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BUILDING A HEALTHY AUSTRALIA

Australian Guidelines to Reduce Health Risks from Drinking Alcohol



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Reducing health risks from drinking alcohol

Alcohol is the most widely used drug in Australia. About 8 in 10 Australian adults drink alcohol. People drink alcohol for a wide range of reasons and in different social and cultural contexts. Alcohol can cause harm to the person who drinks and sometimes to others around them.

Based on the most current scientific evidence, the *Australian guidelines to reduce health risks from drinking alcohol* inform Australians of the health risks of drinking alcohol and provide advice on how to keep these risks low. They help people choose how much alcohol they drink, if any.



1: Adults

To reduce the risk of harm from alcohol-related disease or injury, healthy men and women should drink no more than 10 standard drinks a week and no more than 4 standard drinks on any one day. The less you drink, the lower your risk of harm from alcohol.

Following this guideline keeps the risk of harm from alcohol low, but it does not remove all risk.

If healthy adults were to follow this advice, they would have less than a 1 in 100 chance of dying from an alcohol-related condition. The risk rises the more a person drinks. It is reduced by drinking less often and drinking less on each occasion.

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Reasons for this advice:

- Drinking alcohol increases the risk of many cancers, including bowel and breast cancer. Alcohol can also damage the liver and cause high blood pressure. The level of risk increases as more alcohol is consumed.
- When people drink alcohol they have a greater chance of getting hurt and hurting other people, for example through car accidents, falls or getting into arguments.
- Drinking alcohol can cause mental health problems or make these problems worse.
- In the past, low levels of alcohol were thought likely to protect against heart disease. The evidence is now less clear.

There are some people who are at greater risk of harm from alcohol. These people include:

• adults aged 18-25 years, as alcohol increases the risk of injury and affects brain development



Healthy adults drinking within the guideline

of dying from an alcohol-related condition.

recommendation have less than a 1 in 100 chance

- people aged over 60 years, due to changes to body composition and their ability to process alcohol and in some cases chronic health conditions
- people with a family history of problems with alcohol who may be at greater risk than other people of developing problems with alcohol themselves
- people who use illicit drugs or take medications that interact with alcohol
- people with conditions that can be made worse by alcohol, such as liver disease, hepatitis B and C, obesity or mental health conditions.

People should talk to their doctor if they have questions about how drinking alcohol may be affecting their health.

When less is better

There are times when drinking alcohol can increase the risk of harm. The risk increases even if the amounts are small, for example:

- driving a vehicle
- riding a motorbike or bicycle
- using machinery or other activities that need concentration
- boating, fishing, swimming or other activities on and around the water
- supervising children or when you are responsible for the safety of others
- using certain medicines or drugs.

2: Children and people under 18 years of age

To reduce the risk of injury and other harms to health, children and people under 18 years of age should not drink alcohol.

People under 18 years of age are more likely to suffer harm from alcohol.

- The brain continues to develop until around 25 years of age. This means the brains of people under 18 are more sensitive to damage from alcohol.
- Drinking alcohol can increase risk taking and lead to unsafe sex, car accidents and injuries. It can also increase the risk of self-harm and, in some instances, suicide.
- Drinking alcohol at an early age may increase the risk of developing problems with alcohol, which can appear in early adulthood.

3: Women who are pregnant or breastfeeding

Advice for pregnancy

To prevent harm from alcohol to their unborn child, women who are pregnant or planning a pregnancy should not drink alcohol.

No safe level of alcohol consumption during pregnancy has been identified.

- When a woman drinks alcohol during pregnancy, so does the developing baby. The baby's blood gets about the same level of alcohol as the mother's blood.
- A baby's brain starts growing very early in pregnancy, often before the mother knows she is pregnant. Drinking alcohol in pregnancy can damage the baby's brain which can cause fetal alcohol spectrum disorder (FASD). FASD leads to many lifelong problems including learning and behavioural issues during childhood and adult life.
- The risk of harm to a baby increases the more alcohol a mother consumes, and the more frequently she drinks. It does not mean the developing baby will always be harmed if a woman drinks while pregnant. Every pregnancy is different and there are a range of factors that play a role in determining the risk.

Advice for breastfeeding

For women who are breastfeeding, not drinking alcohol is safest for their baby.

- If a mother drinks when she is breastfeeding, the alcohol crosses into the breastmilk.
- If a mother breastfeeds her baby while there is still alcohol in her breastmilk, the baby also drinks the alcohol.
- When a mother drinks alcohol while breastfeeding, the baby can have problems feeding and sleeping.
- A baby's brain keeps developing after it is born. This means an infant's brain is more sensitive to damage from alcohol than an adult brain.

How the Guidelines were developed

Australia's National Health and Medical Research Council (NHMRC) provides evidence-based advice to government and the community on a wide range of matters including nutrition, infant feeding, infection control, blood lead levels and drinking water quality.

The Australian guidelines to reduce health risks from drinking alcohol are based on a thorough evaluation of the evidence, and guided by a group of independent health experts including doctors, medical and public health professionals, researchers and consumer representatives.

The guidelines summarise the evidence and methods that guided this review, and the conclusions drawn by NHMRC's expert committee.

Summary of the guidelines

Guideline 1: Adults

To reduce the risk of harm from alcohol-related disease or injury, healthy men and women should drink no more than 10 standard drinks a week and no more than 4 standard drinks on any one day.

The less you drink, the lower your risk of harm from alcohol.

This guideline applies to healthy men and women aged 18 years and over. The guideline does not represent a 'safe' or 'no-risk' drinking level, nor does it set an absolute upper limit of intake. It identifies a level of drinking at which, based on the current scientific evidence, the risk of alcohol-related harm remains low over a lifetime, in terms of both risk of death from alcohol-related disease and death from alcohol-related injury.

Key messages

- This guideline provides recommendations to reduce the risk of harm from alcohol, but these recommendations do not completely eliminate all risk from drinking alcohol.
- For both men and women, the risk of dying from alcohol-related disease and injury remains below 1 in 100 if no more than 10 standard drinks are consumed each week and no more than 4 standard drinks are consumed on any one day.
- Every drink above this level increases the lifetime risk of alcohol-related disease and injury. This includes the risk of dying from alcohol-related disease or injury.
- Drinking alcohol increases the risk of many cancers. The level of risk increases as more alcohol is consumed.
- Drinking less frequently, and drinking less on each day or drinking occasion, further reduces the lifetime risk of harm from alcohol.
- Not drinking at all is the best way to reduce the risk of harm from alcohol.
- This guideline applies to most healthy adults; however, there are some people who are at greater risk of alcohol-related harm. Those at greater risk include young adults aged 18–25 years, people aged over 60 years, people with mental or physical health conditions, people with a family history of alcohol dependence, and people who use illicit drugs or take medications that interact with alcohol.
- This guideline does not apply to children and young people under the age of 18 years (who are covered in Guideline 2), or to women who are planning a pregnancy, or are pregnant or breastfeeding (who are covered in Guideline 3).

Guideline 2: Children and people under 18 years of age

To reduce the risk of injury and other harms to health, children and people under 18 years of age should not drink alcohol.

Key messages

There is no clear 'safe' level of alcohol consumption for children and people under 18 years of age. This is because of the increased risks of harm from alcohol for young people, including from injury and potential adverse effects on brain development.

Beginning alcohol use at an early age may also put young people at greater risk of longer term alcohol-related harms, including alcohol use disorders that tend to appear in early adulthood.

To minimise these risks, children and people under 18 years of age should not drink alcohol.

Guideline 3: Women who are pregnant or breastfeeding

- A. To prevent harm from alcohol to their unborn child, women who are pregnant or planning a pregnancy should not drink alcohol.
- B. For women who are breastfeeding, not drinking alcohol is safest for their baby.

Key messages

This guideline is based on evidence of the harms for the developing fetus and for young babies when mothers drink alcohol while pregnant or breastfeeding. It is relevant to women who are pregnant, breastfeeding or may become pregnant in the near future.

The evidence does not indicate a safe amount of alcohol that pregnant women and breastfeeding mothers can drink.

- As there is a risk of harm to the fetus, this guideline takes a precautionary approach and recommends not drinking alcohol when pregnant.
- Similarly, as there is a risk of harm to the baby, this guideline takes a precautionary approach and recommends not drinking alcohol when breastfeeding.

During pregnancy

- Alcohol is a teratogen that is, a substance that can cause permanent harm to a developing fetus. If a woman drinks alcohol during pregnancy, the alcohol passes freely from the mother to the fetus via the placenta, so the blood alcohol levels of the mother and fetus are similar.
- The central nervous system starts developing very early in the pregnancy, and the brain is sensitive to harms from alcohol throughout pregnancy.
- No safe level of alcohol consumption during pregnancy has been identified.
- The risk of harm to the fetus increases the more the mother drinks and the more frequently she drinks.

- Maternal and fetal factors affect the risks from drinking alcohol while pregnant (e.g. genetic differences, metabolic rates, and biochemical and inflammatory responses to alcohol). These factors make it difficult to predict the level of risk in each individual pregnancy.
- Not drinking alcohol during pregnancy, or when planning a pregnancy, prevents the risk of alcohol-related harm to the developing fetus.

When breastfeeding

- For women who are breastfeeding, not drinking alcohol is safest for their baby.
- If a breastfeeding mother drinks alcohol, that alcohol crosses into the breastmilk. Only time reduces the amount of alcohol in the milk.
- Maternal alcohol consumption may adversely affect the feeding behaviour and sleep patterns of the breastfed baby.
- A baby's brain keeps developing after it is born. A growing infant brain is more sensitive to damage from alcohol than an adult brain.

1. Introduction

Alcohol is the most widely used drug in Australia, with about 80% of adults drinking alcohol each year [1]. People drink alcohol for a wide range of reasons, and in different social and cultural contexts.

Alcohol consumption is linked with increased risk of injury, chronic disease, and harm to the fetus and breastfed infant. Moreover, excessive intake of alcohol affects the drinker's health and can also affect other members of the community [2].

1.1 Aim

The aim of these guidelines is to provide the Australian population with clear and evidence-based advice about alcohol, to help people make informed choices about their drinking. The guidelines are also intended to form the evidence base for future policymaking and educational materials.

These guidelines contribute to Australia's National Alcohol Strategy 2019–2028, which aims to prevent and minimise alcohol-related harms by improving awareness and understanding of those harms [3].

1.2 Scope

These guidelines provide accurate and contemporary information about the health risks related to drinking alcohol. The information presented in these guidelines is based on:

- a thorough review of the latest and best available evidence
- · consideration of the quality of the evidence and interpretation of its importance
- consideration of other factors important for guidelines, such as making transparent the reasons for the recommendations.

The guidelines evaluate the extent of risk posed by alcohol at different levels of consumption. They also summarise the evidence on how various levels and frequencies of drinking are likely to affect different aspects of health. The following are not included because they are outside the scope of these guidelines:

- detailed information about the economic and social effects of alcohol consumption
- recommendations about legal or other regulatory processes associated with alcohol
- · detailed recommendations about specific health conditions
- standards of conduct associated with buying, selling and serving alcohol
- the role of health services, including general practice, in the assessment of alcohol-related issues, referral and treatment
- practical advice on how to adjust or change individual alcohol consumption.

As explained above, detailed recommendations relating to specific health conditions are beyond the scope of these guidelines. Thus, specialist professional organisations and societies are encouraged to develop additional guidance to meet such needs.

Efforts to support the implementation of these guidelines are critical. The Australian Government Department of Health has a key role in implementation, as do state and territory health departments and certain non-government organisations. Practical ideas on how to effectively implement the advice and suggestions within these guidelines will be developed separately by these groups.

1.3 Target audience

These guidelines apply to everyone in Australia, particularly those who drink alcohol, those who are considering drinking alcohol, and parents of young people who may be considering drinking alcohol. They provide useful information about the risks involved when alcohol is consumed at different levels and frequencies.

The guidelines are intended as a resource for individuals, organisations, policymakers and decision-makers, planners, health professionals, parents and family members, educators, industry organisations and those responsible for serving alcohol. Hence, the guidelines include a plain English summary.

1.4 How the guidelines were developed

Since 1987, the National Health and Medical Research Council (NHMRC) has published evidence-based guidelines to help Australians reduce the risk of harm associated with drinking alcohol. The previous edition, *Australian guidelines to reduce health risks from drinking alcohol*, was published by NHMRC in 2009 [4]. Research on the health effects of alcohol is continually evolving and new studies are published regularly. Therefore, NHMRC regularly reviews its guidelines to ensure that the advice is up to date and reflects the latest body of evidence.

The Council of NHMRC, in consultation with the Australian Government Department of Health, directed a revision of the alcohol guidelines in 2015. An independent expert committee — the NHMRC Alcohol Working Committee (the Expert Committee) — was appointed to guide this revision. The Expert Committee comprises members with expertise in clinical and public health, alcohol policy, alcohol research, consumer advocacy, epidemiology and biostatistics; its terms of reference and full details of membership are given in Appendix 5.

The NHMRC 2009 alcohol guidelines took a novel approach to reporting on the health risks of drinking, by providing information about the risks of alcohol-related harm over a lifetime. Specifically, the 2009 guidelines conveyed to the Australian public and policymakers the concept that the risk of harm progressively increases as the amount of alcohol consumed increases. In these revised guidelines, NHMRC has retained this approach, but has further simplified the messages by targeting the guidelines to three distinct audiences:

- adults
- children and people under 18 years of age
- women who are pregnant or breastfeeding, or are planning a pregnancy.

An internationally recognised approach was used to synthesise the evidence and support its translation into guidelines and accompanying text. This approach, known as Grading of Recommendations Assessment, Development and Evaluation (GRADE), is described in Appendix 5. In developing the guidelines, quality evidence from a range of sources was considered, as detailed below and depicted in Figure 1.1.

An underpinning principle of GRADE is transparent decision-making. The framework that details this transparency is called an Evidence to Decision (EtD) framework, and the Expert Committee applied this framework as it advised on the wording and strength of the three key guidelines. Appendix 3 provides the EtD framework for each guideline.

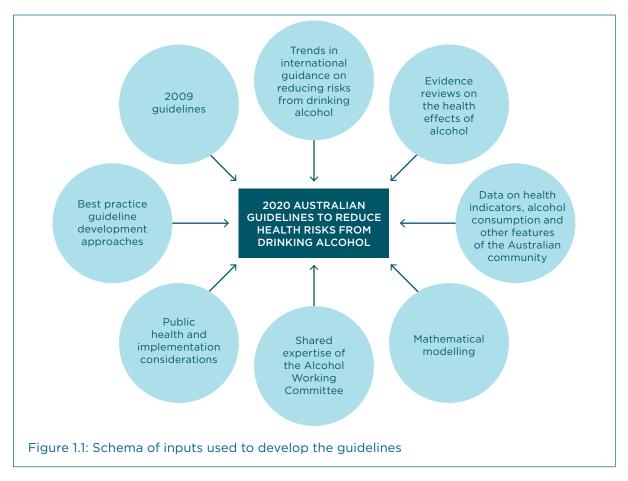
For these guidelines, NHMRC has presented the recommendations and other information in the MAGICapp platform (which incorporates templates for GRADE and integrated reference management) in addition to the PDF format. As a publishing platform, MAGICapp makes it possible to update elements or modules of a guideline and display a 'version history' for any updates. NHMRC will manage any changes to the synthesis of the body of the evidence or the wording of the recommendations in line with the *National Health and Medical Research Council Act 1992*. This may include establishing an expert committee and having a public consultation process. Minor typographical errors or broken links can be amended through scheduled maintenance.

1.5 The evidence base for the guidelines

A range of inputs was considered in updating the 2009 alcohol guidelines. These inputs, portrayed in Figure 1.1, included:

- the 2009 guidelines guideline elements were retained in the updated version unless there were compelling reasons to change them
- the current worldwide evidence on the effects of alcohol relevant to the Australian community, including data from 42 systematic reviews and additional supplementary evidence (reports available at <u>www.nhmrc.gov.au/alcohol</u>)
- data on health indicators, alcohol consumption, sociodemographic and other features of the Australian community
- for Guideline 1, modelling of the relationship between alcohol and a range of outcomes, including cause-specific and all-cause mortality (report available at <u>www.nhmrc.gov.au/</u> <u>alcohol</u>)
- public health and implementation considerations for effective, evidence-based policy and guidance, including for important populations within Australia
- trends in international alcohol consumption guidance
- the shared expertise of the Expert Committee
- NHMRC and international best practice for guideline development.

All of these inputs were used to inform the ultimate recommended maximum levels of consumption for Guideline 1. The recommended limits of up to a maximum of 10 standard drinks a week and no more than 4 standard drinks on any one day strike a balance between the current evidence (from systematic reviews, modelling results and data uncertainties), with the need for straightforward public health guidance relevant to the Australian population. The same inputs, except for the modelling, were used to guide the development of Guidelines 2 and 3.



1.6 Capturing new evidence

Evidence on the health effects of alcohol is evolving continually. To ensure that important evidence published after the initial evidence evaluation was included, the public was given a chance to provide publications of interest, as were members of the Expert Committee. Two additional steps were taken to ensure that these extra publications were appropriately considered before being added to the evidence base of this revised guideline.

The first step was to set certain quality criteria when NHMRC conducted a public call for evidence between 25 November 2016 and 13 January 2017, to capture relevant studies and issues of public concern. To be accepted and used in revising the guidelines, the received publications had to meet these criteria, set by the Expert Committee:

- high-quality (i.e. systematic reviews, randomised controlled trials and observational studies, including cohort, case-control or nested case-control studies)
- published after the search of the literature for the evidence evaluation report was conducted
- publicly available and published in the English language in peer-reviewed journals.

The second step was to accept other high-quality articles and reports published since 2009 suggested by members of the Expert Committee. These articles and reports had to meet the quality criteria set for the public call for evidence.

Evidence from both of these steps was not formally evaluated using GRADE (the system used for the systematic reviews), and thus it did not directly inform the key recommendations within the guidelines. Rather, the additional publications were used to further support and update the information in other sections of the guidelines.

Each guideline section (Sections 4–6) includes a summary of the evidence used to develop the guideline and accompanying information.

An overview of the guideline development process, including the methods for the evidence evaluation, systematic reviews and modelling, is presented in Appendix 5. The reports from all of the evidence activities are on the NHMRC website for the guidelines at <u>www.nhmrc.gov.au/alcohol</u>.

1.7 How the evidence was used

The structure and final wording of the three public health recommendations in these guidelines were based on the multiple inputs outlined above, including evidence evaluation, systematic reviews and mathematical modelling. The committee used GRADE, and its EtD framework (provided for each of the three guidelines at Appendix 3) to finalise the recommendations.

