sustainability, and equity in healthcare for all. (See Chapter 3.3.10)
- **Principle 11** Decision-making about donation and transplantation should be free from coercion, exploitation or financial incentives; this should not preclude coverage of costs associated with donation or transplantation. (See Chapter 3.3.11)

3.2 Values underpinning donation and transplantation activities

3.2.1 Respect for the dignity and autonomy of donors, recipients, and their families and communities

Dignity refers to the inherent and equal value of individual human beings. Recognising and respecting this value in others is the foundation for the ethical obligations or duties that apply in the context of interactions with other people. The implications of respect for dignity are discussed below in Chapter 3.2.1.1.

Autonomy refers to a person's right to self-governance; the right to live their life freely and to make decisions about things that affect them in accordance with their own values, beliefs, and preferences. Respect for autonomy requires efforts to include relevant people in decision-making about donation and transplantation in the clinical context and in policymaking, and to ensure people are supported to make informed and voluntary decisions. Respect for autonomy is discussed further below in Chapter 3.2.1.2.

3.2.1.1 Respect for dignity and its implications

Respect for dignity also has implications for the way we treat the bodies of deceased persons and human cells, tissues and organs that have been removed from living or deceased individuals. Although people may hold different beliefs regarding the inherent value of human body parts, for many people their own cells, tissues and organs, and the bodies of their loved ones may hold special value. Donated cells, tissues and organs used in transplantation should therefore be regarded as ethically 'exceptional' resources that are distinct from other types of medical 'products' or therapeutic devices.[1,28]

Respect for dignity underpins or influences many of the ethical principles and recommendations set out in these guidelines, especially the prohibition of trade in human cells, tissues, and organs (see Chapter 3.3.10), and obligations to avoid exploitation of donors (see Chapter 3.3.11). Respect for dignity may be especially important when individuals have limited capacity for autonomy, which is discussed in Chapter 5.

Respect for the dignity of donors - including potential donors - means that a donor should never be treated solely as a means to achieve the goal of transplantation for another individual. Treating a donor merely as a source of cells, tissues or organs for transplantation constitutes unethical exploitation.

Instead, donors must be recognised as individuals with inherent value and goals or interests of their own. While potential donors may also share the goal of providing cells, tissues or organs for transplantation, the obligation to respect their dignity means that donation goals must be considered in the broader context of donor wellbeing and interests.

In the case of living donation, obligations to avoid exploitation of donors and respect their dignity means that there are limits to the risks or degree of harm to which a donor may be exposed. Despite the substantial potential benefits of donation for a transplant recipient, the wellbeing of the donor should take priority. Ethical considerations with regards to determination of acceptable risk thresholds in living donation are discussed in Chapter 6.1.4.

Acknowledging the invaluable contribution of living and deceased donors is ethically important and respectful of their dignity. Providing formal expressions of gratitude to donors in recognition of their gift and paying respect to the families of deceased donors may also help to encourage donation and foster long-term donor and donor family wellbeing.

3.2.1.2 Respect for autonomy and its implications

People often wish to make decisions about important aspects of their life in collaboration with others. Even when making decisions as an individual, a person's values, beliefs and preferences may be influenced by their relationships, life experiences, faith, or culture, as well as societal factors and the context in which the decision is being made. Autonomy should be thought of as a relational concept, acknowledging the way that various relationships shape the autonomy of a person.

Some decisions may have important implications for members of particular communities or organisations. Respect for autonomy also requires consideration of the interest that communities and organisations may have in governing their collective activities and inclusion of representatives of these groups in decision-making that may affect them. This is particularly important to communities that have historically been disempowered and that continue to experience significant barriers to participation in decision-making about matters that affect them, such as Australia's First Nations peoples.

Some important misconceptions regarding the implications of respect for autonomy and donation are discussed in Chapter 3.2.1.3 below. See Chapter 4 and Chapter 5 for further discussion of ethical considerations relating to this principle in the context of decision-making about donation and transplantation.

3.2.1.3 Misconceptions regarding the implications of respect for autonomy

Respecting a person's autonomy – their interest in making voluntary and informed choices about things that are important to them – does not entail an obligation to provide the person with anything they might choose. In other words, people have a right to autonomy – to be able to govern their own lives – but this should not be confused with other rights or entitlements that they might have.[29]

In the context of health ethics, people sometimes mistakenly assume that if you have an ethical obligation to respect a person's autonomy, this means you may have to do something for that person if they request it. For example, a doctor might feel they are obliged to provide a patient with a medication at the patient's request, even if the doctor believes the medication would be clinically inappropriate. This is incorrect.

In the context of donation and transplantation, individuals have the right to make autonomous decisions about participation in donation or transplantation opportunities. This does not mean they have an unconditional right to become a donor, or to receive a transplant. Individuals may wish to donate or to receive a transplant but may not be clinically suitable. Resource limitations may also mean that some individuals miss

opportunities for donation or transplantation, although it is important to ensure that individuals aren't unfairly excluded from donation and transplantation opportunities, as discussed in Chapter 8.

In these circumstances, respecting a person's autonomy would involve informing them of the options that may be available to them with regards to donation or transplantation, or explaining why options may be unavailable. The individual can then make informed choices where relevant, or at the very least develop an understanding of their situation. Respecting autonomy does not mean that a health professional has an obligation to perform a clinically inappropriate procedure or to violate resource allocation policies.

3.2.2 Promotion of the wellbeing of potential and actual donors, recipients, and their families and communities

Promoting and safeguarding the wellbeing of others means acting with respect for beneficence – the ethical obligation to help benefit others – and for nonmaleficence – the ethical obligation to avoid causing harm to others. Some burdens or risks may sometimes be necessary in order to produce benefits. It is important to ensure that the expected benefits of an action are proportionate to the expected risks or burdens of the action, all things considered.

This principle also underpins obligations to prevent the need for donation and transplantation where possible, thereby promoting population health and wellbeing by reducing the potential burdens of illness or disability and of donation.

See Chapter 6 for discussion of ethical considerations relating to this principle.

3.2.3 Promotion of justice in donation and transplantation of cells, organs and tissues

Justice, or fairness, is important in the context of many different elements of donation and transplantation programs, including the processes for decision-making and implementation of guidelines and policies ('procedural justice') as well as the outcomes of decision-making processes. Specific mechanisms to promote transparency and accountability are often needed to support justice and maintain the trust of stakeholders including the public.

Respecting everyone's right to health requires efforts to ensure that access to beneficial resources such as donated cells, tissues and organs is fair, meaning just or equitable. Achieving equity in the distribution of the benefits and burdens of donation means that unavoidable inequalities in distribution are nevertheless fair. Equity is also essential with regards to opportunities for donation and for access to transplantation services.

Equity is especially important when allocating scarce and valuable resources such as donated organs because there are insufficient organs to meet all needs for transplantation and it is often necessary to discriminate between the competing needs of several individuals who might benefit from an available donor organ. This requires careful selection of clinical criteria and consideration of relevant ethical values to guide decision-making consistently in a way that promotes fairness.

In other contexts, while several individuals might require a transplant, not all transplant candidates may be able to benefit from an available donation due to clinical factors. For example, the need for a donor with a closely matched Human Leucocyte Antigen (HLA)

tissue type means that some candidates for HSC transplants may not find a suitable HSC donor registered with the ABMDR, or in overseas donor registries. In such cases, this means that only some individuals will benefit from transplantation, however these inequalities are currently unavoidable, necessary, and fair, and hence equitable.

Promotion of equity in donation and transplantation requires attention to broader concerns about equity in healthcare and society ('social justice'). Structural inequalities and racism, sexism and other forms of discrimination and bias may negatively influence equity in access to care and quality of care, and may undermine procedural justice (see Chapter 3.6.3), for example through exclusion of individuals or groups from decision-making.

See Chapter 8 and Chapter 9 for a discussion of further ethical considerations relating to this principle.

3.2.4 Promotion of solidarity and community reciprocity

Solidarity is broadly construed as a collective commitment to achieve a shared goal or address common challenges. Solidarity is a value that recognises the importance of helping others, even when some individuals may not be able to contribute to collective efforts and not all individuals may require help.

It is an important foundation for donation and transplant programs, as opportunities for donation and needs for transplantation may not be easily predicted. Solidarity encourages everyone to participate in donation when possible, optimising donation and the probability of individual members of the community receiving a transplant if they require one. In this sense, solidarity goes beyond the notion of reciprocity which is sometimes interpreted as more of a direct exchange of benefits in return for individual contributions.

In the context of donation and transplantation, the principle of reciprocity is often invoked when referring to the idea that those who may serve as potential donors should also be recognised as potential transplant recipients. That is, those who may contribute to meeting needs deserve to benefit from these efforts. Conversely, reciprocity can be framed as an obligation to participate in donation opportunities on the part of everyone who may benefit from transplantation.

This norm is inherent in the ethos of policies aimed at self-sufficiency in donation and transplantation (see Chapter 9.1); it would be unfair to exclude people from accessing the benefits of transplantation if those people are responsible for making those benefits available.

For example, providing access to transplantation in Australia for wealthy patients traveling from other countries at the expense of meeting transplant needs of Australian residents who comprise the pool of potential deceased donors would be inconsistent with reciprocity and hence unfair.

3.2.5 Stewardship of the common good

The donation and transplantation 'sector' comprises a range of systems, programs and organisations as outlined in Chapter 2. These collectively aim to produce benefits for all Australian residents without undermining the wellbeing or interests of any; that is, they aim to promote the 'common good'.

Stewardship refers to the responsibilities and duties of those tasked with overseeing and implementing activities in the sector for the good of everyone. In particular, stewardship entails obligations to manage the sector effectively and efficiently and to ensure ethical custodianship of donated cells, tissues, and organs. It also requires accountability and transparency in decision-making, in order to ensure that activities do indeed serve the good of all.

3.2.5.1 Custodianship

Ethical custodianship is an important aspect of stewardship, as ethical concerns may arise in the context of any donation and transplantation activities. Professionals, organisations, and institutions that may be directly or indirectly involved in these activities have a responsibility to ensure their own actions are ethically appropriate and consistent with the principles set out in these guidelines. All custodians of human cells, tissues and organs should also act in accordance with relevant laws, regulatory frameworks and clinical standards governing their practice.

Custodians also have a responsibility to promote and sustain ethical practice more widely, by taking steps to ensure that when they entrust human cells, tissues or organs to other individuals or organisations, these persons will also maintain clinical and ethical standards of practice. When taking custody of donated cells, tissues or organs, individuals and institutions should strive to verify that previous custodians have maintained clinical and ethical standards and should take action if this is not the case.

Maintenance of clinical standards, in particular with regards to minimum standards for quality and safety, is ethically essential in order to fulfil obligations to prevent harm and to optimise the benefits of donation and transplantation.

See Chapter 9.2 for discussion of ethical considerations relating to custodianship.

3.3 Principles guiding donation and transplantation activities

3.3.1 Principle 1. Decision-making about donation and transplantation should seek out and take account of expressed preferences of donors, recipients, their families and communities, and facilitate self-determination.

This principle reflects the value accorded to the autonomy of potential donors and transplant recipients and their families and communities, as discussed in Chapter 3.2.1. Key ethical considerations when supporting decision-making about donation and transplantation are discussed in Chapter 4.

The principle also highlights the importance of active efforts to engage people in decision-making. Even where individuals may be unable to make decisions on their own behalf, or may not be legally authorised to provide consent for donation or transplantation, their values and preferences should be carefully considered in decision-making as discussed in Chapter 5.1.4).

3.3.2 Principle 2. Decision-making about donation and transplantation should promote cultural safety, demonstrating cultural humility, critical reflection, and awareness of power dynamics.

The concept of cultural safety was first introduced by a Māori scholar and health professional, Dr Irihapeti Ramsden.[30] In 'The National Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025', the Australian Health Practitioner Regulatory Agency (Ahpra) defines cultural safety as follows:

> Cultural safety is determined by Aboriginal and Torres Strait Islander individuals, families and communities. Culturally safe practise is the ongoing critical reflection of health practitioner knowledge, skills, attitudes, practising behaviours and power differentials in delivering safe, accessible and responsive healthcare free of racism.[31]

Cultural safety is a core standard for quality and safety in Australian healthcare; culturally safe care for First Nations healthcare users is associated with better access to care and better quality of care.[32] Engaging in culturally safe decision-making (see Chapter 3.4.2) and acting to promote culturally safe care in donation and transplantation is essential to help address the significant inequities experienced by Aboriginal and Torres Strait Islander peoples in Australia.[33] Previous experiences of healthcare, as well as historical injustices and cultural norms, may influence Aboriginal and Torres Strait Islander peoples' attitudes and choices regarding donation and transplantation opportunities.[34,35] The availability and use of culturally and linguistically appropriate resources for education, information and communication in decision-making about donation and transplantation is therefore important.

Cultural safety is also important in providing care for and addressing inequities experienced by minoritised culturally and linguistically diverse groups.[30] The general principles of cultural safety, in particular with respect to cultural humility, critical reflection, and the recognition of power relations in decision-making are also key requirements for ethical decision-making, as discussed below in Chapter 3.4.2.

3.3.3 Principle 3. Decision-making about donation and transplantation should be free from bias or discrimination based on clinically irrelevant factors such as disability, cultural identity, or social or economic circumstances.

Ensuring that only relevant factors are considered in decision-making is important to promote equity in donation and transplantation (see Chapter 8.2.3).

Attitudes towards donation and transplantation in general and in specific circumstances may differ and are shaped by an individual's own values, experiences, preferences, and beliefs, as well as those of their colleagues, family and/or community. Individuals may also be influenced by prejudices, such as racism, sexism, ableism, and ageism, as well as cultural and cognitive biases, when communicating or processing information and making judgements or decisions.

Cognitive biases and heuristics are common in healthcare (and everyday) decision-making; they involve mental 'shortcuts' in judgements and decision-making that can lead to 'systematic and predictable errors'.[36] Although sometimes helpful in facilitating decision-making when there is limited time, heuristics and cognitive biases on the part of decision-makers and those who are supporting decision-making can also undermine autonomy.[37]

For example, cultural biases may lead some health professionals to make assumptions about the preferences of people who identify with particular religions or cultural groups, which might influence the way that treatment options are presented to those people. While knowledge of common cultural beliefs or values may be helpful in supporting respectful communication and shared decision-making, each person should be treated as an individual and their values, beliefs and preferences should be determined rather than assumed.

Potential strategies to help avoid unfair discrimination, manage biases, and support impartiality in ethical decision-making are discussed in Chapter 3.6.2.

3.3.4 Principle 4. In donation and transplantation activities, potential conflicts of interest should be avoided and, where unavoidable, should be appropriately managed.

Potential conflicts of interest exist when individuals or organisations have multiple commitments, relationships, goals, or values ('interests') that may influence their actions or decisions in a particular situation, and these interests may conflict with one another in a way that may compromise fulfilment of primary duties or obligations, and cause bias in decision-making. Primary duties typically include a health professional's duty of care towards their patients (see Chapter 3.3.4.1), and their duty to respect the dignity and autonomy (see Chapter 3.2.1) of individuals.

Management of potential conflicts of interest is essential not only to ensure the integrity of decision-making about donation and transplantation but also to sustain public trust.

General considerations with regards to conflicts of interest are explored in Chapter 3.8 below and specific contexts in which conflicts may arise are explored in Chapter 5.5.3.3 (living donation by dependent donors), Chapter 8.5.1.3 (allocation of donor tissues), and Chapter 11.3 (end-of-life care).

3.3.4.1 Duty of care

Health professionals are considered to have a primary duty of care towards their patients. This generally means that where a therapeutic relationship has been established between a health professional and a patient, the health professional's first concern should be to fulfil their ethical and professional obligations towards the patient.

Health professionals' duties of care may extend to the family of donors or transplant recipients. Duties of care are also applicable to those who are declined as donors or transplant recipients, and during the screening/evaluation process.

Health professionals often have multiple responsibilities in the context of their professional roles, and if it is necessary to prioritise these responsibilities, the duty of care requires patients to be prioritised.

The primacy of the duty of care does not mean that health professionals are expected to promote the interests of their own patients at the expense of other patients. Nor does it mean that professionals may violate other ethical duties in order to help their own patients. For example, participating in organ trafficking (see Chapter 10.6) in order to help a patient receive an organ transplant would not be justified by the duty of care.

3.3.5 Principle 5. Donation and transplantation activities and decision-making should be transparent and open to scrutiny.

Information about donation and transplantation activities is of public interest because deceased donation and transplantation are a collective societal activity in which individuals depend on other individuals to meet their needs for transplantation. Ensuring that the public good of donation and transplantation is appropriately and optimally managed for the benefit of all requires transparency of policy and practice to facilitate accountability.

See Chapter 7.4 for a discussion of ethical considerations relating to this principle.

3.3.6 Principle 6. Donation and transplantation activities and associated decision-making should protect the privacy of individuals and their families and the confidentiality of information related to donation and transplantation activities.

Noting the principle that information about donation and transplantation activities should be transparent and open to scrutiny, individuals nevertheless have rights to privacy and confidentiality, meaning the right to control access to one's physical person and to manage access to and use of one's personal information. These rights are particularly important in the healthcare context where individuals must be able to trust that health professionals and healthcare institutions will protect their personal information when this is provided to them in confidence for the purpose of receiving medical care. There are some limitations on rights to privacy and confidentiality, usually in circumstances where disclosure of private information may be necessary to prevent serious harm to others.

See Chapter 7 for a discussion of ethical considerations relating to this principle.

3.3.7 Principle 7. Donation and transplantation activities should provide benefit and minimise burdens and risk of harm: where burdens or risks are unavoidable, they should be proportionate to the benefits that are anticipated.

This principle derives from the core value underpinning donation and transplantation in Australia, that of promotion of the wellbeing of potential and actual donors, recipients, and their families and communities (Chapter 3.2.2). Balancing potential benefits and risks of various opportunities for donation and transplantation can be difficult, especially at the individual level where evaluation of risks and potential benefits must be carefully tailored to a person's characteristics and circumstances.

See Chapter 6 for a discussion of some of the ethical complexities associated with fulfillment of this principle.

3.3.8 Principle 8. Donation and transplantation activities should promote equity in the distribution of and access to donation and transplantation of organs and tissues.

This principle derives from the core value of justice (see Chapter 3.2.3) which is a foundation of donation and transplantation in Australia. Upholding that value requires efforts to maximise fairness in the distribution of the potential benefits, risks and burdens of donation and transplantation. Avoiding unfair inequalities in access to

transplantation and in donation is especially important, but can be difficult to achieve. Wider inequities in society can intersect with and exacerbate inequities in donation and transplantation. Strategies to address barriers to donation and transplantation, and evidence-based policies allocating donation and transplantation resources require careful ethical decision-making to ensure that equity is enhanced rather than undermined. Careful attention to potential biases in decision-making is also essential at the level of policy making and individual clinical decision-making.

See Chapter 8 for a discussion of ethical considerations relating to this principle.

3.3.9 Principle 9. Donation and transplantation activities should foster solidarity, efficiency, and sustainability, and support progress towards self-sufficiency with regional and international collaboration where necessary.

Although an individual may sometimes be able to donate directly to another individual in need of transplantation, in most cases people who need transplants will depend on unknown individuals making non-directed donations in order to access a suitable transplant at the right time. The success of transplantation programs, defined by the ability to provide timely access to transplants for people in need, therefore depends on optimising participation in donation opportunities. Consequently, in addition to sustainable and efficient programs, success requires people to act in solidarity (see Chapter 3.2.4) with others by donating when possible, in order to address the shared challenges of meeting transplant needs.

Achieving self-sufficiency means being able to meet a population's collective needs for transplantation using their own resources, or through reciprocal or equitable collaboration with other populations. Progress towards self-sufficiency depends on careful stewardship (see Chapter 3.2.5) of donation and transplantation resources, prevention of population needs for transplantation when possible and ongoing efforts to maintain efficient and effective donation and transplantation programs.

Self-sufficiency may be pursued at the state or territory level, nationally and regionally. Progress towards national self-sufficiency reduces ethical, clinical, and economic risks by decreasing dependence on foreign populations to provide for Australian donation and transplant needs.

In the case of HSC transplantation, the critical challenge is to find a suitable HLA matched donor for a successful transplant, thus Australia must collaborate at the global level to increase the chances of individuals receiving a transplant. It is often difficult to find a clinically suitable and a tissue type matched HSC donor for an Australian among their relatives or those registered in the ABMDR (see Chapter 2.3.7). Many Australians who require an HSC transplant will depend on finding a matching donor from outside Australia via the WMDA, the international network of donor registries to which the ABMDR belongs. By participating in this global network, Australians act in solidarity with others around the world, providing donations that help to save the lives of HSC transplant recipients in other countries, and benefitting from the donations of individuals living in other countries.

See Chapter 9 for a discussion of ethical considerations relating to this principle.

3.3.10 Principle 10. Human organs, tissues and cells should not be treated as ordinary commodities that can be sold or exchanged for profit: any profits arising from the removal, processing, distribution, storage, transfer or use of donated cells, tissues or organs should be used to enhance quality, safety, sustainability, and equity in healthcare for all.

A commodity is something that has a monetary price which makes it interchangeable with other goods of different kinds that have an equivalent financial value. Treating human beings as having a monetary price is considered ethically wrong because it fails to recognise their inherent ethical value or dignity, for which there is no equivalent financial value. This means it risks treating people as interchangeable things rather than individuals with interests, preferences, and goals of their own.

Treating human cells, tissues or organs as commodities may also be considered ethically wrong as this involves practices that risk treating people as commodities; it may also undermine individual and collective efforts to meet needs for transplantation through donation by undermining public trust in donation and transplantation activities.

Treating donated cells, tissues or organs as saleable commodities that can be exchanged or otherwise used for financial gain also violates the spirit of altruistic donation (see Chapter 3.3.10.1), and the expectations of people who make a decision to donate for the purpose of helping others by restoring or improving their health.

There are many activities that may be needed to support development and maintenance of donation and transplantation programs, to ensure the delivery of high-quality care for all, and to inform new policies and practices that will produce better health outcomes. These include but are not limited to various steps in the recruitment and evaluation of potential donors; maintenance of donor and patient registries; removal of cells, tissues, and organs from donors; transport, processing, storage, distribution and transplantation of donated cells, tissues, and organs; and research evaluating performance of donation and transplantation programs and investigating new methods or technologies that may improve practice and outcomes. All these activities will necessarily involve financial transactions; it is important to ensure such transactions are consistent with the ethical values and principles outlined in these guidelines.

See Chapter 10 for discussion of ethical considerations relating to this principle.

3.3.10.1 The nature of donation as a binding and altruistic gift

Donation of human cells, tissues or organs is often described as altruistic, meaning that it involves a gift which is primarily motivated by the desire to help others, rather than by an expectation that the donor will receive a benefit. In particular, donation refers to a gift that is made without expectation of a financial reward, which would transform the gift into an effective sale or trade.

Despite the fact that cells, tissues, and organs are not sold by a donor the way a person might sell their personal property such as a car or television, once donation has occurred it should be considered an ethically binding act. This means that rights of control or use of the donation are permanently transferred to the transplant recipient, or temporarily held by the relevant custodians of the donation. Although a potential donor can change their mind before donation takes place and withdraw consent to the removal or use of their cells, tissues, or organs in transplantation (see Chapter 4.1.4), once donation has taken place the donor can no longer dictate the use of any donated materials or demand their return. That means a living kidney donor cannot, for example, demand the return of the kidney which they donated to a relative; once transplanted, the kidney is now that of the transplant recipient. Nor can a person who has provided

valid consent to donate their femoral head to a tissue bank following a hip replacement recover that tissue once it has been received by the bank.

However, until donations are transplanted, donors are entitled to expect that their donations will be treated by custodians in accordance with expectations set at the time of consent for donation. When making a decision to donate, individuals may in some cases place conditions upon how or for what purpose their donations may be used. For example, a person may provide consent on behalf of a deceased donor for the use of their tissues in transplantation but refuse permission for tissues to be used in research. When these conditions are ethically appropriate and clinically feasible (see Chapter 12.3), and consent for donation is obtained on the basis of these conditions, then these should be followed by custodians of the donated materials. In some cases, donors or donation decision-makers may be consulted after donation and offered the opportunity to consent to a different use or treatment of the donation.

3.3.11 Principle 11. Decision-making about donation and transplantation should be free from coercion, exploitation or financial incentives; this should not preclude coverage of costs associated with donation or transplantation.

In order to respect the autonomy of people making decisions about donation or transplantation, particular behaviours or policies that might undermine voluntariness in decision-making must be avoided (see Chapter 4.1.2).

When a person is forced to make a decision that is not consistent with their own values, goals or preferences, that is, they are compelled to do something against their will, this is considered coercion. Coercion may involve an act of force, or a threat to make a person worse off if they do not make the desired choice. For example, coercing a living donor could involve removing an organ from a person without their consent, or threatening to harm a person if they do not agree to donate their organ.

Wrongful exploitation in decision-making about donation or transplantation may be defined as taking unfair advantage of a person's vulnerability so that they make a decision that they would not otherwise have chosen to make. A range of personal factors may cause people to be vulnerable in decision-making, including emotional, physical or socioeconomic factors. The nature of relationships between people involved in decision-making can also create vulnerabilities. For example, a clinician might take advantage of a transplant candidate's lack of medical knowledge in order to obtain their agreement to or decline of a potential transplant offer.

Use of financial incentives can similarly undermine autonomy in decision-making by influencing decision-making in ways that may take advantage of people's economic vulnerabilities. For example, offering to pay the funeral costs of the family of a potential deceased donor if they agree to authorise donation may make it difficult for a family to refuse if they wished to do so, if they are otherwise unable to afford a funeral for their relative. As discussed in Chapter 10.1.1, use of financial incentives to influence donation decision-making may foster inequities in donation and also violate prohibitions against trade in human cells, organs or tissues.

It is important to note that covering costs associated with donation or transplantation does not necessarily constitute use of financial incentives or violation of prohibitions against trade. As discussed in Chapter 10.4, covering costs may be necessary to remove barriers to donation or transplantation and to avoid causing financial injury to donors or donor families.

3.4 Approach to ethical decision-making

The aim of ethical decision-making in healthcare is to reason through, decide upon and communicate the ethical justification for a clinically appropriate action(s) that meets the patient's goals of care while ensuring respect for all parties' values in situations of conflict or uncertainty. It may be helpful to use a structured approach when contributing to complex ethical decisions in a clinical setting, and when considering dilemmas in policymaking.

Ethical considerations are likely to be embedded in much of clinical decision-making about donation and transplantation. The following sections outline several aspects of ethical decision-making that should be carefully considered throughout the decision-making process.

3.4.1 Framework for ethical decision-making

The following steps are commonly considered as part of structured approaches to ethical decision-making in clinical practice. They are described sequentially but in practice these often occur in parallel.

- **Identification:** Identify the ethical issue or concerns, e.g., potential conflicts between ethical obligations or clinical goals; disagreement regarding the application of policies.
- **Information-gathering:** Determine and collect information relevant to the issue or decision being made, for example:
  - clinical evidence relevant to the decision
  - information about a person's values and preferences
  - consultation with relevant stakeholders and experts.
- **Options:** Determine options for action, that is, the choice(s) that are available with regards to the decision being made.
- **Consideration:** Consider how the available options align with relevant ethical values or principles, legal frameworks or clinical considerations, stakeholder goals and preferences, including potential religious (see Chapter 3.4.3) or cultural (see Chapter 3.4.2) norms, etc.
  - Care should be taken when communicating with others involved in decision-making to ensure there is a shared understanding of relevant considerations (see Chapter 3.4.4).
  - Practice cultural humility and ensure that decision-making occurs in a culturally safe manner (see Chapter 3.4.2).
- **Recommendation:** Determine a course of action that is judged to be the ethically best choice in the given circumstances.
  - Where more than one option may be ethically acceptable, determine who should make the final decision between acceptable options.
  - Communicate the recommendation to relevant stakeholders and document the reasoning and process of decision-making.

- **Implementation:** After reviewing the ethical recommendations, the individual(s) responsible for decision-making should decide a course of action. The chosen course of action should be carefully implemented by the health professionals providing clinical care to the relevant patient(s) or overseeing particular activities in donation and transplantation.
- **Evaluation:** Reflect on the outcomes of the decision-making process and identify opportunities for future improvement.
    - » This should include consideration of the ethical aspects of the decision-making process itself (see Chapter 3.6).

The relative importance of specific components of the ethical decision-making process may shift as more aspects of a particular situation become clear or raise more questions. While the reasoning process itself may be dynamic and iterative, an ethical recommendation or decision should be clear and comprehensive, and well justified.

3.4.2 Cultural safety in care and decision-making

As discussed in the context of Principle 2 (see Chapter 3.3.2), cultural safety in ethical decision-making requires recognition not only of the relationships and structures of power that are embedded in healthcare policy and practice, but also in the 'historical and social dynamics' of healthcare interactions and of ethical frameworks and languages.[30]

The philosophical terms used to refer to specific ethical concepts in these guidelines are grounded in Western European knowledges and cultures, as is the legal framework that governs donation and transplantation in Australia. This may present a barrier to effective engagement in ethical decision-making by and with some First Nations peoples and members of culturally and linguistically diverse communities.

Differences in language may impede communication, but the frameworks and norms outlined in these guidelines may also be ill-suited to support or accommodate different cultural norms, practices, and decision-making frameworks. Practising cultural humility and promoting cultural safety is therefore essential for effective ethical decision-making and practice. The resources section in Appendix 1 provides links to some recommended resources to support culturally safe decision-making and care.

Box 3.1 Definition and practice of cultural safety

From: *Australian Health Ministers Advisory Council. Cultural respect framework 2016–2026 for Aboriginal and Torres Strait Islander health: A national approach to building a culturally respectful health system.*[32]

Cultural safety:

Identifies that health consumers are safest when health professionals have considered power relations, cultural differences, and patients' rights. Part of this process requires health professionals to examine their own realities, beliefs, and attitudes.

Cultural safety is not defined by the health professional but is defined by the health consumer's experience—the individual's experience of care they are given, ability to access services and to raise concerns.[41]

The essential features of cultural safety are:

- An understanding of one's culture
- An acknowledgment of difference, and a requirement that caregivers are actively mindful and respectful of difference(s)
- Informed by the theory of power relations; any attempt to depoliticise cultural safety is to miss the point
- An appreciation of the historical context of colonisation, the practices of racism at individual and institutional levels, and their impact on First Nations people's living and wellbeing, both in the present and past
- Its presence or absence is determined by the experience of the recipient of care and not defined by the caregiver.

3.4.3 Faith and religion

When making ethical decisions in a personal context, some people are guided by the ethical values and principles that are embedded in various faiths or religions or expressed in the form of faith-based obligations. Faith-based beliefs should be treated respectfully and given consideration where relevant in ethical decision-making.

All major religions recognise cell, tissue, and organ donation as an act of charity and goodwill, including donation after death.[38] All major religions either support cell, tissue and organ donation and transplantation or accept the right of individual members to make their own decision about donation or transplantation. For more information about the positions of various religions in Australia on donation and transplantation, please consult the further resources in Appendix 1.

3.4.4 Clarity of communication about ethics

Clarity of communication is particularly important when making ethical decisions in the clinical context. People involved in decision-making may need to process a considerable amount of unfamiliar information, for example information of a clinical or scientific nature, at a time when they may be experiencing significant stress or anxiety.

Ethical values and principles may be explained in different ways in different contexts. Some core concepts that are especially complex may be interpreted or defined in particular ways in specific contexts, requiring careful explanation in those contexts to avoid confusion. If terminology or concepts are used without an explanation of their meanings in specific contexts, this can result in ethical disagreements or confusion between health professionals, patients, and families.

Throughout these guidelines, we strive to explain what is meant when specific terms or concepts are used, and to use these terms consistently as per the Glossary. When managing ethical dilemmas or making ethical decisions in practice, one of the most important steps is to ensure that all those involved in an ethical discussion have a shared understanding of the language that is used. People may disagree with an ethical principle, for example, because they have a different understanding of what is meant by it. Alternatively, people may agree with the principle but disagree regarding the implications of applying it in a particular context. Clarity in communication is essential for effective ethical analysis and decision-making.

3.4.5 The role of advocates in ethical decision-making

Many people may play a valuable role in supporting ethical decision-making in clinical practice by advocating on behalf of potential donors or transplant recipients or on behalf of their families and communities. In some circumstances, individuals may be formally designated as an advocate and assigned specific professional responsibilities in this role.

Formally designated advocates are often mentioned in the context of living directed donation of HSCs or kidneys, and particularly with regards to advocacy on behalf of children or adults lacking decision-making capacity (see Chapter 5). However, advocates may play a helpful and/or necessary role in the care of other people including potential transplant recipients who lack decision-making capacity, and non-directed living kidney donors.

Variations on the term ‘patient advocate’ are common in the literature and in policies and guidelines for living donation and transplantation. It is important to note that the specific role and responsibilities of advocates vary considerably. Clinical guidelines or policies that are used in Australia should clearly specify the role and duties of an advocate in specific contexts, as well as any necessary competencies or qualifications that a particular kind of advocate may need.

Potential roles and responsibilities that may be assigned to or associated with a formally designated advocate:

- **Provision of psychological and/or social support** (e.g., for a prospective living donor or transplant recipient). In this role, an advocate may act as a liaison between the individual and various health professionals or other care providers, for example helping them to access relevant counselling or socioeconomic support services. The advocate may also provide direct support in a counselling role. For example, an advocate may attend meetings between a prospective donor or transplant recipient and clinical teams if helpful to support communication and ensure the patient has opportunities to ask questions, seek clarification and so on. Advocates may also play a role in helping a potential living directed donor or transplant recipient to navigate potential conflicts in decision-making between them and family members and/or health professionals.

- **Indigenous liaison staff** may play a particularly important role as advocates in ensuring Aboriginal and Torres Strait Islander patients and their families receive culturally safe and effective care, as demonstrated by their impact in other clinical settings.[39]
- **Advisor** (e.g., with regards to decision-making about donation or transplantation). In this role, an advocate may serve as a source of independent advice, usually to the prospective living donor or transplant recipient or their substitute decision-maker, regarding the risks and potential benefits of choices that may be available to them. This may be particularly important in the context of living directed organ or HSC donation, where prospective donor and recipient interests intersect, and relationships may complicate decision-making by individuals.
- **Evaluator/Assessor** (e.g., with regards to potential risks and benefits of donation or transplantation for a child or adult lacking decision-making capacity (see Chapter 5)). In this role, a professionally appointed advocate may be tasked, for example, with making an independent assessment of a prospective donor or transplant recipient in order to determine their preferences or interests. The advocate may also be expected to speak for the individual if they are unable to speak on their own behalf. The advocate is responsible for promoting the donor or recipient's interests, wellbeing, and safety, and for ensuring that their expressed preferences are taken into account.

  The need for an advocate of this kind may arise due to the presence of potential conflicts of interest on the part of the prospective donor or recipient's substitute decision-maker, or because of potential conflicts or disagreements between the substitute decision-maker and members of the clinical team. In this role, the assessor should not be considered the final arbiter of disagreements, but rather a person who has responsibility for gathering information to inform decision-making. This differs from **independent decision-makers** (e.g., courts, tribunals, committees) that may be required by law in some circumstances.

Ideally, in relation to potential living donors, an advocate should be appointed early in the process of determining whether an individual will act as a donor (i.e., tissue typing stage) and continue in that role throughout the entire donation process. This enables a trusting relationship to be established between the donor and the advocate.

3.4.5.1 Ethical considerations with regards to formally designated advocates

An independent advocate is expected to perform their duties impartially. Their primary duty of care is towards the person on whose behalf they are advocating. They should ideally be free of potential conflicts of interest in both decision-making and judgement. Recruitment of wholly independent advocates may be difficult in some settings, for example when patients belong to relatively small cultural communities, and pre-existing relationships between patients and potential advocates may be unavoidable. Such relationships may be beneficial but may also increase the risk of potential bias or conflicts of interest on the part of the advocate, for example if a prospective living organ donor's advocate also has relationships with their prospective transplant recipient.

The use of professional advocates in patient care more broadly has been recognised as having both risks and potential benefits. It is important to ensure that advocates are competent to perform the duties associated with their role, and able to respect relevant role boundaries.[40] Care must also be taken to ensure that advocates do not act

paternalistically, and that the values and preferences of individuals on behalf of whom they are advocating are respected to the greatest extent possible.

3.4.6 Resolving conflict or disagreements in ethical decision-making

Conflicts or disagreement are often encountered in the healthcare context. Disagreements can arise, for example, within families, between patients and health professionals, and between health professionals. Disagreements are often the result of breakdowns in communication but may also relate to differences of opinion with regards to treatment decisions. Ethical disagreements or conflicts involve value-based disagreements.

Approaching ethical decision-making using the approach outlined above (Chapter 3.4.1) may help to avoid or resolve existing disagreements. Involving health professionals or clinical ethics consultants who are competent in clinical communication skills and, ideally, trained in mediation, is essential to support effective conflict resolution.

Specific strategies to support conflict resolution or mediation of disagreements have been outlined in the clinical ethics literature (see Appendix 1).[41] Where disagreements cannot be resolved, it may be necessary to engage external mediation services or to obtain independent legal advice.

3.5 Laws

Laws are another important normative framework that sit alongside ethical frameworks and are informed by ethical values and principles. Laws are developed by State, Territory, and the Commonwealth parliaments, as well as made by judges in courts.

As rules that govern many aspects of our society, knowledge of relevant laws is important for appropriate ethical decision-making in donation and transplantation. Failure to follow the law can result in offences being committed or penalties being imposed. This is the case, even if a person does not know about the specific law.

In addition to 'human tissue' legislation which specifically addresses aspects of cell, tissue and organ donation, other laws such as those relating to medical treatment decision-making (see Chapter 4.3.1 (living donation), Chapter 4.4.1 (deceased donation) and Chapter 5.2 (substitute decision-making and medical treatment laws)); privacy (see Chapter 7.1.1); and the regulation of therapeutic goods (see Chapter 3.5.2) may play an important role in guiding practice in donation and transplantation. Relevant legislation for each State and Territory are summarised in this section and in specific sections throughout these guidelines, but these summaries are general in nature and independent legal advice should always be sought when legal issues arise in particular cases.

3.5.1 Human tissue legislation

Legislation in each State and Territory governs donation and transplantation for clinical purposes (see **Table 3.2**). Although referred to as 'human tissue legislation' in accordance with the terminology used in much of this legislation, the legislation is also inclusive of cells and organs.

Common features of this legislation across all Australian jurisdictions include provision of a legal mechanism for authorising living and deceased donation of organs and tissues

(Chapters 4.3.1 and 4.4.1), disclosure of identity of donors and recipients (see Chapter 7.1.1.1), and prohibition against trading in human tissues with some limited exceptions (see Chapter 10.2).

Table 3.2 - Human Tissue Legislation in Australia

Legislation	Hyperlink
ACT Transplantation and Anatomy Act 1978	https://www.legislation.act.gov.au/a/1978-44/
NSW Human Tissue Act 1983	https://legislation.nsw.gov.au/view/html/inforce/current/act-1983-164
NT Transplantation and Anatomy Act 1979	https://legislation.nt.gov.au/Legislation/TRANSPLANTATION-AND-ANATOMY-ACT-1979
QLD Transplantation and Anatomy Act 1979	https://www.legislation.qld.gov.au/view/html/inforce/current/act-1979-074
SA Transplantation and Anatomy Act 1983	https://www.legislation.sa.gov.au/lz?path=/c/a/transplantation%20and%20anatomy%20act%201983
TAS Human Tissue Act 1985	https://www.legislation.tas.gov.au/view/html/inforce/current/act-1985-118
VIC Human Tissue Act 1982	https://www.legislation.vic.gov.au/in-force/acts/human-tissue-act-1982/045
WA Human Tissue and Transplant Act 1982	https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_a364.html

Please note that the above links are current at the time of writing but may lead to out-of-date versions of legislation in future. As legislation is regularly amended, please check that you are viewing the most current version, which should usually be accessible via the website.

3.5.1.1 Determination of death

Human tissue legislation provides a legal mechanism for authorising the donation of cells, tissues and organs following the death of a person.

In most Australian jurisdictions, death is legally defined as:

- irreversible cessation of circulation of blood in the body of the person; or
- irreversible cessation of all function of the brain of the person.

Potential ethical considerations in the determination of death in the context of donation are explored in Chapter 11.2. Clinical considerations in the determination of death and donation are outlined in Chapter 2.4.1.

3.5.2 Therapeutic Goods Act

A regulatory framework under the *Therapeutic Goods Act 1989* (Cth) exists for biological products that are made from or contain human cells or tissues, and which are intended to have a therapeutic purpose. That is, they are used to:

- treat or prevent disease, ailment, defect or injury
- diagnose a condition of a person
- alter the physiological processes of a person
- test the susceptibility of a person to disease
- replace or modify a person's body parts.

These types of products are known as 'biologicals' and fall within a regulatory framework for biologicals. The biological standards specify legal requirements for biologicals, for example in relation to infectious disease minimisation, manufacturing principles, labelling requirements as well as specific requirements relevant to types of tissue. Alternative regulatory pathways exist alongside the biologicals framework.

The Therapeutic Goods Administration (TGA) is the Commonwealth body that regulates and monitors therapeutic goods in Australia (see Chapter 2.3.5). It is responsible for authorising the supply of therapeutic goods through the Australian Register of Therapeutic Goods (ARTG) and monitors the quality, safety, and efficacy of therapeutic products, such as biologicals, in Australia. It is also responsible for licensing the operation of cord blood banks in Australia.

3.6 Ethical decision-making

For health professionals, ethical decision-making, like clinical decision-making, requires effort and training, use of relevant resources such as guidelines and consultation with more expert sources of advice when necessary. Ethical decision-making itself should be conducted ethically; decision-making that is marred by ineffective communication, deception, or prejudices cannot lead to ethically justifiable courses of action.

3.6.1 Responsibilities of health professionals when making ethical decisions

Health professionals should strive to demonstrate the following behaviours and attitudes in their approach to ethical decision-making:

- **Openness:** be open to new information and ideas from a variety of sources
- **Reflexivity:** consider one's own position explicitly, and reflect on perspectives, experiences and potential biases that might influence one's view of a particular situation or issue
- **Cultural humility:** engage in interpersonal thinking and actions that are responsive to the aspects of each person's cultural identity that are important to them[42]
- **Impartiality:** treat like situations alike, and consider information objectively, while being mindful of individual patients' situations and needs
- **Transparency:** communicate clearly the information, actions and reasoning relevant to an ethical decision throughout the decision-making process to affected parties

- **Integrity:** be honest and trustworthy in actions and decisions
- **Accountability:** provide opportunities for others including patients, their families or substitute decision-makers, and colleagues to discuss and evaluate decisions and their outcomes, and acknowledge and respond to feedback.

3.6.2 Promoting impartiality in ethical decision-making

As noted in Principle 3, decision-making about donation and transplantation should be free from bias or unfair discrimination (see Chapter 3.3.3) as a matter of procedural justice (see Chapter 3.6.3). Promoting impartiality in ethical decision-making requires attention to how and what information is gathered, evaluated, communicated, and used in decision-making.

How information is gathered and evaluated may be inappropriately influenced by various forms of bias which leads to poor quality of ethical decision making. Lack of objectivity in evaluation of potential benefits and risks of donation or transplantation, for example, may result in decisions that exacerbate inequities in access to transplantation or prevent the opportunity for an individual to become a donor (see Chapter 6.1.4).

How information is communicated is important not only to promote understanding but to avoid undue influence or manipulation of the beliefs and preferences of decision-makers by health professionals who are supporting decision-making. For example, when communicating risks and benefits of donation or transplantation to patients or their substitute decision-makers, health professionals may be influenced by their own beliefs and preferences, limitations of their clinical knowledge, workplace practices and cultures, or a paternalistic desire to protect patients from harm. These factors may lead to bias in the communication of information to patients and others who may be involved in decision-making.

Information should be provided to decision-makers in a way that respects their autonomy, recognises potential diversity in attitudes and values, and ensures relevant evidence is communicated impartially.

3.6.3 Procedural justice and inclusivity in decision-making

Decision-making relating to policy, practice and governance of donation and transplantation activities should be procedurally fair. This requires equitable inclusion of relevant stakeholders or their representatives in decision-making, and transparency in decision-making.

Representatives of stakeholders including donors, donor family members and transplant recipients should routinely be involved in decision-making about donation and transplantation policies and governance of donation and transplantation programs and activities.

Stakeholder representatives should reflect the diversity of people whom they represent and be inclusive of First Nations peoples, and people from culturally and linguistically diverse communities.

Inclusivity in decision-making requires efforts to identify and address potential cultural, linguistic, literacy and other barriers to communication and participation in decision-making; it also requires a culturally safe decision-making environment (see Chapter 3.4.2). This requires:

- recognition that cultural safety is defined by the individual's experience of care not by the health professional.
- acknowledgement that power relations shape cultural safety in healthcare interactions.
- each person involved in decision-making to have an understanding of their own culture.
- respectful acknowledgement of cultural differences.
- understanding of the historical and current impact of racism and colonisation on the lives and wellbeing of Aboriginal and Torres Strait Islander people.[42]
- increased cultural diversity of the healthcare workforce and provision of training and education for all staff to improve cultural safety in care and decision-making about donation and transplantation.

3.7 Conscientious objection and moral distress

In some circumstances, health professionals working in donation or transplantation may wish to exercise a right of conscientious objection to specific clinical practices or interventions. In this section we explain the concept of a conscientious objection and the ethical considerations relating to the right of conscientious objection, and discuss its potential use in donation and transplantation. We also explain the concept of moral distress and discuss why it is important to recognise and address this when it occurs.

3.7.1 Conscientious objection in healthcare and its limits

When a health professional firmly believes that a lawful clinical resource, practice, or intervention is morally or ethically wrong, they are considered to have a conscientious objection to that practice or intervention. The right of conscientious objection in healthcare refers to a health professional's right to refuse to provide the resource, to practice or to participate in the intervention when this is clinically indicated for patient care.

Generally speaking, health professionals in Australia are permitted to exercise a right of conscientious objection under specific conditions,[43] which typically include ensuring that:

- patients are informed of their conscientious objection
- patients are informed about and referred to alternative care providers from whom they can access the treatment
- where an individual's refusal to provide a treatment may endanger the life of the patient seeking care, for example if no other care provider is available, the health professional has an obligation to provide the treatment
- the health professional does not stigmatise or otherwise treat the patient disrespectfully.

3.7.1.1 Distinguishing conscientious objection from other beliefs that may influence provision of care

It is important to distinguish conscientious objection from other factors that may lead a health professional to refuse to provide a specific treatment in a particular case, such as discrimination or bias against specific individuals or groups, or a clinical rather than ethical judgement that the treatment is inappropriate.

Similarly, although conscientious objection may be associated with moral distress, not all instances of moral distress, or emotional distress more broadly will be related to conscientious objection. For example, if an intensive care nurse is unwilling to continue providing care to a paediatric patient who is awaiting donation after determination of death by neurological criteria, because the nurse is emotionally impacted by the child's death and feels unable to interact professionally with the child's parents, this would not be a case of conscientious objection.

3.7.1.2 Potential benefits and risks of conscientious objection in healthcare

The right of conscientious objection is ethically controversial. It is important to reflect on the potential arguments influencing positions on this right in order to understand different perspectives. These arguments should also be carefully considered when establishing or implementing policies with regards to conscientious objection in the context of donation or transplantation.

Arguments in favour of permitting health professionals to refuse to perform interventions that conflict with their fundamental ethical beliefs or values include claims that:

- respecting health professionals' personal ethical values fosters ethical awareness and encourages health professionals to practice ethically rather than suppressing their ethical commitments
- encouraging health professionals to reflect on the legality of clinical practices and to potentially advocate for changes to law that may be ethically necessary
- compelling health professionals to perform interventions or provide resources they believe to be ethically wrong may lead to behaviours that are harmful to patients, such as attempts by health professionals to create barriers to access to care, to manipulate patient decision-making, or to fail to meet standards of care when performing interventions.

Those that oppose the right of conscientious objection instead argue that:

- it may result in patients being denied access to treatments to which they are lawfully entitled, or may create delays in access that could be harmful to them
- it exacerbates inequities in access to health, for example because people who already face barriers in accessing health services are more likely to have difficulty in obtaining care from another provider if they encounter a conscientious objector
- health professionals who have been trained in public health systems or who have received support in their studies from the public sector have an obligation to provide all necessary care to the public
- health professionals who choose to practice in specific fields in which they may be expected to provide a service to which they conscientiously object should have chosen a different field, as providing the service is an expectation of those who commit to a particular specialty or area of practice

- when a right of conscientious objection is permitted, the burdens of providing the particular intervention will disproportionately impact other health professionals.

3.7.2 Conscientious objections in the context of donation and transplantation

Some health professionals who have specific roles in donation or transplantation, or who work in areas that may intersect with donation or transplantation activities, such as intensive care, may hold ethical beliefs that conflict with some of those activities.

It may be difficult to determine when a valid conscientious objection to a donation or transplantation activity exists. For example, a health professional may ethically support deceased donation, but may disagree with specific clinical protocols for the determination of death. This may lead them to object to deceased donation procedures in circumstances where they do not believe a person to be deceased. Others who hold a conscientious objection to voluntary assisted dying (VAD) may object to being involved in donation or transplantation procedures when a donor has died as a result of VAD (see Chapter 11.7).

Box 3.3 outlines recommendations for managing conscientious objections in the context of donation and transplantation.

Box 3.3 Recommendations for managing conscientious objections in the context of donation and transplantation

In managing conscientious objections in the context of donation and transplantation, health professionals should:

- disclose any conscientious objection which may impact their ability to provide care to patients to their employer or manager
- refrain from communicating personal ethical objections they may hold regarding lawful clinical practices to patients or their families, in order to avoid causing distress or undermining trust, except where disclosure is necessary to ensure that patients or their families have the opportunity to seek care from an alternative provider
- ensure that their objection does not negatively impact opportunities for donation and transplantation or influence decision-making by patients or their families regarding donation and transplantation
- be provided with opportunities to raise and discuss any ethical concerns they may have regarding donation or transplantation activities with healthcare authorities or professional organisations.

Where an individual's refusal to provide a lawful treatment may endanger the life of the patient seeking care, for example if no other care provider is available, the health professional has an obligation to provide the treatment.

3.7.3 Moral distress

If people feel unable to follow what they believe to be the ethically right course of action in a given situation, due to factors that are beyond their control, they may experience psychological distress. The term moral distress is commonly used to describe this phenomenon in settings where health professionals experience distress because they feel that they are prevented from acting in accordance with their ethical values or duties due to institutional constraints or resource limitations.

Sometimes moral distress, or similar terms like 'ethical anxiety', is used to describe a broader range of situations of ethical ambiguity or uncertainty in which psychological distress is linked to a 'moral event'.[44] This includes situations where there are institutional or system constraints on action, where the ethically right thing to do is not evident even after investigation, or where the chosen course of action seems to be the result of the choice between equally poor options. Patients and family members may also experience moral distress, particularly when making decisions on behalf of others.[45,46]

It is important for individuals and institutions to be aware of moral distress and consider ways in which to address it. This is because such distress can be a sign of underlying ethical issues that should be addressed, and because moral distress may be linked to burnout and staff turnover, and to moral injury.[47] Prevention of moral distress is a key component of care for patients, their families and health professionals.

Engaging in explicit ethical deliberation within the healthcare team and with patients and their families throughout the process of making challenging decisions can help individuals to develop a clearer understanding of why decisions are made and their own role in decision-making. This also helps to ensure that everyone has the opportunity to express and explain their own views. Investing time and care in ethical decision-making including recognition and resolution of potential ethical disagreements may help to support acceptance of decisions and reduce the incidence of decisional regret, in which individuals feel the wrong decision was made.

Where moral distress occurs, strategies should be used to support patients, family members and health professionals in managing their distress and prevent the development of longer-term moral injury.[48] These include:

- reflective practices to assist in working through difficult emotions such as counselling and team debriefs
- reviewing ethical decisions and their outcomes in order to inform future decision-making and strategies that prevent future issues may also help to address moral distress
- advocating for changes in constraints that are amenable to change may help people experiencing moral distress to regain a sense of ethical agency in their lives.

3.8 Conflicts of interest in decision-making

Decision-making in healthcare, and especially in the context of donation and transplantation, can involve multiple people and organisations or institutions, all of whom may hold multiple interests of relevance to a particular decision. As outlined in Principle 4, potential conflicts of interest should be avoided and appropriately managed when they are unavoidable (see Chapter 3.3.4).

When a person or other entity has a conflict of interest in a particular situation, this creates concerns about the potential impact of this conflict on decision-making. Specifically, it causes concern that individuals may fail to make decisions or act in accordance with their primary ethical obligation - such as a duty of care towards patients (see Chapter 3.3.4.1) - in a particular situation, due to the influence of their competing interests.

Even when an actual conflict of interest does not exist, but rather a potential or perceived conflict of interest, these must be taken seriously.

A **potential conflict of interest** is present in a situation in which a person or organisation has multiple interests that *could* conflict. Although a direct conflict of interest may not be present, the fact that it could arise requires careful management to ensure it does not occur.

A **perceived conflict of interest** occurs when there is a situation in which there might *appear* to be a conflict of interest, or a potential conflict of interest, even if there is no actual conflict of interest. If people perceive that there is a conflict of interest, this could cause them to lose trust in the decision-making even if there is, in fact, no conflict.

Although some potential conflicts of interest may seem obvious, others may be less readily identified and thus more likely to overlooked. More subtle conflicts of interest include those that may be embedded in institutional policies or systems. Interests that may conflict in a particular situation include potential private or personal, professional, financial, institutional, and spiritual values, goals, commitments, or relationships. Concerns about conflicts of interest in the context of specific donation and transplantation activities are explored throughout these guidelines.

3.8.1 Examples of potential conflicts of interest in donation and transplantation

- A parent has a primary duty of care towards their two children. If one of the children requires a lifesaving bone marrow transplant and the other child is the only suitable donor, the parent has a conflict of interest in making a decision about donation. Their desire to save the life of one child may conflict with their duty to protect their other child who may be at risk of harm from donation (see Chapter 5.5.3.3).
- A person making a decision about tissue donation on behalf of a relative who has died may have an interest in donation taking place, for example, because they expect to feel some comfort if donation occurs or simply because they know that donation is what their relative wanted. They may also have an interest in declining donation, if this means that they will be able to proceed more quickly in making funeral arrangements and removing their loved one's body from the hospital. These two interests or goals may conflict if it is not possible to achieve both without some degree of compromise. In this situation, the person making a decision has a primary duty to respect the deceased's decision or preferences where these are known (see Chapter 4.4.2.2).

3.8.2 Management of conflicts of interest

Several general strategies are recommended to assist in managing perceived, potential and actual conflicts of interest to ensure that these do not inappropriately influence or appear to influence decision-making or practice.[49] These are outlined in **Box 3.4** below.

Box 3.4 - General strategies to assist in management of potential conflicts of interest

1. Disclose interests so that others are aware and hence alert to the risk of potential bias
2. Avoid or remove potential conflicts of interest where possible, e.g., by excluding individuals from decision-making if they hold a significant interest in the decision being made, or by moderating their involvement in decision-making where their inclusion is necessary
3. Use decision-making aids such as clinical guidelines or protocols to guide decision-making so that some decisions are not made by individuals, e.g., organ allocation frameworks that determine the most suitable recipient for an organ based on objective clinical criteria
4. Use independent advocates, boards or institutions to assist or oversee decision-making; e.g., a financially independent board to oversee tissue banks
5. Separate decisions where possible, e.g., decisions about deceased donation should be separated from decisions about cessation of life sustaining treatments
6. Separate clinical roles where duties of specific roles may conflict, e.g., separate clinical teams for living donors and recipients
7. Conduct regular audit of decision-making, outcomes of decisions, and policies and practices to check for signs of potential bias that may reflect the presence of conflicts of interest.

Case Study – Conflicts of interest

Dr H is an orthopaedic surgeon who specialises in hip surgery. They are the head of orthopaedic surgery at a hospital in a large rural city. Dr H recently established the first bone bank in the city, which will collect bone donations from patients who have part of their hip bone removed during hip replacement surgery.

Dr H has been raising awareness of the bank in the community and among staff at the hospital. A nurse from the outpatient surgical clinic has been appointed as a donor coordinator to manage donor recruitment. The donor coordinator provides information to potential donors and obtains written consent for donation from those who wish to donate before they undergo surgery.

Malcolm is a 67-year-old-man who is admitted to the hospital for an elective hip replacement to be conducted by Dr H. Dr H sees Malcolm outside the operating theatre before surgery and says hello. Dr H then tells Malcolm, 'It looks like you didn't sign a consent form to donate your hip bone to our new bone bank. We're removing the bone anyway in order to give you a new hip. If you don't donate it, we'll just be throwing the

bone away. It would be really great if you'd let me send it to the bank instead, where we can transform it into something useful to help other patients.'

Malcolm replies, 'I have a few questions about the bone bank I'd like answered, but I'm probably happy to donate.'

'Well, we don't want to hold everyone up and delay your operation,' says Dr H. 'Let's do the paperwork now and I'll be happy to answer your questions when I see you on the ward tomorrow.' They help Malcolm sign the consent form for donation.

Points to consider:

- This case demonstrates the potential impact of a conflict of interest on decision-making about donation (see Chapter 3.8).
- The following principles may be especially relevant to this case:
  - **Principle 4** In donation and transplantation activities, potential conflicts of interest should be avoided and, where unavoidable, should be appropriately managed.
  - **Principle 11** Decision-making about donation and transplantation should be free from coercion, exploitation or financial incentives; this should not preclude coverage of costs associated with donation or transplantation.
- In this scenario Dr H has a conflict of interest because they have an interest in providing care for their patient, which involves performing the hip replacement surgery, and they also have an interest in increasing donations to the new bone bank.
- These interests both reflect ethically important professional goals that are appropriate for Dr H to hold. However, in this situation the interests may conflict, and Dr H's desire to make the bone bank a success could negatively impact their ability to fulfill their primary duty of care towards Malcolm. Rather than focusing on Malcolm as a patient about to undergo a significant operation, Dr H appears to be focusing more on obtaining his consent for donation.
- In a clinical setting, a health professional must always prioritise their duty of care towards patients, rather than other professional or personal interests they may have (see Chapter 3.3.4.1).
- Dr H's interests in the bone bank may cause them to provide information about donation that is biased. A balanced assessment of potential benefits and risks of donation is essential for donation decision-making, especially in the case of other types of living donation where there may be substantial risks associated with donation (see Chapter 6.3).
- Having a designated person with responsibility for recruitment and gaining consent from potential donors to the bone bank is an important safeguard that should help to avoid situations like this arising. Relying on the donor coordinator, rather than the clinician involved in the patient's care, also helps to support voluntariness in donation decision-making. Malcolm may find it difficult to decline consent when asked to donate by his surgeon, because he may worry that declining could negatively impact his medical care.
- The timing of donation decision-making is also important in avoiding or managing potential conflicts of interest. In this scenario, pressing Malcolm to make a decision just before surgery takes place is problematic as he is in a vulnerable position and there is little time for discussion or reflection before making his decision.

- An additional consideration is whether Malcolm has provided valid consent when signing the donation form. As the previous points indicate, it is unclear if Malcolm's decision was voluntary. It is also unclear if he was adequately informed when making the decision, as he had questions which were not answered. The requirements for consent are outlined in Chapter 4.1.
- In addition to the ethical advice provided in these guidelines, medical practitioners in Australia should be mindful of relevant ethical guidance outlined in *Good medical practice: a code of conduct for doctors in Australia*: https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx

4. Decision-making and consent

Everyone should have the opportunity to consider and decide about donation or transplantation of cells, tissues, or organs when this may be relevant to their interests.

This chapter provides information about key ethical considerations in donation and transplantation decision-making. Many of these are derived from or informed by the core ethical values and principles outlined in Chapter 3.1.

Including people in decision-making about their own healthcare and the legal requirement to obtain valid consent to treatment before performing clinical interventions generally promotes respect for autonomy in clinical practice. However, merely including people in decision-making is not sufficient to ensure their autonomy is respected. Ensuring cultural safety (see Chapter 3.4.2) and paying attention to how best to support a person's decision-making (see Chapter 5.1.3.1) as well as attending to factors that enable active participation in decision-making by all relevant stakeholders is essential.

In this chapter, the core elements of consent are explained, as well as strategies that are used to promote autonomy and support decision-making in situations where it may not be possible to obtain consent directly from an individual about their involvement in donation or transplantation. Situations are also discussed where decision-making may be complicated or where particular attention should be paid to specific aspects of decision-making or consent, in order to ensure that ethical standards are upheld. Specific aspects of decision-making in relation to donation and transplantation in children or adults who may lack decision-making capacity are discussed in Chapter 5.

This chapter should also be read in conjunction with Chapter 6, which examines ethical considerations in evaluating and managing the potential risks and benefits of donation and transplantation. Information about risks and benefits is a key component of ethical decision-making for donation and transplantation, and concerns about risks and benefits can significantly influence the approach to decision-making. Chapter 3.6 also provides advice on ethical decision-making.

Of note, many disagreements with regards to decision-making in healthcare are the result of ineffective or inappropriate communication or lack of timely communication, rather than ethical disagreements as such. Establishing a culturally safe environment for decision-making also supports quality in decision-making and care (see Chapter 3.4.2). Readers are encouraged to explore the recommended resources for this chapter in Appendix 1 which may help to support effective communication and culturally safe decision-making in donation and transplantation.

4.1 General considerations in consent

Valid consent for a decision about donating cells, tissues or organs or receiving a transplant requires that the person making the decision is legally authorised to do so. Considerations with regards to legal authority for decision-making in specific donation and transplantation circumstances are discussed in the relevant sections.

The decision-maker must also meet the following criteria:

- has decision making **capacity**, including the ability to communicate their decision

- is making a **voluntary** decision without undue influence, manipulation, or deceit, and
- has received and **understood** sufficient **information** that is relevant to the decision, including the risks and benefits of relevant interventions, and available alternatives if relevant.

The conditions that must be met for valid consent to be obtained are explained in more detail below.

Of note, consent is commonly regarded as being **specific** to a particular intervention in particular circumstances. Consent should also be **current**; if a preliminary decision is made by a person to undergo transplantation or donation this should be checked to ensure consent remains valid at the time of the actual intervention.

Consent is often a **dynamic** process. For example, a transplant candidate may have consented to a specific transplant procedure when they first joined the organ transplant waiting list or were referred for a corneal transplant. However, when a suitable donor organ or tissue becomes available for transplantation, it's important to ensure that the candidate understands the relevant information that may be specific to the particular organ or tissue being offered, and any other information that may have changed during the intervening time. For example, the candidate's own health status may have changed in ways that mean the expected risks and benefits of the procedure are now different. Similarly, relevant information will likely include information about specific characteristics of the donor organ or tissue.

4.1.1 Decision-making capacity

When a person is tasked with making a decision about donation or transplantation, consideration must be given to their ability ('capacity') to understand the relevant information and to provide legally valid consent for a decision. All adults are presumed to be able to make decisions and in most Australian states and territories, a person over 18 years of age is presumed to have the capacity to make decisions about their own healthcare unless there is evidence to the contrary. Nevertheless, it is important to check that individuals have decision-making capacity.

Individuals are considered to have capacity to give consent to donation or transplantation when they can:

- understand the information involved in making the decision
- understand the possible choices
- weigh up the consequences of the choices
- understand how the consequences may affect them, and
- communicate their decision.

Capacity is **specific** to the decision being made at the time it is being made. This means that a person may have capacity to make a decision about some aspects of their treatment, but not others. A person's decision-making capacity may also fluctuate over time. Increasingly, more attention is being given to how best to support people in their decision-making.

4.1.1.1 Decision-making when capacity may be impaired

People less than 18 years of age may have the capacity to consent in some circumstances which are outlined in Chapter 5.1.2. When a person of any age lacks decision-making capacity to consent to a particular medical decision, others (a 'substitute decision-maker') may be required to provide consent on their behalf. Considerations when decisions are being made by or on behalf of people who may lack capacity to consent are outlined in Chapter 5.3.

Some people with impaired capacity may still be able to make a decision if they are given sufficient assistance to do so. The importance of 'supported decision-making' has been recognised by governments and is discussed in Chapter 5.1.3.1. When a person lacks decision-making capacity it is still important to include them in decision-making to the maximum extent possible.

In some circumstances, such as when a person unexpectedly requires a time-critical life-saving transplant, potential donors, transplant recipients, or their substitute decision-makers may lack the time and emotional calm to gather, process, discuss and reflect on information when making a decision. Some people in such circumstances, and even in non-time critical circumstances claim that their decision to donate or accept a transplant was automatic, and that no further time or information would change their decision. This can raise concerns about their ability to provide valid consent (or refusal) for donation or transplantation, however it should not be assumed that such 'impulsive' decisions are invalid or that people in these circumstances are unable to make an enduring decision about donation or transplantation. Careful assessment and additional supports for decision-making may be required to help ensure valid consent is obtained and to reduce the risk of regret later occurring regarding the decision made (see discussion of 'shared decision-making' in Chapter 4.1.2.1).

4.1.2 Voluntariness

It is important that people make decisions about donation and transplantation voluntarily, meaning freely, without being forced, deceived, or otherwise manipulated. Ensuring that a decision is made voluntarily doesn't mean that a person must make a decision on their own (see Chapter 4.1.2.1).

There are several factors that may raise concerns about whether a person is making a genuinely voluntary decision to become a donor or a transplant recipient. Some of these factors are common to any healthcare decision, such as the involvement of health professionals and a person's relatives or friends who may be influential in decision-making. Other factors may be more specific to decision-making about donation and transplantation, particularly in the context of living directed donation in which decision-making may be complicated by relationships between potential donors and transplant recipients (see Chapter 4.3.3.1).

Specific strategies may be used to safeguard voluntariness in donation and transplantation decision-making, such as the use of independent advocates for decision-makers (see Chapter 3.4.5) and the separation of some decisions, decision-makers, and clinical teams to assist in managing potential conflicts of interest that could unduly influence decision-making (see in Chapter 3.8).

4.1.2.1 Shared decision-making

Shared decision-making is the term used to describe a collaborative approach to healthcare decision-making that is now considered best practice. It involves discussion between the person making the decision, such as the person providing consent to donation or transplantation, and other people who may have relevant expertise, skills or perspectives that will help the decision-maker to determine and reflect on their own values and preferences as they relate to the decision.

In some cases, a prospective donor or recipient's partner, family members or carers may be closely involved in decision-making. For example, family members may also be impacted by the decision being made or may be involved in providing ongoing support to the person following donation or transplantation.

Shared decision-making is especially important when providing care to some Aboriginal and Torres Strait Islander people and others for whom inclusion of extended kinship or family networks in decision-making may be essential. Shared decision-making can help to promote cultural safety, and a layered approach to decision-making may help to support engagement of relevant individuals or groups while ensuring that the autonomy of primary decision-maker(s) is respected.

The collaborative nature of shared decision-making means that the role of health professionals is not simply to provide information to the person making the decision, but to support them in making the decision. Health professionals may also ask the decision-maker questions, in order to develop a better understanding of their values, beliefs and preferences. By finding out what might be considered important by the decision-maker, health professionals may be better able to identify information that the person may value when making their decision (see Chapter 4.1.3).

