Superspecialty service guidelines for acute cardiac interventions

A report by the

Australian Health Technology Advisory Committee

March 1995

Australian Health Ministers' Advisory Council

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This report was prepared by the Australian Health Technology Advisory Committee (AHTAC) at the request of the Australian Health Ministers' Advisory Council (AHMAC) andendorsed by AHMAC at its meeting on 1 March 1995. AHTAC is a standing committee of NHMRC. AHTAC evaluates health technologies and highly specialised services looking at safety, efficacy, effectiveness, cost, equity, access and social impact.

AHTAC reports to both AHMAC and to NHMRC through its National Health Advisory Committee.

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Foreword

These guidelines have been prepared by the Australian Health Technology Advisory Committee (AHTAC), a standing committee of the National Health and Medical Research Council's National Health Advisory Committee. The guidelines were prepared in response to a request from the Australian Health Ministers' Advisory Council for AHTAC to update the **1983 *Guidelinesfor Cardiac Surgery*** taking into account major developments in the treatment of cardiac conditions in Australia. These developments include the very rapid growth in the use of interventional cardiology techniques, continuing rapid growth in the use of surgical procedures and new developments in eletrophysiology.

Superspecialty service guidelines are broadly-based documents intended for use in health services planning, to assist in the national provision of hospital-based superspecialty services and to ensure equity of access to such services throughout Australia. **In** this context, superspecialty services are defined as those which cater for relatively rare diseases or provide unusually lengthy or costly forms of treatment, and which should be planned **on** a State-wide or nation-wide basis. The guidelines are not intended to be definitive documents **on** the detail **of** clinical care. Rather, they are intended to give a general overview of service delivery for the clinical superspecialty involved.

This report presents guidelines **on** adult and paediatric cardiac surgery, interventional cardiology and eletrophysiology procedures. It is confined to therapeutic interventions and does not cover diagnostic technologies or pharmaceutical treatment.

The report is intended to assist those in health authorities, hospitals, professional bodies and other health care providers involved in the planning and provision **of** services for acute cardiac interventions.

In preparing the guidelines, AHTAC consulted widely with State and Territory health authorities, professional medical bodies, consumer organisations and individual experts.

Dr **BJ** Kearney
Chair
Australian Health Technology Advisory Committee

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ABS	Australian Bureau **of** Statistics
AHMAC	Australian Health Ministers' Advisory Council
AHTAC	Australian Health Technology Advisory Committee
AIHW	Australian Institute **of** Health and Welfare
CABG	coronary artery bypass grafting
ECG	electrocardiography
ECMO	extracorporeal membrane oxygenation
HMD	hospital morbidity data
MVD	multivessel disease
NHMRC	National Health and Medical Research Council
NHF	National Heart Foundation
PAP	pulmonary artery pressure
PCWP	pulmonary capillary wedge pressure
PTCA	percutaneous transluminal coronary angioplasty
QALY	quality-adjusted life year
NYHFIII	severity **of** illness New York Heart Foundation grade III
SSS	Superspeciality Services Subcommittee
1VD	single-vessel disease
2VD	double vessel disease

Executive summary

Scope and approach

These service guidelines cover adult and paediatric cardiac surgery, interventional cardiology and electrophysiology procedures. They are confined to therapeutic interventions and do not include consideration of pharmaceutical **or** diagnostic technologies.

Preparation of the guidelines involved development of methods for estimating projected caseloads for each intervention, and a survey **of** Australian cardiac surgery and interventional cardiology units to assess resource requirements. Other data sources included the National Heart Foundation (NHF) and State and Territory hospital morbidity collection. Specialists, professional organisations and State and Territory health authorities were consulted. Critical appraisal was given to a number of relevant papers from the literature. Medical terms are defined in a detailed glossary.

Adult cardiac surgery

Current technologies in adult cardiac surgery include:

- coronary artery bypass grafting (CABG);
- valve surgery;
- insertion of pacemakers; and
- operations **on** the aorta, electrophysiology surgery, surgery **for** cardiac tumours and trauma, and pericardiectomy related to infectious disease.

Cardiomyoplasty, in which skeletal muscle is used to reinforce the failing heart, is currently undergoing trials overseas and may have some impact in Australia in the medium term.

Studies have shown a significant relationship between both surgeon caseload and hospital caseload, and risk-adjusted mortality. It seems unlikely that a cardiac surgery unit could provide a cost-effective service with caseloads of less than 200–300 a year. Moreover, published data indicate that optimal patient outcomes are associated with caseloads of 900 **or** more a year. Optimal performance at institutions with low caseloads (under 400 a year) could be achieved through relationship with a larger institution, involving consultation, and rotation of surgical, anaesthetic, technical and nursing staff This would be of particular benefit to smaller units in regional centres.

Decisions regarding the establishment of cardiac surgery units must also take quality of care, cost, access and the location **of** existing units into account. Health planners should aim for a relatively small number of larger cardiac surgery units rather than a proliferation of small units.

Adult interventional cardiology

Some forms of coronary artery and valve disease can now be treated without open surgery, by means **of** catheter-based techniques including:

- percutaneous transluminal coronary angioplasty (PTCA);
- valvuloplasty;
- stenting;
- atherectomy; and
- laser angioplasty.

Normally, PTCA is undertaken for the treatment of angina but some recent studies suggest that it may have a role as an emergency revascularisation procedure during myocardial infarction. Widespread adoption of this application would result in a very substantial increase in the number **of** procedures performed in Australia. There is, therefore, a need for larger trials, and studies of health outcomes and costs in routine use to determine whether the cost effectiveness **of** PTCA in the treatment **of** myocardial infarction compares favourably with thrombolytic therapy (the use **of** which is more established in this context).

Given the technical difficulty of performing valvuloplasty, it would be inappropriate for a unit to offer the procedure unless there are sufficient cases to maintain skill. The success of stents also depends **on** experience, but their use in emergency situations suggest that they should be available in all units.

About 2% of patients that undergo PTCA require immediate emergency cardiac surgery. It is therefore imperative that the patient can be quickly transferred to a cardiac surgery operating theatre, be it on-site or at a nearby hospital. This should be taken into account in the planning of interventional cardiology units.

Estimated future caseloads, optimal unit sizes, access issues and different State strategies for provision of interventional cardiology services, are all important factors in determining an appropriate number of units for a State. In some cases it may be necessary to accept less than desirable unit sizes, in terms **of** health outcomes and costs, in order to address significant access problems. The potential increase in PTCA caseload through its application in treatment of myocardial infarction must also be considered.

Adult electrophysiology

Most cardiac electrophysiology services are provided by cardiology units. Electrophysiology is primarily concerned with the management of cardiac arrhythmias through:

- pacemakers (some insertions performed in cardiac surgery units);
- anti-tachycardia devices;
- electrophysiology surgery;
- anti-arrhythmia drugs;
- radiofrequency catheter ablation; and
- implantable cardiac defibrillators.

Most electrophysiology services can be expected to continue to have a similar impact **on** resources over the next few years. Radiofiequency catheter ablation has the potential to have a greater impact, but the magnitude of this cannot yet be determined. While the caseload for defibrillator implantation **will** remain relatively **small,** it is growing and the high cost of this technology **will** place increasing demands **on** hospital budgets.

Electrophysiology has specific resource requirements that differ fiom those of interventional cardiology, including qualified electrophysiologists and specialised equipment. Because these requirements are highly specialised, a concentration of services would ensure optimal quality of care and the most cost-effective use of facilities.

Paediatric cardiac services

Most children with congenital heart defects are treated by open surgery but some conditions can now be treated using interventional cardiology techniques. Paediatric cardiac surgery can be grouped into three categories of complexity: simple, major and complex. Paediatric interventional cardiology procedures include dilation procedures, procedures to open absent communications and those to close abnormal communications. New techniques that **will** increase the attractiveness of catheter-based procedures may be developed over the next ten years but their role is likely to remain limited. Arrhythmias requiring intervention rarely occur in children but there is a small caseload needing electrophysiology treatment.

The incidence of congenital heart disease is not expected to change over the next decade other than with changes in the birth rate. Future national caseloads for paediatric cardiac interventions can in general be expected to reflect age-related changes in the population. The impact of changes in technology to the year 2001 is not likely to be large. On this basis the expected caseload for paediatric interventional cardiology should remain **small.**

Only New South Wales, Victoria and Queensland have the full range of paediatric cardiac services including complex surgery. Units in South Australia and Western Australia undertake simple and some major surgical procedures.

General issues

Patterns of use of adult cardiac interventions are changing rapidly, but data to inform planning decisions and help predict future trends remain limited. While the NHF does collect outcome data, it is confined to crude post-operative mortality rates. The collection and risk adjustment of further data **on** outcomes is recommended. These data are also needed for assessing quality of care and consumer satisfaction.

Long-term management of ischaemic heart disease involves medical treatment as well as CABG and PTCA. At those times when there is a choice between angioplasty and CABG, the former appears more cost effective for patients with less severe disease in the short term. The relative cost effectiveness in the long term or in more severe cases is not **known.** CABG appears cost effective in patients with severe angina but this is in patient groups younger than those in which cardiac surgery rates are increasing most rapidly, and the precise effect of age **on** the cost effectiveness of CABG is not **known.**

In view of the increasing caseload for PTCA and the potential impact of indications expanding to include acute myocardial infarction, collection of consistent national PTCA waiting list data would be usefull to ensure reasonable and equitable consumer access.

While there is a lack of Australian data **on** the effectiveness of cardiac rehabilitation programs, overseas evidence supports their benefits. The NHF recommends that all patients who have had acute myocardial infarction, CABG, PTCA or other cardiovascular disease be routinely referred to outpatient programs (for which it has published standards).

Cardiac consumers in regional centres, rural areas and the Territories are disadvantaged by distance. A study of New South Wales CABG rates between 1983 and 1990–91 found that rural residents had fewer procedures than either residents in areas where the procedure was available or metropolitan residents without a referral hospital in their area. The low rates of surgery were not associated with lower rates for heart disease hospitalisation or mortality. The establishment of regional units is only a solution if the quality of care provided by units in capital cities can be maintained.

Projected national caseloads

The most recent estimates for national caseloads for the major cardiac interventions, and projected caseloads for the year 2001, are as follows:

Intervention	National caseload (latest year)	Projected national caseload, 2001	Procedures per million, 2001
Adult interventions			
Adult cardiac surgery	17 100 (1992)	23400–27 700	1210–1430
Adult coronary angioplasty	6700 (1992)	14800–22 600	770–1 170
Pacemaker implantation	4530 (1991-92)	~11000	~580
Radiofrequency catheter ablation	>900 (1993)	>1000	>55
Implantable defibrillators	125 (1992–93)	500–1000	26–52
Paediatric cardiac interventions	1600 (1992)	~2000	~100

Source: Compiled **by** the working party from available data.

Recommendations

Adult cardiac surgery (Chapter 1)

- Outcomes data should be collected specifically for cardiac surgery units and risk adjusted before publication. The work of the Australian Council **on** Health Care Standards in collection and publication of risk-adjusted outcomes data for hospitals is supported.
- Health planners should take into account the following caseload considerations:
  - a relatively small number of larger units is preferable to a proliferation **of** small units;
  - units with caseloads below 400 a year should have formal affiliation with larger units;
  - in areas remote from existing units, a minimum caseload of 200 a year may be acceptable given such affiliation;
  - new units should not be established in cities where a unit already exists unless a start-up caseload of 300 a year can be achieved and 500 a year within 2 years is a reasonable prospect;
  - the effectiveness **of** existing units with caseloads less than 200 a year should be examined and appropriate action taken; and
  - the caseload for a trained cardiac surgeon should be at least 200 a year and preferably more than 250 a year.
- Consideration of the desirable number of cardiac surgery units within individual States should take into account quality of care, cost, access and the location **of** existing services.
- Cardiac surgery units have specific requirements in terms **of staff** beds, operating rooms, equipment and supporting services. Adequate provision of these requirements is necessary ifpatient safety and outcomes are not to be compromised.

Adult interventional cardiology (Chapter 2)

- Outcomes data should be collected specifically for interventional cardiology units and risk-adjusted before publication. Data should be provided separately for conventional balloon PTCA, laser-assisted angioplasty, different types **of** atherectomy, procedures involving the use of stents, and valvuloplasty.
- Health planners should take into account the following caseload considerations:
  - interventional cardiology should be undertaken only in cardiology units with a minimum cardiac catheterisation caseload of 900 to 1000 a year;
  - to maintain expertise in PTCA, a trained interventional cardiologist should undertake at least 75, and optimally more than 200, procedures a year;
  - the minimum caseload for an interventional cardiology unit should be at least 150, and optimally more than 400, coronary angioplasties a year;
  - valvuloplasty services should be restricted to units with a caseload of at least 10 procedures a year;
  - laser-assisted PTCA should only be used in the context of a clinical trial, until good evidence of cost effectiveness emerges;
  - establishment of new interventional cardiology units **on** the basis of the minimum caseload criteria should not be encouraged;

- Before an interventional cardiology unit is established in a hospital without cardiac surgery, it should be demonstrated that the advantages to patient care outweigh the marked disadvantages that can occur without the support of on-site cardiac surgery.
- Cardiology units should ensure that, in an emergency, PTCA patients can be transferred to a fully-staffed cardiac surgery operating theatre within **30** minutes. A cardiology unit in a hospital without a cardiac surgery unit must be able to demonstrate that, under any circumstances, patients can be transferred to a nearby cardiac surgery operating theatre within this time.
- Interventional cardiology units have specific requirements in terms **of** staff beds, equipment and supporting services. These requirements must be met if patient safety and outcomes are not to be compromised.
- Trials **of** PTCA in the treatment of acute myocardial infarction should be kept under review. Consideration should be given to the provision of funds for controlled trials, and studies of health outcomes and costs of PTCA in the routine treatment **of** myocardial infarction.

Adult electrophysiology (Chapter 3)

- Pacemaker implantation should be performed either by an electrophysiologist or by a cardiologist or cardiac surgeon who is able to maintain a caseload of at least 40 implantations a year.
- Radiofrequency catheter ablation should only be performed by electrophysiologists. A caseload of at least 50 a year is required to maintain skills.
- Cardiology units providing electrophysiology services should make adequate provision for the specific resource requirements of these services, in particular the different staff and equipment requirements, to ensure optimum quality **of** care and cost effectiveness.

Paediatric cardiac services (Chapter 4)

- There is a need for data collection and research **on** outcomes other than short-term mortality for paediatric cardiac interventions, including long-term outcomes, and the effects of quality of care **on** these.
- ***Paediatric cardiac surgery:***
  - a paediatric cardiac surgery unit performing the full range of services should have a minimum caseload of 200 a year;
  - small paediatric cardiac surgery units should be supported only at centres remote from large units and only if outcomes are equivalent to those achieved in large units;
  - new paediatric cardiac surgery units should not be established nor existing ones upgraded unless it can be demonstrated that a caseload of at least 200 a year can be achieved; and
  - a paediatric cardiac surgeon should undertake a minimum of **100** procedures a year to correct congenital defects in adults or children, unless it can be shown that special circumstances, such as isolation and acceptable outcomes justify a lower rate.

- ***Paediatric interventional cardiology:***
  - should only be performed at a hospital that can maintain a paediatric cardiac catheterisation caseload of more than **75** cases a year;
  - optimally, the minimum institutional caseload should be at least 25 interventional procedures a year with a diagnostic caseload of well over **75** a year; and
  - there should be **no** more than one centre for paediatric interventional cardiology in each mainland State capital city.
- ***Paediatric cardiac electrophysiology:***
  - a cardiac electrophysiologist undertaking procedures in children should have a minimum caseload for adults and children of 50 a year for radiofrequency catheter ablation and 50 a year for implantation of pacemakers; and
  - implantation of defibrillators should not be undertaken without previous experience in adults.
- **To** ensure equitable access for all Australians to paediatric cardiac services, efficient arrangements for interstate and interhospital transfer should be maintained or put in place, specialised transport services should be available at **no** cost to the patients' families, and affordable accommodation and board should be available for at least one accompanying adult at or near the hospital to which the child is transferred.
- Paediatric cardiac services have specific requirements in terms of staff, beds, equipment and supporting services. Adequate provision of these requirements is necessary if patient safety and outcomes are not to be compromised. Staff caring for these patients need appropriate skills in paediatric care in addition to the usual skills required for cardiac care.

General issues (Chapter 5)

- Collection of consistent and reliable waiting list information for invasive cardiac investigations and interventions should be added to the collection of waiting list information for elective surgery, with appropriate standard definitions being added to the National Health Data Dictionary.
- *All* hospitals with coronary care, cardiac surgery and cardiology units should have arrangements to ensure that cardiac rehabilitation programs are available to all cardiac care consumers. Inpatient and outpatient components of the programs should be integrated.
- Regional cardiac intervention units should not be established unless it is clear that they can maintain a quality of care similar to that provided in the capital cities. This will include the provision of back-up surgery for PTCA.
- **To** ensure equitable access for all Australians to cardiac intervention services, arrangements for interhospital transfer and intra or interstate travel and accommodation for the cardiac care consumer and one significant relative should be maintained or put in place.
- Further research should be undertaken in Australia **on** the effects **on** access to cardiac interventions of geographical location, age, gender, socioeconomic status, ethnicity and aboriginality.

Table 1: ***Cardiac interventions in Australia***

Type of intervention	Indications	Annual caseload (in 1992 unless otherwise stated)
Adult cardiac surgery		
CABG[(a)]	Severe coronary artery disease	12 935
Valve surgery[(a)]	Valve disease	2859
Other cardiac procedures	Aortic aneurism or dissection, cardiac tumour, cardiomyopathy, trauma etc	1200–1500
Catheter-based interventions		
PTCA	Coronary artery disease	6748
Coronary atherectomy	Coronary artery disease	115
Stent insertion	Coronary artery disease, failed angioplasty	131
Laser-assisted coronary angioplasty	Coronary artery disease	*0*
Valvuloplasty	Valve disease	approx 150
Electrophysiological interventions		
Permanent pacemaker insertion	Bradycardia	3700 (1991–92)
Defibrillator implantation	Cardiac arrest, sustained ventricular tachycardia	125 (1992–93)
Radiofrequency catheter ablation	Supraventricular tachycardias	approx 900 (1992–93)
Anti-tachycardia device insertion	Supraventricular tachycardias, ventricular tachycardia	60–80
Electrophysiology surgery	Supraventricular tachycardias, ventricular tachycardia	52
Paediatric services		
Paediatric cardiac surgery	Congenital defects	1619
Paediatric interventional cardiology	Congenital defects	approx 200

(a) Includes those with concomitant procedures.

Source: AHTAC[3], NHF[5], State health authorities hospital morbidity data.

A **major** component **of** background work necessary to prepare these guidelines was the collection **of** data **on** existing services providing acute cardiac interventions in Australia. Data sources included the National Heart Foundation (NHF) and State and Territory hospital morbidity collections. As little information was available **on** current resource usage **for** acute cardiac interventions in Australia, a survey was conducted. Adult and paediatric cardiac surgery and interventional cardiology units in **42** hospitals were surveyed, with **an** overall response rate **of 75%.** Details **of** the survey results are available in a separate report.[3] Other tasks included a literature review **of** the different technologies and **of** costs; resource usage and other guidelines relating to acute cardiac interventions; and the development **of** a methodology to estimate future caseloads **of** the more significant **procedures**.[4]

Consultation process

During preparation of these guidelines, AHTAC consulted with individual experts in specific areas as necessary, with specialists in electrophysiology and paediatric cardiac interventions being consulted frequently throughout the project. At the end of the project, AHTAC **also** undertook a formal consultation process involving State and Territory health authorities, the Cardiac Society of Australia and New Zealand, the Consumers' Health **Forum,** the Royal Australasian College of Physicians, the Royal Australasian College of Surgeons, the Royal Australian College of Medical Administrators and the Royal College of Nursing, Australia.

1 Adult cardiac surgery

1.1 Current technology and projected developments

1.1.1 Coronary artery bypass grafting (CABG)

CABG is a well-established procedure that was developed in the **1960s.** Grafts are used to construct new conduits from the aorta **or** other major artery to points beyond obstructing lesions **on** the coronary arteries thereby allowing adequate blood supply to the myocardium. The procedure is highly invasive. The chest must be opened and, in nearly all cases, the circulation is diverted from the heart and lungs to a cardiopulmonary bypass machine with a pump oxygenator. Segments **of** saphenous vein from the leg **of** the patient have traditionally been used as the graft material. Concerns over the tendency **of** saphenous (leg) vein grafts to block with time have, however, led to a trend to use the left internal mammary artery as graft material. Often, both mammary artery and saphenous vein grafts are used.

While further refinements to CABG can be expected, major changes to the procedure are unlikely in the short term. In the long term, there is some possibility that less invasive percutaneous techniques will be used.

At this stage there is **no** evidence that catheter-based techniques will substantially replace CABG. Percutaneous transluminal coronary angioplasty (PTCA) may have substituted **for** some CABG procedures after its introduction in the early **1980s,** but the annual incidence **of** CABG has continued to rise. The indications **for** the **two** techniques differ, though with a significant overlap. New catheter-based techniques such as excimer laser angioplasty may increase the area **of** overlap, but their effect **on** the demand **for** CABG would be minimal in the short to medium term. Developments in catheter-based techniques are discussed in more detail in Chapter 2 **on** interventional cardiology.

It is possible that gene therapy **or** improved pharmaceutical treatment may provide an alternative to CABG in the long term but it is not anticipated that any such developments will be available **for** routine use in the next ten years.

1.1.2 Valve surgery

Valve surgery involves the repair **or** replacement of mitral, aortic, tricuspid **or** pulmonary valves. It usually requires cardiopulmonary bypass. Valve disease in adults may be age-related, a complication **of** disease such as rheumatic fever, **or** congenital (usually a need **for** re-operation following treatment in childhood).

In Australia, the majority of valve procedures involve replacement of the valve with a mechanical prosthesis, a porcine bioprosthesis **or** a human graft.

Several types of mechanical prosthesis are available, based **on** caged ball, tilting disc **or** bileaflet structures. Bioprostheses consist **of** porcine valves which may be combined with a synthetic suturing ring **or** frame.

Reconstruction by suturing techniques is less commonly used but its use is increasing. Less complex procedures involving opening of fused structures are sometimes undertaken, but have been replaced by catheter-based techniques at least for the mitral valve in selected patients. In the future, catheter-based techniques will continue to substitute for some valve surgery (see Chapter **2).**

1.1.3 Insertion of pacemakers and anti-tachyarrhythmia devices

Cardiac surgery units perform a significant number of pacemaker and anti-tachyarrhythmia device insertions. These technologies are discussed in the section **on** electrophysiology.