As described above, other evidence sources were used to develop the narrative text of the guideline that supports the key recommendations.

1.8 Differences between the current and 2009 guidelines

The 2009 version of these guidelines [4] had a lot of information that is still relevant, and much of its evidence base is still sound. After reviewing the comprehensive range of evidence as part of this update, the Expert Committee advised the following key changes:

- There is now one guideline for adults that captures the amount of alcohol consumed across a week, while bearing in mind how much a person should drink on any one occasion. Guideline 1 replaces advice on long-term and short-term risks, which were previously provided in two separate guidelines.
- Advice is provided on alcohol consumed 'per day' rather than 'per occasion', given that some people may have more than one occasion of drinking in a single day.
- For long-term risks, advice is provided on alcohol consumed per week rather than per day. Guideline 1 recommends drinking no more than 10 standard drinks per week rather than no more than 2 standard drinks per day (as recommended in the 2009 guidelines).
- The advice is tailored to current Australian drinking patterns.
- Guideline 2 is more explicit in specifying that those under 18 years of age should not drink. There is no 'safe' level of drinking alcohol for this age cohort.
- Guideline 2 applies to all people under 18 years of age, whereas the 2009 guideline split the advice for those under 15 years of age and for those aged 15-17 years.
- Guideline 3 is more explicit in advising that women who are pregnant, breastfeeding or planning a pregnancy should not drink alcohol. No safe level of alcohol consumption during pregnancy or breastfeeding has been identified.
- The guidelines are presented in PDF but also in an online platform called MAGICapp. The MAGICapp platform makes it easier to use the guideline and to update parts of the guideline if a body of evidence suggests that updating is needed (see Section 1.4 above).

Elements of the 2009 guidelines that have been retained are:

- a single broad guideline for all adults (rather than advice on a range of numbers of drinks and their associated risks that allows individuals to try to 'calculate' their own risks)
- guidance for adults that applies to both men and women (see Guideline 1)
- guidance that adults drink no more than 4 standard drinks on any one day, to reduce short-term harm
- the use of 'standard drinks' rather than grams of alcohol
- the use of a 1 in 100 risk level for the risk of dying from an alcohol-related harm (see Section 3).

Each of the three guidelines provides more details about what has changed in the advice for the different population groups: adults, those under 18 years of age, and women who are pregnant, breastfeeding or planning a pregnancy.

1.9 Public health evidence

For clinical practice guidelines, randomised controlled trials provide the highest level of evidence on the health effects of a particular intervention. However, in public health there are many situations where such trials are not practical or are unethical. For example, it is not ethical to randomise one group to be exposed to cigarette smoke for 3 years and another to not be exposed, then test the health outcomes of both groups 10 years later.

As a result, much of the evidence for public health guidelines, including evidence relating to alcohol, comes from long-term observational studies, which have some inherent limitations. This does not mean that the quality of evidence is insufficient to provide advice to Australians on the health effects of drinking alcohol. It simply means that the evidence used is the best available for such a public health issue. This evidence is a reliable guide to the underlying facts and the action needed to control hazards to public health, when carefully summarised and interpreted [5]. Each guideline describes the evidence base that underpins the recommendation and the supporting guideline text.

1.10 The guideline format

Section 2 provides background information about alcohol in Australia, and Section 3 explains concepts of risk. Sections 4–6 cover the actual recommendations; each of those sections includes the following:

- *the public health recommendation* central advice based on the key evidence sources, with 'Key messages' providing additional information to support the recommendation
- the rationale an overarching justification for the stated advice
- the evidence base the evidence sources used for the guideline
- additional information a more detailed discussion of the evidence for specific outcomes and population groups.

Information on the GRADE Evidence to Decision (EtD) framework is provided in Appendix 3. The MAGICApp version also has an 'Evidence to decision' tab for each guideline.

A glossary of technical terms is provided in Appendix 6, and acronyms and abbreviations in Appendix 7.

1.11 MAGICapp tabs

The MAGICapp version has the following tabs:

- Evidence to decision captures key information of the EtD framework. This includes the quality of and confidence in the evidence, values and preferences of the target population, impact of the recommendation on health equity, resource implications, and the feasibility and acceptability of the recommendation and other considerations. The section called 'harms and benefits' by the GRADE literature and in the MAGICapp platform refers to health outcomes in relation to alcohol exposure (drinking alcohol at varying levels and patterns).
- *Rationale* provides overarching justification for the stated advice.
- *Practical info* provides practical information and helps puts the guidelines into action and includes links to further information.

2. Background: alcohol in Australia

2.1 Death, injury and disability caused by drinking alcohol

'Burden of disease' refers to the impact of a disease, condition or risk factor (e.g. smoking or drinking alcohol) on the health of a population. It is measured by the number of healthy years lost due to a particular risk factor — the disability-adjusted life years (DALY) measure [6]. Alcohol is the sixth highest risk factor contributing to the burden of disease in Australia; in 2015, it was responsible for 4.5% of the total burden of disease and injury [6]. There are marked gender differences; among women, 2.8% of the disease burden is attributable to alcohol, whereas in men the figure is 6.0% [6].

In 2015, drinking alcohol contributed to a number of diseases and injuries, including [6]:

- 100% of the burden due to alcohol use disorders
- 40% of the burden due to liver cancer
- 28% of the burden due to chronic liver disease
- 22% of the burden due to road traffic injuries involving motor vehicle occupants
- 14% of the burden due to suicide and self-inflicted injuries
- 14% of the burden due to homicide and violence
- 11% of the burden due to drowning.

In 2016, the prevalence of alcohol use disorder in Australia (including harmful use of alcohol and alcohol dependence) was estimated at 4.4% (6.1% in males; 2.7% in females) [7].

Past studies and reviews have shown a causal link between alcohol consumption and more than 40 medical conditions, including several cancers, heart disease, stroke, liver cirrhosis and fetal alcohol spectrum disorder (FASD) [7–9]:

- In 2017, there were 1366 alcohol-induced deaths directly attributable to alcohol
 (e.g. alcoholic liver cirrhosis or alcohol dependence) and another 2820 alcohol-related
 deaths where alcohol was mentioned as a contributory cause of death. However, there
 may have been many more deaths particularly those arising from cancers and injuries —
 that were partially caused by alcohol but where the certifier did not refer to alcohol as the
 underlying or a contributing cause of death [10].
- Between 1 July 2016 and 30 June 2017, there were also 70 011 alcohol-induced hospital separations (i.e. episodes of care) for conditions such as alcoholic liver cirrhosis and alcohol dependence, plus many more for which alcohol consumption was a partial cause [11].

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2.2 Alcohol consumption: patterns and trends in Australia

Drinking alcohol is common in Australia. The 2016 National Drug Strategy Household Survey (NDSHS) reported that 77.5% of the Australian population aged 14 years and older had consumed alcohol in the previous 12 months [1]. A small proportion of people aged 14 years or older drank daily (5.9%), about one-third drank weekly (35.8%), the same proportion (35.8%) drank less than weekly and the remaining 14.5% reported having never consumed a full serve of alcohol (defined as 1 standard drink).

The National Alcohol Strategy 2019-2028 notes that, on average, each person in Australia aged 15 years and over consumed the equivalent of about 2 standard drinks a day in 2017-18 [3].

Most Australians report drinking at levels within NHMRC's 2009 alcohol guidelines, which aimed to keep the risk of alcohol-related harm low [4]. However, some people drink at levels above these recommendations and thus increase their risk of alcohol-related disease and injury.

In 2016, 17.1% of people in Australia aged 14 years and older exceeded the NHMRC's 2009 lifetime risk guideline by consuming more than 2 standard drinks per day, and 25.5% exceeded the single occasion of drinking guideline by consuming more than 4 standard drinks on a single drinking occasion at least once a month (Figure 2.1) [1]. Those who exceeded the lifetime risk guideline were most likely to be aged between 40 and 49 years (20.6%) or between 50 and 59 years (20.4%). Those who were most likely to exceed the single occasion risk guideline at least once a month were aged between 18 and 24 years (42%) [1].

Between 2013 and 2016, the proportion of people exceeding the lifetime risk guideline declined (from 18.2% in 2013 to 17.1% in 2016), but the proportion of people exceeding the single occasion risk guideline remained stable [1]. People generally under-report their consumption in alcohol surveys, so these proportions are likely to be underestimates.

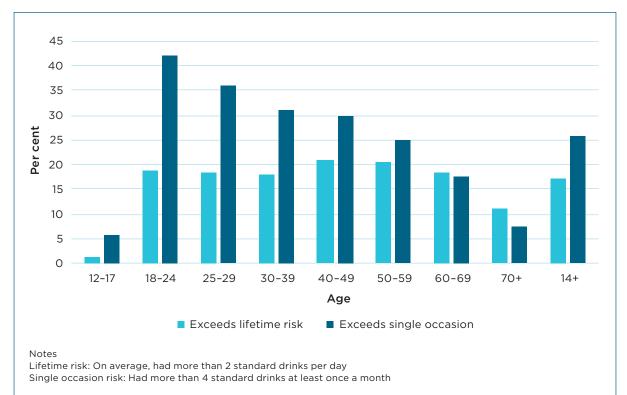
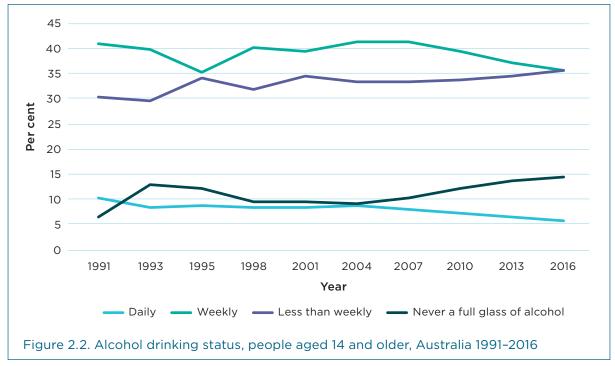


Figure 2.1. Proportion of Australians exceeding the NHMRC 2009 lifetime and single occasion risk guidelines 2016

Source: Australian Institute of Health and Welfare, 2017 [1].

Over time, there have been significant shifts in patterns of drinking, suggesting that Australians' attitudes towards drinking may be changing. The 2016 NDSHS found that Australians are drinking less frequently [1]. In the decade between 2007/08 and 2017/18, per capita consumption of pure alcohol in Australia fell by more than 10%, from 10.8 L to 9.5 L [12]. From 1991 to 2016, the proportion of people drinking daily or weekly declined, while the proportion of people drinking less often increased. The proportion of people who have never had a full serve of alcohol also increased (Figure 2.2) [1]. Declines in drinking have largely been driven by younger generations, with consumption among those over 40 relatively unchanged [13]. Analysis of drinking patterns from the NDSHS shows that, on average, Australians consume alcohol on 3 days per week (see Appendix 1).

The NDSHS survey reported that almost half (48%) of recent drinkers (defined as those who drank at least one serve of alcohol in the past 12 months) had taken action to reduce their alcohol intake [1]. The main reason given for changing drinking behaviours was for health [1].

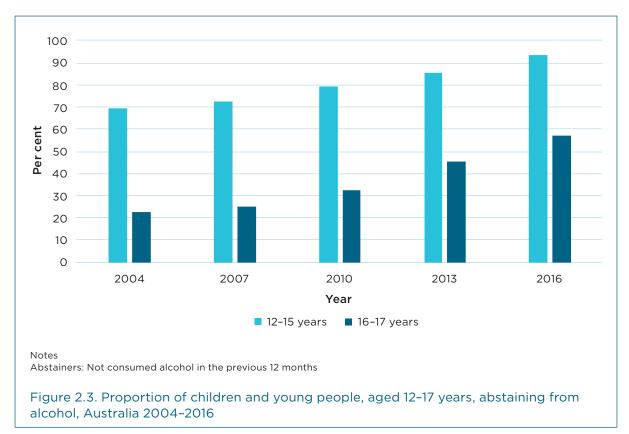


Source: Australian Institute of Health and Welfare, 2017 [1].

2.2.1 Children and people under 18 years of age

In 2016, 7.9% of people in Australia aged 12–15 years and 43.8% of adolescents aged 16–17 years reported consuming at least one full serve of alcohol in the previous 12 months [1]. A friend or an acquaintance (48.1%) and parents (35.2%) were the most common source supplying children and young people (12–17 years of age) with their first glass of alcohol [1]. A small proportion (5.4%) of children and young people reported consuming more than 4 standard drinks on a single occasion at least once a month (Figure 2.3) [1].

The proportion of people aged between 12 and 17 years abstaining from alcohol has significantly increased over time, from 54.3% in 2004 to 81.5% in 2016 [1]. Moreover, the average age at which young people first tried alcohol rose from 14.8 years in 2004 to 16.1 years in 2016 [1].



Source: Australian Institute of Health and Welfare, 2017 [1].

2.2.2 Women who are pregnant or breastfeeding

In 2016, most Australian women (55.6%) abstained from alcohol when pregnant, an increase from 40.0% in 2007 [1]. Despite the increase in the proportion of women abstaining from alcohol, more than one-third of women (34.7%) reported drinking alcohol when pregnant.

Once women found out they were pregnant, many reduced their alcohol consumption. Of those who did drink alcohol during their pregnancy, about half (48.7%) consumed alcohol before they knew they were pregnant, and just over a quarter (25.2%) consumed alcohol after they knew they were pregnant [1]. Among those who drank alcohol while pregnant, 81% consumed alcohol monthly or less often, and 16.2% consumed alcohol 2–4 times a month [1]. When drinking, most pregnant women (97.3%) consumed 1–2 standard drinks [1].

A similar trend was seen for breastfeeding women, with 41.9% of breastfeeding women abstaining from alcohol in 2016, compared with 25.0% in 2007 [1].

2.2.3 People over 60 years of age

In 2016, most adults aged 60–69 (78.7%) or 70 years and over (70.4%) in Australia reported consuming at least 1 full serve of alcohol in the past 12 months [1]. Overall, 18.2% of adults aged 60–69 and 11% of adults aged 70 years and over consumed on average more than 2 standard drinks per day; and 17.3% of people aged 60–69 years and 7.2% aged 70 years and over consumed more than 4 standard drinks on one occasion at least once a month [1].

Older people reported drinking more regularly than those in younger age groups. Those aged 70 years and over were the age group most likely to drink daily, for both males (19.5%) and females (8.7%) [1].

2.2.4 Very high alcohol consumption

Most Australians consume alcohol at low to moderate levels; however, some people drink at substantially higher levels.

In 2016, 15.4% of Australians aged 14 years and older reported consuming 11 or more standard drinks on a single drinking occasion in the past 12 months and about 7% reported doing so at least monthly [1].

2.3 Effects of alcohol

2.3.1 Many factors influence the impact of alcohol

Drinking alcohol has both immediate and cumulative effects. Alcohol-related harm in individuals is influenced not only by the amount of alcohol consumed, but by complex interactions between the age and experience of the drinker, their social environment, their genetics and their general health.

Due to individual variability, there is no amount of alcohol that can be stated as definitely safe for everyone. As discussed below, factors that affect individual responses to alcohol include:

- amount of alcohol consumed, rate and pattern of consumption
- sex
- age
- mental health conditions
- physical health conditions
- medication and drug use
- family history of alcohol dependence.

Amount of alcohol consumed, rate and pattern of consumption

Health risks increase if a given amount of alcohol is consumed over a shorter time or over fewer drinking occasions. Although drinking alcohol, even at low levels, can increase the risk of alcohol-related harm, the risks associated with drinking 1 drink every day of the week are significantly lower than the risk associated with drinking 7 drinks on a single occasion.

Sex

Women are more susceptible to the direct physiological effects of alcohol than men, and the immediate effects of alcohol occur more quickly and last longer for women. The same amount of alcohol leads to a higher blood alcohol concentration in women than in men because women tend to break down less alcohol in their stomachs and, on average, they have a smaller body size with a lower proportion of lean tissue.

At low levels of consumption, the physiological differences between women and men have only a small impact on lifetime risks of harm; hence, **the guidelines are the same for men and women**. However, as consumption increases, lifetime risk increases at a faster rate for women than for men. Conversely, men tend towards higher levels of risk-taking behaviour than women; as a result, they have a greater overall risk of immediate harm from drinking (e.g. road crashes, falls and self-harm), as described in Section 3.

Age

Younger and older people are more vulnerable to the harmful effects of alcohol than other adults [3]. Young people's physical immaturity, developing brain and inexperience of drinking and its effects — combined with an increased propensity towards risk-taking behaviours — expose them to a greater risk of harm. Similarly, older people's risk of harm is increased

because their ability to break down alcohol decreases, as does their tolerance for alcohol. Other risks that increase with age include the risk of falls and driving accidents, and the potential for adverse interactions with medications.

Mental health conditions

People who have a mental health condition, or are vulnerable to developing such a condition (e.g. anxiety, depression or schizophrenia) may experience a deterioration in their mental health after drinking.

Physical health conditions

People who have health conditions that are caused or exacerbated by alcohol are at risk of the condition becoming worse if they drink alcohol. Examples of such conditions include alcohol dependence, any sort of liver disease (e.g. alcoholic hepatitis or cirrhosis, and non-alcoholic fatty liver disease or viral hepatitis), pancreatitis and epilepsy.

Medication and drug use

Alcohol can interact with a wide range of over-the-counter and prescribed medications, herbal preparations and illicit drugs. This can alter the effect of either the alcohol or the other substances, and has the potential to cause serious harm both to the person drinking and to others.

Family history of alcohol dependence

People who have a family history of alcohol dependence (particularly among first-degree relatives) have an increased risk of developing alcohol dependence themselves.

These guidelines provide advice for the general Australian population on how to keep their risk of alcohol-related harm low. Given that alcohol can vary in how it affects individuals (owing to individual characteristics and variability in biological responses), people should take into consideration their own personal characteristics and their own attitudes to risk.

2.3.2 How alcohol affects the body

Alcohol usually starts to affect the brain within 5 minutes of being swallowed. The blood alcohol concentration reaches its peak about 30–45 minutes after the consumption of 1 standard drink (10 g alcohol). Consuming multiple drinks in quick succession results in a higher blood alcohol concentration because the liver has a relatively fixed rate of metabolism, regardless of how many drinks are consumed.