4.1.3 Information and understanding

Information should be provided to people making decisions about donation and transplantation in a manner that is likely to be understood by the relevant decision-makers, appropriate to their individual needs and situations, and sensitive to linguistic, cultural, and spiritual considerations that may affect their understanding and decision-making. People may have different preferences regarding the amount and type of information that they receive when making a decision, but it's important to ensure they have the opportunity to receive and understand the key information that a person would reasonably be expected to need and want in order to make a particular decision. Some people may wish to have a person support them in their decision-making. Adequate time, information, privacy, and support should be made available so that decision-makers make an informed and enduring decision about donation or transplantation. Decision-makers should have the opportunity to ask questions and be assisted to make use of additional sources of information or advice where relevant (see also Chapter 5.1.3.1).

One of the biggest ethical challenges with regards to provision of information when obtaining consent for donation or transplantation is determining what information it is necessary to communicate. Legally, there is an expectation that health professionals will provide information to prospective donors, recipients or their substitute decision-makers about the proposed clinical interventions, including information about any proposed intervention and alternatives, and the consequences and risks of different options. Risks that should be discussed with the person include those that a reasonable person would want to know and also risks to which individuals may attach significance, due to their personal circumstances.

Chapter 6 explores the complexities involved in assessing risks and potential benefits of donation and transplantation which may determine which information is relevant in the context of specific decisions.

In general, information should be provided about

- the intervention that is proposed, such as the surgical or medical procedures that may be necessary for donation and transplantation
- the purpose of the intervention(s) and who will be involved in the process
- the expected outcomes of the intervention and its likely risks and benefits
- alternatives to the intervention including the option of doing nothing
- any limitations on the information provided such as uncertainty regarding potential outcomes
- potential conflicts of interest or other factors that may lead to bias (see Chapter 3.8)
- any limitations of privacy that may be relevant such as the requirement to disclose some clinical information about donors to transplant recipients (see Chapter 7.2.1).

Information that is specifically relevant to the persons involved in decision-making should be provided. For example, the likely risks of removing a kidney in a living donor should be estimated based on the known characteristics of the individual who is considering donating their kidney rather than general population level risks, as these may be different. Some examples of specific information that it may be ethically important to disclose and consider in particular circumstances are provided in the sections below. Key information of potential relevance to non-directed donations is discussed in Chapter 4.1.3.1.

4.1.3.1 Information of potential relevance in non-directed donations

Most Australians likely believe that organs and tissues obtained from deceased donors – and tissues obtained from living donors during therapeutic procedures - will be used for transplantation within Australia.[50] Many may not know that there is a possibility that organs or tissues may be exported overseas in some circumstances (see Chapter 9.3.4). Information about potential exportation of donations may be particularly relevant if the potential donor identifies as Aboriginal and/or Torres Strait Islander, due to the cultural significance of 'Country' for Aboriginal and Torres Strait Islander peoples, and connections between individuals, their kin and communities, and their ancestral lands.

Information about additional options such as whether donated tissues or organs may be used in research if they are unsuitable for transplantation should also be provided (see Chapter 12.7).

Finally, anonymity requirements and expectations regarding contact between donors, donor families and transplant recipients (see Chapter 7.3) should also be discussed.

4.1.4 Valid refusal and the right to withdraw consent

Just as a person is able to consent to interventions or treatment offered to them, a person is also able to decline or refuse consent to participate as a donor or recipient. It is important to ensure that decision-makers are competent, informed and voluntarily refusing the relevant intervention, especially in circumstances where withdrawal of consent may have harmful consequences for others as discussed in the following sections.

Ensuring that all donation decision-makers are fully informed at the time of making a donation decision and have the opportunity and time to reflect on, discuss and affirm an authentic decision in line with their values and beliefs may increase the probability that a donation decision will be enduring.

If a person has provided consent for donation or transplantation, they have the right to withdraw their consent until the donation or transplantation procedure takes place. After donation has occurred but before donations have been transplanted, custodians of donated cells, tissues or organs have the right to decide on use of the donations but should strive to do so in accordance with the expectations and preferences of the donation decision-maker at the time of their consent. As discussed in Chapter 3.3.10.1, once donated cells, tissues, or organs have been transplanted, it is the recipient who has autonomy to make decisions about further treatment of the transplanted tissue they have received.

In exceptional circumstances, custodians of donated cells, tissues or organs may be able and willing to alter the treatment of donations to reflect a change in the preferences of the donation decision-maker where this is feasible. For example, a tissue bank might be able to return a stored donor tissue to be with the deceased body for burial if the tissue has not yet been processed or transplanted. See also Chapter 12.4.3 for discussion of exceptional release of donated umbilical cord blood.

4.1.4.1 Withdrawal of consent for donation of HSCs

In the case of HSC donation, if the prospective living donor withdraws consent after the intended transplant recipient has begun the clinical process of preparing for transplantation – 'conditioning' – and no alternative donor is available, failure to proceed with donation may result in increased morbidity or even the death of the recipient.[51] Despite this risk, respect for autonomy requires that the prospective donor may still withdraw.[9]

Every effort should be made to ensure that the withdrawal decision is fully informed and voluntary; the prospective donor should also be informed of the potential consequences of their withdrawal decision. To reduce the likelihood of this situation occurring this information should also be carefully communicated to prospective donors at the time of their recruitment, and when confirming their initial consent to donation when they are matched with a potential transplant recipient. Use of multiple donation consent points to reaffirm the decision to donate before the intended recipient begins preconditioning for transplantation may also help to reduce the risk of late withdrawals of consent (see Chapter 4.3.4.2).

4.1.4.2 Withdrawal of consent for kidney donation in a paired exchange

In the case of paired kidney donation (see Chapter 2.8.1.2), it is possible that a prospective donor from one pair may choose not to proceed with donation if their own recipient has already received a kidney from the donor in another pair. This would mean that one pair unfairly benefits from transplantation without the burdens of donation. To reduce the risk of this happening, most paired kidney donations occur synchronously, meaning that both donors in a pair undergo donation at the same time.

However, asynchronous paired exchanges are sometimes necessary or valuable, for example when multiple pairs participate in a series of swaps to form a donation chain that enables more swaps – and hence transplants – to occur. When a donation chain is broken because a donor does not donate for any reason, this is called a 'bridge' failure. The majority of 'swap' or 'bridge' failures in paired exchanges, which are estimated to

occur in less than 2% of cases,[52] are the result of circumstances which may render the prospective donor (or recipient) no longer suitable.

In cases where the prospective kidney donor is clinically suitable but no longer willing to donate after their own pair has received a transplant, this raises significant concerns about fairness. Nevertheless, the right to withdraw consent must still be respected. Efforts are then made to reduce the impact of the withdrawal on the pair which has provided a donor kidney but not yet received a transplant, for example by prioritising the recipient in that pair for access to a non-directed donor kidney.

Box 4.1 Summary of general recommendations for ethical practice in supporting donation and transplantation decision-making

- Health professionals have an obligation to obtain valid consent or refusal to donation or transplantation by the appropriate decision-maker(s) by ensuring that decisions are informed and voluntary, and that decision-makers are competent and have the legal authority to make the relevant decision.
    - **Information** should be provided to decision-makers that is current and evidence-based, and the limitations of available information should be clearly and impartially communicated including the potential for bias, gaps in knowledge or conflicting evidence.
        - Information provided should be tailored to the preferences and interests of decision-makers and the circumstances of specific decisions.
        - Decision-makers should be routinely provided with information relating to all available options with respect to donation and/or transplantation, including information about alternative treatments for prospective transplant recipients where relevant.
    - Decision-making **capacity** should be assessed on a case-by-case basis, noting that adults should be presumed to have capacity unless there is evidence to the contrary.
    - **Voluntariness** in decision-making should be evaluated and supported through use of specific safeguards where necessary, including:
        - psychosocial evaluation of prospective living donors and recipients to identify, assess and address risk factors for coercion or manipulation
        - use of independent advocates, counselling and other mechanisms to support individuals in communicating their preferences and to assist in management of potential conflicts of interest
        - where relevant and possible, mandated time periods required for prospective living donors to reflect on decisions before confirming consent and proceeding with donation
        - potential exclusion of prospective living directed donors with regards to whom the intended recipient or related parties may be in a position of relative power or significant social, economic or spiritual influence.
- Individuals have the right to withdraw consent for donation or transplantation when this is clinically feasible prior to the removal or transplantation of donor cells, tissues, or organs.

- Information about the consequences of withdrawal of consent should be provided at the time of initial consent and reiterated during subsequent decision-making.

- Donation and transplantation decisions should be separated, where possible, from decision-making about participation in research.
- Health professionals should address potential barriers to decision-making and any factors that may undermine the quality of decision-making.
  - A collaborative and person-centred approach to shared-decision-making should be used.
  - Decision-aids should be used where helpful in supporting decision-making by individuals and health professionals.
  - Professional interpreters should routinely be used by health professionals where necessary to ensure they can communicate effectively with patients and their families.
  - A supported decision-making approach is recommended for adults who may have a cognitive impairment affecting their decision-making but who may still be able to make a decision or express a preference with sufficient support.
  - Multistep consent processes should be used when appropriate to facilitate complex decision-making, e.g., regarding acceptance of organ transplant offers from extended criteria donors.
  - Health professionals and policy makers should support impartiality in decision-making about donation and transplantation through:
    - routine and consistent implementation of up-to-date, evidence-based guidelines for evaluation of prospective transplant recipients and potential living or deceased donors
    - strategies to prevent and manage any potential conflicts of interest that may influence decision-making
    - routine provision of information to patients and substitute decision-makers on how to access independent professional sources of information and advice.
- Custodians of donated cells, tissues or organs should strive to respect the values and preferences of donors or their substitute decision-makers with regards to the use, treatment or disposition of donations where these values and preferences were expressed and approved as part of the consent process, and/or where preferences may be reasonably presumed.

4.2 Consent for transplantation

The general considerations in consent outlined in Chapter 4.1 should all be applied during the process of decision-making about transplantation by potential transplant recipients and/or their substitute decision-maker (as discussed in Chapter 5.4). Some key considerations in consent for transplantation are outlined below.

Voluntariness: Decision-makers may feel they have limited freedom to decline transplantation if there are no alternative treatment options. They may also be subject to emotional pressure, e.g., from carers or family members, if transplantation represents a life-saving treatment.

Decision-making capacity: Some transplant candidates may be acutely unwell or otherwise at risk of impaired decision-making capacity due to illness.

Information: Information about treatment options available, including, where relevant,

- living as well as deceased donor organ transplantation options, chemotherapy, and autologous transplantation or haploidentical transplantation of HSCs options, tissue graft options including option of non-human animal grafts
- non-transplant related options including conservative or supportive care.

This should include information about the risks and potential benefits of each option (see Chapter 6). The risks and benefits must be carefully evaluated in the context of the individual transplant candidate and their own values and preferences, as well as in the context of the characteristics of the donated cells, tissues or organs that are available at the time of transplantation.

It is important to ensure that all transplant candidates are informed of the human origin of donated materials that will be used in their transplant.

In living directed donation and transplantation, separation of clinical roles and teams should also occur where possible to avoid professional conflicts of interest in decision-making about donation and transplantation; where this is not possible, independent advocates or a review body should be used to protect the interests of prospective donors and transplant recipients in decision-making (see Chapter 4.3.3.1).

4.3 Consent for living donation

Ensuring the validity of consent for living donation is a particular concern in the context of living organ donation and some types of HSC donation, which may require medical interventions and surgical procedures that cause significant inconvenience, discomfort, and potentially serious risks of harm without offering any physically therapeutic benefits to donors. Living tissue donation more commonly occurs in contexts in which a person undergoes a surgical procedure that is beneficial to their own health, such as when a person donates the head of their femoral bone when this is removed as part of hip replacement surgery. Consent is equally important in these situations as a person has the right to choose whether or not to donate their tissues for transplantation.

The general considerations in consent outlined in Chapter 4.1 should be applied to all forms of living donation. Specific considerations and information that may be especially relevant to living donors in particular contexts are discussed in the following sections.

General concerns about voluntariness of consent in living directed donation are discussed below in Chapter 4.3.3.1. Some individuals or groups may also be considered at higher risk of coercion or undue influence when making a decision about living donation as a result of their personal circumstances. These include potential donors who are incarcerated (see Chapter 4.3.2), those who may be at risk of human trafficking (see Chapter 10.6.1.1), and children or adults lacking decision-making capacity (see Chapter 5.5).

Consent for living donation often involves multiple decisions by the prospective donor at different times, each of which require careful consideration of consent. Where further procedures or subsequent interventions may be anticipated, it is important that prospective donors are informed of these early, even if formal consent for those procedures will not be obtained until a later time.

For example, an individual may make an initial decision to donate tissue and to be screened for eligibility as a tissue donor but may later be asked to consent for follow up blood tests to screen for infectious diseases that would preclude use of the donated tissue. Alternatively, individuals who provide consent to placental tissue donation at the time of childbirth may be followed up six weeks after the birth to answer further health-related questions. Prospective living kidney donors may consent to initial screening via review of their medical history before more invasive screening tests are required. Finally, non-directed HSC donors make decisions about joining the donor registry that usually occur long before a decision to proceed with donation when a transplant match is found (see Chapter 4.3.4.2). HSC donors may also be asked to donate a second time (see Chapter 4.3.4.3).

4.3.1 Consent for living donation and the law

Adults with decision-making capacity can consent in writing to donate cells, tissues, or organs for transplantation to another person. Medical practitioners are required to explain the nature and effect of the donation and to certify that the person has provided consent. Non-directed donations by adults are legally permitted (as long as other legal conditions are fulfilled) as there is no limitation on who may receive the organ or tissue.

The Human Tissue Acts distinguish between living donation of 'regenerative' and 'non-regenerative' tissues, and typically specify that the person may consent to the removal of non-regenerative tissue only 'after the expiration of a period of 24 hours from the time at which the consent is signed'.[53] Living donation of regenerative tissues is explicitly permitted for the purpose of therapeutic transplantation or for use in research, whereas the law varies regarding the conditions in which non-regenerative tissue that is removed from a person can be used for research purposes (if at all).

Regenerative tissues are generally defined in legislation as those that 'after injury or removal, [are] replaced in the body of a living person by natural processes of growth or repair';[53] HSCs and the liver are usually considered regenerative whereas kidneys are considered non-regenerative.

The legal aspects of living donation involving adults lacking decision-making capacity and children, and the role of substitute decision-makers are discussed in Chapter 5.5.1.

4.3.2 Consent for living donation by individuals who are incarcerated or otherwise institutionalised

If a potential living donor is currently incarcerated, this presents an additional concern with regards to voluntariness of consent. People who are incarcerated may be more vulnerable to coercion or may be motivated to donate in order to temporarily regain some freedoms or in the hope of their donation influencing future sentencing reviews.[54] However people who are incarcerated may have a genuine desire to donate an organ, cells, or tissues in order to help a loved one or to contribute to society, and they should not be automatically denied this opportunity simply because they are in corrective custody.

Similar issues may arise in the context of those who are housed in juvenile detention facilities; those detained as refugees, asylum seekers or visitors awaiting deportation; or those committed to psychiatric treatment facilities.

Additional efforts will be required to support independence in decision-making involving prospective donors who are incarcerated or institutionalised, to ensure voluntariness of consent, and to minimise any additional risks that may be associated with their imprisonment or other institutionalisation, such as difficulties in accessing the necessary follow up care after donating (see Chapter 6).

4.3.3 Consent in living directed donation

The general considerations in consent outlined in Chapter 4.1 should all be applied during the process of decision-making about living directed donation.

When providing **information** about the risks and potential benefits of living donation (see Chapter 6), this must include information about alternatives to living donation where relevant, with regards to the other options for treatment that the transplant candidate may have (see Chapter 4.2). Information must be carefully evaluated in the context of the individual donor and their intended transplant recipient and their own values and preferences.

Specific information about the privacy of the donor's information and any limits on or risks to privacy in the context of directed donation should be outlined (see Chapter 7.2.2).

In obtaining consent for living directed donation, particular concerns may arise with regards to the **voluntariness** of consent as outlined in Chapter 4.3.3.1.

4.3.3.1 Voluntariness of consent in living directed donation

Potential living donors may feel they have limited freedom to decline donation if there are no alternative treatment options for a close friend or relative who requires transplantation. They may also be subject to psychological and social pressures, e.g., from family members, if living donor transplantation represents a life-saving treatment for the intended transplant recipient.[55,56] Conversely, family or friends may discourage or pressure prospective donors to decline donation.

Relationship dynamics between the prospective donor and the intended transplant recipient and related individuals should be carefully considered through counselling with an appropriately qualified health professional, as these dynamics have the potential to enable, shape or constrain the potential donor's voluntariness in reaching a decision. Complex pressures to donate may exist, especially within families, but also in non-familial arrangements.

Particular **relationship** dynamics may carry an increased risk of undue influence or coercion. For example, some prospective donors may be dependent on the intended recipient or a related individual in some way, and that person may have the ability to apply financial, social, or emotional pressure on the potential donor. Relationships that may cause concern include employee-employer, child-parent, member of faith community and faith leader, student-educator, etc.

However, there may be power differentials in any relationship. Where a relationship between the potential donor and intended recipient (or related individual) involves an imbalance of power, special attention needs to be given to the possibility of undue influence or coercion, but these risks should be considered routinely in donor evaluation and not presumed to exist simply on the basis of specific types of relationship.

Specific safeguards may be needed to help ensure voluntariness in decision making about living directed donation, given the potential impact of donation decisions on the potential donor's relationships with the transplant candidate and their family. These potentially include:

- formal psychosocial evaluation to assess voluntariness of consent (see Chapter 6.1.3), and to identify and evaluate factors that may increase the risk of coercion or manipulation of prospective donors such as:
  - power differentials and influential relationships between potential donors and recipients
  - risk factors for human trafficking (see Chapter 10.6.1.1)
- use of an independent donor advocate (see Chapter 3.4.5) or counsellor
- minimum waiting periods between initial decision-making about donation and donation procedures, where possible
- careful management of potential conflicts of interest (see Chapter 3.8.2)
- use of strategies to support and protect the potential donor if they decline donation and have concerns about disclosing to the transplant candidate that they did not wish to donate. For example, a 'donor alibi' may be offered by the clinical team if desired, communicating to the transplant candidate that the potential donor was not suitable to donate.[57] (See Chapter 7.2.2.1).

Potential exclusion of some prospective living directed donors may be considered where the intended recipient or related parties holds a position of relative power or significant social, economic or spiritual influence over the prospective donor or their kin.

4.3.4 Consent in living non-directed donation

Living non-directed donation may be associated with fewer concerns about potential coercive influences on donation decision-making given the absence of relationships between prospective donors and potential recipient of their donations. Nevertheless, there may be important considerations in particular contexts that could undermine decision-making or compromise consent for living non-directed donation. Information that may be specifically relevant when obtaining consent for non-directed donation is also considered in Chapter 4.1.3.1.

4.3.4.1 Consent in living non-directed organ donation

When individuals volunteer to donate an organ as a non-directed organ donor, concerns may be raised about their **capacity** to consent. This is often because of concerns about the motivations of a person who is willing to assume the significant burdens and risks of living organ donation for the benefit of helping a stranger. For example, there may be concerns that the motivation to donate is a consequence of unresolved psychological issues, lack of understanding of the risks and burdens, or inappropriate expectations of the outcomes of donation, such as establishing relationships with recipients. Concerns may also be raised about the proportionality of risks and benefits of living organ donation when there is no emotional or social tie between donor and recipient, as discussed in Chapter 6.3.4). Careful psychosocial evaluation (see Chapter 6.1.3) is needed to assess these concerns and ensure that valid consent is obtained.

4.3.4.2 Consent in non-directed HSC donation

Donation of HSCs is a much lower risk and considerably less burdensome procedure than living organ donation. Nevertheless, there are important and specific ethical considerations that relate to consent by non-directed HSC donors. The first step in the consent process for non-directed HSC donors occurs when they make a decision to join the Australian Bone Marrow Donor Registry (ABMDR) (see Chapter 2.3.7). The ABMDR provides information to potential registrants via a donor enrolment form.[58]

Eligible registrants provide consent to be **enrolled** as a donor, which includes providing consent to have blood collected for testing, with personal information then stored within the registry, and consent to be contacted if a potential match is found in the future. Registrants may also choose to consent for use of their (deidentified) information in research. Joining the registry does not constitute consent to donate HSCs, but rather consent to have personal information stored in the registry and to be contacted and asked to donate if a match is identified.

When a potential match is found, the potential donor is then asked to provide current and specific consent to a series of procedures leading up to the collection of HSCs for transplantation, including, for example, further tests to confirm whether the individual is clinically suitable to donate and an appropriate match for the intended recipient.

In addition to receiving specific information about each of the procedures to which the potential donor may be asked to consent, the potential donor should also receive or be reminded of information about aspects of donation such as requirements for anonymity and reimbursement of expenses, as outlined by the ABMDR.[59] In particular, the potential donor must be informed of their right to withdraw consent before donation occurs and of the consequences of withdrawing consent if the intended recipient has commenced preconditioning for transplantation (see Chapter 4.1.4.1 above).

4.3.4.3 Consent for subsequent donations of HSCs

After donating HSCs, individuals may sometimes be asked to consider another donation to the same recipient. This could occur soon after the initial donation, for example if the initial transplant was unsuccessful, or at a later stage, for example if the recipient experiences a relapse they could require donor lymphocytes or another HSC transplant. Before their initial donation, all prospective HSC donors should be informed of the possibility of receiving further donation requests following their initial donation. Some individuals may choose not to make an initial donation if they are reluctant to consider subsequent donations.[60]

Requests for repeat donation of HSCs require the same attention when obtaining consent that is given to initial decision-making about donation. As noted in Chapter 6.1, the potential benefits and risks of donation must be current at the time of consent, requiring reassessment at the time of a repeat request for donation. Consent should not be presumed on the basis of a previous decision to donate. Ensuring voluntariness of consent to subsequent donations is important as individuals who have previously donated may be vulnerable to coercion or undue pressure. For example, some may feel that their previous agreement to donate establishes a commitment or obligation to provide ongoing assistance in the form of donation to the transplant recipient when needed. Declining a request for a subsequent donation may also be psychologically difficult if this decision may negatively impact the health of the prospective transplant recipient.

In the case of non-directed HSC donors, independent management of requests for subsequent donations by the ABMDR reduces the risk of conflicts of interest in decision-making. However, in some cases, non-directed donors may have established direct contact with transplant recipients following the initial donation (see Chapter 7.3.2.2). When donors and recipients are known to one another, the relationships between individuals - and their families - may complicate decision-making, requiring additional safeguards to manage potential conflicts of interest and ensure voluntariness of consent.

4.3.4.4 Consent in living non-directed tissue donation

When obtaining consent for tissue donation by individuals undergoing therapeutic surgery, attention to factors that could compromise consent may be needed. These include the potential for **voluntariness** to be undermined if individuals feel obliged to consent as a form of reciprocity for the care they are receiving, or if they feel pressured to do so in case declining a request impacts their care. For example, a woman who is asked to donate placental tissue after giving birth might feel compelled to do so if the request is made by a health professional involved in care of her or her baby. These concerns may be reduced by the use of donor liaison officers or staff from tissue banks in approaching potential donors rather than health professionals providing them with care.

4.4 Consent for deceased donation

In rare circumstances a person may be able to directly provide consent for donation of their cells, organs, and tissues after death, for example if their death is expected to occur after they make a decision to cease life sustaining interventions on which they are dependent (see Chapter 11.6), or if they wish to donate after voluntary assisted dying (see Chapter 11.7). Usually, decisions about deceased donation are made by a person ('donation decision maker') other than the potential donor, following the death of a person, or at a time when the person is acutely unwell and lacking decision-making capacity, for example as a result of a devastating brain injury. Consequently, deceased donation decision making around the time of death is a form of substitute decision-making. It is governed by specific legal and ethical considerations as outlined below.

4.4.1 Consent for deceased donation and the law

Australian legislation provides for an 'opt in' consent model of deceased donation. This generally means that where a potential deceased donor had **expressed a decision to donate**, for example by joining the Australian Organ Donor Register (AODR) (see Chapter 2.5.2.3), there is no evidence that the person objected or had changed their mind prior to death regarding a decision to donate, and coronial approval (see Chapter 4.4.1.1) is not required, the 'designated officer' within the hospital can authorise donation to occur (see Chapter 2.5.2.3).

Despite what is allowed in Australian legislation, in practice, the potential donor's family will routinely be consulted about the possibility of donation and their approval will be sought prior to donation, even if the person is a registered donor (see Chapter 4.4.2.1). Similarly, in countries that permit the use of an opt-out approach for deceased donation, also sometimes referred to as 'presumed' or 'deemed' consent, families are usually consulted about donation decisions, even though the law may allow for organ donation without family approval if the potential donor has not registered an objection to donation.[61]

Where the **decision or preferences of the potential donor are not known**, the legislation provides a mechanism for someone else to authorise (i.e., make a decision about) deceased donation. The legislation specifies who can act as the decision-maker, with this person known as the 'senior available next of kin' (SANOK) or 'senior next of kin' (See **Box 4.2** below).

The legislation also provides a way of resolving disputes about whether deceased donation should occur (see Chapter 4.4.3).

Box 4.2 Senior available next of kin

If the proposed deceased donor is an adult, the list of people who are senior available next of kin (in order of priority) is:

- spouse or de facto, or domestic partner
- son or daughter – 18 years or older
- parent
- brother or sister – 18 years or older.

If a proposed deceased donor is a child, in most Australian jurisdictions the order for senior available next of kin is:

- parent
- brother or sister – 18 years or older
- the child's guardian.

However, in Queensland and Western Australia the domestic partner or spouse of a child will usually be given priority over a parent, sibling, or guardian.

The definition of 'parent' can differ between Australian jurisdictions with some places including 'guardians' and persons considered a parent due to Aboriginal, Torres Strait Islander or other cultural traditions.

- Specific legal guidance is needed to support recognition and respect for relevant kinship relationships in decision-making about deceased donation on behalf of Aboriginal and Torres Strait Islander peoples.

Those responsible for making a final decision about deceased donation and providing legally valid authorisation or refusal for donation are usually substitute decision-makers. This means they are making a decision on behalf of someone else – the potential donor – and are expected to follow the approach to decision-making outlined in Chapter 4.4.2.2.

Decision-making about deceased donation is frequently part of decision-making about end-of-life care. However, individuals with legal authority to make a decision about deceased donation are not always the same as those with legal authority to make medical treatment decisions on behalf of a person who lacks capacity at the end of life.[62] Legal and ethical considerations with regards to substitute decision-making about the use of ante-mortem interventions for deceased donation are discussed in Chapter 11.4.1.

4.4.1.1 Role of the coroner

Coroners are independent judicial officers who are responsible for investigating 'reportable deaths' (e.g. violent, unnatural, or sudden deaths of unknown cause). If the death of a potential organ or tissue donor is in circumstances that constitute a 'reportable death' then consent to proceed with donation may be required from the State or Territory coroner prior to removal of organs or tissues for donation, in addition to the usual consent requirements outlined in Chapter 4.4.1.

Table 4.1 Coroners Acts

Legislation	Hyperlink
ACT Coroners Act 1997	https://www.legislation.act.gov.au/a/1997-57
NSW Coroners Act 2009	https://legislation.nsw.gov.au/view/html/inforce/current/act-2009-041
NT Coroners Act 1993	https://legislation.nt.gov.au/Legislation/CORONERS-ACT-1993
QLD Coroners Act 2003	https://www.legislation.qld.gov.au/view/html/inforce/current/act-2003-013
SA Coroners Act 2003	https://www.legislation.sa.gov.au/lz?path=/c/a/coroners%20act%202003
TAS Coroners Act 1995	https://www.legislation.tas.gov.au/view/html/inforce/current/act-1995-073
VIC Coroners Act 2008	https://www.legislation.vic.gov.au/in-force/acts/coroners-act-2008/042
WA Coroners Act 1996	https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_201_homepage.html

Please note that the above links are current at the time of writing but may lead to out-of-date versions of legislation in future. As legislation is regularly amended, please check that you are viewing the most current version which should usually be accessible via the website to which these links will direct.

4.4.2 Ethical considerations in deceased donation decision-making

In Australia consent or authorisation is always sought from the SANOK (see Chapter 4.4.1) before deceased donation proceeds – even if the deceased has registered their decision to donate and it is therefore lawful for donation to proceed. People are therefore encouraged not only to register their donation decision on the AODR but also to notify their family and friends when registering on the AODR and explain the specifics of their intention to be a donor. The reasons for this are discussed in Chapter 4.4.2.1).

Similarly, if a person hasn't registered, or has registered a preference not to donate, their family will be consulted to make or confirm a decision. Refusal of donation when the potential donor is registered on the AODR and consent for donation when a potential donor has previously indicated a preference not to donate are explored in Chapter 4.4.2.3 and Chapter 4.4.2.4 respectively.

Chapter 4.4.2.2 outlines the ethical considerations that should guide people in making a decision about deceased donation on behalf of a potential donor. See Chapter 11.3 for discussion of management of potential conflicts of interest in the context of deceased donation decision-making.

4.4.2.1 Importance of family consultation in deceased donation decision-making

Consent or authorisation of donation is always sought from the SANOK before deceased donation proceeds, even if the potential donor is registered, in order to ensure that donation decision is what that person would want.

Although registering as a donor is an important indication of a person's willingness to become a donor, the self-directed nature of joining the registry means that it is not possible to ensure that all those who register have made a fully informed, voluntary, and competent decision to donate. In contrast, when people make formal advance directives in healthcare, which are intended to guide or determine decision-making about their healthcare if they are no longer able to participate directly in decision-making, these directives are made with safeguards designed to ensure the person is making a legally valid decision.

People who are considering joining the AODR are encouraged to read information about donation in order to make an informed decision. However, unlike when a person makes a decision about undergoing a particular medical treatment, the process of donor registration does not necessarily involve other people. There is no health professional involved, for example, to ensure that the person joining the registry has decision-making capacity, that they have received and understood the relevant information, and that they are making a voluntary decision.

4.4.2.2 Approach to substitute decision-making in deceased donation

The principles and considerations that underpin substitute decision-making more generally in healthcare are also applicable when making a decision about deceased donation on behalf of another person.

As noted in Chapter 5.3.2, substitute decision-making involves striving to make decisions that are consistent with the known or expected values and preferences of the person on behalf of whom a decision is being made – sometimes referred to as a 'substituted judgement' approach to decision-making. It is also important to consider the welfare and interests of the person on whose behalf a decision is being made – sometimes referred to as the 'best interests' approach to decision-making. Consideration of the best interests of the person becomes particularly important in cases where it may not be possible to know or estimate the likely values or preferences of the person with regards to the decision being made.

In registering or otherwise expressing a decision to become a deceased donor if this is possible, people communicate an important goal that should be considered carefully by donation decision-makers. Donation decision-makers will need to consider this goal in the light of an individual's circumstances at the time of their death. For example, decision-makers may need to consider this goal in the context of other goals relating to the person's end-of-life care. They may also need to make decisions about specific aspects of donation opportunities which the potential donor may not have considered at the time they expressed their decision to donate. These decisions might include deciding:

- which organs and tissues will be donated
- whether donations may be used in research if they cannot be used in transplantation

- whether clinical interventions that might help to facilitate donation should be performed before or after death occurs (see Chapter 11.4).

If a person has not registered as a donor or discussed their donation preferences with their family, donation decision-makers will need to make a decision by considering what they know about the person.

Relevant **information** that should be provided to the donation decision-maker includes information about the possible export or use of donations in research (see Chapter 4.1.3.1). As well as information about:

- any potential interventions before or after death to facilitate donation or increase the probability of donated organs or tissues being successfully transplanted
- relevant donation pathways and processes
- expected burdens and benefits of donation as these relate to the potential donor, including the potential benefits of donation for transplant recipients as these may relate to the potential donor's goals and values.

The potential impact of donation decisions on relevant friends and family should also be discussed and considered, however priority should be given to consideration of the potential donor's likely preferences, all things considered.

4.4.2.3 Refusal of donation on behalf of a person who has registered a decision to donate

In most cases where a person has registered their decision to donate their organs or tissues after death, the person asked to formally make a donation decision on their behalf at the time of their death will consent to donation. In some cases, however, family members including the SANOK may wish to decline donation despite evidence that donation is what the person would have wanted.

Refusal of donation on behalf of a registered donor, is sometimes referred to as **family veto** or **family override** of donor consent.[63-66] It raises concerns about a lack of respect for the potential donor's autonomy and about the impact of a missed opportunity for donation for those who might otherwise have benefitted from transplantation of this person's organs or tissues.

The first priority in managing such a situation should be to ensure that the donation decision-maker is making a voluntary, informed, and competent decision, just as they should be supported to do when making a decision on behalf of someone who is not a registered donor. Providing appropriate emotional support to families making difficult decisions at a very challenging time is essential. It is also important to explain the significance of donor registration and to support decision-makers to respect the known preferences and values of the person on whose behalf they are making a decision.

If donation decision-makers have reason to believe that their loved one did not make an informed decision when joining the registry, this should be taken seriously.

For example, in some cases it might be reasonable to conclude that although a person had indicated their willingness to become a donor, they may have made such a decision based on a particular understanding of the donation process which may not be applicable in the context of their own death. There may also be evidence that a person changed their mind after registering.

Even if it is possible that a potential donor did not make a fully informed decision about donation, their decision to join the donor registry may be considered a clear statement of their values and preferences, generally speaking, with regards to donation. Providing relevant information for donation decision-makers to consider together with that information about the potential donor's values is important.

While the benefits of donation and the importance of respecting a potential donor's expressed goal to become a donor should be given significant consideration, consideration should also be given to the potential impact of donation decisions on the potential donor's family.

4.4.2.4 Donation decision-making on behalf of a person who has indicated an objection to donation

In some cases, donation decision-makers may be asked to confirm a decision on behalf of a **person who has previously documented an objection to donation or expressed a decision not to become a donor**. Occasionally, decision-makers may override a previously expressed objection and approve donation, if there is reason to believe an earlier decision to refuse donation was invalid or inconsistent with the potential donor's likely preferences at the time of their death.

As outlined in the context of decision-making on behalf of those who have registered a positive decision to donate, or whose preferences may be unknown, it is important that donation decision-makers reflect carefully on what they know about the person in the light of the situation in which a decision is being made.

For example, if considerable time has passed since the person expressed a decision not to donate, decision-makers should consider whether it is possible that the person changed their mind. Although previously expressed preferences regarding donation are often a helpful guide for decision-makers, they may not always reflect what a person would want in a specific context. People's values and preferences and the information that preferences are based on may change over time. Donation decision-making at the time of a person's death should be based on information that is current in that specific context, and the person's known values and preferences should be considered in the light of this context.

4.4.3 Disputes in deceased donation decision-making

When families or other individuals are tasked with making decisions on behalf of a person who has died or who faces imminent death, decision-making may be complicated if there is disagreement between the people making the decision and/or other people who are close family or friends of the potential donor. Disagreements are often about who should be involved in making the decision and/or who should have the final say in the donation decision. Importantly, in some cases the individual who has the legal authority to provide consent to donation after a person has died may be different from the individual legally entitled to make substitute decisions in relation to health care for that person while that person is alive.[62]

It is important to try and resolve disagreement when possible, in order to minimise the risk of distress to family members and ensure that the decision being made is consistent with what the potential donor would have wanted. Even if a person has registered their donation decision, family members may disagree about what a person would have wanted.

Where there is a disagreement between donation decision-makers who are SANOKs (see **Box 4.2**), generally the law provides that an objection to donation will be respected over a consent or approval to donate. See for example, s 23(3)(c) NSW Human Tissue Act; S 23(2)(b)(iv) Tasmanian Human Tissue Act; s 22(4) Qld Transplantation and Anatomy Act; s 21(5) SA Transplantation and Anatomy Act; s 22(5) WA Human Tissue and Transplant Act 1982; s 27(5) ACT Transplantation and Anatomy Act 1978. Victoria is the exception, as section 26(6) of its Human Tissue Act provides that a consent will operate regardless of indications to the contrary by other SANOKs.

Box 4.3 Summary of general recommendations for ethical practice in deceased donation decision-making

- Individuals and communities should be supported to make an informed decision about deceased donation during their lives.
  - » Governments should support education campaigns that promote and inform choice about organ and tissue donation and reach all Australians, including Aboriginal and Torres Strait Islander communities and other culturally and linguistically diverse communities.
  - » Health professionals such as general practitioners should encourage and support donation decision-making as part of advance care planning and routine health promotion.
  - » Individuals should discuss their values and preferences with regards to deceased donation with their families and consider registering their decision on the Australian Organ Donation Register (AODR), or by other means of advance planning.
- Individuals who are responsible for making a decision about deceased donation on behalf of a person who has died or whose death is imminent, should strive to do so in accordance with the known or expected values and preferences of the potential donor, where these are based on an understanding of relevant information and with consideration for other known or expected values, preferences or goals with regards to end-of-life care.
  - » When a decision is made about deceased donation at the end of a person's life, donor registration status should routinely be checked (via the AODR) and any documented information regarding end-of-life care preferences should be consulted in order to ensure that the individual's preferences and interests with regards to donation are carefully considered.
  - » Donation specialists should provide guidance and support to decision-makers with regards to the importance of considering and respecting the potential donor's preferences.
  - » Deceased donation decision-makers should be encouraged to make a decision that is consistent with the expected values and preferences of the potential donor in the specific setting.
  - » Donation specialists should seek to determine the donation decision-makers' reasoning to assist them in determining the individual's likely preferences regarding donation in the specific setting.

5. Donation and transplantation in children and adults who lack decision-making capacity

This chapter explores special ethical considerations in the context of donation and transplantation involving children or adults who lack decision-making capacity. Although rare, this group may occasionally be considered as potential living donors of cells, tissues, or organs; children in particular may be considered as donors of HSCs to siblings. More frequently, they may be considered as transplant candidates.

In the first section, general considerations in decision-making involving children or adults lacking capacity are outlined. Legal aspects of substitute decision-making are then reviewed followed by ethical approaches to substitute decision-making. In the following sections specific ethical considerations relating to transplantation and living and deceased donation by children and adults lacking capacity are discussed. This chapter should be read in conjunction conjunction with Chapter 4 and Chapter 6. Further readings and resources relating to this chapter are available in Appendix 1.

5.1 Involvement of children and adults who may lack capacity in decision-making

It should not be assumed that adults who are cognitively impaired or children who are below 18 years of age are incapable of making their own medical decisions, including decisions about potential opportunities for donation or transplantation. Individuals may have capacity to give consent for some, if not all, decisions relating to donation and transplantation.

If loss of decision-making capacity is temporary, then deferring decisions about donation or transplantation until the person has the capacity to consent on their own behalf should be considered where possible.

5.1.1 Determining capacity for decision-making in children

The decision-making capacity of children should be carefully evaluated by suitably qualified professionals. These may be health professionals involved in care of the child or other health professionals. In some cases, assessment of capacity may require involvement of a multidisciplinary team.

5.1.2 Children who may have decision-making capacity and the law

Generally, children under 18 years old are not presumed to have decision-making capacity with regards to their own medical treatment. However, some children - typically adolescents - may be considered competent in specific circumstances to make some of their own health care decisions or specific legislation may exist that applies a presumption of decision-making capacity at a younger age.

The term *Gillick*-competent refers to a child who is assessed as having a sufficient understanding and intelligence to enable the child to understand fully what is proposed with regards to a specific clinical decision. Such children are sometimes referred to as ‘mature minors’.

In the adolescent age group, the capacity to make decisions about transplantation should be determined on an individual basis. Responsibility for determining this capacity rests with the multidisciplinary team involved in the care of the individual.

Where a child is assessed as being *Gillick*-competent they can consent or refuse consent to treatment that is offered to them, including a proposed transplant procedure. Where a dispute arises regarding whether a child is *Gillick*-competent for the decision they have made, or there is a dispute as to whether a decision made by a *Gillick*-competent child is in their best interests, usual processes for resolving disputes should be adopted (see Chapter 3.4.6), but if there is no resolution or an urgent decision is needed an application can be made to a court to make a decision regarding whether the treatment is in that child's best interests.

Although mature minors are permitted to consent to treatment on their own behalf, including transplantation, if a mature minor consents to living donation this consent alone is not sufficient for donation to proceed. Depending on the nature of the donation (i.e., organs or HSCs), legislation may mandate that certain conditions be fulfilled, or a Court order may be necessary to approve the procedure. This is because living organ and tissue donation are not of therapeutic benefit to the minors themselves. The exceptional conditions under which children may be permitted to become living donors are outlined in Chapter 5.5.

5.1.3 Determining decision-making capacity in adults

Adults are normally presumed to have decision-making capacity. However, there will be circumstances where adults may have difficulty in making decisions for themselves and capacity to make transplantation or donation decisions needs to be determined.

Use of a supported decision-making approach (see Chapter 5.1.3.1) is recommended for adults who may have a cognitive impairment affecting their decision-making but who may still be able to make a decision or express a preference with sufficient support.

5.1.3.1 Supported decision-making

'Supported decision-making' is a human rights concept and practical process referring to the provision of decision-making support to a person to make decisions that reflect as much as possible their 'will, preference and rights'. It originates from the *United Nations Conventions on Rights of Persons with Disabilities*,[5] and is particularly relevant for adults with a cognitive impairment.

Rather than making decisions for a person with a cognitive impairment (i.e., substitute decision-making), the emphasis in supported decision-making is on tailoring support for an individual so that their decision-making autonomy is maintained to the maximum extent possible.

Support may be in the form of assistance provided by a trusted individual who assists a person to make decisions by collecting information, providing explanations, discussing options, and helping the individual to have their decision-making autonomy respected. Partners, close family members, friends or carers may act in this role for potential recipients or donors. This practical process of utilising different strategies to support a person to exercise their autonomy and make decisions already happens in many relationships in many aspects of life. In Victoria, the supporter role can be legally recognised through a formal appointment.

A supported decision-making approach should be tried before resorting to substitute decision-making on behalf of an adult.

5.1.4 Involvement of children and adults who may lack capacity in decision-making

Even when individuals do not meet the legal standard for capacity to consent, they should still be involved in decision-making as much as possible to promote their autonomy and understanding of the situation as it affects them and others. This also helps to ensure that decisions are made with consideration of their values, beliefs, and preferences.

Considering a child's expressed preferences, if any, becomes particularly important as a child matures and they develop a greater capacity for understanding and a clearer appreciation of the significance of these decisions. As they mature, children may play an increasingly important role in making decisions that affect them.

Efforts should be made to ensure that information about donation or transplantation is provided to children and adults who may lack capacity that is appropriate for their level of potential understanding. Particular communication strategies may be needed to support their understanding, and assistance should be sought from appropriately qualified health professionals in developing strategies or resources as needed.

5.1.4.1 The importance of assent

Attempts should always be made to obtain **assent** to donation or transplantation from a child or adult lacking decision-making capacity. It is recognised that for infants and young children and adults with severe cognitive impairments this may not be possible.

What is assent?

Assent is a positive expression of agreement, and not merely the absence of an expressed refusal or objection, from a person who lacks capacity to provide consent.

For example, assent from a potential transplant recipient who lacks capacity indicates an agreement to take part in an intervention, in circumstances where obtaining legally valid consent is not possible due to the child's or adult's level of decision-making capacity.

Attention should also be paid to any signs of objection or **dissent** from a child or adult lacking decision-making capacity with regards to undergoing a clinical procedure, particularly in the context of donation. Managing dissent when a parent or substitute decision-maker has provided legally valid consent for a procedure can present ethical challenges for health professionals. Usually, objections by potential donors should be respected given the non-therapeutic nature of the intervention; this is discussed further in Chapter 5.5.2.4.

5.2 Substitute decision-making and medical treatment laws

Legislation governing how decisions can be made for medical treatment on behalf of adults who lack decision-making capacity to consent themselves is complex and differs across Australia. Laws also exist regarding decision-making on behalf of children who are legal minors (usually <18 years old). **Table 5.1** summarises the relevant legislation.

Different terminology for substitute decision-makers or documents exists across States and Territories. This section provides a brief overview of legislation relevant to when a transplantation or donation decision needs to be made on behalf of an adult lacking decision-making capacity or a child. There may be additional requirements for substitute decision-makers and the need for independent legal oversight in relation to donation decisions on behalf of adults lacking decision-making capacity. These are discussed in detail in Chapter 5.5.1.

Ethical concepts underpinning approaches to substitute decision-making on behalf of children and adults lacking decision-making capacity are outlined in Chapter 5.3.

Table 5.1 - Substitute decision-making and medical treatment legislation

Legislation	Hyperlink
ACT Guardianship and Management of Property Act 1991 ACT Medical Treatment (Health Directions) Act 2006 ACT Powers of Attorney Act 2006	https://www.legislation.act.gov.au/a/1991-62/ https://www.legislation.act.gov.au/a/2006-51/ https://www.legislation.act.gov.au/a/2006-50/
NSW Guardianship Act 1987	https://legislation.nsw.gov.au/view/html/inforce/current/act-1987-257
NT Guardianship of Adults Act 2016 NT Advance Personal Planning Act 2013 NT Health Care Decision Making Act 2023	https://legislation.nt.gov.au/Legislation/GUARDIANSHIP-OF-ADULTS-ACT-2016 https://legislation.nt.gov.au/Legislation/HEALTH-CARE-DECISION-MAKING-ACT-2023#
QLD Guardianship and Administration Act 2000 QLD Powers of Attorney Act 1998	https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2000-008 https://www.legislation.qld.gov.au/view/html/inforce/current/act-1998-022
SA Guardianship and Administration Act 1993 SA Consent to Medical Treatment and Palliative Care Act 1995 SA Advance Care Directives Act 2013	https://www.legislation.sa.gov.au/lz?path=/c/a/guardianship%20and%20administration%20act%201993 https://www.legislation.sa.gov.au/lz?path=/c/a/consent%20to%20medical%20treatment%20and%20palliative%20care%20act%201995 https://www.legislation.sa.gov.au/lz?path=/c/a/advance%20care%20directives%20act%202013

Legislation	Hyperlink
TAS Guardianship and Administration Act 1995	https://www.legislation.tas.gov.au/view/html/inforce/current/act-1995-044
VIC Guardianship and Administration Act 2019 VIC Medical Treatment Planning and Decisions Act 2016	https://www.legislation.vic.gov.au/in-force/acts/guardianship-and-administration-act-2019/009 https://www.legislation.vic.gov.au/in-force/acts/medical-treatment-planning-and-decisions-act-2016/012
WA Guardianship and Administration Act 1990	https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_a336.html&view=consolidated

Please note that the above links are current at the time of writing but may lead to out-of-date versions of legislation in future. As legislation is regularly amended, please check that you are viewing the most current version which should usually be accessible via the website to which these links will direct.

5.2.1 Substitute decision-making on behalf of children

Generally, medical decisions are lawfully made on behalf of children (under 18 years old) by their parents or legally appointed guardians who have authority in relation to health care. The general principle that parents and legal guardians must apply in making each medical decision is to consider what is in the best interest of the individual child (see Chapter 5.3.1).

Some mature children or adolescents may be able to make decisions by themselves where they are assessed as being competent to do so. These children are often described as *Gillick* competent or mature minors. The implications of a determination of *Gillick*-competency in the context of transplantation and living donation is discussed in more detail in Chapter 5.1.2.

5.2.2 Mechanisms of substitute decision-making for adults

There are four main ways in a which a decision can be made on behalf of an adult who lacks decision-making capacity to consent to their own healthcare as summarised in **Table 5.2**. Normally, the options in this table are worked through until one mechanism becomes available. For example, if the adult did not have an advance care directive but had appointed a substitute decision-maker when they had capacity, the law would look to that substitute decision-maker to make a medical decision on behalf of the adult.

Table 5.2 Main legal mechanisms of substitute decision-making for adults

Legal mechanism	Description
Advance care directive	A document made in advance of loss of decision-making capacity that outlines the patient's decisions regarding health care. Only if a situation is specifically dealt with in the document will it apply in a given situation. For example, when a person lacks decision-making capacity, reliance on their advance care directive for evidence of consent for a proposed organ transplant is only valid if the advance care directive specifically addresses the person's wish to receive or to refuse a transplant in the event of experiencing organ failure. Depending on the jurisdiction, statutory advance care directives may allow a person to refuse or consent to future treatment that is proposed.[67] In some jurisdictions, these directives may also outline values that can be used to guide decision-making in a range of situations rather than provide consent or refusal to specific medical decisions.
Substitute decision-maker appointed by the person (i.e., Enduring guardian/Enduring power of attorney/medical treatment decision maker/ health care decision maker)	A person appointed by the patient prior to loss of decision-making capacity who is given power to make health care decisions on behalf of the patient when the patient no longer has decision-making capacity.
Substitute decision-maker appointed by a tribunal (i.e., guardian)	Where a patient lacks decision-making capacity a State or Territory Civil and Administrative Tribunal may appoint a person to make health care decisions on behalf of the patient.
Legislative default decision-maker	In the absence of other applicable decision-making mechanisms, most jurisdictions in Australia have legislation that gives lawful authority to a person in a recognised relationship with the patient who is 'deemed' to be the substitute decision-maker for health decisions.

Table adapted from Figure 2 in Then and Martin (2020).[62]

The terms used for each of the four main mechanisms for decision-making for adults lacking decision-making capacity, as described in **Table 5.2**, are outlined in **Table 5.3** below.

Table 5.3 - Terminology in legislation of legal mechanisms of substitute decision making for adults in Australian States and Territories

	Advance care directive	Substitute decision-maker appointed by the person	Substitute decision-maker appointed by a tribunal or court	Legislative default decision-maker
ACT	Health direction	Enduring attorney	Guardian	Health attorney
NSW	(no statutory advance care directive)	Enduring guardian	Guardian	Person responsible
NT	Advance personal plan	Decision maker	Guardian	Health care decision maker
Qld	Advance health directive	Enduring attorney	Guardian	Statutory health attorney
SA	Advance care directive	Substitute decision-maker	Guardian	Person responsible
Tas	Advance care directives	Enduring guardian	Guardian	Person responsible
VIC	Advance care directive	Enduring guardian and/ or Medical treatment decision maker	Guardian	Medical treatment decision maker
WA	Advance health directive	Enduring guardian	Guardian	Person responsible

5.2.3 Disputes in substitute decision-making about transplants

Where disputes arise between substitute decision-makers as to whether to consent or refuse consent to a proposed transplant, or there are concerns that the decision made by the substitute decision-maker is not appropriate, the law provides a legal mechanism for resolving disputes where clinical and ethical processes are unable to resolve the disagreement.

In some Australian jurisdictions (e.g., Queensland and Victoria), recourse can be made to the State official – the Public Guardian or Public Advocate – to mediate or decide a medical decision, particularly for adult patients. In addition, in all jurisdictions an application can be made to the relevant State or Territory Administrative Tribunal or a Supreme Court or the Family Court (in relation to children) to have a substitute decision-maker's decision reviewed and potentially overridden.

See Chapter 4.4 for discussion of disputes in deceased donation decision-making. The legal aspects of substitute decision-making about living donation are discussed in Chapter 5.5.

5.3 Approaches to substitute decision-making

5.3.1 Children: Best interests

The main guiding principle for decision-making regarding medical treatment in children is to consider what is in the particular child's best interests. Consideration of best interests includes best medical or physical interests and also psychological, social, and general welfare considerations. It involves taking into account the known risks and potential benefits of donation or transplantation and the treatment options available. Where a child is able to communicate and has some understanding, their views and preferences should be considered in the assessment of best interests. The more mature a child, the more significance should be attached to their views. The assessment of best interests will usually be undertaken by parents (or legal representatives) in conjunction with the treating team.

5.3.2 Adults lacking decision-making capacity: Substituted judgement and 'will and preferences'

A substitute decision-maker making a decision about transplantation or donation on behalf of a person who lacks decision-making capacity (whether appointed by the person, a tribunal or via legislation as a default decision-maker), will be required to take into account decision-making principles present in the legislation in each Australian jurisdiction. While these are specific to each jurisdiction, common considerations required to be taken into account are:

- the wishes and preferences of the person who lacks decision-making capacity
- adopting a 'least restrictive approach'
- the person's interests and welfare: this is often referred to as considering the person's 'best interests'.

Generally, the legislation in Australia has placed increasing emphasis on substitute decision-makers adopting a substituted judgement approach where the person's known wishes and preferences are prioritised. Where possible, the guiding principle for substitute decision-makers should be to consider what the person would have wanted (substituted judgement). This approach prioritises the previously expressed preferences of the adult (where known) and respects their autonomy.

A more contemporary approach guiding substitute decision-making is derived from human rights concepts that seek to keep the person's 'will and preferences' central to the decision being made. Unlike substituted judgement, determining a person's 'will and preference' does not require a person to have previously expressed a view while competent.[67]

Adults may lack capacity for a variety of reasons. For some adults, incapacity may exist due to a lifelong disability or mental health conditions may result in fluctuating capacity. Alternatively decision-making capacity may only have been lost relatively recently and not be expected to return.

Where loss of capacity is recent, it is likely that some of the person's previous views, preferences and wishes for medical treatment may be known, and these should be used to guide decision-making.

Where an adult's preferences or wishes are unclear or not known, a substitute decision-maker may also be guided by what would be best for the person, considering the potential risks and benefits of the options available (best interests).

5.3.3 Assessment of risks and potential benefits of donation and transplantation on behalf of children and adults lacking decision-making capacity

Evaluation of risks and potential benefits of transplantation or living donation by children and adults lacking decision-making capacity may be complicated. This may be due to difficulties determining the relevant values and preferences of the individual where they are unable to formulate or communicate these, and due to difficulties in appreciating the potential benefits and burdens of various options for individuals with different life experiences.

When asked to advise - or decide as substitute decision-makers - on behalf of a potential donor or recipient - parents, guardians, or carers may have difficulty appreciating the potential burdens or benefits of options for individuals whom they may care for or with whom they may share close emotional ties.

Any person tasked with assessing the potential benefits or risks of options for an individual may find this challenging given that the interests of the child or adult lacking decision-making capacity are likely to be closely embedded in relationships with the prospective donor or transplant recipient or within the broader context of collective familial interests.

Additional supports such as use of an independent advocate should be used and may be helpful in evaluating potential benefits and risks involved in a particular decision and addressing potential sources of bias in decision-making (see Chapter 3.4.5).

Additional procedural protections may be offered by separate medical, psychological, social, ethical, and legal assessments in addition to parental or substitute decision-making consent on behalf of the proposed donor or transplant recipient.

5.4 Transplantation in children and adults lacking decision-making capacity

Making decisions about potential opportunities for transplantation in children and adults lacking decision-making capacity involves the same considerations as outlined in previous chapters. As noted above, qualitative judgements are necessary when evaluating the risks and potential benefits of transplantation for an individual as compared with other treatment options (see also Chapter 6.1). Relevant options may include the choice of conservative or supportive management aimed at symptom palliation rather than restoration of function or extension of life expectancy. Such judgements may be more difficult when the person for whom transplantation is considered is a child or adult lacking decision-making capacity.

5.4.1 Children as potential transplant recipients

Where younger children or infants are potential transplant recipients, they will generally lack the capacity to consent for themselves. Parents or legally appointed representatives will usually be substitute decision-makers for their children. As noted in Chapter 5.3.1, parents or representatives are required to consider what is in the best interests of the child when making a decision on behalf of a child.

When possible, assent for transplantation should be sought from a child who is not considered competent to make their own decisions. Where a younger child expresses an objection or dissent to becoming a recipient, this should be taken into account in

evaluating the child's best interests. Strategies should be adopted to ensure that any concerns of the child causing such dissent are ameliorated. Given that the therapeutic benefit of receiving a transplant may be very high, a child's dissent or objection may be overruled if considered to be in the child's best interests by parents and the treating team.

Case Study – Organ transplantation in child with intellectual disability

Sara is a 7-year-old girl who lives with her parents. Sara has an intellectual disability which means that she communicates through facial expressions and physical gestures. She is expected to require life-long support with activities of daily living. Sara also has nephrotic syndrome, a condition which causes kidney failure. Sara will soon need to commence dialysis or receive a transplant to treat her kidney failure.

Sara's parents discuss the treatment options with their paediatrician Dr B, who has known Sara since she was a baby. Sara's parents express concern about their ability to cope if Sara requires dialysis. They also note that Sara becomes very distressed whenever she has had to receive minor medical treatments in a hospital setting and report that they fear Sara would need to be regularly sedated in order for her to undergo dialysis. Dr B tells them Sara can be referred to see a paediatric nephrologist who will help them to make a decision about treatment, however Dr B expresses concern about the possibility of Sara receiving a transplant. Dr B emphasises that transplantation is a major operation and tells them Sara will need to have lifelong medication and regular check-ups if she receives a transplant. 'I'm not sure that transplant will be in Sara's best interests,' Dr B says. 'Whatever treatment she has will be incredibly burdensome for her and for you. You'll have to decide if it's worth all the effort to wait for her to receive a transplant from a deceased donor, or even to consider donating a kidney to her yourself.'

Points to consider:

- This case highlights the potential complexity of decision-making about organ transplantation ffor a child. (Chapter 5.3.3 and Chapter 5.4.1)
- Three principles may be especially relevant to this case:
    - **Principle 1** Decision-making about donation and transplantation should seek out and take account of expressed preferences of donors, recipients, their families and communities, and facilitate self-determination.
    - **Principle 3** Decision-making about donation and transplantation should be free from bias or discrimination based on clinically irrelevant factors such as, for example, disability, cultural identity, or social or economic circumstances.
    - **Principle 7** Donation and transplantation activities should provide benefit and minimise burden and risk of harm: where burdens or risks are unavoidable, they should be proportionate to the benefits that are anticipated.

- As Sara is a child, and she doesn't have the capacity to make a decision herself, her parents are required to make a decision on her behalf. Although some young children may be able to contribute to decision-making by sharing their values and preferences, Sara's disability means that her parents must draw on their knowledge of her in order to determine what would be in her best interests (see Chapter 5.3).
- The potential benefits and risks of each of the options available must be carefully assessed in light of Sara's clinical situation and her personal life. The impact of potential choices on Sara's family must also be considered as this in turn may affect Sara herself.
- Dr B appears to be expressing their personal views on the relative merits of the treatment options, which may not be accurate or appropriate. Although they plan to refer Sara to a paediatric nephrologist who will be better placed to provide accurate information about the relative burdens, risks and benefits of treatment options for Sara's kidney failure, there is a risk that their views could influence Sara's parents' decision.
- It's important that accurate, evidence-based information is used to guide decision-making about treatment, and that information should be tailored to the individual patient's situation and free from bias (see Chapter 6.1.2). It's possible, for example, that Dr B has previously cared for a patient who had a bad experience with kidney transplantation that might be unduly influencing their perspective on the burdens of living with a transplant.
- It is also essential when evaluating the risks and potential benefits of treatment options that this evaluation is informed by knowledge of the patient's situation, values and preferences. In this case, Sara's parents will have important information to provide that should be considered in decision-making, for example, regarding Sara's potential reactions in particular healthcare settings.
- It is possible that the paediatrician or other clinicians who may become involved in this decision may have difficulty appreciating the potential benefits and risks of some treatment options for Sara. Unconscious bias regarding the impact of disability on Sara's quality of life, or lack of understanding of the potential burdens or impact of particular treatment options on Sara's family could influence decision-making.
- It is also possible that Sara's parents may have difficulty appreciating the potential long-term consequences of some treatment decisions or may be reluctant to disclose some concerns for fear of being perceived as self-interested or 'bad' parents.
- Shared decision-making with a multidisciplinary team will be essential to help support Sara's parents in making the decision. Use of an independent patient advocate may also be helpful.

5.4.2 Adults who lack decision-making capacity as potential transplant recipients

Where the proposed transplant recipient lacks decision-making capacity to consent to receiving a transplant at the time the decision is needed, a substitute decision-maker will usually be required to provide consent on behalf of the person using the approach outlined in Chapter 5.3.2. There are a variety of substitute decision-makers that may be relevant in a given circumstance as summarised in Chapter 5.2.2. In some circumstances, the proposed recipient may have a valid advance care directive which provides consent

or refuses consent to the transplant in advance of the loss of decision-making capacity (see Chapter 5.2.2).

Objection may also be indicated in other ways, whether transiently or maintained over a period of time. Indications of dissent by the adult need to be taken into account by the substitute decision-maker making a decision on behalf of the adult. If an adult is objecting to being a transplant recipient, in Queensland and New South Wales, this objection can only be overridden if the adult has minimal or no understanding of what the treatment involves.

5.5 Living donation by children and adults lacking decision-making capacity

There are special considerations when children or adults lacking decision-making capacity are considered as potential living directed donors of organs or HSCs ('dependent donors'). (Note that here we exclude donation that might arise in the context of an individual undergoing a therapeutic procedure removing tissues).

As discussed in Chapter 6.1.4.1, the invasive and non-therapeutic nature of these types of donations raises concerns regarding the acceptability of imposing burdens and potential risks on donors where their understanding of these issues may be limited. This is despite the potentially significant psychosocial benefits they may experience when donating to a person with whom they have strong emotional ties.

In the case of children and adults lacking decision-making capacity, concerns regarding the potential for exploitation or coercion in living donation are exacerbated because these individuals may not be able to participate in decision-making on their own behalf. This means they are less able to protect their own interests in the decision being made. Conflicts of interests can arise if those who make a decision on their behalf have an interest in the potential donation which may compete with their duty to protect and promote the best interests of the child or adult lacking capacity. Potential donors are also more likely to be in dependent relationships with the potential recipients of donations, which increases the risk of possible undue pressure on the potential donor to assent to donation if asked. Collectively, these factors make children and adults who lack capacity vulnerable to exploitation (see Chapter 3.2.1.1).

Children and adults lacking decision-making capacity are entitled to be treated with respect for their dignity or fundamental moral value (see Chapter 3.2.1). This means that they should never be considered merely as a potential resource for the benefit of another person. They also have the right to bodily integrity and to respect for their autonomy, even when they may have limited capacity to understand and express their preferences with regards to actions that may affect them.

Only in exceptional circumstances should a child under the age of 18 years or an adult lacking decision-making capacity be considered as a living directed donor. In those rare circumstances, additional evaluation of potential donors and safeguards to support decision-making are required to ensure the donation is ethically and legally acceptable. These elements are considered in the following sections.

5.5.1 Legal aspects of living donation by children and adults lacking decision-making capacity

Different legal requirements need to be met depending on the type of tissue that is intended to be removed for donation. The legislation in Australian States and Territories distinguishes between donation of 'blood' (not generally considered in these guidelines), 'regenerative tissue' and 'non-regenerative tissue' (see Chapter 4.3.1). The main legal requirements are outlined below. However, the law on this matter varies through Australia and legal advice may need to be sought for individual cases.

5.5.1.1 HSC donation via bone marrow or peripheral blood collection by dependent donors

HSC donation is the most common type of living donation that a dependent donor may be asked to participate in. As described in Chapter 2.8.3.1, these cells are derived from donor bone marrow (under general anaesthetic) or their blood (via apheresis) and are generally categorised as 'regenerative' tissue in legislation.

Children: Each State and Territory has legislation that governs whether and how regenerative tissue donations from children can occur. For more mature children who can understand the nature and effect of the removal of tissue and the nature of the transplantation, where a parent consents and the child agrees, this is usually sufficient for a mature child to donate to a family member. Exceptions exist in South Australia and the Northern Territory.

For children who do not understand due to age ('immature children'), the legal process varies depending on the State or Territory. In New South Wales, Victoria and Queensland, an immature child can only donate where certain legal conditions are met. For example, that there is minimal risk to the donor, that the recipient's life is threatened without the donation, that multiple medical practitioners are involved in certifying conditions have been met, and that the donation is for a sibling or, additionally in Queensland, a parent.[68]

In all other Australian jurisdictions, or where the legal conditions cannot be satisfied in New South Wales, Queensland and Victoria, a court order from a Supreme Court or the Family Court would be required for a child to lawfully donate HSCs to another person. Such an order would also be necessary if the proposed child donor was not able to understand due to having a cognitive disability. There have been three known cases of a court authorising the removal of bone marrow from a child in Australia for transplantation into a person related to the child donor. In each case the Court assessed whether donation was in the child's best interests.[68]

Adults lacking decision-making capacity: A substitute decision maker is required by law to consider particular factors when consenting to medical interventions on behalf of an adult who lacks decision-making capacity for the donation decision and who is proposed as an HSC donor. There may also be other legal conditions that need to be satisfied. For example, in Queensland the state Civil and Administrative Tribunal is required to provide authority before such a donation can lawfully occur (in the same manner as for organs, discussed in the next section). There has been at least one Supreme Court case involving an adult lacking decision-making capacity as a proposed haematopoietic stem cell donor. In that New South Wales case the court considered what was in the best interests of the donor, ultimately deciding that acting as a donor was in that adult's best interests.[69]

5.5.1.2 Living organ donation by dependent donors

Children: In most Australian jurisdictions, offences or prohibitions exist in relation to the removal of non-regenerative organs from children.

The Australian Capital Territory is the only jurisdiction that provides a legal mechanism for a child to donate a non-regenerative organ, such as a kidney, to a family member. Strict legal conditions must be satisfied including parental consent, child agreement and approval by a Minister appointed committee.

In all other Australian jurisdictions, a court order from a Supreme Court or the Family Court would be required for a child to lawfully donate an organ to another person. There have been no known cases of a court authorising the removal of an organ from a child in Australia for transplantation into another person.

If a child is being considered as a living organ donor, an independent legal assessment should be obtained.

Adults lacking decision-making capacity: Legal restrictions may also exist when an adult who lacks decision-making capacity for a donation decision is proposed as living organ donor. Substitute decision-makers are required by law to consider particular factors when consenting to medical interventions on behalf of someone else (see Chapter 5.3.2).

In some Australian jurisdictions, a further legislative safeguard exists in relation to the removal of non-regenerative tissue and organs from an adult who lacks decision-making capacity to make a donation decision themselves. These provisions are contained in the substitute decision-making legislation (see **Table 5.1** in Chapter 5.2) rather than the human tissue legislation (see Chapter 3.5.1

In the Australian Capital Territory, Northern Territory, Queensland, Tasmania, and Victoria the relevant Civil Administrative Tribunal is required to approve a decision to remove tissue for the purposes of transplantation to another person. Usually, the Tribunal will need to consider or be satisfied of a range of factors. For example, that the risk to the adult is small, that the risk of failure of the donated tissue is low, the nature of the relationship between the proposed donor and recipient and the wishes of the person as far as they can be ascertained. In Queensland, the tribunal cannot consent if the adult objects to the removal of tissue for donation.

A court order from a Supreme Court could also provide authority for an adult lacking decision-making capacity to act as a donor for transplantation into another. A court would consider what is in the best interests of the proposed adult donor in making their decision.

5.5.2 Exceptional circumstances in which living donation by children and adults lacking decision-making capacity may be considered

Living donation by a dependent donor should exceptionally be considered only in circumstances of strict necessity and where the expected benefits of donation substantially outweigh the potential risks. These and other conditions are set out in following sections. Given the substantially greater burdens and risks associated with living organ donation compared with HSC donation, including a risk of death of 0.2% for living liver donation,[70] these considerations should be more stringently applied where organ donation is being considered. This is regardless of whether the organ (e.g., liver) is defined as regenerative or non-regenerative.