1.1.4 Other forms of cardiac surgery

Other cardiac procedures include operations **on** the aorta, electrophysiology surgery, surgery for cardiac tumours and trauma, and pericardiectomy related to infectious disease. Electrophysiology surgery is now being replaced by catheter-based techniques for supraventricular tachycardias, and by implantable defibrillators for ventricular tachycardia in patients not responsive to medical treatment. Further information is *given* in Chapter **3 on** electrophysiology. The need for the remaining procedures **is** expected to continue.

Cardiomyoplasty is a surgical procedure which could be important in Australia in the medium term. It is currently undergoing trials overseas and in Australia. In this procedure, one of the patient's **own** skeletal muscles is used to reinforce a failing heart, thus improving cardiac function and the patient's clinical condition. **An** implanted neuromuscular stimulator or pacemaker is used to stimulate regular contraction of the muscle. Cardiomyoplasty is used in individuals who have severe symptoms in spite **of maximal** medical therapy, and who are unsuitable for heart transplantation. Its long-term effectiveness has not been clearly established and the indications for the procedure have not yet been defined.

1.2 Projected national caseload

National caseloads for CABG and valve procedures from **1984** to **1992** are *given* in Table **2.** The data show increasing caseloads throughout that period. **In 1992** the rate of CABG procedures per **million** population was **740,** and that of valve surgery was **164. In 1992, 9.7%** of CABG procedures were undertaken with a concomitant procedure, with **6.9%** being undertaken with valve **surgery**.[5] About **29%** of valve procedures are undertaken with concomitant **CABG**.[5]

The national caseload for other cardiac procedures is difficult to determine owing to differences in classifying procedures in the different data sources (Table **3).** The data suggest that **1200–1500** cardiac surgical procedures other than CABG and valve surgery were performed in **1992.** This excludes pacemaker and other device insertions, which are discussed in the electrophysiology section.

Table 2; *National caseloads for CABG and surgery for acquired valve disorders by year*

Type of procedure	1984	1985	1986	1987	1988	1989	1990	1991	1992
CABG[(a)]	7246	7822	8048	9236	9566	10 531	11 381	12 649	12 935
Valve surgery	1652	1692	1818	2022	2129	2307	2363	2628	2859

(a) Includes concomitant procedures (including valve surgery)

Source: NHF[5]

Table 3; *Caseload of other cardiac surgery[(a)]*

Type of procedure	NHF 1992	HMD[(b)] 1991–92	Survey[(c)] 1992 or 1993
Cardiac procedures (excluding CABG and valve surgery)			
with cardiopulmonary bypass	–	611	665
with CABG	–	–	229
without CABG	–	–	436
cardiac tumour or myopathy	39	–	–
without cardiopulmonary bypass	–	659[d]	202
pericardiectomy	40	–	–
Operations on aorta	255	–	–
Pulmonary embolectomy	9	–	–
Cardiac trauma	16	–	–

NHF National Heart Foundation HMD hospital morbidity data

(a) Excludes heart and heart–lung transplantation

(b) Excludes Victorian and Northern Territory private hospitals and all Queensland data. Includes closed heart valvotomy, operations on structures adjacent to heart valves, repair of atrial and ventricular septa with prosthesis, heart revascularisation by atrial implant, pericardiotomy, implantation of heart pump or pulsation balloon, repair of heart and pericardium, operations on aorta and open chest cardiac massage.

(c) 70% of units responded.

(d) Some procedures with cardiopulmonary bypass will be classified under those without, due to limited data in some States about multiple procedures during a single admission.

Source: AHTAC[3], NHF[5], State health authority hospital morbidity data.

Table **4** gives projected caseloads for CABG, valve surgery, and other forms of cardiac surgery for **1996** and **2001.** The projections for CABG and PTCA were based **on** detailed data available for Western Australia, with the use of Australian Bureau of Statistics **(ABS)** population data and NHF data to develop national projections (see Appendix **1).** The projections were based **on** the use of asymptotic methods to estimate likely future increases in the number of CABG and PTCA procedures. This was done by modelling past trends in each age–sex group in the ratios **of:**

- initial myocardial revascularisation procedures to new cases of non-fatal coronary heart disease identified clinically; and
- initial CABG operations (versus PTCA procedures) to total initial revascularisation procedures.

In estimating the number of new cases of symptomatic non-fatal coronary heart disease occurring in Australia each year, available data was used to take account of possible variations in incidence between States and Territories, and over time.

Estimated minimum caseloads for valve procedures in **1996** and **2001** were based **on** population projections (Table **4). ** Maximum caseloads were estimated **on** the assumption that the rate in valve procedures between **1984** and **1992** continues to increase, allowing for changes in population. Caseloads for other cardiac procedures in **1996** and **2001** were also estimated **on** the basis of population projections (Table **4).** Estimated rates of CABG, valve and other cardiac procedures are **850–920, 160–210** and **70–90** per **million** population respectively in **1996,** and **970–1060, 170–280** and **70–90** per **million** population respectively **in 2001.**

These estimates do not allow for a possible increase in the proportion of overseas consumers undergoing cardiac surgery in Australia. There could be an increased demand for Australian services particularly **from** Southeast Asia.

It needs to be emphasised that the projections are based **on** likely future increases *given* past trends, and in **no** way represent recommended ideal levels of service provision. Currently there is insufficient knowledge to permit estimation of the optimal level **of** provision of each procedure in Australia in order to maximise health gain, ***given*** the benefits of competing ways of utilising available resources.

Table 4: ***Estimated caseload for cardiac surgery, 1996 and 2001***

	1996		2001	
Type of procedure	**Low**	**High**	**Low**	**High**
CABG[a]				
New South Wales	5430	5910	6490	7070
Victoria	3900	4240	4650	5060
Queensland	2710	2950	3380	3680
South Australia and Northern Territory	1430	1550	1680	1830
Western Australia	1400	1520	1790	1950
Tasmania	410	450	490	530
Australian Capital Territory	190	200	240	270
Australia	15 470	16 830	18 720	20 390
Valve surgery	3040[b]	3950[c]	3310[b]	5550[c]
Other cardiac surgery[b]	1280	1590	1390	1740
Total	19 770	22 370	23 420	27 680

(a) Low estimate is as derived by Martin.[4] High estimates were obtained by multiplying the low estimates by **1.089,** which is the ratio of the actual[5] to the estimated[4] number of CABGs in the whole of Australia in **1991.**

(b) Hospital morbidity data provided age distributions of cardiac surgery caseloads. These were applied to Australian caseloads as reported by the NHF for **1992.** Projections to **1996** and **2001** were then derived using ABS series C population projections by age.

(c) Calculated by applying the median annual increase (excluding population growth) in caseload for **1984** to **1992 (5.8%)** to the NHF **1992** levels to obtain **1996** and **2001** estimates. These were then adjusted according to projected increases in the population.

Note: Small discrepancies may exist between total and State and Territory caseloads and between low and high estimates, due to rounding errors.

Since the working party was convened, a number of States have reorganised their funding of hospital services. Victoria and South Australia have introduced casemix payment systems based **on** diagnosis-related groups while Western Australia has opted for a purchaser–provider model. The incentives generated by these systems of hospital finance will impact **on** the number and types of hospital services which are provided in ways which are not easy to predict. This reinforces the need for data **on** the cost effectiveness of acute cardiac interventions ***so*** that decisions about their future provision can be based **on** estimates of their social worth.

1.3 Outcomes and quality of care

1.3.1 Australian outcomes

The outcome measure most commonly used in assessments of cardiac surgery is post-operative mortality (in-hospital or at **30** days). The post-operative myocardial infarction rate or overall rate of complications may also be used. Longer-term outcomes include survival, freedom from re-operation, freedom from angina, and assessment of well-being by cardiac care consumers after specified periods (ranging from **1–20** years).

The NHF collects Australia-wide mortality data for cardiac surgery. The data take into account deaths in hospital or within **30** days of surgery. **In 1992,** the mortality rate for all CABG, including those with concomitant procedures, was 2.2%.[5] Mortality rates in the region of **2.0–2.5%** have been maintained in Australia since the early **1980s.** The mortality rate for surgery for acquired valve disease was **4.0%** in 1992.[5] Analysis of hospital morbidity data for New South Wales, Victoria, South Australia and Western Australia for **1991–92** gave an in-hospital mortality rate for CABG of **2.4%** and for adult valve procedures of **5.4%.** The Centre for Health Economics Research and Evaluation, Sydney, has published mortality rates for CABG in New South Wales hospitals in **1989–90** and **1990–91.** They ranged from 0.4–3.0%.[6]

Outcomes of CABG at St Vincent's Hospital, Melbourne. during the period **1970–1985,** have been **reported**.[7] Operative mortality rates (deaths in hospital or within **30** days of operation) fell from **9.3%** in **1970–75** to **2.5%** in **1981–85.** Post-operative myocardial infarction remained fairly constant at about 5%, and the rate of stroke was **1.3%.** Longer-term outcomes were also calculated. The five-year survival rate for all patients (including hospital deaths) was **88%,** while the ten-year survival rate was ***65%.*** At five years, **78%** of surviving patients were free of angina, but the figure had dropped to **34%** at ten years. In response to a questionnaire **on** symptoms, activity, medication and general well-being, **90%** of patients considered that they felt better than they did before the surgery.

Australian mortality rates compare favourably with those reported in the United States. A database compiled from **22** states showed a mortality rate of **4.8%** in **1987–88,** and regional centres in northern New England in **1987–89** showed a rate of 4.3%.[8,9] The average mortality rate for CABG in New York State in **1989** decreased from **3.5%** in **1989 to 2.8%** in **1992** despite a concurrent increase in average patient severity of illness. The introduction of a quality improvement program based **on** the collection and dissemination of risk-adjusted mortality data is believed to have contributed to the improved results.[10]

1.3.2 Factors affecting outcomes

Factors affecting outcomes of surgical procedures fall largely into two groups:

- cardiac care consumer variables; and
- institutional quality of care.

For CABG, consumer variables which increase risk of hospital mortality include increased age, female gender, poor left ventricular function, presence of congestive heart failure and greater extent of left main artery disease.[7,11–17]

Institutional quality of care covers clinical and/or surgical skill, quality of anaesthesia and perfusion services, support technology, quality of post-operative intensive care, and rehabilitation and support services. Resources available to the institution and patient caseload may be major factors affecting quality of care.

Several studies in the United States have identified differences in outcomes of CABG for different hospitals or surgeons, and attempted to identify the significance of quality of care by adjusting for the level of risk of the patient in each case.[8,9,17–19] The results indicate that quality of care has a significant impact on the outcomes of CABG and varies substantially from institution to institution. The specific factors contributing to the variations are complex and difficult to identify.

1.3.3 Data collection and risk stratification

Risk adjustment of outcome measures has become well established in the United States. The US Health Care Financing Administration has published risk-adjusted measures of mortality for Medicare recipients since 1987. Pennsylvania has mandated the use of an illness severity index to make possible the publication of risk-adjusted outcomes for all hospitals. California has enacted a law that requires publication of risk-adjusted outcomes.[18]

In Australia, the national goals, targets and strategies for better health outcomes for Australians suggest that stratified criteria of risk be developed so that standards of CABG can be compared, and that the NHF's existing register of cardiac surgery be expanded to include patient stratification and long-term outcomes.[1] The Australian Council on Health Care Standards has started to collect outcomes data from hospitals supplying information for accreditation purposes. There are plans for casemix adjustment of outcomes data in the future.

The National Health and Medical Research Council (NHMRC) working party on guidelines for the procedural and surgical management of coronary heart disease, is considering a system for routine risk stratification of persons undergoing CABG. This initiative is supported, but resources will be required for routine risk stratification.

1.4 Unit and operator caseload

1.4.1 Effect of caseload on outcomes

Ten studies published since 1979 have examined the relationship between hospital caseload and mortality for CABG.[11,19–28] Seven of these found a significant relationship between hospital caseload and risk-adjusted mortality.[11,20–23,25,27] Five studies have examined the relationship between surgeon caseload and mortality for CABG.[11,19–22] Two studies found that mortality rate decreased significantly with increasing surgeon caseload.[11,20] The more recent of these was a particularly detailed study based on 1989 data in New York State for CABG performed without concomitant procedures.[11] The database included nearly 12 500 cardiac care consumers and 126 surgeons. Analysis of risk-adjusted mortality rates by hospital and surgeon caseload showed that the highest mortality rates were recorded for the group with both hospital and surgeon in the lowest caseload category. For each category of hospital caseload there was a clear downward trend in risk-adjusted mortality rates with increasing surgeon caseload (Table 5). This study is discussed further in Appendix 2.

In three studies, the relationship between complication rates and hospital and surgeon caseload for CABG and for PTCA have been examined.[8,29,30] These studies are discussed in the section on interventional cardiology (Section 2.3.2) and in Appendix 2.

Table 5: ***Caseload and risk-adjusted mortality for CABG, New York State 1989***

Hospital caseload	Surgeon caseload	Risk-adjusted mortality rate (%)
1–199	1–54	14.07
	55–89	6.67
	90–259	6.42
	260 and over	3.33
200–889	1–54	9.01
	55–89	5.72
	90–259	3.97
	260 and over	2.88
890 and over	1–54	5.33
	55–89	3.39
	90–259	3.11
	260 and over	2.18

Source: Hannan *et al.*[11]

1.4.2 Effect of caseload on costs

There is no conclusive evidence in favour of economies of scale. Analysis of the excess costs of CABG over thoracic surgery showed no reduction in average costs beyond 100 cases per year.[31] In New South Wales, the cardiac surgery units with the highest throughput also tended to have the lowest average costs per cardiac care consumer. This cost difference cannot be attributed solely to the effects of scale. Other factors such as general management efficiency may also be responsible.[6] While it is possible to reduce the average cost per case by increasing throughput in units which are currently underutilised, there is no evidence to suggest that costs are lower in large as opposed to small units where both are fully utilised.

1.4.3 Current unit and surgeon caseloads in Australia

In June 1994 there were 34 adult cardiac surgery units in Australia. In 1991, there were 22 units and the annual caseload per unit (excluding procedures for congenital conditions) ranged from less than 200 to over 1500 (NHF, pers. comm.). In the Australian Health Technology Advisory Committee (AHTAC) survey, responses were received **from** 20 units with an average annual caseload in 1992 or 1993 of 760 (range 176–1731).[3]

Precise data on surgeon caseload in Australia are not available but NHF data indicate that the average caseload per trained cardiac surgeon was around 300 in **1992**.[5]

1.4.4 Minimum and optimal unit and surgeon caseloads

A number of Australian and overseas bodies have made recommendations **on** unit and operator caseload for adult cardiac surgery.

The 1983 Australian guidelines for cardiac surgery[2] recommended that:

- a unit commencing cardiac surgery should build up to 200 cases a year within two years;
- a caseload of 900–1000 cardiac surgery procedures is likely to result in better quality consumer care and a low mortality rate;
- an average of 650 procedures a year is more likely for Australia; and
- each cardiac surgeon should perform at least five procedures a week to maintain skills.

In a study at the Centre for Health Economics Research and Evaluation, cardiac specialists agreed that a cardiac surgery unit should have a minimum **of** two to three practising surgeons each performing five to ten operations a **week**.[6]

The 1986 Canadian guidelines **on** cardiovascular services[32] recommended that:

- minimum caseload for a cardiac surgery unit should be six heart operations requiring bypass a week; and
- each cardiac surgeon should perform a minimum of **150** procedures a year with more than two to three procedures a week required to maintain skills.

A task force of the American College of Cardiology and the American Heart Association has prepared guidelines for CABG.[33] They recommend that:

- a yearly minimum of 200–300 open heart operations, the majority of which are CABG operations, should be performed in hospitals caring for individuals requiring surgery for ischaemic heart disease; and
- a yearly minimum of 100–150 open heart operations, the majority CABG, should be performed by each surgeon.

The guidelines note that hospitals in large and sparsely populated areas may require different specifically-derived recommendations. The recommendations are largely based **on** the results **of** the study by Hannan et al. in New York State.[11] It is noted that **on** the basis of the data **from** this study the predicted risk-adjusted mortality rate for a hospital caseload of at least 300 and a surgeon caseload of at least **150,** is 3.19%.[33]

Ideally, recommendations **on** caseloads in Australia should be based, at least partly, **on** Australian data. Unfortunately, at present, there is **an** absence of data that could be used for this purpose. In the light of the published overseas evidence that mortality rates are higher at low unit caseloads, and the recommendations of expert bodies, the AHTAC considers that a cardiac surgery unit should have a minimum annual caseload of 200–300. It is recognised that the impact of low unit caseloads **on** mortality may be reduced if a visiting surgeon with high personal caseload performs the procedures. Nevertheless it is unlikely that a hospital could provide the full range of services required for successful cardiac surgery cost effectively, at caseloads below 200–300 a year. Published data indicate that optimal caseloads from the point of view of patient outcome are 900 or more.[11]

For any unit with a caseload below 400 a year, a formal relationship with a larger institution would be needed to ensure optimal performance. The relationship would involve consultation, and rotation of surgical, anaesthetic, technical and nursing staff

The benefits of optimal caseloads have to be weighed against the need for services in areas remote from existing cardiac surgery units. In these areas, units with minimum caseloads of 200 a year may be acceptable provided that they are affiliated with larger units. At 1991 rates of usage, a caseload of 200 a year would require a population base **of** around 230 000.

In cities that already have cardiac surgery units, new units cannot be justified unless they have a start-up caseload **of** 300 a year and a reasonable prospect of reaching 500 a year within two years.

Published evidence and expert opinion indicate that a cardiac surgeon requires a minimum caseload to maintain expertise. While it is difficult to be precise about the figure, the AHTAC considers that it should not be less than 200 cases a year. The optimal caseload for a surgeon would appear to be in excess of 250 cases a year.

1.5 Distribution of services

Table *6* gives the location of the 34 Australian cardiac surgery units, and their distribution between public and private hospitals. All of the States but neither of the Territories had cardiac surgery services in June 1994. *All* but two units were in capital cities.

Table **7** gives the number **of** units per **million** population for each State and Territory. The figures show substantial differences. However, the number of units per **million** population is not necessarily a measure of capacity for cardiac surgery services, nor is it necessarily a reflection of quality **of** care. Indeed, a smaller number **of** units for a given population would result in larger caseloads, which could contribute to improved quality of care. This is a matter which requires detailed consideration in each State.

Table 6: ***Distribution of adult cardiac surgery units in Australia, June 1994***

Location	Number of public units	Number of private units	Total
New South Wales			
Sydney	6	4	10
Newcastle	1	0	1
Victoria			
Melbourne	6	4	10
Queensland			
Brisbane	1	2	3
Townsville	1	1	2
South Australia			
Adelaide	2	2	4
Western Australia			
Perth	2	1	3
Tasmania			
Hobart	1	0	1
Total	**20**	**14**	**34**

Source: Compiled by the working party from available data.

Table 7: ***Cardiac surgery units per million population by State and Territory, June 1994***

State or Territory	Number of units per million population
New South Wales and ACT	1.73
Victoria	2.23
Queensland	1.56
South Australia and Northern Territory	2.44
Western Australia	1.77
Tasmania	2.12
Australia	**1.91**

Source: Calculated from Table 6 and ABS population projections.[68]

1.6 Organisation of services

1.6.1 Medical and administrative direction

A cardiac surgery unit should be under the direction of a cardiac surgeon who is actively involved in surgical procedures. Cardiac surgery and cardiology departments in a hospital should work in close cooperation with each other. While cardiology and cardiac surgery function successfullyas separate entities in many Australian hospitals, it could be advantageous to have a combined cardiovascular division comprising cardiology, interventional cardiology, and cardiac surgery. Within this division the departments of cardiac surgery and cardiology should be headed by appropriate specialists.

1.6.2 Coordination with other hospitals and community services

Some patients may be transferred from other hospitals for cardiac surgery. Mechanisms should be in place to ensure that the transfer is appropriately timed, and that medical records and diagnostic images are transferred from the referring hospital and back to it after the procedure. The hospital should have a process to determine whether a patient will need community services support (such as nursing and meals services) after discharge from hospital. There should be a system to ensure that these services are provided ifnecessary.

1.7 Resource requirements

1.7.1 Survey results and hospital morbidity data

The AHTAC survey specifically addressed resource usage by existing cardiac units in order to determine current practice in Australia.[3] **Most** cardiac surgery units surveyed have their own cardiac intensive care, step-down and general beds, with the number of such beds increasing with annual caseload. Average hospital stays reported were **10** days for CABG, **11–12** days for valve surgery and **9–12** days for other cardiac surgery. The length of stay without complications is commonly about two days shorter. The average length of stay is similar in public and private hospitals.

Approximately nine staff are present during open heart surgery. These include an average of **1.0** surgeons, **1.5** assistants, registrars, or fellows, 1.5 anaesthetists or anaesthetic assistants, **1.0** perfusionists and **2.7** registered nurses or nurse assistants. The nurse-patient ratios are **1:1.1** for cardiac intensive care, **1:2.4** for step-down and **1:5** for general wards. There is considerable variation in the types and number of ancillary staff employed specifically by cardiac surgery units, with secretaries, physiotherapists and counsellors **most** commonly employed. The average number of such staff increases with caseload.

Balloon pumps are used by all cardiac surgery units, for an average of **3.1%** of cases. Transoesophogeal echocardiography is used by **80%** of units for an average of **7.1%** of cases. Left ventricular or biventricular assist devices are used by ***55%*** of cardiac surgery units for an average of **1.1%** of cases.

Hospital morbidity databases provide another source of information **on** length of hospital stays associated with cardiac surgery. In most instances, the average lengths of stay recorded in the hospital morbidity data are longer than those reported in the survey. These are **12.4** days for CABG, **15.2** days for valve surgery and **15.4** days for other cardiac surgery with or without cardiopulmonary bypass.

1.7.2 Staff requirements

A cardiac surgery unit requires **24** hour coverage with adequate staffing at all levels. Qualified medical, surgical, anaesthetic, radiology, nursing and technical personnel should be available for emergency duty at all times. *All* staff must have appropriate training and qualifications It is the responsibility of the professional colleges and other appropriate bodies to determine the qualifications required for cardiac surgeons, anaesthetists, perfusionists, nurses and other staff involved in cardiac surgery.