It generally takes about 1 hour for the body to process 1 standard drink, although this varies on an individual basis. The rate of metabolism depends on factors such as liver health, body mass and composition, and levels of alcohol-metabolising enzymes. Eating when drinking alcohol slows the increase in blood alcohol concentration, because food in the stomach reduces the speed at which alcohol is absorbed into the bloodstream. However, activities such as drinking coffee, having a cold shower or exercising do not reduce the blood alcohol concentration. After a heavy drinking occasion, it takes many hours for the blood alcohol concentration to return to zero.

2.3.3 Immediate and cumulative effects of alcohol

At the individual level, the effects of alcohol consumption include:

- · direct or indirect toxicity to several organs and body systems
- increased risk of a range of harms (e.g. accidents) after acute intoxication
- harms related to alcohol dependence.

Negative impacts on health depend on a range of factors (e.g. frequency of drinking and level of consumption), and can be observed in both the short and long term.

Immediate effects

Alcohol has immediate effects on the brain, beginning with feelings of relaxation and wellbeing, and loss of inhibitions. Many people who drink seek these effects when drinking socially. Alcohol reduces activity in the brain's arousal, motor and sensory centres, leading to diminished reactions to stimuli; it also affects coordination, speech, cognition and the senses.

As the intake of alcohol increases on a single occasion, there is an increase in adverse effects such as drowsiness, loss of balance, nausea and vomiting. Initial adverse effects of alcohol consumption are the potential decrease in fine motor skills and the loss of inhibitions. Individuals can also experience impaired judgement about their level of intoxication and its potential consequences. If the blood alcohol concentration increases, people can experience mental confusion, blackouts (gaps in their memory of events that occurred while intoxicated) and loss of consciousness. At even higher blood alcohol concentration levels, alcohol poisoning can be life threatening through inhibition of breathing, coma and asphyxiation. The risk of alcohol poisoning is increased by drinking alcohol in combination with over-the-counter, prescription or illicit drugs that are sedatives, pain medications or sleep aids, because such drugs suppress areas of the brain that control vital functions such as breathing.

In addition to direct effects on the body, the amount of alcohol consumed on a single occasion affects the risk of accidents and injury during and immediately after drinking. Each additional drink can increase the risk of injury and death for the drinker, and may place others at risk of harm. Adolescents and young adults are particularly vulnerable to these harms because their use of alcohol in social situations can contribute to a pattern of risk-taking behaviour. Alcohol consumption reduces the cognitive or verbal capacity to resolve conflicts, thereby increasing the likelihood of physical violence and other aggressive behaviours.

Cumulative effects

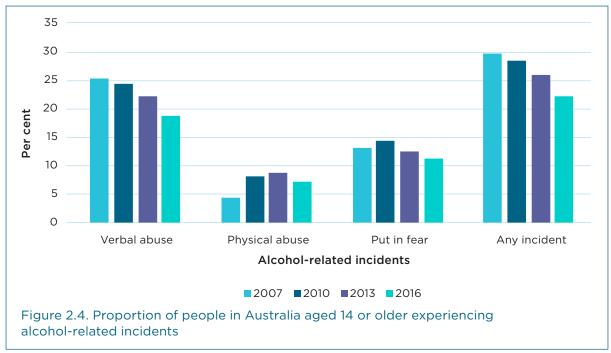
The cumulative effects of alcohol are those that result from drinking on many occasions over an extended period of time. Alcohol consumption has been associated with risks to the fetus during pregnancy (e.g. FASD) and to the baby through breastfeeding. Alcohol has also been associated with a range of long-term conditions such as cardiovascular disease, cancer, type 2 diabetes, nutrition-related conditions, obesity, liver disease, mental health conditions, alcohol use disorders and cognitive impairment [14–17].

The effect of alcohol on the cardiovascular system is complex. In the past, research has suggested that, at low levels, alcohol may confer some protection against heart problems. However, recent evidence has brought these effects into question — suggesting, for example, that they may not be present or that, if they are present, their magnitude may be smaller than previously thought (see the Rationale for Guideline 1). Additionally, alcohol has been linked to heart rhythm problems and heart failure, and to some types of stroke.

Alcohol has complex effects on diabetes and the insulin-glucose system. The effects can vary depending on the level of alcohol consumption (e.g. low or high level) and its duration (e.g. one-off drinking or long term). Pancreatic damage from repeated heavy drinking is a well-recognised cause of secondary diabetes.

Social consequences and costs

Alcohol-related harm may affect family members, bystanders and the broader community. It can contribute to family disruption, violence, crime, road accidents, work-related harms and community safety issues [1, 2, 18]. Alcohol-related incidents are common (reported by 22% of the Australian population in 2016); 'verbal abuse' has the highest reported rates, followed by 'being put in fear by someone under the influence of alcohol' and 'physical abuse' [1]. Figure 2.4 suggests that the prevalence of verbal abuse is declining, but the prevalence of physical abuse is not.

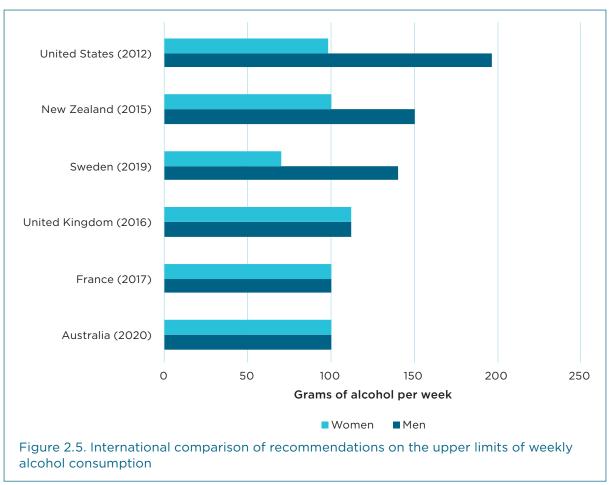


Source: Australian Institute of Health and Welfare, 2017 [1].

When health and social impacts are considered together, harmful alcohol use represents a significant financial burden to society. An Australian study estimated costs to society from alcohol-related problems at \$14.3 billion in 2010 [19]. However, the total cost is likely to be higher when costs associated with broader harms that occur to people other than the drinker are included. Laslett et al. (2010) earlier estimated that the additional tangible and intangible costs of alcohol's harm to others in 2008 were \$14.2 billion and \$6.4 billion respectively [18].

Comparisons with international guidelines

All international guidelines recommend limiting alcohol consumption to reduce harm, and over time guidelines have generally lowered their recommended limits. However, there is no global consensus on the exact level of alcohol consumption recommended to keep the risk of alcohol-related harm low. There is also no global consensus on whether women should drink as much as men or less, or on how a standard drink should be defined. Therefore, alcohol guidelines vary substantially from country to country. Figure 2.5 compares recommendations on weekly upper limits of alcohol consumption for various countries. Not included in this graph is the recommendation from the 2015 Dutch guidelines, which advise no drinking or, at most, 7 drinks or 70 g of alcohol each week (i.e. a single 10 g drink per day)[20].



Source: HealthLink BC, 2019 [21] and International Alliance for Responsible Drinking, 2019 [22].

3. Understanding concepts of risk

The risks associated with drinking alcohol are frequently underestimated. People often do not recognise that they are consuming alcohol in quantities damaging to their health, and tend not to think of themselves as having a problem with alcohol. Many people are unaware, for instance, of how alcohol consumption contributes to cancer, cerebrovascular, cardiovascular, liver and digestive disease [3].

These revised guidelines are based on evidence and current understanding of the harms associated with drinking. They provide a reminder that all alcohol consumption comes with some degree of risk and that these risks can be minimised, but not entirely eliminated, by drinking no more than the recommended maximum levels.

Understanding the risks helps people to make informed choices. Although the evidence shows that there is no level of alcohol consumption that is completely safe, the guidelines provide recommendations and information that can help people make informed choices. This can improve people's health by reducing the risk of alcohol-related harm.

The concept of 'alcohol-related' is central to these guidelines. It refers to an event or outcome of some kind (e.g. road crash, assault, disease, injury, death or hospitalisation) that is more likely to occur when someone consumes alcohol than when they do not consume alcohol. It can include outcomes where the evidence is clear that alcohol either causes the outcome or changes the likelihood it will happen. The term 'alcohol-related' may also refer to outcomes where it is less clear that alcohol directly causes the outcomes, but where epidemiological evidence indicates that an association exists. All of the risk estimates cited in these guidelines, as well as the research evidence and modelling that underpin them, pertain to relationships that have met epidemiological criteria for causality.

3.1 What is risk?

These guidelines use the epidemiological definition of risk, which is similar to, but more precise than, the everyday use of the word.

Risk refers to the probability (or chance) that an outcome may occur (although it is not certain that it will occur). For example, if you toss a coin there is one chance in two that the coin will land heads up. An average person's risk of experiencing a negative health outcome due to drinking alcohol is the probability that the person will develop that outcome in a specified time period (e.g. after 1 night's drinking or across a lifetime). Alcohol-related risk depends on a range of factors, including how much and how often alcohol is consumed.

Lifetime risk refers to the probability that a negative health outcome will occur during an average person's lifetime. A common method of measuring risk is the 'lifetime risk of death'; that is, the probability of dying prematurely from a condition caused by exposure to a hazardous substance or substances.

Lifetime risk of alcohol-related harm refers to an average person's probability (or chance) of experiencing a harm from alcohol at any point over their lifespan. This might include their probability of dying prematurely or being hospitalised because of a harm caused by drinking alcohol.

3.2 Where do the estimates of risk of drinking alcohol come from?

The estimates of risk associated with drinking alcohol presented in these guidelines come from reviews of many research studies that included large numbers of people. Such reviews help to determine the probability (or chance) that an average person will develop a disease over a certain period of time (e.g. over a lifetime) if alcohol is consumed above a given level. Likewise, they help to determine the probability of injury from drinking alcohol, such as having a fall or crashing a car. There is a large amount of research in this area, but consequences from drinking alcohol are complex areas to study and the results of any one study alone are not always reliable or directly applicable to the issue of estimating risk. When many studies are included, their combined results are more likely to be accurate because they smooth out inconsistencies in individual studies related to study design, settings and random chance. A wider breadth of studies can also give a more complete picture of what the risks might be.

These guidelines have assessed the evidence across many studies to determine the overall risk that results from drinking alcohol. In contrast, reports of new single studies in the media often fail to take into account the entire evolving body of evidence. This can create confusion. It is important that public health guidelines are based on the assessment of a large body of evidence.

As well as using evidence across many studies, the development of Guideline 1 made use of mathematical modelling of the relationship between alcohol consumption and disease and death. The modelling made it possible to assess different levels of risk.

3.3 Are the risks the same for men and women?

Women are more susceptible than men to the direct physiological effects of alcohol. For women, the immediate effects of alcohol occur more quickly than for men; they also last longer. In addition, lifetime risk of disease will climb at a faster rate for women once low levels of alcohol use have been exceeded. However, men tend towards higher levels of risk-taking behaviour, and thus have a greater overall risk of immediate harm from drinking (e.g. road crashes, falls and self-harm) [23-28].

Due in part to the countering effects of these sex-based physiological and behavioural differences, *at low levels of alcohol consumption*, lifetime risks of harm are similar for men and women. In the 2009 alcohol guidelines, the guidelines for men and women were the same [4]. The Expert Committee advised that for the current guidelines there was not sufficiently strong new or further evidence (despite the above sex differences) to consider separate guideline advice for men and women (see Section 4.3.1 for more information).

3.4 Risks for each guideline

Each of the three guidelines refers to the risks for their target audience: adults, children and people under 18 years of age, and women who are pregnant or breastfeeding. This subsection explains how the concepts of risks were applied in each case.

3.4.1 Concept of risk for Guideline 1

Guideline 1 provides recommendations to reduce the risk of alcohol-related harm, but it cannot completely rule out all risk from drinking alcohol. The guideline refers to the maximum amount of alcohol that an average, healthy adult could drink without exceeding a 1 in 100 chance of dying from alcohol-related disease and injury over their lifetime. The risk threshold applied in these guidelines of 1 in 100 has been used in Australian alcohol guidelines for more than 10 years. If people were to follow this advice consistently, their lifetime risk of dying from an alcohol-related disease or injury would be less than 1 in 100 on average; that is, fewer than 1 out of every 100 Australians drinking at this level is likely to die of an alcohol-related condition. Different risk thresholds were considered (e.g. 1 in 50, 1 in 100 and 1 in 1000), but the risk threshold of 1 in 100 for lifetime risk of death from an alcohol-related disease or injury was the basis of the previous version of the guideline (2009) [4], and the Expert Committee identified no compelling evidence to suggest that it should be changed.

The level of risk that people and societies consider 'acceptable' is influenced by whether the risk is involuntary or voluntary. Involuntary risks are those that people have no choice over, such as being exposed to potential toxins in water or soil when drinking tap water or working in the garden. Voluntary risks are those over which a person may have some choice, such as choosing to drive a car or take up skydiving.

Generally, acceptable levels of risk for involuntary exposures are set much lower than those for behaviours that are freely chosen. For example, the limit often used in Australia for toxins in drinking water is a risk of 1 in one million of dying [29]. A child drinking tap water is not choosing to take on a risk of poisoning. However, for behaviours that are seen as freely chosen, higher risks are routinely accepted by individuals [30]. For example, the lifetime risk of dying in a car crash in the United States (US) has been calculated to be about 1 in 110 [31].

In drinking alcohol, a person is (at least in some respects) voluntarily accepting these risks. It is important to bear in mind that alcohol also causes harm to communities and to people other than the person drinking. Although this guideline is based on evidence about direct harm to the individual, Guideline 3 in particular considers harms beyond the person drinking.

Judgements about how acceptable a risk is are based on the assumption that there is some benefit to the individual in undertaking that risky activity. However, people do not only assess risk against benefits. They often take into account features such as control over the risk taking, familiarity with the risk, how soon the harm would be experienced, whether the harm might be severe, and whether the harm or benefit is short-term or long-term in nature. All these factors influence individual perceptions of what constitutes 'acceptable versus unacceptable risk'.

What does this mean for Guideline 1?

An individual's perception of risk is complex, and the judgement about balancing risks and benefits may vary with the circumstances, which makes it challenging to clearly communicate the concepts of risk at a population level. The Expert Committee looked at the amount of alcohol consumption related to the population level of risk for a typical Australian drinker (on average drinking 3 times per week). The Expert Committee also considered the importance of clear communication to the public. Given uncertainties over the existence and extent of the protective effects of alcohol, if the Expert Committee had to 'round up' or 'round down' a consumption level, they chose to round down the amount of consumption, taking a precautionary approach.

Guideline 1 in general aims to keep the lifetime risk of dying from an alcohol-related disease or injury below 1 in 100 for average healthy men and women drinkers. Not all people who drink will be comfortable with a 1 in 100 risk. It should also be understood that the risks associated with drinking alcohol can be further reduced (to below 1 in 100) by drinking at levels below these guidelines. Appendix 2 presents tables and figures that illustrate how the different levels of risk (e.g. 1 in 50, 1 in 500 and 1 in 1000) relate to quantities of alcohol use over a week.

3.4.2 Concept of risk for Guideline 2

Guideline 2 considers risk of harms for people under 18 years of age. As well as considering emerging and established evidence of alcohol-related harms to those under 18 years of age, the Expert Committee considered the precautionary principle to supplement its advice to these Australians. This principle is based on the idea that it is better to take preventive or precautionary steps now, rather than have to deal with alcohol-related harms later in life. It is often used when a risk of harm is credible but there is not a large body of evidence to enable clear advice, and where there is a duty or responsibility to act and protect some in the community [32].

There is no clear 'safe' or 'no-risk' level of alcohol consumption for children and young people under 18 years of age. This is because of the increased risks of harm from alcohol for young people, including from physical injury, potential adverse effects on brain development, mental health problems, self-harm and risky sexual activity. More details on these potential harms are given in Section 5.2.

Young people are particularly vulnerable to the harmful effects of alcohol because of their developing body and brain, and their inexperience with the effects of drinking alcohol. These factors, combined with a greater likelihood of risk-taking behaviours, expose young people to a heightened risk of injury.

3.4.3 Concept of risk for Guideline 3

Guideline 3 considers the risk of harms beyond the person drinking: to a fetus and to a baby who is being breastfed. Here, the risk is being borne by a third party who has no voluntary choice; hence, a more conservative concept of risk is employed. As well as considering emerging and established evidence of alcohol-related harms to the fetus and breastfed infant, the Expert Committee applied the precautionary principle for Guideline 3.

Women who are pregnant

Avoiding drinking alcohol during pregnancy prevents the risk of alcohol-related harm to the developing fetus. The existing evidence does not identify a safe amount of alcohol that pregnant women can drink. As there is a risk of lifelong harm to the unborn child, this guideline takes a precautionary approach and recommends not drinking alcohol when pregnant.

The risk of harm to the fetus increases the more the mother drinks and the more frequently she drinks. More details on these potential harms are given in Section 6.1.

A variety of maternal and fetal factors can affect the risks from drinking alcohol while pregnant (e.g. genetic differences, metabolic rates, and biochemical and inflammatory responses to alcohol). These factors make it difficult to predict the level of risk in each individual pregnancy. Thus, the Expert Committee again applied a precautionary approach.

Women who are breastfeeding

The evidence does not identify a 'safe' or 'no-risk' level of alcohol that breastfeeding women can drink. This guideline takes a precautionary approach and recommends that it is safest for the baby if breastfeeding women do not drink alcohol.

4. Guideline 1: Reducing the risk of alcohol-related harm for adults

Guideline 1

To reduce the risk of harm from alcohol-related disease or injury, healthy men and women should drink no more than 10 standard drinks a week and no more than 4 standard drinks on any one day.

The less you drink, the lower your risk of harm from alcohol.

This guideline applies to healthy men and women aged 18 years and over. The guideline does not represent a 'safe' or 'no-risk' drinking level, nor does it set an absolute upper limit of intake. It identifies a level of drinking at which, based on the current scientific evidence, the risk of alcohol-related harm remains low over a lifetime, in terms of both risk of death from alcohol-related disease and death from alcohol-related injury.