In addition to the ethical conditions set out below, the general principles underpinning ethical practice in living donation outlined elsewhere in these guidelines are also applicable to children and adults lacking decision-making capacity. For example, it is important to ensure the welfare of the dependent donor in the immediate, short, medium, and long-term following donation through the provision of best practice care (see Chapter 6.2.1). This includes mobilising formal expressions of gratitude for their involvement (see Chapter 3.2.1.1) and having appropriate medical and psychological follow up of donors. This is particularly necessary where transplant outcomes are poor or result in the death of the recipient who will normally be a close family member of the donor. Consideration should also be given to the long-term impact of donation on children as they mature and as their understanding of their donation experience and its implications grows.

5.5.2.1 Necessity of living donation by dependent donors

Dependent donors should only be considered as potential donors when all other options have been considered and no feasible alternatives can be found. For example, there are no alternative donors available, and no feasible opportunities for a deceased donor transplant (where relevant), and there are no alternative forms of treatment available for the transplant candidate. This is sometimes referred to as the principle of **last resort**.

In implementing the principle of last resort, all feasible alternatives to using the child or adult lacking decision-making capacity as a living donor ought to be considered. This includes exploring the option of obtaining a HSC donation from the available national and international bone marrow donor registries and considering potential adult living donors outside the immediate family with decision-making capacity.

5.5.2.2 Proportionality of risks and benefits of living donation by dependent donors

If living donation by children or adults lacking capacity is considered, the evaluation of risks and potential benefits becomes particularly important. It is more difficult to justify acceptance of any significant risks when a potential donor is unable to autonomously choose to incur those risks.

Rigorous evaluation of the short, medium, and long-term risks and potential benefits of donation for the potential dependent donor - as compared with the expected outcomes for them if donation does not occur - should demonstrate the risks of proceeding with donation are substantively outweighed by the expected benefits.

As discussed in Chapter 6, when living donation is a non-therapeutic procedure, a donor is only likely to derive psychological and social benefit from helping a loved one. It is important to recognise that people who lack decision-making capacity may have strong interests that extend beyond physical health, which should be duly considered when making decisions on their behalf.

Where a proposed donor's current and predicted future decision-making incapacity is severe and prevents any understanding of why a donation is needed or the potential benefits it offers, the psychological benefits of donation to the prospective donor may be harder to justify. However, in cases where donation provides the only opportunity to preserve the life of a close family member such as a parent or primary carer, the broader benefits of donation for the prospective donor may be substantial in comparison to the risks of the family member dying. For example, whilst a potential adult donor with severe cognitive impairment may have limited capacity to experience emotional distress

if their primary carer dies, the loss of that carer in some cases may be highly detrimental to the long-term welfare of the potential donor.

Any potential benefits of donation need to be weighed against the physical burdens and risks of donation. These risks include the potential lack of understanding experienced by the proposed donor if donation proceeds, which may exacerbate distress throughout the donation process and could potentially cause long-term psychological harm. Whether this lack of understanding will change over time (e.g., a child who may come to understand and appreciate their role in helping a loved one as they mature) may also be relevant.

As noted in Chapter 6.1, in the event that an individual is considered as a potential donor on more than one occasion or asked to donate again following a previous donation, the risks and potential benefits must be reassessed.

5.5.2.3 Relationship between intended recipients and potential dependent living donors

Proposed recipients of living donations from dependent donors should generally be close family of the proposed donor, with whom there should be an existing positive psychosocial relationship. Only in the context of a close interpersonal relationship is it likely that the balance of potential benefits and risks associated with living donation may outweigh those associated with a missed opportunity for living donation by a child or adult lacking capacity.

In contrast to adults who have the capacity to make autonomous decisions about donation, a child or adult lacking capacity **should not** be permitted to assume the risks of living donation for purely altruistic purposes (i.e., non-directed living organ donation). Benefits derived from a wish to help (unknown) others should not be considered sufficient to outweigh the risks associated with living donation and the risks of exploitation of those who lack decision-making capacity.

5.5.2.4 Assent for living donation by a dependent donor

Where the potential donor can contribute to decision-making, their voluntary assent (see Chapter 5.1.4.1) to donation is essential. When the child or adult lacking decision-making capacity is able to participate in decision-making about potential living donation, every effort should be made to support their understanding of the situation (see Chapter 5.1.4) and to communicate their preferences regarding donation. The limits of their ability to appreciate the potential consequences of decision-making should be carefully considered. For example, even older children may have limited capacity to imagine their lives and appreciate the potential longer-term impact of organ donation on their future lives, particularly as they are still forming their characters and preferences in response to greater life experience as they mature.

While a child's understanding is likely to increase as they age and it is important to respect the emerging autonomy of children and adolescents, there must also be an awareness that children may be more easily susceptible to pressures to agree within a family unit. Most children are heavily reliant on parents for most of their life activities and are likely to be influenced by the views of their parents.

For *Gillick*-competent children(see Chapter 5.1.2), a refusal to act as a donor must always be respected. Furthermore, any manifest reluctance or objection to acting as a donor by a child or adult lacking capacity must be taken seriously. The non-therapeutic nature of donation means that it is unlikely to be in a child's best interests to donate

where they demonstrate an unwillingness to donate. This may be evident in strong physical objection to interventions and more considered refusals by children or by adults with some understanding who lack capacity. In such cases, attempts to address the potential concerns (e.g., where unwillingness relates to a fear of hospital or pain from needles) can be made. However, where an unwillingness to donate is maintained for a period of time despite such attempts, an objection should be respected.

5.5.3 Requirements for decision-making when children and adults lacking decision-making capacity are considered as potential living donors

A number of strategies are required to address concerns about decision-making regarding potential living donation by children and adults lacking capacity which are set out below.

5.5.3.1 Formal independence in decision-making about living donation by dependent donors

Those ordinarily tasked with making substitute decisions on behalf of adults lacking capacity or children proposed as donors may be in a conflicted position due to their relationships with the potential recipient. An independent decision-maker (for example a court, tribunal, or independent committee) is likely to be best placed, or required by law, to make the final donation decision.

Evaluation of risks and potential benefits of living donation by children and adults lacking capacity may also be complicated, requiring additional safeguards as outlined in Chapter 5.3.3.

5.5.3.2 Independence in the assessment of dependent donors' preferences

The potential donor may be able to participate in decision-making or otherwise influence decision-making by expressing their values and preferences. Children and adults lacking capacity are often highly emotionally, physically, and socially dependent on parents, carers or substitute decision-makers who may have the authority to make a decision for them about donation, or who may be the intended recipients of donation or have conflicting interests with regards to the intended recipient (see below). This means the prospective donors may be vulnerable to the influence of these individuals when formulating or expressing their preferences regarding donation. As is recommended for all living donors, strategies such as the use of an independent advocate (see Chapter 3.4.5) should be implemented to ensure that potential donors are supported to make voluntary decisions or to express their preferences regarding donation free from undue influence or potentially coercive forces.

5.5.3.3 Management of conflicts of interest in living donation by dependent donors

A child or adult lacking decision-making capacity who is considered as a potential living donor may be dependent on the potential recipient as a parent, guardian or carer, or the intended recipient may be another member of the family with close ties to the prospective donor. The prospective donor's natural substitute decision-maker(s) are thus likely to be in a position of conflict of interest (see Chapter 3.8). Members of the clinical team may also have conflicts of interest if they are involved in the care of both the potential donor and the intended transplant recipient.

Specific strategies to assist in managing potential conflicts of interest in decision-making should be implemented (see Chapter 3.8.2), including the involvement of

separate treating health professionals for donors and recipient, independent advocates for donors whose priority it is to protect the best interests of the potential donor, and the requirement for donation decisions to be reviewed and authorised by independent decision-makers (i.e., courts, independent committees etc). The potential donor should have an independent advocate in place from the point of testing for compatibility.

5.5.3.4 Satisfaction of legal conditions for living donation by dependent donors

Importantly, as noted in Chapter 5.5.1, laws exist in Australia that may require steps to be taken before removal of tissue or organs is lawful. For example, it is unlawful to remove an organ from a child without an order from the Court and in some circumstances a Court order is required for removal of HSCs for donation to another. Having this independent legal safeguard ensures the proposed donor best interests remain central to the decision regarding whether to donate. Where exceptional circumstances are considered to exist that may justify living donation by a dependent donor, the legal conditions must be met, and, where necessary, a Court order obtained. The Court will make a decision in the best interests of the proposed donor.

5.6 Deceased donation decision-making for children and adults lacking decision-making capacity

The same process outlined in Chapter 4.4 should be followed when making decisions about deceased donation on behalf of children or adults lacking decision-making capacity. In the case of children, the child's parents are likely to be the senior available next of kin (SANOK) and thus authorised to make donation decisions on their behalf.

Children may join the Australian Organ Donor Registry at the age of 16. Where children of any age, or adults lacking decision-making capacity have expressed a wish to become a donor, these preferences should be given careful consideration in donation decision-making as they would be in the case of any other potential donor.

6. Risks and benefits of donation and transplantation

As outlined in Chapter 4.1.3, decisions about donation or transplantation for an individual must be informed by the specific risks, burdens and potential benefits of available options for that individual, as well as by the individual's own values and preferences with regards to these. The various interests of the individual may also be influenced by, and, in turn, have an impact on, the interests of the person's family and community.

In contrast to most clinical decision-making, where the recipient of the treatment is the focus, in donation and transplantation the assessment of risks, and potential benefits is additionally often complicated because of the need to evaluate risks and potential benefits for both transplant recipients and donors. The characteristics of donors as well as of recipients will often be influential in determining risks and potential benefits, and decision-makers may need to weigh the potential benefits and risks for recipients alongside those of potential donors, especially in the context of living donation.

Many ethical dilemmas in donation and transplantation relate to difficulties in deciding when the expected burdens and risks of donation and/or transplantation are sufficient to justify declining an opportunity for donation or transplantation, and in deciding who should have the authority to make the final decision about the acceptable balance of benefits and risks. This chapter accordingly provides information about key considerations in donation and transplantation decision-making with regards **to the core value** 'Promotion of the wellbeing of potential and actual donors, recipients, and their families and communities' (see Chapter 3.2.2).

Further resources and readings relevant to this chapter can be found in Appendix 1.

6.1 Evaluating potential benefits and risks of donation and transplantation

Assessment of the potential benefits and risks of donation and transplantation is a step of fundamental ethical significance in decision-making about donation and transplantation. It may be practically and ethically challenging as it may involve gathering information, communication of information, and evaluation of information by multiple stakeholders whose personal experiences, beliefs, and values may influence their judgements about risks and benefits in specific cases.

Evaluation of the risks and potential benefits of donation or transplantation should be aimed at informing decision-making and guiding efforts to maximise potential benefits and eliminate or reduce risks and burdens where possible for all relevant stakeholders, in particular donors and transplant recipients.

Information about typical risks and potential benefits associated with particular types of donation and transplantation is available from sources such as DonateLife Australia, Transplant Australia, the Australian Bone Marrow Donor Registry, and EBAANZ. More specific information should be made available to individuals when making decisions about donation and transplantation from health professionals with expertise in the relevant field. The evidence base that informs decision-making is evolving as new research reveals valuable information that may shed light on risks and benefits for particular groups or individuals in specific circumstances.

When identifying and evaluating risks or burdens associated with specific choices, it is important to consider how these may be avoided or reduced; in many cases, risks may be modifiable. For example, clinical risk factors may be responsive to intervention or lifestyle or behavioural modification on the part of living donors or transplant recipients. The addition of social (including cultural) supports may also help to reduce some financial and psychosocial burdens of donation and transplantation (see Chapter 6.2).

Information about some risks revealed during screening or evaluation of potential donors and transplant recipients may require action (see **Box 6.1**) in accordance with the duty of care (Chapter 3.3.4.1).

The assessment of risks and potential benefits of donation or transplantation must be current at the time a donation or transplantation decision is being made. This means that if an individual has previously been assessed as suitable or unsuitable to donate or receive a transplant, this should be reassessed if donation or transplantation is considered again at a later time. The potential impact and outcomes of any previous donation or transplant should be considered as part of the reassessment.

Specific ethical considerations in the evaluation of risks and potential benefits are explored in the following sections.

Box 6.1 General recommendations with regards to management of risk information revealed on screening and follow up care

- Health professionals have obligations to prevent and minimise harms that may be associated with donation or transplantation. These include obligations to:
  - identify and minimise risks associated with donation or transplantation where possible
  - ensure appropriate follow up care of donors and transplant recipients is available and accessible
  - ensure that the expected benefits and risks associated with donation or transplantation are proportionate, and that risks are within a clinically acceptable range.
- Mechanisms to address risk factors identified during evaluation of prospective donors or transplant recipients should be established, e.g., referral pathways for management of conditions requiring treatment that are identified during screening.
- Policies should be in place to guide decision-making if information is detected during evaluation of potential deceased donors that has potential health implications for donor family members, consistent with relevant privacy legislation (see Chapter 7.1).
- Appropriate medical, social, and psychological follow up care should be available and accessible to all living donors and transplant recipients where necessary.
  - Clinical guidelines should communicate clear standards for consistent practice in follow up care in specific circumstances.
  - Follow up care should also be provided when necessary to those who are declined as living donors.

- In the case of transplantation in a child, guidelines should address potential barriers to transitions in follow up care when the child becomes an adult, where relevant.
- Follow up care should routinely incorporate data collection and reporting to relevant registries.

6.1.1 Holistic and person-centred assessment of risks and potential benefits

The importance of considering the psychosocial risks and potential benefits of donation and transplantation, and of declining donation or transplantation, is increasingly recognised. For example, in some cases, the psychosocial impact of a missed opportunity to become a living organ donor might be a worse outcome for the potential donor than proceeding with living donation despite the substantial physical burdens and risks associated with donation.[71] A parent, for example, may be able to save the life of their child by donating part of their liver; this benefit could greatly outweigh the risks of living liver donation.[72]

In some cases, patients and health professionals may disagree regarding the relative importance of specific risks or benefits and regarding the definition of specific measures used in evaluation of outcomes of donation or transplantation. Health professional perspectives and evaluation of risks and potential benefits are important and clinical expertise will determine the options that are clinically feasible in a particular case. However, careful consideration must be given to patient perspectives and preferences when evaluating risks and potential benefits.

Clinical guidelines and research in donation and transplantation are increasingly informed by donor and recipient perspectives,[73–75] but it is important to ensure that any guidelines or evidence-based tools used to support decision-making are critically evaluated in the light of the personal values, experiences and perspectives of the individual potential donor or recipient.

Individuals are usually embedded in families and communities and have multiple relationships that shape their experience of various burdens, risks, and benefits that may be associated with donation or transplantation. Holistic assessment of risks and potential benefits of donation and transplantation requires attention to these relationships and the familial and social context of individual lives.

6.1.2 Promoting objectivity in assessment of risks and potential benefits

The evaluation of risks and potential benefits that may be associated with donation or transplantation in particular circumstances requires assessment of relevant available evidence, and careful discussion and consideration of potential donor and/or recipient values and preferences. Such assessments are qualitative in nature and may be influenced by bias on the part of health professionals as well as patients and others who may be involved directly or indirectly in decision-making.

The strategies listed below may be helpful in reducing bias when evaluating risks and potential benefits of donation or transplantation, or in reducing the potential impact of bias on decision-making about donation or transplantation. Not all strategies may be necessary, depending on the type of transplant or donation, and the circumstances of the prospective donor or transplant recipient.

- Routine and consistent implementation of up-to-date, evidence-based guidelines for evaluation of prospective transplant recipients and potential living or deceased donors.
- Use of trained and experienced health professionals in a multidisciplinary team for evaluation of prospective donors and recipients.
- Use of an advocate who is independent of the evaluation team (see Chapter 3.4.5).
- Routine consultation of or referral to additional physicians or surgeons when disagreements regarding the acceptability of risks and benefits are based on qualitative judgements or concerns about relative contraindications rather than absolute clinical exclusion criteria.
- Routine auditing of decision-making regarding acceptance or refusal of prospective transplant recipients or donors and evaluation of outcomes to identify and address potential sources of bias and inform guidelines and future decision-making.
- Routine provision of information to patients on how to access an independent professional opinion.

Evaluation of risks and potential benefits may be more difficult when there is limited evidence available to inform assessment of specific types of outcomes. This may be because research is lacking, such as research evaluating the longer-term psychosocial impact of being declined as a living directed donor,[71] or because existing evidence is based on research in specific populations who may not be representative of some prospective donors or transplant recipients.[76] The limitations of the available evidence and the implications of these for assessment of risks and potential benefits should be routinely disclosed and considered carefully in decision-making.

6.1.3 Psychosocial evaluation of prospective living donors and transplant recipients

Psychosocial evaluation of prospective living donors and transplant recipients can help to inform evaluation of potential psychosocial benefits and risks as well as management of risks and care of donors and recipients.

Robust psychosocial evaluation should be routinely included in evaluation of all prospective living donors and recipients of HSCs and organs, although the timing and components of psychosocial evaluation may vary according to the relevant clinical and social context. Specific clinical guidelines establishing evidence-based standards for psychosocial evaluation in specific contexts should be developed and routinely implemented.

Psychosocial evaluation can help to identify factors that may influence decision-making or undermine capacity or voluntariness of decision-makers, for example by detecting factors that may make potential living donors vulnerable to coercion or manipulation.[77] It also helps to ensure that prospective transplant recipients are psychologically prepared and supported to manage the impact of transplantation on their lives. In the case of directed donation, psychosocial evaluation of prospective donors and recipients may help to inform future management of relationships that may be impacted by the outcomes of donation and transplantation.

Psychosocial evaluation is also important in identifying and addressing factors that could lead to living donor attrition and facilitating timely decisions not to proceed with donation. This is particularly important when late withdrawal of consent for donation

may result in harm to intended transplant recipients. Such harm may be psychological, in the form of distress or disappointment at a missed opportunity for transplantation. In the case of HSC donation, where the donor rescinds their consent, it may be fatal if an alternative donor cannot be found for a recipient who has commenced conditioning for transplantation (see Chapter 4.1.4.1). Determining when a prospective donor is psychosocially unsuitable to donate, or unlikely to complete donation may also help to avoid some of the costs and burdens that may be associated with medical 'work up' of prospective donors who eventually decide not to donate.

6.1.4 Determining proportionality and acceptability of risks and potential benefits

Prospective transplant recipients and donors or donor families must weigh the risks and potential benefits associated with choosing transplantation or donation against the risks and potential benefits of declining transplantation or donation. For example, some organ transplant candidates may decide that, on balance, the risks and potential benefits of non-surgical treatment for their organ failure may be preferable to those associated with pursuing a transplant opportunity.

Some health professionals will be responsible for determining whether the balance of risks and potential benefits of donation or transplantation in a particular case is sufficiently acceptable, and hence whether to offer an opportunity for transplantation or donation, or whether to support donation or transplantation when this is requested. Health professionals may refuse to proceed with donation or transplantation in a particular case if they believe it will be disproportionately harmful, or insufficiently beneficial to justify proceeding with a case, even if the prospective donor or recipient is willing to proceed. In other words, health professionals may determine the limits of acceptable risk and the threshold of benefit that are required for an opportunity to be considered ethically reasonable. Within those bounds, more weight is likely to be given to the preferences of the potential donor or recipient.

Health professionals (and policy makers see Chapter 6.1.4.2) should recognise that decisions regarding acceptable risk thresholds and proportionality of potential benefits and risk are inherently normative. This means, for example, that in some cases there may be valid clinical disagreement regarding the level of acceptable risk. There may also be explicitly clinical disagreement regarding the probability of specific harms occurring or specific benefits being achieved if donation or transplantation proceeds. Care should be taken to avoid paternalism in decision-making (see Chapter 6.1.4.1) and to support patients and their families in accessing secondary sources of information or advice.[49]

6.1.4.1 Limits of risk acceptance and concerns about paternalism

While an individual has a right to make informed choices about the risks they may assume in their own life, this does not mean that a health professional has an unrestricted obligation to perform clinical interventions at an individual's request irrespective of the risks and benefits involved. Nor are people entitled to claim access to a therapy or intervention that is not clinically indicated (see Chapter 3.2.1.3).

Health professionals generally have a duty of care that, coupled with their duty of nonmaleficence, means they should only perform interventions when these are clinically necessary and when the expected risks and benefits are proportionate.[49,78,79] (See Chapter 3.3.4.1).

On the other hand, health professionals must strive to avoid paternalistic decision-making, in which their own personal beliefs regarding the proportionality of risks and potential benefits in a particular case are valued over those of the individual patient who is best placed to evaluate this in the light of their personal values and preferences. The strategies outlined in Chapter 6.1.2 may be helpful in mitigating the risk of paternalism.

Health professionals and others may be more inclined to act paternalistically or have a lower threshold for risk acceptance when providing care or making decisions about donation or transplantation on behalf of particular groups. This is especially the case when potential donors are unable to participate fully in decision-making, such as children and adults who lack decision-making capacity (see Chapter 5.5). Living organ donors also raise particular concerns given the magnitude of risks that may be associated with living kidney or liver donation (see Chapter 6.3).

6.1.4.2 Balancing quality and safety in risk management at the level of policy making

Decision-making regarding risk acceptance is not always a matter of assessing potential benefits and risks in an individual case, or even at the level of clinical guidelines. Particularly in the case of tissue transplants, risks are often managed at the level of policy making and regulations. This means that ethical decisions regarding risk acceptance and judgements regarding the proportionality of risks and potential benefits of donation and transplantation may be made in a collective context which is removed from consideration of individual values and preferences.

For example, quality and safety standards established by the TGA (see Chapter 2.3.5) may help to eliminate or significantly reduce some risks for transplant recipients but may also have a significant impact on availability of some tissues. Rather than allowing individuals to make a decision about acceptance of a low risk of contracting a serious infectious disease through transplantation, for example, a policy of mandatory testing of all donated tissues for that disease may practically eliminate the risk.

However, the costs of testing might also be disproportionate in some cases to the risk, for example if there is a low probability of donors carrying the disease and the risk can already by reduced by other methods of screening higher risk donors. This is especially concerning if quality and safety regulations result in fewer donations through exclusion of potential donors deemed of higher risk, or undermine sustainability in tissue banking.

6.1.5 Challenges in the evaluation of risks and benefits of transplantation

Evaluating the risks and potential benefits of transplantation may be complicated by the fact that risks and potential benefits may change over time depending on when an opportunity for transplantation occurs, and on the specific characteristics of donated cells, tissues or organs when these become available. For example, the potential benefits and risks associated with organ transplantation in a particular context will depend in part on the characteristics of the donor organ, such as its age, size, immunological type, anatomical features, risk of carrying an infectious disease or malignancy and the duration of organ ischaemia. These characteristics influence the probability of the graft proving functional in the transplant recipient, as well as the likely duration of graft survival and risk of various complications occurring.

Some individuals may have limited options for alternative treatments to consider, while others may need to choose between a range of options which could have implications for future choices. When considering opportunities for transplantation from a living

organ or HSC donor, transplant candidates will also need to weigh the potential benefits and risks as these apply to the donor, particularly in the case of directed donation.

For health professionals, evaluation of the risks and potential benefits of transplantation for a particular individual may also intersect with resource allocation decision-making, which requires careful management to ensure that clinical decision-making is not inappropriately influenced by consideration of resource constraints (see Chapter 8).

6.2 Care of donors and transplant recipients

Providing optimal care for potential and actual donors and transplant recipients and their families where relevant is essential to minimise risks and maximise the benefits experienced by these individuals, regardless of the choices they make with respect to donation or transplantation. For example, living organ donors who may be at risk of financial injury, anxiety, excessive care burdens or particular medical or surgical complications may be able to receive additional supports or expert care that will reduce if not eliminate their risk of harm.[80]

The care required in specific situations will vary; it should be guided by evidence based clinical standards and individuals' personal circumstances and preference. Care should be provided throughout the various steps that may be involved in consideration of donation or transplantation opportunities, evaluation, decision-making, and after donation or transplantation has occurred. Living HSC and organ donors, deceased donor families, and many transplant recipients may require extended follow up care to provide psychosocial support, ongoing clinical care and evaluation of long-term outcomes. Any limitations or potential barriers that individuals may face in accessing recommended care should be carefully considered when making donation or transplantation decisions.

The potential psychosocial impact of donation or transplantation on the family of a donor or recipient should also be considered and care provided where possible to support families or carers. This is particularly important when transplantation is needed to treat a serious or life-threatening condition, when living donation involves substantive risks or burdens, and in the setting of deceased donation.

Referrals should be made when necessary to ensure **multidisciplinary care** is available for donors, donor families and transplant recipients, with inclusion of social workers, grief counsellors, Aboriginal liaison officers, and spiritual and cultural care providers where relevant.

6.2.1 Care of living HSC and organ donors

The risks and burdens of living donation of HSCs and organs – kidneys or liver – vary significantly, according to the material being donated, the specific donation procedures and the characteristics of the donor. For example, the clinical process of donating HSCs via peripheral blood donation involves injection of a medication to stimulate stem cell proliferation which is associated with mild side effects and later a procedure (known as apheresis) that lasts approximately 3 hours during which blood is collected and then returned intravenously after stem cells are removed.[81] In contrast, living kidney donation involves an operation under general anaesthetic, and donors may require six weeks to recover.[82] Kidney donation is also associated with long term effects on kidney health that require life-long follow up in order to identify and manage any complications or ill effects.

Nevertheless, while the probability, duration, and severity of various physical and psychosocial risks of living donation are variable, there are common potential burdens and risks that should be considered and addressed in the care of living donors. These include:

- **Identification of existing health issues** during evaluation of prospective donors that may require treatment; while diagnosing treatable conditions may be a benefit of screening,[83] this can cause anxiety or distress, particularly if these preclude donation and the intended transplant recipient does not have an alternate donor.
- **Financial costs** that may result from taking time off work for evaluation, donation and follow up care, if leave is not covered by employers or the Government's Supporting Living Organ Donors program, or other out-of-pocket expenses relating to the donation process such as travel costs or costs of replacement carers if the donor is unable to perform their usual carer duties.[24]
- **Discovery of misattributed paternity** in which HLA typing reveals that a presumed genetic relationship between the prospective donor and recipient does not exist (see Chapter 7.2.3).
- **Psychological distress**, for example if deemed ineligible for donation or if the transplant recipient has a bad outcome for which the donor may feel responsible.

Provision of appropriate medical and psychological follow up care to all living HSC and organ donors is an important component of efforts to minimise risks associated with donation. There is limited information regarding long term outcomes of living donation, particularly with regards to psychosocial outcomes, and a growing body of evidence suggests that some donors – in particular living kidney donors – may benefit from long term follow up care to reduce their risk of poorer health outcomes and to assist in timely identification and management of complications if these occur.[84–86]

Those who are declined as living donors may also benefit from access to counselling to help them manage psychological distress or anxiety that may result from this decision, for example if this means a loved one cannot obtain a transplant.[71]

6.3 Risk acceptance in living organ donation

Decision making regarding acceptance of living kidney and liver donors often involves ethically challenging decision-making about risks and potential benefits. Transplant professionals frequently cite living organ donation as a source of ethical concern as it imposes unavoidable and significant burdens and risks to the health of the living donor as a result of a clinical intervention that is primarily intended to produce therapeutic benefits in another individual – the transplant recipient. For some health professionals, living organ donation thus seems to violate the duty of non-maleficence, the obligation to avoid causing harm except when necessary to achieve overall health benefits for the individual patient.

In the absence of direct physical benefits to living organ donors, the unavoidable physical and psychosocial burdens associated with evaluation, invasive surgery and the requirement for long term follow up care are sometimes perceived as being 'traded' or weighed against the therapeutic benefits of transplantation for the recipient of a living donor transplant. Even when a living donor makes an informed choice to assume these burdens and risks, health professionals may feel that 'harming the healthy to help the sick' is exploitative or ethically unjustified.

The degree of risk involved for a particular organ donor, the extent to which a living donor transplant is deemed necessary, and the expected benefits for the transplant recipient collectively influence judgements regarding the acceptability of a particular living donor transplant case. The availability of alternative treatment options for the prospective transplant recipient, and their respective risks and benefits, must also be considered.

Generally, living organ donation may be considered ethically justifiable if

- the donor autonomously **chooses** to donate
- living donation is **necessary**, in the sense that there is no alternative treatment for the intended transplant recipient that would be equivalent to the living donor transplant
- the risks of donation fall within a clinically **acceptable** range
- if the expected benefits of donation are **proportionate** to the risks, meaning that the benefits are expected to substantially outweigh any burdens or harms of donation.

Potential challenges in determining the range of acceptable risks (Chapter 6.3.1) and evaluating necessity (Chapter 6.3.2) and proportionality of benefits and risks (Chapter 6.3.3) are discussed in the following sections.

It is important to note that individuals involved in the medical and psychosocial evaluation of a prospective living donor may differ from those who have responsibility for making a decision about acceptance of a prospective living organ donor. Separation of staff who are involved in assessment from those responsible for accepting or declining prospective donors may help to support impartiality in decision-making. In particular, staff involved in the evaluation or decision-making about acceptance of a prospective donor should not be involved in care of the prospective transplant recipient, to reduce conflicts of interest in evaluation and decision-making (see Chapter 3.8).

A shared decision-making approach (see Chapter 4.1.2.1) should be used when determining whether to accept a prospective donor. This should be inclusive of relevant medical, nursing, and allied health staff such as a clinical psychologist and/or social worker, and donor advocates where relevant, as well as the prospective donor when appropriate. In particular, a donor centred approach to evaluation of risks and potential benefits is recommended throughout the assessment and decision-making process (see Chapter 6.3.3).

6.3.1 Defining acceptable risk thresholds for living organ donors

Ethical tensions may arise when health professionals disagree with prospective living donors regarding the level of risk or balance of expected risks and benefits that is deemed ethically acceptable for donation to proceed in a particular case.

There is clear consensus on the **limits of acceptable risk** at the extreme end. For example, donation is unacceptable if it is expected to cause the donor's death (see Chapter 11.1). If donation were expected to impair the donor's health in ways that might be equivalent to any improvement in the health of the transplant recipient as a result of donation, this would also be unacceptable. For example, a person with one kidney would not be permitted to donate this kidney to a family member as this would leave the donor then dependent on dialysis and in need of transplantation.

Thiessen and colleagues suggest that prospective kidney donors may be considered to fall into three categories: 'those who clearly meet all criteria to donate; those for whom there is a clear contra-indication to donation; and those for whom there may be a slightly increased risk of donation due to pre-existing medical conditions, such as obesity. This last group can be considered medically complex donors.'[87] They note that some individuals who are assessed as medically complex donors may choose not to proceed with donation when they are informed of the implications of relevant risks, however some will be willing to assume the increased risk and make an informed decision to donate. These are described as '**discretionary donors**' who may face disagreement from some health professionals regarding their acceptance as donors.[87]

Individual health professionals may have different views regarding the acceptability of risks of living organ donation in such 'medically complex' or higher risk donors. Personal experiences, beliefs and values, local norms and other factors may influence attitudes towards risk acceptance. The real risks of donation in specific cases will also vary to some degree according to the level of experience and skill of individual health professionals and donation programs, the availability of relevant supportive and follow up care programs, and on the characteristics of the populations they serve. If the risks of living donation in a particular case fall within the range of acceptability as reflected in health professional practice around Australia, this condition for living organ donation should be satisfied. If one health professional is reluctant to accept a prospective donor who nevertheless falls within the range of acceptable risks, referring the individual for review by another health professional or assessment at a different transplant program may be appropriate.

6.3.2 Assessing necessity of living organ donation

There may be ethical disagreement between health professionals or between health professionals and prospective donors and transplant recipients regarding the **necessity of living organ donation**. This is particularly relevant in the context of kidney donation, as most potential transplant recipients are able to access alternative kidney replacement therapy in the form of dialysis and some will have the opportunity to obtain a transplant from a deceased donor. While in most cases, living kidney donation may not represent an immediately life-saving opportunity – in contrast to living liver donation in some cases – it may have substantial benefits for transplant recipients compared with alternative treatment options, and hence significant benefits for a living donor.[88,89]

If more than one prospective living organ donor is available for a potential transplant recipient, the necessity for donation by any one individual is reduced, assuming that all may be clinically suitable to donate (see Chapter 6.3.2.1). In practice, consideration of the necessity condition will often be less relevant in determining whether living donation should proceed than assessment of the proportionality of risks and potential benefits (see Chapter 6.3.3).

6.3.2.1 Selecting from multiple available living organ donors

In some cases, more than one potential living organ donor may volunteer to donate to a transplant candidate. If more than one of these individuals is clinically eligible to donate, health professionals may be asked or required to assist in selecting the person who will proceed with donation. Ideally the person who donates will be the individual for whom donation offers the best balance of risks and benefits, with the expectation that this balance is likely to align with what is best for the transplant recipient (see Chapter 6.3.3).

Collaborative discussions with prospective donors as well as the intended transplant recipient may be needed to assist in decision-making as donor evaluation proceeds. Involvement of psychological counsellors and advocates may be helpful in supporting families to navigate complex discussions. Regardless of which person proceeds to donate, the donation will have an impact on other family members and the risks and potential benefits of donation may be considered collectively from the perspective of the family as well as individuals.

Given the costs and other burdens associated with complete evaluation of individual potential donors, it may also be appropriate to select a donor relatively early in the process. However recent research suggests that in the case of living kidney donation, there may be financial benefits to simultaneous rather than sequential assessment of potential donors.[90] If assessments have not been completed, it may not always be possible to predict which of the potential donors is likely to face the lowest risks and/or greatest potential benefits from donation, which could raise ethical concerns. There may also be concerns regarding fairness in selection or voluntariness in consent, for example if bias on the part of health professionals or family members inappropriately influences decision-making when prioritising one of several donor candidates.

Transplant centres should establish clear mechanisms to support decision-making leading to selection of living donors when multiple potential donors are available.

6.3.3 Assessing proportionality in risks and benefits of living organ donation

Determining whether the risks and expected benefits of living organ donation are **proportionate** requires evaluation of potential benefits and risks that the donor may experience as well as the potential benefits and risks for the transplant recipient.

A **donor centred approach to evaluation** of risks and potential benefits is recommended, in which the prospective donor's goals, values and preferences are central.[87] In this, the proportionality of risks and potential benefits should be determined largely by the risks and expected benefits for the donor. That is, the potential benefits and risks for the prospective transplant recipient should be considered in so far as these may impact the donor. The donor's values and preferences are also particularly important in identifying and qualitatively assessing potential benefits and risks.[89]

For example, a health professional may be reluctant to accept a man as a living kidney donor for his wife if the man is at significant risk of developing diabetes as he ages. However, the man may experience substantial burdens in providing ongoing care for his wife and disruption to their lives and household as a result of her dependence on dialysis. Hence the expected psychosocial benefits to him of his wife receiving a transplant may far outweigh the risks of developing diabetes and potentially developing kidney impairment himself in the future.

The potential influence of personal values and preferences as well as potential biases on risk acceptance in living organ donation should be a particular concern when evaluating proportionality of risks and benefits.

While a health professional may refuse to support kidney donation by the man with a potential risk of developing diabetes if the intended recipient is the man's wife, the same health professional may be willing to support donation by the man if the intended recipient is the man's child.

If this were the case, this implies the health professional is making a value-based judgement that the benefits associated with transplantation of the child are greater

than those associated with transplantation of the adult wife. From a clinical perspective, the impact of receiving a timely living donor transplant may well be greater in the case of a child recipient. However, the prospective donor – and his wife – may have different views regarding the relative benefits of transplantation in either case.

Such an approach by a health professional also suggests that it is the magnitude of benefits for the transplant recipient that are being weighed against the potential risks for living donor, rather than the benefits for the donor.

Even if donation by a prospective living organ donor is deemed ethically justifiable according to the conditions discussed above, this does not mean that donation should proceed. The potential transplant recipient may have better options or preferable options for treatment that offer a better balance of potential risks and benefits from the recipient's perspective (see Chapter 6.5.2). The potential recipient may choose to decline an offer of an organ from a living donor and hence donation will not proceed.

6.3.4 Non-directed living organ donors

The potential benefits to a living donor who is able to restore the health or save the life of a loved one who receives a transplant are often significant, and high rates of satisfaction with donation are reported by living directed organ donors.[89,91–93] Although the entanglement of donor and transplant recipient interests can create difficulties in evaluating risks and benefits and cause concerns with regards to potential influences or pressures on donation decision-making, directed living donation has historically been considered less ethically concerning that non-directed living organ donation.

In non-directed donation, the benefits for a living organ donor are primarily related to the psychological rewards of fulfilling a desire to help others. In some cases, such altruistic donation may also be associated with perceived or actual social rewards such as reputational gains although evidence suggests that non-directed kidney donors may be less likely to receive praise for their actions than directed donors.[94] Consequently, non-directed organ donation has sometimes been considered problematic either because of concerns that a decision to make a non-directed donation may reflect psychological issues that could undermine the validity of consent for donation (see Chapter 4.3.4.1) or because of concerns that the risks of donation will not be outweighed by these potential benefits.

A more conservative approach to risk acceptance in the setting of non-directed donation may in some cases be reasonable, however it may be difficult to ethically justify refusal of a prospective non-directed donor if the same individual would otherwise be permitted to assume a particular level of risk in order to donate to a loved one. As noted in Chapter 6.3.3, the paternalism inherent in refusing to allow an autonomous individual to assume risks in one case but not the other entails a value judgement on the part of health professionals.

Investigation of the physical and psychosocial outcomes of non-directed donation suggests that non-directed donors have similar outcomes to directed donors including high rates of satisfaction with their donation decision.[94,95] Ultimately, if a person is considered clinically eligible to donate - in the sense of falling within the range of acceptable risk for living organ donation - and if they make a free and informed decision to donate based on their personal evaluation of the risks and potential benefits of donation, the fact that their intended beneficiary is a stranger should not preclude donation.

6.4 Evaluating risks and benefits of deceased donation

In many cases, the risks and potential benefits and burdens of deceased donation will largely be determined by the impact of donation on the deceased donor's family and the individuals and communities that benefits from transplantation. Adjustments to end-of-life care associated with deceased donation processes, for example, may result in unavoidable burdens for some donor families. Although it is possible to think of a deceased person as having posthumous interests that should be respected, for example by fulfilling their wish to become a donor, they are no longer able to be materially harmed or to benefit from actions that occur after their death. However, in some circumstances, actions may be taken during the perimortem period for the purpose of preserving opportunities for deceased donation that could impact the potential donor prior to their death (see Chapter 11.4).

6.4.1 Evaluating risks and benefits of deceased donation for donor families

Even when a potential donor has died, the impact of donation on their family should be considered when evaluating the risks and potential benefits of donation. This is appropriate given the role that families play in making donation decisions, and in shouldering the burdens associated with dealing with the death of a loved one. It is also appropriate given that in life, many potential donors would likely give consideration to the risks and potential benefits of their donation decisions with respect to their impact on family.

Many families experience significant emotional benefits when donation occurs, enabling them to find some solace in the loss of their loved one. Families that decline an opportunity for donation may also be at risk of later regret. However, there may also be burdens associated with donation, such as the potential impact that donation may have on the timing and location of a person's death.[96-98]

Although the impact on potential donor families should be considered when evaluating the potential risks and benefits of deceased donation, the potential donor's values and preferences should generally take priority in decision-making about donation, as discussed in Chapter 4.4.2.2.

6.4.2 Evaluating risks and potential benefits of deceased donation for transplant recipients

Evaluation of the risks and potential benefits of deceased donation for prospective transplant recipients has a number of ethical implications. Initial evaluation of potential deceased donors at the time of screening to determine their clinical suitability for donation is the first step in a process of decision-making about proportionality of risks and benefits that ultimately determines how many and which individuals may benefit from transplantation. A higher level of caution with regards to some risks may be warranted in some cases but not others. For example, the risk of an infectious disease in a potential tissue donor may be regarded with greater caution given the potential for infection of multiple individuals, compared with the same risk in a potential deceased liver donor when the intended recipient is expected to die if donation does not proceed.

Once a deceased donor has been accepted, evaluation of risks and potential benefits of transplantation shifts to the clinical context where an individual must decide whether to proceed with a transplant when one is offered (see Chapter 6.5.2).

Some deceased – and living - donor tissue transplants may offer only marginal potential benefits in comparison to alternative treatment modalities, which means that very careful consideration of any risks that may be specific to the tissue transplant options is needed. If donated tissues are used in products or treatments that are not clearly of superior efficacy or quality than alternatives, this should prompt consideration of how donated materials may best be used to optimise their therapeutic value.

The challenges of evaluating risks and potential benefits of deceased donor organ transplants are discussed in Chapter 6.5.

6.5 Evaluating proportionality of risks and benefits in the context of organ transplantation

In contrast to many decisions about treatment options in healthcare, decisions about organ transplantation are likely to involve considerable forward planning and uncertainty regarding the specific options for treatment that may eventuate and their risks and potential benefits. In the following sections, specific ethical concerns that may arise in specific contexts when evaluating risks and potential benefits of organ transplantation are explored.

6.5.1 Evaluating general risks and benefits of organ transplantation for an individual

Determining whether an individual is clinically **suitable** for transplantation involves a decision about whether a person would benefit overall from receiving an organ transplant, and whether they are clinically suitable to receive one, irrespective of the opportunities they may have for transplantation.

Evaluating the risks and potential benefits of organ transplantation for an individual may have implications for whether they are referred to join the waiting list for a deceased donor transplant (see Chapter 2.6). Delays in referral can have a significant impact on long term outcomes for those requiring transplantation, and several factors may influence decision-making in ways that underpin inequities in access to transplantation and transplant outcomes.[99–101] Strategies should therefore be implemented to support objectivity in assessment of potential transplant recipients (see Chapter 6.1.2), ensure that assessment is holistic and centred on the potential transplant recipient (see Chapter 6.1.1).

6.5.1.1 Distinguishing suitability to benefit from transplantation from eligibility for deceased donor organ transplantation

Decisions regarding a person's suitability to benefit from organ transplantation should be distinguished from decisions about 'eligibility for transplant' which is a term commonly used in the context of resource allocation decisions, that determine whether an individual is expected to benefit enough to be considered *eligible* for a deceased donor transplant.

The number of individuals who are deemed eligible for transplantation and who therefore join the organ transplant waiting list is much smaller than the number who would be suitable for transplantation and who might benefit significantly from transplantation if sufficient organs were available. Identifying those who would be suitable may be important for several reasons:

1. It is important to recognise people's healthcare needs and acknowledge their right to healthcare even when circumstances prevent the fulfilment of that right in a particular context.
2. It enables quantification of real transplant needs and may motivate and inform efforts to increase our ability to meet those needs. Overtime, criteria for eligibility have become less restrictive as organ availability has increased. For example, older candidates are now accepted on the transplant waiting list.
3. If individuals identify their own needs, for example through consultation of other health professionals or reading about transplant cases involving patients similar to themselves in other countries, they may pursue potentially harmful options such as transplant tourism, if they believe their needs are not respected in Australia (see Chapter 9.4). By recognising needs, health professionals may be able to educate and inform those individuals of the reasons preventing them from accessing a transplant and of alternative treatments and their risks and potential benefits.
4. A person who is not currently eligible for transplantation may become eligible in future, for example if modifiable risks factors are addressed, or the severity of their need for transplantation increases. Recognition of their potential need may help to ensure repeat evaluations occur. Consequently, if they do qualify for transplantation their eligibility will not be missed (see Chapter 6.5.1.3).
5. It empowers individuals to seek a second opinion, if necessary, if there is a concern that clinical judgements regarding their eligibility are not appropriate. It may also empower individuals who are excluded from transplantation as a result of resource constraints and rationing criteria to review allocation policies and potentially advocate for change, as well as to advocate for organ donation.

Recognising that a person who does not meet eligibility criteria for organ transplantation might nevertheless benefit from transplantation does not mean that a full transplantation 'work up' (as would be performed for eligible transplant candidates) should be conducted. The burdens of completing work ups on individuals who are not eligible to join the waiting list may be significant for both the individual and the healthcare system. These include the financial costs of assessment and the potential to foster unrealistic hopes of transplantation that may result in disappointment and distress. However, some evaluation may be needed to help ensure that decisions about potential treatment options, and eligibility for transplantation are evidence-based.

6.5.1.2 Determining eligibility for organ transplantation by evaluating potential benefits and risks of transplantation

The clinical guidelines developed by TSANZ outline specific inclusion and exclusion criteria for eligibility for transplantation of each organ, as well as general conditions that apply across the organ types.[12] In this context, eligibility refers to eligibility to join the waiting list for allocation of a deceased donor organ.

The process of determining eligibility for transplantation involves:

- referral by a specialist physician of an individual, generally with end-stage organ disease, to a transplant unit
- assessment against eligibility criteria by a multidisciplinary team at the transplant unit — this takes into consideration medical history and other relevant factors (such as the ability to adhere to medical therapy) that affect transplantation outcomes.

6.5.1.3 Re-evaluating suitability for organ transplantation and eligibility for deceased donor organ transplantation

Waiting times for transplantation vary according to organ type. Depending on the availability of an organ suitable to the individual and the urgency of the potential recipient's need for transplantation, it may be several years before a candidate on the transplant waiting list is offered an organ.

A person who is deemed eligible for a deceased donor transplant at time X may no longer be eligible at time Y when a transplant becomes available. Alternatively, a person who is deemed unsuitable for organ transplantation when initially evaluated, for example because a transplant is not yet clinically necessary, may become suitable at a later time point.

The transplant team and other relevant health professionals should regularly review potential transplant recipients and arrange re-evaluation of their suitability for transplantation or eligibility for a deceased donor transplant. If a wait-listed individual on the waiting list becomes temporarily unsuitable or ineligible for transplantation, they should be suspended from the list – 'delisted' – and restored if their condition improves and they again meet the relevant criteria without losing their place in the list.

6.5.2 Recipient evaluation of risks and potential benefits of specific organ transplant opportunities

Having determined that an individual is eligible for transplantation, prospective transplant recipients next need to evaluate the risks and potential benefits of transplant options that are available to them. Specifically, they may need to decide whether to pursue a living donor transplant – if this is an option – or to await a deceased donor transplant.

6.5.2.1 Evaluation of risks and potential benefits of deceased donor organ offers

If awaiting a deceased donor transplant, the next decision may be whether to accept a specific offer of a donor organ when one becomes available to the candidate. Decision-making about offers may be especially challenging if:

- the offer involves an organ that is deemed to be of greater than normal risk or lower than normal quality
- the transplant candidate is clinically stable and hence able to consider declining the offer in the hope of receiving a better offer in the future
- the transplant candidate has characteristics which reduce the probability of another suitably matched organ becoming available
- the offer involves an organ that has been retrieved as part of an experimental study for which evidence is currently limited
- there are circumstances, such as a public health crisis in the form of a viral pandemic, which may increase the risks of receiving a transplant at the time of the offer or potentially result in fewer opportunities for transplantation in the future.

Transplant candidates (or their substitute decision-makers) evaluating the risks and potential benefits of a particular offer therefore need to evaluate several possible future outcomes, some of which may be contingent upon the choice they make regarding the offer, but many of which may be difficult to accurately predict. The TSANZ Guidelines

note, for example, that 'The level of risk of disease transmission [from a deceased donor] must be balanced against the risks to an individual patient of not proceeding with transplantation.'[12]

The burdens of decision-making in such contexts may encourage risk-taking or conservative choices, depending on the characteristics of individuals involved and the clinical situation. The limited time available to make a decision about accepting an offer, so that declined offers may be presented to the next transplant candidate in line, also complicates decision-making. Some strategies to support decision-making about transplant offers are presented in Chapter 6.6.

6.5.2.2 Acceptance of organ transplant offers involving ECD and nonstandard risk organs

Efforts to increase the availability of organs for transplantation have expanded the pool of potential living and deceased donors and resulted in more opportunities for organ transplantation. New technologies and interventions, for example, have enabled the utilisation of some organs recovered from individuals who might previously have been deemed clinically ineligible to donate, or from whom some organs may previously have been discarded as unsuitable for transplantation. Such organs are deemed **extended** (or expanded) **criteria donor** (ECD) organs.

Research and follow up of patients post transplantation have also demonstrated that some perceived risk factors that previously excluded individuals from donating organs while alive or after death may be modifiable or may not be sufficiently significant to justify exclusion of donation in particular contexts. For example, although a transplant from an older deceased donor may offer limited benefits for some young transplant recipients compared with the benefits of receiving an organ from a younger donor, the same transplant in an older recipient may be more than adequate to enable them to live a normal life span. (See Chapter 8.4.3.1).

Similarly, organs that may be judged to present higher than normal – **'non-standard' – risks** for recipients, such as those from donors in whom specific infections cannot be excluded or are confirmed, may nevertheless offer sufficient benefits to recipients compared with alternatives to warrant transplantation. In South Africa, for example, an HIV-negative child received a living donor liver transplant from her mother who was HIV-positive, as this was her only option for transplantation and the alternative was death.[102]

The widening of opportunities for deceased and living organ donation, e.g., with greater acceptance of 'discretionary' living donors (see Chapter 6.3.1) means that there is a wide range of quality in donated organs, and health professionals and transplant candidates must carefully consider the potential risks and benefits of accepting the offer of an organ for transplantation in the light of information that may be specific to a particular organ or organ donor.

Internationally, evidence suggests there may be significant variation in acceptance of transplant offers and rates of decline of ECD organs between transplant centres and individual health professionals.[103–106] While some differences may be attributed in part to the characteristics of local donor or transplant candidate populations, some may be the result of limited experience or expertise of transplant centres or health professionals, professional bias, or conflicts of interests that may influence decisions about which offers will be presented to transplant candidates, and how offers are communicated, thus influencing acceptance decisions.[107] Strategies that may support prospective transplant recipients in making decisions about organ offers are discussed in Chapter 6.6.

6.6 Supporting decision-making by potential transplant recipients about transplant offers

Potential recipients of cell, tissue and organ transplants may face a range of difficulties in evaluating the information about potential benefits and risks of the various opportunities they may have for transplantation. In addition to general recommendations outlined with regards to decision-making and consent for transplantation in Chapter 4.2 and Chapter 5.4, a number of strategies to support decision-making that involves appraisal of risks and potential benefits may be helpful. The strategies used will differ according to the type of transplant being considered and the circumstances of individual transplant candidates.

6.6.1 Disclosure and communication about organ transplant opportunities

Respect for autonomy requires that prospective organ transplant recipients – or their substitute decision-makers – have the opportunity to make informed choices about all available options for treatment. This requires:

- discussion of the option of transplantation from a living donor where possible and of the relative benefits and risks of living donor transplants compared with deceased donor transplants where relevant.
- pre-emptive discussion of the types of organ offers that may be made via the allocation system of deceased donor organs, e.g., increased viral risk donors (see Chapter 2.6.1).
- discussion of specific organ offers that are made via the allocation system of deceased donor organs.

There are several potential barriers to direct inclusion of prospective transplant recipients in decision-making about specific transplant offers made via the organ allocation system, as discussed in Chapter 6.6.1.1.

As shared decision-making may not always be possible at the time an offer is made, when a transplant candidate joins the waiting list, health professionals should discuss with them the possible types of offers that may be made, including offers of non-standard risk donor organs. Health professionals should strive to gain an understanding of the candidate's values, beliefs, and preferences so that they may use a substituted judgement approach to decision-making about acceptance or decline of offers, if necessary at a later time (see Chapter 6.6.3).

In order to ensure that unsuitable transplant offers are declined as efficiently as possible, in some cases it may be necessary for transplant professionals to decline an offer without consulting the potential transplant recipient. If the professional instead believes the offer should be accepted or at least considered by the prospective recipient, or if they are uncertain of the prospective recipient's likely preferences with regards to the offer, the offer should routinely be disclosed and discussed. Valid consent to accept a specific organ offer is always required from the transplant recipient or their substitute decision-maker before transplantation can occur.

Transparency around decision making is important. Health professionals should routinely provide feedback to the organ allocation program on the reasons for declining transplant offers to inform revisions to allocation protocols that may reduce the risk of offers being declined and improve efficiency of the allocation system. Decision-making about transplant offers should also be routinely documented in a system suitable for

auditing, with regular auditing used to monitor trends in decisions and to evaluate clinical reasoning in the light of patient outcomes over time.

6.6.1.1 Factors potentially influencing inclusion of candidates in discussion of transplant offers

Barriers to timely and effective communication may discourage or prevent direct inclusion of transplant candidates in discussion of some offers that are made via the deceased donor organ allocation system. This is especially the case when the relevant transplant professional deems an offer to be clinically unsuitable or incompatible with the transplant candidate's known preferences.[108]

Efforts to reach a transplant candidate urgently via telephone to communicate and discuss an offer that the transplant professional expects will be declined may result in delays in reallocation of the relevant organ which could ultimately lead to it being discarded without transplantation. Inefficiencies in the organ allocation system may in some cases result in multiple offers being made that are clinically unsuitable for some transplant candidates.

In some circumstances, particularly when the offer involves an ECD or non-standard risk donor organ, health professionals may be reluctant to disclose or discuss organ offers with transplant candidates even if it is feasible to do so. Such reluctance may be due to fears that transplant candidates may be distressed by discussion of offers that the professional believes should be declined or that candidates may become anxious if they receive extensive information about the limitations or risks of an offer that the professional believes should be accepted.

Some health professionals may simply feel that the decision to accept or decline an offer is a purely medical decision that requires no input from patients.[108] However, many decisions about organ offers involve qualitative judgements about the proportionality of potential benefits and risks associated with specific offers, and hence should be informed by the transplant candidate's values, beliefs and preferences (see Chapter 6.6.1).[109]

Where an offer is declined without consulting the prospective transplant recipient, they should be informed of the offer and the reasons for declining it at an appropriate time. Doing so provides a mechanism for accountability that may reduce the risk of professional bias. It may also help to reassure candidates that they are 'active' on the waiting list and being considered for transplantation.[108]

Case Study – Expanded Criteria Donor (ECD) organ transplant offer

Marwan is a 67-year-old man who has been on the waiting list for a kidney transplant for two years. Marwan does not have a potential living donor. He is also highly immunologically sensitised. This means that he has a below average chance of matching when an organ from a deceased donor becomes available for him.

A kidney becomes available from a deceased donor that is offered to Marwan through the organ allocation system. He is a good match from an immunological perspective, but Marwan's transplant team is concerned that the kidney is from an expanded criteria donor. (See Chapter 6.5.2.2) Marwan's transplant nephrologist, Dr C, tells Marwan about the offer, but explains that they plan to decline it. Dr C says, 'I just don't think this is a

good kidney. Although you'll have to wait longer for a transplant because it might be a while before a suitable match comes up again, I think it's worth waiting for a better offer. If you take this kidney, I don't think it will last you as long and you'll probably become even more sensitised, making it harder to get another match. You're doing well on dialysis, and if you keep fit and wait for a good kidney it will probably last you the rest of your life if you treat it well.'

Points to consider:

- This case highlights the complexity of decision-making about ECD organ offers (see Chapter 6.5.2.2).
- Three principles may be especially relevant to this case:
  - **Principle 1** Decision-making about donation and transplantation should seek out and take account of expressed preferences of donors, recipients, their families and communities, and facilitate self-determination.
  - **Principle 5** Donation and transplantation activities and associated decision-making should be transparent and open to scrutiny.
  - **Principle 7** Donation and transplantation activities should provide benefit and minimise burden and risk of harm: where burdens or risks are unavoidable, they should be proportionate to the benefits that are anticipated.
- The transplant candidate and their health professional team need to weigh up the potential benefits and risks of accepting an organ offer against the benefits and risks of waiting for another offer. In the case of highly sensitised patients, with a lower chance of receiving offers, the risk of missing an opportunity for transplantation if they decline an offer is especially significant.
- It is important that Marwan be involved in this decision as his personal perspective is essential for evaluating the options. It is also vital that his decisions be as informed as possible. For example, it may be helpful for Marwan to receive more specific information about the concerns expressed regarding the quality of the offered kidney and the implications of this for his own long-term outcomes if the offer is accepted.
- It would also be important for Dr C to hear Marwan's perspectives regarding his current situation. For example, although Marwan may be 'doing well' from a clinical perspective while on dialysis, he may be finding dialysis socially burdensome or psychologically difficult.
- Considering the evidence available when estimating potential outcomes of specific treatment options will help to ensure Marwan's decision is informed. For example, although Marwan may be coping well with dialysis, there may be risks associated with prolonged time on dialysis that need to be weighed against the potential benefits of waiting and (possibly) receiving another kidney of greater quality. Similarly, although there may be a risk of Marwan become more sensitised if he accepts the organ offered, this may be less of a concern in his case given his age. If he were aged in his 30s, then it would be more likely that he would need a second transplant during his lifetime so the impact of further sensitisation might be greater.
- It may be helpful for Dr C to involve a colleague in decision-making, to help promote objectivity in decision-making. It is possible that personal biases or assumptions may unduly influence Dr C's assessment of the risks and potential benefits of the offer. For example, Dr C may be feeling unduly optimistic that

Marwan will receive another offer or might be unduly concerned about the impact of a poor outcome on his transplant unit's performance record.

- Planning ahead for complex transplant decision-making like this helps to make decision-making easier when an offer is available (see Chapter 6.6.2). For example, if Marwan has already had a discussion with Dr C about the pros and cons of a transplant involving ECD kidney, it may be easier for him to process the specific information relevant to this offer and make a timely decision.

6.6.2 Planning for complex transplant decision-making

Decision-making in the context of uncertainty regarding deceased donor organ offers requires careful planning and investment of time - and resources where necessary - to support shared decision-making that is centred on the values and preferences of the prospective transplant recipient. Use of a multi-step approach to consent for transplantation may help to prepare transplant candidates for decision-making about transplant opportunities when these arise and ensure more time is allowed for reflection on preferences and decisions.

This is particularly important for prospective organ transplant recipients who may need to make a decision about acceptance of a non-standard risk donor organ within a limited time period. It is also essential as transplant professionals may be required to make a decision about acceptance of an organ offer on behalf of the prospective transplant recipient (see Chapter 6.6.1), so they will need to be familiar with the individual's current values and preferences.

A multi-step approach might involve informing the transplant candidate at the time of being wait-listed about the possibility of receiving an offer of a non-standard risk donor organ. At that time, without a specific offer, the candidate has the opportunity to reflect carefully on the potential benefits and risks of accepting an offer. The possibility is revisited at a later time point to ensure the information is not forgotten and to encourage further reflection. When an eventual organ offer is made the candidate will be asked to make a decision based on the specific information about the offer and their own clinical status at the current time.

Health professionals who may be responsible for making a decision about acceptance of a deceased donor organ on behalf of a patient should also ensure that the individual's personal goals, tolerance for risks, and understanding of potential options for treatment and the likelihood of receiving future transplant offers are regularly revisited in discussions aimed at eliciting or reaffirming the potential recipient's current values and preferences.

6.6.3 Use of decision-making aids

Use of decision-making aids including clinical guidelines, recent research of relevance, and tools that may be specifically designed for the purpose of facilitating decision-making in specific situations may be helpful. For example, an American tool has been designed to help people rapidly estimate the probability of particular outcomes (functioning graft and patient survival) when making a decision about an offer of a donor kidney.[107] The decision will ultimately depend however on the values and preferences and specific clinical situation of the individual transplant candidate, so tools such as this should be used to support decision-making rather than to determine which offers should be accepted. Local tools are being developed in Australia.

Box 6.2 Decision-making about deceased donor organ transplant offers - summary recommendations

- The complexities of decision-making about deceased donor organ transplant offers should be carefully addressed to avoid bias in decision-making, support equity of opportunity for transplantation and to promote autonomy of decision-making in prospective transplant recipients.
  - When a potential transplant recipient is wait listed for a deceased donor organ transplant, a multi-step process for consent with regards to the consideration of offers of non-standard risk donor organs should be implemented where possible and appropriate.
  - Shared decision-making with prospective transplant recipients should aim to elicit their informed values and preferences with regards to potential organ offers.
  - Any potential conflicts of interest or sources of bias that may influence transplant professionals' recommendations regarding acceptance of potential transplant offers should routinely be disclosed to potential transplant recipients.
  - Where appropriate, decision-making aids should be used to support potential recipients in determining their preferences with regards to the range of potential transplant offers they may receive.
- A recipient-centred approach to decision-making about acceptance of deceased donor organ transplant offers should be used.
  - If the transplant professional(s) receiving an offer on behalf of a patient believes the offered organ would be wholly unsuitable for the candidate at this time, the offer may be declined without consulting the candidate.
  - If the transplant professional believes an offer should be accepted or at least considered by the prospective recipient, or if they are uncertain of the prospective recipient's likely preferences with regards to the offer, the offer should routinely be disclosed and discussed directly with the potential recipient.
- Transplant offers received via the deceased donor organ allocation system should be declined or accepted as efficiently as possible to avoid delays that may lead to organs being discarded.
  - Health professionals should routinely provide feedback to the organ allocation program on the reasons for declining transplant offers to inform revisions to allocation protocols.
- Decision-making about deceased donor organ transplant offers should be routinely documented and regularly audited.

7. Privacy and confidentiality

Respecting duties of privacy and confidentiality may be complicated in the setting of donation and transplantation because it may be desirable or necessary to seek, disclose or exchange information about donors to recipients and vice versa, or to their respective family members.

In this chapter, the concepts of privacy and confidentiality are explained, as well as their implications for donation and transplantation activities. Situations are discussed where tensions may arise between obligations to respect a person's privacy and obligations to respect other people's rights to access information that may be important for their decision-making about donation or transplantation. This chapter provides information about key considerations in donation and transplantation decision-making with regards to foundational **Principles 5 and 6**:

- **Principle 5**. Donation and transplantation activities and decision-making should be transparent and open to scrutiny.
- **Principle 6**. Donation and transplantation activities and associated decision-making should protect the privacy of individuals and their families and the confidentiality of information related to donation and transplantation activities.

Further reading and resources of relevance to this chapter can be found in Appendix 1.

7.1 General considerations in privacy and confidentiality

Privacy and confidentiality are inter-related concepts that fall within the scope of an individual's general right to autonomy or self-governance over their own person; including their right to control access to and use of their body and personal information.

Broadly speaking, privacy refers to a person's ability or right to control access to their person, including their physical person or body, and their personal information. Privacy may be thought of as a physical and theoretical space specific to an individual who governs that space. In practice, respect for privacy generally means that consent should be obtained before accessing a space that might be considered private, and a refusal should be respected.

- For example, if a doctor wishes to obtain information about a person's risk of exposure to infectious diseases in order to evaluate whether they may be a suitable living donor, they should seek this information from the potential donor. If the person refuses to disclose their private information, it would be a violation of **privacy** if the doctor tried to obtain the information in other ways, for example by questioning the person's relatives or accessing their medical record for this purpose.

See Chapter 7.1.1 for a summary of the circumstances in which a health provider is generally legally permitted to disclose a person's health information to other people.

Confidentiality concerns the management of private or otherwise secret information. If a person discloses their private information in confidence to another person, that person has an ethical duty to keep it secret or to use and share that information only in accordance with the wishes of the person to whom that information relates.

For example, if a prospective living donor chooses to disclose sensitive information about their risk of infectious disease to a doctor, they may give their permission for that information to be further communicated to a potential recipient of their donated cells, tissue or organ. However, if the doctor were to share the information with someone else, such as a friend of the doctor, this would be a breach of **confidentiality** as the prospective donor did not consent to this disclosure.

In some cases, specific consent to disclosure of confidential information to a specific individual or for a specific purpose may be needed. This is particularly important when there are potential risks associated with the disclosure or use of information in a particular setting, or when it is reasonable to assume that the person would not expect their confidential information to be disclosed or used in a particular way. In other cases, consent may be reasonably presumed.

For example, a doctor providing care to a transplant candidate may share confidential information about the person's medical history with other members of the transplant team, for the purpose of providing care to that person. Members of that team might also access the medical record of the transplant candidate without seeking consent from the person and this would not usually be considered a breach of privacy. This is because the person is presumed to consent to access and use of their medical information for the purpose of the transplant when they consent to receive care within a particular healthcare setting.

7.1.1 Privacy legislation

Commonwealth and State or Territory legislation governs aspects of privacy in health care and creates rules regarding how a health provider can collect, use, or disclose (i.e., share) another person's health information.

The Australian Government and federal, state and territory legislation provide extensive guidance about the protection of private information.[110] Specific legislation (see **Table 7.1**) governs the use of health information, which means that in some jurisdictions health professionals may be legally bound to manage information in particular ways, regardless of how individuals may choose to manage their own personal information. (See also Chapter 7.3 for discussion of anonymity in non-directed donation).

Generally, a health provider can only disclose a person's health information to other people in the following circumstances:

- to fulfil the purpose they collected it for, or if it is directly related to a purpose that the person would reasonably expect – e.g., shared with another health professional in the treating team to provide the person with treatment they have consented to
- the person agrees to the disclosure
- it is required by law (see, for example, Chapter 7.1.1.3)
- it is necessary to prevent a serious threat to life, health or safety and it is not practical to get the person's consent (see, for example, Chapter 7.1.1.2).

Additional legal obligations arise in relation to the identity of donors and recipients in the human tissue legislation (see Chapter 7.1.1.1).

Table 7.1 - Privacy Legislation

Legislation	Hyperlink
Cth Privacy Act 1988	https://www.legislation.gov.au/C2004A03712/latest/text
Cth Australian Organ and Tissue Donation and Transplantation Authority Act 2008	https://www.legislation.gov.au/C2008A00122/latest/text
ACT Health Records (Privacy and Access) Act 1997	https://www.legislation.act.gov.au/a/1997-125/
NSW Privacy and Personal Information Protection Act 1998	https://legislation.nsw.gov.au/view/html/inforce/current/act-1998-133
NSW Health Records and Information Privacy Act 2002	https://legislation.nsw.gov.au/view/html/inforce/current/act-2002-071
NT Information Act 2002	https://legislation.nt.gov.au/Legislation/INFORMATION-ACT-2002
QLD Information Privacy Act 2009	https://www.legislation.qld.gov.au/view/html/inforce/current/act-2009-014
QLD Right to Information Act 2009	https://www.legislation.qld.gov.au/view/html/inforce/current/act-2009-013
TAS Personal Information and Protection Act 2004	https://www.legislation.tas.gov.au/view/html/inforce/current/act-2004-046
VIC Privacy and Data Protection Act 2014	https://www.legislation.vic.gov.au/in-force/acts/privacy-and-data-protection-act-2014/031
VIC Health Records Act 2001	https://www.legislation.vic.gov.au/in-force/acts/health-records-act-2001/049
Note that there is currently no dedicated privacy legislation in South Australia. In Western Australia the government has introduced the Privacy and Responsible Information Sharing Bill 2024.	

Please note that the above links are current at the time of writing but may lead to out-of-date versions of legislation in future. As legislation is regularly amended, please check that you are viewing the most current version which should usually be accessible via the website to which these links will direct.