To ensure continuity of services, a cardiac surgery unit should have the equivalent of at least two qualified full-time cardiac surgeons, unless it is a small unit formally affiliated with a larger unit, or in the commencement phase, when one surgeon may be part-time. For a larger unit the equivalent of three full-time surgeons would be required. The ratio of patients to surgeons should be such that each cardiac surgeon has at least the minimum caseload stipulated in Section **1.4.4.** Estimates of surgeon requirements would need to take into account the likelihood that some will undertake procedures at more than one hospital.

The cardiac surgeon should be primarily responsible for patient care not only during the operation but for the **first** 24–72 post-operative hours, longer if the condition warrants.

The number **of** surgical registrars required depends **on** the unit caseload, but in general would be at least equal to the number of qualified surgeons. Not all the registrars need be in training as cardiac surgeons; some would be training in general surgery and rotating through the cardiac surgical service.

The unit should have access to the services of at least two anaesthetists with training in the requirements of bypass patients, and at least two anaesthetic assistants or registrars.

The intensive care unit may require the services of a specialist in intensive care and a registrar intensivist. Additional support may be required from other registrars. In many institutions, however, the cardiac surgeon and registrars manage the patient totally in the post-operative period.

A trained clinical or medical perfusionist would be required for operation of the cardiopulmonary bypass machine and other perfusion services. It would be desirable for an additional perfusionist to be available to ensure continuity of services. Perfusion should be performed according to the guidelines laid down by the Australian and New Zealand College of Anaesthetists and the Cardiothoracic Section of the Royal Australasian College of Surgeons.

Staff required in the operating theatre will depend to some extent **on** the complexity of the procedure. The staff usually present for a standard procedure requiring cardiopulmonary bypass are:

- one cardiac surgeon;
- two surgical assistants;
- one anaesthetist and one anaesthetic technician;
- two nurses (should be capable of performing cardiac resuscitation);
- one perfusionist and one perfusion technician; and
- one laboratory technician.

More complex procedures may require additional staff. For some procedures a biomedical engineer **might** be required.

Appropriately qualified nursing staff would be required for the operating theatre and post-operative intensive care, as well as general nursing staff. Numbers should be sufficient to ensure 24 hour care, taking into account leave requirements and other **staff** absences. In the post-operative phase, a nurse–patient ratio of 1:**1** is recommended in the intensive care unit, at least while the patient is **on** ventilation (usually **6–8** hours). After the patient is extubated, the nurse–patient ratio can be reduced to 2:**1** if the patient is haemodynamically stable. In step-down beds the nurse–patient ratio should be 2.5:1, and in general wards **5**:**1.**

Bypass patients require intensive physiotherapy after surgery to expand their lungs. A physiotherapist should be assigned to the unit **on** a full or part-time basis, depending **on** the average number of patients. Patients at all three stages of post-operative care would require this service. A full or part-time counsellor and pastoral services should be available. Administrative support such as secretarial and medical records staff will be required by the unit.

1.7.3 Ward and bed requirements

Cardiac surgery post-operative care has specialised requirements in infection control, nursing care, monitoring, and emergency services. A cardiac surgery unit should therefore have a dedicated intensive care ward. After intensive care, high dependency care should be available in a step-down ward, preferably, but not necessarily, within the unit. In general, patients will spend 1–2 days in intensive care and 1–2 days in a step-down bed before proceeding to a general ward.

Table **8** illustrates the minimum number of beds needed for different cardiac surgery caseloads. Extra capacity will need to be available at times to cope with emergency admissions.

Table 8: ***Examples of average bed requirements for different cardiac surgery casemixes[(a)]***

	Example A	Example B	Example C	Example D
Number of procedures				
CABG only	900	550	410	200
Valve (b)	200	130	110	50
Other (b,c)	100	45	25	0
Total	**1200**	**725**	**545**	**250**
Beds				
Cardiac intensive care	7	4	3	2
Step-down	10	6	5	2
General	25	15	11	5
Total	**42**	**25**	**19**	**9**

Source: Estimated by the working party from the AHTAC survey.[3]

(a) It is assumed that demand for all types of beds is equal at all times of the year.

(b) Includes valve or other procedures performed with concomitant CABG, occurring in 25–30% of cases.

(c) Excludes insertion of pacemakers (discussed in Chapter 3 on electrophysiology).

1.7.4 Operating theatre requirements

The average operating time for cardiac surgery is **3–3.5** hours. If an operating theatre is operated from **7** am to **7** pm, including set-up and cleaning time, it can be used for a maximum of three operations a day. Throughput would frequently be lower. It would be desirable for a cardiac surgery unit to have a dedicated operating theatre. **For** units with larger caseloads, **2–4** theatres may be required. As an indication of operating theatre requirements, it is estimated that at the caseload given in Example A above, **two** dedicated operating theatres would be required. For Example **B,** a minimum of one would be needed, and some additional allowance would be realistic.

1.7.5 Equipment and layout requirements

Operating theatre

The equipment required in the operating theatre includes the following:

- extracorporeal bypass machine and related equipment;
- anaesthetic machine and monitoring equipment;
- electrocardiography (ECG) monitors;
- intra-aortic balloon pumps to assist circulation if the patient cannot be weaned from the bypass;
- left ventricular or biventricular assist devices for the support of failing hearts in cases where balloon pumps are inadequate;
- four channel invasive haemodynamic monitoring (Swan-Ganz, PAP, **PCWP,** atrial, central venous pressure);
- internal and external defibrillators in case of ventricular fibrillation; and
- pacemakers, cell saver, diathermy machine, surgeon's head lights, operating table, instrument trolley, instruments and infusion pumps.

Intensive care ward

Cardiac intensive care units should be sited to allow easy access to and from the operating theatre, cardiac catheterisation laboratories and other supporting departments. Infection control and ease of access to the patient are major factors to consider in their design. Beds and patients should be well separated from one another to minimise the risks of cross-infection with 10–20 square metres allowed around each bed. *All* patients have drainage tubes after surgery. Techniques should be in place for the disposal of drainage fluids without risk to patients or staff. Ideally waste disposal systems should be in each cubicle.

Access to patients in an emergency can be difficult because of the presence of monitoring equipment, ventilation tubes, drips and drainage tubes. Electrical connections should be designed to allow easy access. Normally these connections are to the wall behind the patient, but ideally, there should be a power column allowing ***360*** degree access to the patient. The intensive care unit must be a cardiac-protected electrical area, with additional earthing and tripping mechanisms to minimise risks. Oxygen and air should be supplied to each bed for patient ventilation.

It is essential to allow for adequate storage space for drugs, equipment, and **so on.** The following equipment is required:

- cardiac monitors for each bed which give the ECG, central venous and atrial pressures, Swan-Ganz and cardiac output;
- core temperature monitoring devices;
- oxygen saturation monitors;
- blood gas machines measuring oxygen and carbon dioxide levels and providing analyses of potassium, chloride, haemoglobin and pH;
- ventilators;
- intravenous pumps capable **of** delivering drugs at a precisely controlled rate;
- syringe pumps;
- intra-aortic balloon pumps;

- warming blankets to restore patients to normal temperature after surgery;
- a defibrillator;
- a sternotomy tray (equipment to open the patient's chest in an emergency); and
- emergency pacing equipment.

Step-dawn ward

A step-down ward should have the facilities of a **normal** ward. In addition it requires facilities for telemetry and central monitoring, a sternotomy tray, emergency pacing equipment, a defibrillator, infusionpumps and oxygen saturation monitors.

1.7.6 Supporting services and departments

The cardiac surgery unit should have a close working relationship with a cardiology department equipped with a cardiac catheterisation laboratory, electrocardiography **(ECG)** and echocardiography diagnostic services, including transoesophageal echocardiography. It would be desirable to have access to nuclear medicine cardiac diagnostic services. There should be a close link with a cardiac rehabilitation program (see Section **5.3.1).** Other services which should be available include diagnostic imaging, pathology and pharmacy, pulmonary function testing, blood transfusion services, biomedical engineering, haemodialysis, dietetic services, social work and pastoral services.

1.7.7 Summary of resource requirements

Table **9** summarises the major resource requirements for cardiac surgery units.

Table 9: ***Principal resource requirements for a cardiac surgery unit***

Resource	Level required
Staff requirements	
Staff required in operating theatre	Nine for average procedure requiring bypass
Cardiac surgeons	At least two fully qualified full-time; at least two surgical registrars
Anaesthetists	At least two fully qualified, at least two registrars or assistants
Nurses	Nurse–patient ratios;
intensive care	1:1 while patient on ventilation, 2:1 when extubated
step-down ward	**2.5:1**
general ward	5:1
Average bed requirements	Indicative figures: 9 for 250 procedures/year, 42 for 1200 procedures/year

Source: Collated by the working party from the AHTAC survey[3] and State health authority hospital morbidity data.

1.8 Conclusions

Estimated future caseloads, optimal unit sizes (taking account of patient outcomes and cost issues), access issues and different strategies for provision of cardiac services in different States or Territories are all important factors in determining an appropriate number of cardiac surgery units in the future. Information **on** optimal unit caseloads and expected national caseloads indicate a basic level of services could be provided by **22–25** units in **1996** and **27–31** units **in** 2001. The fact that Australia already has **34** units suggests that there is **no** need for a net increase in this country before 2001. However, decisions on cardiac surgery units must take into account distribution and access concerns. Individual States or Territories may recognise the need to adjust numbers of units to meet these concerns. Another factor to be taken into account is the capacity **of** existing units. The survey indicates that, in 1992 and 1993, units were using ***65%*** of their maximum capacity for **CABG.**[3] If problems leading to underutilisation of cardiac surgery facilities are addressed, **any** need for new units would be reduced.

The requirements of cardiac surgery units for staff, beds, equipment and supporting services, have been discussed and are dependent **on** caseload.

1.9 Recommendations — adult cardiac surgery

- *Outcomes data should be collected specifically for cardiac surgery units and risk adjusted before publication. The work* ***of*** *the Australian Council on Health Care Standards in collection and publication* ***of*** *risk-adjusted outcomes data for hospitals is supported* ....(Section 1.3.3)
- *Health planners should take into account the following caseload considerations:*
  - *a relatively small number* ***of*** *larger units is preferable to a proliferation* ***of*** *small units;*
  - *units with caseloads below 400 a year should have formal affiliation with larger units;*
  - *in areas remote from existing units, a minimum caseload* ***of*** *200 a year may be acceptable given such affiliation;*
  - *new units should not be established in cities where a unit already exists unless a start-up caseload* ***of*** *300 a year can be achieved and 500 a year within 2 years is a reasonable prospect;*
  - *the effectiveness* ***of*** *existing units with caseloads less than 200 a year should be examined and appropriate action taken; and*
  - *the caseload for a trained cardiac surgeon should be at least 200 a year and preferably more than 250 a year*..(Section 1.4)
- *Consideration* ***of*** *the desirable number* ***of*** *cardiac surgery units within individual States should take into account quality* ***of*** *care, cost, access and the location* ***of*** *existing services* .... (Sections 1.5,1.**8)**
- *Cardiac surgery units have specific requirements in terms of staff, beds, operating rooms, equipment and supporting services. Adequate provision* ***of*** *these requirements is necessary* ***if*** *patient safety and outcomes are not to be compromised*..(Section **1.7)**

2 Adult interventional cardiology

2.1 Current technology and projected developments

2.1.1 Treatment of coronary artery disease

Some forms **of** coronary artery and valve disease can now be treated without open heart surgery, by means of catheter-based techniques. The best established of these is percutaneous transluminal coronary angioplasty (PTCA), in which a catheter with a balloon annealed near its tip is percutaneously inserted into a major artery. The catheter is threaded through the circulation to the area of the obstruction, and the balloon is inflated with diluted contrast medium, disrupting the plaque and creating a wider passage for blood flow.

While PTCA allows the major trauma of coronary artery bypass grafting (CABG) to be avoided, it has its limitations. It can only be applied to certain types of obstruction and many individuals with cardiovascular disease would not benefit from its use. In addition, while initial success rates are high, there is a high rate of recurrence of obstruction. Generally it is used where lesions are suitable or in patients in whom CABG is contraindicated. More than 10% of current cases have had previous CABG.

Normally, PTCA is undertaken for the alleviation of angina, but there is increasing interest in its use as an emergency revascularisation procedure during myocardial infarction. **Four small** randomised controlled trials in the United States have shown better results for PTCA than for thrombolytic therapy.[34–38] Widespread adoption of this application would result in a very substantial increase in the number of procedures performed in Australia. There is a need for larger-scale trials, economic evaluation, and monitoring of outcomes in routine use to establish whether the use of PTCA in the treatment of myocardial infarction compares favourably to that of thrombolytics.

In recent years, a number **of** other catheter-based techniques for the treatment **of** artery disease have been developed. They include various forms of atherectomy (based **on** mechanical devices for cutting or grinding through obstructions), stenting (using devices that can be expanded within arteries to form tubular supporting structures) and laser angioplasty (using a laser beam to cut through obstructions). At this stage, there is little evidence that laser angioplasty and atherectomy have advantages over conventional balloon angioplasty in most applications. They may, however, have a role in a small proportion **of** cases with lesions which cannot be crossed with a guidewire or which give poor results with conventional angioplasty because of their shape, position or level of calcification.[39,40]

Stents appear to have a role in the prevention and management **of** arterial closure as a complication of angioplasty[41] and in the treatment of saphenous vein graft stenosis.[42] A disadvantage of stents has been the need for anticoagulation therapy to prevent thrombosis and the associated need for a longer stay in hospital, but there is an emerging view that anticoagulant therapy may not be required in selected cases. Randomised trials comparing stents and balloon angioplasty in the primary treatment of coronary artery obstructions showed a **20–30%** reduction in the rate of restenosis at **6–7** months with the use of stents, but an increased risk of vascular complications, and longer hospital stays.[43,44]

Work continues on the development of new catheter-based techniques for the treatment of coronary artery disease, but at present there is no evidence that any new technique will have a major impact. Another area where developments continue is prophylactic treatment to reduce restenosis after PTCA. There is evidence that c7E3, a monoclonal antibody that blocks platelet aggregation, administered at the time of angioplasty, reduces ischaemic events at the time of the procedure and also subsequent restenosis.[45] An angiographically controlled trial is in progress to determine whether c7E3 actually reduces stenosis. In the long term, genetically engineered products may have a role in the management of primary disease as well as restenosis.[46]

2.1.2 Treatment of valve disease

Balloon catheters can be used to treat obstructed valves of the heart in a procedure called valvuloplasty which has been applied to mitral, aortic, and pulmonary valves. In adults, obstructed mitral and aortic valves are usually acquired conditions related to disease or aging, while pulmonary valve obstruction is commonly congenital.

Valvuloplasty is technically demanding with a marked learning curve, but in expert hands it has the advantages over surgery of lower cost, and lower morbidity and mortality. Mitral valvuloplasty gives good results in appropriately selected patients, with the majority maintaining their clinical improvement over five years. Patients at high risk of early restenosis may be better treated surgically, but if surgery is not an option because of advanced heart failure, advanced age or co-existing conditions, or if surgery is refused mitral valvuloplasty may provide substantial short-term palliation.[47]

Valvuloplasty is less successful in treatment of the aortic valve For over 50% of patients, there is restenosis with recurrence of symptoms within 1–2 years.[48] In an Australian series, 73% of patients undergoing aortic valvuloplasty experienced recurrence of symptoms within 21 weeks.[49] Surgical aortic valve replacement gives excellent results and is the treatment of choice in patients with acceptable surgical risk. However, aortic valvuloplasty can provide short-term palliation in cases where advanced age or medical conditions preclude surgery or where surgery is refused.[48–50] It may also have a role as a bridge to aortic valve replacement in critically ill patients by allowing sufficient improvement in their condition for surgery to be undertaken.[48]

Valvuloplasty is a safe and effective treatment for pulmonary valve stenosis in adults as well as children, with good long-term results.[51,52]

2.2 Projected national caseload

Estimation of future PTCA caseloads is based on the method discussed in Appendix 1. Assumptions made in deriving these estimates are also discussed in the cardiac surgery section.

The National Heart Foundation (NHF) data show a rapid increase in PTCA levels since its introduction (Table 10) with the total number of procedures in 1992 being 18% higher than that in 1991. Both NHF data and the survey data indicate that Western

Australia has the highest PTCA rate and Queensland the lowest (NHF, pers. comm.).[3] In 1991 the national PTCA rate was lagging that in Western Australia by four years.[4]

Table 11 gives projected national caseloads for PTCA, by State and Territory for 1996 and 2001. The methodology and assumptions used in the projections are given in Appendix 1. In 1992, 390 PTCA procedures per million population were performed. Increases in this rate are expected, with the estimated rates for 1996 and 2001 being 670–1030 and 770–1170 per million population respectively.

These estimates assume that the PTCA casemix will remain as it is now, but there is a possibility that there will be a substantial increase in its application to the treatment of myocardial infarction. Australian Institute of Health and Welfare *(AIHW)* estimates based on hospital morbidity data indicate that there are at least 30 000 hospital admissions for acute myocardial infarction in Australia each year. Even if only 20% of these were treated by PTCA, it would increase the caseload by 100%.

In 1992–93 percutaneous valvuloplasty was 2% of the national interventional cardiology caseload, with the national valvuloplasty caseload being under 150.[3] No significant changes are expected in caseload of this procedure, and the 2001 caseload should be below 200.

Table 10: ***National PTCA caseload by year***

	1984	1985	1986	1987	1988	1989	1990	1991	1992
No of procedures	737	1244	1840	2383	3153	4219	4904	5726	6748

Source: NHF[53,54]

Table 11: ***Estimated caseload[(a)] for PTCA by State and Territory, 1996 and 2001***

	1996		2001	
State or Territory	**Low**	**High**	**Low**	**High**
New South Wales	4020	6310	4820	7460
Victoria	2910	4570	3480	5460
Queensland	2020	3170	2530	3960
South Australia and Northern Territory	1050	1650	1250	1960
Western Australia	1690	2270	2160	2890
Tasmania	300	480	360	570
Australian Capital Territory	150	240	200	310
Australia	**12 140**	**18 690**	**14 800**	**22 610**

(a) Low estimates for all States and Territories except Western Australia are as derived (from Western Australian data) by Martin.[4] Low estimate for Western Australia has been adjusted by the proportion of actual to projected increase in caseload in 1993–94 (a factor of 1.57). This same factor has been applied to the low estimates for the other States and Territories to obtain high estimates. The high estimate for Western Australia for 1996 is based on the crude rate of PTCA in the United States, and for 2001 is based on proportional differences between low and high estimates being maintained.

2.3 Outcomes and quality of care

2.3.1 Australian outcomes

In analysing the outcomes of PTCA several measures may be used. The primary success rate refers to successful dilation of the stenosis. Definitions of success vary. For example it may be defined as reduction in severity **of** stenosis or increase in lumen diameter by 20, 40 or 50%. The NHF defines it as **an** absolute reduction in the initial degree of luminal diameter stenosis by at least 20%, and a residual diameter stenosis of less than **50%.**[53] The clinical success rate refers to primary success, without major complications. Other important measures are the complication rate (death, myocardial infarction, acute occlusion and emergency bypass surgery), restenosis rate at six months or longer, and the rate of revascularisation at six months or longer. For the newer catheter-based techniques and valvuloplasty, extensive data **on** outcomes in clinical trials have been published, but there is a lack of data **on** outcomes in routine use.

The **NHF** collects Australia-wide data for PTCA. In 1992 there were 6748 PTCA procedures in a total of 27 **units**.[54] Outcomes were as follows:

- primary success rate of 92%;
- clinical success rate of **85%;**
- mortality rate of 0.39% (for 1980–1992 it was 0.40%);
- rate of associated myocardial infarction of 1.3% (four units did not supply data); and
- rate of CABG during the same hospital admission of 1.8% (2.8% for 1980–1991).

For comparison, in New York State in 1991, the primary success rate was 90%, the clinical success rate was **87%,** the mortality rate was 0.63%, the myocardial infarction rate was 1.15%, and the rate of CABG in the same hospital admission was 2.5% (1.7% **emergency**).[55] There was a higher proportion of multi-vessel procedures than in Australia (15% compared with **8%).**

2.3.2 Factors affecting outcomes

Patient risk factors associated with adverse outcomes for PTCA include female gender, haemodynamic instability, shock, low ejection fraction, age over 75, renal impairment, lesion type and number **of** vessels attempted.[11,29,55] In a study of outcomes at the Mayo Clinic, Rochester, in the United States, mortality rates in 1988–90 were significantly higher for women than for men and were significantly higher than they were in 1979–87. The differences were related to increasing age and greater severity of **disease**.[56]

The effects **of** caseload and institutional quality **of** care **on** outcomes **of** PTCA appear to have received less attention than those **on** CABG. Only three papers have been identified. Hartz et **al**.[8,29] were unable to find an association between complication rates and caseload for PTCA or CABG. However, these studies are subject to a number **of** design problems, including inadequate sample size (see Appendix 2). A more recent study by **Jollis** et al. found that 30 day mortality after PTCA rose steadily from less than 3% in hospitals with annual caseloads of more than 400–800, to over **4%** in those hospitals with the smallest caseloads (less than 100–200 per year).[30] Similarly, the proportion of persons undergoing PTCA who had CABG before discharge rose steadily from less than 3% in hospitals with annual caseloads **of** more than **600–800,** to over 5%

in those hospitals with the smallest caseloads. This study included **217 836** Medicare beneficiaries aged over **64** years who underwent PTCA in **1194** hospitals in all parts of the United States between **1987** and **1990.**

2.3.3 Data collection and risk stratification

The national goals, targets and strategies for better health outcomes for Australians propose that stratified criteria of risk should be defined and applied in all units performing PTCA.[2] As for cardiac surgery, the collection of risk-adjusted outcomes data for interventional cardiology units would be desirable (see Sections **1.3.3,** and **1.9).** The collection of specific outcomes data for the newer procedures would provide a basis for the assessment of their short and long-term effectiveness in routine practice, and facilitate the development of guidelines **on** their use. Expansion of the NHF's existing register of PTCA to include patient stratification and long-term outcomes has been suggested by the national goals, targets and strategies for better health outcomes for Australians.[2]

2.4 Unit and operator caseload

2.4.1 Current unit and operator caseloads in Australia

The **NHF** data **show** that, in **1991**, the number of PTCA procedures per unit ranged from **11–656,** with an average of **286**.[53] The **NHF** does not provide information **on** procedures per operator but calculations based **on** their data suggest that each operator performed an average of **71** procedures that year.