Key messages

- This guideline provides recommendations to reduce the risk of harm from alcohol, but these recommendations do not completely eliminate all risk from drinking alcohol.
- For both men and women, the risk of dying from alcohol-related disease and injury remains below 1 in 100 if no more than 10 standard drinks are consumed each week and no more than 4 standard drinks are consumed on any one day.
- Every drink above this level increases the lifetime risk of alcohol-related disease and injury. This includes the risk of dying from alcohol-related disease or injury.
- Drinking alcohol increases the risk of many cancers. The level of risk increases as more alcohol is consumed.
- Drinking less frequently, and drinking less on each day or drinking occasion, further reduces the lifetime risk of harm from alcohol.
- Not drinking at all is the best way to reduce the risk of harm from alcohol.
- This guideline applies to most healthy adults; however, there are some people who are at greater risk of alcohol-related harm. Those at greater risk include young adults aged 18-25 years, people aged over 60 years, people with mental or physical health conditions, people with a family history of alcohol dependence, and people who use illicit drugs or take medications that interact with alcohol.
- This guideline does not apply to children and young people under the age of 18 years (see Guideline 2), or to women who are planning a pregnancy, or are pregnant or breastfeeding (see Guideline 3).

Rationale

Most Australian adults drink alcohol, generally for enjoyment and sociability. At the same time, alcohol is known to cause harm. Alcohol is responsible for 4.5% of the total burden of disease and injury in Australia [6]. It also leads to significant social and financial consequences for individuals and the community [6]; hence reducing alcohol-related harm is a priority.

The aim of Guideline 1 is to provide evidence-based advice on the risk of harms from drinking alcohol, to enable members of the public to make an informed choice on what level of alcohol consumption is acceptable in terms of health.

To reduce the risk of harm from alcohol-related disease and injury, it is recommended that healthy men and women drink no more than 10 standard drinks a week and no more than 4 standard drinks on any one day.

This recommendation is based on a comprehensive evaluation of the evidence, including systematic reviews, meta-analyses, mathematical modelling, public health considerations and expert judgement. The advice in the 2009 version of these guidelines formed the basis of this revised edition, and that advice was updated where the evidence indicated that updating was required. If there were no compelling reasons to change the 2009 version, its content is re-presented here with editorial changes only. For further information about the evidence base and other inputs used to develop the guidelines, see Figure 1.1 in Section 1. Other key considerations are described below.

Risk

There are numerous concepts about the risks of harm from drinking alcohol that are important to understand; these are explained in Section 3.

Balancing the evidence on the range of effects of consuming alcohol

In recent years, clearer evidence has emerged about the harms of alcohol, including new evidence on increased risks of cancer that occur even at low levels of regular consumption. In the past, most researchers considered that low levels of alcohol consumption were likely to provide some protection against coronary heart disease. However, the evidence for such 'protective effects' has faced ongoing challenges for many years; for example, there is a lack of clarity about whether observed changes in drinking patterns, particularly the reduced consumption that occurs as people age, are a consequence or a cause of ill-health.

Gathering accurate information about exposure to alcohol has also been a challenge, because most studies have relied on self-reporting of alcohol consumption, which can often be inaccurate. Doubt about the evidence underpinning protective effects has increased over the past decade, largely as a result of improved approaches to research study designs [33]. These improvements include larger studies, better approaches to controlling confounding and study bias, and the ability to use new kinds of evidence, such as 'Mendelian randomisation' studies (see Appendix 6). These newer studies greatly reduce some of the issues with earlier evidence.

With regard to cardiovascular disease, the evidence of an association between increasing risk of stroke with increasing alcohol consumption has become clearer in recent years, and protective effects for stroke overall seem unlikely [33–35]. The evidence also suggests either that alcohol may not protect against coronary heart disease, or that the extent of protection previously determined was an overestimate [36, 37].

It is important to emphasise evidence from studies that focus on robust clinical endpoints (e.g. stroke and heart attack) rather than markers of disease risk (e.g. blood pressure and lipid levels). Although markers are important as risk factors and are related to alcohol consumption, alcohol is likely to modify other factors (e.g. those related to clotting), meaning that it is not possible to know from studies of markers alone how alcohol influences disease risk. In addition, most studies that show cardiovascular benefits of low-level alcohol consumption also show that any such protection is available at very low doses; for example, at less than 0.5-1 standard drink per day [35, 36, 38], which is well below the level set by most countries in their guidelines to reduce risk from drinking.

The modelling for these guidelines shows that, if any protective effect for coronary heart disease exists, it is likely to only offset harms from alcohol in people 70 years of age and over. Based on current drinking patterns, in those under about 50 years of age, harms from alcohol outweigh these benefits. Because a large proportion of premature deaths occur at older ages, statistical modelling of the impact of alcohol on mortality can be greatly affected by whether or not it is assumed that there are health benefits from alcohol.

Even if it is shown that alcohol has protective effects for coronary heart disease, alcohol consumption will still increase the risk of other health conditions such as cancer and stroke. Further, there are safer ways to reduce risk of coronary heart disease; for example, by maintaining a healthy weight, reducing blood pressure and not smoking [33].

If protective effects are overestimated, then the recommended alcohol consumption limits in the guidelines may be too high. In this case, following the guidelines could expose the population to a risk greater than 1 in 100. By presenting alternative statistical models with potential protective effects either included or excluded (see Section 4.3 and Appendix 2), this report shows the magnitude of the impact of an assumption of protective effects of low levels of alcohol consumption on these guidelines. If the protective effects were excluded, the amount of alcohol able to be consumed to keep the lifetime risk of dying from an alcohol-related disease or injury at less than 1 in 100 would be much less than 10 drinks per week.

Despite the continued uncertainty over the existence and extent of any protective effect, and the fact that evidence continues to emerge, the modelling for this guideline incorporates some protective effects of alcohol where indicated.

Average number of days Australian drinkers consume alcohol

The term 'drinking frequency' in this guideline refers to how many days in a week (7 days) alcohol is consumed; that is, days per week. The research evidence uses the terms 'drinking days' and 'drinking occasions' interchangeably, or does not clearly distinguish between those terms (see Appendix 6 for definitions).

The risk for a given level of alcohol consumption over a week varies depending on how that consumption is spread. For a given quantity of alcohol, consumption on fewer, heavier drinking days poses higher risks than consumption on more frequent, lighter drinking days. To provide clear guidelines, an estimate of the average weekly drinking frequency for Australians was developed. Analysis of Australian drinking patterns from the NDSHS found that, on average, Australians who do drink alcohol consume it on 3 days per week (see Appendix 1). This drinking pattern was used to interpret the modelling results (see modelling report at <u>www.nhmrc.gov.au/alcohol</u>) and to inform the recommendations of this guideline.

4.1 Scientific evidence

These guidelines were informed by a comprehensive evaluation of the evidence, drawing on systematic reviews, meta-analyses and additional scientific evidence. Systematic reviews are quantitative reviews of the scientific evidence that summarise data across multiple studies; they are conducted using standardised criteria and an approach that can be replicated. Meta-analyses synthesise findings from existing studies.

To update the evidence base for this guideline and its recommendations, systematic reviews of the evidence on the health effects of alcohol consumption and mathematical modelling of the harms and benefits of alcohol consumption were conducted.

4.1.1 Systematic reviews

An overview of systematic reviews was completed to consider the short-term and long-term health risks and benefits associated with alcohol exposure (drinking alcohol) (report available at <u>www.nhmrc.gov.au/alcohol</u>). The analysis focused on identifying systematic reviews and meta-analyses published since 2007, to identify areas where the evidence has grown since publication of the 2009 alcohol guidelines. Two additional systematic reviews were completed to fill evidence gaps for the association between drinking alcohol and mental health and cognitive impairment outcomes (reports available at <u>www.nhmrc.gov.au/alcohol</u>). The health outcomes included in the overview of systematic reviews and additional systematic reviews are summarised in Table 4.1. Information about the population, exposure and outcome criteria included is available in the systematic review reports at <u>www.nhmrc.gov.au/alcohol</u>.

Health conditions	
Long-term health conditions	
All-cause mortality	Ovarian cancer
Bladder cancer	Pancreatic cancer
Brain cancer	Prostate cancer
Breast cancer (premenopausal)	Stomach cancer
Breast cancer (postmenopausal)	Thyroid cancer
Cervical cancer	Coronary heart disease
Colorectal cancer	Atrial fibrillation
Endometrial cancer	Heart failure
Gallbladder cancer	Ischaemic stroke
Kidney cancer	Intracerebral haemorrhage
Liver cancer	Subarachnoid haemorrhage
Lung cancer	Hypertension
Hodgkin's lymphoma	Liver cirrhosis
Non-Hodgkin's lymphoma	Pancreatitis
Leukaemia	Type 2 diabetes
Multiple myeloma	Dementia and cognitive decline
Melanoma	Seizures
Mouth and pharynx cancer	Hip fracture
Larynx cancer	Gout
Oesophageal squamous cell carcinoma	Pneumonia
Oesophageal adenocarcinoma	Tuberculosis

Table 4.1. Health conditions included in the overview and systematic reviews to inform Guideline 1

Health conditions	
Short-term health conditions	
Injury	Ischaemic stroke
Fatal motor vehicle injury	Haemorrhagic stroke
Myocardial infarction or coronary event	
Mental health conditions	
Depression / depressive symptoms	Suicide / suicide ideation / suicide attempts
Anxiety / anxiety symptoms	Post-traumatic stress disorder / post-traumatic stress disorder symptoms
Bipolar disorder	
Cognitive impairment conditions	
Cognition	

4.1.2 Modelling

Together with the reviews of the published evidence (see Section 4.1.1), and other inputs (see Figure 1.1 in Section 1) Guideline 1 is informed by mathematical modelling, which estimates the risk of dying from alcohol-related disease and injury from different levels and patterns of drinking. The model simulates the relationship between any given level of alcohol consumption and the risk of disease and death for different age groups in Australia. From this, alcohol consumption levels that corresponded with four different levels of risk of dying from alcohol-related disease or injury (1 in 1000, 1 in 500, 1 in 100, and 1 in 50) were identified.

The risk threshold chosen for this guideline corresponds to a 1 in 100 chance of dying from alcohol-related disease or injury for an average, healthy adult who drinks alcohol (see the Rationale for Guideline 1). This is consistent with the threshold used in the 2009 alcohol guidelines [4]. The analyses from the modelling are outlined in more detail in the modelling report (see www.nhmrc.gov.au/alcohol).

Modelling was undertaken using an adaptation of the Sheffield Alcohol Policy Model v2.7, which is a mathematical simulation model that has previously been used to assess alcohol policy options in the United Kingdom and internationally.

The key data inputs into this Australian adaptation of the Sheffield Alcohol Policy Model were:

- current levels and patterns of alcohol consumption in Australia
- data on alcohol-related morbidity (defined as person-specific hospital admissions) and mortality in Australia
- international and Australia-specific evidence linking different levels and patterns of alcohol consumption to risk of morbidity or mortality for 42 separate health conditions causally related to alcohol consumption, drawn from the overview of systematic reviews (see Section 4.1.1).

Conditions included in the model (outlined in Table 4.2) were divided into four categories:

- 1. *Partially attributable, chronic* These are conditions that can occur without drinking alcohol, but for which the risk of them occurring changes with long-term exposure to alcohol (e.g. breast cancer).
- 2. *Partially attributable, acute* These are conditions that can occur without drinking alcohol, but for which the risk of them occurring changes in the short term with exposure to alcohol (e.g. falls).
- 3. *Wholly attributable, chronic* These are conditions that can only occur from drinking alcohol. The risk of these conditions occurring changes with long-term exposure to alcohol (e.g. alcoholic liver disease).
- Wholly attributable, acute These are conditions that can only occur from drinking alcohol. The risk of them occurring changes with short-term exposure to alcohol (e.g. alcohol poisoning).

Table 4.2. Alcohol-attributable health conditions included in the Australian adaptation of the Sheffield Alcohol Policy Model

Oesophageal cancer Stomach cancer Colorectal cancer Liver cancer Pancreatic cancer Breast cancer Prostate cancer Non-Hodgkin's lymphoma	Other cerebrovascular diseases Chronic hepatitis, fibrosis and cirrhosis of liver Fatty liver disease Acute pancreatitis (other) Chronic pancreatitis (other) Tuberculosis Diabetes (Type 2)
Colorectal cancer Liver cancer Pancreatic cancer Breast cancer Prostate cancer	Fatty liver disease Acute pancreatitis (other) Chronic pancreatitis (other) Tuberculosis
Liver cancer Pancreatic cancer Breast cancer Prostate cancer	Acute pancreatitis (other) Chronic pancreatitis (other) Tuberculosis
Pancreatic cancer Breast cancer Prostate cancer	Chronic pancreatitis (other) Tuberculosis
Breast cancer Prostate cancer	Tuberculosis
Prostate cancer	
	Diabetes (Type 2)
Non-Hodgkin's lymphoma	
	Epilepsy and status epilepticus (seizures)
Hypertension	Pneumonia
Chronic ischaemic heart disease	Gout
Atrial fibrillation	
Partially alcohol-attributable acute conditions	
Intentional self-harm	Accidental poisoning (other)
Unintentional falls (without hip fracture)	Motor vehicle injury
Unintentional falls (with hip fracture)	Other injury and poisoning
Accidental poisoning (by drugs, medicaments, biological substances and other nonmedicinal substances)	Acute myocardial infarction
Wholly alcohol-attributable chronic conditions	
Alcoholic cardiomyopathy	Degeneration of nervous system due to alcohol
Alcoholic liver disease	Alcoholic polyneuropathy
Acute pancreatitis (alcohol-induced)	Alcoholic myopathy
Chronic pancreatitis (alcohol-induced)	Alcohol-induced pseudo-Cushing's syndrome
Alcoholic gastritis	Mental and behavioural disorders due to alcoho

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To model the impacts of drinking on the above health conditions, drinking behaviour in the model was defined as:

- mean (average) weekly alcohol consumption (in standard drinks) for *long-term exposure* to alcohol
- the amount of alcohol consumed on a person's heaviest drinking day during the past year (peak daily consumption) for *short-term exposure* to alcohol.

The model divided the Australian population into 30 groups defined by their age and sex. It combined the risk estimates for each condition to produce an overall estimate of each group's risk of dying due to alcohol for any given level of mean weekly and peak daily alcohol consumption.

From these estimates, a set of risk curves (i.e. curves that show the relationship between lifetime risk of alcohol-attributable mortality and different levels of mean weekly alcohol consumption) were derived for men and women. The curves varied depending on how people who drink spread their alcohol consumption across the week, because this affects peak daily consumption and therefore the risk of acute conditions. For example, the model recognises that consuming 20 standard drinks in 1 day carries a greater risk of acute conditions than spreading those drinks evenly over 7 days, while the risk for chronic conditions stays the same (except for certain circumstances associated with chronic ischaemic heart disease – see the modelling report at www.nhmrc.gov.au/alcohol). Application of the modelling results relied predominantly on estimates assuming that drinking was spread across 3 days a week. This is the average number of days per week that Australians (who consume alcohol) drink, based on analyses of drinking patterns from the NDSHS (see Appendix 1).

Key modelling results are further explained in Appendix 2.

4.1.3 Additional scientific evidence

To complement the systematic reviews (outlined in Section 4.1.1) and the mathematical modelling (outlined in Section 4.1.2), NHMRC made a public call for submissions of evidence on health risks and benefits of alcohol consumption. The public call for evidence helped to identify relevant studies and gaps in the evidence; it also identified areas of concern for the public and stakeholders. The public call had clear inclusion and exclusion criteria to ensure that only studies of a reasonable quality were accepted (see Appendix 5).

Given that this additional literature was collected outside the systematic review process, the submitted evidence could not be evaluated using the GRADE approach that was used for the systematic reviews (see Appendix 5). Instead, the evidence from the public call was considered along with the evidence from the 2009 alcohol guidelines, systematic reviews and modelling to inform the narrative text for this guideline.

4.2 Where has the evidence changed?

Research since the 2009 Australian guidelines to reduce health risks from drinking alcohol [4] has reinforced earlier evidence on the risks of alcohol-related harm for a range of chronic diseases, accidents and injuries. In addition, the growing body of evidence shows the following:

- The relationship between certain cancers and low levels of alcohol consumption (<1 standard drink per day) is now stronger than previously recognised [17].
- Drinking alcohol increases the risk of certain cancers, including breast, liver, pancreatic, colorectal, oesophageal, mouth and throat (pharynx and larynx) cancer [17]. The level of risk increases as more alcohol is consumed.
- Lower levels of alcohol consumption were previously thought to provide some protection against coronary heart disease and type 2 diabetes, with such protection available from about 0.5–1 standard drinks per day. There is now greater uncertainty about the evidence that was previously thought to support this 'protective effect' [33].

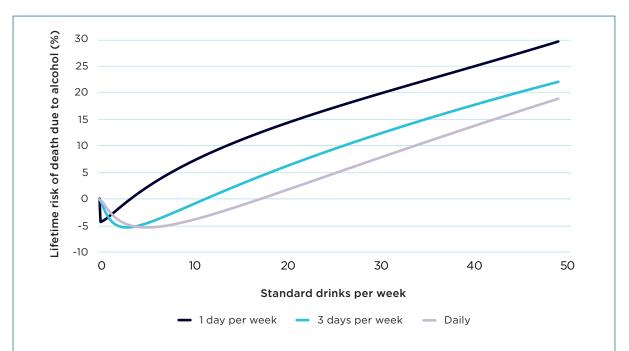
4.3 Patterns and levels of drinking

This guideline often uses the terms 'drinking patterns' and 'drinking levels'. There is no single agreed international consensus on the precise definition of 'drinking pattern', but the term generally refers to a composite measure of both how much (quantity) and how often (frequency) a person drinks alcohol. Heavy regular consumption, low-level occasional consumption and heavy episodic drinking are different types of drinking patterns, any one of which might describe an individual's or a population's usual or average drinking over a specified period of time (e.g. a week or a year). 'Drinking level' specifically concerns how much alcohol someone drinks over a set period of time, measured in grams of pure alcohol or standard drinks; it can be thought of as the quantity component of a drinking pattern.

Figures 4.1 and 4.2 show lifetime risk of death from alcohol for average healthy men and women. They show that risk varies, depending on how much alcohol is drunk in an average week and how consumption of that alcohol is spread over the week. The figures show that once total weekly consumption moves beyond low levels, lifetime risk of alcohol-related death steadily increases as the amount of alcohol consumed increases. The figures are based on modelling that incorporates consideration of protective effects for key conditions, which explains why mortality risk initially falls below zero. Each figure also includes three drinking frequency scenarios: drinking on 7 days a week (daily), drinking on only 1 day a week and drinking on 3 days a week. A comparison of the three scenarios reveals that, for the same total number of standard drinks consumed, the risk of alcohol-related death is higher when that alcohol is consumed on fewer days rather than being spread more evenly across a week. For example, lifetime risk of death is higher when 10 standard drinks are drunk over 7 days. The increased risk of death associated with higher levels of alcohol consumption and with the drinking concentrated on fewer days per week applies to both men and women (see Section 4.3.1).