7.1.1.1 Legal considerations in disclosure of identity of donors and recipients

All governments support a policy that contact between donor families and recipients remain anonymous.[111] In the human tissue legislation (see Chapter 3.5.1), offences exist in some States and Territories applicable to health professionals involved in donation or transplantation who disclose 'to the public' the identity, or identifying information about, donors or transplant recipients. Exceptions do exist for donation agencies where consent to disclosure has been provided by authorised family members and disclosure is related to educational, commemorative or community awareness activities (see ss 58-59, *Australian Organ and Tissue Donation and Transplantation Authority Act 2008*).

7.1.1.2 Lawful disclosure of genetic information in the private health sector

Health practitioners in the private sector may lawfully use or disclose patients' genetic information, whether or not they give consent, in circumstances where there is reasonable belief that doing so is necessary to lessen or prevent a serious threat to the life, health or safety of their genetic relatives.[112]

7.1.1.3 Lawful disclosure of personal health information under public health legislation

State and Territory public health legislation legally requires health practitioners to notify health authorities when individuals are diagnosed with specific communicable (infectious) diseases.[113] Diseases are deemed 'notifiable' if mandatory reporting is considered necessary to protect public health. When a person is diagnosed with a notifiable disease, for example, when being evaluated as a potential living donor, the healthcare practitioner must report the diagnosis to health authorities whether or not the person gives consent to this disclosure.

7.1.2 Limitations on rights to privacy and confidentiality

Although respect for privacy and confidentiality are considered core ethical, professional, and legal obligations in healthcare practice, there are some limits to rights to privacy. In some situations, health professionals may not be required to respect these obligations or may even be required to breach them for specific purposes (see Chapter 7.1.1.3).

Usually, limitations to the duty of respect for privacy and confidentiality relate to obligations to prevent serious harm to other people, as discussed from a legal perspective in Chapter 7.1.1.2. That is, if it is necessary to breach the duty of confidentiality to one person in order to prevent serious harm occurring to another person, this may be considered ethically justifiable, if not ethically obligatory.

Nevertheless, breaches to confidentiality and privacy are considered ethically justifiable – and lawful – only in exceptional circumstances. This means that in situations where there may be tensions between respecting one person's right to privacy and another person's need to obtain private information from that person, care is needed to balance these competing interests and ensure that individual rights are respected.

7.1.3 Privacy of health information in the context of relationships

As noted in Chapter 3.2.1.2, autonomy may be thought of as an individual but also a relational concept, in the sense that while people make decisions about and participate in their own lives as individuals, they general do so in the context of rich networks of relationships with other individuals with whom they share interests and values and goals, and with whom they may make decisions. The relationally complex nature of human lives also has implications for privacy and confidentiality. Personal information about individuals may have significant value for other individuals by virtue of the social, biological, or genetic relationships they share, and individuals may have private information in common, which means that disclosure of information about one individual may also impact others.

Legislation may not always provide clear guidance for dealing with situations in which one person's wish to control disclosure or use of their personal information may conflict with the wishes of another person regarding the same information. In the context of donation and transplantation, this means that health professionals should strive to

anticipate situations in which such conflicts may arise so that decision-makers may consider these in advance and be better supported in managing conflicts if these do arise.

Issues are perhaps most likely to arise when specific information is disclosed or revealed in the course of evaluation of prospective living directed donors and transplant recipients, but it is not always possible to anticipate what information may be discovered or how donors, recipients or their relatives may react to particular information. In the following sections, specific situations in which ethical concerns may arise regarding respect for privacy and confidentiality in the context of donation and transplantation are explored.

7.1.3.1 Information of familial relevance

Information collected in the course of evaluating a potential donor or transplant recipient, like any information gathered during a clinical consultation, may have implications for other family members. With the exception of information relating to notifiable diseases (see Chapter 7.1.1.3) or, in some cases, genetic conditions that pose an immediate and serious risk to others (see Chapter 7.1.1.2),[114] such clinical information must be treated in confidence regardless of whether family members may have an interest in accessing this. Health professionals may counsel and encourage individuals to disclose relevant information to other family members, but they may not breach privacy and confidentiality obligations without consent.

In some cases, e.g., living directed donor transplantation or deceased donation, prospective transplant recipients or family members may be closely involved in the process of potential donor evaluation and decision-making about donation. This may complicate efforts to manage information disclosure and protect confidentiality if the person to whom a duty of confidentiality is owed wishes to withhold some but not all information from others (see Chapter 7.2).

7.2 Management of private and confidential information during donor and recipient evaluation and care

When potential living and deceased donors and transplant recipients are evaluated, the information obtained is considered private and confidential, like all information that is obtained in the course of healthcare delivery. In contrast to routine healthcare delivery, however, there are several aspects of information management in the context of donation and transplantation that may require specific ethical considerations.

Specific ethical considerations regarding privacy when referring or seeking advice regarding clinical eligibility of some potential deceased donors prior to discussion of donation with the potential donor's family are explored in Chapter 11.5.3.

7.2.1 Disclosure of clinically relevant information to support decision-making

At least some of the private information obtained in the setting of donation will be disclosed as necessary to provide clinical care to people other than the person from whom it is obtained, i.e., transplant recipients. Some private information may also be disclosed in the setting of directed living donation, in which individuals may make decisions about donation and transplantation in part based on knowledge of the risks and potential benefits of these procedures for their intended donor or recipient (see Chapter 6).

When the relevant people involved agree on the disclosure or exchange of specific information, then information may be shared freely without breaching privacy or confidentiality. In other cases, careful communication of information may enable the exchange of necessary information without breaching the limits of what individuals may be willing to disclose. For example, clinically relevant information may be communicated without disclosure of historical or narrative details which might be considered more personally sensitive, or which may risk identification of a non-directed donor and/or their family.

7.2.1.1 Disclosure of donor information to transplant recipients

Most commonly, some information about the donor of cells, tissues, or organs may be disclosed to a prospective transplant recipient in order for them to make an informed decision when consenting to receive a transplant. As discussed in Chapter 4.2 and Chapter 6.5.2.1, it is necessary for the person providing consent to transplantation to receive clinically relevant information about the donated material that may influence the risks and potential benefits of a transplant opportunity.

Clinically relevant information may be limited, particularly in the setting of tissue transplants that have undergone significant processing. A recipient might, for example, learn only basic details about the graft they are to receive which contain no information that is specific to the individual donor.

On the other hand, clinically relevant information may be extensive and highly specific to an individual donor. However, this can usually be provided without disclosure of details that might facilitate identification of the donor. For example, a person making a decision about acceptance of a deceased donor organ offer should receive information about the clinical characteristics or qualities of the organ, rather than events in the donor's life or death that may have impacted the qualities of the organ.

Where there is uncertainty regarding the potential impact of some events or donor behaviours during life on the donated organs or tissue, which may influence the potential benefits and risks of accepting a transplant offer, it may be necessary to disclose some information. This should be communicated in a general way, for example by describing any ante-mortem interventions the donor may have received that could influence the qualities of the transplant or by explaining why it may not be possible to exclude the presence of a specific infectious disease in the donor.

7.2.2 Protection of privacy in the setting of directed living donation

When a living person plans to donate cells, tissues or an organ to someone they know, confidentiality and privacy remain important even though the potential donor and recipient are likely to share a lot of personal information with one another. It is important not to make assumptions regarding the information that prospective living donors or recipients may wish to disclose to one another, or information that they may already hold. Even within close families or spousal relationships, some elements of an individual's social, psychological, or medical history may be highly sensitive. See, for example, the discussion of misattributed genetic relationships that may be revealed through living donor evaluation in Chapter 7.2.3.

Individuals should be supported in managing the exchange of information that may be necessary to ensure that both parties can make an informed decision about donation or transplantation. Some individuals may assume they are entitled to access or receive information about their donor or recipient, and the importance of respecting

confidentiality and privacy within the donor-recipient relationship should be discussed early in the evaluation process to ensure that expectations are established and that boundaries are defined where necessary.

In some cases, it may be difficult for a potential living donor or transplant recipient to decline a request for or an offer of donation, as this might cause emotional distress or tensions within relationships. Potential coercive influences (see Chapter 4.1.2 and Chapter 4.3.3.1) may also create difficulties in declining donation or transplantation opportunities within the context of familial or social relationships. Individuals should be given opportunities to privately discuss any concerns they may have regarding donation or transplantation, and they should be supported in communicating their decisions or declining donation or transplantation opportunities while avoiding conflict within relationships (see Chapter 7.2.2.1).

7.2.2.1 Strategies to support privacy in directed living donation

Potential living directed donors and transplant recipients may need help to protect their personal information, for example, in situations where family members or others may pressure them to disclose information. Provision of counselling may help individuals to manage difficult disclosures of sensitive information where necessary. Professional mediation of group discussions may be helpful in ensuring that information disclosures and discussions are respectful of the privacy of individuals.

When prospective living directed donors do not wish to proceed with donation but are reluctant to disclose this to the intended transplant recipient or family members, consideration may be given to use of an 'alibi'. The term 'medical alibi' has been used to describe the occasional practice of health professionals providing potential living directed donors – usually kidney donors – with a statement or justification for the relevant transplant centre to decline the donor, so that the potential donor may avoid disclosing their unwillingness to donate to the potential recipient or their family.

In such cases, transplant centres are correct in describing the potential donor as *ineligible* to donate because they do not meet the essential criterion for donation of voluntariness. However, an alibi does not communicate this reasoning, and is generally considered or used to imply that the potential donor is not clinically suitable or is medically ineligible to donate.

Potential risks and ethical concerns regarding use of a donor alibi include the following:

- may involve withholding information from or providing misleading or even dishonest information to a potential transplant recipient.
- providing a plausible 'alibi' may be difficult depending on the clinical characteristics of the potential donor and recipient, on the communication skills of the health professional providing the alibi, and on whether the prospective recipient or their family are likely to probe the information provided.
- if it is suspected or inadvertently revealed that an attempt has been made to deceive, use of a medical alibi may undermine trust on the part of the prospective transplant recipient, especially if there has not been a clear separation between the healthcare staff involved in evaluation of the potential donor and care of the prospective transplant recipient.
- alibis may not fully address the issues faced by the potential donor, for example if they are at risk of physical, emotional or financial abuse by family members despite providing an external reason to justify the decision not to proceed with donation.

Potential benefits of offering a donor alibi:

- in some circumstances provision of an alibi may be a necessary protection for a potential living donor who is experiencing significant pressure to donate.
- awareness of the availability of an alibi may be helpful in ensuring that prospective donors are confident in their ability to withhold or withdraw consent safely.[57]

Living donation programs should establish a clear policy with regards to provision of alibis and provide education and guidance to relevant staff regarding their use in order to optimise their benefits and reduce potential risks if alibis are used.

7.2.3 Misattributed genetic relationships in evaluation of living directed donors

In some cases of directed living donation, the process of donor and recipient evaluation may reveal information that indicates an unexpected genetic relationship – or lack of relationship – between some individuals. For example, when evaluating potential living kidney donors and determining who is a suitable immunological match for a particular recipient, it is estimated that roughly 0.5% of living donor cases are found to involve misattributed paternity.[115] This means that a prospective living donor and recipient pair who presented their relationship as that of a genetic father and child do not in fact have such a genetic parental relationship.

Misattributed paternity is often identified in other clinical settings, such as when individuals undergo genetic testing. In general, ethical guidelines for both transplantation and other settings sometimes advise health professionals that there is no obligation to disclose a finding of misattributed paternity to affected individuals, or advise not to disclose such findings unless there is a medical reason to do so.[116,117] Other guidelines urge donation programs to ensure a policy is in place with regards to management of findings such as misattributed relationships and recommend disclosure of this possibility to prospective donors and transplant candidates so they may choose whether to be informed of such findings.[118,119]

Nondisclosure policies are usually underpinned by concerns about the potential psychosocial harm of such disclosures, uncertainty regarding whether the individuals affected would wish to receive the information, and the belief that disclosure is usually not medically necessary or beneficial. The potential clinical relevance of such a disclosure is likely to depend on the context in which the information is revealed, as well as other information about the affected individuals. The increasing value placed on genetic knowledge in the prevention and management of disease suggests that the perceived benefits of disclosure are likely to increase.[120]

In the context of donation and transplantation, additional considerations may include the possible impact of disclosure on the willingness of potential donors to donate, and the impact of disclosure on familial relationships at a time when family members are likely to be experiencing significant stress as a result of the transplant candidate's illness. When the transplant candidate is a child, concerns relating to their ability to cope with the information and the impact on their development may complicate concerns about disclosure.[117]

Given the uncertainty regarding the risks and benefits of disclosure of misattributed paternity in the setting of living donor transplantation and the complexities of managing situations in which several individuals may be impacted by a disclosure in different ways, there is currently no clear guidance as to whether or how disclosure should routinely be made. It is recommended that:

- transplant centres establish a policy to ensure consistency of practice and establish strategies to manage incidents of misattributed paternity when they occur
- individuals presenting for evaluation as a living donor or their recipients should be routinely informed of the risk of incidental findings being discovered during testing, including the possibility of misattributed paternity, and should discuss how these should be managed
- transplant centres consult with genetic counselling services to help establish plans to support individuals who may be affected by the discovery or suspicion of misattributed paternity.

Box 7.1 Summary key ethical recommendations regarding privacy in donation and transplantation

- The right to autonomy encompasses rights to control access to and use of personal information, however these rights may be limited in some circumstances. These include:
  - legally mandated disclosures to health authorities, e.g., notification of specific infectious diseases
  - disclosure of private information in some circumstances, where necessary to avoid causing serious harm to others.
- Prospective donors, donor families and transplant recipients should be informed of potential limits on or risks to privacy or confidentiality at the time of decision-making about donation or transplantation. They should also be advised of strategies to reduce the risk of privacy breaches.
- If it is necessary to disclose private or confidential personal information after donation or transplantation has taken place, in order to prevent serious harm to others, consent should be obtained when possible from the person(s) to whom the information relates. Information disclosed should be limited to that which is necessary to reduce the risk of harm.
- Specific safeguards may be needed to protect privacy and manage disclosure of personal information in the context of living directed donation.
  - Individuals presenting for evaluation as living directed donors and transplant recipients should be routinely informed of the risk of incidental findings being discovered during testing, and should discuss how these should be managed, including the risk of discovering misattributed genetic relationships.
  - Centres performing living directed donor transplants should establish policies to ensure consistency of practice and strategies to manage incidents of misattributed paternity when they occur.

7.2.4 Protection of privacy in non-directed donation

The exceptional nature of donation and transplantation of human cells, tissues and organs means that both donors and recipients (and their families) may have a personal interest in obtaining information about one another for non-clinical reasons, even when there is no pre-existing relationship between them. For example, a deceased donor family may wish to know how many people benefited from the donation of their loved one's organs and tissues, in order to celebrate this while grieving for their loved one.

In the context of non-directed donation, anonymity of donors and recipients is routine (see Chapter 7.3), such that neither donors (or donor families) nor recipients are known to one another. Protecting the privacy of donors and recipients means that confidential information should not be disclosed without consent, except where disclosure of some information may be necessary to support informed decision-making as noted in Chapter 7.2.1.

Although many people are willing to make a non-directed donation of cells, tissues or organs in order to help others without receiving any specific information about how their donation was used, many donors and donor families value receiving information about the impact of their gift. It is common for some information to be provided to donors and donor families as this provides an important acknowledgement of the value of their donation decision. It may also be psychologically beneficial to them and benefit the public because it may encourage others to donate.

For many donors, donor families and transplant recipients, donated cells, tissues and organs may form the basis of a perceived or desired emotional or social connection between donors or donor families and recipients. Some transplant recipients and non-directed donors or donor families may wish to know more about the social or clinical details of their respective donors or transplant recipients. This may be because they wish to identify and establish a relationship with the other party or because this information is of personal interest to them as a result of the psychosocial value placed in donation and transplantation.

Information that is commonly provided to deceased donor families or non-directed living HSC or organ donors includes confirmation of how donation(s) were used, e.g., how many known individuals may have received an organ or tissue transplant from a deceased donor, and basic demographic information about transplant recipients such as their general age category and the organ or tissue they received. In order to preserve anonymity, as required by legislation and consistent with governmental policy,[111] such information is provided in a manner that reduces the risk of recipients being identified.

Contact between non-directed living donors or deceased donor families and transplant recipients is permitted when mutually agreed but is restricted by default to **anonymous communication** in which any potentially identifying details are removed by the organisation responsible for overseeing such correspondence.

For example, the ABMDR oversees correspondence between non-directed HSC donors and transplant recipients. Correspondence from donors is sent directly to the ABMDR which then forwards the correspondence to relevant transplant centres where staff are responsible for forwarding this to the relevant recipient if they have agreed to receive correspondence. Transplant recipients may write to donors by sending correspondence directly to the ABMDR or via their transplant centre. Both the ABMDR and the transplant centres take responsible for reviewing correspondence and removing any identifying information that may lead to a breach of privacy or loss of anonymity. Similar processes are in place, for example at DonateLife and some eye and other tissue banks, to facilitate anonymous correspondence between deceased donor families and recipients of deceased donor transplants.

7.3 Anonymity in non-directed donation

Most donation in Australia is anonymous, with the exception of living directed HSC or organ donation. Anonymity in donation means that when a person donates, their cells, tissues or organs are allocated and transplanted in people whose identity remains unknown to the donor (or the donor's family). Transplant recipients likewise are not informed of the identity of the person(s) from whom they have received a donation.

As noted in Chapter 7.1.1.1, legislation in some Australian jurisdictions permits disclosure of identifying information with the consent of the person to whom the information relates. This means that in some circumstances it may be lawful for individuals to identify themselves and establish direct contact with donors, donor families or recipient.

Donors, deceased donor families, and transplant recipients all have rights to privacy, and when consenting to non-directed donation or transplantation both parties should be informed of the requirement for anonymity in the donation relationship and the relevant limits of information disclosure. They should also be informed about relevant opportunities for contact and the default restriction to anonymous communication (see Chapter 7.2.4), as well as strategies to reduce the risk of privacy breaches (Chapter 7.3.3).

There are several ethical considerations underpinning the norm of anonymity in donation.[121] First, anonymity is needed, at least initially, to support equity in the allocation of donated cells, tissues, or organs. If donation decision-makers were informed in advance of the identity of potential recipients, some might wish to withdraw consent or – where possible – direct donations to other transplant candidates on the basis of personal values and preferences (see Chapter 12.3). Second, anonymity protects the rights of donors, recipients and their families to privacy. Some donors, donor families or recipients may not wish to have their identity disclosed.

Assuming that in some cases, both donors (or donor families) and their recipients may be willing to disclose their identity to one another, such disclosure may no longer be a breach of privacy. However, there are concerns that disclosure and non-anonymous contact between donors and recipients who are otherwise unrelated could in some cases lead to harm. On the other hand, identity disclosure and the establishment of connections between donors and recipients can be mutually beneficial. Chapter 7.3.1 summarises the potential benefits and risks of waiving anonymity in non-directed donation. In the following sections, specific considerations with regards to waiver of anonymity in deceased donation and transplantation (Chapter 7.3.2.1), non-directed HSC donation (Chapter 7.3.2.2), and transplantation in children (Chapter 7.3.2.3) are explored.

7.3.1 Potential benefits and risks of waiving anonymity in non-directed donation

Disclosure of identity when mutually agreed between donors or donor families and transplant recipients may have significant benefits. These potentially include:

- Providing an opportunity for transplant recipients to express their gratitude, which may feel more impactful when identities are disclosed and/or direct interactions and communications are possible, compared with anonymous communication (see Chapter 7.2.4).
- Providing an opportunity for donor families and recipients of deceased donor transplants to emotionally process the death of a deceased donor together.

- Assuaging uncertainty or anxiety of recipients, donors, and donor families regarding the identity of other parties, and personalising individuals who have played a major role in their lives as donors or recipients of donations.
- Encouraging public support for donation. For example, many donor families and transplant recipients who wish to establish contact with one another are motivated by the belief that communicating the story of their meeting and/or ongoing relationship may help to encourage public support for donation.

Waiving anonymity may also be associated with significant risks. These include:

- Potentially harmful psychological impact of discovering information about a donor or recipient that is personally distressing or disappointing. For example, if a donor or donor family believes the recipient is unworthy or ungrateful for the donation or if a recipient discovers that the donor has characteristics which they find personally distasteful, this may cause emotional distress.
- Possibility that one party may place pressure on the other to establish or maintain a social relationship which is not mutually desired.
- Potential for one party to seek to exploit the other for financial or other purposes. For example, a living non-directed HSC or organ donor may place pressure on a transplant recipient to reward them for their decision to donate, or an organ transplant recipient might place pressure on a deceased donor family to provide financial support so that they can maintain their transplant.

7.3.2 Disclosure of identity and direct contact between donors, donor families and transplant recipients

When non-directed living donors, deceased donor family members or transplant recipients seek to disclose their identity to another party and establish direct contact, they may ask donation agencies or transplant centres to facilitate this. As discussed in the following sections, specific ethical and legal considerations may apply in the context of deceased donation (Chapter 7.3.2.1) and non-directed HSC donation (Chapter 7.3.2.2), and when the transplant recipient is a child (Chapter 7.3.2.3).

Regardless of whether health professionals or agencies are able to facilitate and oversee disclosure of identities and direct contact between various parties, individuals may independently seek to identify and/or contact others with whom they share some form of donation relationship.

Presumptive identification may occur via social media or other means such as analysis of media reports of donation or transplantation cases. Factors that may increase the risk of privacy breaches and strategies to protect the privacy of donors, donor families and transplant recipients are discussed in Chapter 7.3.3.

These efforts may be at higher risk of causing harm due to the possibility of mistaken connections, the potential burdens of unsolicited contact, and lack of support in managing contact and complications that might arise (see Chapter 7.3.1).

Case Study – Anonymity in Haematopoietic Stem Cell (HSC) non-directed donation

Genevieve is a 28-year-old woman who joined the Australian Bone Marrow Donor Registry (ABMDR) three years earlier. She is contacted by the registry staff to inform her that she is a match for an Australian patient in need of HSC transplant. After being informed of the donation procedures, including their risks and benefits, and counselled about her decision, Genevieve consents to donate.

The day before she is scheduled to donate, Genevieve contacts the ABMDR to say that she would like to know more about the recipient of her donation. She clarifies that she is 'just curious' and indicates that she is also 'hopeful that maybe I can connect with the recipient one day to find out more about them and how they feel after the transplant.'

The ABMDR staff explain to Genevieve that they are not able to disclose personal details about the intended transplant recipient. They advise her that she will have the opportunity to communicate with the recipient provided that the recipient also wishes to connect, but that the policy requires that communication take place at least two years after the donation and transplant. Genevieve expresses disappointment, saying, 'I don't understand why we have to wait. Why can't you at least tell me more about them now? I want to feel like I'm doing this for a person, not just donating to some random stranger.'

Points to consider:

- This case highlights the issue of anonymity in non-directed donation. (See Chapter 7.3)
- The following principle is especially relevant to this case:
    - **Principle 6** Donation and transplantation activities and associated decision-making should protect the privacy of individuals and their families, and the confidentiality of information related to donation and transplantation activities.
- Like some donors, or donor family members, Genevieve would like to connect with the recipient of her donation or at least to find out more about them as a person. Several factors may determine what information about a transplant recipient can be disclosed to a non-directed donor or deceased donor family member. In particular, there are laws that determine when, if ever, people's private information, such as information about their health, may be disclosed to other people (see Chapter 7.1.1.1).
- In the case of HSC donation, it may be legally possible for information to be exchanged between a non-directed donor and the transplant recipient, including information that would enable the donor and recipient to identify one another, provided that both parties consent to the release of this information.
- However, there are several reasons why disclosing private information about the recipient (with their first-person consent) to Genevieve may be problematic, especially at this moment when she is about to donate. Some of the most important considerations are as follows:
    - First, it is essential that any disclosure of personal information about the recipient occurs with their consent. It is possible that the recipient does not wish to connect with their donor, especially at this time when they are preparing to undergo a serious medical treatment and may be very unwell.

- Second, if prospective donors received information that enabled them to identify and contact the recipient at the time of the donation, this may influence their decision to donate or could place the recipient at risk of exploitation. For example, a prospective donor might inform the recipient that they will only proceed with donation if the recipient rewards them in some way.
- Third, it is important that both non-directed donors and recipients have the chance to reflect before making an informed decision to establish contact, so that any psychosocial risks can be managed effectively.

- Current policy at the ABMDR manages these risks by stipulating when and how donors and recipients may communicate with one another, and providing support for contact between donors and recipients when this is mutually desired. Please see Chapter 7.3.2.2.
- Additional ethical complexities may arise in the context of non-directed donations when recipients or donors or donor family members wish to connect with one another. These are discussed in more detail in Chapter 7.3.

7.3.2.1 Waiver of anonymity between deceased donor families and transplant recipients

A number of countries are considering giving deceased donor families and recipients of deceased donor transplants the option of waiving anonymity.[122] This option has been available in the United States and Israel for several decades; however, in the United States, only 1% of donor families establish direct contact with one or more recipients of their loved one's organs or tissues.[123,124] For many people considering waiving anonymity and seeking direct contact with a donor, donor family or transplant recipient(s), it is probable they may be disappointed if the other party declines the opportunity to establish contact.

There are specific ethical and legal complications with regards to privacy and disclosure of the donor's identity in the case of deceased donation in Australia. Health professionals and others involved in deceased donation activities should not disclose identifying details about donors unless their disclosure falls within known legal exceptions (see Chapter 7.1.1.1). At present, deceased donation and transplant agencies in Australia therefore do not facilitate direct contact between deceased donor families and recipients. They instead provide advice on protecting privacy and managing the risks of independent efforts to establish direct contact (see Chapter 7.3.4).

The disclosure of a deceased donor's identity and the revelation of information regarding the recipients of their donation notably may have an impact on several members of the donor's family. Not all family members may wish to receive information about the recipient(s), and it may be difficult to respect their interest not to be informed if other family members choose to receive this. If a donor family member wishes to pursue non-anonymous contact with transplant recipients, they should be advised to consider counselling to help support them in making the decision with other members of their family, and to assist them in navigating contact with the recipient(s).

7.3.2.2 Waiver of anonymity between non-directed HSC donors and transplant recipients

In the case of non-directed HSC donation, both donors and transplant recipients may be able to provide consent to disclosure of their identity to the other party, allowing health professionals to disclose this information on request if both parties consent to waive anonymity.

To reduce the risk that a transplant recipient or non-directed donor may feel obliged to agree to waive anonymity, contact should only be facilitated if both the recipient and the donor independently request direct contact. Individuals choosing to disclose their own identity should be informed that the other party will not be aware of their request for direct contact unless they also choose to waive anonymity.

The ABMDR has established further conditions aimed at supporting donors and transplant recipients to make an informed and voluntary choice about waiving anonymity and establishing direct contact and reducing the risks that may be associated with loss of anonymity. These include:

- 2 year waiting period following donation and transplantation before identifying information may be shared between the donor and recipient. This helps to ensure that individuals make an enduring decision and provides recipients with time to recover from the physical and psychosocial impact of transplantation.
- Both donors and recipients must be counselled before providing consent to disclose their identity. Counselling addresses
  - obligations to respect the privacy of the other party
  - risks related to loss of anonymity (see Chapter 7.3.1), including, for the recipient, the risk of negatively influencing future decision-making by the donor if a second or subsequent donation is required
  - expectations regarding the potential experience and outcomes of identity disclosure, include the possibility that the other party will not choose to disclose their identity, and that direct contact, if established may not result in a positive or ongoing relationship.
- Even if both parties have consented to contact after receiving counselling, contact will not be facilitated by the ABMDR if the recipient is currently seeking another HSC transplant.

7.3.2.3 Protecting the privacy of transplant recipients who are children

When considering waiver of anonymity in donation or transplantation, particular consideration should be given to the interests of transplant recipients who are children, and who may be unable to provide consent to the disclosure of their own identity. Consideration should be given to protecting their anonymity until they are able to make a choice on their own behalf, which may occur before they reach the legal age of majority (usually 18 years) in some 'mature' minors (see Chapter 5.1.2).

7.3.3 Protecting privacy in non-directed donation and transplantation

Reducing the risks of privacy breaches requires efforts to inform and support those who may be at risk, as well as education and training of health professionals who may have responsibility for maintaining privacy and confidentiality in particular settings. Potential non-directed living donors, deceased donation decision-makers, and transplant candidates should be informed of their rights and obligations with regards to anonymity

prior to donation or transplantation, including their obligations not to violate the privacy of others.

In some circumstances, donors, donor families or transplant recipients may be at greater risk of privacy breaches and unsolicited contact from another party. For example, if living non-directed organ donors and recipients are cared for in the same hospital, if donation occurred following a death that received widespread media attention, if a rare and serious disease is transmitted following deceased donation, or if a relatively novel procedure is performed such as the first transplant of a particular kind. Such cases are not only more likely to elicit significant media interest and reporting (see Chapter 7.3.4) but are also more likely to involve communication of specific details about donors or recipients that may facilitate identification and/or identification of a likely donation relationship.

Vascularised composite allografts, such as face or limb transplants, for example, are not only rare procedures which attract significant media attention, but they may also require specific consent from donation decision-makers which might enable them to identify transplant recipients more readily.

Counselling of non-directed donors, deceased donor families and transplant recipients should be provided prior to donation or transplantation to assist in prevention and management of the privacy risks specific to particular circumstances, as well as general advice regarding management of social and news media risks (see Chapter 7.3.4). For example, advice on the limitations of privacy protections in online settings such as closed Facebook groups, and on ways to communicate experiences without disclosing identifying details may be helpful.

Advice should also be provided to help people in making an informed decision about whether to independently pursue contact with others, for example via social media or community networks. Those considering waiving anonymity should be provided with information about the potential benefits and risks, which may vary according to individual circumstances and the particular context of donation and transplantation involved (see Chapter 7.2.4). Advice should highlight the importance of respecting the privacy of others and may include strategies to assist in management of issues that may arise. All potential donors, donor families and transplant recipients should be provided with information about potential opportunities to communicate with one another where these exist, such as the opportunity to communicate anonymously via correspondence managed by transplant centres and donation agencies (see Chapter 7.2.4).

7.3.4 News and social media

News and social media are frequently used by health professionals, donation and transplantation agencies and members of the public to communicate stories about people whose lives have been affected by donation and transplantation. Many stories play an important role in informing the public about the value of donation and transplantation and encouraging participation in donation opportunities. Media reports and social media interactions also serve to highlight new developments in transplantation medicine, to celebrate the role of donors and to share information about how to become a donor.[125,126]

A number of ethical concerns may arise in the context of news media and professional and personal use of social media to communicate about donation and transplantation, particularly with regards to protection of privacy and confidentiality. Disclosure of information that may encourage or facilitate identification of potential donation

relationships should be made with care and only with the consent of individuals who may be affected to reduce the risk of undesired identity disclosure or unsolicited contact.

Particular care should be taken when seeking consent to disclose personal information about a donation or transplantation experience from people who may be emotionally vulnerable, such as those in need of or who have recently received a life-saving transplant or those who have just experienced the death of a relative. These individuals may be vulnerable to inadvertent exploitation or coercion, for example by feeling that they have an obligation to share their stories or because sharing their stories may seem necessary to save lives.

News and social media may also be used in efforts to solicit potential living organ donors, raising additional ethical concerns that are explored in Chapter 12.1.

Box 7.2 Summary of ethical recommendations regarding anonymity in donation

- Anonymity in non-directed donation should be routinely protected to ensure the privacy rights of donors, donor families and transplant recipients are respected.
- Prospective non-directed living donors, transplant recipients and deceased donor families should be informed of the requirement for anonymity in the donation relationship, as well as:
  - the potential benefits and risks of loss of anonymity
  - strategies to minimise risks of privacy breaches
  - obligations to respect the privacy of others
  - legal barriers to disclosure of private or identifiable information about donor or transplant recipients by health professionals and others involved in donation and transplantation activities
  - options for anonymous communication between donors, donor families and recipients where relevant.
- If further information is desired by a donor, donor family or recipient about another party involved in a non-directed donor transplant, this should only be disclosed in accordance with relevant legislation or policies relating to privacy protections, including anonymity requirements.
- In the case of non-directed HSC donation, both donors and transplant recipients may be able to provide consent to disclosure of their identity to the other party, allowing health professionals to disclose this information on request if both parties consent to waive anonymity.
- The following conditions for facilitating contact between donors and recipients where this is legally possible are recommended:
  - contact should only be facilitated if both the recipient and the donor independently request direct contact
  - a minimum waiting period should elapse following donation and transplantation before identifying information is shared between the donor and recipient, to allow time for reflection on experiences and decisions to waive anonymity

- both donors and recipients should be counselled before providing consent to disclose their identity. Counselling should address:
  - obligations to respect the privacy of the other party
  - risks related to loss of anonymity including, e.g., for HSC recipients, the risk of negatively influencing future decision-making by the HSC donor if a second or subsequent donation is required
  - expectations regarding the potential experience and outcomes of identity disclosure, include the possibility that the other party will not choose to disclose their identity, and that direct contact, if established may not result in a positive or ongoing relationship
- contact should not be facilitated if the recipient is currently seeking another HSC transplant.

- If non-directed living organ or tissue donors or deceased donor families and the relevant transplant recipients mutually agree to waive anonymity, both parties should be encouraged to consider the risks and potential benefits of making contact, and to implement strategies that may be helpful in minimising risks, e.g., mediated meetings and use of counsellors.
- If the transplant recipient is a child, parents should consider the potential impact of waiving anonymity on the child, and they are encouraged to defer disclosure of the child's identity until the child is capable of making a decision on their own behalf regarding waiver of anonymity.

7.4 Data collection and reporting in donation and transplantation

Data related to donation and transplantation are essential in identifying opportunities to improve the care of donors and recipients, the donation and transplantation process, and outcomes for recipients and living donors (see Chapter 2.9). Data are also essential for informing and evaluating policies and practices, and to support transparency and accountability.

In addition to personal data contained in medical records, which health authorities are permitted to audit for quality and safety purposes, or use in public health research in specific circumstances, data pertaining to donation and transplantation are also collected and stored in registries.

There are a range of different registries that may collect important data about donation and transplantation including patient or clinical registries,[127] e.g., ANZDATA, ACGR, and transplant waiting lists and donor registries such as the AODR and the ABMDR (see **Table 7.2**).

All registries are required to comply with the ethical and legal standards governing privacy of health information in Australia. The collection, storage and use of data and information by donation and transplant registries should follow relevant legislation and guidance for good governance of registries (e.g., the Commonwealth's Clinical Quality Registry Strategy).[128]

Several ethical considerations may arise with regards to collection, storage and use of information (data) held by donation and transplant registries which are briefly outlined below.

Table 7.2 Examples of registries and other organised repositories of information about donation and transplantation

- Australia and New Zealand Transplant and Cellular Therapies Registry (ANZTCT)
- Australian Bone Marrow Donor Registry (ABMDR)
- Australia and New Zealand Dialysis and Transplant Registry (ANZDATA)
- Australia and New Zealand Organ Donor Registry (ANZOD)
- Australia and New Zealand Living Kidney Donation Registry (ANZLKD)
- Australia and New Zealand Eye & Tissue Donation (ANZETD)
- Australia and New Zealand Islet and Pancreas Transplant Registry (ANZIPTER)
- Australia and New Zealand Liver and Intestinal Transplant Registry (ANZLITR)
- Australian Corneal Graft Registry (ACGR)
- Australian Organ Donor Register (AODR)
- The Organ and Tissue Authority (OTA) national performance data and reports.
- The Global Observatory on Donation and Transplantation (GODT) from the World Health Organization collects activity data across a global network of health authorities responsible for transplantation, and releases related publications.

7.4.1 Individual control of personal information

At a minimum, respect for privacy and autonomy means that individuals have the right to be informed about when, how, and why their personal information is collected in registries, and about how their information may be used, by whom, and for what purposes. The extent to which individuals are able to choose whether their personal information is collected, and to determine how it is used may be limited. For example, as noted earlier, privacy laws permit the use of personal health information in audits and in public health research without consent of the relevant individuals in some circumstances. Generally, the ethical justification for this limitation of individual autonomy is that such use is necessary to achieve substantive benefits for public health, and will pose negligible risks of harm to the individuals concerned.

In the case of registries relating to transplant recipients and donors, there may be variable approaches to consent for data collection and use. In some cases, it may be reasonable to presume consent to data collection or use, for example when donor and recipient information is used for vigilance and surveillance.

Reporting of data from health professionals or clinical units to registries held by governments or regulatory bodies should generally not include information that would allow identification of donors or recipients. However, it should be possible to link registry data to the medical records of specific individuals, as part of vigilance and surveillance systems that facilitate timely responses to adverse events such as unexpected transmission of a serious disease via donation (see Chapter 2.9.1).

In the case of prospective donor registries such as the ABMDR or the AODR, the nature of the registries requires individuals to make informed choices about the collection

of their data and how it may be used, as demonstrated in information provided to prospective donors.[58] In the case of the ABMDR it is essential to collect personal information about prospective donors in order for them to be contacted if they are identified as a match for a potential transplant recipient.

Registries have obligations to openly communicate information that is gathered for the purpose of maintaining transparency in donation and transplantation activities and supporting informed decision-making by the public. Annual reports are commonly published for this purpose, with information presented in a manner that protects individual privacy.

7.4.1.1 Use of registry data in research

As noted in Chapter 12.7, donation and transplantation activities may intersect with research activities which require specific ethical consideration. For example, the ABMDR specifically invites prospective donors to make a decision about use of their de-identified data in research when joining the registry within the enrolment form.[58] The form also provides the option of consenting to be contacted by the registry if there is an opportunity for the registrant to 'actively participate' in a research study.[58]

Registries often contain information in the form of personal health data that represents a valuable resource for researchers. Ethical considerations relating to the **use of registry data in research** are beyond the scope of these guidelines. Please see the NHMRC ethical guidelines for the conduct of human research for further guidance.[17,19]

7.4.2 Governance of registries

As repositories of personal health information, registries require careful governance to ensure appropriate clinical and ethical standards are upheld. Inclusion of relevant stakeholders in governance of registries is essential to ensure that the interests of stakeholders are represented and that they have a voice in decision-making. Governance also requires mechanisms for accountability and oversight of registry operations.

7.4.2.1 Data sovereignty and inclusion of Aboriginal and Torres Strait Islander people in data governance

It is particularly important to include members of Aboriginal and Torres Strait Islander communities in governance of registries. Inclusion of Aboriginal and Torres Strait Islander peoples in data governance helps to ensure that data are used respectfully and effectively to support and promote the health of First Nations peoples, and that data are collected which align with the priorities and values of relevant communities.[129] Inclusion may also help to promote cultural safety, for example by supporting a strengths-based approach to communication of data about Aboriginal and Torres Strait Islander peoples in registry reports.

Earning and maintaining trust in donation and transplantation registries by Aboriginal and Torres Strait Islander peoples may encourage trust in donation and transplantation programs more broadly. This is especially important given the longstanding history of exploitation and disenfranchisement of First Nations peoples in research involving the collection, storage and use of biological samples and health data, as well as widespread discrimination against individuals and groups who identify as Aboriginal or Torres Strait Islander peoples.

The First Nations principles of ownership, control, access and possession (OCAP®) provide guidance on how data from Indigenous peoples should be 'collected, protected, used and shared.'[130]

Policies led by Aboriginal and Torres Strait Islander people should be developed to support governance of data in donation and transplantation registries. The Catching Some Air project, which asserted information rights for Aboriginal and Torres Strait Islander in the context of renal disease, articulated the following valuable principle:

> Renal health data which can support and promote Aboriginal and Torres Strait Islander renal health should be used to monitor renal health, report renal health advancement, and inform Aboriginal and Torres Strait Islander people of activities and outcomes directed toward closing the gap in renal health and renal disease.[131]

Based on this, donation and transplantation data that can support and promote Aboriginal and Torres Strait Islander health should be used to monitor outcomes of donation and transplantation, report progress and developments in donation and transplantation, and inform Aboriginal and Torres Strait Islander people of activities and outcomes directed toward reducing inequities in donation and transplantation for Aboriginal and Torres Strait Islander people.[132]

7.4.3 Obligations to collect data about donation and transplantation

Although it may be difficult in some cases to obtain data about donation or transplantation outcomes, for example if there are no or limited clinical requirements for follow up care of recipients, registries should be established to monitor use and outcomes of all donation and transplantation activities.[133] Registries and relevant professional organisations should establish clear expectations regarding the duties of individuals or institutions with regards to data collection and reporting in registries, and provide appropriate training to ensure responsibilities are effectively fulfilled.

In some cases, mandatory reporting of specific data to registries may be considered where this is deemed necessary to prevent harm and where voluntary compliance by relevant health professionals may be unreliable.

7.4.4 Sharing and collaboration between registries

Establishing mechanisms that enable linkage or consolidation of some registries may be needed to help ensure that data collection, storage and use are effective and efficient, and to support collaborative work that will inform policy and practice aimed at improving access, fairness, and quality of outcomes of donation and transplantation.

For example, linkage of tissue registries may help in the assessment of supply and demand for tissues for transplantation and the evaluation of distribution and costs of tissues.[134,135] Alternatively, linkage of the ANZLKD to ANZDATA and Australian death registries can help in the evaluation of kidney-related morbidity and mortality in living donors.

Collaboration with international or global registries or networks of registries may be necessary to support effective sharing of resources (e.g., the World Marrow Donor Association (WMDA) network which facilitates matching of non-directed HSC donors and recipients globally) or to evaluate Australia's performance in comparison with that of other countries (e.g., the GODT), helping to inform the public as well as health professionals and policy makers.

Box 7.3 Summary of ethical recommendations regarding collection of donation and transplantation data

- Information about donation and transplantation activities should be routinely collected and reported to relevant registries - or other data repositories - for the purpose of promoting quality and safety, informing guideline or policy development, and informing future decision-making by individuals and health professionals.
    - Individuals should be informed of the nature and purpose of data collection activities and their rights to control the collection and use of their personal data, including the right to withhold or withdraw personal information where relevant.
    - Health professionals should be trained and supported to fulfil their duties with regards to collection, reporting and use of donation and transplantation data.
    - Collective data about donation and transplantation activities should be readily accessible to the public and routinely communicated in reports aimed at informing public understanding of donation and transplantation.
    - Potential conflicts of interest that may influence the collection, reporting or use of data should be carefully managed.
- Governance of repositories of personal information should be inclusive of representatives of those whose data are collected, in particular by Aboriginal and Torres Strait Islander peoples.
    - The values of individuals and communities whose data are collected should guide collective decision-making.
    - Where relevant and feasible, individuals or communities should
        - retain ownership of their personal information
        - be able to access and make use of their information
        - play a leading role in decision-making about further use of personal information.
- Donation and transplantation data that can support and promote Aboriginal and Torres Strait Islander health should be used to monitor outcomes of donation and transplantation, report progress and developments in donation and transplantation, and inform Aboriginal and Torres Strait Islander people of activities and outcomes directed toward reducing inequities in donation and transplantation for Aboriginal and Torres Strait Islander people.
- Data should be routinely collected and reported to help inform estimates of needs for transplantation and to evaluate performance of donation and transplantation activities.
    - Formal waiting lists for transplantation or equivalent methods to monitor demand for and use of cells, tissues and organs should be maintained.

- Data should be collected, for example, regarding prevalence of end stage organ failure in the population, unmatched candidates for HSC transplantation, and clinical requests for tissues that cannot be met.
- Policies and data should be open to public scrutiny in order to maintain accountability to the public.

- Registries of recipients of transplants should be established and maintained for the purpose of vigilance and surveillance and follow up care of transplant recipients and to assist in evaluating outcomes of allocation policies and decisions.
  - Registries reporting outcomes for living organ and HSC donors should be established and maintained, and used to evaluate policies guiding selection, management and follow up care of donors.
  - Consideration should be given to mandatory reporting of kidney failure in living kidney donors.
- Repositories of donation and transplantation data should be designed to facilitate sharing of data where appropriate to optimise the value of these data in informing donation and transplantation activities and decision-making.
  - Standardised nomenclature and consistent terminology should be used to assist in cross-linkage and comparison of data where relevant.
  - National and international sharing of data should be facilitated where appropriate to better inform evaluation of local activities and to support ethical exchange of donated cells, tissues and organs.
  - Access to and sharing of data should only occur when relevant safeguards are in place to protect privacy and security of data, and when data are shared in accordance with the values, goals and priorities of relevant governance frameworks.
- Regular audits should be conducted to review decision-making, outcomes of decisions, and policies and practices in donation and transplantation.

8. Equity in opportunities for donation and transplantation

Justice is a primary ethical and social concern of individuals and communities, especially when there are insufficient supplies of vital goods such as healthcare resources to provide for all those who need them. The right to health means that everyone has an equal right to benefit from healthcare resources if necessary. This in turn means that if not all needs can be met, the inevitable inequalities in access to these resources should be as fair as possible.

In the setting of donation and transplantation, concern for justice or fairness is particularly acute because the population directly contributes to meeting needs via donation of cells, tissues, and organs. Consequently, society has a fundamental interest in ensuring that the distribution of benefits and burdens of donation and transplantation is fair or equitable.

Promotion of justice is a foundational value underpinning donation and transplantation in Australia (see Chapter 3.2.3). Concerns for fairness in the allocation or distribution of goods (e.g., healthcare resources), services or opportunities (e.g., access to healthcare) are considered matters of **distributive justice**. These intersect with concerns for **procedural justice**, or fairness in the processes of decision-making, implementation of policies, and practices in which justice may be enacted.

For example, procedural justice requires that there are mechanisms for people to review, question and revise guidelines for allocation of health resources when these may be unfairly designed or when they may result in unfair outcomes. More broadly, **social justice** concerns fairness and the avoidance of unfair inequalities within society, which often influence inequities in health.

This chapter explores some of the foundational concerns of justice in the setting of donation and transplantation and provides information about key considerations for donation and transplantation decision-making in particular contexts.

Further readings and resources relevant to this chapter can be found in Appendix 1.

8.1 The concept of equity in health

The terms just, fair, and equitable - or justice, fairness, and equity - are often used interchangeably in ethical discussions about the allocation of resources, or distributions of health outcomes. It is important to note that equality is not synonymous with equity. Although equality is often a key consideration of justice, and justice in health is grounded in the recognition that everyone has an equal right to health, this doesn't mean that giving everyone an equal share of resources or aiming to achieve equality in health outcomes is necessarily fair or possible.

Equity in health is a term that is used to describe a distribution of health outcomes or healthcare resources, in which inequalities are unavoidable, necessary or fair.[136] Conversely, inequity refers to the presence of inequalities – or differences between groups – that may be avoidable, unnecessary and unfair.

Promoting and sustaining equity in donation and transplantation means taking steps to eliminate or reduce inequalities that are avoidable, unnecessary, or unfair. For example,

if some groups are more likely to develop the need for kidney transplantation, this may result in an unequal distribution of needs for transplantation. If those needs can be prevented, then this is an inequity that should be addressed. If some groups are less likely to receive a tissue transplant, due to higher rates of poor health literacy or reduced access to specific healthcare services, then efforts should be made to address these barriers to care, reducing inequalities and improving equity of access. Some examples of potential inequities and equitable inequalities in donation and transplantation are described in Chapter 8.1.1 and Chapter 8.1.2 respectively.

Determining which principles or criteria to use to guide resource allocation or policymaking aimed at improving equity, and the relative weight to place on specific principles or criteria requires value judgements; it also requires consideration of empirical evidence. In comparison with ethical decision-making about specific treatments for individual patients, decision-making about resource allocation and policy making tends to be more ethically complicated as it not only affects large populations but often requires more complex analysis and management of competing ethical goals and values. Potential goals, principles and values that may be considered for use in decision-making are explored in Chapter 8.2.

8.1.1 Examples of potential unfair (inequitable) and fair (equitable) inequalities in donation

Many factors may underpin inequalities in living or deceased donation of cells, tissues, and organs.[135] Concerns may be raised about inequalities in the distribution of donors due to fear that some individuals or groups might receive an unfair share of the potential burdens or risks of donation. There may also be concerns that some individuals or groups are unfairly excluded or disadvantaged in accessing opportunities for donation and hence the benefits of donation.

Some inequalities in donation may be *unavoidable*. For example, a person may wish to donate their organs and tissues after death, but they may not be clinically eligible to donate as a result of damage or disease which makes their organs and tissues unsuitable for transplantation.

Other factors may be avoidable but *necessary*, for example to achieve a greater good. For example, it may be possible to overcome some barriers to deceased donation in remote parts of Australia by transporting people via plane to retrieve tissues or even organs from individuals who die in remote places. However, there would likely be significant costs associated with such efforts, including the costs of sending trained health professionals who might otherwise be providing essential care to patients, and the benefits may be limited, for example if a team is sent which then discovers the potential donor is unsuitable. Investing in removal of some barriers to donation may, for example, come at the expense of efforts to address other barriers that would have a bigger impact on more people.

If inequalities are unavoidable or necessary, they may be equitable. Nevertheless, some inequalities in donation may be avoidable, unnecessary and unfair, and hence result in inequities. Often, such barriers reflect common barriers in access to healthcare including financial costs of accessing care, poor health literacy, racism, and other forms of bias and discrimination (see Chapter 8.3.1). For example, if a donor coordinator fails to raise the possibility of deceased donation with a family because they incorrectly assume the potential donor is ‘too old’, or an organ transplant coordinator fails to inform a transplant candidate of the possibility of a living donor transplant because they believe

the family's 'culture wouldn't support this', this unfairly discriminates against individuals and groups who may miss opportunities for donation or transplantation as a result.

8.1.2 Examples of potential unfair (inequitable) and fair (equitable) inequalities in transplantation

When allocating transplant resources in the form of donor cells, tissues, or organs, some inequalities may be **necessary** and not unfair due to elements that might be thought of as luck (or bad luck). For example, an individual might miss out on all opportunities for organ transplantation as a result of having rare immunological or anatomical characteristics which require a specifically matched organ that never becomes available. Similarly, some people have a much lower chance of finding a precisely tissue-typed match with a non-directed HSC donor via the ABMDR because there are fewer registered donors of some ethnicities.

To some extent, these types of inequalities may be avoidable. For example, efforts to increase the size and diversity of relevant donor populations using targeted recruitment campaigns may help to reduce the extent of inequalities making the distribution of transplants more equitable. The ABMDR, for example, also reduces such inequalities via collaboration with the global network of HSC donor registries so that people in need of HSC transplants within Australia can access donations from around the world.

Some inequalities may be **unavoidable**, at least for a period of time. For example, there are usually insufficient deceased donor organs to meet the needs of all people for whom an organ transplant would be beneficial. This means that when allocating the available organs, some people will necessarily miss out.

Imagine, for example, that two donor organs are available for transplantation. There is a group of 100 people, all of whom require organ transplantation. Only two of the group are suitable matches for the available organs, and thus receive transplants. Ninety-eight do not receive a transplant, indicating an **inequality** in the distribution of organ transplants. However, this is not **an inequity**, as the allocation to the two suitably matched candidates was necessary and fair; that is, there was a valid reason for providing these two matched individuals with the organs, as the organs would not have benefited any of the other transplant candidates.

On the other hand, imagine a third member of the group was also a suitable match for one of the available organs, but was not considered for transplantation because they lacked the money to pay for the transplant operation. This *would* represent **an inequity** in Australia, where it is agreed that a patient's financial status should not influence decision-making or determine access to organ transplantation.

That is, while it may be fair to discriminate between individuals when allocating resources according to some criteria – such as level of therapeutic need, capacity to benefit due to appropriate matching – it may be unfair to discriminate on other grounds, such as financial status, religion, gender, or race.

8.2 Principles of justice

The starting point for justice is the recognition that individuals are moral equals, by virtue of their inherent value as human beings. This provides the basis for fundamental human rights including the human right to health.[4] The right to be treated justly or fairly does not mean that everyone should necessarily receive an equal share of resources, but

it does mean that when inequalities are necessary or unavoidable, inequalities should be distributed in ways that are fair.

When distributing - sharing - healthcare resources or opportunities, justice requires that we aim to reduce or eliminate unfair inequalities (inequities). The challenge lies in determining when specific inequalities may be unfair, and/or which criteria, values or principles should be used to discriminate between individuals or groups when discrimination is necessary.

In practice, a range of factors are used to guide decision-making, with differing weights given to specific factors in particular settings. The factors which are selected are informed by the overarching goals of allocation in a particular setting, and the success of allocation guidelines or frameworks may be evaluated by examining the outcomes which result from their application. For example, if the primary goal of a particular allocation policy is to save as many lives as possible, but the results of the policy's implementation suggest that an alternative approach may in fact result in more lives being saved, this may indicate the need to revise the policy.

At times, specific goals of allocation and values or principles of relevance in allocation decisions may conflict with one another. In practice, compromises are often necessary to best satisfy the core goals and values that may be considered relevant in a particular context. This is one reason why it is particularly important to ensure that individuals and members of communities who may be affected by allocation decisions are able to participate in the development of allocation policies so that their values and preferences will be reflected in the policies that affect them.

8.2.1 Goals, principles, and values of distributive justice

Some of the goals, values and principles that may be considered relevant in decision-making about donation and transplantation resources are explained briefly in the following sections. Some individuals or groups may prefer specific values or principles to be used in decision-making about distribution of donation and transplantation resources in Australia, or may wish to prioritise particular goals in resource allocation. The goals, principles and values are presented here to help readers understand commonly used concepts and potential approaches to decision-making about resource allocation; they do not represent recommendations for practice. Specific frameworks to guide access to transplantation or allocation of organs, cells and tissues for transplantation represent clinical tools that are outside the scope of these guidelines.

8.2.1.1 Equality of opportunity

Grounded in respect for the equal right to health, this principle or goal primarily supports efforts to remove barriers that may prevent individuals or groups from accessing donation or transplantation, and to maximise equality of access to the benefits of transplantation.

When opportunities for transplantation, for example, are limited, equality of opportunity might theoretically be achieved by allocating resources in a way that gives transplant candidates an equal chance of receiving a transplant.

Using a lottery approach to allocation of deceased donor organs, for example, has been proposed by philosophers as one way to achieve genuine equality in opportunities for transplantation, or in resource allocation more generally.[137] A lottery would give each transplant candidate an equal chance of receiving a transplant – assuming that the available organs were clinically suitable for all the participants in the lottery. Lack of

support for such an idea shows that although equality of opportunity is considered important in health resource allocation, other ethical principles or values are also considered important.

8.2.1.2 'Fair innings'

The 'fair innings principle' holds that healthcare resources should be distributed in way that help to promote equality in life span across populations, or to ensure that people can live a 'normal' life span.[138]

Application of this principle might, for example, justify prioritisation of younger people for life saving transplants over those who have already 'enjoyed' an average life span. Again, this is a principle that has been considered for use in organ allocation in combination with other principles.[139]

8.2.1.3 'Maximin' or 'prioritarianism'

The 'maximin' principle is also known as 'prioritarianism' and is based on the work of philosopher John Rawls.[137,140] Rawls argued that justice requires inequalities to be arranged so that they are to the advantage (or overall benefit) of those who are worst off.[140]

In the context of donation and transplantation, application of this principle might mean that priority should be given in some cases to those who are already more disadvantaged in terms of experiencing poor health outcomes. It could also mean that specific distributions are considered fair, even if there are significant inequalities, as long as the distribution overall is better for those who are worst off.

For example, although allowing deceased donors to direct their donations to specific groups of people might exacerbate inequalities in access to transplantation (see Chapter 12.3), some have argued that this could result in more people getting transplants overall, which might be fair according to the maximin principle.[140]

8.2.1.4 Necessity

When resources are limited, the principle of necessity is a valuable reminder that resources should only be allocated when they are needed. Reference to necessity usually implies that there is no alternative way of meeting the needs.

For example, if some people's needs for heart valve replacement can be met using animal derived or mechanical valves, whereas other people require a human tissue valve replacement, it would be unfair to allocate scarce human donor valves to people who have the option of receiving a mechanical valve.

Similarly, in the broader context of resource allocation issues, efforts should be made to prevent needs for transplantation where possible, to ensure that when needs are unavoidable, we are better able to meet them. Investment in public health measures that reduce the incidence of end stage organ failure, for example, is a vital component of efforts to meet needs for organ transplantation.

8.2.1.5 Reciprocity and solidarity

Reciprocity and solidarity are core values underpinning donation and transplantation in Australia, as outlined in more detail in Chapter 3.2.4. When applied as a principle of justice, reciprocity reflects the idea of balance between obligations to contribute to the achievement of some good and rights to benefit from that good and is commonly

considered in the context of individual rights and obligations with regards to donation and transplantation. Solidarity refers more to collective efforts to help meet shared needs.

8.2.1.6 Rule of rescue

This principle encourages allocations that prioritise the needs of those at immediate risk of death or severe disability. Although emotionally compelling, if applied in isolation this principle can – counter-intuitively – lead to significant loss of life and disability. This is because efforts to rescue those at immediate risk may sometimes be futile – unlikely to be successful – and may occur at the expense of efforts to save others who would indeed benefit from treatment. See Chapter 8.2.1.8.

8.2.1.7 Utility

Utility may broadly refer to the potential beneficial outcomes of a particular allocation framework or more specifically to the potential therapeutic benefits of an individual receiving a specific transplant. This means that when used as a principle to guide resource allocation, allocation decisions aim to maximise utility overall, or at the level of individual transplants.

Although maximising utility is a common consideration in allocation of donated organs, cells, or tissues, it is rarely the only consideration.

How utility is measured plays an important role in resource allocation decisions. For example, the utility of individual A receiving a kidney transplant from donor B might be measured by the expected duration of graft survival. Alternatively, utility might be measured by the impact of this transplant, including expected graft survival, on A's physical, social and psychological wellbeing. A's wellbeing may in turn impact the lives and wellbeing of others, such as family members, and so on. The healthcare system for example, may save considerable costs associated with dialysis if A receives a transplant.

Finally, utility might also be evaluated by considering the potential loss of utility that could result from specific allocations. For example, if A doesn't receive the kidney transplant, this could result in a significant loss of utility for A (e.g., as a result of premature mortality or increased morbidity over time) and for others (e.g., such as those who might have benefited if A had received a transplant and been able to return to work and contribute to the wellbeing of their community).

When utility is used as a consideration in resource allocation or policy making, it is essential to define – and agree upon – what is being measured as utility, and how utility is to be measured. It may also be difficult to accurately predict which actions or choices may lead to outcomes that maximise utility overall.

8.2.1.8 Avoidance of futile treatment

This principle refers to the duty to avoid allocating healthcare resources in treatments that are not expected to work nor to achieve the goals of treatment. For example, performing a bone transplant aimed at improving mobility in a person who is otherwise critically ill, unable to mobilise and expected to die shortly regardless of treatment would be futile. This is because the goal of the bone transplant – improving mobility function in the recipient – is not expected to be realised.

8.2.2 Balancing competing principles and goals in resource allocation

If only one principle were used to guide resource allocation, then decision-makers could simply strive to allocate resources in ways that would maximise utility overall, or optimise equality of opportunity for transplantation and so on. However, the consequences of such approaches are usually undesirable; in most cases people recognise the importance of considering a number of values or allocation goals. For example, people often have an interest in maximising utility and in promoting equality of opportunity when allocating transplantation resources, given that some groups may otherwise be consistently disadvantaged and excluded (see Chapter 8.2.2.1).

Frameworks used to support decision-making about allocation of resources usually incorporate several principles. They also include more specific principles and criteria that help to guide decision-making in ways that align with the overarching goals or principles. For example, a resource allocation framework that aims to promote utility may include a principle recommending that futile treatment be avoided and set out clinical criteria to determine when a person may or may not benefit from a particular treatment.

In order to balance consideration of potentially competing principles or goals, decision-making frameworks may also provide guidance on which principles should take priority when there is a potential conflict, or give specific weight or priority to particular criteria. Specific 'tiebreaker rules' may be used to decide between competing claims on resources that are otherwise equal (see Chapter 8.2.2.2). See **Box 8.1** for a summary of recommendations for ethical policy making in the allocation of organs, cells and tissues.

8.2.2.1 Tensions between promotion of utility and equality of opportunity

Resource allocation frameworks that aim to maximise the utility produced by distributing healthcare resources may further disadvantage individuals and groups who are already worst off with regards to health, unless other goals are given consideration. In particular, the goal of maximising utility is often in tension with the goal of promoting equality of opportunity to benefit from transplantation, because prioritising transplantation of those who may be most likely to experience a significant therapeutic benefit may result in systematic exclusion of individuals or groups who are comparatively less likely to benefit from transplantation.

For example, depending on which measures are used to evaluate utility, prioritisation of healthier transplant candidates may lead to nominally better outcomes of transplantation and thus increase utility. Efforts to maximise utility of health resources may thus systematically disadvantage and exclude those who are already unwell or who may suffer from poorer quality of life and who may thus be seen as less likely to produce utility if they receive a transplant.

This is sometimes referred to as 'double jeopardy', especially when utility is measured by calculating the duration and quality of life that an individual is expected to gain, if they receive a specific treatment.[141] Saving the life of an individual who is deemed to have a lower quality of life due to the presence of disability or chronic health conditions will produce less perceived utility than a person who has better health, assuming that both would have a similar life expectancy if they received treatment.

8.2.2.2 Use of 'tiebreakers' in allocation of donor organs and tissue

In Australia, specific allocation criteria or policies are required for distribution of scarce transplant resources such as deceased donor organs and some tissues from living and deceased donors, in order to discriminate fairly between potentially competing needs.

Allocation of donor organs or tissues in Australia is commonly guided by consideration of utility and how this may be maximised, as well as equality of opportunities for transplantation. The rule of rescue may also play a role, giving a degree of priority to those in need of life saving treatment, or of treatment to prevent or address more severe illness or disability.

In many cases, more than one individual might have the same capacity to benefit from a particular transplant that is available, and a decision must be made regarding which candidate should be prioritised. This requires use of some form of 'tiebreaker' or method of discriminating between cases of equivalent potential utility without undermining equality of opportunity.

In theory, equality of opportunity might be achieved by tossing a coin, for example, or using a lottery so that everyone eligible for a particular transplant has an equal chance of receiving it (see Chapter 8.2.1.1). However, in practice, potential candidates for transplantation are routinely differentiated using a more pragmatic criterion, that of 'time waiting'.

Candidates for corneal transplantation, for example, will be offered a transplant according to 'time waiting' from the moment when they are referred for a corneal transplant and a request is made to obtain donor tissue for them, unless a particular candidate has a clinically urgent need. Organ transplant candidates instead join a queue in the form of a waiting list, with time spent on the waiting list taken into consideration together with other clinical variables that are deemed to align with goals such as maximising of utility (see Chapter 8.2.3).

HSCs from non-directed donors are necessarily collected and distributed only when a tissue-typed match is found for a person in need of transplantation. Due to the difficulties of HSC matching, the chances of an individual donor being a suitable match for more than one person in need of HSC transplantation at a particular time is very small. This means that HSC transplant recipients are not competing, as it were, for resources.

Some alternative types of tiebreakers sometimes used in transplantation include the prioritisation of people who have previously donated or registered to donate organs and tissues, which is discussed in Chapter 8.4.2.3.

8.2.3 The role and potential limitations of 'objective' criteria in allocation policies

Several clinical, demographic and social criteria may be considered for use in health resource allocation policies. Such criteria are used to inform and guide allocation decisions in ways that will achieve normative goals such as maximising utility, saving lives or addressing known inequities.

Use of allocation criteria that are considered purely clinical or 'objective' are sometimes thought to promote fairer decision making, as they appear less likely to be influenced by subjective values or biases.

For example, a liver transplant candidate who has a higher Model for End stage Liver Disease (MELD) score than another candidate, may seem to be in more clinically urgent need of a transplant, and should thus be offered a transplant if it becomes available, despite both candidates being a suitable match. Alternatively, a kidney transplant candidate who has been waiting longer than another candidate might be given priority for a transplant.

Criteria that involve independently measurable information rather than more qualitative judgements do play a vital role in decision-making about resource allocation. Drawing on a robust evidence base to inform decision-making is essential. However, it is important to reflect critically on all allocation criteria, regardless of how objective they may appear to be. For several reasons, the use of objective criteria may be prone to biases and influences, just like more overtly value-laden criteria and principles:

- The choice of criteria, and the weight given to specific criteria in decision-making is itself a **value-based judgement**. Thus, prioritising liver transplant candidates with higher MELD scores may reflect an ethical commitment to the principle of 'rule of rescue'.
- Commonly used tools may not always be the most **effective** way of measuring particular criteria.

For example, the MELD score may not be the most accurate measure of severity of need for liver transplantation in all populations, or consideration of other clinical features of specific cases might help to improve accuracy.

- Some clinical criteria may also be prone to **bias in clinical evaluation**, for example when health professionals are assessing the likelihood of a transplant candidate adhering to follow up care or medication regimes.
- Criteria that seem to provide an impartial way of discriminating between competing needs, such as consideration of 'time waiting' for transplantation, may in fact be heavily influenced by other factors such as **structural inequities** in access to healthcare (see Chapter 8.3.1).
- Application of clinical criteria that in theory should promote the goals of a particular allocation framework, such as maximising utility and equality of opportunity, may in practice produce outcomes that undermine one or more of these goals.

Maximising the utility of organ transplants may theoretically favour allocation rules that will minimise the distance that allocated organs are required to travel. In practice, this could mean that specific populations such as patients living far from major transplant hubs may have fewer opportunities for transplantation.

- Some criteria that indirectly or directly influence the allocation of resources are not considered within the scope of resource allocation frameworks, as they are presumed to be logistical constraints or elements that have no relevance to resource allocation per se.

  These often include factors that influence an individual's ability to access healthcare services. If these elements are not considered, their potential impact on equity in allocation may be inappropriately overlooked. Positive engagement with such elements in resource allocation policies may help to improve equity (see Chapter 8.3.1).

Box 8.1 General recommendations for allocation of organs, cells and tissues

- Allocation policies should articulate relevant goals, values and principles with clear and specific clinical criteria to guide decision-making in accordance with the normative framework.
  - When utility is used as a consideration in resource allocation or policy making, it is essential to define – and agree upon – *what* is being measured as utility, e.g., 'therapeutic benefits', and *how* utility is to be measured, e.g., using the outcome of duration of graft survival.
  - In order to balance consideration of potentially competing principles or goals, decision-making frameworks for resource allocation should provide guidance on which principles should take priority when there is a potential conflict, or give specific weight or priority to particular criteria.
  - Criteria that may be used to discriminate between clinically equivalent candidates for transplantation should be carefully reviewed to ensure these do not unfairly disadvantage individuals or groups, for example those who may face structural barriers to accessing healthcare.
- Criteria used in allocation of donor organs or tissues should be carefully evaluated to ensure these are:
  - informed by current evidence
  - free from bias
  - explicitly aligned with relevant normative values or principles of the allocation policy
  - regularly reviewed to ensure they are effectively measured or evaluated.
- Health professionals and policy makers responsible for design or implementation of resource allocation policies should support impartiality in decision-making about donation and transplantation through:
  - routine and consistent implementation of up-to-date, evidence-based guidelines for evaluation of prospective transplant recipients and potential living or deceased donors
  - use of strategies to prevent and manage any potential conflicts of interest that may influence decision-making
  - routine provision of information to patients and substitute decision-makers on how to access independent professional sources of information and advice.
- Prioritisation of some individuals or groups in allocation of some organs for transplantation may be appropriate where it serves to:
  - address structural disadvantages or barriers to transplantation that disproportionately affect some groups, e.g., children for whom appropriately sized donor organs may be less readily available

- expand opportunities for transplantation without unduly disadvantaging other groups, e.g., survival matching of organs that enables efficient use of extended criteria donor organs and reduces the need for repeat transplants in younger individuals
- promote reciprocity and reduce potential barriers to living organ donation, e.g., prioritising prior living organ donors whose need for transplantation is a consequence of their donation, or kidney transplant candidates who have experienced a swap failure during participation in a paired organ exchange.