The Australian Health Technology Advisory Committee (AHTAC) survey collected caseload dated from **23** cardiology units performing interventional cardiology or electrophysiology procedures in **1992, 1992–93** or **1993**[3]. Diagnostic cardiology made up **84%** of the total caseload with **an** average caseload of **1444** per unit (range of **476–3304).** Only three of the units had diagnostic cardiology caseloads **of** less than **1000** a year. Coronary angiography comprised **97%** of diagnostic cardiology. The total interventional cardiology caseload was **6560,98%** of which was PTCA, with an average total caseload per unit of **312** (range **4–900),** and an average PTCA caseload per unit of **307** (range **4–874).** Two units performed fewer than 100 angioplasties annually, six between 100 and 200. Nine units performed valvuloplasty with an average caseload of **13** per unit (range **1–41** with five units performing fewer than 10 procedures). There appeared to be **no** direct relationship between caseloads ***of*** angioplasty and valvuloplasty. The average PTCA caseload for public cardiology units was **315,** compared with **281** for private cardiology units. Private hospitals performed 21% of the total interventional cardiology caseload but did not perform any valvuloplasty.

In most units, emergency coronary angioplasties comprised less than **8%** of the angioplasty caseload (average **7%;** range 0–42%). **An** average of 11% of **all** angioplasties were performed immediately after angiogram Eight units used atherectomy devices; these units did **so** in a total **of 137** coronary angioplasties, averaging **3.9%** of all the angioplasties they performed. Thirteen units used stents; these units did **so** in a total of **179** coronary angioplasties, averaging **3.7%** of all the angioplasties they performed. There appeared to be **no** direct relationship between PTCA caseload and the use of atherectomy devices or stents. **No** unit reported the use **of** lasers in angioplasty.

2.4.2 Minimum and optimal unit and operator caseloads

The 1986 Canadian guidelines **on** cardiovascular services noted that the greater the workload in coronary angiography at a unit, the greater the skill and experience that can be applied to PTCA. The guidelines recommended that, at start-up, a unit should undertake at least one case of PTCA per week. It was considered that a cardiac catheterisation laboratory would have to perform at least 1000 coronary angiograms a year to have a sufficient patient base **to** meet this requirement.[32]

In guidelines **on** PTCA published in 1993, a task force of the American College of Cardiology and the American Heart Association recommended that a trained interventional cardiologist should perform at least **75** PTCA procedures a year to maintain competence.[33]

On the basis of this figure, and the premise that a viable unit would require the equivalent of at least **two** full-time interventional cardiologists, a minimum caseload per unit would appear to be 150. In addition, the unit would need to maintain a substantial caseload of coronary angiography.

It is emphasised that these figures represent a minimal standard and are certainly not optimal. New units should not be encouraged to open **on** the basis of these minimum criteria. Optimal caseloads would probably be in excess of 200 per operator annually for PTCA in units performing well over 1000 coronary angiogram a year.

The national caseload for valvuloplasty continues to be small. Given the marked learning curve for this technology, it would be inappropriate for a unit to commence providing valvuloplasty unless there are sufficient cases to maintain skill. The caseloads at most Australian units appear to be inadequate for this purpose. There is a need to find a balance between optimising access to the procedure, and optimising outcomes. This may best be achieved by restricting services to units undertaking at least 10 valvuloplasties per year.

For stents, success may also depend **on** experience but their use in emergency situations suggest that they should be available in all units. At present, laser-assisted PTCA is not used in Australia. Its use could only be justified in the context of a clinical trial.

2.5 Distribution of services

Table 12 gives the location of the 32 Australian adult interventional cardiology units and their distribution between public and private hospitals in October 1994. *All* of the States but neither of the Territories had interventional cardiology services. In some hospitals the services were only just being established. *All* but four units were in capital cities.

Table **13** gives the number of units per **million** population for each State and Territory. The figures **show** substantial differences. As for cardiac surgery services, the number of units per **million** population is not necessarily a measure **of** capacity or quality of care.

Table 12: ***Distribution of adult interventional cardiology units in Australia, October 1994***

Location	Number of public units	Number of private units	Total
New South Wales			
Sydney	5	4	9
Newcastle	1	0	1
Victoria			
Melbourne	5	2	7
Queensland			
Brisbane	1	2	3
Townsville	1	1	2
Gold Coast	0	1	1
South Australia			
Adelaide	3	1	4
Western Australia			
Perth	3	1	4
Tasmania			
Hobart	1	0	1
Total	**20**	**12**	**32**

Source: Compiled by the working party from available data.

Table 13: ***Interventional cardiology units per million population by State and Territory, October 1994***

State or Territory	Number of units per million population
New South Wales and ACT	1.57
Victoria	1.56
Queensland	1.88
South Australia and Northern Territory	2.44
Western Australia	2.35
Tasmania	2.10
Australia	**1.79**

Source: Calculated from Table 12 and ABS population projections.[68]

2.6 Organisation of services

2.6.1 Relationship with diagnostic cardiology

Interventional cardiology is generally an integral part of a cardiology unit providing principally diagnostic cardiac catheterisation services. While not all cardiologists working in the unit would necessarily undertake interventional procedures, technical and nursing staff should be able to assist at both diagnostic and therapeutic procedures.

2.6.2 Medical and administrative direction

A cardiology unit performing interventional procedures should be under the direction of a practising cardiologist.

The corresponding section in Chapter 1 **on** cardiac surgery discusses relationships between cardiac surgery and cardiology departments.

2.6.3 Surgical backup

In about **2% of** cases, patients undergoing PTCA need to be transferred from the cardiology unit to a cardiac surgery operating theatre for immediate emergency surgery within **30** minute^.^^?^^ Cardiology units must ensure that such transfers can be effected at any time coronary angioplasties are likely to be performed. When the cardiology and cardiac surgery units are in the same hospital, any procedural or physical difficulties within the hospital in effecting such a transfer need to be identified and resolved. **If no** backup cardiac surgery exists within the hospital, patients would need to be transferred to the operating theatre of a cardiac surgery unit in a nearby hospital within **30** minutes. The logistics **of** doing **so** are formidable, since institutional barriers need to be crossed, ambulance services be **on** hand at all times and traffic delays contended with as well as all the difficulties associated with moving critically ill patients between **two** hospitals. In addition, the cardiology unit would need to keep abreast of ***ad hoc*** difficulties such as streets blocked **off** for repairs, parades and other reasons.

2.7 Resource requirements

2.7.1 Survey results and hospital morbidity data

The AHTAC survey specifically addressed resource usage by existing cardiology units to determine current practice in Australia.[3] All cardiology units surveyed have their **own** monitored coronary care beds and most have telemetry and general beds, with the number of such beds increasing with annual caseloads. Average hospital stays **of 2.4** days for PTCA and **1.8** days for percutaneous valvuloplasty were reported. The average length **of** stay for PTCA [illegible] probably be lowered in the future. The average length of stay reported for emergency PTCA is **3.2** days, longer than that for elective PTCA **(1.9** days). The average length of stay is **1.3** days for diagnostic angiography and **1.2** days for other diagnostic cardiac catheterisation. Many institutions now undertake elective angiograms as day cases where the patient remains in hospital for less than eight **hours.**

Nurse–patient ratios are **1:1.9** for coronary care, **1:4.1** for telemetry beds and **1:5.8** for general wards. Survey respondents recorded an average of **17.7** staff used to operate their procedure suites, of whom **5.4** were cardiologists. However, this is likely to overestimate staff levels since some units provided the total number of cardiologists (and possibly other staff) using the suite, rather than their full-time equivalents. As well as cardiologists, most units use registrars (average **of 2.1),** radiographers (average of **1.8),** cardiac technicians (average of **2.9)** and registered nurses (average of 5.5). Other staff used by some units include nurse assistants, anaesthetists, orderlies or porters, secretaries and administrative officers. Staff levels are higher in private hospitals (average of **22)** than in public hospitals (average of **18).**

Cardiology units had an average of 1.5 procedure suites, with **39%** of surveyed units having more than one suite. Overall, **43% of** cardiology suites have digital radiology equipment.

Hospital morbidity databases provide another source of information on length of hospital stays associated with cardiology procedures. The average length of stay recorded in hospital morbidity data for PTCA is considerably longer (5.1 days) than that recorded in the survey. PTCA without concomitant cardiac surgery is associated with a slightly shorter average hospital stay of 4.8 days. However, these data will include cases where the main reason for the hospital stay was unstable angina or myocardial infarction and the angioplasty procedure was incidental to this. In these cases, the length of hospital stay reflects the underlying disease rather than the angioplasty procedure. The average length of hospital stay recorded for percutaneous valvuloplasty is 4.3 days, and for diagnostic cardiology 4.1 days. The average length of stay for diagnostic cardiology decreases to 3.1 days for admissions with no concomitant cardiac surgery or interventional cardiology, with 8% of admissions being day cases. Admissions without concomitant surgery comprise 90% of the caseload recorded for diagnostic cardiology.

2.7.2 Staff requirements

A cardiology unit requires a multi-disciplinary team of clinical, nursing, technical and support staff able to work together effectively. All staff must have appropriate training and qualifications It is the responsibility of the professional colleges and other appropriate bodies to determine the qualifications for cardiologists, cardiac technicians, nurses and other staff involved in interventional cardiology.

A minimum of two cardiologists would be required for a viable unit undertaking interventional cardiology. A unit where more than 150 coronary angioplasties and 1000 diagnostic procedures are performed a year would require at least three qualified cardiologists (one of whom may not be performing interventional procedures). In addition there would be a need for at least two cardiology registrars in a teaching hospital setting. One to two radiographers, one to two cardiac technicians, three nurses and at least the part-time services of a radiation physicist would also be required. Nursing staff should be capable of cardiac resuscitation and a nurse–patient ratio of 1:2 is recommended in coronary care, reducing to 1:4 in telemetry beds and 1:6 in general beds. In addition an orderly, and administrative support such as secretarial and medical records functions, will be needed. The unit should have part-time access to other staff such as an anaesthetist and data processing staff Some interventional cardiology units find that employing sufficient fully trained cardiac technicians obviates the need for nurses in the immediate vicinity of the catheter laboratory.

2.7.3 Bed requirements

The facilities required for coronary care and cardiology telemetry beds differ from those needed in cardiac surgery beds. Coronary care beds require continuous electrocardiography (ECG) monitoring, together with a capacity for intravascular pressure measurement, intra-aortic balloon pumping, and pacemaker insertion, but do not need the ventilator capacity usually provided for intensive care.

Full coronary care is not always necessary for interventional cardiology patients but must be available. Approximately one quarter of the beds used for interventional cardiology will require intravascular pressure monitoring in addition to ECG telemetry. Coronary care type monitoring is required at least after complex angioplasty procedures, although telemetry beds are acceptable for low risk angioplasties. In some centres in the United States very simple low risk angioplasties have been performed as outpatient procedures.

Patients undergoing elective angioplasty usually require **1–2** days in a telemetry or coronary care (monitored) bed. Those with unstable angina or acute myocardial infarction commonly require **2–3** days in a coronary care bed; when indicated, angioplasty would be performed during this time. Some will stay in hospital for longer periods because of complications.

Table **14** gives estimates of the minimum number of beds needed for different cardiology caseloads. **An** average of **two** days in a telemetry (or monitored) bed for **PTCA** and for percutaneous valvuloplasty was used for the calculations. While diagnostic cardiology is not specifically covered by these guidelines, it will always be associated with interventional cardiology and has been included in the estimates. ***An*** average stay of **1.5** days in a general bed was used for diagnostic procedures. Extra capacity would need to be available at all times to cope with emergency admissions.

Table 14: ***Examples of average bed requirements for different cardiology casemixes[(a)]***

	Example A	Example B	Example C	Example D
Number of procedures				
Diagnostic	1000	1350	1300	1750
Interventional[(b)]	200	150	*300*	750
Total	**1200**	**1500**	**1600**	**2500**
Beds[(c)]				
Telemetry	1	1	2	**4**
General	4	6	*6*	8
Total	**5**	***7***	**8**	**12**

(a) It is assumed that demand for all types of bed is equal at all times of the year.
(b) PTCA and percutaneous valvuloplasty.
(c) Some coronary care bed days will also be required.
Source: Estimated by the working party from the AHTAC survey.[3]

2.7.4 Equipment and layout requirements

These guidelines cover the equipment requirements relevant to interventional cardiology. Equipment purely for non-invasive cardiological procedures is not included.

In the design **of** a cardiac catheterisation laboratory, important factors include radiation safety, temperature control, and space requirements. The laboratory should be lead-lined, with a lead glass partition between the procedural and monitoring areas. Radiation protection within the procedural area **will** require lead glass shields and lead aprons and collars. The imaging equipment generates substantial heat and adequate, reliable air conditioning is essential for protection of computers. Estimates of space needs should allow for ease of access to the patient and monitoring needs, and for access to equipment for maintenance purposes.

A high standard **of** imaging equipment is needed for interventional cardiology, which requires 1024x1024 pixel resolution and 15–30 frames per second. New technology is all digital, which has major advantages over **film,** allowing manipulation and enhancement of images, and storage **on** optic disc. Quality control tests which are suitable for the hospital environment and which use standard units must be available. Monitoring systems should incorporate **ECG,** electrophysiology, haemodynamics and oxygen saturation. Facilities for dye dilution and measurement of activated clotting times are also necessary.

The unit will need to have adequate supplies of angiography and balloon catheters in a range of sizes, guidewires and contrast medium. Non-ionic medium should be available at least for high risk patients and for angioplasty. *All* units should have stents available for emergency use, provided that at least one of the cardiologists has been trained in their use. It is not recommended that atherectomy devices should be available in all units.

Suitable storage space should be available for imaging data of tapes and optic discs, for catheters and for contrast medium. It would be desirable to have a room adjacent to the cardiac catheterisation laboratory for preparation of the patient, and examination of the results of previous diagnostic tests. **A** remote work station is desirable, to allow cardiologists to access raw data, manipulate images and prepare reports, away from the catheterisation laboratory.

2.7.5 Supporting services and departments

The requirement for back-up surgical facilities has been discussed above. Other departments and services which should be available to the unit include non-invasive diagnostic cardiac services (including stress testing, nuclear medicine tests, echocardiography), radiology, pathology, pharmacy, pulmonary function testing, blood transfusion services, biomedical engineering, haemodialysis, dietetic services, social work and pastoral services. Cardiac care consumers should have the opportunity to participate in a cardiac rehabilitation program.

2.7.6 Summary of principal resource requirements

Table **15** summarises the principal resource requirements for a cardiology unit undertaking interventional cardiology.

Table 15: ***Principal resource requirements for interventional cardiology***

Resource	Level required
Staff requirements	
Cardiologists	At least two for a viable unit, at least three if more than 150 interventional and 1000 diagnostic procedureslyear
Radiographers	1–2
Cardiac technicians	1–2
Nurses	Nurse–patient ratio
coronary care	1:2
telemetry ward	1:4
general ward	1:6
Bed requirements	Indicative minimum figures: 5 for 1200 procedureslyear including 200 interventional; 12 for 2500 procedureslyear including 750 interventional

Source: Collated by the working party from the AHTAC survey[3] and State health authority hospital morbidity data.

2.8 Conclusions

Estimated future caseloads, optimal unit sizes (taking account of patient outcomes and cost issues), access issues and different strategies for provision of interventional cardiology services in different States and Territories are all important factors in determining an appropriate number of interventional cardiology units in the future. However, uncertainties about future caseloads make it difficult to determine the number of units that will be needed by 2001. If an average annual caseload of 400 interventional procedures per unit is used, 30–47 units will be needed in 1996 and 37–57 units in 2001.

The survey recorded that approximately one half of a unit's capacity to perform interventional cardiology is actually used, with a higher proportion used in the public sector than in the private sector.[3] Availability of suitable staff and beds may be a limiting factor in some instances. This would indicate that an average annual caseload of closer to 450 interventional procedures a year might be possible if difficulties preventing maximum usage were removed and an average of 80% usage was achieved. In this case, 21–32 units would be needed in 1996, and 26–38 in 2001.

However, a larger number of units with a smaller average annual caseload might be necessary to address access difficulties. Moreover, it is likely that, at least in selected cases, emergency PTCA will be used increasingly as a first line treatment for acute myocardial infarction. Routine emergency use of PTCA for acute myocardial infarction has great implications for the national PTCA caseload, with the consequences being up to 100% increase in the projected caseload. Confirmation of effectiveness in large-scale clinical trials and in routine use, and detailed studies on cost effectiveness are needed to determine whether a major expansion of services for this application is justified.

The requirements of interventional cardiology units for staff, beds, equipment and supporting services, have been discussed and are dependent on caseload.

2.9 Recommendations — adult interventional cardiology

- *Outcomes data should be collected specifically for interventional cardiology units and risk-adjusted before publication. Data should be provided separately for conventional balloon PTCA, laser-assisted angioplasty, different types of atherectomy, procedures involving the use of stents, and valvuloplasty*.....(Section 2.3.3)
- *Health planners should take into account the following caseload considerations:*
  - *interventional cardiology should be undertaken only in cardiology units with a minimum cardiac catheterisation caseload of 900 to 1000 a year;*
  - *to maintain expertise in PTCA, a trained interventional cardiologist should undertake at least 75, and optimally more than 200, procedures a year;*
  - *the minimum caseload for an interventional cardiology unit should be at least 150, and optimally more than 400, coronary angioplasties a year;*
  - *valvuloplasty services should be restricted to units with a caseload of at least IO procedures a year;*
  - *laser-assisted PTCA should only be used in the context of a clinical trial, until good evidence of cost effectiveness emerges; and*
  - *establishment of new interventional cardiology units on the basis of the minimum caseload criteria should not be encouraged* ....(Section 2.4.2)

- *Before an interventional cardiology unit is established in a hospital without cardiac surgery, it should be demonstrated that the advantages to patient care outweigh the marked disadvantages that can* ***occur*** *without the support* ***of*** *on-site cardiac surgery...*(**Section 2.6.3)**
- *Cardiology units should ensure that, in an emergency, PTCA patients can be transferred to a fully-staffed cardiac surgery operating theatre within* ***30*** *minutes. A cardiology unit in a hospital without a cardiac surgery unit must be able to demonstrate that, under any circumstances,patients can be transferred to a nearby cardiac surgery operating theatre within this time.............................***(Section 2.6.3)**
- *Interventional cardiology units have specific requirements in terms* ***of*** *staff, beds, equipment and supporting services. These requirements must be met* ***if*** *patient safety and outcomes are not to be compromised...................................*(**Section 2.7)**
- *Trials* ***of*** *PTCA in the treatment* ***of*** *acute myocardial infarction should be kept under review. Consideration should be given to the provision* ***of funds*** *for controlled trials, and studies* ***of*** *health outcomes and costs* ***of*** *PTCA in the routine treatment* ***of*** *myocardial infarction...*(**Section 2.8)**

3 Adult electrophysiology

3.1 Current technology and projected developments

Cardiac electrophysiology is primarily concerned with the management of cardiac arrhythmias, abnormal heart rhythms which can originate in different regions of the heart. Bradycardias are abnormally slow rhythms. Tachycardias are paroxysmal accelerations of the heart rate which may originate in the atria, ventricles, atrio-ventricular node or an atrioventricular accessory pathway. Fibrillation is a state of rapid chaotic activity which may occur in the atria or ventricles. Without medical intervention, ventricular fibrillation results in circulatory arrest and death. Sustained ventricular tachycardia is life threatening as it can convert to fibrillation. The supraventricular arrhythmias are not as dangerous but can have serious effects.

Electrophysiology testing is basic to therapeutic electrophysiology interventions. It is undertaken to diagnose and evaluate arrhythmias, identify and map conduction pathways, test the efficacy of anti-arrhythmia drugs, and measure threshold values for defibrillation. Diagnostic and therapeutic electrophysiology procedures (other than pacemaker insertion) require an electrophysiology laboratory and an operator with highly specialised expertise.

Pacemakers are a long-established means of treating bradycardias. Other forms of therapy for arrhythmias include anti-arrhythmic drugs, surgery, radiofrequency catheter ablation, anti-tachyarrhythmia devices, and implantable cardiac defibrillators.

3.1.1 Pacemakers

Cardiac pacemakers are electronic devices that deliver electrical stimuli to the heart to correct bradycardias. A pacemaker consists of a power source (usually a battery), electronic circuitry to regulate the timing and characteristics of the stimuli, connecting leads, and electrodes in contact with the heart for sensing and stimulus delivery. While external devices can be used for temporary pacing, permanent pacemakers are implanted. In Australia, cardiology units are responsible for most pacemaker implantations.

The first implantable pacemakers were developed in the 1950s. Since then, there have been major advances in the technology, and modern pacemakers are compact, weigh 23–75 grams, can be programmed non-invasively, and last for 6–10 years.[57]

There is general agreement that pacemaker implantation is warranted for symptomatic permanent or recurrent bradycardia. This condition is usually due to atrioventricular block or sick sinus syndrome. In the United States, sick sinus syndrome accounts for 46% of pacemaker implants and atrioventricular block for 31%.[57] The incidence of sick sinus syndrome is related to ageing and to the use of drugs for the treatment of angina, hypertension and congestive heart failure. One form of sick sinus syndrome has both tachycardia and bradycardia components. Drugs used to treat the tachycardia may exacerbate the bradycardia component, leading to the need for a pacemaker.[58] Thus, to some extent, the need for pacemakers results from previous medical care.

A characteristic of the evolution of pacemaker technology has been that, as new developments were introduced to overcome problems with previous models, new problems arose. For example, devices developed in the sixties caused a condition called pacemaker syndrome, in which loss of atrioventricular synchrony resulted in symptoms such as dizziness, fatigue and fainting. Later devices produced the side effect of pacemaker-mediated tachycardia, a problem that has been largely but not completely resolved.[57]

Further improvements in the technology are expected, giving greater flexibility in the self adjustment of rate, output and sensitivity. Systems that can store consumer details and use sophisticated algorithms to diagnose rhythm disturbances are being developed.[57]

3.1.2 Anti-tachycardia devices

Anti-tachycardia devices can be used for the management of atrioventricular and ventricular tachycardias but they have limitations. They are complex, requiring constant attention and programming, but they may not allow drug therapy to be avoided. They can trigger fibrillation, making them high risk therapy for people with ventricular tachycardia.

Recent developments have limited the caseload suitable for anti-tachycardia devices. Radiofrequency catheter ablation is now the preferred therapy for many people with supraventricular tachycardias, while implantable cardiac defibrillators incorporating anti-tachycardia devices are now used for some people with sustained ventricular tachycardia (see Section **3.1.6).**

3.1.3 Electrophysiology surgery

Regions of myocardial tissue responsible for arrhythmias can be excised surgically. Electrophysiology surgery is associated with considerable morbidity and has high complication rates. Surgery for ventricular arrhythmias is particularly difficult and the mortality rate can be high. Radiofrequency catheter ablation and implantable defibrillators are replacing electrophysiology surgery.