The risk threshold selected for this guideline relates to a 1 in 100 (i.e. 1%) chance of dying from an alcohol-related condition, given the average level of consumption for the Australian population. Detailed information about alternative risk thresholds and different levels and patterns of drinking is provided in Appendix 2.

The data presented in Figures 4.1-4.3 include consideration of a protective effect of alcohol, which is increasingly being questioned (see the Rationale for Guideline 1). Protective effects were included in the main modelling for this guideline. In the modelling analysis option where protective effects are removed, the level of weekly alcohol consumption that corresponds to a 1 in 100 risk of dying is considerably lower — about 3 standard drinks per week for both men and women. Appendix 2 provides more details about these results.



Notes:

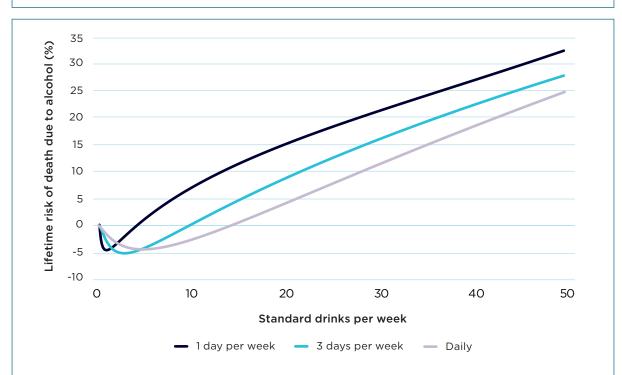
1. Y-axis represents absolute lifetime risk.

2. X-axis represents the average total number of standard drinks (each, 10 g pure alcohol) consumed over a 7-day period.

3. Risk curves relate to healthy men.

4. The risk threshold selected for this guideline is a 1 in 100 (1%) chance of dying from an alcohol-related condition.

Figure 4.1 Lifetime risk of alcohol-related death for Australian men by drinking frequency and average quantity consumed (standard drinks) over a week



Notes:

1. Y-axis represents absolute lifetime risk.

2. X-axis represents the average total number of standard drinks (each, 10 g pure alcohol) consumed over a 7-day period.

3. Risk curves relate to healthy women.

4. The risk threshold selected for this guideline is a 1 in 100 (1%) chance of dying from an alcohol-related condition.

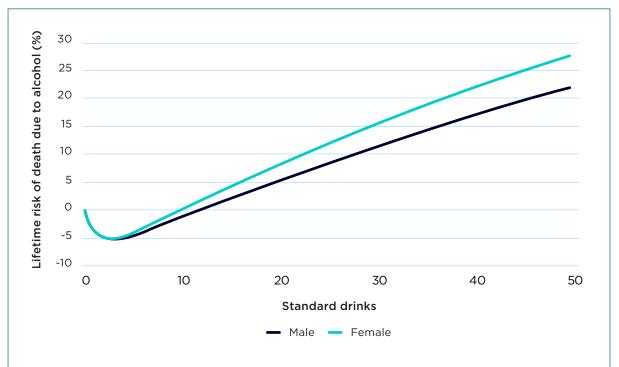
Figure 4.2 Lifetime risk of alcohol-related death for Australian women by drinking frequency and average quantity consumed (standard drinks) over a week

4.3.1 Alcohol impacts in men and women

Alcohol has broadly similar effects in both sexes. At low levels of consumption, the physiological differences between women and men have only a small impact on the risk of harms. As explained in section 3, the immediate effects of alcohol occur more quickly and last longer for women. The same amount of alcohol leads to a higher blood alcohol concentration in women than men because women tend to break down less alcohol in their stomachs; also, women generally have a smaller body size and a lower proportion of lean tissue than men. Men, however, tend towards higher levels of risk-taking behaviour than women and, as a result, they have a greater overall risk of immediate harm from drinking (e.g. road crashes, falls and self-harm).

At low levels of consumption, the physiological differences between women and men have only a small impact on lifetime risks of harm; however, as consumption increases, lifetime risk of harm increases at a faster rate for women.

Figure 4.3 compares the risk curves for men and women who spread their alcohol consumption evenly across 3 days per week. This figure shows that women have a higher lifetime risk of dying from disease or injury caused by alcohol than men at all levels of consumption. However, the absolute difference is small at lower levels of consumption and larger at higher levels. This general trend applies, regardless of how people spread their drinking across a week.



Notes:

1. Y-axis represents absolute lifetime risk.

2. X-axis represents average total number of standard drinks (each, 10 g pure alcohol) consumed over a 7-day period.

- 3. Risk curves relate to healthy men and women.
- 4. The risk threshold selected for this guideline is a 1 in 100 (1%) chance of dying from an alcohol-related condition.

Figure 4.3. Lifetime risk of alcohol-related death for Australian men and women when alcohol consumption is spread over 3 days in a week.

4.4 How was this recommendation developed?

The Expert Committee determined the most appropriate and scientifically supported recommendation for the maximum number of standard drinks that healthy Australians may consume before substantially elevating their risk of dying from alcohol-related disease or injury. To do this, the Expert Committee took into account the more general inputs into the guidelines (see Section 1) and combined all of the relevant data and information, including the systematic reviews, mathematical modelling and additional evidence (see Sections 4.1.1–4.1.3).

Current evidence indicates that Australian adults who consume alcohol do so, on average, on 3 days per week (see Appendix 1). Given this frequency of alcohol consumption, consuming 10 standard drinks or fewer per week corresponds to a 1 in 100 risk of dying from alcohol-related disease or injury for men and women, or less (see the Rationale for Guideline 1). Consuming no more than 4 standard drinks on any one day for both men and women is also consistent with this risk threshold.

These levels of consumption represent the appropriate evidence-based guidance, at this point in time, for Australians. The guideline takes into consideration a range of factors, including average patterns of drinking in Australia, the need to have straightforward advice that can be used by both men and women, the uncertainty about protective effects outlined above and the need for a precautionary approach. Section 1 provides information about how the guidelines were developed and the evidence base used, with Figure 1.1 depicting the evidence and other inputs used to develop the guidelines.

4.5 Other considerations about the harms associated with drinking alcohol

The immediate risk of harm from drinking alcohol increases as the amount of alcohol consumed increases. A person's blood alcohol concentration reflects the amount of alcohol consumed and the level of risk the person may experience from the acute effects of alcohol. The immediate risk of harm from drinking a given amount of alcohol is higher in some situations than in others. Alcohol also contributes to violence, including domestic violence [39, 40]. These situations are described below.

4.5.1 Activities that require attention, concentration or psychomotor skills

A raised blood alcohol concentration is associated with reduced performance; this is important for those undertaking activities that require attention, concentration or psychomotor skills.

As reported in the 2009 NHMRC alcohol guidelines [4], blood alcohol concentrations of up to 0.05 g/dl may not significantly impair psychomotor performance, but can impair cognitive function sufficiently to impair performance. For example, maritime cadets showed significantly impaired performance on simulated ship handling at blood alcohol concentrations of 0.04–0.05 g/dl [41].

In 44% of all watercraft-related drownings reported in an American study, the deceased had a blood alcohol concentration of 0.05 g/dl or higher [42].

Given that alcohol consumption affects performance, and that the acute effects of drinking can endanger the lives of both the person who has been drinking and others, in some situations the safest option is to not drink; for example, when:

- taking part in activities that require attention, concentration or psychomotor skills, such as driving, riding a bicycle, water activities, snow sports, flying an aircraft or operating heavy machinery
- supervising others who are taking part in such activities
- supervising children.

The acute harmful effects of alcohol may be increased by interactions between alcohol and illicit drugs. They can also be increased by interactions with prescribed and over-the-counter medications and sedative substances.

4.5.2 Driving

Drinking at levels resulting in a blood alcohol concentration greater than 0.05 g/dl can interfere with coordination and judgement, and thus increase the risk of motor vehicle accidents [17, 43]. Australian state and territory laws set a maximum blood alcohol concentration of 0.05 g/dl while driving for full licence holders, and require a blood alcohol concentration of zero for learner and provisional drivers.

To protect public safety, those who operate commercial aircraft, public or heavy vehicles, commercial vessels, machinery, and mobile plant or farm equipment may be required to comply with a lower blood alcohol concentration.

4.6 Special population groups

Although this guideline applies to most healthy men and women, there are some people who may experience an increased risk of harm if they drink alcohol and may therefore need to seek professional advice about drinking. These people include:

- young adults aged 18–25 years
- people aged over 60 years
- people with physical health conditions affected by alcohol
- people with mental health conditions
- people with a family history of alcohol dependence
- people who use illicit drugs or take medications that interact with alcohol.

These people are considered in detail below. Issues relevant to those under 18 years of age are considered in more detail under Guideline 2. For issues relevant to women who are pregnant or breastfeeding, see Guideline 3.

4.6.1 Young adults aged 18-25 years

Young adults aged 18–25 years are likely to be at an increased risk of alcohol-related harm, particularly injury.

In addition to following Guideline 1, young adults are encouraged to take steps to minimise their risk of accidents and injury, and of other harms related to alcohol. The issues for young adults are similar to those for adolescents (see Guideline 2), specifically:

- alcohol affects the young person's developing brain; thus, drinking, particularly heavy drinking, at any time before brain development is complete (which is not until around 25 years of age) may adversely affect later brain function
- as with adolescents, young adults tend to be greater risk takers than older adults, a factor that is reflected in the high levels of injuries sustained by this age group
- young adults are less experienced at certain tasks that require attention and psychomotor coordination.

4.6.2 People aged over 60 years

For people aged over 60 years, drinking alcohol increases the risk of falls and injuries, as well as some chronic conditions. People in this age group are more vulnerable to the effects of alcohol, due to changes that occur with age such as body composition, decreased metabolic capacity, having other health conditions and taking medications that regulate these conditions [44]. People aged over 60 years should not exceed this guideline recommendation and are advised to consult a health professional about the most appropriate level of drinking for their health.

4.6.3 People with physical health conditions affected by alcohol

Drinking leads to poorer outcomes for people with certain diseases and conditions, including alcohol-related diseases. Anyone with such a condition or with any other problem that might be affected by alcohol should discuss their alcohol intake with a health professional. In many instances, not drinking alcohol temporarily or permanently may be necessary.

Alcohol-related diseases

For people who have serious diseases directly related to alcohol consumption (e.g. cirrhosis of the liver or alcoholic pancreatitis), further drinking is likely to aggravate the condition [45, 46]. This can cause immediate problems or worsening of the prognosis in the longer term.

Diabetes

People with diabetes may need to take special precautions with drinking and should discuss alcohol use with a health professional. Alcohol can interfere with the action of insulin, medicines that promote the release of insulin (insulin secretagogues) and glucagon. Alcohol can also increase the risk of hypoglycaemia in people with type 1 or 2 diabetes who take these medications, particularly if they drink on an empty stomach [47, 48]. In addition, alcohol can worsen medical conditions associated with diabetes, such as liver disease and advanced neuropathy [47, 49].

Other conditions affected by alcohol

People with certain other health conditions may also need to seek medical advice about drinking, because alcohol may worsen the condition or interfere with treatment:

- *Surgical conditions* alcohol can increase the risk of complications of surgery, including infections, and can slow wound healing. Some medical centres recommend not drinking alcohol in the month before surgery [50].
- *Infectious diseases* heavy alcohol consumption may impair immune function, leading to an increased risk of infections (e.g. skin and respiratory infections). Those who contract infections and drink alcohol tend to have poorer outcomes from infectious diseases [51].

- Liver diseases of any form drinking alcohol can increase the severity of liver damage in those with hepatitis C, non-alcoholic fatty liver and other drug-induced liver injury. Reducing alcohol consumption can restrict the severity of liver injury in those with other liver disorders [52–54].
- Sleep disorders alcohol causes interruptions to normal sleep patterns, in particular to the later, heavier part of the sleep cycle [55]. Although alcohol may induce sleep in the short term, it leads to increased arousal and wakefulness several hours after consumption [55, 56]. Sleep disruption and chronic sleep deprivation can increase the risk of injury, disrupt cognitive processes and trigger a variety of mental health conditions [55, 57, 58].
- Sexual dysfunction alcohol use can cause or exacerbate a range of sexual problems in men and women. At low levels, alcohol can reduce inhibition and increase sexual desire [59].
 Women who consume alcohol heavily have a greater likelihood of heavy or irregular menstrual periods, spontaneous abortion and infertility [60].

4.6.4 People with mental health conditions

Alcohol plays a complex role in the development and progression of mental health conditions. Drinking can lead to poorer outcomes for people who have a mental health condition, whether it is a common condition such as depression or a less common condition such as schizophrenia. Anyone at risk of, or under treatment for, a mental health condition should discuss their alcohol intake with a health professional.

Recommendations about drinking will vary depending on the presenting mental health condition and medication regimes. In many instances, not drinking alcohol temporarily or permanently may be necessary. However, in some instances (e.g. for stabilised patients) the recommendations for the general population may apply.

People with, or at risk of, a mental health condition are more likely to use alcohol than those without such a risk [61]. Drinking can promote the development of mental health conditions in at-risk people (e.g. those prone to depression or anxiety) [62-67]. Rates of alcohol use disorders also appear to be higher among individuals with mental health conditions, including post-traumatic stress disorder, social phobias and panic disorder, depression, bipolar disorder and schizophrenia [68-74].

4.6.5 People with a family history of alcohol dependence

People with a family history of alcohol-related problems, including alcohol dependence, are at greater risk of developing problematic patterns of drinking than the general population.

Family history is a strong predictor of developing an alcohol use disorder. The children of parents with alcohol dependence are at significantly greater risk of dependence than those of parents without alcohol use disorders [75, 76].

Anyone with a close relative with alcohol dependence should consider discussing their own alcohol intake with a health professional.

Genetics

Genetic factors play an important role in how an individual responds to alcohol, including the risk of dependence or tissue injury. For example, some individuals inherit variations of the genes that encode the enzymes that regulate alcohol metabolism (alcohol dehydrogenase, aldehyde dehydrogenase and microsomal P4502E1) [77]. This may influence their susceptibility to heavy drinking, alcohol dependence and alcohol-related liver disease [78].

Animal models and human studies suggest that familial risk of alcohol dependence can be influenced by genes encoding DRD2 and ANKK1 [79-81]. Although such studies are of interest, it is not currently possible to use genetic testing as a means of identifying individuals at increased risk of alcohol dependence or alcohol-related tissue damage with the degree of accuracy that would be useful to clinicians or individuals. Multiple genes influence risk, and the contribution of any particular gene to these risks appears small in most situations.

4.6.6 People who use illicit drugs or take medications that interact with alcohol

Illicit drugs

Consuming alcohol together with illicit drugs can have dangerous or lethal consequences. When drugs such as cannabis, methamphetamines, ecstasy, cocaine and heroin are used with alcohol, this places people at greater risk of harm. Studies have reported that any level of alcohol consumption is a significant predictor of nonfatal and fatal drug overdose [82, 83]. People who use illicit drugs can be unaware of the potentiating effects of alcohol on illicit drugs [84, 85].

Alcohol is a central nervous system depressant; thus, drinking at around the same time as using other central nervous system depressant drugs (e.g. opioids such as heroin, or benzodiazepines) increases the risk of fatal overdose from respiratory depression [86]. Combining alcohol with central nervous system stimulants such as cocaine, methamphetamines and ecstasy also increases risk (e.g. of dehydration, cardiac arrhythmias and seizures) [87].

Medications that interact with alcohol

Alcohol interacts with many other drugs, including prescription and over-the-counter medications, and herbal preparations. Alcohol can exert direct effects on the absorption of medications, change the way medications are metabolised (especially in the liver) or interfere with the effect of the medication at its site of action [88].

The effects of combining alcohol with medications depend on the type and dosage of medication, and the volume of alcohol consumed; they also depend on personal factors such as genetics, gender and comorbid health conditions [88]. Commonly prescribed classes of medications (e.g. benzodiazepines, opioids, analgesics, antidepressants, anticoagulants, anticonvulsants, antibiotics, antihistamines, anti-inflammatories, antipsychotics, and medications used to treat erectile dysfunction or diabetes) have known interactions with alcohol and the combination can have serious side effects [89].

People taking medications (including herbal preparations) should check with their doctor or pharmacist about possible interactions between their medications and alcohol, and should read any information on alcohol interactions included in the packaging. Not drinking alcohol temporarily or permanently may be necessary, particularly for people taking multiple medications.

Taking prescription medications in a way other than prescribed can have added risk of harms when combined with alcohol.

5. Guideline 2: Children and people under 18 years of age

Guideline 2

To reduce the risk of injury and other harms to health, children and people under 18 years of age should not drink alcohol.

Key messages

There is no clear 'safe' level of alcohol consumption for children and people under 18 years of age. This is because of the increased risks of harm from alcohol for young people, including from injury and potential adverse effects on brain development.

Beginning alcohol use at an early age may also put young people at greater risk of longer term alcohol-related harms, including alcohol use disorders that tend to appear in early adulthood.

To minimise these risks, children and people under 18 years of age should not drink alcohol.

Rationale

The aim of Guideline 2 is to provide evidence-based advice about alcohol consumption for children and people under 18 years of age. The guideline offers clear and unambiguous advice about alcohol consumption for young people themselves, and for parents or others who may be advising adolescents about not drinking. It also provides evidence-based information for policymakers, clinicians and educators.

Parents and carers often express concern about young people drinking, and feel they need to make decisions on whether or when to offer them alcohol. Adolescents themselves may be interested to learn about or experience the effects of alcohol. Parents sometimes consider providing their children with alcohol, with the intent of reducing the risk of alcohol-related harm; however, evidence suggests that this can in fact be harmful [90].

Parents hear many mixed messages about young people's drinking. They are often not present when their teenage children start to socialise outside the family home and may be first exposed to alcohol; hence, parents may not have the chance to advise their children about the possible harms from drinking alcohol at that time.

Alcohol use is a leading cause of premature death and morbidity among young Australians, largely because it increases the risk of injury, including alcohol poisoning [91]. Alcohol-related emergency department injury presentations are higher among Australian teenagers 15–19 years of age than in other age cohorts [92]. Recent evidence shows that:

- 7.9% of those aged 12-15 years and 43.8% of those aged 16-17 years reported consuming at least one full serve of alcohol (defined as 1 standard drink) in the past 12 months [1]
- around one-quarter of those aged 16 years and one-third of those aged 17 years reported drinking alcohol in the past week, with 9% of those aged 16 years and 13% of those aged 17 years drinking 5 or more standard drinks on at least 1 day in the past week [93]
- nearly two out of every five (38%) young people 12-17 years of age that drank on at least 1 day in the previous week intended to get drunk most of the times or every time they drank [93]
- a friend or an acquaintance (48.1%) and parents (35.2%) were the most common source to supply teenagers with their first glass of alcohol [1].