8.3 Equity in access to opportunities for donation and transplantation

The allocation of scarce health resources is well recognised as a matter of justice, requiring careful ethical decision-making to promote equity in health. In contrast, although equity of access to healthcare is a major ethical concern, much of the focus on equity of access relates to removal of practical barriers to care rather than ethical decision-making as such. Some aspects of clinical decision-making may influence access to opportunities for donation and transplantation, and thus promote or undermine equity of access. Concerns about allocation of scarce resources may also directly or indirectly influence access to opportunities for donation or transplantation. Health professionals and policy makers should strive to identify and address these various barriers in order to promote equity in donation and transplantation (see Chapter 8.3.1).

Where individuals may be restricted from accessing specific healthcare services as a result of their citizenship, residency status, or healthcare insurance status, the implications of these restrictions with regards to their opportunities for donation or transplantation should be carefully reviewed to identify and address potential inequities.

Specific factors that may influence equity in access to HSC transplantation and to organ transplantation are discussed in Chapter 8.3.2 and Chapter 8.3.3 respectively.

8.3.1 Structural barriers to donation and transplantation that may produce inequities

Failure to address structural systemic barriers in access to donation and transplantation programs and health professional bias in considering, offering, or supporting opportunities for donation and transplantation are key factors that may undermine equity. In some cases, bias may be the result of value judgements regarding the potential risks and benefits of donation or transplantation in specific cases (see Chapter 6.1). **Box 8.2** outlines some strategies that may help to improve equity in opportunities for donation and transplantation.

Box 8.2 Strategies to promote equity in opportunities for donation and transplantation

Health professionals and authorities should

- Routinely provide individuals and families with information about donation and transplantation opportunities.
- Increase the cultural and ethnic diversity of staff involved in donation and transplantation activities and provide training for all staff to assist in provision of culturally safe care and effective communication about donation and transplantation opportunities. This is particularly important in the context of Aboriginal and Torres Strait Islander communities who may experience multiple barriers to donation and transplantation.[100,101,142]
- Make decisions about potential donation and transplantation opportunities based on clinical evidence and guidelines, with regular audit of decision-making and outcomes to identify potential sources of bias or discrimination.
- Provide public information and health campaigns that are designed to be accessible to and engaging of all communities, irrespective of age, gender, race, religion or other cultural or social affiliations.
- Identify and evaluate potential clinical, socioeconomic and cultural barriers to donation and transplantation and address these when possible.
- Implement strategies to address specific barriers to donation and transplantation in particular communities noting, for example, inequities in rates of living donor kidney transplantation in Australia according to sociodemographic status.[143]

8.3.2 Equity in access to HSC transplantation

As is the case for organ transplantation (see Chapter 8.3.3) there may be factors such as those outlined in Chapter 8.3.1 which produce barriers to referral for HSC transplantation, and barriers to living directed HSC donation. Such barriers may result in inequities in access to HSC transplantation.

Once an individual's request for HSC transplantation is referred to the ABMDR, the chance of finding a matching non-directed donor may be largely a matter of luck. The specificity required in matching HSC donors to recipients means that allocation of donated cells is almost wholly determined by the immunological characteristics of transplant candidates and those of available donors. The resulting inequalities in access to HSC transplants are thus not inequities, as they are *unavoidable*. However, as noted in Chapter 8.1.1, efforts to expand the diversity of the global HSC donor pool may help to reduce such inequalities.

Global health and socioeconomic inequities, rather than inequities in allocation of HSC donation may influence access to HSC transplants. For example, members of minority migrant communities in Australia may have difficulty finding a matching HSC donor in part due to a lack of HSC donor registries in their countries of origin. Efforts to support the development of HSC donation and transplantation programs in other countries may not only improve access to transplantation in those countries but could also help to improve access to HSC transplantation in Australia's ethnically diverse population (see also Chapter 9.1.3).

8.3.3 Equity in access to organ transplant waiting lists

Although equity in the allocation of deceased donor organs is often the focus of ethical concern (see Chapter 8.4), for many people a major barrier to obtaining an organ transplant occurs before organ allocation is considered. In Australia, in order to be considered as a candidate for an organ from the deceased donor pool, an individual must first join the transplant waiting list. This requires that an individual is recognised as requiring and clinically **suitable** for a transplant, determined to be **eligible** for transplantation, and then **referred** to the waiting list (see Chapter 6.5.1). For some patients, limited access to specialist care may delay their referral to the transplant waiting list, which can negatively impact on time to transplantation and on outcomes of transplantation.

Eligibility for organ transplantation in Australia refers to whether a person is considered eligible to join the waiting list for a deceased donor transplant, not whether they are clinically suitable for transplantation as such (see Chapter 6.5.1.1). This means that although the transplant waiting list provides an important measure of current needs for organ transplantation, it does not accurately capture the extent of potential needs.

Although the organ allocation guidelines provide guidance on determining when a person is eligible to join the waiting list, decision-making about eligibility may be influenced by biases or conflicts of interest, as well as professional perspectives regarding their ethical obligations towards individual patients.[144] As discussed in Chapter 6.5.1, it is important to ensure that decision-making about the proportionality of risks and benefits of transplantation is procedurally fair, and that individuals have the opportunity to appeal against a decision if they believe they have been inappropriately excluded from the waiting list.

8.3.3.1 Eligibility for repeat organ transplantation

Ethical concerns are sometimes raised when an individual is considered for a second transplant following the failure of a previous graft. These concerns usually relate to justice; specifically, whether offering a second transplant to one individual is fair given other transplant candidates may have had no opportunities for transplantation.

There may be a perception that a person who has previously received a transplant has already received their 'share' of the benefits of transplantation, and thus that other people who have not yet received a transplant should be given priority in allocation. However, in some cases, those who have already received a transplant may well be worse off than those who have not yet been allocated an organ. Public or professional discomfort with repeat transplantation may also reflect assumptions that recipients requiring repeat transplantation may be less deserving, for example due to a perception that they have failed to maintain their transplant.

Guidelines generally recommend that previous transplants should not be considered in allocation of organs,[145] except in so far as information about previous transplantation may inform evaluation of a person's current situation and their suitability for transplantation and eligibility to be relisted on the waiting list for a deceased donor transplant. Information about the previous transplant(s) may help to inform evaluation of the risks and potential benefits that may be associated with a new transplant or other treatment options, as well as strategies to reduce risks.

A key reason for not considering previous transplants is that organs are typically allocated based on assessment of current transplant candidates' needs and capacity to benefit from transplantation, not on assessment of past benefits. Efforts to increase

equality of opportunities for organ transplantation by prioritising candidates who have not previously received a transplant could undermine the achievement of other allocation goals, such as efforts to promote utility and avoid loss of life.

8.3.3.2 Access to deceased donor organ transplantation in Australia for international patients

Another key consideration in determining eligibility to access the waiting list for deceased donor organs in Australia is whether the potential transplant candidate is an international patient. TSANZ previously defined international patients as 'non-citizens and non-permanent residents of Australia and New Zealand', and excluded such patients from the waiting list in most circumstances.[146] However, more recent guidance instead restricts access to patients who reside in Australia (AU) or New Zealand (NZ) 'and who are eligible for publicly funded treatment for end stage organ failure within AU/NZ … except under exceptional circumstances.'[12] This topic is discussed further in Chapter 9.4.3.

8.4 Allocation of deceased donor organs

As deceased donor organs represent an exceptional public resource, the values that underpin their allocation among members of the public should be consistent with societal values. The procedures governing, and outcomes of, organ allocation should also be open to public scrutiny. However, allocation policies may not always be in perfect alignment with the expressed values and priorities of the public. This is because public opinion is not always a consensus, and because trade-offs between some goals or values may be necessary to achieve a functional allocation system.

Most people are supportive of organ allocation frameworks that consider utility, avoiding waste and striving to make the most of donations, as well as equality of opportunity, aiming to give more people the chance to benefit from transplantation. The currently adopted TSANZ guidelines for organ allocation in Australia reflect these goals (see Chapter 8.4.1). Several other considerations, such as helping those most in need (the rule of rescue), and avoiding consideration of discriminatory factors such as race, gender or religion are also commonly invoked in surveys of public and professional opinions about organ allocation, as discussed in Chapter 8.4.2.

8.4.1 TSANZ guidelines for allocation of deceased donor organs

The Transplantation Society of Australia and New Zealand (TSANZ) has established clinical guidelines that govern allocation of organ from deceased donors within Australia.[12] Allocation frameworks have been designed specifically for particular types of organ transplantation and provide information regarding the clinical criteria that are used to guide decision-making in particular circumstances. The guidelines have been designed with the aim of promoting equality of opportunity for transplantation (referred to as 'equity' in the TSANZ guidelines) while striving to maximise utility, which is broadly defined as 'the community should derive the maximum possible benefit from the limited number of organs available for transplantation.'[12]

In practice, the allocation guidelines primarily use expected survival following transplantation as a measure of utility, although expected quality of life is a key consideration of decision-making about eligibility for transplantation. Length of time waiting for a transplant, the quality of the match between potential transplant candidates and available organs, logistical considerations and the immediate risk to a

transplant candidate's life are all highlighted as relevant criteria which are considered to a varying extent in the context of different organs.

The guidelines highlight the following considerations as ethically relevant in decisions regarding organ allocation and eligibility for transplantation:

- relative urgency of need
- medical factors which affect likelihood of success (e.g., comorbidities, tissue matching)
- relative severity of illness and disability
- relative length of time on the waiting list
- likelihood that the recipient will be able to comply with the necessary ongoing treatment after transplantation.[12]

8.4.2 Potential considerations in deceased donor organ allocation

Some additional principles or values are often discussed by members of the public, policy makers, philosophers, and health professionals with regards to deceased donor organ allocation, which we briefly examine in the following sections. Additional considerations relating to directed or conditional donation of deceased donor organs are explored in Chapter 12.3.

8.4.2.1 Prioritisation according to age

When considering the allocation of scarce health resources, or other resources with potential lifesaving implications, many people commonly express a preference to prioritise the needs of children or younger people. Around the world, organ allocation policies often include a degree of prioritisation of children.[147] This may reflect consideration of the 'fair innings' principle (see Chapter 8.2.1.2), the belief or expectation that utility will be maximised by treating children (on the assumption children will live longer than an older person receiving the same resource), and/or the belief that there is a special ethical obligation to care for children.

If consideration is giving to prioritising children – to some extent – in organ allocation, it is important to determine whether this is aimed at maximising the therapeutic gains of transplantation, helping to ensure that children achieve a more normal life span, or simply helping more children to have opportunities for transplantation. Depending on the clinical circumstances and the organ allocation system as a whole, these goals may not necessarily be achieved by prioritisation, and additional or alternative adjustments to allocation protocols may be needed.[147]

Prioritisation of children (or other groups) may notably be considered as a means to reduce an existing disadvantage, rather than to give them an advantage over other groups. For example, given that most deceased organ donors are adults, there may be fewer donor organs available that are suitable for transplantation in children due to difficulties in size matching of organs. This could mean that without prioritisation, children may have a lower chance of receiving a deceased donor organ transplant compared with adults. Providing a degree of priority to children in organ allocation may thus help to compensate for the reduced donor pool to which they have access, thereby reducing an existing inequality.

In contrast, some people may wish to give priority to older people. Some Aboriginal and Torres Strait Islander communities, for example, may prefer to prioritise transplantation of older people in accordance with cultural norms of respect for older people, or at least

to ensure they are not excluded from accessing transplantation as a result of resource constraints and rationing. In particular, some may wish to give priority to Elders, who play a vital role in First Nations communities and who are often older members of these communities.[33] Prioritising Elders may not only be considered a matter of respect for reciprocity; it may also be judged to maximise utility within some First Nations communities by restoring the health or extending the lives of Elders who can therefore continue to contribute to community wellbeing.

8.4.2.2 Medication adherence and drug and alcohol use

In some cases, there may be a perception that some people in need of organ transplantation are personally responsible for their illness and hence are less deserving of treatment.[148] For example, a person who develops liver failure as a consequence of alcohol dependence might be considered by some people to be less deserving of a transplant than someone whose liver failure is a consequence of a congenital disease.

Such beliefs often reflect a lack of understanding of the nature of substance use disorders, and the factors that may influence their development, as well as social biases about specific conditions or behaviours.[149] Discriminating between needs for healthcare based on perceptions about the degree of personal responsibility for ill health is not appropriate for several reasons.[150] In particular, it is extremely difficult to determine the extent to which any individual might be considered truly responsible for their own ill health.

Concerns about factors that may impede medication adherence or access to follow up care, and about use of drugs, cigarettes or alcohol by prospective transplant recipients may sometimes be considered when determining eligibility for transplantation or organ allocation. While these factors may be clinically relevant in determining the likely risks and benefits of transplantation in an individual, and the utility of transplantation, they should not be considered grounds for routine exclusion from transplantation.

In many cases, these risk factors or behaviours may be modifiable, and transplant candidates should be supported and encouraged to address any issues that may negatively impact their chances of receiving and benefiting from transplantation. It is also important to ensure that factors which may be associated with social stigma are not given undue consideration compared with other, less stigmatising clinical risk factors that could jeopardise transplant outcomes. Poor medication adherence, attendance at follow up care and behaviours such as smoking are often associated with socioeconomic disadvantage and structural inequalities, and hence are reflective of inequities.

8.4.2.3 Prioritisation of living kidney donors in kidney allocation

In some organ allocation systems internationally, individuals who have previously donated a kidney as a living donor may be awarded a degree of priority in allocation of deceased donor kidneys if they develop a need for transplantation in the future.[151] Priority for living kidney donors represents a potential strategy to minimise harm to living donors who may have a comparatively higher risk of developing kidney failure as a result of donation. Providing a degree of priority could thus help to encourage living donation by reassuring prospective donors that if they do develop kidney failure, they will be more likely to receive a transplant.

It should be noted that offering priority to living kidney donors should not be considered an incentive for for living donors, as prioritisation will not leave them better off as a result of their decision to donate. A person who requires a kidney transplant

after having donated one of their kidneys is in fact likely to have been better off if they had not donated at all. In this sense, offering living donors a degree of priority in allocation of kidneys in the future helps to reduce the risks associated with living donation and to compensate them for the fact that they might not have needed a transplant if they had not donated one of their own kidneys.

Awarding living kidney donors a degree of priority in kidney allocation may also be justified as a matter of reciprocity or fairness, compensating individuals who have already directly contributed to efforts to meet transplant needs. The degree of priority to be awarded should be determined as part of allocation algorithms to ensure that it does not unduly impact the achievement of other allocation goals and values.[151]

If a degree of priority is offered to living kidney donors, it is important that prospective living kidney donors are aware that this priority does not guarantee them a kidney transplant from a deceased donor in the event that they later require one. Prospective donors should be carefully counselled to ensure they are not falsely reassured or do not disregard the risks of developing kidney failure on the assumption they will be readily able to access a transplant in future.

In the event that a person travelled to Australia for the purpose of donating a kidney to an Australian citizen or resident (see Chapter 9.4.2), they may not be eligible to access the Australian transplant waiting list in future and hence would not be able to benefit from priority in deceased donor kidney allocation in the event of developing kidney failure in future, if such priority was incorporated into the allocation framework.

8.4.2.4 Multi-organ transplantation

Allocation of organs to candidates who require more than one organ to be transplanted may raise ethical concerns as multi-organ transplantation can reduce opportunities for transplantation for other candidates.[152] Allocation of a kidney and a liver from a single deceased donor to person A, for example, may deprive two people of a transplant rather than simply one missing out if a kidney or a liver is allocated to person A rather than person B.

The opportunity costs associated with multi-organ transplantation complicate the existing difficulties of balancing equity in individual opportunities for transplantation with efforts to promote utility of transplantation for individual recipients and collectively.

Allocation algorithms should strive to ensure the common values and principles that underpin all organ allocations are also applied in the case of multi-organ allocations. That is, the impact of multi-organ allocation rules on efforts to save lives, promote utility, and reduce inequalities in access to transplant opportunities should be carefully evaluated.

Although multi-organ transplantation is likely to reduce opportunities for transplantation for some individuals, this fact alone does not mean that multi-organ transplantation is ethically unacceptable. Just as individuals who require repeat transplantation may be perceived as taking more than a fair share of opportunities for transplantation (see Chapter 8.3.3.1), perceptions that individuals receiving multi-organ transplants are unfairly benefitting are misplaced. This is because strict equality in the distribution of organs does not entail equity; equal shares are not necessarily fair (see Chapter 8.2.1.1). Some individuals may require a greater share of resources than others in order to achieve similar health outcomes, and are equally deserving of the opportunity to benefit from transplantation where possible.

8.4.3 Implementing values and principles in organ allocation frameworks

Despite general agreement on relevant considerations and principles that should be used to guide decision-making, in practice the specifics of organ allocation frameworks and algorithms may produce very different results depending on how specific considerations are weighted or measured. This means that the incorporation of clinical criteria in allocation guidelines requires careful scrutiny and evaluation of outcomes in order to determine whether the goals of the allocation process are being achieved.

This is particularly important where allocation rules may allow for flexibility of interpretation or require qualitative judgements. Consequently, measures to promote procedural justice should be highlighted in allocation guidelines, such as the role of audits and data reporting to facilitate oversight of practice and outcomes and the right of appeal, for example if a person is excluded from the transplant waiting list or feels they may be disadvantaged by the allocation framework (see Chapter 8.6).

8.4.3.1 Allocation of extended criteria donor (ECD) organs and survival matching

The increasing use of ECD and non-standard risk donor organs (see Chapter 6.5.2.2) requires ongoing review of allocation guidelines and more sophisticated protocols to assist in making use of organs that might offer less utility for some individuals, in terms of shorter expected graft survival, but which may provide excellent outcomes for other individuals who might otherwise miss the opportunity for transplantation.

Age-, longevity-, or survival-matching is an emerging approach aimed at making better use of organs. In essence it involves preferentially allocating organs from older donors or organs that are otherwise expected to have a shorter duration of graft survival to transplant candidates with a shorter life expectancy. Matching may be approximate.

This approach may help to avoid 'waste', which can occur if a person dies with a well-functioning graft that could otherwise have extended survival in another person. It also helps to avoid the waste that occurs if an organ is discarded altogether rather than being transplanted. Survival matching may also mean that people may be offered a transplant who might otherwise have been excluded from transplantation, because their life expectancy is not considered sufficiently long to warrant transplantation. Furthermore, survival matching may help to improve outcomes for younger kidney transplant recipients who are more likely to require a second transplant over their lifetime; by avoiding use of kidneys of shorter expected graft survival the need for a second transplant can be delayed.

There are potential concerns about the impact of survival matching on equity in transplantation which require careful attention in the design of allocation protocols and decision-making for individuals. For example, if kidneys from older donors are preferentially allocated to older transplant candidates, and the majority of donors are older, then young people may be disproportionately affected by survival matching and have fewer opportunities for transplantation. On the other hand, some research suggests that allocating ECD kidneys to older recipients may lead to poorer outcomes, if other factors are not carefully considered.[153–155] Survival matching considerations must be carefully evaluated in the context of other variables to ensure that the overarching goals of the allocation framework are supported.

8.4.3.2 Impact of precision medicine

The emergence of precision medicine has significant implications for organ allocation.[156] As more sophisticated tools emerge to predict the outcomes of allocations if donor organs are matched more precisely to recipient characteristics, it may be possible to evaluate the utility gains of specific allocations with greater precision. While this has potential advantages for transplant recipients, it also risks disadvantaging individuals or groups who may be less likely to achieve a match that offers optimal utility. On the other hand, precision medicine tools may be able to assess utility in matching more accurately and objectively than health professionals, reducing the impact of professional bias in decision-making about eligibility for transplantation as well as allocation and acceptance of transplant offers.

8.5 Equity in distribution of donor tissues

Promoting equity in the distribution of donor tissues and in access to tissue transplantation requires attention to the same ethical considerations that are discussed in the context of organ transplantation (see Chapter 8.4). Differences in the systemic organisation of tissue banking and transplantation of tissues mean that different allocation guidelines and systems are required, however the ethical values and principles guiding practice remain the same.

8.5.1 Importance of transparency and oversight of tissue allocation decision-making

Tissue transplantation provides substantial benefits to recipients with regards to improvements in health and quality of life and is sometimes lifesaving. However, in comparison with needs for organ transplantation, needs for tissue transplantation are less commonly quantified and monitored via waiting lists for transplantation.[135] This may be because transplants are more readily available, so there is less demand for a central allocation system to adjudicate between the competing needs of different individuals and consideration of time spent waiting for a transplant is not required as a tiebreaker in allocation decisions.

In many cases, there are sufficient tissues available to meet most urgent, if not all, needs for transplantation. This reduces potential concerns about inequities in allocation. Most tissues can also be transplanted without the need for immunological matching between donors and recipients, although some tissues such as cardiac valves (e.g., paediatric valves) or mass bone allografts may require specific matching for size. There is also some benefit for tissue matching of corneas in recipients that are considered at high risk of immunological rejection.

Consequently, tissue banks, including eye banks, rarely share waiting lists with other banks, and may not maintain formal waiting lists at the institutional level. Banks may simply supply available tissues as requests are made by health professionals or organisations, applying a ‘first come, first served’ principle, leaving those individuals to then distribute specific tissues to patients as needed.

Lack of formal allocation systems for tissues and tissue products does not necessarily reflect the absence of inequalities or indeed inequities in access to these resources. If supplies are plentiful, then concerns about inequities may only arise in the setting of unexpected surges in demand for specific tissues or crises in tissue availability (see Chapter 8.5.1.1). Without established ethical frameworks and protocols for allocation

in these circumstances, such as agreements for sharing of resources and prioritisation of specific needs through collaboration of various tissue banks, unexpected shortages could lead to acute inequities in distribution of valuable resources.

The EBAANZ Ethical framework, for example, recommends the establishment of transparent allocation criteria and policy to guide decision-making about allocation of eye tissues 'during periods of insufficiency in supply'.[157] EBAANZ members have established a memorandum of understanding with regards to sharing of eye tissues that has improved efficiency in supply and equity in the distribution of eye tissues across Australia.

Even when supplies are plentiful, lack of attention to the details of distribution and monitoring of needs for specific types of tissue transplants – which could be facilitated through waiting lists or registries of transplant candidates, recipients or tissue utilisation – could result in neglect of unrecognised inequities (see Chapter 8.5.1.2).

8.5.1.1 Informal approaches to prioritised allocation of donor tissues

Informal allocation guidelines may be applied in the context of eye banks and tissue banks that manage tissues and tissue grafts that are less readily standardised, and which may require a level of specification before allocation to particular transplant candidates. For example, cardiac valves must be matched by size to paediatric transplant recipients, which means a waiting list may be established for such patients.

In the setting of emergencies requiring urgent tissue transplants for multiple people, such as mass casualty events in which several people suffer severe burns, available tissues such as skin grafts may be allocated ad hoc by health professionals with primary consideration of utility gains, in terms of likely patient survival and severity of needs.

Eye banks, for example, may prioritise occasional patients who have an urgent clinical need such as threatened perforation (due to injury, infection, or disease), or intractable severe pain, for urgent surgery, and those with unilateral sight over those with bilateral sight. Corneas may also be allocated according to specific characteristics of both donors and prospective recipients.

8.5.1.2 Potential inequities in distribution of donor tissues

In the absence of formal waiting lists or other systems for objectively assessing potential needs for tissue transplantation, tissue banks may be dependent on evaluating *ad hoc* requests from health professionals to determine whether there is unmet demand for a particular type of tissue. This may result in skewed perspectives of needs and undermine the ability to meet real needs. Although health professionals are well placed to evaluate the potential benefits of transplantation in specific patients, there is significant potential for inequities to develop in the absence of formal allocation guidelines and measures designed to ensure routine review of outcomes and accountability for decision-making, especially - but not only - when resources may be limited.

For example, if health professionals find it difficult to obtain specific tissues or are unaware of the availability of particular types of tissues, they may use biosynthetic or alternative tissues that may be less beneficial for patients. In the absence of apparent demand for a particular graft type, tissue banks may in turn continue to prioritise the preparation of donor tissues in ways that are in fact less therapeutically valuable, but which appear to be more in demand. Consequently, the benefits of donated tissues may not be fairly distributed across the population of potential transplant recipients, and utility of donation may not be optimal for the community.

Lack of formal allocation systems and reliance on informal approaches to tissue allocation (see Chapter 8.5.1.1) may also increase the risk of perverse incentives or conflicts of interest inappropriately influencing decision-making about investment in and distribution of tissue products (see Chapter 10.5), as it is more difficult to evaluate the prevalence and magnitude of therapeutic needs for tissue transplants and which needs are being met.

8.5.1.3 Potential conflicts of interest in allocation of tissues

In the absence of formal tissue allocation frameworks, concerns about potential conflicts of interest in decision-making may be more acute (see Chapter 3.8).

There is an inherent conflict of interests when a health professional involved in the allocation of tissues requests tissues for their own patients. The primary duty of care that health professionals have is to prioritise the wellbeing of patients with whom they have an established therapeutic relationship (see Chapter 3.3.4.1). Although health professionals also have duties towards the wider community and an obligation to manage health resources efficiently and effectively, it is important that there are independent persons involved in decision-making about allocation of tissues and others who may advocate for the potential transplant needs of other patients. For example, if two burn centres simultaneously request skin allograft for the treatment of different patients, a tissue bank may need to facilitate discussion between health professionals at each centre if it is necessary to prioritise allocation of available grafts to specific patients.

Potential conflicts of interest may also arise due to the relationships between tissue bank staff responsible for tissue distribution and those requesting tissues for transplantation. For example, if donor tissues are obtained at the same hospital at which a patient requires a tissue transplant, or if the surgeon requesting a graft for a patient has a relationship with or role in the providing tissue bank, these represent potential conflicts of interest. In some cases, some donor tissues may be 'reserved' for use in the institution in which the donations are obtained, or the institution may be given some priority in accessing tissues. Financial conflicts of interest may also arise, which are discussed in Chapter 10.5.

8.6 Considerations for procedural justice in distribution and allocation of donor tissues and organs

The following steps are recommended to assist in promoting equity and avoiding inequities in the distribution of donor tissues and organs:

- All institutions or organisations involved in distribution or allocation of donor tissues or organs should have a clear and publicly communicated policy governing decision-making about the allocation or distribution of tissues or organs.
- Policies should detail the ethical values and principles guiding decision-making and provide information on the goals of the policy, how decisions are made and how the impact of the policy is evaluated.
- Policies should be informed by the values and preferences of the communities in which they are implemented.

- Policies should make provision for how donated tissues and organs may be shared between institutions or organisations such as tissue banks or transplant centres, or between jurisdictions, including provision of guidance on
    - how donations will be allocated in the event of temporary or longer-term insufficiency of supplies to meet all demands
    - how urgent and severe needs will be met.
- In the case of tissue banks, policies should also detail the priorities accorded to specific clinical indications for tissue transplantation and utilisation of specific graft types in settings of insufficient supply.
- Data should be routinely collected to help inform estimates of needs and priorities for transplantation.
    - for example, regarding clinical requests for tissues and any other information that may be used to estimate the prevalence of needs, if not demand, for tissue products.
- Data should be routinely collected to help inform estimates of needs and priorities for transplantation, for example:
    - regarding clinical requests for tissues and any other information that may be used to estimate the prevalence of needs, if not demand, for tissue products
    - regarding prevalence of end stage organ failure in the population.
- Registries of recipients of transplants should be established and maintained not only for the purpose of vigilance and surveillance and follow up care of transplant recipients but also to assist in evaluating outcomes of allocation policies and decisions.
- Policies and data should be open to public scrutiny to maintain accountability to the public as donors of these materials and beneficiaries of these community resources (see Chapter 8.4), and policies should be reviewed at defined intervals and revised where needed.

9. Sufficiency and sustainability in donation and transplantation

Self-sufficiency is a strategic and ethical objective of organ and tissue donation and transplantation programs in Australia, consistent with the recommendations of the WHO. In the national context, the term refers to the goal of being able to meet the needs of people living in Australia for organ and tissue transplantation using resources from within the country. This means being able to rely on the Australian resident population for donation of organs and tissues without outsourcing burdens or responsibilities to other countries, and being able to reliably deliver necessary services to donors and transplant recipients within Australia that are safe and of high quality.

Self-sufficiency may be pursued at a local or national level, or, in some cases in international collaboration with other populations who may choose to work together in solidarity and share resources to meet collective needs more effectively. Although the term self-sufficiency is rarely applied to HSC donation and transplantation (see Chapter 9.1.3), solidarity, sufficiency, safety, quality and sustainability of supply are equally important in the context of HSCs.

Further readings and resources relevant to this chapter can be found in Appendix 1.

9.1 Ethical values embedded in the self-sufficiency concept

The globalisation of health care provides opportunities for international exchange of cells, tissues, and organs as well as travel by individuals to access donation or transplantation. This may assist individuals in meeting transplant needs in the short term, but may also exacerbate inequities in donation and access to transplantation, cause harm to donors or transplant recipients, or negatively impact the long-term sustainability of donation and transplantation programs in Australia and internationally.

Progress towards national self-sufficiency in donation and transplantation is valuable because it means that Australia is better able to meet its own needs for transplants, and thus able to ensure that donation and transplantation activities meet our national ethical and clinical standards of quality, safety and care in donation and transplantation practice. Reduced dependence on other populations to help us meet needs for transplantation means that we are less exposed if events within or outside Australia negatively impact supply or exchange of cells, tissues or organs.[158]

It also means that we are better able to ensure that the potential benefits and burdens of donation are shared equitably within the community.

Promoting self-sufficiency does not entail self-centredness or selfishness. Collaboration with other populations in order to meet needs for some resources may be necessary and mutually beneficial (see Chapter 9.1.3), and sharing of our own resources with individuals or populations outside Australia may be ethically appropriate in some circumstances. Adopting the goal of self-sufficiency implies a commitment to efforts to meet our own transplant needs rather than outsourcing these efforts to other populations, which occurs when individuals or national authorities purchase organs or tissues from people who are unable to access the benefits of transplantation.

Progress towards self-sufficiency depends on respect for equity, reciprocity and solidarity in donation and transplantation (see Chapter 3.3.9). It is a communal goal, which means that all those on whom we depend as potential donors within the resident population may be offered the option to donate and should be entitled to benefit from transplants when these are available and necessary, although not all members of the population will have the opportunity to donate, and not all will need a transplant.

9.1.1 Self-sufficiency in organs or tissues at the local level within Australia

Self-sufficiency in some organs or tissues is sometimes pursued at the local level within a nation, particularly where local donations of a particular resource such as corneas may be sufficient to meet local needs for transplantation of that resource. It is possible that activities or policies in one region may sometimes have a negative impact on other regions. Mergers or formal exchange of resources may in some cases be beneficial for smaller populations that join together to pursue self-sufficiency, but they may also risk undermining programs that are strategically important at the local level. Oversight at the national level is needed to ensure that collaboration between the various donation and transplant programs is equitable and contributes to efficiency and sustainability of all programs.

Where self-sufficiency in particular tissues or organs is pursued at the level of states, territories or other subnational regions in Australia, the same principles governing self-sufficiency and ethical considerations outlined in this chapter are relevant.

9.1.2 Regional self-sufficiency in deceased organ donation

Australia collaborates with New Zealand in the context of deceased organ donation, such that in specific circumstances some organs from deceased donors based in Australia may be exported for transplantation in New Zealand and vice versa. Organs are shared between these two countries when it is necessary to help meet urgent needs for a transplant in one country, or when no suitable recipient for a particular organ is available within the donor's country. These exchanges are consistent with pursuit of self-sufficiency because residents of both countries may contribute to and benefit from this sharing agreement.

9.1.3 Global sufficiency in HSC donation

In the case of HSC donation, the difficulties of finding a suitably matched donor for individual recipients and the diversity of many populations means that international collaboration is necessary to meet more needs for HSC transplantation. Immunological difficulties in matching potential HSC donors with recipients means that it is often necessary to draw on a very large and diverse pool of donors in order to find a suitable match for a recipient. Consequently, national donor registries such as the ABMDR are connected via the WMDA, which helps to facilitate international matches where necessary.

Donors in Australia therefore routinely contribute to meeting transplant needs in other countries and foreign donors help to meet needs in Australia. Currently, most non-directed HSC donations used for transplantation in Australia are in fact from international donors.[159] Nevertheless, reduced dependence on international donors and progress towards self-sufficiency in HSC donation within Australia are valued as this reduces the risks of disruption to supply if international events impact donations or distribution of donations from other countries to Australia.[158]

The ABMDR works with partner organisations in Australia such as LifeBlood to support recruitment of non-directed HSC donors within Australia. By expanding the potential HSC donor pool within Australia, we are better able to meet domestic needs for transplant and to reciprocate the contributions of international donors by contributing donations to other countries.

Domestic donor recruitment programs, including targeted campaigns to recruit donors from groups that are under-represented in the ABMDR, thus play an important role in improving equity of access to HSC transplantation (see Chapter 8.3.2) and equity in the exchange of HSC donations internationally.

9.1.4 Barriers to self-sufficiency in tissues and organs

A major challenge in achieving self-sufficiency is the insufficient supply of organs and some tissues within Australia. This may be due to missed opportunities for donation or short-term difficulties in meeting specific needs or addressing unexpected surges in demand for specific organs or tissues. For example, an infectious disease outbreak may temporarily exclude potential donors in Australia, or a bushfire crisis resulting in increased needs for skin graft transplants could create or exacerbate existing shortages of supply of organs or tissues.

There may also be shortages in supply of specific tissues or tissue-derived medical products if these are not recovered or produced in Australia. This may occur, for example, because infrequent demand for a specific type of tissue or tissue-derived product means it is economically difficult to develop and maintain the relevant program within Australia.

9.2 Ethical obligations of custodians when receiving or transferring donor cells, tissues or organs

Stewardship of the common good is a core value underpinning donation and transplantation in Australia (see Chapter 3.2.5). This means that professionals and organisations involved in receiving or transferring donated cells, tissues or organs for use in transplantation have ethical obligations as custodians or prospective custodians of these materials. In particular, they have obligations to ensure that:

- relevant legal, clinical, and ethical conditions relating to removal, transfer, import or export of human cells, tissues and organs have been met
- traceability of donated materials is maintained from donation to transplantation
- relevant clinical and ethical standards in the care of donated materials are maintained throughout the period of custodianship
- donor cells, tissues and organs are received from or entrusted to organisations or individuals who are suitably qualified, accredited and competent to ensure that ethical and clinical standards are maintained in all activities relating to donation, storage, distribution or use of donor cells, tissues or organs.

Although individuals or organisations may not be accountable for the actions of others from whom they receive or to whom they entrust donated materials in all circumstances, they have a responsibility to ensure that sufficient mechanisms and standards are in place to warrant trust. It is the responsibility of custodians and prospective custodians to take action in response to signs or reports of potential ethical concerns, ensuring a chain of ethical custodianship is maintained.

Specific ethical considerations with regards to the import or export of donor cells, tissues, and organs are discussed in Chapter 9.3.

9.3 Ethical conditions for the international import and export of donations

For the purpose of these guidelines, international importation is defined as the transfer into Australia of human cells, tissues or organs, including tissue-derived products, that were donated outside Australia's borders for use in transplantation by Australian residents. Legislation governing import and export of human cells, tissues and organs is briefly addressed in Chapter 9.3.5.

Similarly, international exportation is defined as the transfer outside of Australia of human cells, tissues or organs, including tissue-derived products, that were donated within Australia's borders for use in transplantation by individuals or populations that are not resident in Australia.

In the following sections we discuss specific ethical considerations that may be relevant in the context of import and export of donor cells (Chapter 9.3.1), and of donor tissues and organs (Chapter 9.3.2 and Chapter 9.3.3).

9.3.1 Ethical considerations in the import and export of donor cells

As noted in Chapter 9.1.3, international exchange of donated HSCs is necessary in order to better meet needs for HSC transplants worldwide. Import and exchange of donor cells is therefore routine.

Key ethical considerations guiding import and export of donor HSCs to and from Australia include the ethical obligations of custodians as outlined in Chapter 9.2. The ABMDR works closely in collaboration with the WMDA and collaborating donor registries worldwide to ensure that established clinical and ethical standards are maintained throughout the global network.

9.3.2 Ethical considerations in the import of donor organs and tissues

Occasional **importation** of donor organs or tissues into Australia may be ethically appropriate if:

- It is necessary to meet (an) urgent, serious, and unavoidable need(s) for transplantation, and if importation is limited to the immediate period of necessity. For example, if a disaster results in significant demand for life-saving skin grafts and there are insufficient supplies of donor skin grafts within Australia, it may be appropriate to import available grafts from another country.
- Importation is not expected to negatively impact people in need of transplants within the donor country. For example, importation of skin grafts from the United States of America would not be expected to diminish American citizens' access to such grafts.
- The imported materials were obtained and processed in accordance with ethical and clinical standards equivalent to those of Australia. For example, skin grafts should not be imported if they were obtained from a country that is suspected of removing tissues from donors without valid consent, or if traceability of donors is not possible, as these raise ethical and safety concerns.

- Importation is not expected to negatively impact donation and transplantation in Australia.
- The circumstances underpinning the need for importation are reviewed to determine if strategies can be implemented to reduce the risk of future needs for importation, and steps are taken to reduce reliance on importation at the earliest opportunity.

If it is determined that regular importation of specific organs or tissues may be necessary and beneficial, for example in the context of a collaborative sharing agreement, it is important to ensure the arrangement is equitable, sustainable, and that ethical, clinical, and regulatory standards are met in the country of export as well as in Australia. The arrangement for organ sharing between Australia and New Zealand is an example of occasional importation that satisfies these criteria.[12]

Care should be taken in particular to ensure that importation of tissues does not have a negative impact on local tissue banking.[157] As discussed in Chapter 10.5, substantive importation of specific tissues or tissue-derived products may jeopardise sustainability of local donation and manufacturing activities.

9.3.3 Ethical considerations in the export of donor organs and tissues

In pursuing self-sufficiency in organs and tissues, the needs of Australian residents for transplantation should generally be prioritised. This may be considered fair as a matter of reciprocity (see Chapter 8.2.1.5), given that it is this population which contributes the invaluable resources necessary for transplantation by donating organs and tissues. For example, it is only in exceptional circumstances that foreign patients visiting Australia may be considered eligible to receive a deceased donor organ transplant (see Chapter 9.4.4 for a discussion of international travel for transplantation).

In some circumstances, organs or tissues donated in Australia may be available for transplantation that are surplus to the needs of Australian residents, or for whom a matching recipient isn't available in Australia. For example, while some tissues may be stored for later use within Australia, some donations may be wasted if it is not possible to transplant them in a timely manner.

When this occurs, or when the availability of stored tissues outweighs the predicted needs, the possibility of sharing these resources with those in imminent need of transplantation outside Australia may be considered.

Exportation is defined as the transfer outside of Australia of organs or tissues that were donated within Australia's borders for use in transplantation by individuals or populations that are not resident in Australia.

Occasional exportation of organs or tissues from Australia may be ethically appropriate if the following conditions are satisfied:

- It is necessary to avoid wasting donations that would otherwise be discarded, or if it is necessary to assist in saving lives in other countries and will not jeopardise lives within Australia. For example, a liver may be available from an Australian deceased donor for whom no suitable liver transplant candidate is available within Australia, but an eligible recipient is available in New Zealand.
- It is reasonable to presume that relevant donors would be willing for their donations to be exported or if explicit consent for export has been provided (see Chapter 9.3.4).

- Exportation is not expected to negatively impact donation or transplantation programs within Australia or within the recipient country. For example, regular exportation of donor tissues from Australia could discourage efforts in destination countries to establish or sustain their own donation programs or could discourage donation within Australia.
- The donated materials meet clinical standards in the destination country, and will be used lawfully in the destination country in accordance with ethical standards equivalent to those set out in these guidelines.
- Any charges for the provision of organs or tissues that are exported by Australia are consistent with the costs of providing equivalent services within Australia and aimed at recovery of costs, not generation of profits (see Chapter 10.5.2).
- Decisions regarding the distribution of Australian organs or tissues (including tissue-derived products) via export are determined using equivalent values and principles that guide equitable allocation of these resources within Australia (see Chapter 8).
- The circumstances underpinning the need or opportunity for exportation are reviewed to determine if strategies should be implemented to ensure better management of donation and transplantation activities within Australia and/or to establish formal collaborations with other countries for the regular exchange of resources.

9.3.4 Implications of import and export of donor organs and tissues for consent

The possibility of receiving a transplant using organs or tissues that have been donated outside Australia, and of organs and tissues donated within Australia being exported for transplantation in other countries, have important implications for consent.

Information about these possibilities may be relevant to some people when making a decision about donation or transplantation and hence should be disclosed if necessary to ensure valid consent is obtained (see Chapter 4.1.3). Strategies to ensure that potential donors, deceased donation decision-makers and transplant recipients are making informed decisions with regards to donations that may be imported or exported from Australia should be tailored to specific contexts.

While it is reasonable to presume that donors would want their donations to be used to help others, this does not mean that all donors would be willing for their donations to be exported outside of Australia. If people are unaware, and unwilling for their donations to be shared with people in other countries, discovery of this after donation has occurred may lead to a loss of trust in donation.

Many people in Australia may make a decision about donation with the understanding that their gifts will be used to help other people living within Australia, as promotion of organ and tissue donation focuses on the importance of meeting needs for transplantation within Australia. There may be circumstances in which individuals would prefer not to donate if their donation was likely to be exported. In particular, some Aboriginal and Torres Strait Islander people may object to exportation of their donated organs or tissues due to their connection to Country.

Case Study – Consent for deceased donation and export of tissues

Jake is a 36-year-old man who suffers a devastating brain injury as a result of a car accident. Despite surgery, Jake's condition worsens and the intensive care team determine that he meets the criteria for neurological determination of death ('brain death'). They explain this to his family, and after a general discussion about the implications of this, Jake's sister asks if it is possible for him to donate his organs. Jake is not registered as a donor.

A donor coordinator meets with Jake's family to discuss the possibility of organ and tissue donation. Jake's mother, partner and his sister all state that they believe Jake would want to be a donor, given his cousin received a kidney transplant some years ago, and several of his family members are on dialysis. The family agrees to authorise donation including all organs and tissues, except his corneas, as his mother says she doesn't feel comfortable with the idea of eye donation.

The donor coordinator is new and seeks advice from a senior colleague, asking, 'Should I encourage the family to think more about the possibility of corneal donation? And should I tell them there's a possibility that some of the tissues could be exported overseas?' The senior colleague replies, 'It's probably a cultural thing so there's no point talking further with them about the eye donation. But you should let them know that some tissues might be sent to recipients in other countries if there's no suitable recipient in Australia.'

Points to consider:

- This case illustrates some of the complexities of deceased donation decision-making.
- Two principles are especially relevant to this case:
    - **Principle 1** Decision-making about donation and transplantation should seek out and take account of expressed preferences of donors, recipients, their families and communities, and facilitate self-determination.
    - **Principle 2** Decision-making about donation and transplantation should promote cultural safety, demonstrating cultural humility, critical reflection, and awareness of power dynamics.
- It is important not to make assumptions about the reasons why a potential donor or relative of a potential donor may wish to decline donation of specific organs or tissues. While some people may hold cultural or religious beliefs that could influence their attitudes towards donation of particular tissues or organs, many people who share a common culture or religion may hold different attitudes. Many people may feel uncomfortable with the idea of donating particular body parts for reasons they may have difficulty explaining, and which may not be related to culture or religion at all.
- Cultural factors may play an important role in decision-making about donation or transplantation. It's essential that decision-making takes place in a culturally safe environment, in which health professionals practise cultural humility. This involves being conscious of one's own culture, respectful of potential cultural differences, and mindful of the ways that historical and contemporary cultures may influence power dynamics in relationships. That requires health professionals, like the donor coordinator in this case, to create an environment in which Jake's family is empowered to express their views and beliefs and

supported to make decisions that are consistent with their values (see Chapter 3.4.2). As donation decision-makers, they should be encouraged to make decisions using a 'substituted judgement' approach that prioritises what they believe Jake would have wanted (see Chapter 4.4).

- It would be appropriate for the donor coordinator to respectfully explore Jake's mother's concerns about eye donation, as her reluctance to approve donation might be based on mistaken beliefs or lack of knowledge of what is involved in donation or of the benefits of corneal transplantation. Ensuring that donation decision-making is informed helps to ensure that families make the right decision for them and reduces the risk they could regret their decision at a later time (see Chapter 4.4.2).
- It is important to disclose information about the possibility that some donated tissues might later be exported. Any family making a decision about donation may have an interest in knowing about the possibility that tissues or organs may be shared with people in other countries. While some may not care about this possibility, it could be an important consideration in decision-making for some people due to personal or cultural values and beliefs (see Chapter 9.3.4).

9.3.5 Legislation governing import and export of human cells, organs and tissues

Organs, tissues and cells imported for the purpose of therapeutic transplantation are not regulated by the TGA but are subject to the prohibition of commercial trade that exists in all State and Territory human tissue legislation. Therapeutic products derived from human cells, organs and tissues may be imported if they constitute a Biological that is on the Australian Register of Therapeutic Goods. Other forms of approval can also be sought from the TGA, for example, for products given during clinical trials or the prescription of unapproved therapies. The importation of material derived from human embryo clones is regulated by the NHMRC. Importing human remains or ashes (for burial) may be subject to biosecurity requirements.

The export of human cells, organs and tissues and substances or products derived from those sources is generally regulated via permission from the TGA. There are different pathways for authorisation: for example, as an exception to the Customs (Prohibited Export) Regulations 1958 or as a Biological on the Australian Register of Therapeutic Goods. Beyond the TGA, the NHMRC can issue permits for export of material derived from human embryo clones and the export of human remains or ashes generally does not require permission.

9.4 International travel for organ or tissue transplantation or donation

Due to the difficulties of transporting human organs across long distances while maintaining their viability for transplantation, and to the chronic shortage of organs for transplantation in most countries, there is limited international exportation or importation of organs, except within regions such as the European Union. However, it is estimated that thousands of people travel across national borders each year for the purpose of accessing organ transplantation or serving as a living organ donor in other countries.[160,161] Only a small number of Australians are estimated to travel internationally for organ transplantation.[162]Some people may also travel occasionally for the purpose of accessing tissue transplants.

Some travel for transplantation may be ethically problematic (see Chapter 9.4.1). Health professionals providing care to patients who may be considering or who may have engaged in unethical travel for transplantation have potential ethical obligations to address this which are discussed in Chapter 9.4.2.

Some people who are traveling for other purposes may also unexpectedly become organ or tissue donors or transplant recipients (see Chapter 9.4.4).

9.4.1 Ethical travel for organ or tissue transplantation vs 'transplant tourism'

Travel for organ or tissue transplantation may be ethically appropriate in a range of circumstances. For example, a person may live abroad for work and return to their home country to undergo transplantation, or a person may travel to donate an organ to a friend or relative living in another country. Alternatively, people who live in countries that lack organ transplantation programs may travel abroad with their prospective living directed donor to access transplantation services.

Travel for transplantation becomes ethically problematic and may be referred to as 'transplant tourism', if it involves organ trafficking (see Chapter 10.6) or undermines self-sufficiency in the destination country.[6] Although travel for tissue transplantation could also involve trafficking or undermine self-sufficiency in destination countries, the term transplant tourism is typically associated with organ transplantation.

Self-sufficiency would typically be undermined if people traveling for transplantation make use of resources such as deceased donor organs or tissues or transplantation services which then become unavailable to local people in need of transplantation. For example, in some countries foreign transplant patients are able to pay more money to access transplant programs than local residents, and health professionals or institutions may prioritise income generation at the expense of equity of access to transplantation.

9.4.1.1 Hazards of 'transplant tourism'

In addition to the potential impact of travel for transplantation on self-sufficiency, travel involving organ trafficking raises specific ethical concerns. Buying and selling organs means that organs are not recognised as ethically exceptional, and are instead treated like ordinary commodities. This is a problem that is discussed in detail in Chapter 10.6.1.

Where organ trafficking occurs, people who may be potential organ donors can become a target for human traffickers or others seeking to exploit people who are vulnerable as a result of poverty or coercive relationships. Most transplant tourism involves markets in kidneys obtained from living individuals, although liver lobes from living 'donors' are also bought and sold. Evidence shows that those who sell their organs in such markets have rarely provided valid consent. They are often financially exploited, receive no follow up care, and suffer significant long-term damage to their physical and psychological health, and social status.[163–166] Those who purchase transplants involving trafficked organs are at significant risk of clinical complications and infection as a result of poor donor screening and quality of care.[162,167,168] Recipients may also be at risk of criminal prosecution.

While some poor individuals arguably make a voluntary decision to sell an organ for transplantation, many have been victims of human trafficking. In addition, in China, a former transplant tourism 'hot spot', organs used in transplantation for foreign (and domestic patients) have historically been obtained from executed prisoners.[169] Consequently, when individuals participate in transplant tourism, they may not only cause harm to donors or incur risks to their own well-being, they also risk supporting

and encouraging practices that may violate fundamental human rights and core ethical standards in organ donation. Furthermore, transplant tourism and the organ trafficking it encourages undermine efforts in destination countries to establish effective altruistic deceased and living organ donation programs due to their impact on public trust and motivations for donation.

9.4.2 Provision of care to Australians who may travel overseas for organ donation or transplantation

Although evidence is limited due to lack of systematic collection of data regarding international travel for donation or transplantation by Australians, it is estimated that few Australian residents travel overseas for organ transplantation or to serve as living organ donors, and even fewer are suspected of traveling for the purpose of obtaining a transplant involving organ trafficking or selling their own organ.[162]

When providing care for transplant candidates or potential donors who may consider or be considering travelling abroad for donation or transplantation, it is important that health professionals fulfil their duties with regards to prevention of transplant tourism, as highlighted in the *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*,[1] *The Declaration of Istanbul on Organ Trafficking and Transplant Tourism*,[6] and the *World Medical Association Statement on Measures for the Prevention and Fight Against Transplant-Related Crimes*.[170]

Health professionals should **assist in deterring** transplant tourism by Australian residents by:

- **educating** transplant candidates about the hazards of transplant tourism (see Chapter 9.4.1.1)
- ensuring that transplant candidates are **informed** of options for transplantation within Australia and **supported** in accessing these
- **declining to clinically facilitate** travel for transplantation for candidates when the risk of organ trafficking cannot be excluded, or when the health professional is unable to ascertain relevant details of the planned transplant in a foreign country. Examples of actions that may clinically facilitate travel for transplantation include ordering of tissue typing tests or radiological investigations as part of a pre-transplant work-up.

Professionals should also ensure they provide support for those who may be traveling legitimately for transplantation. Health professionals who are providing care to Australian residents who are considering **legitimate travel abroad for organ transplantation**, or to foreign residents who wish to travel to Australia for organ donation and transplantation have the following obligations to:

- ensure that prospective transplant travellers will be lawfully accessing treatment and receiving appropriate clinical care at their destination
- ensure that transplant recipients and donors will be able to access appropriate follow up care where relevant
- communicate effectively with patients and care providers in foreign countries where necessary to ensure continuity of care
- inform patients of potential risks that may be associated with travel for transplantation or donation, and the limitations of their knowledge where relevant regarding foreign health care systems
- ensure that mechanisms for traceability of organs are established.

Actions that may be taken by health professionals providing care to a person who is suspected or known to have participated in organ trafficking in another country are discussed in Chapter 9.4.2.1.

9.4.2.1 Provision of care to patients who may have participated in transplant tourism

When providing care to an individual who is known or suspected to have participated in transplant tourism, the patient's health should be the first priority of the healthcare team. Necessary medical care should never be withheld or delayed due to concerns about the possibility of organ trafficking. If a health professional feels that they are unable to retain objectivity in providing care to a patient known to be a transplant tourist, they should provide all necessary care until the responsibility for care can be transferred to another health professional.

Irrespective of whether a patient may have participated in transplant tourism, health professionals should collect and report available data that would routinely be collected from a transplant recipient or donor and provide this to the relevant transplant registry.

Health professionals may also assist in preventing transplant tourism by collecting and disclosing information about cases of suspected transplant tourism following the return of patients to Australia after receiving transplantation abroad, where information is:

- disclosed to an appropriate authority or data registry subject to ethical governance and protections
- used to inform efforts to prevent further organ trafficking, not to punish transplant recipients or organ donors who may be victims of human trafficking
- disclosed in accordance with relevant privacy laws.

Further work is needed to provide a national framework and clear guidance for data collection and reporting that will respect patients' rights to privacy and confidentiality, while protecting potentially vulnerable participants in trafficking destinations including organ sellers and transplant professionals who may be endangered if they assist in whistleblowing (see also Chapter 10.6.1.2 on organ trafficking). In the United Kingdom, for example, reporting of all cases of transplantation that occur outside the country became mandatory in 2024, regardless of whether trafficking is suspected.[171]

When providing care to individuals (i.e., donors) who are suspected or known to have been victims of human trafficking for organ removal, the care of the individual should be the first priority. Health professionals should also:

- collect data that would routinely be collected from a living organ donor and provide this to the relevant donor registry
- refer the individual to relevant organisations for social support
- consider sharing information with human trafficking authorities in relevant jurisdictions.

9.4.3 People traveling to Australia for organ or tissue donation or transplantation

Although in the past Australia has permitted some foreign nationals to travel to Australia to await organ transplantation,[172] Australia is not a popular destination for organ transplant travel as deceased donor organs allocated are not usually available to foreign patients who travel for the purpose of accessing transplantation (see Chapter 8.3.3.2 and Chapter 9.4.5).[12]

People traveling for transplantation with a prospective living organ donor may also be more likely to choose transplantation centres closer to their own countries that actively recruit foreign transplant patients, such as some transplant centres in India, Singapore or the United States. It is nevertheless possible that some people may seek to travel to Australia for the purpose of undergoing living donor organ transplantation with their own directed living donor. In small numbers, such patients are unlikely to jeopardise the ability of Australian transplant programs to meet the needs of local patients, but care should be taken to ensure this does not occur, and to ensure that stringent efforts are made when evaluating foreign donors or recipients to identify and address possible risk factors for organ trafficking (see Chapter 10.6.1.1).

Some people who travel to Australia for the purpose of accessing health care services may do so in order to access tissue transplants that are not available in their own country, or they may be incidentally offered tissue transplantation as part of another therapeutic procedure. Although tissue transplants are more readily available than organs it is important that monitoring of tissue transplant activities evaluates the potential impact of foreign patients on supply and distribution of donor tissues in Australia.

Access to tissue transplants within Australia may be provided to individuals who travel to Australia for the primary purpose of accessing tissue transplantation, or who require a tissue transplant while visiting Australia in some circumstances, if:

- providing the transplant will not undermine the ability to provide necessary tissue transplants for patients who are resident within Australia
- evaluation of the person demonstrates that they will be able to access any necessary follow up care on returning to their home country.

Health professionals providing care to foreign patients receiving transplants in Australia or to individuals who travel to Australia for the purpose of making a living directed donation to a transplant candidate resident in Australia should also be mindful of the ethical obligations outlined in Chapter 9.4.2.

In all circumstances where foreign residents are granted access to cell, tissue or organ transplants within Australia, these transplants should be documented and data collected and reported to the relevant transplant registries, with information regarding the residency status of the recipient.

9.4.4 Unplanned donation by or transplantation of travellers in Australia

Rarely, people who have travelled to Australia for non-transplant related reasons, and who are not citizens or permanent residents, may unexpectedly develop a need for transplantation. For example, tourists or refugees, or other longer-term residents who do not have permanent residency or citizenship status.

If these ‘foreign’ individuals develop an urgent and serious need for organ transplantation and are clinically suitable for transplantation, some may be granted access to the waiting list for deceased donor organs on the grounds that ‘exceptional circumstances’ apply (see also Chapter 8.3.3).

In general, the conditions of permitting foreign patients to join the deceased donor organ transplant waiting list would include the following:

- the person is clinically suitable for transplantation, has a serious and urgent need for transplantation, and is unable to return to their home country or access alternatives such as a living donor transplant
- at the time of traveling to Australia, the person could not foreseeably have known that they would develop a need for transplantation during their time in Australia, or has clearly travelled for a different purpose, i.e., the person has not travelled to Australia for the purpose of obtaining an organ transplant
- evaluation of the person indicates they will be able to access follow up care including transplant medications in their home country that will ensure the viability of their graft.

Granting unplanned 'compassionate access' of this kind to travellers to Australia may in rare cases lead to a delayed or even missed opportunity for transplantation by an Australian resident, for example if a foreign patient is in more urgent need of a life-saving transplant than a local patient who then does not receive a suitably matched organ in time to save their own life. This may suggest that unplanned compassionate transplant offers are ethically inconsistent with the goals and values of policies aimed at achieving self-sufficiency in donation and transplantation. However, two key ethical considerations support the provision of unplanned compassionate access in exceptional circumstances.

1. Australian residents who are traveling abroad in other countries may also on occasion benefit from similar compassionate access policies.
2. Travellers to Australia may on rare occasions contribute to the deceased donation program if they die unexpectedly during their visit and their family makes a decision for them to donate. Similarly, Australian residents have occasionally become deceased donors while traveling in other countries. Unplanned compassionate access policies may therefore be underpinned by reciprocity and solidarity.

Planned compassionate access for international transplant candidates is explored in Chapter 9.4.5.

9.4.5 Foreign transplant candidates who plan travel for the purpose of transplantation

It is important to ensure that 'compassionate access' policies are not exploited by individuals seeking to take advantage of the availability of deceased donor organs and tissues in other countries. While it is understandable that people who are unable to obtain a timely transplant in their own country might wish to seek one in Australia, providing organs or tissues to those individuals – even if Australia had a more plentiful supply of donor organs – may be inconsistent with principles of equity in allocation. Those who are able to travel for the purpose of transplantation may not represent those who are most in clinical need of transplantation, and/or most likely to benefit from transplantation.

If wealthy patients are able to travel abroad to access deceased donor transplantation, this may also undermine efforts to establish effective deceased donation programs in their own country. For example, it may reduce political pressure on health authorities to invest in deceased donation programs in their home countries.

10. Commodification of cells, tissues, and organs and financial neutrality in donation

The availability of medical resources that consist of human cells, tissues or organs depends on the willingness of individuals to donate components of their own bodies, or on the willingness of families to authorise such donations on their behalf following their death. Donation may have risks or burdens for those individuals, and donors and their families may have specific and strong preferences about how donated cells, tissues or organs are treated. Consequently, cells, tissues and organs that are donated for transplantation are considered ethically exceptional medical resources that are distinct from other healthcare resources such as pharmaceutical products or therapeutic devices.

When human cells, tissues or organs are traded – i.e., bought and sold or otherwise exchanged in ways that treat them as if they have a monetary price – they are treated as if they are interchangeable with other saleable commodities such as dialysis machines, antibiotics, shoes, or televisions. This phenomenon is known as commodification. While some people may not mind if their body parts are traded for money, or otherwise treated just like ordinary, interchangeable goods, for many people this raises serious ethical concerns.

These concerns commonly relate to the potential impact of commodification on people's willingness to donate cells, tissues, and organs, and on equity in the donation or allocation of cells, tissues and organs. They also relate to the ways that we might treat human beings if we think of our own bodies or those of other people as having a monetary value or saleable price, for example by exploiting poor people's bodies in order to make money. Respect for the dignity of donors, recipients and their families and communities is a core value underpinning donation and transplantation in Australia which is threatened by practices that commodify human cells, tissues and organs (see Chapter 3.2.1 and Chapter 3.3.10).

Further readings and resources relevant to this chapter can be found in Appendix 1.

10.1 Ethical concerns about trade in human cells, tissues, and organs

Ethical concerns about the potential consequences of trade in human cells, tissues and organs, as well as the widely held belief that treating human body parts as ordinary commodities is inconsistent with respect for the inherent value or dignity of human beings (see Chapter 3.2.1) have underpinned widespread prohibitions of trade in human cells, tissues and organs in Australia and internationally. Laws governing trade are discussed in Chapter 10.2.

Common ethical concerns about trade in human cells, tissues and organs are informed by observation of the real impact of markets in human bodies – both legal and illegal – in various parts of the world. They include the following:

- Trade may result in unethical donor recruitment practices, such as use of financial incentives for donation that could exploit financially vulnerable people

who may be forced to sell their body parts in order to repay debts or cover the costs of meeting basic needs such as healthcare, education or funeral expenses (see Chapter 10.1.1).

- The ability to buy and sell human cells, tissues or organs for a profit might
  - encourage or incentivise use of unethical or illegal methods to obtain these materials from potential donors
  - undermine equity by incentivising allocation to those with the ability to pay or to pay more for transplants
  - encourage practices that lead to maximisation of financial profits rather than high quality care for donors and recipients and maximisation of the therapeutic benefits of donation for all
  - stigmatise donation and promote distrust in donation programs, such that only those in financial distress agree to provide their cells, tissues or organs for use in transplantation.

All of these concerns may also apply to practices that involve commercialisation of donation or transplantation activities such that individuals or organisations are driven by financial goals or individual stakeholder interests rather than the goal of promoting better access to the benefits of transplantation for all.

10.1.1 Incentives for donation

An incentive is something that is offered to an individual in order to influence their decision to make a particular choice. An incentive is thus usually an offer that is perceived as likely to leave the individual better off in some way.

For example, if a person is offered money in exchange for registering as a donor, this represents an incentive for registration. If the person registers, they will be financially better off than they would be if they chose not to register.

In contrast, if a donation program offers to cover the parking fees associated with parking while an individual completes the donor registration process at a particular location, this is not an incentive for donation. The payment for parking may ensure the individual is not worse off financially and will not leave them better off than they would be if they chose not to register.

An incentive is not inherently unethical, however **financial incentives for donation** are likely to violate the prohibition against trade in organs and tissues; they also raise concerns about voluntariness of consent and inequities in donation. For example, financial incentives are likely to have a more powerful effect on the decision-making of people who are in financial difficulty, and for whom the opportunity to gain financially may be necessary.

If financial incentives are offered to potential donation decision-makers, it is the poor or financially desperate who are likely to become donors. This would constitute exploitation of their financially vulnerable situation and may lead people to make decisions that they would otherwise prefer not to make. For example, if a family in financial difficulty lacks trust in the deceased donation program or does not wish to approve donation due to religious or cultural values and beliefs, they may feel compelled to agree to donation if offered a financial reward or some other reward of material value (e.g., a funeral for their loved one) in exchange for their consent. While such strategies may temporarily increase donation rates, they fail to address the

underlying factors that may be barriers to donation. In fact, financial incentives are likely to exacerbate such barriers by fostering distrust in donation programs.

The importance of financial neutrality in donation, which entails not only avoidance of incentives but also removal of financial *disincentives* for donation, is discussed in Chapter 10.4.

10.2 Legal aspects of prohibition of trade in human cells, tissues, and organs

In all Australian States and Territories there is a general prohibition in human tissue legislation against trading in human tissue, which encompasses organs and cells (see Chapter 3.5.1). In some jurisdictions it may also be an offence to perform acts related to buying and selling or advertising the buying or selling of human tissues or organs.

There are two common exceptions to this general prohibition, although these are not expressed uniformly across Australia. The sale or supply of tissue may be legally permitted

- where it has been subjected to processing or treatment and sale is for therapeutic or scientific purposes; or
- where the State or Territory Minister has approved a permit for sale in relation to human tissue.

Some States and Territories have specific exceptions for the operation of tissue banks allowing recovery of costs related to the direct provision of service (see Chapter 10.3). Limited exceptions also exist in some States and Territories for some blood products.

10.3 Distinguishing trade in cells, tissues, and organs from cost recovery in donation and transplantation

Trade may involve offering money or goods or services of financial value in exchange for consent to donation by potential donors or those making decisions about donation on behalf of potential donors. It may also involve offering donated cells, tissues, or organs to potential transplant recipients in exchange for money or goods or services of financial value.

For example, if an individual is evaluated as a potential kidney donor for their friend, and identified as a clinically suitable match, but agrees to donate only on the condition that the friend buys the donor a new car, this would constitute trade in organs. The car has a monetary value, and would be exchanged for the kidney, effectively setting a price on the kidney equivalent to that of the car. The donor would be financially better off as a result of donating, assuming that any costs for them associated with donation - such as taking time off work or traveling to the place where donation occurs - would be far less than that of the price of a new car. This would contravene the principle of financial neutrality in donation (see Chapter 10.4).

The term **'fee for service'** is sometimes used to refer to payments that may be associated with specific activities that are necessary to facilitate donation or transplantation. Such fees may also be referred to as costs of donation or transplantation activities. A range of steps (see Chapter 2) may be involved in removing cells, tissues, or organs from one person, processing or preparing this material for use

in transplantation, storing, transferring, and ultimately transplanting this into another person(s). At each step there are costs associated with these activities or services.

Covering these costs, which are necessary to facilitate donation and transplantation, is not considered trade in cells, tissues or organs as such. The costs associated with donation for donors or donor families may also be ethically and lawfully covered as discussed below in the context of financial neutrality in donation (Chapter 10.4).

Setting a fee or paying the costs for recovering or transplanting an organ or tissue is not the same as setting a price on or charging for an organ or tissue itself, as the examples below illustrate.

- A tissue bank which provides the bone graft to an orthopaedic surgeon may receive a fee in return for the service they have performed in supplying the graft through a specific cost assigned to the distributed graft. Payment of this fee is not for the tissue itself, but for the associated services required to make the graft available. In a cost-recovery model, this fee should reflect the apportioned costs associated with the range of services involved in removal, testing, processing, quality controls, storage and distribution of tissues. The orthopaedic surgeon, in turn, is paid to perform the procedure in which a patient receives a bone graft; they are not paid for the bone graft itself.
- A donation specialist, for example, may be paid a salary for time spent providing care to potential donors and donor families. This does not constitute payment for any organs or tissues recovered when donation proceeds.

However, it may be difficult to determine appropriate fees for services or to distinguish these from inappropriate financial profits. Some financial charges associated with services relating to donated cells, tissues and organs, may appear to set a price on the donated materials themselves, and thus to constitute trade in cells, tissues or organs. These issues are discussed further in Chapter 10.5.

10.4 Financial neutrality in donation

Financial neutrality in donation is a principle or concept meaning that donors or donor families should neither lose nor gain financially from donation.[173,174] Just as it is important to ensure that donation is not associated with a financial gain which would constitute payment for donation and hence violate the prohibition of trade in organs and tissues, it is important to ensure that people are not financially harmed as a result of their decision to donate.