3.1.4 Anti-arrhythmia drugs

Long-term therapy with anti-arrhythmia drugs is successful in many cases but has limitations. Often the drugs are ineffective, there can be side effects, and there is a small but definite risk of life threatening toxicity or proarrhythmia. Patients may find them unacceptable.[59] The problems with anti-arrhythmic drugs have stimulated interest in the development of safe alternatives.

3.1.5 Radiofrequency catheter ablation

Radiofrequency catheter ablation is a minimal access, catheter-based technique for the treatment of some cardiac arrhythmias. It is a relatively recent development but diffused rapidly after its efficacy was demonstrated. It was introduced into Australia in **1988.**

The procedure involves locating the pathway responsible for triggering the arrhythmia and using radiofrequency current delivered by a catheter probe for controlled ablation of pathway tissue. The procedure is performed with the assistance of fluoroscopic imaging. It has been particularly successful in treating arrhythmias associated with accessory atrioventricular pathways, and surgery for these conditions is now obsolete. It has also been effective in the treatment of a number of other supraventriculartachyarrhythmias.

Radiofrequency catheter ablation has two significant limitations. The procedure can be lengthy (resulting in sigmficant exposure to radiation), and only small, shallow regions of tissue can be ablated. At present, the procedure is suitable for only a small proportion of people with ventricular tachycardia. For those with ventricular tachycardia foci caused by myocardial infarction, a technique capable of destroying larger areas of tissue is needed. In current research, there is interest in new power sources such as microwave energy, which would permit the ablation of larger **areas**.[59] In the medium to long-term future, developments in this area could result in effective catheter ablation techniques for the treatment of most cases of ventricular tachycardia.

3.1.6 Implantable cardiac defibrillators

Implantable defibrillators are used to treat those who are at high risk of sudden cardiac death and in whom arrhythmia drug therapy is ineffective or drugs cannot be tested. They are usually survivors of sudden cardiac arrest, or subject to sustained ventricular tachycardia.

The usual cause of cardiac arrest is ventricular fibrillation, which can develop from sustained ventricular tachycardia. Implantable cardiac defibrillators detect ventricular fibrillation and respond by delivering electric shocks to the heart, restoring normal rhythm- They can also detect and terminate sustained ventricular tachycardia.

Earlier devices had severe limitations. Implantation required major surgery and at around 270 grams each, the devices were much heavier and bulkier than pacemakers. Shocks were the only form of therapy they could deliver. They could respond inappropriately to **minor** arrhythmias, delivering unnecessary shocks. Recently there have been major developments in the technology. Transvenous leads are now available, allowing less invasive implantation, and pacing functions have been incorporated. A tiered approach to therapy for ventricular tachycardia has been developed, with pacing as the **first** line therapy, followed by low-energy shocks if pacing is unsuccessful, and high energy shocks as a last resort. The new devices deliver biphasic shocks, reducing energy use and consumer discomfort. Generators have been reduced in size from 270 grams to 17–190grams, they are programmable to allow flexibility in therapy patterns, and incorporate a memory function, allowing information **on** detection and reversion of arrhythmias to be saved and checked.

Limitations remain. For around 10% of candidates for implantable defibrillators, the transvenous leads are ineffective. There continue to be problems with inappropriate responses to minor **arrhythmias**.[60] In some cases, pacing or low-energy shocks accelerate ventricular tachycardia instead of terminating it, resulting in ventricular fibrillation and high energy **shocks**.[61]

3.2 Projected national caseload

3.2.1 Pacemakers

No estimates have been found for the incidence and prevalence of bradycardia in Australia and it has not been possible to estimate future pacemaker caseloads **on** the basis **of** need.

It is estimated that **3700** consumers received permanent pacemakers in Australia in **1991–92.** Of these, **15%** were replacements **of** previously implanted devices. **In** addition, **825** consumers received temporary pacemakers. Table **16** shows that the rate **of** pacemaker implantation in Australia is about half that in the United States. While it is likely that by Australian standards there is overuse in the United States, the difference between the figures suggest that there is potential for a higher rate of usage in Australia.

Table 16: ***Incidence and rates ofpacemaker implantation, Australia and the United States***

Country and type of pacemaker	incidence of pacemaker implantation	Rates of implantation per million population
Australia 1991–92		
Permanent	3700	212
Permanent and temporary	4525	259
USA (estimated current usage)		
Permanent	110000–125000	433–492

Source: Australian data are estimated from hospital morbidity data. The **US** data are estimates from industry sources.

According to industry sources, the incidence of pacemaker implantation in Australia is increasing at the rate of 2% a year. However Medicare data indicate that over the period **1984–85** to **1991–92,** there was an average annual increase **of** nearly **16%** in the number of procedures for which Medicare benefits were paid (procedures **on** private consumers). These make up less than **40%** of all procedures. If it is assumed that the incidence **of** procedures involving public consumers remains static, and the growth in the incidence for private consumers is **16%,** the current overall growth rate would be about ***6%.*** If usage in the public sector increases by **2–3%,** equivalent to growth in the population aged 65 and over, the overall growth rate would be **7–8%.** Expert advice is that the current growth rate is 5–10% (Dr **P** Kertes, Austin Hospital, Melbourne, pers. comm.). Table **17** gives projected caseloads at different growth rates. A growth rate of 10% **will** result in a rate **of 580** implantations per **million** population **in 2001.**

3.2.2 Anti-tachycardia devices

Results **from** the Australian Health Technology Advisory Committee (AHTAC) survey indicate that **60–80** anti-tachycardia devices are implanted in Australia each year.[3] It is not expected that the caseload **will** increase during the next decade and in fact, it may decline. The caseload in **1996** and 2001 is likely to be in the range **40–80** a year.

Table 17: *Projected caseloads for pacemaker implantation, Australia 1996 and 2001*

Annual growth rate (%)	1996 Permanent	1996 All	2001 Permanent	2001 All
2	4020	4920	4440	5430
4	4380	5370	5330	6530
6	4780	5850	6390	7830
8	5200	6360	7640	9350
10	5650	6910	9100	11 130

Source: Estimated using data from Table 16 and ABS projected population growth.[68]

3.2.3 Electrophysiology surgery

In 1992, 52 electrophysiology surgical procedures were performed for the excision of tissue responsible for tachyarrhythmias.[5] The incidence of these procedures is declining and is expected to be less than 50 a year in both 1996 and 2001.

3.2.4 Radiofrequency catheter ablation

In Australia, 50 000–90 000 people may suffer to some degree from supraventricular tachycardias.[62] In the great majority of cases, symptoms would not be significant enough to warrant treatment. In 1991, it was predicted that radiofrequency catheter ablation would be used in the treatment of 700–900 consumers a year.[62] The AHTAC survey indicates that it is already being used to treat over 900 consumers a year.[3] It is likely that the introduction of this relatively safe, minimally invasive technique is leading to an expansion of the indications for intervention in cases of supraventricular tachycardias. There is also a risk that the technology will be applied in a number of cases with uncertain justification.

Future caseload for this technology is impossible to predict with any certainty. It has been suggested that while current growth rates are high, there should be a levelling out in about two years (Dr P Kertes, pers. comm.). On the basis of population growth and current indications, the caseload would be about 970 cases a year in 1996 and 1050 cases (or 60 cases per million population) in 2001. It is more likely that widening indications and greater demand will lead to higher caseloads.

3.2.5 Implantable cardiac defibrillators

While the incidence of defibrillator implantation has grown from less than 50 a year in 1990 to around 125 a year in 1992–93, it is well below the potential demand. In a 1990 study of implantable cardiac defibrillators, it was estimated that on conservative indications (use only if anti-arrhythmia drugs were ineffective) there could be 250–470 cases suitable for defibrillator implantation each year in Australia. If the defibrillator was used as the first line of approach in the treatment of survivors of sudden cardiac arrest and consumers with sustained ventricular tachycardia, potential demand could be 500–1000 cases (or 26–52 cases per million population) a year.[63]

Hospital budgets are a major constraint on the use of this high cost treatment (around $34 000 per procedure), and may keep usage below potential demand in the future. Nevertheless, growth in its use is expected to continue. In 1996 the caseload may be 200–300 a year, while in 2001 it may be 500–1000 a year.

3.3 Outcomes and quality of care

Pacemaker implantation is a safe, simple procedure performed under local anaesthesia, with a **high** success rate and a very low complication rate. Rarely, lead-related thrombosis and obstruction of the superior vena cava may occur. In the past, long-term side effects of pacemaker implantation were common. They included pacemaker syndrome, a condition with symptoms such as dizziness and fainting caused by inadequate timing **of** atrial and ventricular contractions, and pacemaker-mediated tachycardia. These problems have largely been overcome by improvements in the technology.[57]

Electrophysiology surgery has significant mortality and complication rates. In Australia in **1992** the mortality rate was 5.8%.[5]

For radiofrequency catheter ablation, the success rate in Australia is about **90%,** and the rate **of** recurrence of arrhythmias in successful cases is about **4%.** The mortality rate is very low. **A** major complication occurring in about 1% of cases is heart block requiring permanent pacemaker implantation.[64]

There is general consensus that implantable cardiac defibrillators reduce the rate of sudden death due to arrhythmias more effectively than available medical therapy. It is less certain that they reduce the rate of death from all causes. Implantation with conventional epicardial leads is a major operation, and mortality rates reported in the literature are in the range 3–6%.[65] In Australia in **1992,** it was 1.7%.[5] Implantation with transvenous leads is a much simpler procedure and a mortality rate of 0.4% has been reported.[66]

Studies of the effects **of** quality of care **on** outcomes are believed to be in progress for pacemaker and defibrillator implantation, but **no** published results have been located.

3.4 Unit and operator caseload

On the basis of expert advice, it is considered that pacemaker implantation should be performed either by an electrophysiologist or by a cardiologist or cardiac surgeon who is able to maintain a caseload **of** at least 40 implantations a year. Radiofrequency catheter ablations should only be performed by electrophysiologists and a caseload of at least 50 a year is required to maintain skills.

For implantable cardiac defibrillators, the surgeon performing implantation with epicardial leads should have had some training in defibrillator implantation. A trained electrophysiologist would have the necessary skills for the tests required. For transvenous implantation, the electrophysiologist should be active in pacemaker implantation, which is very similar, but does not need to perform a specific number **of** defibrillator implantations.

3.5 Distribution of services

It is estimated that **23** cardiology units in Australia undertake electrophysiology procedures, but complete details are unavailable. **Of** the units responding **to** the AHTAC survey, 18 undertook diagnostic electrophysiology studies, 20 supplied permanent (15) or temporary (18) pacemakers, 12 performed radiofrequency catheter ablation, and 11 supplied implantable cardiac defibrillators.[3] Pacemakers are also inserted by 12 cardiac surgery units. Table 18 gives the location of cardiology units providing electrophysiology services. This (incomplete) information indicates that electrophysiology services are available in the capital cities of all the mainland States but not in Tasmania or the Territories, with only one non-metropolitan centre providing these services.

Table 18: ***Distribution of identified electrophysiology services, Australia 1992–93***

State	Diagnostic studies	Pacemakers	Radiofrequency catheter ablation	Implantable defibrillators
New South Wales	5 public, 2 private	5 public, **4** private	3 public, 1 private	3 public, 2 private
Victoria	5 public, 1 private	5 public, 2 private	5 public	3 public
Queensland	1 public	1 public	1 public	1 public
Western Australia	2 public	2 public	1 public	1 public
South Australia	2 public	2 public	1 public	1 public

Source: Compiled by the working party from available data.

3.6 Organisation of services

Electrophysiology is generally included in cardiology departments, although it requires specific training. At this stage there appears to be **no** trend towards forming separate electrophysiology departments.

3.7 Resource requirements

Insertion of pacemakers is provided by both cardiac surgery and cardiology units, while other electrophysiology services are provided by cardiology units only. To some extent the sections **on** cardiac surgery and cardiology have already covered electrophysiology requirements. Only specific requirements not already covered have been included in this section.

3.7.1 Survey results and hospital morbidity data

The survey specifically addressed resource usage by cardiac surgery and cardiology units providing electrophysiology services to determine current practice in Australia.[3] **Forty** per cent of cardiology units surveyed had separate electrophysiology laboratories.

Average lengths of stay in cardiology units are 1.3 days for electrophysiology studies, 1.8 days for radiofrequency ablation, 4.5 days for insertion **of** anti-tachyarrhythmia devices and 1.9 days for insertion of permanent pacemakers.[3] Cardiac surgery units report an average stay of 2.6 days for insertion **of** a pacemaker.

An average of 4.5 staff are present in the operating room of a cardiac surgery unit when a pacemaker is being inserted. Staff include an average **of** 0.9 surgeons, 0.7 registrars, surgical assistants or surgical technicians, an anaesthetist, anaesthetic assistant or anaesthetic technician, and 1.7 nurses or nurse assistants.

Hospital morbidity databases provide another source of information **on** length of hospital stays associated with electrophysiology procedures. These data record the average length of stay for electrophysiology studies and cardiac mapping to be 5.6 days. For 19% of these admissions, cardiac surgery or an interventional cardiology procedure is also performed; the average stay for the remainder is **4.3** days. For implantation of a defibrillator the average stay is 19.1 days. Average stays are 6.9 days for insertion of temporary or permanent pacemakers, and **4.5** days for radiofrequency catheter ablation. Some centres now undertake pacemaker and electrophysiology procedures (including catheter ablation) as day case procedures.

3.7.2 Staff requirements

An electrophysiologist is a trained cardiologist with specialised expertise and training in electrophysiology techniques. A cardiology department providing electrophysiology services requires at least one and preferably **two** fully trained electrophysiologists. For pacemaker implantation, usually performed in the cardiac catheterisation laboratory, the operator should be assisted by a cardiac technician and a nurse. Radiofrequency catheter ablation requires an electrophysiologist, a cardiac technician and at least **two** nurses. It would be desirable for the operator to have an assistant. *All* staff involved in electrophysiology procedures must have appropriate training and qualifications. At present there are **no** Australian regulations **on** qualifications required for electrophysiology. It is suggested **an** electrophysiologist should have at least one year's training in electrophysiology in addition to the full training required for cardiology. The training should cover pacemakers and defibrillators, and should include participation in **30** catheter ablation procedures.

Defibrillator implantation requiting open chest surgery is performed in a cardiac surgery operating theatre. A cardiac surgeon, an electrophysiologist, an anaesthetist, and at least **two** nurses should be present. In addition, specialised technical staff provided by the manufacturer (usually **two** people) need to be present. It is not feasible for hospitals to employ these people because of the small defibrillator caseload. For defibrillator implantation using transvenous leads, operating theatres tend to be used, with a surgeon present because there could be a need to switch to epicardial implantation. In the future this procedure is likely to be performed more commonly in the cardiac catheterisation laboratory, with staff requirements as for pacemaker implantation, plus the manufacturer's technical staff

3.7.3 Bed requirements

Average bed day requirements are 1–2 days for electrophysiology studies, pacemaker insertion and radiofrequency ablation, five days for anti-tachyarrhythmia device insertion, and **6–7** days for implantable defibrillator insertion. In some centres approximately 50% of pacemaker insertions and **70%** of radiofrequency ablations are day cases.

After insertion of an implantable defibrillator, approximately one day in cardiac intensive care and **two** in a telemetry bed **will** be needed. Cardiac intensive care and telemetry beds **will** not normally be needed following insertion of a pacemaker.

An annual caseload **of** 50 pacemaker insertions **will** add an average **of 0.2** beds to the general ward bed requirements of a cardiac surgery or cardiology unit, whereas 150 pacemaker insertions **will** add **an** average of 0.6 beds to a unit's requirements.

Electrophysiology studies will have a similar impact on bed requirements. Neither type of procedure will have a significant impact on cardiac intensive care or telemetry beds. A cardiology unit performing 50 radiofrequency ablations each year can expect an additional 0.2 telemetry and general beds to be needed.

3.7.4 Equipment requirements

Ideally the electrophysiology laboratory would be separate from the conventional cardiac catheterisation laboratory, but separate facilities are usually impractical in the Australian context. In some hospitals an older laboratory is used for electrophysiology after a new one is commissioned for cardiac catheterisation.

Electrophysiology procedures require permanently installed standard fluoroscopy equipment with a C-arm, programmable stimulators for generating electrical impulses, and dedicated computerised equipment for recording, storing, and analysing stimuli delivery and electrocardiography (ECG) data. Capacity to monitor haemodynamic data is desirable but not usually essential. A radiofrequency energy generator meeting electrical safety standards is required for radiofrequency catheter ablation.

A defibrillator should be available, together with full facilities for resuscitation, including drugs and respiratory therapy equipment. Pulse oximetry should be available. *All* equipment should meet electrical safety standards. For defibrillator implantation, electrophysiologic equipment is transported to the operating theatre. Emergency equipment must be available.

3.7.5 Supporting services and departments

Electrophysiology services in general require the same supporting services as interventional cardiology, including access to emergency cardiac surgery.

3.8 Conclusions

While some pacemaker insertion is performed by cardiac surgery units, most electrophysiology services are provided by cardiology units. With the exception of radiofrequency catheter ablation, electrophysiology services can be expected to continue to have a similar impact on the resources of units relative to other services over the next few years. Radiofrequency catheter ablation has the potential to have a greater impact, but the magnitude of this cannot be determined at present. While the caseload for defibrillator implantation will remain relatively small, it is growing and the high unit cost of this technology will place increasing demands on hospital budgets.

Electrophysiology has specific resource requirements that differ from those of interventional cardiology, including qulified electrophysiologists and specialised testing and monitoring equipment.

Given the highly specialised expertise required for electrophysiology other than pacemaker services, a concentration of services is needed to ensure optimum quality of care and the most cost effective use of facilities.

3.9 Recommendations — adult electrophysiology

- *Pacemaker implantation should be performed either by an electrophysiologist or by a cardiologist or cardiac surgeon who is able to maintain a caseload of at least 40 implantations a year.* ....(Section **3.4)**
- *Radiofrequency catheter ablation should only be performed by electrophysiologists. A caseload of at least 50 a year is required to 'maintain skills.* ....(Section **3.4)**
- *Cardiology units providing electrophysiology services should make adequate provision for the specific resource requirements of these services, in particular the different staff and equipment requirements, to ensure optimum quality of care and cost effectiveness.* ....(Section **3,8)**

4 Paediatric cardiac services

4.1 Current technology and projected developments

The term 'paediatric services' refers to the management of children up to the age of 15 years, but the division between paediatric and adult services is not clear-cut. In the case of paediatric cardiac services, where ongoing management is often required, a paediatric specialist may continue to manage a patient up to the age of 18 or beyond.

The great majority of children requiring cardiac interventions have congenital heart disease. Some congenital conditions are abnormalities of the heart itself or of the heart valves, while others are defects of the great vessels, such as the aorta and the pulmonary artery. In many cases they are combinations of defects. Table 19 lists the most common congenital conditions occurring in Australia and the percentage of children with each condition. In addition to congenital conditions, there are occasional cases of acquired heart disease such as valvular disease resulting from rheumatic fever, cardiac tumour or trauma.

Most children with congenital heart defects are treated by open surgery, usually in infancy or early childhood. Some conditions can now be treated using interventional cardiology techniques. Rarely, children may suffer from arrhythmias and require electrophysiology services.

4.1.1 Paediatric cardiac surgery

Paediatric cardiac surgery covers a wide range of procedures with varying complexity. For the purposes of this study, these have been grouped into three categories:

- Simple procedures — are well established and do not require outstanding expertise in cardiac surgery. Some are closed heart procedures that do not require cardiopulmonary bypass. Examples include closure of a patent ductus arteriosus (a closed heart operation) and closure of an atrial defect (open heart).
- Major procedures — are well established and performed relatively often, but substantially more difficult than routine procedures. Examples include repair of a ventricular septal defect and of tetralogy of Fallot.
- Complex procedures–involve rarer' and particularly difficult cases. Examples include combined atrial and arterial switch repair, and repair of Ebstein's anomaly.

In recent years a trend towards undertaking definitive treatment of defects at a younger age has emerged. As a result, it can be expected that in the future there will be fewer two-stage procedures in which a palliative intervention is later followed by a curative intervention.

Table 19: *Congenital heart conditions, Australia 1991*

Condition	Cases with condition: Number	Cases with condition: Per cent[(a)]	Treatment type[(b)]
Ventricular septal defect	416	35.4	Major surgery
Patent ductus arteriosus	216	18.4	Simple surgery or interventional cardiology
Atrial septal defect ostium secundum type	127	10.8	Simple surgery or interventional cardiology
Pulmonary valve malformations	113	9.6	Major surgery or interventional cardiology
Transposition of great arteries	88	7.5	Major surgery
Hypoplastic left heart syndrome	72	6.1	Complex surgery
Tetralogy of Fallot	62	5.3	Major surgery
Coarctation of aorta	62	5.3	Simple surgery
Endocardial cushion defect	52	4.4	Major surgery
Great vein malformations	48	4.1	Major surgery
Tricuspid valve atresia or stenosis	39	3.3	Major surgery
Aortic valve stenosis or insufficiency	35	3.0	Major surgery or interventional cardiology
Other aorta malformations	29	2.5	Major surgery
Pulmonary artery malformations	26	2.2	Major or complex surgery
Mitral valve stenosis or insufficiency	20	1.7	Major surgery or interventional cardiology
Common (double inlet) ventricle	19	1.6	Complex surgery
Ebstein's anomaly	12	1.0	Complex surgery
Common truncus (truncus arteriosus)	4	0.3	Major surgery
Other	57	4.9	Major or complex surgery

(a) Percentages add up to more than 100% because many children have more than one condition. The relative incidence of different lesions listed above does not correlate with that of corresponding procedures (Table 21). This may be due to differences in classification *of* disorders with multiple lesions, as well as the contributions of staged operations and procedures on overseas cases.

(b) Treatment type categories are intended to give an indication only of degree of difficulty and may vary from case to case. Where two or more conditions occur together, the surgical degree of difficulty will increase.

Sources: AIHW National Perinatal Statistics Unit[67]; treatment categorisation based principally on information from Royal Children's Hospital, Melbourne.

4.1.2 Paediatric interventional cardiology

Catheter-based techniques can now be used for the treatment of congenital heart defects. The following is a list of paediatric interventional cardiology procedures.