Over time, the proportion of people aged between 12 and 17 years abstaining from alcohol has increased significantly, from 54.3% in 2004 to 81.5% in 2016; also, the average age at which young people first tried alcohol has risen from 14.8 years in 2004 to 16.1 years in 2016 [1]. Over 30 years, the proportion of people aged 16-17 years drinking 5 or more drinks on a single occasion also decreased, from 20% in 1984 to 11% in 2017 [93].

Why there is a single recommendation for children and people under 18 years of age

The previous edition of these guidelines split the advice for those under 15 years of age and for those aged 15–17 years. In contrast, the current guideline has a single recommendation that provides advice for all adolescents under 18 years of age, based on the following considerations:

- There continues to be clear evidence that the patterns of drinking and the physiology of people under 18 years of age make them particularly vulnerable to the harms of alcohol.
- There is now more evidence about the impact of drinking on altered brain development in people aged under 18.
- There is no specific evidence identifying separate risks for different age groups under 18 years of age.
- One guideline for all adolescents under 18 years of age provides a clear message that is aligned with the current evidence.

The harms of concern include injury, alcohol poisoning, risk taking, altered brain development and the potential for developing harmful drinking patterns later in life. The Expert Committee used the available and emerging evidence, coupled with the precautionary principle (which takes extra consideration of the more vulnerable members of our society) in advising on having one clear message for all adolescents under 18 years of age that the risks and harms are lowest when they do not drink alcohol.

5.1 Scientific evidence

These guidelines were informed by a comprehensive evaluation of the evidence, drawing on systematic reviews, meta-analyses and additional scientific evidence. Systematic reviews are quantitative reviews of the scientific evidence; they summarise data across multiple studies and are conducted using standardised criteria and an approach that can be replicated. Meta-analyses synthesise findings from existing studies.

Guideline 2 was developed taking into account all the scientific evidence available. The Expert Committee used the evidence from one systematic review and from additional studies to add to the information used to inform the previous (2009) alcohol guideline [4].

5.1.1 Systematic review

A systematic review was undertaken to fill evidence gaps for the association between alcohol consumption and mental health in young people. Studies examining the association between different levels and patterns of alcohol consumption and a range of mental health outcomes in young people under 18 years of age were considered in developing this guideline. The systematic review report — including information about the population, exposure and outcome criteria — is available at <u>www.nhmrc.gov.au/alcohol</u>.

5.1.2 Additional evidence

To complement the systematic review referred to above, NHMRC made a public call for submissions of the evidence on the health risks and benefits of drinking alcohol. This public call for evidence helped to identify relevant studies and gaps in the evidence, and identified areas of concern for the public and stakeholders. The public call had clear inclusion and exclusion criteria, to ensure that only studies of a reasonable quality were accepted (see Appendix 5).

Given that this literature was collected outside the systematic review process, the submitted evidence could not be evaluated using the GRADE approach that was used for the systematic reviews (Appendix 5). Instead, the evidence from the public call was considered — along with the evidence from the NHMRC 2009 alcohol guideline and systematic reviews to inform the narrative text for this guideline.

5.1.3 Limitations of the evidence

There is strong evidence that alcohol can cause serious immediate harm in people under 18 years of age. Much of this research relates to heavy episodic drinking — the typical pattern for young drinkers — and focuses particularly on injury, alcohol poisoning and death. There is limited research on the impacts on young people under 18 years of age drinking lower amounts of alcohol (e.g. 1–2 drinks intermittently or daily).

5.2 Risk of injury and harm

People under 18 years of age are particularly vulnerable to the harmful effects of alcohol because of their developing body and brain, and their inexperience of the effects of drinking alcohol. These factors, combined with a greater likelihood of risk-taking behaviours, expose young people to a heightened risk of injury. Suicide/self-inflicted injuries, alcohol use disorder, road traffic injuries/motor vehicle occupant injuries, and depressive disorders were the top four causes of burden of disease for males aged 15–24 years. In females for the same age group, the top four causes were suicide/self-inflicted injuries, back pain, alcohol use disorders and poisoning [94].

5.2.1 Physical injury

There is considerable evidence that alcohol use is a major risk factor for a range of teenage injuries. Much of the evidence is based on US populations, where the minimum legal drinking age (i.e. 20 or 21 years) has been higher than in Australia for many decades. As a result, most studies include teenagers up to 19 years of age because they are considered 'under-age', and few studies align precisely with the Australian legal purchase and drinking age of 18 years.

Sindelar et al. (2004) reviewed 20 alcohol use and injury studies conducted in medical settings (e.g. in emergency departments) that were focused on young people aged 13-19 years [95]. Most studies used blood tests or medical records to distinguish between alcohol and non-alcohol-related attendances. The review found that teenagers who tested positive for alcohol when they presented for medical treatment were more likely to have had an injury — most often due to a road crash, assault or self-harm — than those who had not consumed alcohol. Alcohol-exposed injured teenagers were also more likely to have incurred an injury considered to be of a serious nature (e.g. requiring a hospital stay) and to have been intentionally caused (e.g. arising from assault or self-inflicted) [95].

Using systematic methods, Newbury-Birch et al. (2009) undertook a wide-ranging review of previously published reviews on alcohol use and its impacts on young people (15-19 years of age) for the then United Kingdom Department for Children, Schools and Families [96]. The review confirmed the Sindelar et al. (2004) [95] finding that young people who drink alcohol have higher risks of injury, and added that 'adolescents and young people who drink drive, or allow themselves to be carried by a drink driver are more likely to be involved in a car accident' (p.37) [96].

In 2009, a large cross-sectional study that included more than 22 million emergency department injury presentations among young people aged 13–20 years across 50 US states described how alcohol-related injuries were distributed by individual ages. Alcohol-related visits increased with increasing age such that, by 16 years of age, frequency of presentation was triple that for those aged 14 years. However, rather than increasing uniformly from year to year, spikes in risk were apparent at ages 16 and 18 years, coinciding with major teenage milestones such as gaining a vehicle licence [97].

In Australia, male and female teenage (15–19 years) alcohol-related emergency department injury rates were more than double the rate for the total population in 2012. Despite the fact that young people aged 15–17 years have restricted legal access to alcohol, teenage rates were also higher than for those aged in their twenties [92]. A 2004 report based on data from mid-1990 to 2002 identified the top five causes of alcohol-related deaths specific to under-aged Australian drinkers (14–17 years of age). The leading causes of alcohol-related death were road injury in a vehicle or as a pedestrian; these two causes accounted for more than 50% of all alcohol-related deaths; followed by suicide, assault and drowning [91].

Although dated, these figures concur with US findings and with recent Australian data that highlight injury as the main cause of premature death among people 15–24 years of age [94].

5.2.2 Risky sexual behaviour

There is an increased likelihood of adolescents engaging in risky sexual behaviour when alcohol is involved [98]. A study of Victorian high school students found that the likelihood of experiencing risky sex and regretted sex was increased by heavy episodic drinking (binge drinking) and by drinking in a manner that, once started, is difficult to stop [99].

5.2.3 Mental health and self-harm

A review of 20 studies examined the association between heavy episodic drinking and depression. For adolescents, the review found that heavy episodic drinking predicted increased levels of depressive symptoms. This association was stronger in females than in males [100].

Adolescents who start drinking early may have various reasons to do so (e.g. childhood trauma, reduced adult supervision or risk-taking personality). These same predisposing factors may contribute to the adverse health outcomes from adolescent alcohol consumption, including self-harm, suicidal thoughts and death by suicide [101].

Alcohol-induced disinhibition is a risk factor for self-harm among teenagers having suicidal thoughts. Two large cross-sectional studies on adolescents reported that both heavy episodic drinking and drunkenness were linked with suicidal ideation or suicide attempt (or both). One of these studies reported that 'drinking while down' (i.e. feeling down being the motive for drinking) was a stronger predictor of suicide attempt than the drinking of alcohol itself [100].

Alcohol use disorders, in conjunction with major depression, represent an especially high-risk profile for adolescent suicidal behaviour and completed suicide [102]. In addition, adolescents with alcohol use disorders tend to complete suicide at a greater rate than those without alcohol problems [102]. It has been suggested that adolescents who use drinking as a method of coping are more likely to suffer from depression, precipitating heavy drinking, which is itself predictive of suicidal behaviour [103].

5.2.4 Effect on brain development and cognition

Adolescence is a time of significant neurodevelopment, with key brain regions (e.g. prefrontal cortex, limbic system and cerebellum) being particularly vulnerable to the effects of alcohol during this period [104, 105]. Adolescents who engage in heavy drinking have been found to have alterations in both grey and white matter (e.g. smaller or thinner cortical and subcortical structures, and decreased white matter integrity), abnormalities in brain activity [106, 107] and altered brain growth trajectories [108]. These alterations in brain structure and function are likely to be related to findings of poorer neurocognitive performance on tests for attention, working memory, spatial functioning, verbal and visual memory, and executive functioning in heavy-drinking adolescents [109].

5.3 Age of first drinking and longer term outcomes

In addition to the outcomes noted above, recent reviews of the evidence have indicated that early-onset alcohol use (generally under 18 years of age) is likely to be a risk factor for a range of longer term health outcomes in adulthood. These outcomes include a greater risk of heavy drinking, alcohol use disorders (including dependence), road accidents involving alcohol, anxiety, depression and drug-related problems [110–112].

However, the overall quality of studies included in these reviews was low and the evidence was somewhat mixed; hence, there is a need for more evidence from well-designed, long-term cohort studies before it can be concluded that early initiation to alcohol is a primary cause of these outcomes. Also, it is important to account for the characteristics of people who tend to drink at early ages, such as socioeconomic status or family history [113, 114].

At the same time as acknowledging these limitations, a narrative review relating primarily to alcohol consumption for people under 18 years of age points out that heavy alcohol consumption in late adolescence appears to persist into adulthood and is associated with alcohol problems, including dependence, premature death and diminished work capacity [114]. The author notes that early identification of adolescent risk factors may be helpful in preventing or attenuating risk.

6. Guideline 3: Women who are pregnant or breastfeeding

Guideline 3

- A. To prevent harm from alcohol to their unborn child, women who are pregnant or planning a pregnancy should not drink alcohol.
- B. For women who are breastfeeding, not drinking alcohol is safest for their baby.

Key messages

This guideline is based on evidence of the harms for the developing fetus and for young babies when mothers drink alcohol while pregnant or breastfeeding. It is relevant to women who are pregnant, breastfeeding or may become pregnant in the near future.

The evidence does not indicate a safe amount of alcohol that pregnant women and breastfeeding mothers can drink.

- As there is a risk of harm to the fetus, this guideline takes a precautionary approach and recommends not drinking alcohol when pregnant.
- Similarly, as there is a risk of harm to the baby, this guideline takes a precautionary approach and recommends not drinking alcohol when breastfeeding.

During pregnancy

- Alcohol is a teratogen that is, a substance that can cause permanent harm to a
 developing fetus. If a woman drinks alcohol during pregnancy, the alcohol passes
 freely from the mother to the fetus via the placenta, so the blood alcohol levels of
 the mother and fetus are similar.
- The central nervous system starts developing very early in the pregnancy, and the brain is sensitive to harms from alcohol throughout pregnancy.
- No safe level of alcohol consumption during pregnancy has been identified.
- The risk of harm to the fetus increases the more the mother drinks and the more frequently she drinks.
- Maternal and fetal factors affect the risks from drinking alcohol while pregnant (e.g. genetic differences, metabolic rates, and biochemical and inflammatory responses to alcohol). These factors make it difficult to predict the level of risk in each individual pregnancy.
- Not drinking alcohol during pregnancy, or when planning a pregnancy, prevents the risk of alcohol-related harm to the developing fetus.

When breastfeeding

- For women who are breastfeeding, not drinking alcohol is safest for their baby.
- If a breastfeeding mother drinks alcohol, that alcohol crosses into the breastmilk. Only time reduces the amount of alcohol in the milk.
- Maternal alcohol consumption may adversely affect the feeding behaviour and sleep patterns of the breastfed baby.
- A baby's brain keeps developing after it is born. A growing infant brain is more sensitive to damage from alcohol than an adult brain.

Rationale

The aim of Guideline 3 is to provide evidence-based advice for women who are pregnant, planning a pregnancy or breastfeeding, about the risks of harm to their baby from their drinking alcohol.

When a woman drinks alcohol during pregnancy (including before she knows that she is pregnant) or while breastfeeding, the developing fetus or baby are at risk of harm. Australian women vary in their levels and patterns of alcohol consumption during pregnancy and while breastfeeding.

A substantial proportion of women are unaware of the risks associated with alcohol use during pregnancy. However, many women try to avoid alcohol in pregnancy; for example, in 2016, 55.6% of women abstained from alcohol when pregnant — an increase from 40% in 2007 [1]. Despite that increase in the proportion of women abstaining from alcohol, more than one-third of women (34.7%) reported drinking alcohol when pregnant. However, once women found out they were pregnant, many reduced their alcohol consumption. Of those who did drink alcohol during their pregnancy, 48.7% consumed alcohol before they knew they were pregnant and 25.2% consumed alcohol after they knew they were pregnant [1].

Among the 34.7% who drank alcohol while pregnant, 81% consumed alcohol monthly or less, and 16.2% consumed alcohol 2-4 times a month. When drinking, most women (97.3%) consumed 1-2 standard drinks. Despite these findings, Australia has one of the world's highest rates of alcohol consumption during pregnancy [115].

A similar trend for breastfeeding women was seen, with 41.9% of breastfeeding women abstaining from alcohol in 2016, compared with 25.0% abstaining in 2007.

6.1 Pregnancy

Guideline 3A is based on systematic reviews of the literature. The existing evidence does not identify a safe amount of alcohol that pregnant women can drink. Because there is risk of lifelong harm to the unborn child, this guideline takes a precautionary approach and recommends not drinking alcohol when pregnant.

Alcohol is a teratogen (a substance that causes fetal abnormalities) that crosses the placenta. When a woman who is pregnant drinks alcohol, the fetus experiences a blood alcohol concentration similar to that of the mother [116].

Maternal alcohol consumption can harm the fetus in a number of ways, and the type and severity of harm depends on how much alcohol the pregnant woman drinks, the pattern of drinking, and the stage of pregnancy when the drinking occurs (Figure 6.1). Alcohol exposure at any stage during pregnancy (including before pregnancy is confirmed) can have consequences for the developing fetus [117].

Brain development begins in utero (see Figure 6.1) and continues through to the early adult years. Alcohol interferes with the chemicals necessary for normal brain development. The developing brain of an embryo, fetus or infant is more vulnerable to damage than the mature brain of an adult [118].

The risk of harm to the fetus increases the more alcohol the mother consumes and the more frequently she drinks. However, the exact level at which maternal alcohol consumption begins to harm the fetus is not known, and no 'safe' level of alcohol exposure has been identified. Although the risk of harm to the fetus from low levels of alcohol (e.g. <1 standard drink per day) is likely to be low, there is not enough evidence to say that it is safe.

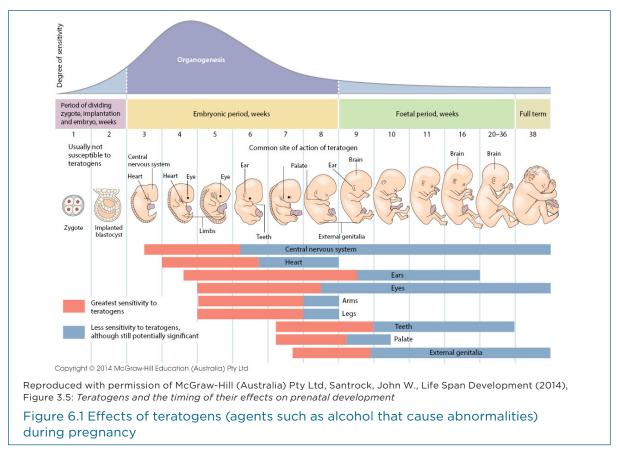
A variety of maternal and fetal factors can affect the risks from drinking alcohol while pregnant; for example, genetic factors, metabolic rates, maternal diet and the woman's biochemical and inflammatory responses to alcohol. Genetics plays a role in determining the effects of alcohol on the developing fetus, with some genotypes conferring increased risk of harm and others providing protection [119]. Genetic factors influence maternal and fetal metabolic rates, their risk of reacting adversely to alcohol breakdown products, and their biochemical and inflammatory responses to alcohol at a cellular level. The likely variation in risk factors among mothers and babies makes it difficult to predict the level of risk from alcohol in each individual pregnancy [117].

Drinking by the partner of a pregnant woman can affect the pregnant woman's alcohol consumption [120]. In addition, preconception drinking by the male partner may have direct effect on fetal development [120].

Ceasing alcohol consumption during pregnancy will provide the best start to health for the developing baby.

If women are concerned about their alcohol consumption, or find it difficult to stop drinking alcohol while pregnant, it is recommended that they speak to their health professional.

Avoiding alcohol during pregnancy prevents risk to the fetus. Women who have consumed alcohol during pregnancy should be advised to stop drinking alcohol because this will prevent further risk to the fetus. Pregnant women who find it difficult to stop drinking alcohol should be offered support and be referred to appropriate services [121].



6.1.1 Scientific evidence

These guidelines are informed by a comprehensive evaluation of the evidence, drawing on systematic reviews, meta-analyses and additional scientific evidence. Systematic reviews are quantitative reviews of the scientific evidence; they summarise data across multiple studies and are conducted using standardised criteria and an approach that can be replicated. Meta-analyses synthesise findings from existing studies. Guideline 3 uses the evidence from systematic reviews and additional studies to supplement the information from the 2009 NHMRC alcohol guideline [4].

Systematic reviews

An overview of systematic reviews was completed to consider the short-term and long-term health risks and benefits associated with alcohol exposure (i.e. from drinking alcohol). This review included 38 systematic reviews for 53 health outcomes, which included systematic reviews on specific pregnancy health outcomes of preterm birth, low birthweight, small for gestational age, child motor function and communication delay.

A systematic review was undertaken to fill evidence gaps for the association between maternal alcohol consumption and pregnancy outcomes — specifically, birth defects and behavioural problems in babies and young children. The review reported on 21 studies for birth defect outcomes and four studies for behavioural outcomes.