Financial costs may be incurred by living donors and the families of deceased donors, and even by those who consider donation opportunities but who may not proceed to donate. Costs may be related to taking time off work for donation, or to provide care for a living donor. Costs might also be associated with travel, accommodation, telecommunications, or healthcare investigations and consultations related to donor screening, donation decision-making, donation itself, or follow up care for living donors.[173,175]

Promoting financial neutrality in donation is important not only because it reduces the risk of financial harm to donors and those who may be exploring opportunities for donation, but also because it reduces potential financial barriers to participation in donation opportunities. This means that it supports equity in donation and may enable more people to access transplantation.

10.4.1 Challenges in implementing policies to support financial neutrality

The type of costs incurred as a consequence of donation will differ for individuals, and some may be covered by donation programs, transplant recipients, social welfare or other governmental programs. For example, some living donors may have work related costs including leave covered by their employer, e.g. via the Supporting Living Organ Donors Program.

There are often concerns about which costs should be covered under the principle of financial neutrality, for fear of providing payments that might actually represent a financial incentive for donation (see Chapter 10.4.1.1). Although it is important to consider common costs associated with donation in particular settings, defining specific costs as eligible for coverage may not ensure financial neutrality for all donors. A fixed payment for donor travel costs, for example, might not cover all the costs of travel for some donors, but may represent a financial profit for others.

Although the term 'reasonable costs' may sometimes be used to describe costs associated with donation that should be covered, it may be difficult to determine when costs are 'reasonable'. It may be easier to distinguish between costs that are necessary and unavoidable, and hence which should be covered, and unnecessary costs. Payment of unnecessary costs may constitute a financial incentive or reward (see Chapter 10.4.1.1).

For example, a prospective living HSC donor might fly interstate in a private airplane and stay at a luxury hotel while undergoing further tests to determine if they are suitable donor. Although these may be genuine costs associated with donation, they are largely avoidable as the prospective donor may be able to undergo evaluation and complete donation in their state of residency. Even if travel is necessary, use of a private jet and luxury hotel stay would be avoidable.

10.4.1.1 Distinguishing coverage of donation costs from incentives or rewards for donation

In some cases, confusion may arise because people consider coverage of costs as a form of reward or recognition of donation, rather than a way to achieve financial neutrality of donation and avoid causing financial harm to those who donate.

For example, in some countries, families who approve deceased donation are rewarded by payments that are intended to cover the costs of a funeral for the deceased donor. However, such payments often serve as an incentive to donate, because they represent a financial gain for families who approve donation (see Chapter 10.1.1). These families would otherwise have to pay for the funeral of their loved one, so the cost of the funeral is not actually a cost of donation.

A simple way to determine whether a cost is donation-specific and, as such, whether it should be covered for or reimbursed to donors, is to ask whether the individual or family concerned would have incurred this cost in the absence of donation.

Care should be taken to establish clear policies or guidelines to support coverage or reimbursement of necessary costs associated with donation. If policies are not clearly communicated, for example, they may inadvertently cause harm. Announcements that donors will be paid to donate or will receive a lump sum of money to cover travel costs, for example, may incentivise or stigmatise donation even if the actual payments do not leave donors financially better off.

The way that costs are covered may differ in specific settings and some flexibility may be required to reduce administrative burdens on donors as well as healthcare institutions. Programs that cover costs directly, for example by providing travel or parking vouchers for prospective donors undergoing screening, may be more effective in reducing barriers to donation and achieving neutrality, and less burdensome than programs which reimburse costs once these have been incurred.

The value of donation is priceless, and the gifts of donors are made without expectations of or entitlement to rewards. Donors should be celebrated, and their gifts acknowledged (see Chapter 3.2.1.1) using a range of strategies, such as public tributes, commemorative events and memorials and communication of thanks. Such acknowledgements should not take the form of rewards of financial value.

10.5 Cost recovery and profit management for donation and transplantation

In addition to the costs potentially incurred by donors or donor families, the costs of donation and transplantation may also include fees for services or goods that are necessary for the safe and effective performance of donation and transplantation, as noted in Chapter 10.3. In many cases, this may result in generation of a financial surplus or profits by organisations involved in donation and transplantation activities, especially in the context of tissue banking (see Chapter 10.5.1.1).

This is an important consideration because when professional activities in donation and transplantation are perceived to create significant or inappropriate profits, this may undermine public trust in the integrity of donation and transplantation programs and discourage participation in donation. Generation of profits may give the impression that the financial gain is produced from the removal or exchange of cells, tissues or organs which may indirectly or directly treat donated materials as commodities.

It may sometimes be difficult to determine when profits are appropriately generated and used, in part due to difficulties in defining costs and set fees for services for reasons outlined in Chapter 10.5.1. Potential strategies to guide determination of ethically appropriate costs and fees for services are discussed in Chapter 10.5.2.

In some circumstances generation of profits from donation and transplantation activities may be ethically appropriate, when this is necessary to cover the costs associated with achievement of the goals of donation and transplant programs. However, generation of profits may also reflect ethically inappropriate 'profiteering' activities that seek to create profits in ways that undermine the values and goals of donation and transplant programs. Ethical considerations with regards to generation and management of profits are discussed in Chapter 10.5.3.

10.5.1 Difficulties in defining and quantifying costs of donation and transplantation activities

Defining and quantifying specific costs for particular donation and transplantation activities may be difficult for several reasons. First, standardising legitimate costs across Australia is difficult because costs may fluctuate over time and may differ according to the particular context in which donation and transplantation occurs and in which organ transplantation services or tissue banks operate.

For example, larger tissue banks with a higher volume of activity may be able to operate more cost effectively, as a result of economies of scale. Similarly, some hospitals may face higher costs in retrieving organs from deceased donors, for example when a surgical team is required to travel for donation surgery or when donated organs must travel interstate for transplantation.

Fluctuations in donor numbers may also impact cost recovery in tissue banks, when costs are covered via fees associated with supply of grafts. The major costs of operating a tissue bank, for example, with staff salaries and maintenance of facilities and equipment may remain largely the same regardless of the level of activity. However, cost recovery will be influenced by fluctuations in donor numbers and proportionate to the number of grafts supplied. This problem is reduced when operational costs are partly covered as public health funding.

Second, in order to recover the costs of performing donation and transplantation activities, some organisations or institutions may effectively set a price on cells, tissues or organs at the point of delivery for transplantation. For example, a tissue graft may be purchased by a hospital for use in a transplant procedure, and the fee paid to the tissue bank that provides this product will contribute to the costs of employing staff, maintaining the tissue bank infrastructure and the various activities of the bank in procuring, processing, storing and distributing various tissue products, and maintaining regulatory compliance. It may thus be difficult to determine whether the specific price set for this tissue product is equivalent to the direct costs associated with its production, and hence whether the price is legitimate.

Third, lack of data about the various costs and factors influencing donation and transplantation activities in particular contexts, and the complexities of funding associated with related healthcare institutions and systems make it difficult to obtain a clear picture of the 'economy' of donation and transplantation and to make comparisons between the fees or costs charged by various stakeholders.

10.5.1.1 How cost recovery models may complicate tissue banking

If fees for services or prices associated with removal, storage or distribution of tissue donations are too high, this could mean that the organisation responsible for these activities is obtaining a profit from the donation, and effectively trading in tissues. If too low, this could mean the organisation is not adequately covering its costs and may thus be jeopardising its economic sustainability and ability to provide high quality services.

As noted in Chapter 10.5.1, the costs of producing specific tissue grafts within a particular bank may vary for several reasons. This means that when particular grafts are purchased by health professionals, the same type of graft may be cheaper if obtained from one tissue bank rather than another.[176] Thus the distribution of tissue products within Australia may in some circumstances operate like an open market in ways that can impact the sustainability of individual tissue banks, as some banks may be forced to offer products at a cost that is not sustainable or risk being outpriced by a competing bank.

This can also influence decision-making with regards to manufacture of particular tissue grafts, as some tissues may be processed for use in grafts that will attract a higher fee than others despite costs of production that may be similar. Importation of tissue grafts from outside Australia may also threaten sustainability or influence decision-making about fees charged for supply of particular grafts (see Chapter 9.3.2).

Cost recovery models are also challenging for the economic stability of tissue banks as processed tissues may often be stored for significant periods of time, resulting in variable time lags between expenditure and recovery of incurred costs. This may encourage or necessitate generation of a financial surplus in order to protect against periods in which costs cannot be recovered. Finally, the expenses involved in the development of new technologies and introduction of new tissue grafts may not be accounted for in cost-recovery modelling, hindering growth and innovation.

10.5.2 Determining ethically appropriate costs and fees for services relating to donation and transplantation activities

Determination of legitimate fees for services or costs of goods required for donation and transplantation activities should be guided by consideration of the fees and charges associated with similar activities or goods outside the context of donation and transplantation. Fees for services such as medical consultations, investigations and procedures should be consistent with fees associated with similar activities which do not involve donation and transplantation. By calculating reasonable fees and charges, and the proportion of these costs that may be associated with eventual supply of specific types of cells, tissues, or organs for transplantation, it should be possible to estimate the overall costs that may need to be recovered by particular service providers.

For example, the general costs associated with removal of a kidney for therapeutic purposes should be similar to those of removing a kidney for the purpose of donation, although some elements may differ (e.g., complexity of operation and related investigations and follow up may be different). Similarly, fees for services such as collection, transport and storage of human tissues should be consistent with fees associated with similar activities involving medical products of nonhuman origin, noting that some elements may differ (e.g., costs associated with maintaining necessary systems for traceability of tissues, biovigilance and surveillance).

When setting a price on goods and services relating to donation and transplantation, this should be determined by what is

- necessary to provide high quality, safe care to potential and actual donors and transplant recipients
- proportionate to equivalent activities outside the context of donation and transplantation
- necessary to promote and maintain sustainable and equitable programs of donation and transplantation within Australia.

These considerations in turn will require further specification, for example in determining what is necessary to provide high quality care for donors and transplant recipients. For example, there may be research and development costs associated with efforts to improve the quality of organ or tissue grafts, and costs of training staff involved in various donation and transplantation activities. Some such costs may be considered necessary, in the strictest sense, but not in all circumstances. Coverage of these more indirect costs associated with donation or transplantation is discussed in the context of ethical profit management in Chapter 10.5.3.1, as profits may sometimes be generated or used to support activities such as research or training.

10.5.3 Managing profits in donation and transplantation

It is not always feasible to associate individual donations or specific cells, tissues or organs that are made available for transplantation with an itemised fee reflecting the relevant proportion of all costs associated with removal, storage, distribution, and quality assurance of the cells, tissues or organs, given the economic complexities outlined in Chapter 10.5.1. This means that on a case-by-case basis, not all costs may be recovered, or profits – a financial surplus – may be generated. Collectively, donation or transplantation activities in specific settings may run at a financial loss, or conversely generate profits in excess of the costs incurred in performing these specific donation and transplantation activities.

If profits are used to cover the costs incurred by other donation and transplantation activities this may not be problematic, provided that efforts to subsidise the costs in one part of the sector do not undermine equity of access to transplantation. For example, profits generated by supply of some tissue grafts by a tissue bank may be used to subsidise costs associated with supply of other types of graft. The fundamental concerns are that donation and transplantation should not be driven by financial gain; access to donation and transplantation should be equitable and not influenced by the ability of donors or recipients to pay for donation or transplantation; the overall costs associated with donation and transplantation activities should be covered fairly; and donated cells, tissues, and organs should not be treated as commodities. Profit generation may also be associated with increased costs of donation and transplantation services that could negatively impact equity of access to donation and transplantation.

In some cases, significant profits may be inadvertently or intentionally accrued. When accrued inadvertently, review should help to determine the cause(s) of profit production and how to resolve this, for example by lowering the charges associated with performance of particular activities or delivery of particular organs or tissue products. Profits that are unintentionally accrued should be managed according to the principles set out for management of intentionally generated profits (see Chapter 10.5.3.1).

In order to ensure the ethical governance of donation and transplantation activities, economic or financial aspects of these activities must be routinely and transparently disclosed (see Chapter 10.5.3.2).

10.5.3.1 Conditions in which intentional generation of profits from donation or transplantation activities may be considered ethically acceptable

Profit generation should only be pursued

- when necessary to support the goals and values that underpin public engagement in donation, such as the equitable allocation of cells, tissues or organs to those in need of transplantation
- if the pursuit of profits does not jeopardise these goals and values
- if activities and financial data are routinely and transparently reported to allow public scrutiny and oversight (see Chapter 10.5.3.2).

Reasons for which generation of profits might be ethically pursued:

- to cover anticipated future costs of maintaining donation and transplantation programs, for example to enable investment or renewal of core infrastructure at a tissue bank

- to improve the quality of care for donors or transplant recipients, for example by investing in research that will inform clinical practice or development of better therapeutic products
- to provide a level of financial insurance against unexpected future costs or financial injury.

10.5.3.2 Requirement for financial transparency in donation and transplantation activities

To ensure the integrity of donation and transplantation activities, and so that individuals and organisations involved in these activities may be held accountable to the public, the economic activities of the sector should be transparent.

Transparency should also assist in review of the various sectors to ensure that the broader Australian economy and healthcare funding systems are not jeopardising the sustainability of individual organisations such as tissue banks or donation or transplant programs.

Requirements for transparency and accountability include

- the maintenance of records for auditing purposes
- communication of fees and charges
- justification of costs and prices in accordance with the principles outlined in Chapter 10.5.2
- definition of profits arising from donation and transplantation activities and explanation and justification of how these are managed.

Case Study – Management of profits in a tissue bank

Mariela is the Chief Executive Officer of a not-for-profit tissue bank. When reviewing the annual accounts with her finance officer, she notes that the bank has earned a significant amount of money from the supply of X, a specific type of tissue product derived from bone. This product has been extremely popular in orthopaedic surgeries over the past year after an influential surgeon published the results of research which showed excellent patient outcomes in procedures using X.

A high fee was charged for supply of X because of the substantial infrastructure and training costs associated with development and manufacture of the product, and because Mariela had assumed that there would be limited demand for X, making it difficult to cover costs. However, due to the high level of demand, the bank in fact earned substantially more money than was expended on the production and supply of X, generating a large net financial gain.

The financial officer asks Mariela what she would like to do with the surplus funds.

Points to consider:

- This case highlights the potential complexities of charging fees for service in tissue banks that will cover costs without creating undue profits (see Chapter 10.5.2).

- Two principles are especially relevant to this case:
  - **Principle 10** Human organs, tissues and cells should not be treated as ordinary commodities that can be sold or exchanged for profit: any profits arising from the removal, processing, distribution, storage, transfer or use of donated cells, tissues or organs should be used to enhance quality, safety, sustainability, and equity in healthcare for all.
  - **Principle 11** Decision-making about donation and transplantation should be free from coercion, exploitation or financial incentives; this should not preclude coverage of costs associated with donation or transplantation.
- There are several factors that may determine whether Mariela decides to adjust the fee for this particular tissue product, and if so, how she adjusts fees, as well as what she plans to do with the surplus funds. For example, the profits generated from supplying X might be used to subsidise the cost of other products which are expensive to produce, making it easier for the bank to supply those products at a lower cost. This in turn may improve access to important therapeutic products.
- However, if fees for various products are adjusted to cover costs overall and to improve availability of products, it is important that the tissue bank gives consideration to which products may be most therapeutically valuable to patients. The level of demand for a product may not reflect its therapeutic value, and in turn could be influenced by the fees charged for supply.
- Mariela may also consider using the profit gained from supply of X to invest in quality improvements in the bank or in research.
- It is important that tissue banks regularly audit their finances so that decision-making about fees for service can be informed by an understanding of costs across the bank as a whole (see Chapter 10.5.3).

10.6 Organ and tissue trafficking

Organ and tissue trafficking may involve one or more of a range of activities that effectively treat organs and tissues as saleable commodities or otherwise violate the legal and ethical requirements for donation (see **Box 10.1**).

Trafficking of both organs and tissues may cause significant harm to donors and their families and communities. Trafficking also undermines safety, quality, and equity of access to transplantation and undermines public trust in living and deceased donation programs. Worldwide, up to 10% of solid organ transplants are estimated to involve organ trafficking;[161] however the extent of trafficking in human tissues is unknown.[177] Data relating to trafficking activities are scarce, and only sporadic reports of trafficking cases in the media shed light on the ways in which organs and tissues have been stolen or taken by force from donors, and/or sold or otherwise exchanged for financial gain.

Box 10.1 Definition of organ (or tissue) trafficking

The Declaration of Istanbul on Organ Trafficking and Transplant Tourism defines organ trafficking activities as follows:

a) removing organs from living or deceased donors without valid consent or authorisation or in exchange for financial gain or comparable advantage to the donor and/or a third person

b) any transportation, manipulation, transplantation, or other use of such organs

c) offering any undue advantage to, or requesting the same, by a health professional, public official, or employee of a private sector entity to facilitate or perform such removal or use

d) soliciting or recruiting donors or recipients, where carried out for financial gain or comparable advantage, or

e) attempting to commit, or aiding or abetting the commission of, any of these acts.[6]

The same types of activities involving human tissues rather than organs would constitute trafficking in human tissues.

Health professionals and institutions involved in donation and transplantation activities have ethical and legal obligations to refrain from involvement in trafficking of organs or tissues, to assist in preventing trafficking where possible, and to take action in response to potential trafficking that may have occurred. These duties are discussed in the context of organ trafficking in Chapter 10.6.1 and trafficking of tissues in Chapter 10.6.2.

10.6.1 Organ trafficking

Organ trafficking, particularly the sale of kidneys from living 'donors', has attracted widespread attention since the 1990s. Reports of the 'black market' in organs have stimulated efforts to prevent trafficking as well as so-called 'transplant tourism.' Transplant tourism is associated with travel of wealthy patients from countries like Australia to purchase organs on the black market in other countries (see also the discussion of transplant tourism in Chapter 9.4.1). It is estimated that few Australians are involved in organ trafficking each year, based on the small number of Australian patients who are annually removed from the dialysis registry after receiving a transplant outside the country, not all of which may involve trafficking.[162] Anecdotal reports of patients who return to Australia after receiving another type of organ transplant involving trafficking are also rare, as are cases of attempted trafficking within Australia.[178]

Nevertheless, in the absence of systematic reporting of international travel for organ transplantation from Australia and lack of formal mechanisms within Australia for reporting cases of suspected travel involving trafficking, it is difficult to quantify the extent of Australian involvement in organ trafficking. Reports of attempted and proven trafficking from around the world highlight the importance of ongoing vigilance and efforts to deter and detect trafficking involving Australians.[177]

Australians may be involved in organ trafficking in the following ways:

- a person travels from Australia to another country for the purpose of obtaining a transplant that involves a trafficked organ ('transplant tourism', see Chapter 9.4.1)
- a person travels to Australia from another country for the purpose of buying an organ that will be transplanted within Australia
- a person travels to Australia from another country for the purpose of selling an organ that will be transplanted within Australia
- a person within Australia may seek to sell or purchase an organ for transplantation within Australia (domestic organ trafficking).

Of note, intent to buy or sell an organ constitutes involvement in organ trafficking, regardless of whether organ removal or transplant in fact occurs, as per the definition in **Box 10.1**.

Internationally, organ trafficking is associated with exploitation, coercion and significant long term physical, and psychosocial harm to organ sellers and their communities,[179] as well as serious risks of medical complications and criminal prosecution for recipients of their organs.[163–166,180,181]

In many circumstances, involvement in these activities may constitute trafficking in human beings, which involves movement of people across jurisdictional borders for the purpose of exploitation using coercion or deception. In Australia there are criminal offences associated with trafficking people for the purpose of them acting as a living donor (see *Criminal Code Act 1995* (Cth), chapter 8, Div 271, Subdiv BA). These offences are applicable to situations of trafficking within Australia, as well as when trafficking involves the removal of someone from Australia or bringing someone into Australia.

10.6.1.1 Prevention of organ trafficking from living donors within Australia

The prevention of organ trafficking within Australia is a key priority. It is also important to prevent, where possible, Australian involvement in trafficking activities overseas (see Chapter 9.4.2), and to support other countries in their efforts to address trafficking. A number of potential strategies for prevention of organ trafficking within Australia are outlined in **Box 10.2**. Transplant professionals may require training to implement these and other potential strategies effectively.

Box 10.2 Potential strategies to address organ trafficking within Australia

Careful evaluation of prospective living donors and recipients helps to identify and prevent cases of living donor organ trafficking. This requires:

- **Routine and standardised psychosocial evaluation of all prospective living donors** (see Chapter 6.1.3)[177]
- **Attention to potential donor risk factors for organ trafficking such as**
  - financial vulnerability, including precarious employment, debts
  - power differentials between prospective donors and recipients (and families), e.g., employee-employer relationship, significant differences in economic status
  - lack of evidence of interpersonal relationship between donor and recipient, or unclear motivation for donation
  - presence of apparent substantive cultural, linguistic or social differences between donors and recipients
  - indicators of potential human trafficking.[182]
- **Use of appropriately trained staff**. Multidisciplinary teams should include:
  - routine use of interpreters when there is one or more parties for whom English is not a first language
  - social workers and clinical psychologists
  - staff with relevant cultural or linguistic knowledge to enable culturally safe and informed assessment of relationships between prospective living donors and transplant recipients that may present differently as a result of cultural norms.
- **Time** as necessary to ensure quality of screening, support for decision-making and provision of support to prospective donors who may wish to withdraw consent.

When a confirmed or suspected case of organ trafficking is identified within Australia this should be referred to relevant authorities for investigation, noting that support services are available for victims of human trafficking in Australia. Ethical considerations with regards to reporting of transplant-related crimes are discussed in Chapter 10.6.1.2.

10.6.1.2 Reporting transplant-related crimes

Health professionals are legally required to disclose confidential information about patients in specific circumstances according to mandatory notification duties. These include circumstances where the health professional has reason to believe children may be at risk of harm. In some jurisdictions medical practitioners may also have a mandatory duty to report patients who present with firearms injuries, and in others may be permitted to report such injuries with protection from liability for any breach of privacy. As discussed in Chapter 7.1, these types of legal exceptions to privacy and confidentiality duties are justified ethically on the grounds that disclosure of such information to relevant authorities is necessary to prevent significant harm to others.

In the case of organ trafficking, there is currently no requirement to disclose suspected or even established cases of trafficking or attempted trafficking, however medical practitioners are explicitly urged to report suspected human trafficking for organ removal within Australia.[178] Health professionals may hesitate to report potential transplant-related crimes due to concerns about legal liability or due to the belief that organ trafficking is not something which represents a significant harm to others.

However, there are several reasons to consider reporting of organ trafficking, especially when this occurs within Australia. These include the following:

- reporting may be necessary to ensure that sufficient protections are provided to individuals who may be victims of human trafficking and at risk of further significant harm
- reporting may lead to identification of individuals who may be operating as organ 'brokers' and facilitating domestic or international trafficking rings, and hence may result in prevention of further trafficking activities
- failure to report may lead individuals who have attempted trafficking within Australia to seek care at other transplant centres where donation and transplantation may proceed without recognition of trafficking activities.

In addition to the harm that may be prevented by reporting, reporting also serves to protect the integrity of Australia's donation and transplant programs. Given that organ trafficking – when successful in leading to transplantation – necessarily involves health professionals and organisations, if trafficking activities are later revealed to have taken place within Australia, this can undermine public confidence and raise suspicions regarding the possible involvement or tolerance of trafficking by donation and transplantation programs. The Australian Government notably encourages medical professionals to report cases where they are 'aware of, or suspect someone has been, or will be trafficked' to the Australian Federal Police.[178]

10.6.2 Trafficking in human tissues

With regards to tissue trafficking, key strategies to prevent tissue trafficking include a restriction on imports of tissue products to those that are clearly traceable via systems that meet Australian standards for ethical practice and are compliant with the requirements of the Biologicals regulatory framework (see Chapter 3.5.2). Scrupulous governance of deceased donation programs and the tissue banking sector, including transparent reporting of activities (see Chapter 7.4), also helps to prevent illicit trade in organs and tissues.[177,183]

11. Ethical issues in deceased donation of organs and tissues

Individuals' values and preferences should be of paramount importance in end-of-life decision-making, including, where relevant, their potential preference to become a deceased donor if possible. However, health professionals must balance their duty to respect the autonomy of patients with other ethical, legal and professional duties. While every effort should be made to support deceased donation of organs and tissues where possible, ethical issues may arise where the goals of donation may conflict to some extent with other goals relating to end-of-life care, or with ethical and professional obligations on the part of health professionals. Safeguards are thus needed to protect the integrity of decision-making in the context of end-of-life care, including decision-making about donation opportunities.

In this chapter a number of specific ethical issues are briefly explored that are relevant to donation and transplantation of organs and tissues from deceased donors. These relate to:

- The 'dead donor rule' (Chapter 11.1)
- The determination of death (Chapter 11.2)
- Potential conflicts of interest in end-of-life care (Chapter 11.3)
- Ante-mortem interventions for deceased donation (Chapter 11.4)
- Routine consideration of opportunities for deceased donation (Chapter 11.5)
- Donation by individuals who choose to cease life sustaining treatment (Chapter 11.6)
- Donation after voluntary assisted dying (Chapter 11.7)
- Donation by infants with anencephaly (Chapter 11.8)
- Post-mortem interventions for deceased donation (Chapter 11.9)

Additional issues relating to deceased donation are discussed in Chapter 12, including directed and conditional donation (see Chapter 12.3.3). Further readings and resources relevant to this chapter can be found in Appendix 1.

11.1 Understanding the 'dead donor rule'

One of the most important ethical norms in donation and transplantation is the requirement that organs or tissues should not be removed from a person for the purpose of transplantation if their removal is expected to result in the death of the donor. That is, donation should not cause the death of the donor; donation should only take place after the donor has died.

Often referred to as 'the dead donor rule',[184–186] this means that a person must be determined to be dead in accordance with the relevant clinical and legal standards (see Chapter 3.5.1.1), before vital organs such as the heart, the liver, both lungs or kidneys are removed.

Although tissues are frequently overlooked when the 'dead donor rule' is discussed, there is an implicit expectation that tissues required for normal functioning, such as the corneas, muscles, bones and so on should also not be removed from a living person for transplantation, except when these are removed for therapeutic purposes or in the specific conditions under which living donation is ethically permissible.

Interventions that are intended to cause or hasten death for the purpose of enabling organ donation are also considered to breach the dead donor rule,[184] even though organs may not be removed until after death has occurred. That is because it is donation which indirectly causes death, even if it is not the removal of organs itself that causes death. This implies that decisions which may result in the death of a person should not be influenced by donation goals. That is, a person should not be permitted or supported to cease life sustaining interventions or to hasten their death – for example via voluntary assisted dying – for the purpose of becoming a donor, as this would breach the rule. Individuals are entitled to make decisions about cessation of life sustaining treatment or use of voluntary assisted dying in a range of circumstances, but these decisions must be made independently of donation decisions. See Chapter 11.6 and Chapter 11.7.

As an ethical standard, the dead donor rule is of fundamental importance because it enables the public to trust in deceased donation programs. It makes clear that choosing to be a donor will not place individuals at risk of being killed or severely harmed by people seeking to obtain organs and tissue for use in transplantation, and that end-of-life care will not be compromised for the purpose of facilitating donation.

11.1.1 Perceived limitations of the dead donor rule

Some commentators have suggested that the dead donor rule may act as a barrier to donation and should be relaxed in some circumstances.[187,188] This is because the requirement to await the death of the donor before commencing donation may sometimes prevent or reduce the probability of successfully retrieving organs or tissues for transplantation.

These commentators suggest that if a person is definitely going to die because a decision has been made to cease efforts to keep them alive using life sustaining interventions, then if that person wishes to become a donor it should be possible to remove their organs before life sustaining interventions are ceased, and hence before the person actually dies, so that the organs are well perfused and suitable for transplantation. Such a position effectively suggests that it wouldn't matter if removing organs and tissues caused the death of a person, if that person was going to die soon anyway, and the removal before death was necessary to achieve their goal of successfully donating.

Some people appear to be less concerned about respect for the dead donor rule if it undermines opportunities for donation.[185] In some individual cases it may seem frustrating to require that a person is dead prior to donation, if this means that the person misses the opportunity for donation and others miss the opportunity to benefit from transplantation.[187] However, if the standard of the dead donor rule were undermined, as it would be if exceptions were permitted, this could risk greatly undermining public trust in deceased donation. This is because of the risk that conflicts of interest might lead health professionals or family members to make decisions in favour of donation that may cause harm to potential donors (see Chapter 11.3). It is probable that if the dead donor rule was abandoned, loss of public trust would result in far fewer donations overall. Furthermore, use of new technologies is increasing the successful recovery and transplantation of organs in circumstances where the dead donor rule has been considered a barrier to donation. For example, in the setting of donation after circulatory determination of death, machine perfusion of organs following donation and before transplantation is improving successful recovery of donor hearts.[189]

11.2 Ethical considerations in the determination of death

When clinical interventions aimed at prolonging life are discontinued and a person dies, the person's family or friends may commence the social and cultural processes that take place following the death of a loved one, such as transferring a person's body from a hospital to a funeral home in preparation for burial or cremation. If a decision has been made in favour of donation of organs or tissues after death, the determination of death is also critical as it means that donation procedures can now commence, in accordance with the dead donor rule (see Chapter 11.1).

The determination of death is a clinical process in which a qualified medical practitioner assesses a person in order to make a diagnosis of death. This clinical determination of death must satisfy the legal requirements for determination of death (see Chapter 3.5.1.1) Death may be determined using neurological or circulatory criteria (see Chapter 2.4.1). The colloquial terms 'brain death' and 'cardiac death' are sometimes used to refer to diagnoses of death using these respective criteria. However, use of these terms should be avoided as they may create confusion or give the impression that a person is not genuinely dead in some circumstances despite being dead according to legal and clinical criteria. It is vital that people have confidence in the ability of health professionals to accurately diagnose death.

The ANZICS Statement on Death and Organ Donation provides detailed clinical guidance on the determination of death, including in circumstances where organ and tissue donation are considered.[13] There are various procedures and protocols that may be used to clinically determine death in accordance with the established legal standards, which are described in the ANZICS statement. Of note, this statement refers to 'permanency', rather than 'irreversibility', when describing clinical criteria used in the determination of death, which is consistent with international practice and recommendations.[13,190,191]

A number of ethical considerations may arise with regards to the determination of death. In the context of deceased donation, the main ethical concern is to ensure that potential conflicts of interest with regards to donation opportunities do not undermine the integrity of the determination of death (see Chapter 11.2.2). When people hold different beliefs regarding the determination of death, this can also result in ethical concerns (see Chapter 11.2.1).

11.2.1 Different perspectives regarding the determination of death

The determination of death must always be made in accordance with established clinical standards that satisfy the legal definition of death (see Chapter 2.4.1). However, it is also important to be mindful of the cultural and spiritual aspects of death and dying which may not always align precisely with clinical and legal standards. Individuals may hold different beliefs regarding the concept of death, and some individuals may thus have different perspectives regarding the clinical determination of death. For example, some people may believe that a person is only deceased when their heart is no longer beating, and therefore may not recognise death when this is determined by neurological criteria. In some cases, such perspectives may influence decision-making about end-of-life care and about opportunities for deceased donation. It is important that health professionals provide culturally safe care when supporting patients and families, and engage respectfully with different perspectives regarding death in the context of end-of-life decision-making.

Where a health professional holds personal beliefs regarding the determination of death that may influence their attitudes towards deceased donation, they should take steps to ensure that these do not inappropriately influence opportunities for individuals and families to make informed and voluntary decisions about donation (see the discussion regarding conscientious objection in Chapter 3.7).

11.2.2 Conflicts of interest in the determination of death in potential deceased organ donors

Due to the significance of the 'dead donor rule', it is essential that potential conflicts of interest in the determination of death in potential organ donors are carefully managed (see Chapter 11.3). This also includes perceived conflicts of interest. If there is a perception that health professionals involved in the determination of death have an interest in declaring death prematurely (i.e., before a person has actually died), for example in order to successfully obtain organs that may be used in transplantation, this may greatly undermine trust in deceased donation.

Use of standardised procedures and criteria for the determination of death, and separation of the roles of individuals who may be involved in determination of death from those of individuals who may be involved in removal of organs or tissues after death helps to ensure integrity in the determination of death in potential donors (see Chapter 11.3). As discussed in Chapter 3.8, such strategies are aimed at reducing the potential influence of competing interests on decision-making and the fulfilment of primary duties.

Specific procedures and standards are in place for the determination of death by neurological criteria, which include a requirement for two medical practitioners to confirm the diagnosis of death. These measures ensure there are clear standards for the determination of death by neurological criteria irrespective of whether donation is a possibility. The requirement for two medical practitioners to independently confirm the diagnosis also acts as safeguard to ensure the clinical diagnosis is appropriate (see Chapter 2.4.1.1).

Diagnosis of death using circulatory criteria is less clinically complex than that using neurological criteria and is the most commonly used method for determination of death. However, additional safeguards are needed to ensure that potential or perceived conflicts of interest relating to donation after circulatory determination of death are managed. This is especially the case when organ donation following circulatory determination of death is considered, because the duration of time that is used to make a diagnosis of death following the cessation of circulation may negatively impact the chance of organs being successfully retrieved for use in transplantation (see Chapter 2.4.1.2).

ANZICS provides clear guidance regarding the clinical standards for the determination of death following cessation of circulation when organ donation is considered. These include the requirement for a period of observation following cessation of circulation before death is declared and organ donation can proceed, in circumstances where a decision has been made to cease or not to initiate interventions that may sustain or restore cardiorespiratory functions.[13] Other guidelines of relevance are noted in the further resources for this chapter in Appendix 1.

11.3 Management of potential conflicts of interest in deceased donation and end-of-life care

Separation of clinical roles and responsibilities with regards to end-of-life care, donation decision-making, determination of death in a potential donor and any subsequent donation or transplantation procedures is an important strategy in managing actual, potential and perceived conflicts of interest. The person or persons with clinical responsibility for the determination of death in a potential donor should not be involved in subsequent donation procedures in that individual.

As discussed in Chapter 3.8, role separation can help to avoid conflicts of interest, for example by ensuring that those with duties to provide optimal end-of-life care to a potential donor do not also have obligations to obtain organs for transplantation in other patients that might inappropriately influence their actions when providing end-of-life care to the potential donor.

Role separation is particularly important where there may be a direct conflict of interest. A direct conflict would occur, for example, if a donation specialist providing care to a potential donor is concurrently providing care for a transplant candidate who might benefit if the donation proceeds.

Clear separation, definition, and disclosure of roles in particular contexts help to promote transparency and trust and ensure that patients and their families are provided with support and advice from suitably qualified health professionals with regards to different aspects of care.

Separation of roles should not preclude a collaborative approach to care of potential donors nor continuity of care throughout the end-of-life period.[192] Regardless of roles, the wellbeing of a potential donor prior to their death should always be a clinical priority in accordance with the duty of care (see Chapter 3.3.4.1).

Of note, health professionals may play multiple different roles in different contexts. For example, a health professional who has part time duties as a donation specialist may not always be acting in a donation specialist role. Regardless of the role that a health professional is performing when providing care, they should be mindful of professional and personal interests and attitudes that may influence their approach to care.

Separation of decision-making is also an important element of managing potential conflicts of interest in end-of-life care of potential donors. In particular, decisions about the cessation of life sustaining interventions should be separated from decisions about deceased donation.

Although it is possible that individuals or their families may wish to discuss the potential for deceased donation when discussing a patient's prognosis or end-of-life care, they should be encouraged to focus first on making relevant decisions about end-of-life care. Only when a decision has been made to cease or not to initiate life sustaining treatment should decision-making about deceased donation opportunities occur.

If a decision has been made to proceed with deceased donation following a decision to cease or not to initiate life sustaining interventions, further decisions may be required about end-of-life care that may include consideration of ante-mortem interventions aimed at facilitating successful donation (see Chapter 11.4). In such cases, it may not be possible or appropriate to separate decision-making about donation from general decisions about end-of-life care. **In all such decisions, the interests and wellbeing of the potential donor should be prioritised.**

Additional strategies to assist in managing potential conflicts of interest in end-of-life decision-making may be needed (see Chapter 3.8).

11.4 Ante-mortem interventions for deceased donation

A range of interventions may occur prior to a person's death that may help to preserve or provide opportunities for them to become a donor, or to increase the probability of donation leading to successful transplantation (see Chapter 2.5.4). These are particularly important in the context of organ donation after circulatory determination of death but may also be relevant in other donation contexts.

Ante-mortem interventions for donation are considered non-therapeutic interventions, meaning that their primary purpose is to facilitate donation, not to restore or enhance the health of the potential donor. These interventions may cause uncertainty or ethical concern regarding consent, privacy (see notification of potential deceased donors in Chapter 11.5), conflicts of interest in decision-making (see Chapter 11.2.2 and Chapter 11.3), proportionality of risks and potential benefits, and equity of opportunity for donation. There may also be legal uncertainty regarding some interventions in some jurisdictions (see Chapter 11.4.1).

Some ante-mortem interventions may involve minimal burdens or risks to the potential donor. For example, blood tests may be taken to determine eligibility for deceased donation (e.g., screening for infectious disease and tissue typing), or physiotherapy may be used to preserve the quality of lungs in an intended donor. The more invasive and potentially burdensome the intervention, the more concern there may be to ensure that decisions are being made in the interests of the potential donor. Regardless of which type of intervention is concerned, decision-making about ante-mortem interventions for the purpose of donation, like all end-of-life care decisions, should prioritise the interests of the individual as the patient to whom is owed a primary duty of care.

11.4.1 Legal aspects of ante-mortem interventions for deceased donation

When a person is competent, they may directly consent to ante-mortem interventions (see Chapter 11.6). However most decision-making about ante-mortem interventions for deceased donation involves substitute decision-makers, at a time when the potential donor is critically ill and unable to make decisions on their own behalf. The law in most of Australia (with the exception of Victoria and New South Wales) is unclear regarding whether substitute decision-makers are able to lawfully consent to ante-mortem interventions which are non-therapeutic in nature and predominantly aimed at improving the chances of a person successfully donating organs after their death.

This means that in some circumstances there may be no specific guidance regarding the requirements for obtaining legally valid consent to specific interventions.

In contrast Victoria and New South Wales have amended their human tissue legislation to clarify that ante-mortem interventions (called 'Ante-mortem procedures' in the legislation) are lawful. The legislation allows a designated officer (see Chapter 4.4.1) to authorise these interventions including where a substitute decision-maker in Victoria or senior available next of kin in NSW has consented to those interventions.[193,194]

Legislative amendments to provide clarity regarding consent for ante-mortem interventions for deceased donation in every jurisdiction are strongly recommended.[195] Where legal uncertainty is present, health professionals and organisations should seek

legal advice when establishing policies or protocols regarding use of ante-mortem interventions. At a minimum, when making a decision about potential ante-mortem interventions, health professionals should always obtain consent from the potential donor's lawful decision-maker.

Substitute decision-makers (or senior available next of kin in NSW) are recommended (unless otherwise directed by law) to apply the approach outlined in Chapter 4.4.2.2 and Chapter 5.3.2 with regards to use of substituted judgement to make decisions on behalf of individuals who are unable to make their own decisions. Where it is not possible to determine the likely preferences of the individual with regards to use of ante-mortem interventions, the lawful decision-maker should generally use a best interests approach to decision-making.

11.4.2 Preserving opportunities for deceased donation and facilitating successful donation

Some ante-mortem interventions may be aimed at preserving opportunities for deceased donation, including interventions that may simply provide time for appropriate individuals to make a decision about donation.

For example, in some cases when a person has suffered a critical illness or injury and it is expected that they will not survive, temporary provision of life sustaining treatment may preserve the individual's organ functions for long enough for a decision to be made about deceased organ donation if this is a possibility. If a decision is made in favour of donation, then continuation of treatment may be necessary for donation to take place successfully.

A key example of such interventions is that of 'elective ventilation' which refers to initiation of intubation and mechanical ventilation of a person for the purpose of facilitating organ donation, rather than for the purpose of providing a therapeutic benefit to that person.[196,197]

As a highly invasive procedure, such non-therapeutic mechanical ventilation may be deemed unduly burdensome when it is not clinically beneficial for the person who is ventilated. Given the potential for conflicts of interest to influence decision-making (see Chapter 11.3), there may be substantial concerns about substitute decision-makers approving burdensome non-therapeutic interventions that are solely aimed at supporting deceased donation. The potential donor in such cases may be regarded as vulnerable to harmful exploitation, and at risk of having their dignity violated; that is, at risk of being treated merely as a means to achieving the goals of others. However, without elective ventilation, a person with a strong wish to donate may never have the chance to realise this important goal.

Several interventions may be considered in potential deceased donors that aim to increase the probability of successfully retrieving organs and tissues for transplantation after death. The potential burdens, risks, and benefits of these interventions must be carefully considered in the context of the individual. Some interventions may also impact the family of a potential donor, for example, when the donation protocol influences the location in which death occurs or limits the ability of the family to be present with the potential donor throughout the dying process.

As noted in Chapter 11.4.1, persons who are responsible for making decisions about any interventions during the end-of-life period on behalf of a potential donor should generally consider what the person concerned would want, if they were able to make the decision on their own behalf. This decision should be informed by consideration of the risks and potential benefits of treatment options including interventions aimed at facilitating successful organ donation.

If the potential donor is known or considered likely to have had a strong interest in becoming a donor, and the potential burdens of an intervention can be alleviated – for example through appropriate palliation of symptoms (see Chapter 11.4.3) – then the potential benefits of a non-therapeutic intervention such as elective ventilation may justify proceeding. It is important that all potential risks are carefully considered. These may include the serious risk that an intervention might result in the person surviving in a state that is inconsistent with their expressed wishes.

The risk of missing an opportunity for donation by an individual who would have been willing to assume the potential burdens of ante-mortem interventions in order to realise their wish to donate must also be carefully considered.

11.4.3 Quality of end-of-life care for potential deceased donors

The wellbeing of the potential deceased donor should remain the priority throughout the ante-mortem period. This means that the treating team – rather than donation specialists – continue to lead the care of the potential donor and ensure that usual standards of care are met with regards to palliation of any symptoms.

Analgesia or sedation is routinely provided to people during the end-of-life period with the primary goal of relieving suffering. In some cases, such medications may have the secondary effect of hastening - or may be perceived to hasten - the onset of death.

Concerns may be raised about provision of analgesia or sedation to potential donors if it is feared that this is provided with the aim of hastening death in order to facilitate organ donation, rather than to provide appropriate care for the potential donor. Anxiety regarding this potential conflict of interest in decision-making about end-of-life care may lead some health professionals to avoid adequate provision of analgesia or sedation with the result that patients who are potential donors could experience poorer quality of end-of-life care.[192] Australian guidelines make clear that donation is compatible with effective end-of-life care.[13]

While management of potential or perceived conflicts of interest in end-of-life care is important (see Chapter 11.3 above), it is vital that potential donors receive appropriate care, including necessary analgesia or sedation. ANZICS provides explicit advice on this as follows:

> It is the responsibility of the treating team, and no-one else, to ensure that sedatives and opioids are administered in the same way ('no more and no less') that they would be used for a patient in a similar end-of-life situation who was not donating organs.[13]

11.5 Routine consideration of opportunities for deceased donation

Providing people with the opportunity to become donors after death depends on consideration of feasibility of deceased donation in all end-of-life circumstances, and notification of potential donors to individuals or organisations responsible for deceased donation. Donation services may assist in determining whether potential donors are clinically eligible to donate and whether the person's donation wishes are known, and in organising donation.

11.5.1 Routine notification of potential donors

Routine notification of all individuals at the end of life who meet appropriate clinical criteria indicating they may potentially become donors after death helps to promote equity of opportunity for donation (see Chapter 8.1). In avoiding missed opportunities for donation, routine notification also helps to maximise the potential of donation and hence transplantation of organs and tissues. Routine notification and use of decision-making aids or expert consultation to evaluate donation opportunities in individual cases helps in reducing the effect of potential health professionals' bias or lack of knowledge regarding various types of deceased donation opportunities (see Appendix 1).

Routine notification of potential donors should be aimed at ensuring all potential donors have the opportunity to have their donation wishes considered, or for their families to make a decision about donation on their behalf, not at ensuring all potential donors actually donate.

11.5.2 Consultation of the AODR and donation decision-making

Consultation of the AODR enables those supporting donation decision-makers to ensure that decision-making is informed by the wishes of the potential donor if these are known (see Chapter 4.4.2).

As outlined in the ANZICS Statement and recommended in national guidelines for offering donation, the AODR is routinely consulted to determine if a person's donation preferences are registered prior to staff raising the possibility of deceased donation with a person's family.[13,23] This step should only be taken after the person has died, or after there is medical consensus that continuing active treatment will not be of benefit to the patient.

11.5.3 Screening and notification of potential deceased donors and donation decision-making

When a person is considered as a potential deceased donor, determination of the individual's clinical suitability for donation may sometimes occur contemporaneously with donation decision-making (see Chapter 2.5.3). In some cases, notification of potential donors to staff or organisations that may assist in screening of eligibility for donation follows a decision by the potential donor's family to support or at least consider donation, and hence the notification is made with the consent of the relevant donation decision-maker(s).

However, notification of potential donors often takes place before donation has been discussed with donation decision-makers. For example, when a person dies in hospital or another care facility, staff may consult donation agencies or the local eye or tissue

bank to seek advice regarding whether the person may be clinically eligible to become a deceased organ or tissue donor. Staff may seek advice in this way from donation agencies before consulting the person's family about their donation wishes, to avoid taking up more of the family's time and energy, or to avoid causing disappointment or distress if a donation decision were made by the family only to later discover that the person is not eligible to donate.

Detailed information gathering and processing of any tests for assessment of donor suitability only occur after consent for donation has been received.

Regardless of the timing of family discussions about donation (see Chapter 2.5.2), families should be routinely informed when donation has been considered, especially when the potential donor was registered on the AODR. It is important that families are aware that donation was considered even where a person was deemed unsuitable to donate organs or tissues, so the family knows donation was not overlooked.

Staff should be provided with appropriate training to ensure that consultation of families is timely and effective, and designed to avoid raising unrealistic expectations of donation where relevant. If there are concerns that consultation with families may lead to extended discussions about donation decision-making in cases where there is no clinical possibility of donation, it is important for the donation specialist staff to be involved as they have the required training and tools to assist in determination of clinical eligibility for specific donation opportunities.

11.5.3.1 Privacy concerns about preliminary screening of potential donors after death has occurred

In some States, there are notification systems for tissue donation with tissue banks automatically notified of deaths in hospitals or other facilities. Tissue bank staff then contact the relevant health professionals, e.g., nurse or physicians in hospitals, to obtain further information about the deceased person to determine their eligibility to donate. If the person is deemed potentially eligible to donate from a clinical perspective, the tissue bank staff then contact the person's next of kin to discuss the possibility of donation.

Such notification and consultations of tissue banks may involve disclosure of some limited personal health information such as the cause of the person's death and any conditions they were known to have that might influence their eligibility to donate.

Consequently, some practices may raise concerns about violations of privacy laws because disclosure of health information in this way may not be considered to fall within the scope of privacy laws that allow for communication between health professionals under specific circumstances. As noted in Chapter 7.2.1, these circumstances typically involve disclosure that is necessary for patient care, or which might reasonably be expected, and for which consent to disclosure may therefore reasonably be presumed. However, there may be some legal uncertainty about such disclosures given that the person to whom the information relates is deceased. Exemptions from relevant privacy legislation may be granted to donation organisations or tissue banks, e.g., by statutory officials, on the grounds that consideration of donation opportunities may be considered an extension of a person's care, and hence that sharing of information between relevant health professionals involved in that care is permitted when necessary.

11.6 Deceased donation by competent individuals who choose to cease life sustaining treatment

Most decisions about deceased donation in the context of end-of-life care are ultimately made by substitute decision-makers on behalf of people who lack decision-making capacity as a result of catastrophic injury or illness, as discussed in Chapter 4.4. In rare cases the person making decisions about end-of-life care and donation may be the potential donor. This is usually in the context of people who are dependent on a life sustaining intervention for survival, and who make a decision to cease life support. For example, people who depend on mechanical ventilation to breathe, or on a cardiac device to maintain circulation. Such individuals, if they have decision-making capacity, have a right to refuse further use of these devices, just as any adult with decision-making capacity has the right to refuse medical treatment even if doing so is likely to result in their death.

Individuals in these circumstances may wish to become a donor after their death if that is possible, and in principle their right to do so should be respected. Care should be taken to support informed and voluntary decision-making in these circumstances, and to manage potential conflicts of interest as discussed in Chapter 11.6.1.

11.6.1 Supporting decision-making when a person chooses to cease life sustaining treatment and wishes to become a deceased donor

Concerns may arise with regards to potential conflicts of interest in decision-making, in particular the concern that the individual may choose to proceed with cessation of life support in order to achieve their goal of becoming a donor. That is, the possibility of donating may influence their decision to cease life sustaining treatment and cause them to choose death when they might otherwise have chosen to continue receiving treatment. Becoming a deceased donor is not considered an ethically valid motivation to end life-sustaining treatment, and may be considered to breach the dead donor rule given that, but for the possibility of donation, death would not otherwise occur at this time (see Chapter 11.1).

As is the case when substitute decision-makers are involved, decisions about the cessation of life-sustaining treatment should be separated from donation decision-making. Once a competent person has made the decision to cease life sustaining treatment, for example on the grounds that they do not wish to continue living due to their experience of poor quality of life and irresolvable suffering, they should be supported to make a decision about deceased donation if this is clinically possible.

If a decision is made to proceed with deceased donation, the individual should be supported to consider the risks and potential benefits of potential ante-mortem interventions for donation in the context of their end-of-life care. Care should be taken to ensure that the individual does not feel compelled to compromise the quality of their end-of-life care in order to support achievement of their donation goals, and they should be given opportunities to reconsider their decisions about cessation of treatment and donation.

See **Box 11.1** for a summary of ethical recommendations to support donation after discontinuation of life sustaining treatment.

11.7 Deceased donation after voluntary assisted dying (VAD)

Voluntary assisted dying (VAD) occurs when a person who wishes to die, usually because they are experiencing unrelieved suffering due to a terminal illness, is given medical assistance in dying. In most of Australia, legislation has been passed allowing people in specific circumstances to access medical treatment that will hasten their death.

Various models of VAD are now legal in most Australian jurisdictions. Information about current VAD laws is available here: https://end-of-life.qut.edu.au/assisteddying.

Some people who wish to access VAD may also wish to donate their organs or tissues after they die. It may be clinically possible for some of these people to donate, although many may not be eligible, for example due to the presence of a cancer or because the nature of their death precludes organ donation. A number of people have now donated organs and tissues following VAD in Australia.[198] In countries such as Belgium, the Netherlands, Canada and Spain, many people have donated organs after VAD and even more have donated tissues.[199,200]

In jurisdictions where a person is lawfully entitled to access VAD, the same person should be entitled to become a deceased donor if they are clinically suitable. The right to access a lawful clinical intervention – VAD – should not limit their right to donate organs or tissues after their death when this is possible.[201]

It is important to distinguish between donation of organs or tissues that occurs after a person has died following VAD, and so-called 'organ donation euthanasia'. 'Organ donation euthanasia' is a hypothetical practice which would be unlawful in Australia, and which raises specific and substantial ethical concerns (see Chapter 11.7.2).

Nevertheless, there are important ethical considerations relating to donation after VAD, in particular with regards to management of potential conflicts of interest in decision-making (see Chapter 11.7.1). In jurisdictions where VAD is possible, donation programs should take steps to ensure that guidelines, policies, staff training and other resources are in place so that requests for donation by people considering VAD are managed appropriately.[202,203]

11.7.1 Decision-making about donation after VAD

The foremost concern about donation after VAD is that the possibility of becoming a donor may represent a conflict of interest in decision-making about VAD. A person's interest in successfully donating may also conflict with their interests in end-of-life care, such as interests relating to the place, time and manner of their death.

For example, a person who undergoes VAD may be more likely to have an opportunity for donation because they are able to plan the timing of their death and hence to plan for donation, whereas for a person whose time of death is uncontrolled, opportunities for donation may be missed. The possibility of donating might also encourage a person to undergo VAD sooner than they otherwise would, for example if they fear that prolonging their survival may result in a deterioration of their health that could impact the suitability of their organs or tissues for use in transplantation.

VAD is generally considered ethically justifiable, particularly by health professionals, when it is desired by a person in order to relieve their suffering. It is not considered ethically appropriate if a person is motivated to access VAD in order to help others, for example by relieving them of care giving burdens. It must meet strict legislated criteria and requires official approval by a closely regulated system of approvals.

If the decision to access VAD was motivated by the goal of donating organs or tissues, this would effectively mean that a person was choosing to end their life for the purpose of donating organs or tissues. As discussed above, if death would not occur but for the goal of donation, then this may be considered a breach of the spirit of the dead donor rule. Approval of a request for VAD should not be made on the grounds that VAD provides an opportunity for donation, it must be made on independent grounds as outlined in relevant VAD legislation.

Consequently, decision-making about deceased donation should be carefully separated from decision-making about VAD. Only after a decision has been made and confirmed by a person to access VAD should the possibility of donation be discussed if the person wishes to do so.

Once a person has made lawful decisions to proceed with VAD *and* with donation (if this is clinically feasible), particular care will be needed to support them in making further decisions about end-of-life care. As discussed in the context of individuals who wish to donate after making a decision to cease life sustaining treatment, it is important to ensure that individuals can make voluntary and informed decisions about potential ante-mortem interventions to facilitate organ donation and other aspects of end-of-life care (see Chapter 11.6.1).

It is important that end-of-life care prioritises the welfare of the individual and that the possibility of donation does not unduly influence their commitment to VAD. Specific protocols may be needed to assist in providing opportunities for people to change their mind about donation and about VAD, and to ensure that the possibility of donation does not determine their ultimate decision about VAD.

For example, some people seek approval to access VAD but after receiving approval they choose not to make use of this opportunity. They may simply value having the option of VAD, may change their mind, or may die before making use of VAD. Those who make a decision to donate after being approved to access VAD should be assured that they may revoke their decision to donate at any time without this affecting their ability to access VAD.[203] Individuals should be supported to revisit and re-evaluate their donation decision and the decision to undergo VAD, while avoiding undue burdens that might result if they are required to repeatedly revisit or reaffirm their decisions.

Box 11.1 Summary recommendations for supporting donation after a decision to cease life sustaining treatment or undergo VAD

- Decisions regarding the use or cessation of life sustaining interventions or regarding VAD should be separated from decisions regarding opportunities for donation after death.
  - » Only after a decision has been made and confirmed by a person to access VAD or to discontinue a life sustaining treatment should the possibility of donation be discussed if the person wishes to do so.

- Specific protocols should be implemented to assist in providing opportunities for people to change their mind, and to ensure that the possibility of donation does not determine their ultimate decision about VAD or cessation of life sustaining treatment, while avoiding undue burdens on the person such as those that might result if they are required to repeatedly revisit or reaffirm their decisions.

- Those who make a decision to donate after being approved to access VAD or making a decision to discontinue life sustaining treatment should be assured that they may revoke their decision to donate at any time without this affecting their ability to access VAD or cease life sustaining treatment.
- If a decision is made to proceed with deceased donation after a planned withdrawal of life sustaining treatment or VAD, the prospective donor should be supported to make decisions regarding aspects of end-of-life care and potential use of pre-mortem interventions for the purpose of facilitating donation after death.
- Directed donation of organs or tissues following VAD or a personal decision to cease life sustaining treatment, should only be considered in exceptional circumstances. See Chapter 12.3.3.1.

  - Additional safeguards will be needed to evaluate the potential influence of opportunities to direct donation on the decision to proceed with VAD or to cease life sustaining treatment.

11.7.2 'Organ donation euthanasia'

Donation after VAD must be strictly distinguished from so-called 'organ donation euthanasia', 'euthanasia via living organ donation', or 'heart-beating organ donation euthanasia'.[204,205] These terms were coined to describe a hypothetical practice in which a person who chooses voluntary assisted dying would be permitted to undergo surgery that would remove their vital organs for use in transplantation, and in doing so cause their death.[204]

Proponents of this practice suggest that it could assist in successful removal of organs for transplantation from people who choose to undergo VAD. However, this would clearly violate the dead donor rule, and carry all the concerns associated with violations of the dead donor rule as outlined in Chapter 11.1. Organ donation euthanasia is not currently permitted in any country.

11.8 Organ and tissue donation by infants with anencephaly

In rare circumstances, the possibility of organ or tissue donation may be considered on behalf of an infant born with the central nervous system disorder anencephaly. If a fetus is diagnosed with anencephaly in utero, the pregnant woman may also seek to determine if organ donation, in particular, will be a possibility.

Anencephaly, in which much of the core brain tissues and surrounding structures are absent, is not curable. The infants die within hours to days unless life sustaining interventions are implemented. Parents of an infant with anencephaly may have a strong interest in the possibility of organ donation in order to help other children via organ transplantation, so that the tragic loss of their own infant has a positive outcome for others.

The usual ethical and legal standards that apply in the context of organ donation also apply to infants with anencephaly, including the obligation to respect the dead donor rule (see Chapter 11.1). Infants with anencephaly do not meet the criteria for neurological determination of death due to the frequent preservation of the brainstem, and there may be clinical complexities or barriers to determination of death by neurological criteria in these infants.[206,207] However, donation following circulatory determination of death may be possible in some cases.

Health professionals and members of the public may hold diverse opinions with regards to the ethical acceptability of initiating life sustaining interventions in a newborn infant for the purpose of facilitating organ donation,[208] and some professionals may choose to conscientiously object to involvement in end-of-life care in such cases (see Chapter 3.7.1). Decisions made regarding end-of-life care including use or cessation of life-sustaining interventions should be made with regards to the best interests of the infant (see Chapter 5.3.1 and Chapter 11.4).

Parents expecting the birth of an infant with anencephaly require careful support in planning for the birth and managing expectations with regards to donation opportunities that may arise. Options including donation of umbilical cord blood (see Chapter 12.4) and tissue donation should also be explored in conjunction with any discussion of potential organ donation.[207]

11.9 Post-mortem interventions for deceased donation

To preserve or facilitate opportunities for donation and increase the chances of successfully recovering and utilising donated organs in transplantation, there are several interventions that may be performed in the body of a potential donor after death has occurred. Like ante-mortem interventions (see Chapter 11.4), such post-mortem interventions may cause uncertainty or concern regarding legal and ethical aspects of decision-making, and about potential breaches of the dead donor rule (see Chapter 11.9.1).

The legal and ethical (or moral) status of an individual changes at the time of their death. This means that there are likely to be fewer concerns about the risk of post-mortem interventions harming the potential donor, except in the context of specific interventions such as use of normothermic regional perfusion (NRP) technologies (see Chapter 11.9.1.1). Nevertheless, ethical treatment of the deceased requires respect for their interests and dignity in decision-making and care, as well as attention to the potential impact of interventions on their families and communities.

Continuation of mechanical ventilation and other forms of cardiorespiratory support are common post-mortem interventions in potential donors who have been declared dead on the basis of neurological criteria, for example. The care of such individuals and their families in the ICU in the lead up to donation will be very similar to that of living patients in the ICU.

There may be legal uncertainty regarding authority for decision-making about use of non-therapeutic clinical interventions after death, as human tissue legislation currently provides guidance only with respect to authorisation of donation after death and, in some jurisdictions, decision-making about ante-mortem interventions for donation. In practice, despite potential transitions in legal authority for decision-making,[62] individuals tasked with substitute decision-making on behalf of a potential donor immediately prior to death are likely to remain involved in decision-making that continues after death.

Regardless of legal requirements, health professionals should routinely inform the prospective donor's family and their lawful decision-maker(s) about potential opportunities for use of post-mortem interventions and discuss the potential benefits and risks of these where relevant, consistent with the approach to decision-making about ante-mortem interventions for donation.

11.9.1 Post-mortem interventions and the dead donor rule

As discussed in Chapter 2.4.1.2, in practice the clinical determination of death using circulatory criteria relies on a standard of permanency which means that circulation cannot or will not be restored. In order to ensure that donation following circulatory determination of death respects the dead donor rule, it is therefore essential that any post-mortem interventions in a potential donor do not restore circulation such that the determination of death would be invalidated.

Some potential interventions, such as chest compressions for the purpose of circulating intravenous heparin in the body of the potential donor, may be considered to restore circulation and technically breach the dead donor rule, given the current statutory definition of death in Australia. The use of normothermic regional perfusion (NRP) is a specific type of intervention that has significant implications for the dead donor rule, as discussed in Chapter 11.9.1.1).

11.9.1.1 Normothermic regional perfusion

The use of NRP technologies, which re-establish circulation to organs within the abdominal or abdominal and thoracic regions of the donor's body after death, has substantially contributed to improved utilisation of organs from donors following circulatory determination of death in several countries.[209,210] However, use of NRP is currently controversial, in particular due to concerns that its use, especially in the case of thoraco-abdominal NRP, may breach the dead donor rule.[211–213]

In Australia, NRP is not currently practiced. When a donor has been declared dead on the basis of circulatory criteria that are aligned with the Australian statutory definition of death, which refers to the 'irreversible cessation of circulation of blood in the body of the person' (see Chapter 2.4.1), the reestablishment of oxygenated blood flow to part of the donor's body may be considered to invalidate the diagnosis of death. Subsequent organ recovery would consequently violate the dead donor rule.

In contrast, most countries undertaking NRP have a definition of death that is consistent with the unified brain-based concept of death, where death is defined as the permanent loss of the capacity for consciousness, all brainstem function and capacity to breathe, as a consequence of permanent cessation of blood flow to the brain or a catastrophic brain injury.[213] Some commentators consider that abdominal NRP does not invalidate death determined according to this definition, as there is little likelihood of brain blood flow being re-established during regional perfusion of the abdomen. However, in the case of thoraco-abdominal NRP, there is a substantive risk that inadvertent reperfusion of the brain may result through collateral circulation from the thoracic vessels. Some commentators note that a small risk of cerebral reperfusion may be present in both abdominal and thoraco-abdominal NRP.[214 215]

12. Miscellaneous issues in donation and transplantation

In this chapter, a number of ethical issues relating to donation and transplantation of cells, tissues and organs are briefly explored. These include ethical considerations with regards to:

- Public solicitation of living organ donors (Chapter 12.1)
- Vouchers for living kidney donors (Chapter 12.2)
- Directed, restricted and conditional donation (Chapter 12.3)
- Umbilical cord blood banking (Chapter 12.4)
- Uterus donation and transplantation (Chapter 12.5)
- Vascular composite allografts (Chapter 12.6)
- Intersections between donation and transplantation and research (Chapter 12.7)

Further readings and resources of relevance to this chapter can be found in Appendix 1.

12.1 Public solicitation of living organ donors

Public solicitation of living organ donors refers to a variety of strategies that a person in need of a kidney, or liver transplant (or someone acting on their behalf) may use to recruit potential donors from their communities and the wider public. This may involve posting notices on social media, joining online platforms that aim to connect potential organ donors and recipients, or making public appeals for donors via stories published in news media.

In many countries, people may be legally prohibited from advertising their need for a living donor because of laws aimed at preventing organ or tissue trafficking. In Australia, some jurisdictions have laws prohibiting advertising the buying or selling of human tissues, i.e., when 'valuable consideration' is offered for organs or tissues (see Chapter 10.2). However, the prohibition does not apply to adverts seeking an unpaid altruistic donor.

Such donors may be described as directed donors, as they are recruited with the plan of directing their donation to specified individuals. Unlike most directed donors, however, those who are recruited via public campaigns may be strangers to the intended recipients prior to their recruitment. In some cases, efforts to recruit a living organ donor may result in individuals volunteering to donate who are part of the intended recipient's wider acquaintance or community but who do not have a close relationship with them.

Ethical considerations with regards to public solicitation of living organ donors are summarised in Chapter 12.1.1 and recommendations to manage these are explored in Chapter 12.1.2.

12.1.1 Ethical considerations in public solicitation of living organ donors

Depending on the nature of the strategies used to recruit potential donors and of the relationship that exists between prospective donors and the intended organ recipient, several ethical concerns may arise. These include:

- The possibility that donors recruited via public solicitation methods may seek to obtain payment for their donation and/or that those soliciting a donor may offer such payment in order to secure the donation.
- If public solicitation leads to donation by a person who was not previously known to the transplant recipient, the donor and recipient pair will not have the anonymity that is usually present when a person volunteers to make a non-directed donation to a stranger. This raises concerns about the risks involved in waiving anonymity in donation that are outlined in Chapter 7.3.2, such as the potential for exploitation, or psychosocial difficulties in managing relationships.
- Not all people in need of transplants may have the ability to publicly recruit an organ donor, and some may have advantages when they do solicit a donor. For example, public solicitation may be more likely to be successful if the transplant candidate and/or their family has specific characteristics that are deemed more socially desirable. Others have socioeconomic advantages that enable them to advertise their need for transplantation effectively. This raises concerns about inequities in access to transplantation, with public solicitation sometimes described as a kind of 'beauty contest'.[216,217]
- If public solicitation occurs, public perception of inequities may also undermine trust in donation programs. For example, if a wealthy individual advertises widely for a living donor, people may feel that individual has effectively bought a transplant, even if the donation that occurs is altruistic. This could undermine the willingness of some members of the public to participate in regular donation programs.
- Public campaigns seeking living organ donors may sometimes result in large numbers of potential donors seeking information from donation agencies or volunteering. This can place significant burdens on organisations that are responsible for screening prospective donors. This is especially problematic if there is a high rate of attrition of prospective donors whose response to the campaign may reflect an impulsive decision rather than a deeper commitment to donation.

On the other hand, permitting public solicitation of living organ donors in some circumstances, for example where screening procedures and counselling can be used to reduce the risk of exploitation, trafficking, or other harmful outcomes, may have general benefits. These include the following:

- Public solicitation efforts may draw attention to the wider problem of donor shortages and may motivate more people to become living non-directed donors. For example, some individuals who volunteer to donate to a person who has solicited a donor may be willing to donate to someone else if they do not qualify as a suitable match.
- Some organ transplant candidates may feel more comfortable seeking a donor via public solicitation than asking a relative or friend to consider donating. The candidate's friends or relatives may be inspired to volunteer as a directed donor in response to a more public call for donors.
- Although some transplant candidates may be unfairly advantaged in recruiting donors via public campaigns, if they are successful this does not disadvantage

other candidates awaiting organ transplantation. In fact, other candidates may also benefit if public solicitation effectively increases the organs available for transplantation by expanding the living donor pool. Public solicitation may also directly reduce pressure on waiting lists for deceased donor organs by meeting the need of individuals who might otherwise have received a deceased donor organ.

- Public solicitation may be a key strategy necessary for obtaining a transplant for some individuals who have substantive difficulties obtaining a suitably matched organ or tissue, for example by enabling recruitment of potential donors who belong to the same ethnic group as that of the transplant candidate.

Nevertheless, public solicitation of living organ donors that results in a directed donation to the person soliciting a donor may not be as beneficial overall as altruistic non-directed living donation (see Chapter 2.8.1.1). Organs from non-directed living donors can be allocated so as to maximise the benefits of transplantation, for example by using a non-directed kidney donor to initiate a series of paired kidney exchanges that result in several transplants that may not otherwise be possible.