Dilation procedures:

- **dilation of valves—most frequently the pulmonary valve, sometimes the aortic valve, and very occasionally the mitral valve (mitral valve stenosis is usually associated with other problems requiring surgery);**

- dilation of recoarctation of aorta;
- dilation of pulmonary artery stenosis; and
- dilation of intracardiac stenosis (non-valvular).

Creation of communication:

- balloon septostomy (palliative procedure to allow oxygenation of tissues in the condition 'transposition of the great arteries' — surgery likely to follow after about a week).

Closure of communication:

- embolisation **of** aorta-pulmonary collaterals;
- transvascular closure of patent ductus arteriosus;
- closure of atrial and ventricular septal defects; and
- closure of residual systemic to pulmonary artery shunts or intracardiac communications after complex surgical procedures.

Balloon valvuloplasty for dilation of pulmonary valve stenosis is the most common paediatric interventional cardiology procedure and the treatment of choice for this condition. It can allow postponement of surgical valve replacement for decades. It replaces major surgery with bypass, providing the benefits **of** reduced morbidity and shorter hospital stays. Australian Health Technology Advisory Committee (AHTAC) has been advised that valve replacement **will** be required for few if any of these patients, and that the incidence and severity of pulmonary incompetence with this procedure is much lower than that in patients who have undergone surgical valvotomy (**Dr G** Sholler, Royal Alexandra Children's Hospital, Sydney, pers. comm.).

Treatment of recoarctation of the aorta also replaces major surgery, reducing morbidity and hospital stays, but not all cardiologists would agree that it is the best treatment. Balloon septostomy is a well-established procedure. Associated with a trend towards earlier surgery, there is a trend towards performing septostomy in newborn intensive care units under echocardiographic control, rather than in the cardiac catheterisation laboratory.

The place of the other interventional cardiology procedures in patient management is not yet clear. In these cases, results may be poorer than for surgery or there are significant risks, while surgery is likely to be highly effective. In the case of treatment **of** patent ductus arteriosus, the interventional cardiology procedure is not always applicable, has a risk **of** residual leak, and has to compete with a simple, low **risk**, closed heart operation. In the case of atrial septal defect, the interventional cardiology procedure involves insertion of a metal device which increases the risk of thrombosis. In general, interventional cardiology techniques for the closure of septal defects are **still** under investigation.

New techniques that **will** increase the appeal of catheter-based procedures may be developed over the next ten years but their role is likely to remain very limited at least in the medium term.

4.1.3 Paediatric cardiac electrophysiology

Arrhythmias requiring intervention occur rarely in children but there is a small caseload needing treatment. The following conditions are treated:

- ***Supraventricular tachyarrhythmias*** are treated conservatively in children, as the spontaneous resolution rate is high. If medication fails completely, radiofrequency catheter ablation is considered. It is done at the same time as electrophysiology testing. With children, diagnostic procedures are not performed alone. Radiofrequency catheter ablation is performed under general anaesthesia and involves exposing the child to ionising radiation for **40–70** minutes.
- ***Refractory ventricular tachycardia*** occurs occasionally in children, for example as a side effect of cardiac surgery. It can be treated by defibrillator implantation if the child is old enough.
- ***Atrial flutter*** can occur particularly after repair **of** complex heart disease. It can be treated by radiofrequency catheter ablation.
- ***Refractory atrial fibrillation*** can be treated by using radiofrequency catheter ablation to burn the bundle of His, and implanting a permanent pacemaker. This is however a treatment of last resort.
- ***Bradycardias*** are treated with permanent pacemakers. If the child is under 12 kg, epicardial leads are used. If the child is over 12 kg, transvenous leads are used.

Open heart electrophysiology surgery is not commonly performed **on** children.

4.2 Projected national caseload

The incidence **of** congenital heart disease is not expected to change greatly over the next decade other than with changes in birth rates during this time. Table 20 provides estimates of the incidence of different congenital heart conditions for 1996 and 2001.

Paediatric cardiac surgery is a complex area that can be classified in different ways. Table 21 summarises caseload levels by type of condition. In 1992, 90 paediatric cardiac surgery procedures were performed per **million** population. In the AHTAC survey, respondents were asked to provide information by complexity; it indicates that the national caseload comprises 26% simple, 52% **major** and 22% complex procedures.[3]

Future national caseloads for paediatric cardiac interventions can in general be expected to reflect changes in incidence and have been estimated **on** the basis of age-related changes in the population (Table 22). **An** estimated 100 procedures will be performed per **million** population in 2001.

The impact of changes in technology to 2001 is not likely to be large. On this basis the expected caseload for paediatric interventional cardiology should remain small.

Approximately 5% of paediatric cardiac cases are overseas patients. Caseload estimates assume that a similar proportion of the national caseload will continue **to** come from overseas in the next few years.

Table 20: *Estimated incidence of congenital heart conditions by year, Australia*[(a)]

Condition	1991	1996	2001
Ventricular septal defect	416	462	470
Patent ductus arteriosus	216	230	235
Atrial septal defect (ostium secundum type)	127	146	150
Pulmonary valve malformations	113	125	125
Transposition of great vessels	88	98	100
Hypoplastic left heart syndrome	72	63	65
Tetralogy of Fallot	62	56	60
Coarctation of aorta	62	84	85
Endocardial cushion defect	52	62	65
Great vein malformations	48	48	50
Tricuspid valve atresia or stenosis	39	44	45
Aortic valve stenosis or insufficiency	35	40	40
Other aorta malformations	29	39	40
Pulmonary artery malformations	26	30	30
Mitral valve stenosis or insufficiency	20	24	25
Common ventricle	19	18	20
Ebstein's anomaly	12	10	10
Common truncus	4	15	15
Other	57	79	80
Total	**1497**	**1673**	**1710**

(a) Estimated using **ABS** age-sex population projections applied to the rates of congenital malformations reported for 1989 to 1991.[67,68]

Table 21: *Existing paediatric cardiac surgery caseload by year, Australia*

Type of procedure	1984	1985	1986	1987	1988	1989	1990	1991	1992
Patent ductus arteriosus	224	165	162	196	195	228	164	165	127
Valve defects	108	110	68	66	67	51	72	81	60
Aortic coarctation	138	135	142	162	99	126	103	109	102
Atrial septal defect	173	179	201	209	266	232	245	249	265
Ventricular septal defect	232	213	209	257	234	218	231	252	254
Tetralogy of Fallot	146	141	116	169	156	140	116	144	169
Transposition of great vessels	80	113	91	104	123	98	108	108	93
Other conditions	256	320	367	386	385	472	455	496	549
Total	**1357**	**1376**	**1356**	**1549**	**1525**	**1565**	**1494**	**1604**	**1619**

Source: NHF[5]

Table 22: ***Estimated Australian caseloads for paediatric cardiac interventions by year(a)***

	Cardiac surgery			Interventional	
Year	Simple	Major	Complex	cardiology	Total
1992	425	841	353	~200	1819
1996	436	866	364	~200	1866
2001	464	920	387	~200	1971

(a) Estimates of cardiac surgery caseloads were derived as follows: hospital morbidity data provided sex-age breakdowns of Australian paediatric cardiac surgery caseloads. These were applied to total caseloads as reported by the NHF.[5] Rates per population were obtained from ABS series C population data, and ABS population projections used to obtain estimates for 1996 and 2001.[68,69] Survey data was used to split surgery into simple, major and complex procedures. Interventional cardiology caseloads are not available from any data source and were estimated on the basis of information provided by Dr G Sholler (Royal Alexandra Children's Hospital, Sydney) and Dr J Wilkinson (Royal Children's Hospital, Melbourne).

4.3 Outcomes and quality of care

4.3.1 Outcomes of paediatric cardiac surgery in Australia

Mortality is the only outcome measure for paediatric cardiac surgery for which data are routinely collected in Australia. In 1992, there were a total of 1619 paediatric cardiac surgery procedures in Australia, and the overall mortality was 3.9%. In calculations based on the data that could be separated into simple and major or complex categories, the mortality rate for simple procedures was 1% and for major or complex procedures *6%.*

The NHF has categorised caseload and mortality data in terms of the age of the patient and whether the procedure was a closed (no bypass) or open operation (requiring bypass). The mortality rates in each of these categories are given in Table 23.

Table 23: ***Mortality rates for congenital heart disease cardiac surgey procedures, Australia 1991 and 1992***

	Mortality rate (%)	
Procedure and age	1991	1992
Closed procedure		
under one month	1.7	7.9
1–6 months	2.1	6.4
more than 6 months	3.3	1.5
Total	**2.6**	**4.7**
Open procedure		
under one month	7.9	9.3
1–6 months	4.9	3.7
more than 6 months	2.4	2.7
Total	**3.3**	**3.6**
Total	**3.06**	**3.89**

Source: NHF[5]

4.3.2 Outcomes of paediatric interventional cardiology and electrophysiology in Australia

Australian data **on** the outcomes of routine paediatric interventional cardiology and electrophysiology are not yet available, but the National Heart Foundation (NHF) is now collecting data for both adult and paediatric balloon valvuloplasty. Advice from service providers is that mortality and morbidity are low. However, the procedures involve exposure of the child to ionising radiation for periods of 40–70 minutes.

In an American study comparing outcomes and costs of transcatheter and surgical closure of patent ductus arteriosus, the transcatheter was successful in 77% of cases compared to 100% **of** cases with surgery. There were major complications in 2.7% of transcatheter cases compared with 0.2% of surgical cases.[70] A comparison of results for balloon dilation and surgical treatment of aortic coarctation gave better results for the surgical procedure.[71]

4.3.3 Factors affecting outcomes

No broad studies of the factors affecting outcomes of paediatric cardiac interventions have been identified. The Australian mortality data demonstrate that the complexity of the procedure required and patient age affect mortality, and an Australian study has shown that birth weight below 2000 grams is a major risk factor.[72]

Casemix may be an important factor affecting the outcomes of a unit. In a study of the outcomes of paediatric intensive care in the United States, it was found that differences in mortality rates observed among nine paediatric cardiac intensive care units could be explained by differences in severity of illness.[73]

As observed in adult cardiac surgery, it would be expected that quality of care would affect outcomes, and that unit and operator caseload would affect quality of care.

4.4 Unit and operator caseload

4.4.1 Paediatric cardiac surgery

Of six paediatric cardiac surgery units identified in Australia, five responded to the AHTAC survey. The average caseload **of** the five units was 305.[3] For the units with caseloads below the average, 36% **of** their total caseload comprised simple procedures and 11% were complex. For the units with caseloads above the average, 24% of their total caseload comprised simple procedures and 24% were complex. In the smallest unit, most cases were simple and there were **no** complex cases. It has not been possible to calculate an average caseload per surgeon in Australia.

The 1983 guidelines for cardiac surgery in Australia recommended that the minimum caseload for a paediatric cardiac surgeon should be 100 cases a year unless it is mixed with an adult caseload.[2] The guidelines made **no** recommendations **on** unit caseloads.

The Health Council of the Netherlands recently published guidelines **on** heart surgery and interventional cardiology for children.[74] The guidelines emphasised that heart surgery for congenital disease was essentially different from surgery for acquired conditions. The guidelines recommended that a paediatric cardiac surgeon should have a minimum annual caseload of 100 procedures to correct congenital defects (in children or adults), to maintain skills in this area.

The Dutch guidelines also recommended that a paediatric cardiac surgery unit should have at least **two** paediatric cardiac surgeons.[74] This implies a minimum caseload of 200 a unit. In the Netherlands, there were nine paediatric cardiac surgery units. It was recommended that the number be reduced to three.[74] In Australia, at least one unit, and probably **two,** would not meet the standards set by the Dutch guidelines.

While the Dutch recommendations are reasonable, their appropriateness in Australia needs to be viewed in the light **of** the problems of Australian distances. The minimum number of procedures required to maintain **skills** in simple procedures for congenital conditions may well be lower if other heart surgery is undertaken, perhaps around one procedure a week. Nevertheless, small units performing primarily simple procedures should be supported only if they can demonstrate that they achieve acceptable outcomes. In addition it is difficult to justify two units in one city if one of these has a caseload below 200 a year.

Maintenance of skills **is** not just a matter for the surgeon. Caseload levels will also affect the **skills** of paediatric cardiologists, intensivists, and other specialised staff, as well as team efficiency. A minimum caseload of 200 a year would be desirable to ensure an acceptable level of skill for the unit as a whole.

4.4.2 Paediatric interventional cardiology

Paediatric interventional cardiology is available in six Australian hospitals, all with paediatric cardiac surgery units. The total Australian caseload is at present very small (about 200 a year). The caseload per unit ranges from 10 to about 100 procedures a year. (These figures exclude myocardial biopsies).

The Dutch guidelines **on** heart surgery and interventional cardiology for children has recommended that a paediatric interventional cardiologist should perform or be involved in **75** diagnostic cardiac catheterisations a year as well as a number of therapeutic procedures.[74]

The AHTAC notes that in adult interventional cardiology a minimum of 75 coronary angioplasties a year are considered necessary to maintain **skills,** in addition to a diagnostic workload (Section 2.4.2). Maintaining **skills** in several paediatric interventional cardiology procedures, each performed in very small numbers presents a major challenge. A high diagnostic workload would be essential. However, the paediatric cardiac catheterisation caseload has declined with the availability of high quality echocardiography, which has become the primary paediatric diagnostic procedure.

Optimally, a paediatric interventional cardiologist would perform at least 25 interventional procedures a year and have a diagnostic cardiac catheterisation caseload well in excess of **75** a year.

4.4.3 Paediatric cardiac electrophysiology

A cardiac electrophysiologist would need to undertake adult as well as paediatric procedures in order to have a sufficient caseload to maintain **skills.** The minimum caseload required would be one a week for radiofrequency catheter ablation, and one a week for pacemakers. In addition some experience with defibrillators would be desirable.

4.5 Distribution of services

Table 24 **gives** the location of paediatric cardiac services in Australia. **All** are in public hospitals. Only New South Wales, Victoria and Queensland have the full range of services including complex surgery. Units in South Australia and Western Australia undertake simple and some major surgical procedures. There are **no** services in Tasmania, the Australian Capital Territory or the Northern Territory.

There is a need for arrangements to ensure equitable access to the full range of services for all Australians. Mechanisms need to be in place ***so*** that patients from other States or Territories can be referred to paediatric cardiac services. Similarly, within a State, referral and access mechanisms should allow patients **from** other hospitals or remote **from** a paediatric cardiac service to obtain appropriate services.

Table 24: ***Distribution of paediatric cardiac services, Australia 1994***

Location	Surgery	Interventional cardiology	Electrophysiology
Sydney	2	2	1
Melbourne	1	1	1
Brisbane	1	1	1
Perth	1	1	1
Adelaide	1	1	1(a)
Total	**6**	**6**	***5***

(a) Service provided for older children only.

Source: Compiled by the working party from available data.

4.6 Organisation of services

4.6.1 Medical and administrative direction

A paediatric cardiac surgery unit should be under the direction of a paediatric cardiac surgeon. Paediatric interventional cardiology and paediatric electrophysiology services should be provided by cardiology departments with a **high** level of expertise in paediatric cardiology. For both paediatric surgery and cardiology, **links** should be in place with adult services to ensure continuity of care from childhood through adolescence to adulthood.

4.6.2 Coordination with other hospitals

For the optimal management of patients transferred from another hospital in the same or another State, a high level of interhospital coordination is necessary. Matters requiting coordination include the following:

- timing of the transfer, to ensure dovetailing of the child's arrival and the scheduling of the procedure, availability of a bed and support services, availability of accommodation for the accompanying adult;
- transfer of medical records and diagnostic images; and
- mechanisms for exchange of information after transfer back to the 'home' hospital, to reduce the need for further visits to the operating hospital during follow-up.

There is a need for agreements **on** interstate charging by State health authorities.

4.7 Resource requirements

4.7.1 Survey results and hospital morbidity data

The **AHTAC** survey specifically addressed resource usage by existing paediatric cardiac units to determine current practice in Australia.[3] The survey found that, while larger units were more likely to have their **own** beds, the number of beds a unit has does not appear to correlate with caseload. Average lengths of stay are 6.5 days for simple procedures, 11.7 days for major procedures, and 25.3 days for complex procedures.

Average nurse–patient ratios were **1:1.1** for cardiac intensive care beds, 1:2 for step-down beds and **1:4** for general beds. Eight to ten staff were reported to be present during procedures, with an average of two more staff members present during complex procedures than during simple procedures. There was considerable variation in the types and number of ancillary staff specifically employed by units, with cardiologists, administrative staff and cardiac technicians most commonly employed.

Most larger paediatric cardiac surgery units use left ventricular or biventricular assist devices in an average of **1.9%** of cases. Extracorporeal membrane oxygenation **(ECMO)** and transoesophageal echocardiography are used less commonly, with only two units using them in less than **1%** of surgical cases.

From the hospital morbidity data, the average length **of** stay for seven of the major paediatric cardiac procedures (for example procedures for transposition **of** great vessels, patent ductus arteriosus, coarctation **of** aorta, tetralogy of Fallot, septal and valve defects) is 12.5 days.

4.7.2 Resource requirements for paediatric cardiac surgery

Staff requirements

A paediatric cardiac surgery unit requires **24** hour coverage with adequate staffing at all levels. Qualified medical, surgical, anaesthetic, nursing and technical area staff with appropriate **skills** in paediatric care should be available for emergency duty at all times. *All* staff must have appropriate qualifications and training. **It** is the responsibility of the professional colleges and other appropriate bodies to determine the appropriate training and qualifications for paediatric cardiac surgeons, anaesthetists, perfusionists, nurses and other staff involved in paediatric cardiac surgery.

A unit providing the full range of surgery should have a minimum of **two** qualified full-time paediatric cardiac surgeons. The ratio of patients to surgeons should be such that each surgeon is actively involved in surgery at least three days a week. In addition at least two surgical registrars should be available.

Children, particularly newborns and other infants, need highly specialised expertise in all areas of care, not just surgery. At least two paediatric cardiologists (three in larger units) should be available to the unit for diagnosis and medical therapy, and the services of at least one paediatric intensivists would be required. Anaesthetists need to have training in the needs of paediatric cardiac surgery, and nursing staff need to have specific paediatric training, particularly in intensive care.

The staff required in the operating theatre during a procedure are:

- one paediatric surgeon;
- one and possibly two other surgeons or surgical assistants;
- possibly one surgical or cardiac technician;
- two anaesthetists or an anaesthetist with an assistant;
- one or two perfusionists; and
- two or three nurses (should be capable of cardiac resuscitation).

In post-operative intensive care, a nurse–patient ratio of 1:1 is recommended during the **first** 24–48 hours. A nursepatient ratio of 1:2 is recommended subsequently, in high dependency care. Well qualified senior nurses are required in the step-down and general wards as well as the intensive care ward.

Paediatric cardiac surgery units will also require the services of a physiotherapist. Counselling support will be necessary for consumers' families. Clerical and administrative support is needed.

Bed requirements

Bed usage for paediatric cardiac surgery patients varies depending **on** the complexity of surgery. Total bed usage can be expected to be **6–8** days for simple procedures, 12 days for major procedures and 20–30 days for complex procedures. Patients can be expected to be in a cardiac intensive care bed for about one day following a simple procedure, three days following a major procedure and six days following a complex procedure. Corresponding stays in step-down beds are **two,** four and eight days.

For a unit performing 300 procedures annually with half being major procedures, one quarter simple and one quarter complex procedures, an average of 12–13 paediatric beds are needed, of which three should be cardiac intensive care beds and four step-down beds. Sufficient capacity needs to be available to cope with fluctuations in requirements.

Equipment requirements

Major items of equipment needed by paediatric cardiac surgery operating theatres include:

- extracorporeal bypass machine and related equipment;
- anaesthetic machine and monitoring equipment;
- electrocardiography (ECG) monitors;
- intra-aortic balloon pumps;

- four channel invasive haemodynamic monitoring (Swan-Ganz, **PAP, PCWP,** atrial, central venous pressure);
- defibrillators;
- ventricular assist device; and
- pacemakers, cell saver, diathermy machine, surgeon's head lights, operating table, instrument trolley, instruments and infusion pumps.

In the intensive care ward, each bed requires cardiac monitors with full **ECG** and full intravascular monitoring and ventilators. Haemoglobin saturation monitoring is also required. Other equipment which must be available in the ward include intravenous and syringe pumps, warming blankets, defibrillators, emergency pacing equipment and a sternotomy tray.

The step-down ward requires facilities for telemetry and central monitoring, a sternotomy tray, emergency pacing equipment, a defibrillator, infusion **pumps** and haemoglobin saturation monitors. **ECMO** should be available to the unit for emergency use.

Supporting services and departments

Accommodation for parents is an essential requirement. Others include a close working relationship with a cardiology department which has a cardiac catheterisation laboratory and echocardiography equipment. The hospital should have the standard services listed in Chapter 1 **on** adult cardiac surgery.

Summary of resource requirements for paediatric cardiac surgery

Table **25** summarises the principal resource requirements for a paediatric cardiac surgery unit undertaking the full range of procedures.

Table *25:* ***Principal resource requirements for a full-sized paediatric cardiac surgery unit***

Resource	Level required
Staff requirements	
Paediatric cardiac surgeons	At least two fully qualified, full-time, at least two surgical registrars
Paediatric cardiologists	At least two
Paediatric intensivist	One
Anaesthetists	At least two with one to two registrars or assistants
Nurses	Nurse–patient ratios
intensive care	1:1
step-down	1:2
general	1:4
Bed requirements	12–13 for a unit performing 300 procedures/year, including three intensive care and four step-down

Source: Collated by the Working Party from the AHTAC survey[3] and State health authority hospital morbitity data

4.7.3 Resource requirements for paediatric interventional cardiology

Staff requirements

Paediatric interventional cardiology would be provided by a cardiology department that has specialised expertise in paediatric cardiology but is not necessarily exclusively paediatric. If caseload is large enough, it would be desirable to have **two** paediatric interventional cardiologists to ensure year round availability of the service. Where caseloads are too small to provide an adequate caseload for more than one paediatric interventional cardiologist, alternative arrangements should be in place to maintain availability **of** the service.

Support staff would be drawn from the general staff During **an** average procedure the following staff would be required:

- one interventional cardiologist;
- one senior assistant (a Fellow or another cardiologist);
- two nurses (should be capable **of** cardiac resuscitation);
- one anaesthetist or senior anaesthetic registrar (some procedures require sedation strong enough to warrant the presence of an anaesthetist);
- one cardiac technician; and
- one radiographer.