The systematic review reports, including information about the population, exposure and outcome criteria, are available at <u>www.nhmrc.gov.au/alcohol</u>.

Additional evidence

To complement the systematic reviews referred to above, NHMRC made a public call for submissions of evidence, including evidence on the health risks and benefits of women drinking alcohol during pregnancy or breastfeeding. The public call had clear inclusion and exclusion criteria, to ensure that only studies of a reasonable quality were accepted (see Appendix 5).

Given that this literature was collected outside the systematic review process, the submitted evidence could not be evaluated using the GRADE approach that was used for the systematic reviews (see Appendix 5). Instead, the evidence from the public call was considered along with the evidence from the NHMRC 2009 alcohol guidelines and systematic reviews to inform the narrative text for this guideline.

6.1.2 Adverse effects of maternal alcohol consumption at different life stages

Fetal, neonatal and early childhood outcomes

A meta-analysis of studies that examined maternal alcohol consumption and risks of preterm birth, low birth weight and the infant being small for its gestational age provided evidence that these risks increase with alcohol consumption and are similar across the trimesters [122]. Risks of low birth weight and of being small for gestational age increase as the mother's alcohol intake increases, beginning at an average of just over 10 grams of alcohol a day (about 1 standard drink). The risk of preterm birth increases as maternal alcohol consumption increases.

These findings concur with an earlier systematic review; however, that review found that studies of low levels of consumption suffered many limitations — such as failing to account for alcohol drinking patterns (e.g. heavy episodic drinking [5+ standards drinks] versus regular consumption) — and produced inconsistent results [123]. This led the authors to conclude that on the basis of (then) current evidence, it was not possible to determine whether drinking alcohol at low levels during pregnancy (defined as <1 standard drink a day) was safe. Along similar lines, Australian researchers have argued that the timing and intensity of maternal alcohol intake has rarely been adequately considered by past studies, and this may have masked substantial prenatal effects, particularly harms caused to the fetus by heavy episodic drinking [124].

There is clear evidence that heavy drinking is harmful to the developing fetus. For example, an Australian population-based cohort study used alcohol diagnosis in health records as a proxy for heavy consumption among pregnant women. It found a significantly greater risk of poor pregnancy outcomes — including small for gestational age, preterm delivery and low APGAR (appearance, pulse, grimace, activity and respiration) scores — among babies from women with an alcohol diagnosis (i.e. heavy drinkers) than among mothers who did not have an alcohol diagnosis [125].

Alcohol consumption during pregnancy has been associated with fetal craniofacial abnormalities [126]. A meta-analysis of studies examining maternal alcohol consumption and birth defects was possible for the outcomes of cleft lip, cleft palate and spina bifida. The meta-analysis did not show a link between the level and pattern of maternal alcohol consumption in the first trimester and these birth defects outcomes [127]. A number of single studies that assessed a range of other birth defects found no reliable evidence of a link between drinking alcohol and neural tube defects or heart defects. However, a single study in the meta-analysis reported increased rates of cryptorchidism (undescended testes), neural tube defects and two abnormalities of abdominal development (gastroschisis and omphalocele). In contrast, one other single study reported decreased rates of congenital limb deficiencies, spina bifida and strabismus following alcohol exposure in pregnancy.

The US Institute of Medicine has classified a range of birth defects as alcohol-related birth defects; such defects are relatively rare and may also be caused by other factors. Thus, future research studies examining the risk of birth defects from fetal alcohol exposure need to have a large number of participants.

An Australian data-linkage study that used 'alcohol diagnosis' included in health records to identify women drinking heavily during pregnancy examined the risk of birth defects in their children [128]. The study identified an increased risk of heart defects, kidney defects, skeletal abnormalities and microcephaly (small head and brain) when the mother had an alcohol diagnosis recorded during pregnancy.

Fetal alcohol spectrum disorder

The Australian guide to the diagnosis of FASD refers to FASD as the umbrella term for the spectrum of adverse effects that can be seen in infants, children and adolescents exposed to a range of amounts of alcohol during pregnancy [117]. These effects can include lifelong physical, cognitive, behavioural and neurodevelopmental abnormalities, and restricted growth. The level and nature of the conditions can be related to the amount of alcohol consumed and the developmental stage of the fetus.

Health professionals in Australia are often unaware of the FASD diagnostic criteria and they do not routinely ask pregnant women about their alcohol use, so FASD often goes undiagnosed [117]. FASD is seldom diagnosed at birth; instead, the developmental problems are often noticed at school, when learning and behavioural difficulties become more evident [129]. People with FASD experience increased rates of mental illness, and drug and alcohol problems [130]; also, they are more likely to be in juvenile detention or have contact with the justice system [131, 132].

The diagnosis of FASD requires evidence of prenatal alcohol exposure and severe impairment in three or more domains of central nervous system structure or function. A diagnosis of FASD is further divided into one of two subcategories: FASD with three sentinel facial features or FASD with less than three sentinel facial features. For further information see the *Australian guide to the diagnosis of FASD* [117].

Developmental delay and behavioural problems

Evidence from the following systematic reviews suggest that drinking high levels of alcohol during pregnancy may increase the risk of the child having poor gross motor skills. However, the reviews did not find evidence of a negative impact of alcohol exposure on language development or some behavioural outcomes:

- The review by Bay (2011) reported that maternal drinking of alcohol at more than 4 drinks per day (where 1 drink was defined as 12 g of alcohol), increased the risk of poor gross motor skills for the child [133]. Drinking between 10 and 30 alcoholic drinks per week showed inconsistent results, making it difficult to determine whether there are any effects at this level of alcohol consumption. This review looked at 23 case-control and cohort studies. Interpretation of the results was limited by the fact that the included studies used different scales to measure child motor function.
- The review by O'Keeffe et al. (2014), of three cohort studies, reported no statistically significant effect of low to moderate maternal alcohol consumption (defined as an average of <10 g [1 standard drink] per day or 70 g per week during pregnancy) and the child's language development measured between 1 and 3 years [134].
- The systematic review by Cochrane Australia and SAHMRI (2018) of four cohort studies found [127]:
 - a limited association between one or more 'binge' episodes (>5 drinks on one occasion) a week in weeks 0-6 of pregnancy, and worse behavioural outcomes in infants (difficult temperament, sleeping problems and being demanding and/or irritable)
 - no reliable evidence of an association for these outcomes with the same amount of alcohol consumed less than once a week in weeks 0-6 of pregnancy
 - no reliable evidence of associations between alcohol consumption (in the first trimester or throughout pregnancy) and conduct problems and hyperactivity in children at 3-4 years of age.

Other studies have documented neurological effects from maternal alcohol consumption, including reduction in nerve-conduction velocity and amplitude in children [135]; a dose-dependent decrease in visual acuity in infants [136]; and a dose-dependent reduction in the size of the frontal cortex (but not of other brain structures) at levels of 2–6 standard drinks per day [137]. This latter finding is consistent with impairment of executive function, working memory and attention observed in children with FASD.

Childhood and adolescence

There are few published evidence reviews on the effect of varying amounts of maternal alcohol consumption in pregnancy on the offspring once they have grown into childhood or adolescence. Outcomes of interest for these young people would include growth, educational achievement, future drug and alcohol dependence, mental health outcomes, impact on later employment and any problems with the law.

Limitations of undertaking such research include difficulties in accurately documenting the quantity, timing and frequency of alcohol intake in pregnancy, and difficulties in accounting for factors that could interfere with the results (i.e. potential 'confounding factors'). Single studies reported in the 2009 NHMRC guideline relate to some of these outcomes of interest and are discussed below [4].

Growth

A single study on adolescents 14 years of age, whose mothers drank an average of 3 or more drinks per week in the first trimester, showed a decreased weight, height, head circumference and skin-fold thickness compared with children of mothers who did not drink alcohol or drank at a lower level [138]. The authors observed a dose-response relationship between growth deficit and prenatal alcohol exposure, with effects on growth of children at 14 years of age detectable at intakes of less than 1 drink per day on average; effects were most marked with exposure in the first trimester.

Educational achievement and cognitive abilities

Compared with children of mothers who did not drink alcohol while pregnant, children who were exposed to alcohol in utero because their mother drank an average of more than 1.4 standard drinks per day had deficits at 7.5 years of age in 'working memory and executive function' (the set of processes required to manage oneself in order to achieve a goal). This effect increased with increasing alcohol consumption; it was most marked for numeracy tasks and it persisted after controlling for IQ. The effects were more noticeable in children born to mothers aged over 30 years. The same children did not have deficits in impulse control or their ability to pay attention for sustained periods of time [139, 140].

Children 10 years of age whose mothers drank 3 or more drinks per week while pregnant showed significant negative effects on their verbal and nonverbal learning and memory score [141]. These children were tested again at 14 years of age [142], when deficits were found in the verbal domain of learning and short-term and long-term memory. In both age groups, problems with learning and memory were seen even when the mother drank less than 4.2 standard drinks per week.

Adolescent children 14 years of age whose mothers drank an average of 1 standard drink per day in early pregnancy showed no detectable effect on intellectual ability, learning and attention [143]. The children showed decreased cognitive ability if their mother drank more than 5 drinks on one or more occasions. There was a linear relationship between the frequency of heavy maternal consumption of alcohol and the later decreased cognitive ability of the child.

A study of pregnant women from lower socioeconomic backgrounds who drank less than 1 drink per day on average in the first and second trimesters indicated a link between low to moderate prenatal alcohol exposure and poor overall school performance at 10 years of age [144]. Deficits in reading comprehension and teachers' rating of poor school performance were significantly associated with maternal consumption of 4 or more alcoholic drinks per occasion in the second trimester.

Social interactions and/or problems with the law

Children aged 6-7 years with any prenatal alcohol exposure scored higher for externalising (aggression and delinquency) and internalising (anxiety, depression and withdrawal) behaviours [145]. This effect was present after adjusting for other factors that might affect the results (confounders). The chances of the child displaying delinquent behaviour were significantly higher in children whose mothers drank any alcohol than in children whose mothers did not drink. These adverse effects on behaviour were dose-related and were evident at low average levels of drinking (an average of 0.6 standard drinks per day).

Adulthood

There are few studies examining outcomes from prenatal alcohol exposure in adults. For individuals diagnosed with FASD, deficits in motor function, including balance and fine motor skills, have been shown to last into adulthood [146]. Impaired fetal growth (e.g. being small for gestational age) can persist into adulthood and can have adverse effects over the long term [147].

6.2 Breastfeeding

The evidence does not identify a 'safe' or 'no-risk' level of alcohol that breastfeeding women can drink. As mentioned in the above section on pregnancy, the developing infant brain is more vulnerable to damage from alcohol than the mature brain of an adult [118]. Hence, this guideline takes a precautionary approach and recommends that it is safest for the baby if women who are breastfeeding do not drink alcohol.

6.2.1 Alcohol and breastmilk

Alcohol easily crosses into human breastmilk, so breastmilk has the same concentration of alcohol in it as the mother's blood within an hour [148]. At moderate to high levels of maternal drinking, the alcohol concentration in breastmilk can be even higher than that in the mother's blood [149]. For an average woman, it takes about 2 hours from the start of drinking to clear 1 standard drink of alcohol from human milk. Only when the mother's blood alcohol has gone back to zero is human milk free of alcohol. Expressing or 'pumping and dumping' does not speed up the process or lower the alcohol concentration in the remaining milk [148, 149].

6.2.2 The context of breastfeeding in Australia

Australian and international guidelines recommend exclusive breastfeeding of babies for the first 6 months, and then continued breastfeeding while solid foods are introduced and until 12 months of age and beyond, for as long as the mother and child desire [150].

The 2010 Australian National Infant Feeding Survey [151] indicated that 96% of Australian mothers start breastfeeding. The 2017-18 National Health Survey [152] reported that almost 62% of infants are exclusively breastfed at age 4 months, and by 12 months some 28% of children are still being breastfed [153].

Few Australian studies have reported on the prevalence and patterns of alcohol consumption while breastfeeding. However, available studies have indicated that many women who abstain from alcohol during pregnancy resume drinking alcohol after giving birth [154, 155], with most drinking alcohol at low levels and infrequently [156].

The limited data on alcohol use while breastfeeding suggest that many women in Australia who drink while breastfeeding employ strategies such as timing of alcohol use, to minimise alcohol exposure to their infants [154-156].

6.2.3 Scientific evidence

This guideline uses the evidence from a systematic review and additional studies to add to the information in the 2009 alcohol guideline [4].

Systematic review

A systematic review was undertaken to fill evidence gaps for the association between maternal alcohol consumption and breastfeeding outcomes. That review reported on one study of sedation in breastfeed babies.

Additional evidence

To complement the systematic review referred to above, NHMRC made a public call for submissions of evidence on the health risks and benefits of drinking alcohol during breastfeeding. The public call had clear inclusion and exclusion criteria, to ensure that only studies of a reasonable quality were accepted (see Appendix 5).

Given that this literature was collected outside the systematic review process, the submitted evidence could not be evaluated using the GRADE approach that was used for the systematic reviews (Appendix 5). Instead, the evidence from the public call was considered along with the evidence from the NHMRC 2009 alcohol guideline and systematic reviews to inform the narrative text for this guideline.

6.2.4 The impact of alcohol on breastfeeding and the infant

There is a lack of good-quality evidence on the effect of maternal alcohol consumption while breastfeeding on babies' breastfeeding, interaction and behaviour, and all areas of development. There is, however, considerable evidence regarding the effect of alcohol in breastmilk on infant sleep. Even at low maternal alcohol consumption, alcohol can adversely affect the sleep-wake patterns of breastfed infants. Although the mechanism has not yet been identified, it is well established that small amounts of alcohol (e.g. <0.3 g/kg), have a measurable effect on sleep patterns and an infant's 'ability to modulate behaviours' [148].

A 2006 review reported that drinking 2 standard drinks of alcohol or more per day while breastfeeding was associated with [148]:

- decreased ability to successfully breastfeed (decreased milk production by the mother and decreased milk consumption by the baby)
- stopping breastfeeding earlier
- deficits in infant psychomotor development
- disrupted infant sleep-wake behavioural patterns.

In contrast, a 2017 study reported that babies did not show any negative effects on breastfeeding duration, infant feeding or sleeping behaviour when their mothers consumed low levels of alcohol (defined as ≤14 standard drinks per week and <3 standard drinks per occasion) and used strategies to minimise their baby ingesting any alcohol through breastmilk. These effects were tested at 2 and 12 months of age [155]. However, there was the potential for reporting bias because mothers self-reported their alcohol use at 8 weeks for the first 2 months after the baby was born and after the behaviour problems had occurred.

The concentration of alcohol in the breastmilk is essentially the same as the concentration in the mother's blood — only time reduces the alcohol level.

Table 6.1 shows the estimated length of time after drinking alcohol before a zero level of alcohol will be reached in the breastmilk of an average woman of a given body weight [157]. The actual time will vary for each individual woman.

Maternal	Australian standard drinks						
weight (kg)	1	2	3	4	5	6	7
50	1:51	3:43	5:35	7:27	9:18	11:11	13:03
59	1:42	3:26	5:09	6:52	8:36	10:19	12:02
66	1:37	3:15	4:53	6:31	8:10	9:48	11:26
70	1:33	3: 07	4:41	6:15	7:50	9:24	10:57

Table 6.1. Estimated time taken for alcohol to clear from breastmilk (hours:minutes)

Note: Time is calculated from the beginning of drinking. Assumptions made: alcohol metabolism is constant at 15 mg/dl per hour; height of the women is 163 centimetres.

Source: Giglia & Binns 2006 [148] (adapted from Ho et al. 2001 [157]).

Appendix 1: Drinking frequency

An estimated average drinking frequency of 3 days per week for current adult drinkers in Australia was used to inform Guideline 1. This appendix briefly outlines the methods used to determine that estimate. From a review of data sources, the only estimates of drinking frequency in the located published evidence were categorical data provided in the published report for the National Drug Strategy Household Survey (NDSHS), conducted by the Australian Institute of Health and Welfare [1]. More detailed evidence on drinking frequency was required for the guidelines. Therefore, additional analyses were conducted using two key data sources: the Australian National Health Survey (NHS) of 2014-15, conducted by the Australian Bureau of Statistics [158] and the NDSHS of 2016 [1]. This appendix presents the results of those analyses.

In each analysis, the aim was to estimate the average number of drinking days per week for the Australian population of adults who consume alcohol. This entailed combining individual drinking frequencies, which varied from daily drinking through to occasional drinking, into a single overall average. The key results of these analyses are presented in Table A1.1.

Data and method	Estimate
National Health Survey 2014-15 - single question	2.06
National Drug Strategy Household Survey 2016 - single question	2.06
National Drug Strategy Household Survey – graduated frequency questions	3.34

Table A1.1. Estimated drinking days per week, for Australian adults who drink alcohol

Table A1.1 shows that the estimate of drinking frequency was 2.06-3.34 days per week, depending on the data source and methods used. The NDSHS items on graduated frequency provide greater reliability and detail on drinking patterns (see below), so greater weight was given to these than to the single questions estimates. Hence, 3 drinking days per week is considered the best evidence on current Australian population drinking patterns to inform Guideline 1. The details of the analyses for the three estimates given in Table A1.1 are presented below.

National Health Survey estimate

Data from the 2014–15 NHS (2016) were analysed, excluding drinkers under the age of 18 years [158]. The NHS collects data on drinking frequency using a simple broad question: 'How often did you have an alcoholic drink of any kind in the last 12 months?'. The response options are provided below in Table A1.2. Each response was converted into an annual number of drinking occasions by using the midpoint of the frequency range; for example, someone who reported drinking on 5–6 days per week was estimated to have 286 (i.e. 5.5 × 52) drinking occasions per year. The implied drinking occasions are detailed in Table A1.2.

Table A1.2. Drinking frequency response items and implied annual drinking occasions, National Health Survey 2014-15

Response categories for alcohol frequency item	Implied annual drinking occasions
Every day	365
5-6 days per week	286
3-4 days per week	182
1-2 days per week	78
2-3 days per month	30
About 1 day per month	12
Less often than 1 day per month	6

Each respondent was assigned an annual number of drinking occasions, based on their response to the broad single question on drinking frequency (e.g. some respondents had 6 drinking occasions per year whereas some had 365). These figures were then transformed into weekly frequencies by dividing by 52 for each individual, and the average across the entire sample was calculated. This resulted in an estimated population average of 2.06 drinking occasions per week (excluding nondrinkers and nonresponders).