12.1.2 Ethical management of public solicitation of living organ donors

Health professionals providing care to organ transplant candidates who may require a living donor should ensure that candidates (or their families) are:

- aware of and supported in recruitment of appropriate potential living donors from among family and friends
- informed of prohibitions regarding trade in organs and the implications of these for recruitment of living donors
- advised of opportunities to help contribute to general public campaigns promoting living and deceased donation
- advised of potential benefits and risks if they seek to recruit potential living donors via public solicitation, and the implications of public solicitation – if any – with regards to screening or acceptance of potential donors (see below).

Donation agencies or programs that are approached by prospective living organ donors – either independently or together with the relevant transplant candidate – in response to a public call for a donor by a specific candidate may implement some or all of the following strategies:

- perform routine screening and comprehensive psychosocial evaluation (see Chapter 6.1.3) in order to
  - » determine eligibility for donation
  - » identify any signs of potential coercion or use of unlawful incentives that would constitute trade in organs or tissues (see also Chapter 10.6.1.1), and
  - » identify factors that may increase the risk of poor psychosocial outcomes for donor or recipient, e.g., as a result of expectations with regards to the future relationship between the donor and their intended recipient
- arrange counselling for the potential donor and recipient to assist in managing future relationships
- appoint an independent donor advocate when obtaining consent for donation (see Chapter 3.4.5)
- refer the potential donor to the non-directed donation program if current policies prevent directed donation of this kind, or if they are not selected, where appropriate.

12.2 Living organ donor vouchers

In the United States, a program has been introduced that allows individuals who make a non-directed living kidney donation to receive a voucher that gives one of the donor's close relatives a degree of priority in obtaining a kidney via the paired exchange program in the future.[218,219] The program is designed to address the problem of so-called 'chronological incompatibility' in living kidney donation. This refers to situations in which a person is willing and able to donate a kidney to a close relative, but the relative does not require a transplant at the time. Instead, the relative is expected to need a kidney transplant in the future, but at a time when the potential donor may no longer be able to donate.

For example, a 56-year-old woman may wish to donate a kidney to her 6-year-old granddaughter who is diagnosed with polycystic kidney disease. The grandmother is fit and eligible to serve as a living donor. However, the granddaughter does not yet have kidney failure, and may not develop kidney failure and require a transplant for another 30 years. In 30 years, the grandmother would be 86, and likely unfit to donate her kidney. Such cases mean that an opportunity for a living directed kidney donation may be missed.

With the voucher program, the grandmother in this case can make a nondirected donation to the paired exchange program, which benefits those currently in need of kidney transplants. In return, the grandmother may designate her granddaughter as a beneficiary of a voucher that may be redeemed in the future when the granddaughter requires a kidney transplant. The voucher does not guarantee that the beneficiary will obtain a transplant, but it may increase their chances of receiving a living donor transplant by giving them priority in accessing a kidney from the paired exchange program.

There are several potential benefits from a program like this, such as:

- potential for increased non-directed living kidney donation if vouchers remove a potential disincentive or provide an incentive to donate
- avoidance of missed opportunities for living donation arising due to chronological incompatibility between potential donors and recipients.

There also potential ethical concerns, including:

- disappointment or frustration if vouchers are ineffective in improving timely opportunities for transplantation for voucher beneficiaries, e.g. due to system failures arising because of insufficient donations or excessive uptake of voucher programs[218]
- disputes arising due to limitations of voucher transferability, e.g., if voucher cannot be regifted to another beneficiary who develops a more urgent need for transplantation than the original beneficiary
- the potential for financial transactions to influence gifting of vouchers.

More information about these ethical considerations and about the American voucher program can be found in the resources listed in Appendix 1. Currently, there is no voucher program in Australia.

12.3 Directed, restricted or conditional donation of cells, tissues or organs

Donation of cells, tissues and organs is usually non-directed, with the exception of living organ donation and some HSC donation. This means that individuals' donations are not directed towards – i.e., given – to other specified individuals, but rather allocated or otherwise distributed without regard for any personal relationships or preferences the donor may have regarding the beneficiaries of their gift.

In many cases directed donation is not practically feasible, as discussed in Chapter 12.3.1. In the following sections, we explore ethical concerns that may arise in specific circumstances in which directed or conditional donation may be considered.

12.3.1 Practical constraints on directed donation

Directed donation is often unfeasible or undesirable for practical reasons. For example, most people who have an opportunity to donate organs or tissues after death, to donate tissues when undergoing a therapeutic procedure, or to donate HSCs as a living donor do not know a person who would benefit from receiving their donation at that time.

Even if, for example, a person willing to donate their femoral head while undergoing a hip replacement had a friend who might need a bone graft, it would be much more efficient for that friend to obtain a graft that is already manufactured and available from a tissue bank, rather than to wait for the donor's bone to be specially processed for use in their graft. Where some tissues are concerned, more than one donor may also be required to provide specific tissues used in manufacture of specific grafts.

For cells, organs and some tissues, the need to find a suitable immunological or anatomical match for a particular transplant candidate means that an individual's donations may not be suitable for use by a transplant candidate even if they are genetically related.

Reliance on non-directed donation generally helps to enable more efficient and equitable systems of allocation of donor cells, tissues, and organs. This is because non-directed donations can be allocated with regard for the needs and interests of all members of the community rather than being responsive to the unpredictable and sometimes biased personal preferences of individuals who encounter an opportunity for donation.

Those in need of a deceased donor transplant are most likely to receive one if most potential deceased donors become donors and if they do not direct their donations, increasing the probability that a suitably matched organ or tissue will be available when an individual requires one. Similarly, optimising participation in public umbilical cord blood banking rather than private family-directed banking has benefits for the public (see Chapter 12.4.2).

12.3.2 Directed living donation of cells and organs

It is ethically acceptable for living organ and HSC donors to direct their donations to people with whom they have a social, emotional, or biological relationship, provided they are suitably matched from a clinical perspective and that other requirements for living donation are met. These include the requirement for valid consent to donation and transplantation; in some cases, the nature of relationships between prospective

living directed donors and their intended recipients may raise concerns about the voluntariness of donation (see Chapter 4.3.3.1).

Most HSC donors are non-directed, due to difficulties finding suitably matched donors even within families. Individuals are most likely to be able to donate HSCs to a biological sibling; haploidentical HSC transplants from a biological parent or child may also be possible.

In contrast, directed living kidney donation is far more common than non-directed kidney donation (in which an individual donates an organ for allocation via the transplant waiting list or the paired exchange program). This is in part because the significant burdens associated with living kidney donation mean that people are more likely to be motivated to donate a kidney to a person with whom they have a relationship. It is also possible for some people to overcome potential immunological barriers to directed living kidney donation by participating in the paired exchange program (see Chapter 2.8.1.2).

Rarely, an individual may seek to make a directed living donation to a person with whom they have no pre-existing relationship in response to a public campaign to recruit a donor. Ethical considerations in these circumstances are explored in Chapter 12.1.

12.3.3 Directed deceased donation of organs and tissues

In rare cases, a person may die in circumstances where they may be able to donate their organs and tissues and where there is a transplant candidate with whom they have a relationship. In some such cases, it may be known that the potential deceased donor was willing to donate organs or tissues to the transplant candidate. For example, a person may have been evaluated as a potential living organ donor for a friend or relative, and then may die before living donation could proceed.

Alternatively, it may be reasonable to presume that the deceased would have been willing to donate to the transplant candidate if they knew the possibility might arise. For example, a parent who was supporting a child awaiting a lung transplant might reasonably be presumed to be willing to donate their lungs after death to their child.

If the relevant donation decision-makers believe that the potential deceased donor would have wished to make a directed donation of organs or tissues to a particular individual in need of transplantation, permitting directed donation may be ethically appropriate in some circumstances. These circumstances include when:

- It is clear that that such a decision is consistent with the likely values and preferences of the potential donor.
- Potential conflicts of interest in end-of-life care including donation decision-making will be carefully managed if decision-makers have a personal interest in transplant opportunities (see Chapter 11.3).
- Directed donation is clinically appropriate, meaning that:
    - the potential donor is clinically eligible to donate
    - directed donation is logistically feasible
    - the intended recipient is a suitable match
    - the directed donation is expected to offer significant therapeutic benefits for the recipient compared with awaiting a transplant from another source.

- The intended transplant recipient is willing to accept the offer of a directed donation. They should be counselled regarding risks and potential benefits that may be associated with the directed donation including the lack of anonymity, the potential for psychological harm, and the implications for the recipient's relationship with the donor family.

These circumstances are only likely to prevail in the setting of a close relative or friend in need of a solid organ transplant. For example, if a request was made to direct a corneal donation to a relative of the deceased, the logistical burdens and psychosocial risks associated with directed donation would likely outweigh the potential benefits of a directed donor transplant.

Considering the potential psychosocial risks of directed deceased donation is particularly important given that families are making decisions at the time of a loved one's death. The emotional impact of the death may make it difficult for individuals and families to fully appraise the potential long-term consequences of the directed donation. These include the psychological effects of receiving a transplant from a deceased family member or close friend or knowing that a relative or friend has received a transplant because of a loved one's death. In contrast, in living directed donation and transplantation, prospective donors and recipients receive counselling, are carefully evaluated, and are usually given time to reflect on their decisions before proceeding with donation and transplantation (see Chapter 6.1.3 and Chapter 4.3.3.1).

Specific concerns may arise if directed donation is considered by a person seeking to donate following VAD or cessation of life sustaining treatment (see Chapter 12.3.3.1), or if directed deceased donation is considered in the absence of a relationship between the potential donor and the intended transplant recipient (see Chapter 12.3.3.2).

12.3.3.1 Directed donation after VAD or a personal decision to cease life sustaining treatment

Specific concerns arise when a person who seeks to become a deceased donor after ceasing life sustaining treatment or undergoing VAD wishes to direct their organ(s) or tissue(s) to a specific recipient. In particular, a request to make a directed donation in these circumstances may raise concerns that donation is the primary motivation for the decision to cease life sustaining treatment or seek VAD. A potential interest in saving the life of a loved one, for example, through organ transplantation, might unduly influence a person and motivate their decision to hasten their own death.[202,220]

In exceptional circumstances, where it is clear that the decision to undergo VAD or cease life sustaining treatment has been made, and would be made, irrespective of the opportunity to make a directed donation of organs or tissues after death, directed donation may be considered.[220]

12.3.3.2 Directed deceased donation to a person with whom the potential donor had no relationship

Although rare, it is possible that the family of a potential deceased donor may seek to direct donation of an organ or tissue to a specific individual with whom the donor – if not the family – had no prior relationship. This could occur, for example, if that individual's need for transplantation is publicly known because of a news story about a person in need of transplantation or of a public donor recruitment campaign (see Chapter 12.1).

Such requests should not be supported for the reasons outlined below in the context of restricted or conditional donations (see Chapter 12.3.4), most notably with regards to the impact on equity in allocation of deceased donor organs and tissues. Allowing directed donations in the absence of a relationship between the potential donor and recipient could exacerbate inequities in access to transplants and reduce the utility or benefits of donation overall for communities. If all donors were able to direct their donations to specified individuals, even if those individuals needed transplants and were able to benefit from them therapeutically, there may be other individuals who would benefit more, or who may have more urgent needs for transplantation.

12.3.4 Restricted or conditional non-directed donations

While respecting the autonomy of potential non-directed living or deceased donors is important, there are limitations on the extent of control potential donors may have over their cells, tissues, or organs if they choose to donate these for the purpose of transplantation.

For example, potential deceased donors - or those making a decision about deceased donation on their behalf - are permitted to choose which organs or tissues will be donated, however they are only permitted to direct donations to specific individuals in particular circumstances as discussed in Chapter 12.3.3.

In the following sections, circumstances in which donors or donation decision-makers may seek to place restrictions or conditions upon donations are discussed, and the limitations of rights to restrict or set conditions on non-directed donation are described.

12.3.4.1 Ethically permissible restrictions on non-directed donation

Efforts to enable informed choices by donation decision-makers are vital, and - where possible - strategies to enable them to choose how donations will be used in specific contexts may be a valuable means of enhancing autonomy and ensuring that the values and preferences of donors are reflected in the organisation and activities of donation and transplantation programs.

Potential donors (or those making a decision about donation on behalf of a potential donor) may be able to direct or restrict the ways in which donations are *used*. For example, donors may indicate if they are willing for donated cells, tissues, or organs to be used in research if they cannot be used in transplantation.

When relevant information is provided during the consent process, donation decision-makers may also decide to decline donation if they cannot satisfactorily control the way their donations may be used. For example, a donation decision-maker may refuse consent for eye tissue donation to an eye bank that routinely exports tissue overseas. Similarly, a person might choose not to join the ABMDR because a condition of joining is that HSC donations may be shared with recipients around the world.

12.3.4.2 Restrictions on donation that may negatively impact equity

Some potential living or deceased donors (or deceased donation decision-makers) may seek to restrict donations in ways that undermine equity and may foster distrust in donation and transplantation programs.

Rather than specifying individuals who might receive donations, some donation decision-makers might request to restrict allocation of donated cells, tissues, or organs to specific groups of people, or to exclude some groups. For example, some may prefer

that donated organs are used for transplantation in children rather than adults or seek to exclude members of particular religious or ethnic groups from receiving their cells, tissues, or organs.

This type of restricted donation is sometimes described as 'conditional donation', as people may only consent to donation on the condition that their allocation preferences are followed. This should not be permitted in Australia, not only because it would likely be unfeasible or impractical to implement, but also because it unfairly discriminates against individuals or groups. Such discrimination would conflict with the goals of our donation and transplant programs to promote equity and maximise the benefits of donation and transplantation for all (see Chapter 3.1). Recommendations for responding to requests for conditional donation are provided in Chapter 12.3.4.3.

Some have argued that allowing conditional donations, for example by potential deceased donors or potential non-directed living donors, should be permitted in some circumstances. Specifically, they argue that if a person cannot be persuaded to agree to unconditional non-directed donation, then it is better to accept their conditional donation than to miss the opportunity for donation altogether.

Proponents of this view claim that if conditional donation is allowed, some people in need of transplantation will still benefit directly from the donation, and those who are excluded from benefiting directly may indirectly benefit because they will be competing with fewer people for the other available transplants. At the very least, it is argued, no one will be disadvantaged by permitting conditional donation, because those who are excluded would not otherwise benefit because the donation will not proceed if conditional donation is not permitted.

However, the potential wider and long-term risks of permitting conditional donations are considered to outweigh any potential benefits in individual cases. Specifically, allowing conditional donations could exacerbate inequities in access to transplants and reduce the utility or benefits of donation overall for communities.

Furthermore, restricting donations to particular groups on the basis of criteria such as ethnicity, age, gender, sex, religion, or similar factors constitutes unfair discrimination as discussed in Chapter 8.1. Restrictions of this kind may also therefore violate anti-discrimination laws.

Discriminatory restrictions may undermine public trust in the integrity of donation and allocation programs, and hence discourage participation in donation activities. Permitting conditional donations could also lead more people to consider and request conditional donations, and risk undermining the efficiency of the donation systems. For example, routine discrimination could lead to some groups effectively being excluded from deceased donor organ transplantation opportunities, which in turn may encourage those groups to restrict donations to their own members, eventually resulting in a fragmented and unfeasible deceased organ donation program.

12.3.4.3 Responding to requests for conditional non-directed donation

If a prospective non-directed living donor or deceased donation decision-maker requests that their donation be restricted for use by members of specific groups, or that members of specific groups are excluded from accessing the donation(s), this request should be declined. Those supporting donation decision-making should seek to understand the reasons for the request and should explain the reasons for declining the request.

For example, some potential donors may not be motivated by a desire to exclude specific individuals or groups but rather by a preference to help members of specific groups via donation. This could be due to perceptions regarding groups that may experience disadvantages in accessing specific kinds of transplants, or due to a perceived affinity between the potential donor and members of a particular group.

In explaining the reasons for declining a request, health professionals should make clear the ways that all donations may be helpful to members of various groups either directly or indirectly. Many donation decision-makers may be willing to proceed with donation; those who make consent conditional upon restrictions that are not ethically justifiable should be declined.

12.4 Ethical considerations in umbilical cord blood banking

Some of the ethical considerations set out in these guidelines have specific implications in the context of donation of umbilical cord blood, in part due to the conceptual complexities of such donation outlined in the following section. These considerations are briefly outlined below.

12.4.1 Conceptual complexities of umbilical cord blood donation

Umbilical cord blood donation is a form of living donation occurring in the context of a therapeutic procedure for the donor, in that blood is taken from the umbilical cord associated with a living infant and woman during the final stages of childbirth. The infant is typically separated from the umbilical cord during the childbirth procedure, and hence removal of blood from the cord for the purpose of donation may be considered akin to removal of amnion tissue from the placenta following childbirth, or of other tissues during therapeutic procedures. Umbilical cord blood may provide valuable HSCs for use in transplantation (see Chapter 2.1.1).

There may be philosophical or legal debate regarding whether the infant or the woman delivering the infant should rightly be considered the donor of the umbilical cord or its blood, given the complex biological relationship between woman and fetus and structures such as the placenta and the umbilical cord.[221] Most commonly, the infant is considered the donor of cord blood, and the mother will provide consent on behalf of their child with regards to donation.

In contrast to other forms of living donation discussed in these guidelines, umbilical cord blood donation requires a decision whether to obtain and store cord blood for use for future autologous use or living directed donation, or to donate for allogeneic use in a public bank (see Chapter 12.4.2).

12.4.2 Decision-making regarding public or private banking of umbilical cord blood

Information provided to prospective parents regarding the possibility of umbilical cord blood donation make clear the choices available to them, namely that they have the option of donating cord blood to a public bank that is part of the AusCord network, to a private bank, or not donating at all.[222]

If the choice is made to store cord blood in a private bank, this means that the family can access the donation more readily in the event that it is needed for an autologous HSC transplant for the child in future, or if it is needed for an allogeneic transplant in

a family member for whom it is a match. If the donation is instead made to a public bank, it may be used in the treatment of any suitably matched recipient to whom it is allocated via the ABMDR, and may only be accessed for personal use in exceptional circumstances (see Chapter 12.4.3).[222]

Several commentators including professional medical societies have expressed concern regarding the potential high costs borne by the parents associated with private cord blood storage and the low probability that children or families will benefit from such storage unless there is a known clinical indication for future HSC transplantation within the family.[223] Concerns have also been expressed regarding equity of access to private banking, and about the oversight of some private banks internationally and the potential for for-profit banks to exploit families financially by overstating the potential benefits of storing cord blood in the absence of a known indication.[224]

Professional guidance on cord blood banking generally recommends that parents make an informed choice regarding donation to a public or private – 'family-directed' – bank. Education regarding the choices available should include the provision of information about the potential benefits of public cord blood banking. Parents' expectations regarding the future potential benefits of stem cell-derived treatments should also be explored to ensure these are evidence-based.

12.4.3 Exceptional access to umbilical cord blood stored in a public bank for personal use

As umbilical cord blood donations are made unconditionally to public cord blood banks for public use in treatment of approved conditions, donors have no legal entitlement to access the donation. It is important that prospective parents making a decision about cord blood banking do not make a decision in favour of public cord banking on the assumption that they will be able to access the donation for personal use in future.

Donated cord blood is therefore not stored in public banks for future autologous use. However, in exceptional circumstances, public cord blood banks in Australia may consider releasing donated cord blood for personal use by the donor or their family, if the donation has not been used at the time a request for release is made. In assessing a request for release, decision-makers should consider:

- If the intended use is for treatment of an approved condition. That is, the donation is expected to be used in accordance with the standards normally applied when releasing any HSC donation to a matching recipient for use in transplantation. Alternatively, the cord blood may be released for use in a formally approved clinical trial of autologous HSC.
- If retrieval and allocation of the stored donation is clinically and economically feasible.
- The utility or potential therapeutic value of the donated cord blood unit, as determined by the size of the donation and the relative rarity of its HLA type.

These considerations are necessary to uphold the values and goals of public HSC donation programs, including the aim to maximise the benefits of donations and equity of opportunity for HSC transplantation.

12.4.4 Use of embryo selection for the purpose of HSC donation

The 2017 NHMRC guidelines on assisted reproduction (updated 2023) provide advice with regards to the use of pre-implantation genetic testing of embryos for the purpose of selecting 'an embryo with compatible tissue for subsequent stem cell therapy intended for a parent, sibling or other relative'.[18] This practice has been described as the creation of 'saviour siblings.'[225]

The ethical implications of selecting embryos for this purpose are complex.[18] Regardless of the circumstances in which a child who is a potential living donor was created, the ethical principles outlined in these guidelines with regards to living donation by children remain the same (see Chapter 5.5). This means that the best interests of the child, including the potential future interests of an infant or child from whom umbilical cord blood, or other forms of HSCs may be obtained, should be considered when making donation decisions on their behalf (see Chapter 5.3.1).

12.5 Uterus transplantation

Uterus transplantation is a potential treatment for absolute uterine factor infertility, which means that a person is unable to carry a pregnancy through to term due to the absence of a functional uterus. Donation and transplantation of the uterus are relatively new clinical procedures that are still considered experimental.[226] Several successful cases of childbirth following uterus transplantation have occurred using living donors and, more recently, some using organs from deceased donors.[227–230]

It is expected that more people will seek the opportunity for uterus transplantation as uterus transplantation programs expand and success rates increase. While the evidence base for uterus donation and transplantation procedures is growing, it is important that the limitations of current knowledge and experience in the field are recognised. This means that prospective candidates for uterus transplantation or living uterus donation should be acknowledged as potential participants in research. Ethical design and oversight of trials should be consistent with Australian standards for the ethical conduct of research,[19] and of clinical innovations (see Chapter 12.7). Expert independent advice on additional ethical and clinical complexities relating to donation and transplantation may be needed to inform ethics review. In 2019, the first trial of living donor uterus transplantation in Australia was approved, and the first transplant was performed in 2023.[230]

Uterus transplantation should be recognised as a kind of Assisted Reproductive Treatment (ART), and should therefore be guided by relevant ethical considerations applicable to ART, e.g. in the NHMRC Guidelines,[18] in addition to those specific to donation and transplantation as outlined in the following sections.

12.5.1 Uterus transplant recipients

A number of specific ethical issues may arise in the context of uterus transplantation, in addition to the usual ethical considerations in organ transplantation outlined in these guidelines and the ethical considerations of uterus transplantation as an experimental procedure.

12.5.1.1 Determining access to uterus transplantation

The eligibility criteria for access to uterus transplantation should be guided by the same considerations outlined in Chapter 6 with regards to evaluation of potential benefits and risks, and with regards to equity of access if resources are limited, as discussed in Chapter 8.

The possibility of providing uterus transplantation in the future to people who are infertile following gender confirmation surgery, including for the purpose of alleviating gender dysphoria has been discussed.[231] The potential interests of persons who are transgender should be considered when developing guidelines for access to uterus transplantation and allocation of deceased donor uteri (Chapter 12.5.3.1).

12.5.1.2 Decision-making regarding attempted pregnancies and uterus graft removal

For most organ and tissue transplants, the primary goal of transplantation is to maintain a functional graft for as long as possible, so long as the burdens or complications of the transplant are outweighed by the functional benefits. In contrast, uterus transplantation – at least currently – is performed in the hope of realising reproductive goals. The goal of transplantation is thus to maintain a functional uterine graft only as long as necessary to achieve the primary goal of gestating and delivering a child or children. Once this goal is achieved, the significant burdens and risks associated with ongoing immunosuppression to maintain the graft mean that graft removal is necessary.

Dilemmas may arise if the transplant recipient wishes to retain a graft for the purpose of attempting gestation despite health professionals' concerns that the risks outweigh the potential benefits. The timing of attempted pregnancies and graft removal should be carefully considered using a process of shared decision-making that centres the interests and preferences of the transplant recipient while acknowledging the potential limitations of risks that may be accepted.[232] While the transplant recipient must consent to graft removal, health professionals are not obliged to perform ART procedures in the transplant recipient to facilitate pregnancy and gestation, if the risks to the recipient or potential children (see Chapter 12.5.4) are disproportionate.

12.5.2 Living uterus donation

In addition to the considerations of participation in trials of living donor uterus transplantation from a research ethics perspective, the usual considerations with regards to living donation explored throughout these guidelines also apply to living uterus donors.

Evaluation of the potential benefits and risks of living uterus donation may involve additional complexities with regards to the potential psychosocial impact on donors of the transplant recipient bearing a child.[233,234] The burdens and risks of the major surgery currently required for living donation of the uterus must be weighed against the potential benefits for the donor, which are likely to include benefits relating to a possibility of successful transplantation and delivery of a child by the recipient.

Relationships between living uterus donors and transplant recipients may have additional psychosocial complexities given that the purpose of donation and transplantation in this context is to facilitate the birth of a child. Many living uterus donors notably share a close relationship with recipients as sisters or mothers of recipients. Guidelines used in evaluation and counselling of gamete (egg and sperm) donors and gestational surrogates may be helpful in guiding care of uterus donors and recipients.

The success of deceased donor uterus transplantation has raised questions regarding the justifiability of living uterus donation, given that the risks to the living donor may be avoided by use of deceased donors.[235,236] The currently limited activity in uterus transplantation means that there may be sufficient deceased donors available for transplants without requiring living donors. However, use of living donors has some potential advantages with regards to planning of transplantation and potentially with regards to clinical outcomes, and there may be insufficient numbers of clinically suitable deceased uterus donors if demand for uterus transplant expands.

12.5.3 Deceased uterus donation

As a novel procedure that typically garners considerable public attention, uterus transplantation using uteri from deceased donors should entail additional considerations in deceased donation decision-making. Donation decision-makers should have the option of declining or choosing to approve removal of the uterus for use in transplantation; they should also be made aware if there is a risk that anonymity may be lost, and the identity of the donor or recipient may be revealed (see Chapter 7.3.3). If anonymity is lost or waived, specific counselling may be required to support donor families, particularly with regards to the potential psychological impact of learning that a child has been born as a result of the donation.

As uterus transplantation programs expand, specific criteria and allocation frameworks may be required to ensure equity in the allocation of deceased donor uteri, as discussed in Chapter 12.5.3.1.

12.5.3.1 Allocation of uteri from deceased donors

Specific guidelines for allocation of uteri from deceased donors should be developed. As a time-limited or ephemeral transplant procedure that aims to restore organ function for the purpose of achieving a specific goal – that of delivering a child or children – it may be reasonable to consider some non-clinical factors in organ allocation. For example, clinically suitable individuals with congenital absolute uterine factor infertility might be prioritised to receive a uterus transplant over other individuals who have successfully borne children prior to developing uterine factor infertility.

There is limited ethical guidance available with regards to specific allocation of ART resources including donor gametes. Use of ART is typically treated as a private domain in which the ability of individuals to access specific resources, including resources of human origin, is often largely determined by their personal financial resources or their ability to recruit living gamete donors or gestational surrogates. Nevertheless, the NHMRC outlines important principles that should help to guide the development of allocation guidelines for uterus transplantation. In particular,

> Processes and policies for determining an individual's or a couple's eligibility to access ART services must be just, equitable, transparent and respectful of human dignity and the natural human rights of all persons, including the right to not be unlawfully or unreasonably discriminated against.[18]

12.5.4 Consideration of the interests of children produced via uterus transplantation

As with other forms of ART, uterus transplantation and the associated procedures aimed at facilitating gestation and delivery of a child have implications not only for those undergoing fertility treatment but also for those children who may be created via the treatment.

This means that when evaluating the risks and potential benefits of uterus transplantation, the potential benefits and risks of the various procedures for children who may be born via uterus transplantation must also be considered.

12.6 Ethical considerations of vascular composite allografts

Transplantation of specific vascular composite allografts such as face and limb transplants are rare in Australia and internationally. Like uterus transplants, these transplants require specific ethical guidance to address potential concerns regarding:

- the proportionality of risks and potential benefits of the graft
- preservation of anonymity in deceased donation and the privacy of the transplant recipient
- eligibility criteria for transplantation
- allocation of donor tissues
- the innovative nature of the procedure, and the implications of this with regards to limitations of knowledge and clinical expertise, and potential conflicts of interest on the part of health professionals and healthcare institutions (see Chapter 12.7.1).

When contemplating a novel or rare transplant procedure, health professionals should draw on existing ethical guidelines and discussions from the international experience, in addition to international clinical expertise. Such guidelines and experience will require careful translation in the local context and specific consideration of the individual(s) in whom the procedure is being considered.

12.7 Intersections between donation and transplantation and research

Consideration of ethical issues with regards to research in donation and transplantation or donation of cells, tissues or organs for use in research are beyond the scope of these guidelines, and readers are referred to the NHMRC guidelines for the ethical conduct of human research.[17,19]

However, research activities may sometimes intersect with routine donation and transplantation activities in ways that may occasionally create ethical uncertainty, or that may require specific ethical attention. Some of these are briefly highlighted below. Ethical considerations of research involving data collected during routine donation and transplantation activities are also briefly noted in Chapter 7.4.1.1.

12.7.1 Innovative transplantation practice and research

Donation and transplantation are rapidly evolving fields, with new technologies and techniques emerging or changing as part of efforts to improve the availability of transplants and also the quality of donation and transplantation outcomes. Some new developments may be introduced in clinical practice via medical or surgical innovation pathways rather than via formally conducted clinical trials (see Chapter 12.7.1.1).[237]

As the *National Statement on Ethical Conduct in Human Research* notes,

> [T]he distinction between research and innovative clinical practice is [sometimes] unclear. For example, innovative clinical practice occurs on a spectrum from minor changes at the border of established practice that pose little change in risk to patient safety to novel interventions that should only be introduced as part of an ethically approved research protocol.
>
> Whether an innovative clinical practice should be undertaken only as clinical research may depend on the extent to which the procedure departs from established practice. Importantly, even if the introduction of an innovative practice falls within existing clinical guidance, its implementation and the associated collection of data for monitoring and reporting may require notification to the institution/s where the practice is taking place.
>
> When it is not clear whether an innovation should be implemented only as research, it may be necessary to seek advice from a Human Research Ethics Committee or other institutional review process on the review required for the new intervention.[19]

12.7.1.1 Ethical approaches to clinical innovations in donation and transplantation

When changes to donation or transplantation practices are introduced via the innovation pathway rather than clinical research, relevant institutional guidelines for ethical innovation in medicine or surgery should be followed.

The following steps should be considered in the light of existing ethical frameworks for clinical innovations such as the IDEAL framework.[238,239]

1. The new procedure or practice – including changes to policies – should be independently reviewed by a suitably competent ethics board or committee at the relevant institution, professional organisation or health department.
    a. The methods and rationale of the innovation should be clear, and informed where possible by international experience or relevant research in related fields.
    b. A process to monitor, evaluate and communicate the outcomes of the innovation should be established to ensure timely response to any unforeseen risks and to facilitate rapid translation of beneficial innovations.
    c. Any potential conflicts of interest on the part of health professionals (and institutions) involved (see Chapter 3.8.) should be carefully evaluated and mechanisms established to manage these.
2. Advice should be sought from a human research ethics committee if there is uncertainty regarding whether the innovation constitutes research or if further ethical guidance is needed.

3. Individuals who may be impacted by innovations, such as potential donors or recipients (or their substitute decision-makers), should be informed of the innovation and its risks and potential benefits when consent is obtained and the implications of any limitations of knowledge regarding the innovation should be explained.
4. Plans to convert the trial of an innovation to a clinical research study should be implemented early to ensure that a robust evidence base is developed even as innovations may be rapidly and widely adopted. These plans should include long term monitoring of outcomes where relevant.

12.7.2 Opportunities to participate in research at the time of donation or transplantation decision-making

Discussion of potential opportunities to participate in research may be an important component of discussions relating to donation or transplantation decision-making in several contexts:

- potential donors (or their substitute decision-makers) may be asked to choose whether donated cells, tissues or organs can be used in research if they are not suitable for transplantation.
- potential donors (or their substitute decision-makers) may be asked to choose if information or biological materials collected at the time of donor registration (e.g., in the case of HSC donation) or evaluation (e.g., in the case of deceased donation) may be used for research purposes.
- potential donors (or their substitute decision-makers) may be asked to choose if they are willing to participate in research relating to donation, such as trials of clinical interventions aimed at improving donation or transplantation outcomes.
- prospective transplant recipients may be asked for consent to participate in a clinical trial involving transplantation, or may be offered the opportunity to participate in a research study after receiving a transplant.

It is important that donation and transplantation decisions are separated, where possible, from decision-making about participation in research. Potential conflicts of interest may arise, for example, when those responsible for supporting donation or transplantation decision-making are also involved in research or recruitment for research. It is essential to ensure that ethical guidelines for research are followed, and that appropriate mechanisms are in place to manage potential conflicts of interest that may influence decision-making about donation or research participation.

Glossary

Term	Definition
advance care directive	A type of written advance care plan recognised by common law or specific legislation that is completed by a competent adult. It can record the person's preferences for future care and appoint a substitute decision-maker to make decisions about health care. In some Australian jurisdictions, these are known as advance health directives, health directions or advance personal plans (see Chapter 5.2.2).
advocate	A person who speaks up for or on behalf of another person. In donation and transplantation, the term may be used to describe a range of roles that are summarised in Chapter 3.4.5.
allogeneic transplant	A donation of cells, organs or tissues from one individual that is transplanted in another individual.
altruism	A willingness to act for the benefit of others. Behaviour is normally described as altruistic when it is motivated by a desire to benefit someone other than oneself for that person's sake.
assent	Expression of approval, or agreement, from a person who lacks capacity to provide consent (see Chapter 5.1.4.1).
authorisation	Legally valid approval that deceased donation may proceed, or is refused (see Chapter 4.4.1).
autonomy	A person's interest in making voluntary and informed choices about things that are important to them (see Chapter 3.2.1).
best interests	An evaluation of a person's general welfare that includes consideration of their physical health as well as psychological and social wellbeing, all things considered (see Chapter 5.3.1).
clinical standards	Expectations regarding the care that should be provided to patients in specific circumstances, and practices that should be implemented within healthcare systems with regards to quality and safety.
commodification	Treating something as if it is a **commodity**, i.e. something that has a monetary price which makes it interchangeable with other goods of different kinds that have an equivalent financial value (see Chapter 10).
compassionate access	Policy in which international residents may be permitted to access deceased donor organs.

Term	Definition
conditional donation	When a person wishes to place conditions upon a **non-directed donation**, for example by agreeing to donate only if the donation will be distributed to members of particular groups (see Chapter 12.3.4.2).
conditioning for HSC donation	A process that destroys the prospective transplant recipient's own bone marrow which will then be replaced with donated HSCs.
confidentiality	The right to manage access to and use of one's private information.
conscientious objection	When a health professional, as a result of a conflict with his or her own personal ethical beliefs or values, refuses to provide, or participate in, a legally valid treatment or procedure which would be deemed medically appropriate in the circumstances under professional standards (see Chapter 3.7).
cultural humility	Self-awareness of one's own culture and the way this may influence beliefs, attitudes and behaviours towards others, as well as interpersonal thinking and actions that are responsive to the aspects of a person's cultural identity that are important to them (see Chapter 3.6.1).
cultural safety in healthcare	Environment or conditions in which a person experiences care that is provided with an understanding of the person's culture and respectful acknowledgement of cultural difference(s), and in which care providers critically reflect on their own knowledge and behaviours as well as power differentials and contextual racism both past and present.[31,32] See Chapter 3.4.2.
custodian; custodianship	A custodian is a person or entity that has responsibility for taking care of or protecting someone or something. Custodianship of human cells, tissues, or organs is transferred from the donor to the health professionals who remove these during donation, and then to other professionals or institutions that may be involved in transporting, processing, storing, or transplanting donations. The recipient of a transplant is usually the final custodian of donations. Each custodian has responsibility for the donation while it is in their care (see Chapter 9.2).
decision-making aid	Also known as decision support, **decision aid, decision tool, etc.** Anything which may guide or support decision-making, e.g., clinical guidelines, risk communication tool, choice frameworks.

Term	Definition
decision-making capacity	Ability to understand relevant information and evaluate the potential consequences of choices in order to make and communicate a decision in a specific context (see Chapter 4.1.1).
dependent donor	A person who is not able to provide legally valid consent to living donation, such as a young child or adult who lacks decision-making capacity (see Chapter 5.5).
designated officer	A health professional appointed under a state *Human Tissue Act* to authorise, amongst other functions, the removal of tissue from a body after death for transplant or other therapeutic, medical or scientific purposes (see Chapter 2.5.2.3).
directed donation	Donation in which the donor or donation decision-maker specifies the individual(s) who will receive the donation for use in transplantation; the transplant recipient usually has an existing social, emotional, or familial relationship with the directed donor. In contrast, donations from **non-directed donors** are offered to any suitably matched transplant recipient in accordance with relevant systems for allocation or distribution of donated cells, tissues, or organs.
dissent	Expression of disagreement (see **assent**).
donation and transplantation activities	These include but are not limited to various steps in the recruitment and evaluation of potential donors; maintenance of donor and patient registries; removal of cells, tissues, and organs from donors; transport, processing, storage, distribution and transplantation of donated cells, tissues, and organs; and research evaluating performance of donation and transplantation programs and investigating new methods or technologies that may improve practice and outcomes.
donation decision-maker	Refers to a person making a decision about deceased donation, usually in the context of substitute decision-making for deceased donation.
donation specialist	Specially trained professionals in the practice of organ and tissue donation who support the family and donation process and provide education to the community and health professionals.
end-of-life care	Health care that individuals receive in the last days of their lives that aims to minimise the distress and grief associated with death and dying for the individual, and for their family, friends and carers.

Term	Definition
equity	Equity is the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically (see Chapter 8.1).
extended criteria donor	Also known as **expanded criteria donor**. Donors or donor organs with characteristics outside of ideal or standard criteria, usually associated with poorer functional transplantation outcomes and/or increased risk of donor-derived disease transmission. See also **non-standard risk donor**.
family	Those who are closest to the patient in knowledge, care and affection. This may include the biological family, the family of acquisition (related by marriage or contract), and the family and friends of choice.
financial neutrality in donation	The idea that donors or donor families should not lose or gain financially as a result of their decision to donate (see Chapter 10.4).
***Gillick* competent**	A child who is assessed as having a sufficient understanding and intelligence to enable the child to understand fully what is proposed with regards to a specific clinical decision. Such children are sometimes referred to as 'mature minors'. See Chapter 5.1.2.
haematopoietic stem cell (HSC)	Cells that can be found in bone marrow and blood, which may be transplanted in potentially curative treatments for patients with a variety of blood disorders and other diseases (see Chapter 2.1.1).
human leucocyte antigen (HLA)	'A type of molecule found on the surface of most cells in the body. Human leukocyte antigens play an important part in the body's immune response to foreign substances. They make up a person's tissue type, which varies from person to person.'[240] Some transplants require a close match between the tissue type of the donor and of the transplant recipient. (See Chapter 2.1.1).
human trafficking for organ removal	'Trafficking in persons for the purpose of organ removal is the recruitment, transportation, transfer, harbouring, or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of the removal of organs.'[6] (See Chapter 10.6).

Term	Definition
institution	Public and private institutions, such as hospitals, tissue banks, donation services, the Organ and Tissue Authority and distributors or sponsors of imported tissues.
medical product	A therapeutic good, e.g. medication, that is used in treatment to restore or preserve health. Donated cells, tissues or organs used in transplantation are sometimes referred to as 'medical products of human origin'. The extent to which donations are processed before they are suitable for transplantation differs greatly. Regardless of the extent of processing or manufacturing involved in modifying donations, e.g., when developing tissue grafts for transplantation, all transplants that include donated human material are considered ethically exceptional. This means their inherent ethical value which derives from that of donor(s) must be respected (see Chapter 3.2.1.1).
moral distress	Psychological distress that occurs when a person is prevented from acting - or otherwise feels unable to act - in accordance with their ethical values or perceived ethical duties, for example, due to institutional constraints or resource limitations. See Chapter 3.7.3.
non-directed donation	See **directed donation**.
norm	A standard or expectation.
non-standard risk donor	A person whose donated organs or tissues may present higher than normal risks for transplant recipients. The term is now considered inclusive of **extended criteria donors** (see Chapter 6.5.2.2).
notification of a potential donor	When information about a person who may be eligible to donate is provided to a donation specialist, e.g., at the end of life, in order to facilitate consideration of the opportunity for donation by the relevant decision-maker(s).
paired kidney donation	Potential donor-recipient pairs who are incompatible with each other are matched with other incompatible donor-recipient pairs to 'exchange' organs by transplantation (see Chapter 2.8.1.2).
ante-mortem interventions	Also known as pre-mortem interventions, procedures or practices. Interventions that take place before the death of a potential organ donor, that are not for the therapeutic benefit of the prospective donor but which either preserve a donation opportunity or optimise the function of organs retrieved after death for transplantation (see Chapter 11.4).

Term	Definition
privacy	The right to control access to one's physical person and personal information (see Chapter 7.1).
procedural justice	Fairness in the processes and procedures for decision-making, as well as the implementation of guidelines and policies and mechanisms for accountability (see Chapter 8.6).
registry	System in which information is collected, e.g. regarding clinical outcomes of donation or transplantation, for the purpose of monitoring and reviewing activities and outcomes or for use in research (see Chapter 7.4).
self-sufficiency in donation and transplantation	Able to meet a population's collective needs for transplantation using their own resources, including donations, or through reciprocal or equitable collaboration with other populations (see Chapter 9.1).
senior available next-of-kin	The person who may authorise, in writing, consent for organ and tissue donation, as defined in state *Human Tissue Acts* (see Chapter 4.4.1).
solidarity	Commitment to working together to achieve common goals and address shared challenges (see Chapter 8.2.1.5).
substitute decision-maker	A person permitted under the law to make decisions on behalf of someone who does not have capacity, in health care according to state *Guardianship Acts*, medical decision-making legislation or *Human Tissue Acts* (see Chapter 5.2).
substituted judgement	An approach to decision-making on behalf of a person who no longer has decision capacity that gives primary consideration to what the wishes of the person with the mental incapacity would have been had she or he not been incapacitated (see Chapter 5.3.2).
supported decision-making	A human rights concept and practical process referring to the provision of decision-making support to a person to make decisions that reflect as much as possible their 'will, preference and rights' (see Chapter 5.1.3.1).
tissue-derived product	A term sometimes used to describe tissues used in transplantation that have been which have been subject to and transformed by processing and manufacture (see **medical product**).
tissue typing	The assessment of the immunological compatibility of tissue from separate sources (potential donors and recipients), particularly prior to HSC or organ transplantation (see **HLA**).

Term	Definition
transplant tourism	Travel for transplantation when it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals and transplant centres) devoted to providing transplant to patients from outside a country undermine the country's ability to provide transplant services for its own population.[179] (see Chapter 9.4.1).
vascularised composite allograft	The transfer of a vascularised human body part containing multiple tissue types (skin, muscle, bone, nerves, and blood vessels) as an anatomical and/or structural unit from a human donor to a human recipient, typically face and hand transplantation (see Chapter 12.6).
voluntary assisted dying	Voluntary assisted dying (VAD) occurs when a person who wishes to die, usually because they are experiencing unrelieved suffering due to a terminal illness, is given medical assistance in dying (see Chapter 11.7).

References

1. WHO (World Health Organization), 'WHO guiding principles on human cell, tissue and organ transplantation: Sixty-Third World Health Assembly', *Cell and Tissue Banking*, 2010, 11(4):229-233, doi:10.1097/TP.0b013e3181ec29f0.
2. UN (United Nations), *UN Declaration on the Rights of Indigenous Peoples* (A/RES/61/295), 2007, accessed 23 November 2024.
3. UN, *UN Convention on the Rights of the Child*, 1989, accessed 23 November 2024, doi:10.1111/j.1467-9515.1989.tb00500.x.
4. UN, *Universal Declaration of Human Rights*, 1948, accessed 23 November 2024.
5. UN, *Convention on the Rights of Persons with Disabilities*, 2007, accessed 23 November 2024, doi:10.5463/DCID.v29i4.656.
6. 'The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 Edition)', *Transplantation*, 2019, 103(2):218-219, doi:10.1097/TP.0000000000002540.
7. GAEBA (Global Alliance of Eye Banking Associations), 'The Barcelona Principles: A Global Bioethical Framework', *International Journal of Eye Banking*, 2020, 8(3).
8. WMDA (World Marrow Donor Association), 'International Standards for Unrelated Hematopoietic Stem Cell Donor Registries [PDF 473KB]', WMDA, 2024, accessed 23 November 2024.
9. R Bakken, AM van Walraven and T Egeland, 'Donor commitment and patient needs', *Bone Marrow Transplantation*, 2004, 33(2):225-230, doi:10.1038/sj.bmt.1704323.
10. WMA (World Medical Association), *WMA Statement on Organ and Tissue Donation*, 2017, accessed 23 November 2024.
11. R Weinkove, ZK McQuilten, J Adler, MR Agar, E Blyth, AC Cheng, ...and BW Teh, 'Managing haematology and oncology patients during the COVID-19 pandemic: interim consensus guidance', *Medical Journal of Australia*, 2020, 212(10):481-489, doi:10.5694/mja2.50607.
12. TSANZ (Transplantation Society of Australia and New Zealand), *TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors (Version 1.13)*, TSANZ, 2024, accessed 23 November 2024.
13. ANZICS (Australia and New Zealand Intensive Care Society), *The Statement on Death and Organ Donation (Ed 4.1)*, 2021, accessed 23 November 2024.
14. EBAANZ (Eye Bank Association of Australia New Zealand), *Medical and Quality Standards for Eye Donation and Eye Tissue Banking (2nd Ed)*, 2009, accessed 23 November 2024.
15. CERA, (Centre for Eye Research Australia), How to register as an eye donor, CERA website, 2021, accessed 23 November 2024.
16. ABMDR (Australian Bone Marrow Donor Registry), Why become a stem cell donor?, Stem Cell Donors Australia website, 2024, accessed 23 November 2024.
17. NHMRC (National Health and Medical Research Council), *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders*, 2018, accessed 23 November 2024.

18. NHMRC, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2017 (Updated 2023)*, 2023, accessed 23 November 2024.

19. NHMRC, *National Statement on Ethical Conduct in Human Research* (2023), 2023, accessed 23 November 2024.

20. KM Dwyer, AR Webb, HS Furniss, KE Anjou, JM Gibbs-Dwyer, DB McCombe, … and WA Morrison, 'First hand transplant procedure in Australia: Outcome at 2 years', *Medical Journal of Australia*, 2013, 199(4):285-287, doi:10.5694/mja12.11554.

21. TGA (Therapeutic Goods Administration), *Australian Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products*, tga.gov.au, 2013, accessed 23 November 2024.

22. NHMRC, *Ethical Guidelines for the Care of People in Post-Coma Unresponsiveness (Vegetative State) or a Minimally Responsive State*, 2008, accessed 23 November 2024.

23. OTA (Organ and Tissue Authority), *Best Practice Guideline for Offering Organ and Tissue Donation in Australia (Edition 2)*, 2021, accessed 23 November 2024.

24. DHAC (Department of Health and Aged Care), 'About the Supporting Living Organ Donors Program', DHAC website, 2024, accessed 23 November 2024.

25. SR Knight, KN Cao, M South, N Hayward, JP Hunter, J Fox, 'Development of a clinical decision support system for living kidney donor assessment based on national Guidelines' *Transplantation*, 2018, 102(10):e447-e453 doi:10.1097/TP.0000000000002374.

26. Department of Health, *Review of the HPC Sector Final Report*, 2018, accessed 23 November 2024.

27. DHAC, *National Haemopoietic Progenitor Cell (HPC) Framework*, 2021, accessed 23 November 2024.

28. DE Martin, 'Ethical aspects of medical products of human origin,' *ISBT Science Series*, 2017, 12(1):281-287, doi:10.1111/voxs.12304.

29. DE Martin and E Muller, 'In defense of patient autonomy in kidney failure care when treatment choices are limited', *Seminars in Nephrology*, 2021, 41(3):242-252, doi:10.1016/j.semnephrol.2021.05.005.

30. E Curtis, R Jones, D Tipene-Leach, C Walker, B Loring, SJ Paine and P Reid, 'Why cultural safety rather than cultural competency is required to achieve health equity: A literature review and recommended definition', *International Journal for Equity in Health*, 2019, 18(1):1-17, doi:10.1186/s12939-019-1082-3.

31. AHPRA (Australian Health Practitioner Regulation Agency), *The National Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025*, 2020, accessed 23 November 2024.

32. Australian Health Ministers' Advisory Council's National, Aboriginal and Torres Strait Islander Health Standing Committee. *Cultural Respect Framework 2016-2026 for Aboriginal and Torres Strait Islander Health*, 2016, accessed 23 November 2024.

33. JT Hughes, L Dembski L, V Kerrigan, SW Majoni, PD Lawton and A Cass, 'Gathering perspectives - finding solutions for chronic and end stage kidney disease', *Nephrology*, 2018, 23:5-13, doi:10.1111/nep.13233.

34. J Devitt, K Anderson, J Cunningham, C Preece, P Snelling and A Cass, 'Difficult conversations: Australian Indigenous patients' views on kidney transplantation', *BMC Nephrology*, 2017, 18(1):1-14, doi:10.1186/s12882-017-0726-z.

35. P Secombe, E Lankin, R Beadle, G McAnulty, A Brown, M Bailey, ...and D Pilcher, 'Aboriginal and Torres Strait Islander attitudes to organ donation in Central Australia: a qualitative pilot study', *Transplantation Direct*, 2024, 10(9):e1692, doi:10.1097/TXD.0000000000001692.

36. JS Blumenthal-Barby and H Krieger, 'Cognitive biases and heuristics in medical decision making: A critical review using a systematic search strategy', *Medical Decision Making*, 2015, 35(4):539-557, doi:10.1177/0272989X14547740.

37. JS Blumenthal-Barby, 'Biases and heuristics in decision making and their impact on autonomy', *American Journal of Bioethics*, 2016, 16(5):5-15, doi:10.1080/15265161.2016.1159750.

38. ATCA (Australasian Transplant Coordinators Association), *National Guidelines for organ and tissue donation 4th Ed*, 2008, accessed 1 October 2021.

39. EV Taylor, M Lyford, L Parsons, T Mason, S Sabesan and SC Thompson, ''We're very much part of the team here': A culture of respect for Indigenous health workforce transforms Indigenous health care', *PLoS One*, 2020, 15, doi:10.1371/journal.pone.0239207.

40. RE Hays, D LaPointe Rudow, MA Dew, SJ Taler, H Spicer, DA Mandelbrot, 'The independent living donor advocate: A guidance document from the American Society of Transplantation's living donor community of practice (AST LDCOP)', *American Journal of Transplantation*, 2015, 15(2):518-525, doi:10.1111/ajt.13001.

41. EJ Bergman, 'Identifying Sources of Clinical Conflict: A Tool for Practice and Training in Bioethics Mediation', *The Journal of Clinical Ethics*, 2015, 26(4):315-323,

42. JN Hook, DE Davis, J Owen, EL Worthington and SO Utsey, 'Cultural humility: measuring openness to culturally diverse clients', *Journal of Counselling Psychology*. 2013, 60(3):353-366, doi:10.1037/a0032595.

43. AMA (Australian Medical Association), *AMA Position Statement - Conscientious Objection*, AMA, 2019, accessed 23 November 2024.

44. G Morley, C Bradbury-Jones and J Ives, 'Reasons to redefine moral distress: a feminist empirical bioethics analysis', *Bioethics*, 2021, 35(1):61-71, doi:10.1111/bioe.12783.

45. K Mooney-Doyle and CM Ulrich, 'Parent moral distress in serious pediatric illness: a dimensional analysis', *Nursing Ethics*, 2020, 27(3):821-837, doi:10.1177/0969733019878838.

46. A Ullrich, M Theochari, C Bergelt, G Marx, K Woellert, C Bokemeyer and K Oechsle, 'Ethical challenges in family caregivers of patients with advanced cancer - A qualitative study', *BMC Palliative Care*, 2020, 19(1):1-13, doi:10.1186/s12904-020-00573-6.

47. G Morley, C Bradbury-Jones and J Ives, 'Moral distress in end-of-life care', in N Emmerich, P Mallia, B Gordjin and F Pistoia, eds, *Contemporary European Perspectives on the Ethics of End of Life Care*, Springer, 2020, pp 335-353, doi:10.1007/978-3-030-40033-0.

48. K Ducharlet, J Philip, H Gock, M Brown, S Gelfand, E Josland and F Brennan, 'Moral Distress in Nephrology: Perceived Barriers to Ethical Clinical Care', *American Journal of Kidney Diseases*, 2020, 76(2):248-254, doi:10.1053/j.ajkd.2019.09.018.

49. MBA (Medical Board of Australia), *Good Medical Practice: A Code of Conduct for Doctors in Australia*, 2020, accessed 23 November 2024.

50. HM Machin, L Buckland, C Critchley, S Wiffen, G Sutton and PN Baird, 'Determining the willingness of Australians to export their corneas on death', *PLoS One*, 2021, 16:1-12, doi:10.1371/journal.pone.0246622.

51. O Iuliani, C Passeri, F Papola, P Accorsi, 'The withdrawal of consent to haematopoietic stem cells (HSC) donation: The complicated balance between donor's rights and patient's protection', *Transfusion and Apheresis Science*, 2020, 59(4):17-18, doi:10.1016/j.transci.2020.102813.

52. N Cowan, HA Gritsch, N Nassiri, J Sinacore and J Veale, 'Broken chains and reneging: a review of 1748 kidney paired donation transplants', *American Journal of Transplantation*, 2017, 17(9):2451-2457, doi:10.1111/ajt.14343.

53. *Human Tissue and Transplant Act 1982* (WA)

54. LF Ross and JR Thistlethwaite, 'Prisoners as living donors: a vulnerabilities analysis', *Cambridge Quarterly of Healthcare Ethics*, 2018, 27(1):93-108, doi:10.1017/S0963180117000433.

55. AM Kisch, A Forsberg, I Fridh, M Almgren, M Lundmark, CL Loven, ...and A Lennerling, 'The meaning of being a living kidney, liver, or stem cell donor - a meta-ethnography', *Transplantation*, 2018,102(5):744-756, doi:10.1097/TP.0000000000002073.

56. MC Garcia, JR Chapman, PJ Shaw, DJ Gottlieb, A Ralph, JC Craig and A Tong, 'Motivations, experiences, and perspectives of bone marrow and peripheral blood stem cell donors: thematic synthesis of qualitative studies', *Biology of Blood and Marrow Transplantation*, 2013, 19(7):1046-1058, doi:10.1016/j.bbmt.2013.04.012.

57. C Thiessen, YA Kim, R Formica, M Bia and S Kulkarni, 'Opting out: confidentiality and availability of an 'alibi' for potential living kidney donors in the USA', *Journal of Medical Ethics*, 2015, 41(7):506-510, doi:10.1136/medethics-2014-102184.

58. ABMDR (Australian Bone Marrow Donor Registry), 'Donor enrolment form [PDF 229KB]', ABMDR, 2021, accessed 1 October 2021.

59. ABMDR, 'Donor Information - Work Up', ABMDR website, 2021, accessed 1 October 2021.

60. D Confer, B Shaw and D Pamphilon, 'WMDA guidelines for subsequent donations following initial BM or PBSCs', *Bone Marrow Transplantation*, 2011, 46:1409-1412.

61. J Delgado, A Molina-Pérez, D Shaw and D Rodríguez-Arias, 'The role of the family in deceased organ procurement: a guide for clinicians and policymakers', *Transplantation*, 2019, 103(5):e112-e118, doi:10.1097/TP.0000000000002622.

62. SN Then and DE Martin, 'Transitions in decision-making authority at the end of life: A problem of law, ethics and practice in deceased donation', *Journal of Medical Ethics*, 2022, 48(2):112-117, doi:10.1136/medethics-2020-106572.

63. M Toews and T Caulfield, 'Evaluating the 'family veto' of consent for organ donation', *Canadian Medical Association Journal*, 2016, 188(17-18):E436-E437, doi:10.1503/cmaj.160752.

64. A Albertsen, 'Against the family veto in organ procurement: Why the wishes of the dead should prevail when the living and the deceased disagree on organ donation', *Bioethics*, 2019, 46:272-280, doi:10.1111/bioe.12661.

65. D Shaw, D Georgieva, B Haase, D Gardiner, P Lewis, N Janson, ...and ELPAT Working Group on Deceased Donation, 'Family over rules? an ethical analysis of allowing families to overrule donation intentions', *Transplantation*, 2017, 101(3):482-487, doi:10.1097/TP.0000000000001536.

66. KA Bramstedt, 'Family refusals of registered consents: The disruption of organ donation by double-standard surrogate decision-making', *Internal Medicine Journal*, 2013, 43(2):120-123, doi:10.1111/imj.12029.

67. SN Then, B White and L Willmott, 'Adults who lack capacity: substitute decision-making', in B White, F McDonald, L Willmott and SN Then, eds, *Health Law in Australia*, 4th edn, Thomson Reuters Australia, Sydney, 2024, pp 221-286.

68. SN Then, IH Kerridge and M Marks, 'Children as haematopoietic stem cell donors: ethically challenging and legally complex', *Medical Journal of Australia*, 2018, 208(8):334-338, doi:10.5694/mja17.00758.

69. *Northern Sydney and Central Coast Area Health Service v CT [2005] NSWSC 551*.

70. YL Cheah, MA Simpson, JJ Pomposelli and EA Pomfret, 'Incidence of death and potentially life-threatening near-miss events in living donor hepatic lobectomy: A world-wide survey', *Liver Transplantation*, 2013, 19:499-506, doi:10.1002/lt.

71. PP Reese, MB Allen, C Carney, D Leidy, S Levsky, R Pendse, ...and EJ Emanuel, 'Outcomes for individuals turned down for living kidney donation', *Clinical Transplantation*, 2018, 32(12):1-12, doi:10.1111/ctr.13408.

72. F Rössler, G Sapisochin, GW Song, YH Lin, MA Simpson, K Hasegawa, ... and PA Clavien, 'Defining benchmarks for major liver surgery: A multicenter analysis of 5202 living liver donors', *Annals of Surgery*, 2016, 264(3):492-499, doi:10.1097/SLA.0000000000001849.

73. MA Dew, Z Butt , Q Liu, MA Simpson, J Zee, DP Ladner, ...and AF Dimartini, 'Prevalence and predictors of patient-reported long-term mental and physical health after donation in the adult-to-adult living-donor liver transplantation cohort study', *Transplantation*, 2018,102(1):105-118, doi:10.1097/TP.0000000000001942.

74. A Tong, J Gill, K Budde, L Marson, PP Reese, D Rosenbloom, ...and Song-Tx Investigators, 'Toward establishing core outcome domains for trials in kidney transplantation: report of the standardized outcomes in nephrology-kidney transplantation consensus workshops', *Transplantation*, 2017, 101(8):1887-1896, doi:10.1097/TP.0000000000001774.

75. GA Abel, R Albelda, N Khera, T Hahn, DY Salas Coronado, OO Odejide, ...and R Soiffer, 'Financial hardship and patient-reported outcomes after hematopoietic cell transplantation', *Biology of Blood and Marrow Transplantation*, 2016, 22(8):1504-1510, doi:10.1016/j.bbmt.2016.05.008.

76. PP Reese, N Boudville and AX Garg, 'Living kidney donation: Outcomes, ethics, and uncertainty', *The Lancet*, 2015, 385(9981):2003-2013, doi:10.1016/S0140-6736(14)62484-3.

77. K Lentine, AD Waterman, M Cooper, S Nagral, D Gardiner, M Spiro, ...and FL Delmonico, 'Expanding opportunities for living donation: recommendations from the 2023 Santander Summit to ensure donor protections, informed decision making, and equitable access', *Transplantation*, 2024, doi:10.1097/TP.0000000000005124.

78. AMA, *AMA Code of Ethics 2004. Editorially Revised 2006. Revised 2016*, AMA, 2017, accessed 23 November 2024.

79. AMA, 'Position Statement on End of Life Care and Advance Care Planning 2014 [PDF 108KB]', AMA, 2014, accessed 23 November 2024.

80. MA Dew, AF Dimartini, AJ Devito Dabbs, A Zuckoff, HP Tan, ML McNulty, ...and A Humar, 'Preventive intervention for living donor psychosocial outcomes: feasibility and efficacy in a randomized controlled trial', *American Journal of Transplantation*, 2013, 13(10):2672-2684, doi:10.1111/ajt.12393.

81. ABMDR, 'Donor information – collection' ABMDR website, 2021, accessed 1 October 2021.

82. KHA (Kidney Health Australia), *An Introduction to Kidney Donation by Live Donors*, KHA, 2017, accessed 23 November 2024.

83. A Hoffman, K Tendulkar, S Merani, A Maskin and A Langnas, 'Fortuitous benefits of living kidney donation: Diagnosis of serious medical conditions during the living donor evaluation', *Clinical Transplantation*, 2018, 32(3):1-5, doi:10.1111/ctr.13204.

84. E Shukhman, J Hunt, D LaPointe-Rudow, D Mandelbrot, RE Hays, V Kumar, ...and KL Lentine, 'Evaluation and care of international living kidney donor candidates: Strategies for addressing common considerations and challenges', *Clinical Transplantation*, 2020, 34(3):1-11, doi:10.1111/ctr.13792.

85. KE Manera, CS Hanson, JR Chapman, J Kanellis, J Gill, JC Craig, ...and A Tong, 'Expectations and experiences of follow-up and self-care after living kidney donation: A focus group study', *Transplantation*, 2017, 101(10):2627-2635, doi:10.1097/TP.0000000000001771.

86. KL Lentine, NN Lam and DL Segev, 'Risks of living kidney donation: Current state of knowledge on outcomes important to donors', *Clinical Journal of the American Society of Nephrology*, 2019, 14(4):597-608, doi:10.2215/CJN.11220918.

87. C Thiessen, EJ Gordon, PP Reese and S Kulkarni, 'Development of a donor-centered approach to risk assessment: rebalancing nonmaleficence and autonomy', *American Journal of Transplantation*, 2015, 15(9):2314-2323, doi:10.1111/ajt.13272.

88. VK Sigurjonsdottir and PC Grimm, 'Living or deceased donor kidney transplantation in children', *Current Opinion in Pediatrics*, 2019, 31(2):232-236, doi:10.1097/MOP.0000000000000740.

89. SE Van Pilsum Rasmussen, M Robin, A Saha, A Eno, R Lifshitz, MM Waldram, ...and ML Henderson, 'The tangible benefits of living donation: results of a qualitative study of living kidney donors', *Transplantation Direct*, 2020, 6(12):e626, doi:10.1097/TXD.0000000000001068.

90. S Habbous, L Barnieh, S Klarenbach, B Manns, S Sarma, MA Begen, ...and AX Garg, 'Evaluating multiple living kidney donor candidates simultaneously is more cost-effective than sequentially', *Kidney International*, 2020, 98(6):1578-1588, doi:10.1016/j.kint.2020.06.015.

91. VR Humphreville, DM Radosevich, A Humar, WD Payne, R Kandaswamy, JR Lake, ...and S Chinnakotla, 'Longterm health-related quality of life after living liver donation', *Liver Transplantation*, 2016, 22(1):53-62, doi:10.1002/lt.24304.

92. JR Rodrigue, JD Schold, P Morrissey, J Whiting, J Vella, LK Kayler, ...and KDOC Study Group, 'Mood, body image, fear of kidney failure, life satisfaction, and decisional stability following living kidney donation: Findings from the KDOC study', *American Journal of Transplantation*, 2018, 18(6):1397-1407, doi:10.1111/ajt.14618.

93. A Menjivar, X Torres, D Paredes, N Avinyo, J Maria Peri, E De Sousa-Amorim, ... and I Revuelta, 'Assessment of donor satisfaction as an essential part of living donor kidney transplantation: an eleven-year retrospective study', *Transplant International*, 2018, 31(12):1332-1344, doi:10.1111/tri.13334.

94. H Maple, J Chilcot, L Burnapp, P Gibbs, A Santhouse, S Norton, ...and N Mamode, 'Motivations, outcomes, and characteristics of unspecified (nondirected altruistic) kidney donors in the United Kingdom', *Transplantation*, 2014, 98(11):1182-1189, doi:10.1097/TP.0000000000000340.

95. MH Raza, MH Kim, L Ding, TL Fong, C Romero, Y Genyk, ...and J Emamaullee, 'Long-term financial, psychosocial, and overall health-related quality of life after living liver donation', *Journal of Surgical Research*, 2020, 253:41-52, doi:10.1016/j.jss.2020.03.025.

96. AJ Sarti, S Sutherland, A Healey, S Dhanani, A Landriault, F Fothergill-Bourbonnais, ...and P Cardinal, 'A multicenter qualitative investigation of the experiences and perspectives of substitute decision makers who underwent organ donation decisions', *Progress in Transplantation*, 2018, 28(4):343-348, doi:10.1177/1526924818800046.

97. N Kentish-Barnes, LA Siminoff, W Walker, M Urbanski, J Charpentier, M Thuong, ...and E Azoulay, 'A narrative review of family members' experience of organ donation request after brain death in the critical care setting', *Intensive Care Medicine*, 2019, 45(3):331-342, doi:10.1007/s00134-019-05575-4.

98. LJ Taylor, A Buffington, JR Scalea, N Fost, KD Croes, JD Mezrich and ML Schwarze, 'Harms of unsuccessful donation after circulatory death: An exploratory study', *American Journal of Transplantation*, 2018, 18(2):402-409, doi:10.1111/ajt.14464.

99. M Ladhani, JC Craig, G Wong, 'Obesity and gender-biased access to deceased donor kidney transplantation', *Nephrology Dialysis Transplantation*, 2020, (35):184-189.

100. N Khanal, PD Lawton, A Cass and SP McDonald, 'Disparity of access to kidney transplantation by Indigenous and non-Indigenous Australians', *Medical Journal of Australia*, 2018, 209(6):261-266, doi:10.5694/mja18.00304.

101. PD Lawton, SP McDonald, PL Snelling, J Hughes and A Cass, 'Organ transplantation in Australia: inequities in access and outcome for Indigenous Australians', *Transplantation*. 2017, 101(11):e345-e346, doi:10.1097/TP.0000000000001911.

102. J Botha, F Conradie, H Etheredge, J Fabian, M Duncan, AH Mazanderani, ...and CT Tiemessen, 'Living donor liver transplant from an HIV-positive mother to her HIV-negative child: opening up new therapeutic options', *AIDS*, 2018, 32(16):F13-F19, doi:10.1097/QAD.0000000000002000.

103. E Mitchell, KM Loomes, RH Squires and D Goldberg, 'Variability in acceptance of organ offers by pediatric transplant centers and its impact on wait-list mortality', *Liver Transplantation*, 2018, 24(6):803-809, doi:10.1002/lt.25048.

104. MS Mulvihill, HJ Lee, J Weber, AY Choi, ML Cox, BA Yerokun, ...and MG Hartwig, 'Variability in donor organ offer acceptance and lung transplantation survival', *Journal of Heart and Lung Transplantation*, 2020, 39(4):353-362, doi:10.1016/j.healun.2019.12.010.

105. SA Husain, KL King, S Pastan, RE Patzer, DJ Cohen, J Radhakrishnan and S Mohan, 'Association between declined offers of deceased donor kidney allograft and outcomes in kidney transplant candidates', *JAMA Network Open*, 2019, 2(8):2-13, doi:10.1001/jamanetworkopen.2019.10312.