In some cases support would be needed from an additional cardiologist and assistant. For a particularly sick patient, special staff may be required. *All* staff must have appropriate training and qualifications. It is the responsibility of the professional colleges and other appropriate bodies to determine the appropriate qualifications for staff involved in paediatric interventional cardiology.

Bed requirements

Paediatric interventional cardiology patients would usually require 1–2 days in a telemetry or general bed after the procedure. Some cases would be critically ill patients who come from an intensive care unit and return there.

Equipment requirements

Equipment required is as given in chapter 2 **on** interventional cardiology, with the following additional requirements:

- the fluoroscopic imaging equipment must have a capacity for biplane imaging; and
- non-ionic contrast medium must be used in infants.

Supporting services

Paediatric interventional cardiology services should be provided in a hospital with a paediatric cardiac surgery unit, but it is not necessary to have a cardiac surgery team **on** standby. Other support services are as for adult interventional cardiology.

4.7.4 Resource requirements for paediatric electrophysiology

Staff requirements

A paediatric cardiac electrophysiology service requires a cardiologist with full training in electrophysiology. If procedures are performed for very small children, additional paediatric training is required or a paediatric cardiologist should be present.

The following staff would be required during a procedure:

- one cardiac electrophysiologist;
- one paediatric cardiologist if the patient is an infant or very young child;
- one anaesthetist;
- one nurse;
- one cardiac technician; and
- possibly one radiographer.

Bed requirements

As for adult patients, average bed day requirements would be **1–2** days for electrophysiology studies, pacemaker insertion and radiofrequency ablation, five days for anti-tachyarrhythmia device insertion, and **6–7** days for implantable defibrillator insertion.

After insertion of an implantable defibrillator, approximately one day in cardiac intensive care and two in a telemetry bed will be needed. Cardiac intensive care and telemetry beds will not normally be needed following insertion of a pacemaker.

Equipment requirements and supporting services

As noted for adult electrophysiology, these procedures require standard fluoroscopy equipment with a C-arm, programmable stimulators for generating electrical impulses, and dedicated computerised equipment for recording, storing, and analysing stimuli delivery and ECG data. A capacity to monitor haemodynamic data is desirable. A radiofrequency energy generator meeting electrical safety standards is required for radiofrequency catheter ablation.

A defibrillator should be available, together with full facilities for resuscitation, including drugs and respiratory therapy equipment. Pulse oximetry should be available. All equipment should meet electrical safety standards.

4.8 Conclusions

Future requirements in paediatric cardiac surgery and cardiology are expected to change in line with changes in the population. Current paediatric cardiac surgery services are likely to be adequate for the next few years, but equitable access of all Australians to these services should be established. There should be **no** further diffusion of paediatric interventional cardiology services.

4.9 Recommendations — paediatric cardiac services

- *There is a need for data collection and research on outcomes other than short-term mortality for paediatric cardiac interventions, including long-term outcomes, and the effects of quality of care on these.*..(Section **4.3.3**)

- **Paediatric cardiac surgery:**
  - *a paediatric cardiac surgery unit performing the full range of services should have a minimum caseload of 200 a year;*
  - *small paediatric cardiac surgery units should be supported only at centres remote from large units and only if outcomes are equivalent to those achieved in large units;*
  - *new paediatric cardiac surgery units should not be established nor existing ones upgraded unless it can be demonstrated that a caseload of at least 200 a year can be achieved; and*
  - *a paediatric cardiac surgeon should undertake a minimum of 100 procedures a year to correct congenital defects in adults or children, unless it can be shown that special circumstances, such as isolation and acceptable outcomes justify a lower rate.*...(Section **4.4.1**)

- **Paediatric interventional cardiology:**
  - *should only be performed at a hospital that can maintain a paediatric cardiac catheterisation caseload of more than 75 cases a year;*
  - *optimally, the minimum institutional caseload should be at least 25 interventional procedures a year with a diagnostic caseload of well over 75 a year; and*
  - *there should be no more than one centre for paediatric interventional cardiology in each mainland State capital city.*..........................(Section **4.4.2**)

- **Paediatric cardiac electrophysiology:**
  - *a cardiac electrophysiologist undertaking procedures in children should have a minimum caseload for adults and children of 50 a year for radiofrequency catheter ablation and 50 a year for implantation of pacemakers; and*
  - *implantation of defibrillators should not be undertaken without previous experience in adults.*..(Section **4.4.3**)

- *To ensure equitable access for all Australians to paediatric cardiac services, efficient arrangements for interstate and interhospital transfer should be maintained or put in place, specialised transport services should be available at no cost to the patients' families, and affordable accommodation and board should be available for at least one accompanying adult at or near the hospital to which the child is transferred.*...(Section **4.5**)

- *Paediatric cardiac services have specific requirements in terms of staff, beds, equipment and supporting services. Adequate provision of these requirements is necessary if patient safety and outcomes are not to be compromised Staff caring for these patients need appropriate skills in paediatric care in addition to the usual skills required for cardiac care.*...(Section **4.7**)

5 General issues

5.1 Cost issues

Economic evaluation of the treatment of ischaemic heart disease is complicated by the chronic nature of the disease. Long-term management involves medical treatment as well as coronary artery bypass grafting (CABG) and percutaneous transluminal coronary angioplasty (PTCA). The interventions are best regarded as complementary to each other, not as alternatives. Many patients may undergo both CABG and PTCA, perhaps more than once, and continue to take medication.

However, at any time during the course **of** a patient's clinical management, a choice may arise between angioplasty and CABG. This raises the question **of** what types of patient have a choice **of** treatment option and under what circumstances is one option more cost effective than the other.

Available data **on** economic evaluation are considered in Appendix **3.** There are **many** limitations to the data but, in summary, PTCA appears more cost effective than CABG for patients with less severe disease in the short term. The cost effectiveness of PTCA relative to that of CABG in the longer term, or in patients with more severe symptoms or disease is not **known.** Compared with competing uses of scarce health care resources, CABG is cost effective in patents with severe angina. However, the available evidence relates to patients who are generally younger than the patient groups in which cardiac surgery rates are increasing most rapidly. There is some evidence to suggest that cost effectiveness may be worse among such patients but the precise effect is not **known.**

5.2 Waiting list management

Some respondents to the Australian Health Technology Advisory Committee (AHTAC) survey3 commented that waiting lists are too **long,** but consistent waiting list data are not available **on** a national basis. The Australian Institute of Health and Welfare was funded to develop, with the Commonwealth and the States and Territories, nationally consistent and comparable waiting list data, and collect and publish these data **on** an annual basis. **An** interim report has been published, but contains data which are not complete or consistent across all States and Territories. The **first** national report, using nationally consistent data, is expected to be published in February **1995.** Some of the interim waiting list data, together with comments about its nature and problems, are presented in Appendix **4** but need to be used cautiously.

In view of the increasing caseload for PTCA and the potential impact of indications expanding to include acute myocardial infarction, collection of consistent national waiting list data for this procedure would be useful to ensure reasonable and equitable access of consumers.

5.3 Rehabilitation

5.3.1 Scope and effectiveness of cardiac rehabilitation

A comprehensive cardiac rehabilitation program should offer:

- early ambulation;
- psychosocial intervention (alleviation of anxiety, explanation, education and counselling);
- health education for cardiac care consumers and their relatives (including advice on lifestyle changes);
- fostering of peer support from consumers who have experienced cardiac intervention and rehabilitation (these should contribute to alleviation of anxiety and provide lifestyle advice);
- risk factor evaluation and counselling on modification;
- physical training in outpatient groups;
- post-discharge follow-up and support;
- vocational counselling;
- long-term community based programs;
- consumer-friendly information, including the availability of such information in languages other than English and the use of interpreters; and
- regular use of quality assurance measures designed from the perspective of the consumer.

While there is a lack of Australian data on the effectiveness of cardiac rehabilitation programs, some overseas evidence supports their benefits. For example, in a Swedish study, one group of consumers from a coronary care unit received a comprehensive rehabilitation program, while a similar group at a different hospital did not. After five years, the group receiving rehabilitation showed significantly fewer non-fatal myocardial infarctions, hospital re-admissions, sudden deaths, and overall deaths.[75] The rehabilitation program not only reduced risk factors and improved outcomes, but was also cost effective.[76] In a Finnish study, there were significantly fewer incidences of sudden death and coronary mortality in a group of individuals suffering myocardial infarction who underwent a comprehensive rehabilitation program than in the control group.[77]

The World Health Organization has recommended that rehabilitation care should be available to all persons with cardiovascular disease.[78] The National Medical Scientific and Education Advisory Committee of the National Heart Foundation (NHF) has stated that secondary prevention programs, including cardiac rehabilitation, should be available to all patients in Australia who have had acute myocardial infarction, coronary artery bypass grafts, PTCA or other cardiovascular disease. Unless contraindicated, these patients should be routinely referred to hospital or community-based outpatient programs. The NHF has published minimum standards for outpatient cardiac rehabilitation in Australia.[79]

5.3.2 Organisation of cardiac rehabilitation programs

A cardiac rehabilitation program in a major hospital should be under the direction of a cardiologist with experience in rehabilitative techniques, and be undertaken by a multidisciplinary team of health care professionals that includes registered nurses, a physiotherapist, a dietitian, an occupational therapist, a psychologist, a social worker, a program coordinator and administrative officers. The role of coordinating, managing and evaluating many cardiac rehabilitation and secondary prevention programs has been undertaken by critical care trained nurses who have the diversity of skills, knowledge and training these programs demand. At a smaller hospital, a minimum requirement would be the services of a physician and specifically trained registered nurses or other health professionals with expertise in exercise physiology, dietetics and other such health areas. Hospital programs should have links with external rehabilitation programs.

5.4 Access to services

5.4.1 Effect of geographic location

Cardiac care consumers in regional centres, rural areas and the Territories are disadvantaged by distances. In addition to travelling to a capital city for the operation itself, visits may need to be made for consultation and pre-operative tests, and for post-operative checks. As well as the cost of travel for the consumer, the cost of travel and accommodation for a spouse or other family member during the hospitalisation will need to be borne.

A study of CABG rates in New South Wales over the period 1983 to 1990–91 found that rural residents had fewer procedures per 1000 population than either residents in areas in which the procedure was available or metropolitan residents without a referral hospital in their area.[80] However, there was **no** evidence suggesting a lower disease burden in the rural population; the low rates of surgery were not associated with lower rates for heart disease hospitalisation or mortality.

As a means of improving access to cardiac interventions outside the capital cities, the establishment of more regional units might be considered. However, if a regional unit cannot maintain the quality of care provided in capital cities, cardiac care consumers **will** be at increased risk, while those who live at a distance from the regional centre **will still** be disadvantaged by the need to travel. The need for and the availability of essential back-up facilities must be taken into account, for example the need for back-up emergency cardiac surgery for PTCA.

5.4.2 Effect of age

CABG was once considered too risky for individuals over **70** but is **now** applied increasingly to older age groups. Figure 1 gives the age distribution of persons who underwent CABG in 1991–92 in Australia (excluding those treated in Queensland and in private hospitals in Victoria). **Most** consumers were in the 60–64 year and 65–69 year age groups, but **24%** were aged **70** or more. Women comprised **3**1% of the CABG caseload for those aged **70** or more, but only 20% of the CABG caseload for those aged under **70.** There were 109 consumers **of** 80 years or more.

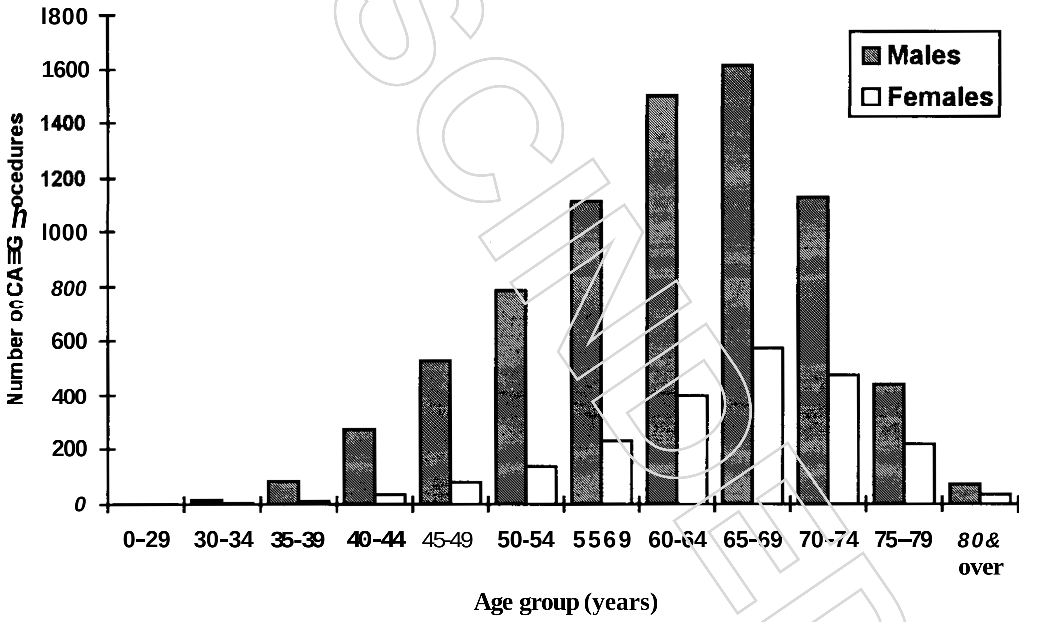
PTCA is a much less invasive procedure than CABG. It could be seen as particularly suitable for the treatment of older individuals who may be too frail for CABG, even if it could not achieve complete revascularisation. In fact, published results indicate that there is a significant mortality rate for older people who have this procedure, particularly for those over eighty.[81]

Age is not necessarily an indicator of clinical status.[82] It would be simplistic to suggest that there should be an upper age limit for cardiac **or** other major interventions. Decision making **on** intervention for an aged consumer would include assessment **of**

- the consumer's condition in relation to **known risk** factors for complications;
- whether quality of life gains as a result of the procedure would balance the potential **risks,** stress, morbidity and mortality associated with it;
- whether there are any co-existing conditions which would limit life expectancy;
- the consumer's **own** wishes in the light of a complete explanation of the **risks** and benefits, taking into account whether he/she has the mental capacity to appreciate these; and
- whether failure to perform an elective procedure would result **in** a high **risk** of an emergency procedure **or** additional long-term treatment.

Such considerations would, of course, apply to all consumers, not just older people.

Figure 1: ***Number of CABG procedures performed in 1991–92 for Australia by sex and age group(a)***



(a) Excludes all data for Queensland and private hospital data for Victoria.
Source: State health authorities hospital morbidity data.

5.4.3 Sex differences in coronary artery revascularisation

Studies of people with a clinical diagnosis of coronary artery disease, in which a substantial proportion of individuals have not yet had a coronary angiogram to confirm the diagnosis, have consistently found that a substantially higher proportion of men than women subsequently undergo CABG and/or PTCA.[83–87] On the other hand, studies of people with **angiographically-demonstrated** coronary artery lesions have consistently found **no** difference between men and women in their subsequent utilisation of CABG and/or PTCA.[88,89] There is also clear evidence that the difference between these two groups of studies is due to a substantially smaller proportion of women, whose symptoms and non-invasive tests suggest a diagnosis of coronary artery disease, having significant coronary artery lesions **on** their angiogram.[89-92] Associated with this, clinicians are less likely, prior to coronary angiography, to predict significant lesions in symptomatic **women**[92] and less likely to refer them for this test.[83,84,92]

Given that coronary angiography has a small but demonstrated risk of serious complications and that there is a greater likelihood that symptomatic women to be found to have coronary arteries that appear normal radiographically, a less frequent use of the test in women is appropriate. However, there is conflicting evidence in the medical literature as to whether clinicians have over-reacted in the extent to which they refer relatively fewer symptomatic women for coronary angiography than symptomatic men. For example, Tobin et al.[83] found that, even after adjusting for prognostic factors such as age and the presence of previous myocardial infarction, men with an abnormal radionuclide exercise test result were six times more likely to be referred for coronary angiography than women with an abnormal test. Consistent with this, Steingart et al.[88] found, in a group of men and women who had suffered a previous myocardial infarction, most men were twice as likely to have had a coronary angiogram as women prior to their myocardial infarction. This was despite women being just as likely as men to have had angina or antianginal drugs and women having more disabling symptoms than men, prior to their infarction. On the other hand, Mark et al.[92] found that correct pre-test predictions by clinicians of a lower probability of significant coronary artery lesions in women accounted entirely for their lower rate of coronary angiography.

The criteria that are used to identify persons in whom coronary angiography is appropriate are based **on** symptoms and non-invasive tests. The fundamental problem is that, while these criteria are good predictors in men, they are of limited usefulness in women. For example, a positive result from an exercise test, which is commonly used in helping to decide whether individuals should undergo coronary angiography, is a much less specific indicator of coronary artery disease in women. Sullivan et al.[89] found, in persons who had undergone coronary angiography, that the preceding exercise test had given positive results in **29%** of women with normal coronary arteries, compared with **7%** of men with normal coronary arteries.

Previous studies had shown that substantially fewer women with a positive result from an exercise test went **on** to have a coronary angiogram. For example, Tobin et al.[83] found that only **4%** of women with an abnormal radionuclide exercise scan were referred for coronary angiography, as compared with **40%** of men.

There may be an association between the limited value of existing criteria in determining the likelihood of coronary heart disease in women and the finding that women are referred for **CABG** at a later stage **of** the disease process when they are sicker, which results in higher operative mortality.[93] These findings are not surprising, given that coronary heart disease has been studied far more extensively in men.[94] Further studies are needed to determine sensitive methods for identifying those symptomatic women whose probability of significant coronary artery disease is **high** enough to justify them undergoing coronary angiography.

5.4.4 Effect of socioeconomic status, ethnicity and aboriginality

There has been little study of the effect of socioeconomic status **on** access to cardiac interventions in Australia, although a Western Australian study has found that the proportion of revascularisations performed for men in professional or administrative occupations was greater than would be expected from the corresponding proportion of myocardial infarctions.[95]

Studies in the United States have indicated differences in CABG rates by race, income and insurance status.[96,97] In the United States and Canada, ischaemic heart disease is most common in the lowest income groups, and in Canada, which has universal health insurance, those living in the poorest areas have higher rates of CABG. However, in New York and California, rates of CABG increase with the average income of the area of residence. The CABG rates in these higher income areas are much higher than the Canadian rates.[96]

A study of cardiac investigations and revascularisation in the South West Thames region of Britain showed considerable differences in the waiting times for angiography and revascularisation between the National Health Service and the private sector.[98] Long waiting times in the public sector constitute a barrier to access for lower income groups.

While there has been considerable work in Australia on the relationship between ethnicity or aboriginality and cardiovascular disease, there appear to have been little study of access to cardiac interventions for these groups

5.5 Recommendations — general issues

- *Collection of consistent and reliable waiting list information for invasive cardiac investigations and interventions should be added to the collection of waiting list information for elective surgery, with appropriate standard definitions being added to the National Health Data Dictionary*.................(Section 5.2; Appendix 4)
- *All hospitals with coronary care, cardiac surgery and cardiology units should have arrangements to ensure that cardiac rehabilitation programs are available to all cardiac care consumers. Inpatient and outpatient components of the programs should be integrated*..(Section 5.3.2)
- *Regional cardiac intervention units should not be established unless it is clear that they can maintain a quality of care similar to that provided in the capital cities. This will include the provision of back-up surgery for PTCA*.............(Section 5.4.1)
- *To ensure equitable access for all Australians to cardiac intervention services, arrangements for interhospital transfer and intra or interstate travel and accommodation for the cardiac care consumer and one significant relative should be maintained or put in place*. ....(Section 5.4.1)
- *Further research should be undertaken in Australia on the effects on access to cardiac interventions of geographical location, age, gender, socioeconomic status, ethnicity and aboriginality*...(Section 5.4)

Appendix 1

Methodology for projecting national caseloads for CABG and PTCA

Long-term trends in rates of coronary artery revascularisation procedures (CABG and PTCA) in Western Australia were examined in detail and used to project caseloads for these procedures to 2001.[99] As much of the data used in this process were not available for the other States and Territories, the specific age-sex rates of CABG and PTCA that were estimated for Western Australia were, together with Australian Bureau of Statistics **(ABS)** population data, used to estimate CABG and PTCA caseloads.[4] The resultant estimates for CABG caseloads are provided as the low estimates in Table 4. High estimates in Table 4 were obtained by adjusting the low estimates using 1991 NHF data.

The data did not allow accurate estimates of incidence rates **for** patients aged under 40. These were inferred **on** the assumption that the ratio of cases of myocardial revascularisation (CABG **or** PTCA) without a prior revascularisation procedure to new cases of symptomatic non-fatal coronary heart disease was the same **for this** age group as for those aged 40–49 years.

This method of estimation makes some assumptions **on** the incidence of coronary artery disease and its treatment. **First,** other States and Territories are assumed to have the same treatment rates as Western Australia. In fact, in 1991 there was considerable variation between States in rates **of** both CABG[5] and PTCA (NHF, pers. comm.). **For** CABG, the Western Australian rate is similar to the national rate, ***so*** that national estimates should be reasonably accurate in this regard, with individual State and Territory estimates less ***so.***

Second, it assumes that there is **no** change in the incidence of coronary artery disease within different age-sex groupings. However, significant changes in mortality from coronary heart disease have been noted as being associated with corresponding changes in animal fat consumption and smoking.[100,101] Programs aimed at modifying coronary heart disease risk factors through behaviour and lifestyle changes have the potential to decrease the incidence of coronary artery disease in the future. ***On*** the other hand, Martin and Henstridge found that the rate of men aged 55–64 years who were discharged from hospital with a diagnosis of myocardial infarction varied little in Western Australia in the five years between 1988 and 1992, and between States in 1991–92.[99]

Third, while changes in CABG rates in different age-sex groups were projected, **no** other changes in indications were allowed for. It would seem, however, that the most important change in the indications for CABG is an increased treatment rate in older persons. **For** example, the 7% increase in CABG procedures between 1983 and 1990–91 in New South Wales was **almost** entirely confined to individuals aged 65 and over.[80] In the future, an increased number of individuals aged 75 **or** over can be expected to undergo CABG **or** PTCA.

Recent information shows that the number of PTCA procedures performed in Western Australia in 1993–94 was 80% higher than that in 1991–92, while the projected increase in this period was only approximately 15%. Therefore, the number of procedures predicted in 2001, which was based on a deceleration in the rate of increase between 1986 and 1992, has already been reached, seven to eight years earlier. Reasons for the recent acceleration in the rate of increase in PTCA include:

- improvement in the quality and variety of equipment available;
- improvements in 'bail out' equipment and techniques;
- price reductions for some equipment;
- improved operator experience and training as a result of larger institutional volumes; and
- a broadening of indications, partly as a result of the factors mentioned above.

It seems likely that a comparable acceleration in the rate of increase is also occurring in other Australian States and Territories, and that predictions for 1996 and 2001, based on rates in Western Australian between 1986 and 1992, will be reached or even exceeded. Therefore, these estimates have been included as the low estimates in Table 11. In addition, the Western Australian low estimates were multiplied by a factor of 1.57 (that is the proportion of the actual increase in caseload to the projected increase in caseload for 1993–94) to compensate for the unexpectedly large increase in that State in the last two years. The factor of 1.57 was also used to calculate the high estimate for the other States and Territories which represents the likely number of procedures should their PTCA rates approach that in Western Australia.

The high estimate for Western Australia in 1996 is based on the crude rate of PTCA in the United States in 1990 (1205 per million). The high estimate in 2001 is based on the proportionate difference in the high and low estimates in 1996 being maintained. It should be noted that the United States has by far the highest rate of PTCA in the world.

NHF and survey data suggest that, between 1991 and 1992–93, PTCA rates in Queensland and South Australia increased less than in New South Wales, Victoria and Western Australia (where rates increased by 20% or more). A more precise comparison was not possible, however, because the coverage of the survey was incomplete.

Appendix 2

Effect of caseload on outcomes – appraisal of key papers

In **two** studies, Hartz et al.[8,29] were unable to find an association between complication rates and caseload for PTCA or CABG. However, there are a number of problems with the design of the studies. These are summarised below.

- Lack of statistical power due to small sample size. In one study, for example, there were only approximately 1600 coronary angioplasties and 1600 CABGs and those were performed in 19 hospitals over a 26-month period.[29]
- Possible selection bias because neither hospital included all institutions or proceduralists in a given area. One study used a group of hospitals from various States of the United States that used the MedisGroups method for monitoring quality of care and utilisation of resources.[8] The other used an approximately 70% sample (drawn non-randomly according to their Medicare hospital bills) of Medicare patients in Wisconsin.[29] Both studies excluded individuals with acute myocardial infarction and one study excluded those with cardiogenic shock,[29] resulting in the exclusion of 20% of cases in one study[29] and an unspecified number in the other.[8]
- A lack of inclusion of medium to high volume institutions. In one study, 25 out of 29 institutions performed less than 200 coronary angioplasties a year (maximum 430), and 23 out of 28 institutions performed less than 400 CABGs a year (maximum 511).[8] In the other study, the annual institutional volumes were even lower.[29]
- Absence of important variables. Neither study included information **on** the type of lesion **on** which PTCA was attempted. The larger study did not include information on proceduralist or surgeon volume.[8]
- Possible bias due to missing or poor quality data. One study did not seem to have a system for checking and updating missing or inconsistent data. For example, data **on** ejection fraction in 45% of cases of PTCA and 29% of cases of CABG was lacking.[29] The other study did not discuss data quality at all.[8]

In contrast, studies by Hannan et al.[11,55] are probably the most rigorous yet reported in this area. Hannan et al. have shown a clear relationship between the outcome of CABG and hospital and surgeon volume.[11] They reported data **on** risk factors in 5827 persons undergoing PTCA in the first half of 1991, and the impact of institutional and operator volumes will be the subject of a further report when more data are available.[55] Relevant features of the studies by Hannan et al. are:

- large sample size. Their study of CABG outcome included 12 448 cases performed in 30 hospitals over a 23 month period;[11]
- inclusion of all revascularisation procedures performed in New York State;
- inclusion of an appreciable number of high volume institutions. Their study of CABG outcome included eight out of **30** institutions that performed more than 600 CABG procedures a year;[11]
- inclusion of most important variables. For example, their study of PTCA outcomes included worst lesion type attempted and number of vessels attempted, and these were found to be important predictors;[55] and

- a system for checking records **soon** after collection and updating missing **or** inconsistent data. ***Also,*** the coordinating centre conducted site visits to check the accuracy of recorded data.

A more recent study by **Jollis** et al. found that hospitals performing more **PTCA** procedures have lower rates of both short-term mortality and **CABG** after the procedure.[30] The positive features of the study are:

- large sample size. The study included **2** 17 **836** persons who underwent **PTCA** in **1194** hospitals in all parts of the United States over a four-year period;
- inclusion of many high volume institutions, for example, **128** hospitals that performed more than **400** to **800** procedures **in** 1990; and
- adjustment for age, sex, race and year of procedure.

Drawbacks of this study are:

- only includes United States Medicare beneficiaries aged over **64** years;
- **no** adjustment for clinical indicators of severity or individual proceduralist caseloads; and
- did not include repeated **PTCA** performed in the same hospitalisation.

Appendix 3

Economic evaluation of CABG and PTCA

The results of the most comprehensive economic evaluations of CABG and PTCA are summarised in Table **26. Most** of these studies compare CABG with PTCA in patients with mild disease.102-108 *All* conclude that PTCA is as effective as CABG and is cheaper than CABG up to one year post treatment even when the costs of surgery in patients whose angioplasty has failed to achieve patency are taken into account. The initial failure rate of angioplasty would need to exceed 60% before CABG became more cost effective.103

Two studies have compared CABG with medical treatment.[109,110] In each of these studies, health outcomes were measured in terms of quality-adjusted life years (QALYs). Each study reached similar conclusions. The cost per QALY gained as a result of CABG was lower among patients with more severe cardiac disease.110 In patients with mild angina, the additional cost per QALY from CABG was extremely sensitive to the assumptions made about the value of relieving symptoms.109

The additional cost per QALY gained from CABG was also lower than a range of other health care procedures suggesting that CABG represents an efficient use of health service resources.110 However, the methods used to weight quality of life in each of these studies was rather crude and, more generally, both the use of QALYs as a measure of health outcome and the construction of QALY league tables to prioritise spending decisions have been criticised.111,112

Each of these studies relied upon observational data and ***so*** some selection bias is unavoidable. **Most** of the studies involved patients with single-vessel disease, but even ***so,*** severity of disease as measured by the New York Heart Foundation score was generally higher in CABG patients. None of the studies made proper risk-adjusted comparisons.

Other factors also limit the usefulness of this evidence. First, the average age of patients treated in the studies lies between 55 and 60 years yet surgical intervention rates are increasing most rapidly among those aged over 65.113 It might be expected that cost effectiveness in such patients will be worse than the average results suggested in studies to date, as both lengths of stay (costs) and mortality rates are higher in elderly patients.7,12,13

Second, cost estimates are typically based **on** hospital charges rather than real resource use and the savings realised as a result of switching from CABG to PTCA are much lower than the difference in reported charges.106

Third, follow up is restricted to, at most, one year post-treatment. This is important given the different time profile of costs and benefits of the two procedures. CABG is initially more expensive than PTCA but the difference in cost is likely to decrease the longer the period of follow up as the costs of repeat procedures are included. The rate at which symptoms return is also lower with CABG than with PTCA.106 The cost effectiveness of CABG relative to PTCA therefore improves over time until a repeat CABG is necessary.

Fourth, the evaluations tend to focus **on** single-vessel disease where the current consensus favours PTCA. **NHF** data show that **91%** of coronary angioplasties are performed for patients with single-vessel di~ease.53 However, as the benefit–risk ratio of PTCA improves, the circumstances under which a choice of treatment option becomes feasible [illegible] extend to patients with more severe disease.114 With the exception of repeat procedures in the ***first*** year, PTCA in patients with multivessel disease achieved similar outcomes to PTCA in patients with single-vessel disease.115

At present, only **6–10%** of individuals with three (or more) vessel disease are suitable for PTCA. For example, only **6%** of individuals with triple vessel disease in a major trial **m** the United States were eligible for PTCA at initial screening and only **2.5%** actually proceeded to this form of treatment.[116] For those with three (or more) vessel disease who are suitable for PTCA, the risks and costs are higher than for single-vessel disease but **no** higher than for initial CABG.55,117

On the other hand, revascularisation is less complete than with CABG and many individuals with multivessel disease have single-vessel (culprit lesion) angioplasty. Associated with this, individuals with three (or more) vessel disease require considerably more repeat revascularisation procedures after PTCA than after CABG.118 *Also,* with the exception **of** repeat procedures in the **first** year, PTCA in individuals with multivessel disease has been found to achieve similar outcomes to angioplasty in individuals with single-vessel disease. While the situation for **two** vessel disease can be regarded as being intermediate between that for single and three (or more) vessel disease, there is some evidence to suggest that the risks and outcomes of PTCA in **two** vessel disease are closer to those for single-vessel disease.55

A task force of the American College **of** Cardiology and the American Heart Association concluded that, in elderly patients with multivessel disease, CABG conferred a substantial survival benefit over PTCA.115 However, the study they cite in support **of** this conclusion reported that at one year risk-adjusted survival was higher among patients who had undergone PTCA and at five years, survival probabilities were equivalent119

Finally, there is a lack of comparative studies involving the use of interventional coronary artery procedures in complex cases where multiple balloons, stents, or directional atherectomy devices are used. The techniques used in these cases are a recent and rapidly evolving area of medical technology.

Table ***26:*** ***Results of economic evaluations of CABG and PTCA***

Study	Treatments compared	Study design	Age (mean)	Severity of disease	Sample size	Follow up period	Costing method	Summary of results
Weinstein (1982)109	CABG medical	Simulated	55 (men)	> 50% obstruction 1–3 vessels	Not applicable	Not applicable	Charges	Cost per QALY ranged from $3800 in MVD to $30 000 in IVD. Results sensitive to weight given to relief of angina.
Reeder (1984)102	PTCA CABG	Observation	53.4 54.8	58% v 87% in NYHF III	79 89	12 months	Charges	Cost of PTCA = 85% that of CABG. No difference in effectiveness.
Jang (1984)103	PTCA CABG	Observation	52 + 9 56 + 9	1VD	86 175	6–12 months	Charges	Costs of procedures are equal if initial failure rate in PTCA exceeds 60%.
Kelly (1984)104	PTCA CABG	Observation	53–56 (+8–12)	1VD	78 65	12 months	Charges	Cost of PTCA = 59% that of CABG.
Williams (1985)110	CABG PTCA medical	Simulated	Not specified	1VD–MVD	Not applicable	Not applicable	costs	Cost per QALY ranged from £1000 in MVD with severe angina to £12 600 in 2VD with mild angina. For IVD, PTCA was more cost effective than CABG.
Black (1988)105	PTCA CABG	Observation (matched)	56 + 11 58 + 9	2VD	100 100	12 months	Charges	Cost of PTCA = 40% that of CABG.
Hiatky (1990)[106]	PTCA CABG	Observation	Not specified	Not specified	115 274	None	costs – 4 models	Cost of PTCA = 47–58% that of CABG. Difference in costs smaller than difference in charges. Cost savings = 19–78% of difference in costs.
van de Brand (1990)107	PTCA CABG	Observation	53 53	1VD – 91% – 18%	896 1041	12 months	Costs	Cost of PTCA = 64% that of CABG.
Cohen (1990l108	PTCA Atherectomy Stenting CABG	Observation	59 + 11 59 + 10 57 + 12 63 + 9	MVD – 38% – 21% – 38% – 95%	No details	No details	Adjusted charges	Cost of PTCA = 25% that of CABG. Cost of atherectomy = 26% that of CABG. Cost of stenting = 35% that of CABG.

Abbreviations:
- MVD multi-vessel disease
- 1VD single-vessel disease
- 2VD double-vessel disease
- NYHF III severity of illness New York Heart Foundation grade III
- QALY quality-adjusted life year

Appendix 4
Waiting list data

Waiting list data falls into **two** categories: snapshot and throughput. Snapshot data include the number of consumers **on** a waiting list at a point in time, and the length of time these consumers have been waiting up until that point in time. Throughput data include the number of consumers added to or removed from a waiting list over a period of time, and the lengths of time waited prior to admission by consumers admitted during a specified period of time. Snapshot data overestimate the average waiting time since many consumers are treated within relatively **short** times and are thus not detected in the snapshot. Throughput data may underestimate the incidence of long waits if there is a large proportion of consumers not treated within the throughput data collection period. The Australian Institute of Health and Welfare *(AIHW)* has suggested that the emphasis in describing waiting lists should be shifted from the total number of people waiting to the numbers of people waiting an 'inappropriately' long time.[120] The length of waiting time considered reasonable depends on clinical and social factors.

A small proportion of CABG consumers will be admitted as emergency cases and **will** not go **on** a waiting **list**. Even fewer PTCA consumers will be admitted as emergency cases, unless PTCA replaces thrombolytic therapy as a treatment for acute myocardial infarction. If this happens and there is **no** corresponding increase in facilities, waiting times for other PTCA consumers could increase.

Estimates of waiting **list** figures for cardiothoracic surgery in Australia have been derived from data collected from all States and Territories except Victoria and Queensland.[121] The estimates have limitations. For example, different States count different types of consumers in their statistics, seasonal effects may result from States collecting data at different times, and there may be consumers **on** waiting **lists** managed by doctors where the hospital has not been notified of their need for admission.

An estimated **9.2** people per **100** 000 population were **on** cardiothoracic waiting **lists** in Australia at October **1993,** of whom **3.8** had been waiting less than one month, 4.1 for **1–6** months and **1.3** for over ***six*** months.[121] The number of people per **100** 000 population cleared per month from elective cardiothoracic surgery waiting lists were **9.1,** of whom **8.3** had been routinely admitted and the remainder removed from the waiting list for other reasons. Clearance time is the time that it would take to admit all consumers currently **on** the waiting list, at the historical rate of admission, if **no** further people were added to the list. The estimated clearance time for cardiothoracic waiting **lists** is one month, compared with an overall time for all elective waiting lists of **1.8** months. At the time of the *AIHW* study, **41%** of people **on** cardiothoracic waiting lists had been waiting less than one month and **14%** for over ***six*** months, compared with **29%** and **31%** respectively for all elective surgery waiting **lists.**[121] However, the ***mix*** of degrees of urgency of consumers **on** the cardiothoracic surgery waiting list is likely to be different than that for other elective surgery.

Work is being undertaken to add a set of waiting **list** definitions and data items to the National Health Data Dictionary (a set **of** standardised data definitions to be used to collect national institutional health data)[122] and to collect more consistent waiting **list** data that includes information **on** clinical urgency. Both snapshot and throughput data will be collected nationally **on** an annual basis for cardiothoracic surgery, and for **CABG** as one of a set of indicator procedures. These initiatives have been set in motion for elective surgery.

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Royal North Shore Hospital
Royal Prince Alfred Hospital
St George Hospital
St Vincent's Hospital
St Vincent's Private Hospital
Strathfield Private Hospital
Sydney Adventist Hospital
Westmead Hospital

Victoria

Cabrini Hospital
Epworth Hospital
Geelong Hospital
Monash Medical Centre
Royal Children's Hospital
Royal Melbourne Hospital
St Vincent's Hospital
John Fawkner Hospital
The Alfred Hospital
The Austin Hospital

Queensland

Prince Charles Hospital
Princess Alexandra Hospital
St Andrew's Hospital
Townsville General Hospital

South Australia

Adelaide Children's Hospital
Ashford Private Hospital
Flinders Medical Centre
Royal Adelaide Hospital
Wakefield Memorial Hospital

Western Australia

Royal Perth Hospital
Sir Charles Gairdner Hospital

Tasmania

Launceston General Hospital
Royal Hobart Hospital

Glossary

Cardiac conditions

Acquired valve disease	Valve disease not genetic **or** present at birth, but produced by outside influences.
Angina	Pain **or** tightness in the centre of the chest which occurs when the coronary arteries are unable to provide an adequate blood supply to meet the demands of the heart muscle.
Arrhythmia	Any abnormality in the regularity of the heart beat (caused by a defect in the generation **or** conduction of electrical impulses in the heart).
Atresia	Absence **or** closure of a normal orifice.
Atrial septal defect	A hole in the wall between the upper **two** chambers of the heart.
Atrioventricular block	Block of the electrical impulses controlling contractions of the heart with the block occurring in transmission between the atria and ventricles.
Bradycardia	A slow heart rate.
Bundle of His	Band of muscle fibres that transmits electrical impulses controlling contractions of the ventricles of the heart.
Cardiomyopathy	A disease of heart muscle often of obscure **or** of unknown cause.
Coarctation of aorta	Congenital narrowing of a short section of the aorta.
Conduction defect	A failure of the normal passage of electrical impulses through the conduction muscle fibre of the heart.
Congenital heart defect	A range of heart disorders of varying severity, present at birth.
Congestive heart failure	Condition in 'which the heart is **no** longer capable of pumping a sufficient volume of blood to meet the body's needs for oxygen and nutrition.
Coronary artery disease	Any disease of the coronary arteries, particularly atherosclerosis **or** other arteriopathy, that reduces the **flow** of blood and hence the oxygen supply to the heart muscle.
Ebstein's anomaly	Congenital malformation **of** the tricuspid valve of the heart.
Endocardial cushion defect	Defect of the heart caused by developmental abnormalities of the atrioventricular canal.

Fibrillation	Rapid uncoordinated, chaotic activity of the muscle fibres of the heart.
Ischaemic heart disease	Heart diseases caused by inadequate **flow** of blood to the heart. Symptoms include angina and acute myocardial infarction.
Myocardial infarction	Death and coagulation of part of the heart muscle deprived of an adequate blood supply by coronary artery blockage (heart attack).
Myopathy	Any disease or disorder of muscles. (***see also*** Cardiomyopathy)
Patent ductus arteriosus	A congenital heart defect in which the ductus arteriosus, which during foetal life allows the blood to bypass the lungs, fails to close at or **soon** after birth.
Stenosis	Narrowing **of** a duct, orifice or tubular organ such as a blood vessel or valve.
Sick sinus syndrome	A condition where periods of bradycardia (slow heart rate) alternate with tachycardia (fast heart rate).
Supraventricular tachycardia	Episodes of abnormally fast heart rate lasting for hours or days. It is caused by fast spontaneous impulses, arising in the upper chambers of the heart, that override the natural pacemaker.
Tachyarrhythmia	**An** excessively rapid and sometimes irregular heart beat.
Tachycardia	A rapid heart rate from any cause.
Tetralogy of Fallot	A common congenital heart disease consisting of four defects: narrowing of the main artery to the lungs (pulmonary artery); a hole in the wall between the two lower chambers of the heart; defective positioning of the aorta; and thickening of the right ventricle **of** the heart.
Truncus arteriosus	A congenital defect where one artery replaces the aortic and pulmonary arteries.

Cardiac interventions and equipment

Anti-tachycardia device	An implantable device for the automatic reversion of arrhythmias.
Angioplasty	A method of treating blockage or narrowing of a blood vessel by inserting a catheter with a balloon attached into the constriction and dilating the balloon to open it.
Atherectomy	Use of mechanical devices for cutting or grinding through obstructions in arteries.

Automatic implantable cardiac defibrillator	A defibrillator implanted in a subcutaneous pocket in the axilla abdomen. Designed to detect and automatically terminate ventricular fibrillation or tachycardia. **(see *also*** Defibrillator)
Balloon pump	**A** pump inserted into the circulation (usually the aorta) to support the pumping action of the heart.
Balloon septostomy	Using a balloon to surgically create a septal defect.
Cardiology	Study of the heart and its functions.
Cardiomyoplasty	**A** procedure where one of the patient's **own** skeletal muscles is used to reinforce a failing heart.
Cardioversion	A carefully timed direct current shock administered to the heart through the chest wall to reinstate a normal heart rhythm in patients with **an** abnormally fast or irregular beat.
Coronary angiogram	X-ray **film** produced by injecting coronary blood vessels with a radio-opaque substance.
Coronary artery bypass grafting (CABG)	Grafting of blood vessels to bypass obstructions in coronary arteries and improve circulation of blood to the heart.
Defibrillator	An apparatus used to terminate fibrillation by application of a brief electroshock to the heart, directly or through electrodes placed **on** the chest wall.
Diathermy	Use of high frequency electromagnetic radiation to heat tissue used as a form of physical therapy or to cut or remove tissue in surgical procedures.
Electrophysiology	Study **of** electrical phenomena associated with physiological processes.
Excimer laser	Laser emitting a beam of pulsed ultraviolet light.
Extracorporeal bypass carbon machine	Device where the blood is circulated outside the body for dioxide-oxygen exchange.
Extracorporeal membrane oxygenation (ECMO)	A technique for supplying oxygen to the blood during circulation outside the body.
Interventional cardiology	Use of catheter-based techniques to treat heart diseases.
Laser angioplasty	Using a laser beam to cut through obstructions in blood vessels.
Coronary angioplasty	Angioplasty (see above) applied to a coronary artery.
Left ventricular or biventricular assist devices	Mechanical circulatory support devices.
Myocardial revascularisation	Re-establishment of blood supply to the muscles of the heart by blood vessel graft or other conduit.

Percutaneous transluminal coronary angioplasty (PTCA)	The **full** name **for** coronary angioplasty, describing the insertion **of** the angioplasty catheter through the skin into a **major** blood vessel before being threaded through the circulation to the heart.
Pericardiectomy	Excision of the pericardium (sac surrounding the heart).
Pericardiotomy	Cutting into **or** through the pericardium.
Pulmonary embolectomy	Surgical removal **of** an embolus (clot **or** other obstruction) **from** the pulmonary arteries.
Oximetry	Use of a photoelectric device **for** determining the oxygen saturation **of** the blood.
Radiofrequency catheter ablation	A catheter-based technique **for** the treatment. **of** some cardiac arrhythmias.
Radionuclide exercise test	A test in which the response **of** the blood flow in the heart to exercise is measured by nuclear medicine techniques.
Stent	Devices that can be expanded within arteries to **form** tubular supporting structures.
Sternotomy tray	Equipment to open the patient's chest in an emergency.
Telemetry	Making **of** measurements at a distance from the subject, the measurements being transmitted by radio signals.
Transoesophageal echocardiography	A method of graphically recording information about the movement and structure **of** the heart by the echo obtained from beams **of** ultrasonic waves directed through the chest wall, where access is gained via the oesophagus.
Valvotomy	**An** operation that opens up a stenosed (unnaturally narrow) heart valve and allows it to function properly.
Valvuloplasty (balloon)	A balloon catheter technique for repair **of** a narrowed valve of the heart.
Valvuloplasty	Procedure **for** the repair of an abnormal valve of the heart.

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