106. AY Choi, MS Mulvihill, HJ Lee, C Zhao, M Kuchibhatla, JN Schroder, ...and MG Hartwig, 'Transplant center variability in organ offer acceptance and mortality among US patients on the heart transplant waitlist', *JAMA Cardiology*, 2020, 5(6):660-668, doi:10.1001/jamacardio.2020.0659.

107. A Wey, N Salkowski, WK Kremers, CR Schaffhausen, BL Kasiske, AK Israni and JJ Snyder, 'A kidney offer acceptance decision tool to inform the decision to accept an offer or wait for a better kidney', *American Journal of Transplantation*, 2018, 18(4):897-906, doi:10.1111/ajt.14506.

108. H Cardinal, F Ballesteros Gallego, A Affdal and MC Fortin, 'Canadian transplant nephrologists' perspectives on the decision-making process for accepting or refusing a kidney from a deceased organ donor', *Clinical Transplantation*, 2020, 34(3), doi:10.1111/ctr.13793.

109. G Wong, M Howell, E Patrick and J Yang, 'Taking kidneys for granted? Time to reflect on the choices we make', *Transplantation*, 2017, 101(12):2812-2813, doi:10.1097/TP.0000000000001850.

110. OAIC (Office of the Australian Information Commissioner), 'What is privacy?' OAIC website, nd, accessed 23 November 2024.

111. DHAC, Disclosure of information provisions in Commonwealth and state and territory Acts [PDF 135KB], Donatelife website, 2023, accessed 5 October, 2024.

112. *S 95AA Privacy Act and Associated Guidelines*.

113. OAIC, Guide to health privacy, OAIC, 2019, accessed 23 November 2024.

114. N Meggiolaro, K Barlow-Stewart, K Dunlop, AJ Newson and J Fleming, 'Disclosure to genetic relatives without consent - Australian genetic professionals' awareness of the health privacy law', *BMC Medical Ethics*, 2020, 21(1):1-10, doi:10.1186/s12910-020-0451-1.

115. A Young, SJ Kim, EM Gibney, CR Parikh, MS Cuerden, LD Horvat, ...and AX Garg, 'Discovering misattributed paternity in living kidney donation: Prevalence, preference, and practice', *Transplantation*, 2009, 87(10):1429-1435, doi:10.1097/TP.0b013e3181a4eae5.

116. JR Botkin, JW Belmont, JS Berg, BE Berkman, Y Bombard, IA Holm, ...and JD McInerney, 'Points to consider: ethical, legal, and psychosocial implications of genetic testing in children and adolescents', *American Journal of Human Genetics*, 2015, 97(1):6-21, doi:10.1016/j.ajhg.2015.05.022.

117. MA Freeman and LS Parker, 'Answers to questions that weren't asked: the ethical complexities of identifying misattributed paternity during the transplant evaluation process', in RA Greenberg, AM Goldberg and D Rodriguez-Arias, ed.s, *Ethical Issues in Pediatric Organ Transplantation*, Springer, 2016, pp 43-59, doi:10.1007/978-3-319-29185-7_3.

118. DC Wheeler and WC Winkelmayer, 'KDIGO Clinical Practice Guideline on the Evaluation and Care of Living Kidney Donors', *Transplantation*, 2017, 101(8S):S1, doi:10.1111/nep.13602.

119. S Jacobson, J Eggert, J Deluca and D Speckhart, 'Misattributed paternity in hematopoietic stem cell transplantation: The role of the healthcare provider', *Clinical Journal of Oncology Nursing*, 2015, 19(2):218-221, doi:10.1188/15.CJON.218-221.

120. L Hercher and L Jamal, 'An old problem in a new age: Revisiting the clinical dilemma of misattributed paternity', *Applied and Translational Genomics*, 2016, 8:36-39, doi:10.1016/j.atg.2016.01.004.

121. DE Martin, *Contact between Donor Families and Transplant Recipients*, DonateLife website, 2017, accessed 1 October, 2021.

122. C Petrini, L Riva, G Floridia and C Mannelli, 'Anonymity and organ donation: ethical and policy implications after the opinion released by the Italian Committee for Bioethics', *Transplantation Proceedings*, 2020, 52(5):1525-1527, doi:10.1016/j.transproceed.2020.01.079.

123. AK Vajentic, 'Correspondence and personal contact between donor families and organ recipients: One OPO's procedure and experience', *Journal of Transplant Coordination*, 1997, 7(3):106-110, doi:10.7182/prtr.1.7.3.y71142l18j6k4067.

124. L Clayville, 'When donor families and organ recipients meet', *Journal of Transplant Coordination*, 1999, 9(2):81-86, doi:10.7182/prtr.1.9.2.0046q06v05v6652v.

125. NH O'Donnell and JPD Guidry, '#BeTheMatch: Assessing how testimonials on Reddit promote the importance of donating bone marrow', *Journal of Health Communication,* 2020, 25(8):660-670, doi:10.1080/10810730.2020.1836088.

126. SE Morgan, TR Harrison, SD Long, WA Afifi, MS Stephenson and T Reichert, 'Family discussions about organ donation: How the media influences opinions about donation decisions', *Clinical Transplantation*, 2005, 19(5):674-682, doi:10.1111/j.1399-0012.2005.00407.x.

127. DME Hoque, V Kumari, M Hoque, R Ruseckaite, L Romero and SM Evans, 'Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review', *PLoS One*, 2017, 12(9):1-20, doi:10.1371/journal.pone.0183667.

128. DHAC. *A National Clinical Quality Registries and Virtual Registries 2020-2030*, DHAC, 2021, accessed 23 November 2024.

129. J Walker, R Lovett, T Kukutai, C Jones and D Henry, 'Indigenous health data and the path to healing', *The Lancet*, 2017, 390(10107):2022-2023, doi:10.1016/S0140-6736(17)32755-1.

130. FNIGC (First Nations Information Governance Centre), *The First Nations Principles of OCAP®*, FNIGC, nd, accessed 23 November 2024.

131. L Mick-Ramsamy, J Kelly, D Duff, A Cass, L Ross, D Croker, ...and JT Hughes, *Catching Some Air - Asserting Aboriginal and Torres Strait Islander Information Rights in Renal Disease Project - The Final Report* [PDF 2.9MB], Menzies University, 2019, accessed 23 November 2024.

132. ANZDATA (Australia and New Zealand Dialysis and Transplant Registry), *Guidance on Data Requests Relating to Patient Ethnicity*, ANZDATA, 2021, accessed 23 November 2024.

133. B Dominguez-Gil, M López-Fraga, E Muller, L Potena, DE Martin, A Perez Blanco, ...and FL Delmonico, 'Santander Global Summit in Transplantation: supporting global convergence in the shared goals of sufficiency, transparency and oversight', *Transplantation*, 2024, doi:10.1097/TP.0000000000005222.

134. DHAC, *Final Report Analysis of the Australian Tissue Sector*, DHAC, 2016, accessed 23 November 2024.

135. DE Martin, K Van Assche, L Cervantes, JLR Forsythe, T Muller, A Perez-Blanco, ...and M Lopez-Fraga, 'Towards equity in global access to SoHO-based therapies: recommendations for action', *Transplantation*, 2024, doi:10.1097/TP.0000000000005106.

136. M Whitehead, 'The concepts and principles of equity and health', *International Journal of Health Services*, 1992, 22(3):429-445, doi:10.2190/986L-LHQ6-2VTE-YRRN

137. G Persad, A Wertheimer and EJ Emanuel, 'Principles for allocation of scarce medical interventions', *The Lancet*, 2009, 373(9661):423-431, doi:10.1016/S0140-6736(09)60137-9.

138. NS Jecker and LJ Schneiderman, 'Is dying young worse than dying old?', *Gerontologist*, 1994, 34(1):66-72.

139. LF Ross, W Parker, RM Veatch, SE Gentry and JR Thistlethwaite, 'Equal opportunity supplemented by fair innings: Equity and efficiency in allocating deceased donor kidneys', *American Journal of Transplantation*, 2012, 12(8):2115-2124, doi:10.1111/j.1600-6143.2012.04141.x.

140. RM Veatch, 'Egalitarian and maximin theories of justice: Directed donation of organs for transplant', *Journal of Medicine and Philosophy*, 1998, 23(5):456-476, doi:10.1076/jmep.23.5.456.2570.

141. P Singer, J McKie, H Kuhse and J Richardson, 'Double jeopardy and the use of QALYs in health care allocation' *Journal of Medical Ethics*, 1995, 21(3):144-157, doi:10.1136/jme.21.3.144.

142. JT Hughes, N Freeman, B Beaton, AM Puruntatemeri, M Hausin, G Tipiloura, ... and R Kirkham, 'My experiences with kidney care: A qualitative study of adults in the Northern Territory of Australia living with chronic kidney disease, dialysis and transplantation', *PLoS One*, 2019,14(12), doi:10.1371/journal.pone.0225722.

143. BS Grace, PA Clayton, A Cass and SP McDonald, 'Transplantation rates for living- but not deceased-donor kidneys vary with socioeconomic status in Australia', *Kidney International*, 2013, 83(1):138-145, doi:10.1038/ki.2012.304.

144. A Tong, K Howard, G Wong, A Cass, S Jan, M Irving and JC Craig, 'Nephrologists' perspectives on waitlisting and allocation of deceased donor kidneys for transplant', *American Journal of Kidney Diseases*, 2011, 58(5):704-716, doi:10.1053/j.ajkd.2011.05.029.

145. MD Huesch, 'One and done? Equality of opportunity and repeated access to scarce, indivisible medical resources', *BMC Medical Ethics*, 2012, (13), doi:10.1056/nejm200209193471225.

146. TSANZ. *Clinical Guidelines for Organ Transplantation from Deceased Donors Version 1.6 [PDF 1.7MB]*, TSANZ, 2021, accessed 4 June 2021.

147. S Schicktanz, A Simon, S Raphael and M Ahlert, 'The ethical debate over child priority in post-mortem organ allocation: A scoping review and practical-ethical outlook', *Transplantation Reviews*, 2020, 34(3):100543, doi:10.1016/j.trre.2020.100543.

148. MJ Irving, A Tong, S Jan, G Wong, A Cass, RD Allen, ...and K Howard, 'Community preferences for the allocation of deceased donor organs for transplantation: A focus group study', *Nephrology Dialysis Transplantation*, 2013, 28(8):2187-2193, doi:10.1093/ndt/gft208.

149. PA Ubel, C Jepson, J Baron, T Mohr, S McMorrow and DA Asch, 'Allocation of transplantable organs: Do people want to punish patients for causing their illness?', *Liver Transplantation*, 2001, 7(7):600-607, doi:10.1053/jlts.2001.25361.

150. P Friesen, 'Personal responsibility within health policy: Unethical and ineffective', *Journal of Medical Ethics*, 2018, 44(1):53-58, doi:10.1136/medethics-2016-103478.

151. JL Wainright, AY Kucheryavaya, DK Klassen and DE Stewart, 'The impact of the new kidney allocation system on prior living kidney donors' access to deceased donor kidney transplants: an early look', *American Journal of Transplantation*, 2017, 17(4):1103-1111, doi:10.1111/ajt.14102.

152. SG Westphal, ED Langewisch, AM Robinson, AR Wilk, JJ Dong, TJ Plumb, ...and CD Miles, 'The impact of multi-organ transplant allocation priority on waitlisted kidney transplant candidates', *American Journal of Transplantation*, 2021, 21(6):2161-2174, doi:10.1111/ajt.16390.

153. R Hellemans, A Kramer, J De Meester, F Collart, D Kuypers, M Jadoul, ...and KJ Jager, 'Does kidney transplantation with a standard or expanded criteria donor improve patient survival? Results from a Belgian cohort', *Nephrology Dialysis Transplantation*, 2021, 36(5):918-926, doi:10.1093/ndt/gfab024.

154. ND Eklou, BM Jänigen, P Pisarski, G Walz and J Schneider, 'Evaluation of deceased donor kidney transplantation in the eurotransplant senior program in comparison to standard allocation', *Annals of Transplantation*, 2022, 27, doi:10.12659/AOT.936514.

155. K Patel, A Brotherton, D Chaudhry, F Evison, T Nieto, D Dabare and A Sharif, 'All expanded criteria donor kidneys are equal but are some more equal than others? A population-cohort analysis of UK Transplant Registry data', *Transplant International*, 2023, 36, doi:10.3389/ti.2023.11421.

156. T Caulfield, B Murdoch, R Sapir-Pichhadze and P Keown, 'Policy challenges for organ allocation in an era of 'precision medicine.'', *Canadian Journal of Kidney Health and Disease*, 2020, 7, doi:10.1177/2054358120912655.

157. EBAANZ, *Bioethical Framework for Policy and Procedure 2015*, EBAANZ, 2015, accessed 23 November 2024.

158. J Szer, D Weisdorf, S Querol, L Foeken and A Madrigal, 'The impact of COVID-19 on the provision of donor hematopoietic stem cell products worldwide: collateral damage', *Bone Marrow Transplantation*, 2020, 55(10):2043-2044, doi:10.1038/s41409-020-0873-x.

159. ERS Cliff and J Szer, 'We must grow the Australian Bone Marrow Donor Registry' *Internal Medicine Journal*, 2021, 51(11):1771-1772, doi:10.1111/imj.15570.

160. GL Irish, RAS Fadhil, E Rondeau, S Nagral, M Ahmadipour, PT Coates and DE Martin, 'International travel for organ transplantation: A survey of professional experiences and attitudes toward data collection and reporting', *Transplantation Direct*, 2024, doi:10.1097/TXD.0000000000001655.

161. Y Shimazono, 'The state of the international organ trade: A provisional picture based on integration of available information', *Bulletin of the World Health Organization*, 2007, 85(12):955-962, doi:10.2471/BLT.06.039370.

162. G Smith, D Gujari, O Russell, L Palmer, M Toews, G Wong, ...and PT Coates, 'International travel by Australians for overseas transplantation', *Medical Journal of Australia*, 2019, 211(10):460, doi:10.5694/mja2.50333.

163. RL Mendoza, 'Colombia's organ trade: Evidence from Bogotá and Medellín', *Journal of Public Health*, 2010, 18(4):375-384, doi:10.1007/s10389-010-0320-3

164. M Moniruzzaman, ''Living cadavers' in Bangladesh: Bioviolence in the human organ bazaar', *Medical Anthropology Quarterly*, 2012, 26(1):69-91, doi:10.1111/j.1548-1387.2011.01197.x.

165. F Moazam, R Moazam Zaman and AM Jafarey, 'Conversations with kidney vendors in Pakistan: An ethnographic study', *Hastings Center Report*, 2009,39(3):29-44, doi:10.1353/hcr.0.0136

166. S Yea, 'Masculinity under the knife: Filipino men, trafficking and the black organ market in Manila, the Philippines', *Gender, Place and Culture*, 2015, 22(1):123-142, doi:10.1080/0966369X.2013.832657.

167. M Torres Soto and CN Kotton, 'Infectious disease complications of transplant tourism', *Expert Review of Anti-Infective Therapy*, 2021, 19(6):671-673, doi:10.1080/14787210.2020.1851196.

168. L Wright, JS Zaltzman, J Gill and GVR Prasad, 'Kidney transplant tourism: Cases from Canada', *Medicine, Health Care and Philosophy*, 2013, 16(4):921-924, doi:10.1007/s11019-012-9450-4.

169. GM Danovitch, J Chapman, AM Capron, A Levin, M Abbud-Filho, M Al Mousawi, ... and FL Delmonico, 'Organ trafficking and transplant tourism: The role of global professional ethical standards - The 2008 declaration of Istanbul', *Transplantation*, 2013, 95(11):1306-1312, doi:10.1097/TP.0b013e318295ee7d.

170. WMA, *WMA Statement on Measures for the Prevention and Fight against Transplant-Related Crimes*, WMA, 2020, accessed 23 November 2024.

171. Human Tissue Authority, *The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024*, legislation.gov.uk, 2024, accessed 23 November 2024.

172. M Ishikawa, SV Lynch, GA Balderson, RW Shepherd, TH Ong and RW Strong, 'Liver transplantation in Japanese and Australian/New Zealand children with biliary atresia: A 10-year comparative study', *European Journal of Surgery*, 1999, 165(5):454-459, doi:10.1080/110241599750006695.

173. FL Delmonico, D Martin, B Domínguez-Gil, E Muller, V Jha, A Levin, GM Danovitch and AM Capron, 'Living and deceased organ donation should be financially neutral acts', *American Journal of Transplantation*, 2015,15(5):1187-1191, doi:10.1111/ajt.13232.

174. DE Martin, K Van Assche, B Domínguez-Gil, M Lopez-Fraga, R Garcia Gallont, E Muller and AM Capron, 'Strengthening Global Efforts to Combat Organ Trafficking and Transplant Tourism: Implications of the 2018 Edition of the Declaration of Istanbul', *Transplantation Direct*, 2019, 5(3):1-13, doi:10.1097/TXD.0000000000000872.

175. DE Martin, AM Capron, RAS Fadhil, JLR Forsythe, B Padilla, A Perez-Blanco, ...and M Lopez-Fraga, 'Supporting financial neutrality in donation of organs, cells, and tissues', *Transplantation*, 2024, doi:10.1097/TP.0000000000005197.

176. FDAC, *Review of the Australian Organ Donation, Retrieval and Transplantation System -Final Report*, FDAC, 2018, accessed 23 November 2024.

177. DE Martin, AM Capron, RAS Fadhil, JLR Forsythe, B Padilla, A Perez-Blanco, ... and M Lopez-Fraga, 'Prevention of trafficking in organs, tissues, and cells', *Transplantation*, 2024, doi:10.1097/TP.0000000000005212.

178. Australian Government, Organ trafficking fact sheet: Information for medical professionals, ag.gov.au, 2022, accessed 23 November 2024.

179. DE Martin, K Van Assche, B Domínguez-Gil, M Lopez-Fraga, R Garcia Gallont, E Muller, ...and AM Capron, 'A new edition of the Declaration of Istanbul: updated guidance to combat organ trafficking and transplant tourism worldwide', *Kidney International*, 2019, 95(4):757-759, doi:10.1016/j.kint.2019.01.006.

180. S Columb, 'Excavating the organ trade: An empirical study of organ trading networks in Cairo, Egypt', *British Journal of Criminology*, 2017, 57(6):1301-1321, doi:10.1093/bjc/azw068.

181. M Goyal, RL Mehta, LJ Schneiderman and AR Sehgal, 'Economic and health consequences of selling a kidney in India', *Journal of the American Medical Association*, 2002, 288(13):1589-1593, doi:10.1001/jama.288.13.1589.

182. Australian Federal Police, Human trafficking and slavery, AFP, 2021, accessed 23 November 2024.

183. Parliamentary Assembly - Council of Europe, *Recommendation 2173 (2020) Combating Trafficking in Human Tissues and Cells*, assembly.coe.int, 2020, accessed 23 November 2024.

184. JA Robertson, 'The Dead Donor Rule', *Hastings Center Report*, 1999, 29(6):6, doi:10.2307/3527865.

185. MJ O'Leary, G Skowronski, C Critchley, L O'Reilly, C Forlini, L Sheahan, ...and I Kerridge, 'Death determination, organ donation and the importance of the Dead Donor Rule following withdrawal of life-sustaining treatment: a survey of community opinions', *Internal Medicine Journal*, 2022, 52(2):238-248, doi:10.1111/imj.15221.

186. A Omelianchuk, 'The inviolateness of life and equal protection: a defense of the dead-donor rule', *Theoretical Medicine and Bioethics*, 2022, 43(1):1-27, doi:10.1007/s11017-022-09557-4.

187. W Tuohy, 'Angus wanted to donate his organs, but they all went to waste. His mother wants change', *The Age*, 17 April 2023, accessed 8 October, 2024.

188. FG Miller, RD Truog and DW Brock, 'The dead donor rule: Can it withstand critical scrutiny?' *Journal of Medicine and Philosophy*, 2010, 35(3):299-312, doi:10.1093/jmp/jhq019.Feizpour CA, Gauntt K, Patel MS, et al. The impact of machine perfusion of the heart on warm ischemia time and organ yield in donation after circulatory death. *Am J Transplant*. 2022;22(5):1451-1458. doi:10.1111/ajt.16952

189. CA Feizpour, K Gauntt, MS Patel, B Carrico, PA Vagefi, D Klassen and M MacConmara, 'The impact of machine perfusion of the heart on warm ischemia time and organ yield in donation after circulatory death', *American Journal of Transplantation*, 2022, 22(5):1451-1458, doi:10.1111/ajt.16952.

190. DM Greer, SD Shemie, A Lewis, S Torrance, P Varelas, FD Goldenberg, ...and G Sung, 'Determination of Brain Death/Death by Neurologic Criteria: The World Brain Death Project', *JAMA*, 2020, 324(11):1078-1097, doi:10.1001/jama.2020.11586.

191. SD Shemie, L Hornby, A Baker, J Teitelbaum, S Torrance, K Young, ...and L Noel, 'International guideline development for the determination of death', *Intensive Care Medicine*, 2014, 40(6):788-797, doi:10.1007/s00134-014-3242-7.

192. FMP van Haren, A Carter, E Cavazzoni, M Chapman, RL D'Costa, SL Jones, ... and D Martin, 'Conflicts of interest in the context of end of life care for potential organ donors in Australia', *Journal of Critical Care*, 2020, 59:166-171, doi:10.1016/j.jcrc.2020.06.016.

193. *Human Tissue Amendment (Ante-Mortem Interventions) Act 2024 No 13 (NSW)*

194. *Human Tissue Amendment Act 2020 (No. 42 of 2020) - Sect 5 (Vic)*

195. SN Then, DE Martin, A Mcgee, D Gardiner and N El Moslemani, 'Decision-making About Premortem Interventions for Donation : Navigating Legal and Ethical Complexities', 2023, 107(8):1655-1663, doi:10.1097/TP.0000000000004591.

196. UK Donation Ethics Committee, 'Nontherapeutic elective ventilation [PDF 177KB]', aomrc.org.uk, 2016, accessed October 8, 2024.

197. J Coggon, 'Elective ventilation for organ donation: Law, policy and public ethics', *Journal of Medical Ethics*, 2013, 39(3):130-134, doi:10.1136/medethics-2012-100992.

198. L Woodyatt, R D'Costa, M Plas and S Radford, 'Australia's first experience of organ donation after voluntary assisted dying - a experiential review', *Transplantation*, 2023,107(10S1):104-104.

199. J Mulder, H Sonneveld, D Van Raemdonck, J Downar, K Wiebe, B Dominguez-Gil, ... and G Olthuis, 'Practice and challenges for organ donation after medical assistance in dying: A scoping review including the results of the first international roundtable in 2021', *American Journal of Transplantation*, 2022, 22(12):2759-2780, doi:10.1111/ajt.17198.

200. J Mulder, H Sonneveld, A Healey and D Van Raemdonck, 'The first international roundtable on 'organ donation after circulatory death by medical assistance in dying' demonstrates increasing incidence of successful patient-driven procedure', *American Journal of Transplantation*, 2022, 22(3):999-1000, doi:10.1111/ajt.16879.

201. R Ray and D Martin, 'Missed opportunities: saving lives through organ donation following voluntary assisted dying', *Internal Medicine Journal*, 2023, 53(5):861-865, doi:10.1111/imj.16085

202. J Downar, SD Shemie, C Gillrie, MC Fortin, A Appleby, DZ Buchman, ...and MD Sharpe, 'Deceased organ and tissue donation after medical assistance in dying and other conscious and competent donors: guidance for policy', *Canadian Medical Association Journal*, 2019, 191:e604-13, doi:10.1503/cmaj.

203. K Wiebe, LC Wilson, K Lotherington, C Mills, SD Shemie and J Downar, 'Deceased organ and tissue donation after medical assistance in dying: 2023 updated guidance for policy', *Canadian Medical Association Journal*, 2023, 195(25):E870-E878, doi:10.1503/cmaj.230108

204. D Wilkinson and J Savulescu, 'Should we allow organ donation euthanasia? alternatives for maximizing the number and quality of organs for transplantation', *Bioethics*, 2012, 26(1):32-48, doi:10.1111/j.1467-8519.2010.01811.x.

205. JAM Bollen, D Shaw, G de Wert, R Ten Hoopen, D Ysebaert, E van Heurn and WNKA van Mook, 'Euthanasia through living organ donation: Ethical, legal, and medical challenges', *Journal of Heart and Lung Transplantation*, 2019, 38(2):111-113, doi:10.1016/j.healun.2018.07.014.

206. Canadian Paediatric Society, 'Use of anencephalic newborns as organ donors (Position statement B2005-01)', *Paediatrics and Child Health*, 2005, 10(6):335-341, doi:10.1093/pch/10.6.335.

207. UK Donation Ethics Committee, *Organ Donation from Infants with Anencephaly-Guidance from the UK Donation Ethics Committee [PDF 86KB]*, aomrc.org.uk, 2016, accessed 23 November 2024.

208. A Jivraj, A Scales and J Brierley, 'Elective ventilation to facilitate organ donation in infants with anencephaly: Perinatal professionals' views and an ethical analysis', *Acta Paediatrica*, 2016, 105(5):494-498, doi:10.1111/apa.13281.

209. E Miñambres, B Estébanez, MÁ Ballesteros, E Coll, EM Flores-Cabeza, F Mosteiro, ...and B Dominguez-Gil, 'Normothermic regional perfusion in pediatric controlled donation after circulatory death can lead to optimal organ utilisation and posttransplant outcomes', *Transplantation*, 2023, 107(3):703-708, doi:10.1097/TP.0000000000004326.

210. I Jochmans, AJ Hessheimer, AP Neyrinck, D Paredes, MI Bellini, JH Dark, ... and CJE Watson, 'Consensus statement on normothermic regional perfusion in donation after circulatory death: Report from the European Society for Organ Transplantation's Transplant Learning Journey', *Transplant International*, 2021, 34(11):2019-2030, doi:10.1111/tri.13951.

211. AE Wall, A Fiedler, S Karp, A Shah, G Testa, 'Applying the ethical framework for donation after circulatory death to thoracic normothermic regional perfusion procedures', *American Journal of Transplantation*, 2022, 22(5):1311-1315, doi:10.1111/ajt.16959.

212. NB Murphy, M Slessarev, J Basmaji, L Blackstock, M Blaszak, M Brahmania, ...and C Weijer, 'Ethical issues in normothermic regional perfusion in controlled organ donation after determination of death by circulatory criteria: a scoping review', *Transplantation*, 2024, doi:10.1097/TP.0000000000005161.

213. JL Bernat, B Domínguez-Gil, AK Glazier, D Gardiner, AR Manara, S Shemie, ... and FL Delmonico, 'Understanding the brain-based determination of death when organ recovery is performed with DCDD in situ normothermic regional perfusion', *Transplantation*, 2023, 107(08):1650-1654, doi:10.1097/TP.0000000000004642.

214. JW Entwistle, DH Drake, KN Fenton, MA Smith, RM Sade and Cardiothoracic Ethics Forum, 'Normothermic regional perfusion: Ethical issues in thoracic organ donation', *Journal of Thoracic and Cardiovascular Surgery,* 2022, 164(1):147-154, doi:10.1016/j.jtcvs.2022.01.018.

215. M Royo-Villanova, E Miñambres, JM Sánchez, E Torres, C Manso, MÁ Ballesteros, ...and B Dominguez-Gil, 'Maintaining the permanence principle of death during normothermic regional perfusion in controlled DCD: Results of a Prospective Clinical Study, *American Journal of Transplantation*, 2024, 24(2):213-221, doi:10.1016/j.ajt.2023.09.008.

216. G Moorlock, 'Directed altruistic living donation: What is wrong with the beauty contest?', *Journal of Medical Ethics*, 2015, 41(11):875-879, doi:10.1136/medethics-2014-102230.

217. EM Neidich, AB Neidich, JT Cooper and KA Bramstedt, 'The ethical complexities of online organ solicitation via donor-patient websites: Avoiding the 'beauty contest.'', *American Journal of Transplantation*, 2012, 12(1):43-47, doi:10.1111/j.1600-6143.2011.03765.x.

218. JL Veale, AM Capron, N Nassiri, G Danovitch, HA Gritsch, A Waterman, ...and S Kapur, 'Vouchers for future kidney transplants to overcome 'chronological incompatibility' between living donors and recipients', *Transplantation*, 2017, 101(9):2115-2119, doi:10.1097/TP.0000000000001744.

219. M Cooper, DB Leeser, SM Flechner, JL Beaumont, AD Waterman, PW Shannon, ... and JL Veale, 'Ensuring the need is met: A 50-year simulation study of the National Kidney Registry's family voucher program', *American Journal of Transplantation*, 2021, 21(3):1128-1137, doi:10.1111/ajt.16101

220. GM Casey, M Kekewich, VN Naik, M Hartwick and A Healey, 'A request for directed organ donation in medical assistance in dying (MAID)', *Canadian Journal of Anesthesia*, 2020, 67(7):806-809, doi:10.1007/s12630-020-01632-5.

221. CL Stewart, LC Aparicio and IH Kerridge, 'Ethical and legal issues raised by cord blood banking - The challenges of the new bioeconomy', *Medical Journal of Australia*, 2013, 199(4):290-292, doi:10.5694/mja12.11668.

222. AusCord, *About AusCord and public cord blood banking*, thewomens.org.au, 2023, accessed 23 November 2024.

223. WT Shearer, BH Lubin, MS Cairo and LD Notarangelo, 'Cord blood banking for potential future transplantation', *Obstetric and Gynecological Survey*, 2018, 73(3):135-136, doi:10.1097/01.ogx.0000531866.75606.5a.

224. B Murdoch, AR Marcon and T Caulfield, 'The law and problematic marketing by private umbilical cord blood banks', *BMC Medical Ethics*, 2020, 21(1):4-9, doi:10.1186/s12910-020-00494-2.

225. S Sheldon and S Wilkinson, 'Should selecting saviour siblings be banned?', *Journal of Medical Ethics*, 2004, 30(6):533-537, doi:10.1136/jme.2003.004150.

226. LM Ngaage, S Ike, A Elegbede, CJ Vercler, S Gebran, F Liang, ...and YM Rasko, 'The changing paradigm of ethics in uterus transplantation: a systematic review', *Transplant International*, 2020, 33(3):260-269, doi:10.1111/tri.13548.

227. BP Jones, S Saso, T Bracewell-Milnes, MY Thum, J Nicopoullos, C Diaz-Garcia, ... and JR Smith, 'Human uterine transplantation: a review of outcomes from the first 45 cases', *BJOG: An International Journal of Obstetrics and Gynaecology*, 2019, 126(11):1310-1319, doi:10.1111/1471-0528.15863.

228. L Johannesson, G Testa, JM Putman, GJ McKenna, EC Koon, JR York, ...and AR Gregg, 'Twelve live births after uterus transplantation in the Dallas UtErus Transplant Study', *Obstetrics and Gynecology*, 2021, 137(2):241-249, doi:10.1097/AOG.0000000000004244.

229. R Flyckt, T Falcone, C Quintini, U Perni, B Eghtesad, EG Richards, ...and A Tzakis, 'First birth from a deceased donor uterus in the United States: from severe graft rejection to successful cesarean delivery', *American Journal of Obstetrics and Gynecology*, 2020, 223(2):143-151, doi:10.1016/j.ajog.2020.03.001.

230. R Deans, J Pittman, B Gerstl, K Haghighi, H Pleass, PD Kahler, ...and J Abbott, 'The first Australian uterus transplantation procedure: A result of a long-term Australian-Swedish research collaboration', *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 2023, 63(3):418-424, doi:10.1111/ajo.13678.

231. BP Jones, A Rajamanoharan, S Vali, NJ Williams, S Saso, MY Thum, ...and JR Smith, 'Perceptions and Motivations for Uterus Transplant in Transgender Women', *JAMA Network Open*, 2021, 4(1):1-11, doi:10.1001/jamanetworkopen.2020.34561.

232. L Johannesson, A Wall, AM Warren, AR Gregg and G Testa, 'Decisions on second pregnancy after uterus transplantation and timing for removal of the uterus—DUETS (Dallas UtErus Transplant Study)', *BJOG*, 2021, 128(10):1610-1614, doi:10.1111/1471-0528.16685.

233. S Järvholm, AM Warren, M Jalmbrant, N Kvarnström, G Testa and L Johannesson, 'Preoperative psychological evaluation of uterus transplant recipients, partners, and living donors: Suggested framework', *American Journal of Transplantation*, 2018, 18(11):2641-2646, doi:10.1111/ajt.15039.

234. G Testa, EC Koon and L Johannesson, 'Living donor uterus transplant and surrogacy: ethical analysis according to the principle of equipoise', *American Journal of Transplantation*, 2017, 17(4):912-916, doi:10.1111/ajt.14086.

235. B Bruno and KS Arora, 'Uterus transplantation: the ethics of using deceased vs. living Donors', *American Journal of Bioethics*, 2018, 18(7):6-15, doi:10.1080/15265161.2018.1478018.Uterus.

236. B Bruno and KS Arora, 'Ethical implications of donor type for uterus transplantation: Why we should remain wary of using living donors', *Yale Journal of Biology and Medicine*, 2020, 93(4):587-592.

237. J Earl, 'Innovative practice, clinical research, and the ethical advancement of medicine', *American Journal of Bioethics*, 2019, 19(6):7-18, doi:10.1080/15265161.2019.1602175.

238. P McCulloch, JA Cook, DG Altman, C Heneghan, MK Diener and IDEAL Group, 'IDEAL framework for surgical innovation 1: the idea and development stages', *BMJ*, 2013, 346:f3011, doi:10.1136/bmj.f3011.

239. A Hirst, Y Philippou, J Blazeby, B Campbell, M Campbell, J Feinberg, ...and P McCulloch, 'No surgical innovation without evaluation: evolution and further development of the IDEAL framework and recommendations', *Annals of Surgery*, 2019, 269(2):211-220, doi:10.1097/SLA.0000000000002794.

240. NCI (National Cancer Institute), NCI Dictionary of Cancer Terms, NCI, 2021, accessed 23 November 2024.

Appendix 1 – Further reading and resources

This Appendix provides a summary of recommended readings and resources for each of the chapters in these Guidelines.

Chapter 3 Resources

Australian ethical frameworks and guidelines relating to donation and transplantation

- AMA Position Statement on Organ and Tissue Donation and Transplantation. 2017. https://ama.com.au/sites/default/files/documents/AMA_Position_Statement_on_Organ_and_Tissue_Donation_and_Transplantation_2017_1.pdf
- The Australian and New Zealand Intensive Care Society Statement on Death and Organ Donation. Edition 4.1 2021. https://www.anzics.com.au/wp-content/uploads/2022/04/ANZICS-Statement-on-Death-and-Organ-Donation.pdf
- Australian Commission on Safety and Quality in Health Care. 2019. Shared decision making. Available at: https://www.safetyandquality.gov.au/our-work/partnering-consumers/shared-decision-making
- Australian Commission on Safety and Quality in Health Care. 2017. User guide for Aboriginal and Torres Strait Islander Health. https://www.safetyandquality.gov.au/sites/default/files/migrated/National-Safety-and-Quality-Health-Service-Standards-User-Guide-for-Aboriginal-and-Torres-Strait-Islander-Health.pdf
- Donate Life. Position statement on the legal framework for consent to donation. https://donatelife.gov.au/about-us/who-we-are/national-program/position-statement-legal-framework-consent-donation

Organ donation by prisoners

- British Transplant Society. 2016. Statement on living organ donation by prisoners. Available at: https://bts.org.uk/wp-content/uploads/2016/09/04_BTS_Donation_Prisoners-1.pdf

Ethical and legal issues relating to deceased donation decision-making

- Albertsen A. Against the family veto in organ procurement: Why the wishes of the dead should prevail when the living and the deceased disagree on organ donation. Bioethics. 2020 Mar;34(3):272-80.
- Bramstedt KA. Family refusals of registered consents: the disruption of organ donation by double-standard surrogate decision-making. Internal Medicine / journal. 2013 Feb;43(2):120-3.
- Morgan J, Hopkinson C, Hudson C, Murphy P, Gardiner D, McGowan O, Miller C. The Rule of Threes: three factors that triple the likelihood of families overriding first person consent for organ donation in the UK. Journal of the Intensive Care Society. 2018 May;19(2):101-6.
- Sharif A, Moorlock G. Influencing relatives to respect donor autonomy: Should we nudge families to consent to organ donation? Bioethics. 2018 Mar;32(3):155-63.
- Shaw D, Georgieva D, Haase B, Gardiner D, Lewis P, Jansen N, Wind T, Samuel U, McDonald M, Ploeg R. Family over rules? An ethical analysis of allowing families to overrule donation intentions. Transplantation. 2017 Mar 1;101(3):482-7.

- Then SN, Martin DE. Transitions in decision-making authority at the end of life: a problem of law, ethics and practice in deceased donation. Journal of Medical Ethics. 2022 Feb;48(2):112-117.

International guidelines on decision-making about donation and transplantation

- KDIGO. Chapter 2. Informed consent. https://kdigo.org/wp-content/uploads/2017/07/2017-KDIGO-LD-GL.pdf
- Human Tissue Authority. 2021. Code A: Guiding principles and the fundamental principle of consent. https://content.hta.gov.uk/sites/default/files/2020-11/Code%20A.pdf
- UK Donation Ethics Committee. 2016. Involving the family in deceased organ donation. Available at: http://www.aomrc.org.uk/wp-content/uploads/2016/07/Involving_family_deceased_organ_donation_0416-2.pdf
- NHS Blood and Transplant. 2015. Guidelines for consent for solid organ transplantation in adults. Available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4378/guidelines_consent_for_solid_organ_transplantation_adults.pdf

Chapter 5 Resources

Paediatric living organ donation

- Ross LF, Thistlethwaite JR. Minors as living solid-organ donors. Pediatrics. 2008 Aug 1;122(2):454-61. https://pediatrics.aappublications.org/content/122/2/454
- Campbell M, Wright L, Greenberg RA, Grant D. How young is too young to be a living donor?. American Journal of Transplantation. 2013 Jul;13(7):1643-9.
- Thys K, Van Assche K, Nobile H, Siebelink M, Aujoulat I, Schotsmans P, Dobbels F, Borry P. Could minors be living kidney donors? A systematic review of guidelines, position papers and reports. Transplant International. 2013 Oct;26(10):949-60.
- Thys K, Borry P, Schotsmans P, Dobbels F. Should minors and young adults qualify as potential live kidney donors? The views of international transplant professionals. Pediatric Transplantation. 2019 Sep;23(6):e13526.
- Biller-Andorno N, Agich GJ, Doepkens K, Schauenburg H. Who shall be allowed to give? Living organ donors and the concept of autonomy. Theoretical Medicine and Bioethics. 2001 Aug;22(4):351-68.

Paediatric organ and tissue transplant recipients

- Benson H, Bondoc A, Cuenca AG, Gigli KH, Laventhal N, Nakagawa T, Committee on hospital care, section on critical care, secion on surgery, Committee on bioethics. Pediatric Organ Donation and Transplantation: Across the Care Continuum. Pediatrics. 2023; 152 (2): e2023062923. 10.1542/peds.2023-062923
- Marchac A, Kuschner T, Paris J, Picard A, Vazquez MP, Lantieri L. Ethical issues in pediatric face transplantation: should we perform face transplantation in children? Plastic and Reconstructive Surgery. 2016 Aug 1;138(2):449-54.
- Statter MB, Noritz G, Committee on Bioethics. Children with intellectual and developmental disabilities as organ transplantation recipients. Pediatrics. 2020 May 1;145(5).

Paediatric donation of Haematopoietic stem cells

- Then SN, Kerridge I, Marks M, Children as Allogeneic Haematopoietic Progenitor (Stem) Cell Donors: ethically challenging and legally complex. Medical Journal of Australia. (2018) 208(8) 334.
- SN Then, Children as Tissue Donors: Regulatory Protection, Medical Ethics and Practice, Springer, 2018.

Chapter 6 Resources

Care of donors and transplant recipients

- KDIGO guidelines. 2017. Evaluation and care of living kidney donors. Chapter 16. Psychosocial evaluation. https://kdigo.org/wp-content/uploads/2017/07/2017-KDIGO-LD-GL.pdf
- WMDA. How to ensure donor care. https://wmda.info/professionals/promoting-donor-care/donor-care/
- WMDA. Recommendations on donor medical suitability. https://share.wmda.info/display/DMSR/WMDA+Donor+Medical+Suitability+Recommendations+Main+page

Risk acceptance in living organ donation

- Reese PP, Boudville N, Garg AX. Living kidney donation: outcomes, ethics, and uncertainty. The Lancet. 2015 May 16;385(9981):2003-13.
- Thiessen C, Gordon EJ, Reese PP, Kulkarni S. Development of a donor-centered approach to risk assessment: Rebalancing nonmaleficence and autonomy. American Journal of Transplantation. 2015 Sep;15(9):2314-23.

Decision-making about non-standard risk donor organ transplants

- Wong G, Howell M, Patrick E, Yang J. Taking kidneys for granted? Time to reflect on the choices we make. Transplantation. 2017 Dec 1;101(12):2812-3.
- Gordon EJ, Butt Z, Jensen SE, Lok-Ming Lehr A, Franklin J, Becker Y, Sherman L, Chon WJ, Beauvais N, Hanneman J, Penrod D. Opportunities for shared decision making in kidney transplantation. American Journal of Transplantation. 2013 May;13(5):1149-58.

Chapter 7 Resources

Privacy

- OAIC. 2019. The Australian Privacy Principles Guidelines. https://www.oaic.gov.au/privacy/australian-privacy-principles-guidelines
- Thiessen C, Kim YA, Formica R, Bia M, Kulkarni S. Opting out: Confidentiality and availability of an 'alibi'for potential living kidney donors in the USA. Journal of Medical Ethics. 2015 Jul 1;41(7):506-10.
- Meggiolaro N, Barlow-Stewart K, Dunlop K, Newson AJ, Fleming J. Disclosure to genetic relatives without consent–Australian genetic professionals' awareness of the health privacy law. BMC Medical Ethics. 2020 Dec 1;21(1):13. https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-020-0451-1

Misattributed paternity

- Freeman MA, Parker LS. Answers to Questions that Weren't Asked: The Ethical Complexities of Identifying Misattributed Paternity During the Transplant Evaluation Process. In Ethical Issues in Pediatric Organ Transplantation 2016 (pp. 43-59). Springer, Cham.
- Jacobson S, Eggert J, Deluca J, Speckhart D. Misattributed paternity in hematopoietic stem cell transplantation: The role of the healthcare provider. Clinical Journal of Oncology Nursing. 2015 Apr 1;19(2):218-21.
- Young A, Kim SJ, Gibney EM, Parikh CR, Cuerden MS, Horvat LD, Hizo-Abes P, Garg AX, Donor Nephrectomy Outcomes Research (DONOR) Network. Discovering misattributed paternity in living kidney donation: prevalence, preference, and practice. Transplantation. 2009 May 27;87(10):1429-35.

Ethical governance of donation and transplantation registries

- Australian Commission on Safety and Quality in Healthcare. 2014. Framework for Australian Clinical Quality Registries. https://www.safetyandquality.gov.au/sites/default/files/migrated/Framework-for-Australian-Clinical-Quality-Registries.pdf
- WMDA. 2021. International standards unrelated haematopoietic stem cell donor registries. https://wmda.info/wp-content/uploads/2021/01/WMDA-2020-Standards_AM1_Jan2021-1.pdf
- Maiam Nayri Wingara. Various resources on Indigenous Data Sovereignty. Available at: https://www.maiamnayriwingara.org/news-and-updates

Anonymity in non-directed donation

- Pronk MC, Slaats D, van der Pant KA, Vervelde J, Dooper IM, Dor FJ, Weimar W, van de Wetering J, Zuidema WC, Massey EK. Toward a conditional approach to anonymity? An explorative multicenter longitudinal study among anonymous living kidney donors and recipients. Transplant International. 2017 Dec;30(12):1243-52.
- Petrini C, Riva L, Floridia G, Mannelli C. Anonymity and Organ Donation: Ethical and Policy Implications After the Opinion Released by the Italian Committee for Bioethics. Transplantation Proceedings 2020; 52(5):1525-7.
- De Santo NG, Cirillo M, De Santo LS, et al. Legislative proposal in Italy to facilitate contacts between deceased organ donor families and transplant recipients. Journal of Nephrology. 2020 Dec;33(6):1333-42.
- Le Clainche-Piel M. How the face became an anonymous organ. Surgeons and transplant patients struggling with the anonymous donation policy in France. Sociologie. 2020;11(2):149-66.
- National Kidney Foundation. National Communication guidelines Regarding Communication Among: Donor Families, Transplant Candidates/Recipients, Health Care Professionals. https://www.kidney.org/national-communication-guidelines

Chapter 8 Resources

Principles used in resource allocation

- Persad G, Wertheimer A, Emanuel EJ. Principles for allocation of scarce medical interventions. The Lancet. 2009 Jan 31;373(9661):423-31.

Equity in access to transplantation

- Grace BS, Clayton PA, Cass A, McDonald SP. Transplantation rates for living-but not deceased-donor kidneys vary with socioeconomic status in Australia. Kidney International. 2013 Jan 1;83(1):138-45.

Organ allocation

- TSANZ (Transplantation Society of Australia and New Zealand), *TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors (Version 1.13)*, TSANZ, 2024.
- OPTN. Impact of multiorgan transplants on equity of organ allocation. https://optn.transplant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf
- OPTN. Ethical principles in the allocation of human organs. https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/
- Caulfield T, Murdoch B, Sapir-Pichhadze R, Keown P. Policy Challenges for Organ Allocation in an Era of 'Precision Medicine'. Canadian Journal of Kidney Health and Disease. 2020;7, doi:10.1177/2054358120912655.
- Veatch RM. Egalitarian and maximin theories of justice: directed donation of organs for transplant. Journal of Medicine and Philosophy. 1998;23(5):456-76.
- Schicktanz S, Simon A, Raphael S, Ahlert M. The ethical debate over child priority in post-mortem organ allocation: A scoping review and practical-ethical outlook. Transplantation Reviews. 2020 Jul 1;34(3):100543.
- Tong A, Howard K, Wong G, Cass A, Jan S, Irving M, Craig JC. Nephrologists' perspectives on waitlisting and allocation of deceased donor kidneys for transplant. American Journal of Kidney Diseases. 2011 Nov 1;58(5):704-16.

Chapter 9 Resources

Self-sufficiency

- Delmonico FL, Domínguez-Gil B, Matesanz R, Noel L. A call for government accountability to achieve national self-sufficiency in organ donation and transplantation. The Lancet. 2011 Oct 15;378(9800):1414-8.
- World Health Organization. Madrid resolution on organ donation and transplantation. Transplantation. 2011;91(Suppl 11):S29.
- Third WHO Global Consultation on Organ Donation and Transplantation: Striving to Achieve Self-Sufficiency, March 23–25, 2010, Madrid, Spain. Transplantation. 2011 Jun 15;91:S27-8.

Import and export of tissues

- Martin DE, Kelly R, Jones GL, Machin H, Pollock GA. Ethical issues in transnational eye banking. Cornea. 2016 Nov 16;36(2):252-7.
- Machin HM. Should Australia Export Corneas? Eye Banks, Exports and Australian Opinion: Exploring national utility of human corneal tissue donation [Internet]. 2021 [cited 2024 Oct 6]. Available from: http://hdl.handle.net/11343/280527.
- Machin H, Sutton G, Baird PN. Do Eye Bank Models and Competitive Practice Affect International Cornea Allocation? Cornea. 2021;40(7):936–41.
- Schulz-Baldes A, Biller-Andorno N, Capron AM. International perspectives on the ethics and regulation of human cell and tissue transplantation. Bulletin of the World Health Organization. 2007;85:941-8.
- Córdoba A, Mejía LF, Mannis MJ, Navas A, Madrigal-Bustamante JA, Graue-Hernandez EO. Current global bioethical dilemmas in corneal transplantation. Cornea. 2020 Apr 1;39(4):529-33.

International travel for organ transplantation

- Council of Europe. 2017. Resolution CM/Res(2017)1 on principles for the selection, evaluation, donation and follow-up of the non-resident living organ donors https://www.edqm.eu/sites/default/files/cmres_2017_1-on_principles_for_selection_eval_donation_and_follow_up_of_nrld.pdf
- Domínguez-Gil B, Danovitch G, Martin DE, López-Fraga M, Van Assche K, Morris ML, Lavee J, Erlich G, Fadhil R, Busic M, Rankin G. Management of patients who receive an organ transplant abroad and return home for follow-up care: recommendations from the Declaration of Istanbul Custodian Group. Transplantation. 2018 Jan 1;102(1):e2-9.
- Martin DE, Van Assche K, Domínguez-Gil B, López-Fraga M, Gallont RG, Muller E, Capron AM. Strengthening global efforts to combat organ trafficking and transplant tourism: implications of the 2018 edition of the Declaration of Istanbul. Transplantation Direct. 2019 Mar;5(3).

Compassionate access to deceased donor organs

- Fortin MC, Greenberg RA. Should Transplantation Be Offered to Pediatric Foreign Nationals?. In Ethical Issues in Pediatric Organ Transplantation 2016 (pp. 237-257). Springer, Cham.
- Fortin MC, Williams-Jones B. Should we perform kidney transplants on foreign nationals? Journal of Medical Ethics. 2014 Dec 1;40(12):821-6.
- Van Biesen W, Vanholder R, Vanderhaegen B, Lameire N, Wanner C, Wiecek A, Sever MS, Feehally J, Kazancioglu R, Rondeau E, Levin A. Renal replacement therapy for refugees with end-stage kidney disease: an international survey of the nephrological community. Kidney International Supplements. 2016 Dec 1;6(2):35-41.
- Glazier AK, Danovitch GM, Delmonico FL. Organ transplantation for nonresidents of the United States: a policy for transparency. American Journal of Transplantation. 2014 Aug;14(8):1740-3.
- Delmonico FL, Gunderson S, Iyer KR, Danovitch GM, Pruett TL, Reyes JD, Ascher NL. Deceased donor organ transplantation performed in the United States for noncitizens and nonresidents. Transplantation. 2018 Jul;102(7):1124.

- Lee BP, Terrault NA. Liver transplantation in unauthorized immigrants in the United States. Hepatology. 2020 May;71(5):1802-12.
- Sinnenberg L, Machado SR, Ostrominski JW, Stehlik J, Mehra MR, Vaduganathan M. Citizenship Status and Cardiothoracic Organ Transplantation in the United States. Circulation: Heart Failure. 2020 Dec;13(12):e007788.
- Yu E, Wightman A. Pediatric kidney transplant in undocumented immigrants: An American perspectives. Pediatric Transplantation. 2020 Jul 28:e13788.

Chapter 10 Resources

Financial neutrality of donation

- Delmonico FL, Martin D, Domínguez-Gil B, Muller E, Jha V, Levin A, Danovitch GM, Capron AM. Living and deceased organ donation should be financially neutral acts. American Journal of Transplantation. 2015 May;15(5):1187-91.
- Capron AM, Delmonico FL, Dominguez-Gil B, Martin DE, Danovitch GM, Chapman J. Statement of the Declaration of Istanbul Custodian Group regarding payments to families of deceased organ donors. Transplantation. 2016 Sep 1;100(9):2006-9
- Tushla L, Rudow DL, Milton J, Rodrigue JR, Schold JD, Hays R. Living-donor kidney transplantation: reducing financial barriers to live kidney donation—recommendations from a consensus conference. Clinical Journal of the American Society of Nephrology. 2015 Sep 4;10(9):1696-702.

Cost recovery and tissue banking

- Canadian Blood Services. Report on ethics consultation (2011) with reference to financial transactions in tissue banking and export. https://profedu.blood.ca/sites/msi/files/Canadian-Blood-Services-Ethics-Consultation-Report-final.pdf

Organ trafficking

- Martin DE, Van Assche K, Domínguez-Gil B, López-Fraga M, Gallont RG, Muller E, Capron AM. Strengthening global efforts to combat organ trafficking and transplant tourism: implications of the 2018 edition of the Declaration of Istanbul. Transplantation Direct. 2019 Mar;5(3).
- Martin DE, Van Assche K, Domínguez-Gil B, López-Fraga M, Budiani-Saberi D, Lavee J, Tibell A, Moazam F, Muller E, Danovitch GM, Codreanu I. Prevention of transnational transplant-related crimes—What more can be done? Transplantation. 2016 Aug 1;100(8):1776-84.
- Muller E, Dominguez-Gil B, Martin D. The Declaration of Istanbul on organ trafficking and transplant tourism (2018 Edition) introduction. Transplantation. 2019 Feb 1;103(2):217.

Chapter 11 Resources

End of life care and deceased donation

- The Australian and New Zealand Intensive Care Society Statement on Death and Organ Donation. Edition 4.1 2021. *https://www.anzics.com.au/wp-content/uploads/2022/04/ANZICS-Statement-on-Death-and-Organ-Donation.pdf*
- OPTN. Living donation by persons with certain fatal diseases. https://optn.transplant.hrsa.gov/resources/ethics/living-donation-by-persons-with-certain-fatal-diseases-white-paper/
- McGee AJ, White BP. Is providing elective ventilation in the best interests of potential donors?. Journal of Medical Ethics. 2013 Mar 1;39(3):135-8.
- Gardiner D, Shaw DM, Kilcullen JK, Dalle Ave AL. Intensive care for organ preservation: A four-stage pathway. Journal of the Intensive Care Society. 2019 Nov;20(4):335-40.
- UK Donation Ethics Committee, 'Nontherapeutic elective ventilation [PDF 177KB]', aomrc.org.uk, 2016
- van Haren FM, Carter A, Cavazzoni E, Chapman M, D'Costa RL, Jones SL, McGee A, Moodie S, Nunnink L, O'Leary M, Opdam H. Conflicts of interest in the context of end of life care for potential organ donors in Australia. Journal of Critical Care. 2020 Oct;59:166-171.

Donation following voluntary assisted dying

- Philpot SJ. Organ donation after circulatory death following voluntary assisted dying: practical and ethical considerations for Victoria. Critical Care and Resuscitation. 2018 Dec;20(4):254
- Downar J, Shemie SD, Gillrie C, Fortin MC, Appleby A, Buchman DZ, Shoesmith C, Goldberg A, Gruben V, Lalani J, Ysebaert D. Deceased organ and tissue donation after medical assistance in dying and other conscious and competent donors: guidance for policy. CMAJ. 2019 Jun 3;191(22):E604-13. . http://www.cmaj.ca/lookup/doi/10.1503/cmaj.181648

Donation by infants with anencephaly

- Organ donation from infants with anencephaly —guidance from the UK Donation Ethics Committee. Available at: http://aomrc.org.uk/wp-content/uploads/2016/06/Organ_Donation_-infants_anencephaly_020316-2.pdf
- Byrne P, Canadian Paediatric Society (CPS), Bioethics Committee. Use of anencephalic newborns as organ donors. Paediatrics & Child Health. 2005 Aug 1;10(6):335-7.

Chapter 12 Resources

Public solicitation of living donors

- British Transplantation Society. Guidelines for directed altruistic organ donation. 2014. Available at: https://bts.org.uk/wp-content/uploads/2016/09/16_BTS_Directed_Altruistic_2-1.pdf
- Fortin MC, Buchman D, Wright L, Chandler J, Delaney S, Fairhead T, Gallaher R, Grant D, Greenberg R, Hartell D, Holdsworth S. Public solicitation of anonymous organ donors: a position paper by the Canadian Society of Transplantation. Transplantation. 2017 Jan 1;101(1):17-20.
- Henderson ML, Clayville KA, Fisher JS, Kuntz KK, Mysel H, Purnell TS, Schaffer RL, Sherman LA, Willock EP, Gordon EJ. Social media and organ donation: Ethically navigating the next frontier. American Journal of Transplantation. 2017 Nov;17(11):2803-9. https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.14444
- OPTN. How to find a living donor. https://optn.transplant.hrsa.gov/media/2267/find_a_living_donor.pdf

Living kidney donor 'vouchers'

- Cooper M, Leeser DB, Flechner SM, Beaumont JL, Waterman AD, Shannon PW, Ronin M, Hil G, Veale JL. Ensuring the need is met: A 50-year simulation study of the National Kidney Registry's family voucher program. American Journal of Transplantation. 2021 Mar;21(3):1128-37.
- Veale JL, Capron AM, Nassiri N, Danovitch G, Gritsch HA, Waterman A, Del Pizzo J, Hu JC, Pycia M, McGuire S, Charlton M. Vouchers for future kidney transplants to overcome 'chronological incompatibility' between living donors and recipients. Transplantation. 2017 Sep 1;101(9):2115-9.
- Martin DE, Danovitch GM. Banking on living kidney donors—A new way to facilitate donation without compromising on ethical values. The Journal of Medicine and Philosophy. 2017;42(5): 537-558.

Umbilical cord blood donation

- Samuel GN, Kerridge IH. Equity, utility, and the marketplace: emerging ethical issues of umbilical cord blood banking in Australia. Journal of Bioethical Inquiry. 2007 Apr;4(1):57-63.
- Shearer WT, Lubin BH, Cairo MS, Notarangelo LD. Cord blood banking for potential future transplantation. Pediatrics. 2017 Nov 1;140(5). https://pediatrics-aappublications-org.ezproxy-b.deakin.edu.au/content/pediatrics/140/5/e20172695.full.pdf
- Petrini C. Ethical issues in umbilical cord blood banking: a comparative analysis of documents from national and international institutions. Transfusion. 2013 Apr;53(4):902-10.
- Murdoch B, Marcon AR, Caulfield T. The law and problematic marketing by private umbilical cord blood banks. BMC Medical Ethics. 2020 Dec;21(1):1-6.
- Rubeis G, Steger F. Saving whom? The ethical challenges of harvesting tissue from savior siblings. European Journal of Haematology. 2019 Nov;103(5):478-482.
- Stewart CL, Aparicio LC, Kerridge IH. Ethical and legal issues raised by cord blood banking—the challenges of the new bioeconomy. Medical Journal of Australia. 2013 Aug;199(4):290-2.

- Smith MK, Taylor-Sands M. Comparing non-medical sex selection and saviour sibling selection in the case of JS and LS v Patient Review Panel: Beyond the welfare of the child? Journal of Bioethical Inquiry. 2018 Mar;15(1):139-53.

Uterus donation and transplantation

- Lefkowitz A, Edwards M, Balayla J. Ethical considerations in the era of the uterine transplant: an update of the Montreal Criteria for the Ethical Feasibility of Uterine Transplantation. Fertility and Sterility. 2013 Oct 1;100(4):924-6.
- Allyse M, Amer H, Coutifaris C, Falcone T, Famuyide A, Flyckt R, Gargiulo A, Heimbach J, Johannesson L, Jowsey-Gregoire S, Khan Z. American Society for Reproductive Medicine position statement on uterus transplantation: a committee opinion. Fertility and Sterility. 2018 Sep 1;110(4):605-10.
- Bruno B, Arora KS. Uterus transplantation: the ethics of using deceased versus living donors. The American Journal of Bioethics. 2018 Jul 3;18(7):6-15.
- Ngaage LM, Ike S, Elegbede A, Vercler CJ, Gebran S, Liang F, Rada EM, Cooney C, Brandacher G, Redett RJ, Johannesson L. The changing paradigm of ethics in uterus transplantation: a systematic review. Transplant International. 2020 Mar;33(3):260-9.

Vascular composite allografts

- Ngaage LM, Elegbede A, Sugarman J, Nam AJ, Cooney CM, Cooney DS, Rasko YM, Brandacher G, Redett RJ. The Baltimore Criteria for an ethical approach to penile transplantation: a clinical guideline. Transplant International. 2020 May;33(5):471-82.
- Kruvand M, Vanacker B. Facing the Future: Media Ethics, Bioethics, and the World's First Face Transplant. Journal of Mass Media Ethics. 2011 Apr 15;26(2):135-57.
- Agich GJ, Siemionow M. Until they have faces: the ethics of facial allograft transplantation. Journal of Medical Ethics. 2005 Dec 1;31(12):707-9.
- Shaul RZ, Borschel GH, Flynn J, Hanson MD, Wright L, Zuker RM. Ethical issues in pediatric vascularised composite allotransplantation. In Ethical Issues in Pediatric Organ Transplantation 2016 (pp. 169-191). Springer.

Medical and surgical innovations

- McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, Nicholl J, Balliol Collaboration. No surgical innovation without evaluation: the IDEAL recommendations. The Lancet. 2009 Sep 26;374(9695):1105-12.

13. Appendix 2: Development of the Ethical Guidelines for Donation and Transplantation in Australia

13.1.1.1 Background

Following a joint request from the Transplantation Society of Australia and New Zealand (TSANZ) TSANZ and the Organ and Tissue Authority (OTA), the National Health and Medical Research Council (NHMRC) undertook the development of *Ethical guidelines for organ transplantation from deceased donors* (2016 Ethical Guidelines) which were released in April 2016.

The NHMRC subsequently received independent expert advice that the following NHMRC ethical guidelines on organ and tissue donation and transplantation, published in 2007, and collectively referred to as the '2007 NHMRC ethical guidelines,' also required review to ensure their accuracy and currency:

- *Organ and tissue donation after death, for transplantation – Guidelines for ethical practice for health professionals, 2007*
- *Making a decision about organ and tissue donation after death, 2007*
- *Organ and tissue donation by living donors – Guidelines for ethical practice for health professionals, 2007*, and
- *Making a decision about living organ and tissue donation, 2007*.

It was determined that development of a single, comprehensive resource containing updated ethical guidance from all the above guidelines and addressing new and emerging ethical considerations of relevance to donation and transplantation would be most useful to consumers and stakeholders.

The development of these Ethical Guidelines was managed by the Office of NHMRC and resourced by OTA and NHMRC under a Memorandum of Understanding.

13.1.1.2 Stage One - Expert Working Committee

The first stage of development of these Ethical Guidelines was overseen by the Australian Health Ethics Committee (AHEC) with advice from an expert working committee established under Section 39 of the *National Health and Medical Research Council Act 1992* (NHMRC Act).

Following provision of nominations from relevant organisations and consultation with OTA regarding final membership, the NHMRC CEO established the Organ and Tissue Working Committee (OTWC) to advise AHEC on the review of NHMRC ethical guidelines on organ and tissue donation and transplantation.

Chaired by Professor Ian Olver, who was Chair of AHEC when appointed to this Committee, the OTWC was established on 1 July 2017 and ran to 30 June 2020. Its Members (**Table B1**) were given the following Terms of Reference:

1. Taking into account the recently finalised *Ethical guidelines for organ transplantation from deceased donors*, advise on the review of the following NHMRC ethical guidelines on organ and tissue donation and transplantation:
    - *Organ and Tissue Donation After Death, for Transplantation – Guidelines for Ethical Practice for Health Professionals, 2007*

- *Making a Decision about Organ and Tissue Donation after Death, 2007*
- *Organ and Tissue Donation by Living Donors – Guidelines for Ethical Practice for Health Professionals, 2007*
- *Making a decision about living organ and tissue donation, 2007*
- Identify how all NHMRC ethical guidelines on organ and tissue donation and transplantation could be brought together in a cohesive fashion.
- Advise on the recommendation from NHMRC's Principal Committee Indigenous Caucus regarding the development of separate guidance that specifically addressed issues related to Aboriginal and Torres Strait Islander people and organ and tissue donation and transplantation.
- Develop advice in the form of ethical guidelines for consideration by NHMRC's Australian Health Ethics Committee.

The OTWC met formally on six occasions from August 2017 to March 2019, held eight workshops on specific issues, and provided out of session feedback on various drafts. The process also involved discussions with individual members of the OTWC regarding specific issues.

The work of the OTWC was used to inform the second stage of development of these guidelines.

Table B1 Members of the NHMRC Organ and Tissue Working Committee

Professor Ian Olver (Chair)	Dr Dominique Martin
Professor Stephen Alexander	Reverend Kevin McGovern
Ms Kelly Anstey	Ms Eva Mehakovic
Associate Professor Mark Arnold	Mr Barry Moroney
Professor Steve Chadban	Dr Helen Opdam
Ms Tina Coco	Dr Graeme Pollock
Associate Professor Marisa Herson	Mr Paul Robertson
Professor Ian Kerridge	Dr Shih-Ning Then
Ms Claire Leonard	Mr Allan Turner

13.1.1.3 Stage Two – Development of Draft Guidelines

The term of the OTWC concluded in May 2020. In September 2020 the OTA in consultation with the NHMRC commissioned OTWC member Dr Dominique Martin to further develop and complete the draft guidelines in consultation with a number of stakeholders and expert advisors. The Transplant Reference Liaison Group and the Eye and Tissue Advisory Committee at the OTA were consulted to identify individuals who could assist in further development and review of the draft guidelines. The OTA drafted Chapter 2, providing an overview of the sector. Individuals who contributed to the development, review and revisions of the draft guidelines are listed in **Table B2**.

13.1.1.4 Stage Three – AHEC review and targeted consultation.

In 2022, the draft ethical guidelines were reviewed by AHEC who revised the overarching principles outlined in Chapter 3, produced an abbreviated version of the document, and provided advice on the structure of the original extended version. In 2023, the new shortened Guidelines together with the Extended Guidelines were reviewed and revised to harmonise changes and facilitate cross-referencing. The two documents were again reviewed by AHEC and released via a targeted consultation with key clinical stakeholders for further feedback on content and structure.

Targeted consultation resulted in the progression of the original extended version of the guidelines to the stage of public consultation.

Individuals who contributed to the development, review and revisions of the draft guidelines are listed in **Table B2**.

Table B2 Contributors to the Ethical Guidelines

Professor Dominique Martin (lead author)	Ms Candice McKenzie
Professor Shih-Ning Then (co-author)	Professor Ainsley Newson (AHEC member)
Professor Jeremy Chapman	Associate Professor Helen Opdam (OTA)
Professor Emerita Mary Chiarella (AHEC member)	Associate Professor Helen Pilmore
Professor Toby Coates	Professor Henry Pleass
Professor Rosalie Grivell (OTA)	Dr Graeme Pollock
Mr Matty Hempstalk	Ms Lisa Smith
Associate Professor Marisa Herson	Ms Debbie Stracey
Ms Alison Hodak (OTA)	Associate Professor Jeff Szer
Associate Professor Jaqui Hughes	Mr David Toner
Associate Professor Nikky Isbel	Ms Jane Treloggen
Ms Margie Krueger	Professor Ingrid Winship (AHEC Chair)
Dr Nick Larkins	Dr Kate Wyburn
Associate Professor Fiona Mackie	Office of NHMRC
Dr Alexandra Markwell (AHEC member)	

13.1.1.5 Stage Four – Public consultation and revision of draft Guideline

Public consultation took place between 15 January and 15 March 2024. Fifteen submissions were received from a diverse set of organisations and individuals.

After public consultation, feedback was collated and synthesised and presented to AHEC for consideration. AHEC agreed to progress to a final revision the Guideline. OTA continued to work closely with the National Health and Medical Research Council (NHMRC) to progress the development of new draft guidelines for cell, tissue and organ donation and transplantation in Australia.

NHMRC

Australian Government

Organ and Tissue Authority

DonateLife

donatelife.gov.au