National Drug Strategy Household Survey estimate

Similar analyses were conducted using data from the 2016 NDSHS, again starting with the broad single question on drinking frequency [1]. This question had the same wording as the previously described NHS question, and used the same response categories. Again, nondrinkers and nonresponders were excluded, and analyses were limited to adults. Based on these data, a population average of 2.06 drinking days per week was estimated.

Both this estimate and that from the NHS are broadly consistent with a statistical average of 2 drinking occasions per week. However, it is well established in alcohol survey research that this type of simple broad question leads to significant under-reporting of drinking practices (via recall bias and other issues consistent with self-reported data). In general, the more questions you ask a respondent about their drinking habits, the more reliable the responses you receive [159]. Thus, a further set of analyses using the graduated frequency questions in the NDSHS were conducted. These items asked respondents to report how often they drank various amounts of alcohol (e.g. 'how often in the past 12 months did you drink 1–2 standard drinks in a day') for seven different levels of drinking. These more detailed questions elicit a better overall estimate of population drinking [160].

The same approach as described above was taken, with frequencies of drinking at each level converted into an annual number of drinking occasions, based on the midpoints of the frequency categories. The total number of drinking occasions was then calculated across the seven drinking levels, to provide an overall number of drinking occasions. Respondents who accidentally provided responses that led to more than 365 drinking occasions per year had their number of occasions capped at 365 (e.g. a respondent might say that they drank 1-2 drinks on 5-6 days per week and 3-4 drinks on 3-4 days per week, which would lead to an estimate of 468 drinking occasions per year); see Greenfield (2000) [161] for more details of this method.

Again, annual frequencies were converted to weekly frequencies and the population mean estimates were calculated, with nondrinkers and nonresponders excluded. This approach indicates that, on average, Australian drinkers consume alcohol on 3.34 days per week.

Although these estimates contain considerable uncertainties, they represent the best currently available evidence for Australia. Population-level alcohol consumption in surveys captures about 50% of the volume of alcohol recorded via more objective measures (e.g. sales and tax collection) [13], so this frequency estimate is likely to be an underestimate. Importantly, similar underestimates are likely in the studies used to evaluate alcohol-related risks for mortality and other outcomes that are considered in the systematic reviews, modelling and additional studies for the guidelines. Thus, the potential bias due to under-reporting in the estimate of drinking frequency produced here is likely to be counterbalanced by similar under-reporting in the underlying epidemiological studies of risk. Hence, the estimates used provide the best available data for the current guidelines, to be considered in the context of the other guideline inputs.

Appendix 2: Guideline 1 modelling results

The lifetime risk threshold selected for this guideline was a 1 in 100 (1%) chance of dying from an alcohol-related condition (see the Rationale for Guideline 1). Table A2.1 presents consumption levels corresponding to this risk threshold, and provides a comparison of consumption levels with alternative risk thresholds of 0.1% (1 in 1000), 0.2% (1 in 500) and 2.0% (1 in 50). This table is not intended to be used for individual interpretation of risk levels given individual drinking patterns. Rather, the information is intended to support population-level advice, as explained below.

Considering that the average drinking frequency in Australia is 3 days per week (see Appendix 1), the number of standard drinks corresponding to the 1% risk threshold is 12.5 standard drinks per week for men and 10.5 standard drinks per week for women (Table A2.1).

Table A2.1 Number of standard drinks per week associated with alternative lifetime mortality risk thresholds, depending on number of days alcohol is consumed per week

		Risk	level	
Drinking frequency	0.1% (1 in 1000)	0.2% (1 in 500)	1% (1 in 100)	2% (1 in 50)
Men	Standard drinks (per week)			
Daily	18.5	18.7	20.2	21.9
6 days/week	17.1	17.2	18.6	20.2
5 days/week	15.5	15.7	16.9	18.5
4 days/week	13.6	13.7	14.9	16.4
3 days/week	11.3	11.4	12.5	13.8
2 days/week	8	8.1	9	10.1
1 day/week	3.4	3.4	4.1	4.9
Women	Standard drinks (per week)			
Daily	14	14.1	15.3	16.7
6 days/week	13.3	13.4	14.5	15.8
5 days/week	12.3	12.5	13.5	14.8
4 days/week	11.1	11.2	12.1	13.3
3 days/week	9.5	9.6	10.5	11.6
2 days/week	7	7.1	7.8	8.8
1 day/week	4.1	4.1	4.7	5.4

In any public health guideline, it is important that advice is consistent, clear and cautious, erring on the side of protecting health. To check that the recommendations are robust when different types of evidence are considered, and to determine what might happen if that evidence varied, alternative scenarios were considered. The impact of the different considerations and scenarios on the weekly drinking amounts corresponding to risk levels are outlined in Tables A2.1 and A2.2.

This guideline and the previous (2009) alcohol guidelines [4] both applied a 1% lifetime risk threshold; however, some international guidelines consider a 0.1% (1 in 1000) risk to be more appropriate. For a lifetime risk threshold of 0.1%, corresponding total weekly alcohol use is about 10% lower than that indicated for a 1% threshold; that is, 11.3 standard drinks per week for men and 9.5 standard drinks per week for women for an average of 3 drinking days per week.

Further, total weekly alcohol levels associated with risk thresholds vary, depending on the average number of days per week alcohol is consumed. Table A2.1 shows that when drinking occurs only once a week, then the weekly limit at the 1% level would be 4.1 standard drinks for men and 4.7 standard drinks for women. For daily drinking, the corresponding weekly limits would be 20.2 and 15.3 standard drinks, respectively.

Finally, when protective effects are removed from the analysis, weekly alcohol consumption levels that correspond to a given risk threshold are much lower than those in the general model on which the main recommendations are based (see Table A2.2), being below 3 standard drinks per week for both men and women.

These different scenarios show the general range and magnitude of uncertainty about the amount of alcohol that relates to a 1% lifetime risk threshold (i.e. a 1 in 100 chance of dying from alcohol-related harm). The evidence is clear that alcohol consumption at higher levels leads to overall harm, but the evidence for overall risk of harm is less certain at lower levels of use. Much of this uncertainty arises from scientific debate regarding whether or not alcohol has protective effects at lower levels of consumption.

The recommended limits within the guideline do not rely solely on the modelling results. They are based on a wide range of inputs, outlined in Figure 1.1 in Section 1. The guidelines aim to strike a balance by incorporating what is known about average drinking patterns and the harms related to different levels of consumption, while acknowledging uncertainties in the evidence, particularly about protective effects. Ultimately, some consideration of the protective effects of alcohol was taken into account in determining the recommended number of standard drinks, while erring on the side of caution.

The results presented in Table A2.1 and Table A2.2 represent the average risk of death associated with different levels and patterns of alcohol consumption for Australian men and women; they do not represent the risk faced by any given individual. The level of risk faced by an individual and the health conditions from which they are at risk vary, depending on a range of sociodemographic, psychological, biological and situational factors [33]. The results presented in these tables come from the mathematical modelling that was used to help inform the development of the guidelines, but represents only one of a number of inputs considered in the guideline development process (see Figure 1.1 in Section 1). For these reasons, it is not appropriate to use the results presented in this appendix to construct specific guidance for individuals based on their specific pattern of drinking; and the modelling results cannot be used without considering the other inputs used in the guideline development process to construct a population-based guideline for Australians.

	M	lale	Female			
Drinking frequency	Protective No protective effects effects		Protective effects	No protective effects		
	Standard drinks (per week)					
Daily	20.2	2.9	15.3	2.3		
6 days/week	18.6	2.8	14.5	2.2		
5 days/week	16.9	2.5	13.5	2.2		
4 days/week	14.9	2.6	12.1	2.1		
3 days/week	12.5	2.5	10.5	2.5		
2 days/week	9.0	2.6	7.8	2.2		
1 day/week	4.1	0	4.7	0.1		

Table A2.2. Number of standard drinks per week associated with a 1 in 100 risk of mortality according to whether protective effects of alcohol are considered

Appendix 3: GRADE Evidence to Decision frameworks

An important step in the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guideline development process is for the Expert Committee to consider and develop an Evidence to Decision (EtD) framework for each recommendation. The EtDs for each of the three guidelines are provided below.

Guideline 1: Adults

Confirming a priority issue

Is the problem a priority?

Yes (see the Rationale for Guideline 1)

Benefits and harms

How substantial are the harms and benefits of alcohol consumption?

Keeping your alcohol consumption within this guideline reduces the risk of alcohol-related harm, compared with drinking above the guideline.

For both men and women, the risk of death from alcohol-related injury and disease remains below 1 in 100 if no more than 10 standard drinks are consumed each week and no more than 4 standard drinks are consumed on any one day.

Drinking above this guideline further increases the risk of death from alcohol-related disease and injury. Not drinking at all is the best way to reduce the risk of harm from alcohol.

Certainty of the evidence

What is the overall certainty/quality of the evidence?

Systematic reviews of the published evidence on the health effects of consuming alcohol and mathematical modelling of the relationship between consumption and harm formed the evidence base for this guideline.

The systematic reviews considered the **long-term** health risks and benefits of alcohol consumption on the following health conditions:

- all-cause mortality
- cancer: bladder cancer, brain cancer, breast cancer (premenopausal), breast cancer (postmenopausal), cervical cancer, colorectal cancer, endometrial cancer, gallbladder cancer, kidney cancer, leukaemia, liver cancer, lung cancer, Hodgkin's lymphoma,

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non-Hodgkin's lymphoma, melanoma, mouth and pharynx cancer, larynx cancer, multiple myeloma, oesophageal squamous cell carcinoma, oesophageal adenocarcinoma, ovarian cancer, pancreatic cancer, prostate cancer, stomach cancer and thyroid cancer

- cardiovascular disease: coronary heart disease, atrial fibrillation, heart failure, ischaemic stroke, intracerebral haemorrhage, subarachnoid haemorrhage and hypertension
- central neurological disorders: seizures and dementia and cognitive decline
- diseases of the digestive system: liver cirrhosis and pancreatitis
- other conditions: hip fracture, type 2 diabetes, gout, pneumonia and tuberculosis.

The systematic reviews also considered the **short-term** health risks and benefits of alcohol consumption on the following outcomes: injury, fatal motor vehicle injury, myocardial infarction or coronary event, ischaemic stroke and haemorrhagic stroke.

The evidence base for this recommendation also included a systematic review of individual studies evaluating the association between alcohol consumption and mental health disorders, and an additional systematic review of individual studies evaluating the association between different levels and patterns of alcohol consumption and long-term mild cognitive impairment.

The quality of the evidence included in these systematic reviews varied across the critical outcomes. GRADE rates the type of epidemiological evidence typical of broad public health exposures as low to very low; hence, the certainty in the overall evidence was rated accordingly as very low.

Higher 'quality' study designs that are more typical for clinical practice guidelines — such as randomised control trials — are not appropriate for most public health interventions. **Well-designed observational studies are often the best source of evidence on public health** issues, but due to study design limitations, they are often attributed a GRADE rating of low to very low.

The mathematical modelling examined relationships between consumption levels and mortality and morbidity, using parameters derived from Australian population data, Australian alcohol consumption data and risk functions largely derived from the systematic reviews.

Preference and values

Is there variation in how much value people place on the desirable and undesirable effects of alcohol consumption?

It is expected that there is variability in how much value Australians place on the desirable and undesirable effects of alcohol consumption. It is also expected that there is variability in how much risk people are willing to take when it comes to consuming alcohol.

Despite the expected variability in people's preferences and values, the government has an important role in providing Australians with evidence-based recommendations to reduce harm from drinking alcohol.

The Foundation for Alcohol Research and Education's 2019 Annual Alcohol Poll reported that [162]:

- more than four in five Australians believe that people have a right to know about alcohol-related harm
- three-quarters (75%) of Australians believe that more needs to be done to reduce the harm caused by alcohol-related illness, injury, death and related issues.

Equity

What would be the impact on health equity if Australians consumed alcohol at these proposed levels?

'Health equity is the notion that everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential if it can be avoided' [163].

In Australia, the disease and injury burden from alcohol use is skewed towards people in the lowest socioeconomic groups. In 2011, the greatest amount of burden was experienced by those in the lowest socioeconomic group (55 807 DALY; 5.2% of total DALY), while the lowest burden was experienced by those in the highest socioeconomic group (31 281 DALY; 4.4% of total DALY) [164].

It is expected that health equity would be improved if this recommendation were implemented and widely adopted by the Australian population. Drinking alcohol within the guideline recommendation aims to minimise the risk of alcohol-related harm for Australian men and women. In doing so, those currently disadvantaged by not being aware of these risks or by being in contexts with high levels of consumption will have a better chance of realising their full health potential.

The recommendation should not create new health inequities or worsen any current inequities, but if it is not effectively implemented it may miss the opportunity to reduce inequities. The messages need to reach those most vulnerable to alcohol-related harm.

Acceptability

Would this proposed recommendation, to reduce the lifetime risk of harm from drinking alcohol, and to reduce the risk of injury on a single occasion of drinking, be acceptable to the Australian public?

It is expected that Australians will vary in their views regarding whether they consider this recommendation acceptable. However, it is expected that most Australians will find it acceptable for the government to provide evidence-based advice to reduce harm from alcohol consumption.

In 2019, more than four in five Australians reported that they believe people have a right to know about alcohol-related harm, and three-quarters (75%) of Australians reported that more needs to be done to reduce the harm caused by alcohol-related illness [162].

Furthermore, it is evident that there are many Australians who overestimate the amount of alcohol an adult can drink before putting their health at risk, highlighting the need for these recommendations.

The AIHW National Drug Strategy Household Survey reported that [1]:

- more than 30% of Australian males (aged 14 years or over) overestimated the number of standard drinks an adult male could consume before putting his health at risk over his lifetime, and almost 60% overestimated the number of standard drinks an adult male could drink over a 6-hour period before putting his health at risk
- 9% of females (aged 14 years or over) overestimated the number of standard drinks an adult female could drink per day before putting her health at risk over her lifetime and more than 30% overestimated the number of standard drinks an adult female could drink over a 6-hour period before putting her health at risk.

Feasibility

Is the option realistic and practical (feasible) to implement?

It is considered feasible to implement the recommendations, given they are similar to the 2009 recommendations, which the majority of the population drink in accordance with.

In 2016, about 17% of Australians exceeded NHMRC's lifetime risk guideline by drinking more than 2 standard drinks per day, and 26% of Australians consumed 5 or more standard drinks on a single drinking occasion at least once a month [1].

The success of the guidelines in improving health outcomes is entirely dependent on their successful implementation, including dissemination, public communications and ongoing community awareness-raising about the guidelines (including to health professionals), for which the Australian Government is responsible.

Resources and other considerations

Does this proposed recommendation have resource implications (costs)?

Harmful alcohol use represents a significant financial burden to society. An Australian study by Manning et al. (2013) [19] estimated costs to society from alcohol-related problems at \$14.3 billion in 2010. However, the total cost is likely to be higher when costs associated with broader harms that occur to people other than the drinker are included. Laslett et al. (2010) [18] earlier estimated that the additional tangible and intangible costs of alcohol's harm to others in 2008 were \$14.2 billion and \$6.4 billion, respectively.

It is expected that if Australians consumed alcohol in line with this recommendation, there would be savings in respect of the health costs to society from alcohol-related problems.

AIHW, Australian Institute of Health; DALY, disability-adjusted life years; GRADE, Grading of Recommendations Assessment, Development and Evaluation; NHMRC, National Health and Medical Research Council.

Guideline 2: Children and people under 18 years of age

Confirming a priority issue

Is the problem a priority?

Yes (see the Rationale for Guideline 2)

Benefits and harms

How substantial are the harms and benefits of adolescents under 18 drinking alcohol?

There are substantial net benefits for children and young people under 18 years of age in not drinking any alcohol, as advised by this guideline, as opposed to drinking alcohol.

Please see Section 5.2 of the guideline for more details on the associations between alcohol consumption and mental health disorders in young people, as well as other important health outcomes.

Certainty of the evidence

What is the overall certainty/quality of the evidence?

Part of the evidence supporting this recommendation comes from a systematic review evaluating the association between alcohol consumption and mental health disorders.

The quality of the evidence included in this systematic review varied across the critical outcomes. GRADE rates epidemiological evidence typical of public health as low to very low quality; hence, the certainty in the overall evidence was rated accordingly as very low.

Higher 'quality' study designs that are more typical for clinical practice guidelines — such as randomised control trials — are not appropriate for most public health interventions. **Well-designed observational studies are often the best source of evidence on public health issues**, but they would be attributed a GRADE rating of low to very low.

Preference and values

Is there variation in how much value people (including their parents or carers) place on the desirable and undesirable effects of alcohol consumption for adolescents under 18?

It is expected that there is variability in how much young people and their parents or carers value minimising alcohol-related harm to young people, and in how the balance of the desirable and undesirable effects are considered.

It is expected that Australians value being able to make informed choices.

Equity

What would be the impact on health equity if Australian adolescents consumed alcohol at these proposed levels?

'Health equity is the notion that everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential if it can be avoided' [163].

It is expected that health equity would be increased if this recommendation was implemented and adopted by young people and their parents or carers.

The recommendation should not create new health inequities or worsen any current inequities; however, if it is not effectively implemented, the opportunity to reduce inequities will be missed. The messages need to reach those most vulnerable to alcohol-related harm.

Information about the associations between alcohol consumption and outcomes for young people is detailed in the guideline. Drinking alcohol within the guideline recommendation aims to minimise the risk of alcohol-related harm for young people, so that those young people currently disadvantaged by not being aware of these risks (and by their parents or carers not being aware) will have a better chance of realising their full health potential. Of note, socioeconomic status does not determine whether an adolescent drinks alcohol or not.

Acceptability

Would recommending not drinking for this age group in order to minimise harm be acceptable to adolescents and their parents or carers?

As the recommendation is consistent with the previous 2009 recommendation, it is expected that it will be generally acceptable to most Australian parents or carers and young people. There may be variability in the acceptability of the guideline among young people.

Feasibility

Is the option realistic and practical (feasible) to implement?

The recommendation is expected to be feasible because it is consistent with the 2009 recommendation.

The success of the guidelines in improving health outcomes is entirely dependent on their successful dissemination, public communications and ongoing community awareness-raising about the guidelines (including to health professionals), for which the Australian Government is responsible.

Resources and other considerations

Does this proposed recommendation have resource implications (costs)?

There are expected costs associated with implementing this recommendation through health promotion and other policy activities. However, it is expected that if children and young people do not consume alcohol (i.e. if they align with this recommendation), there would be health-related savings by preventing short-term and long-term harm, and therefore minimising the impact on the health system.

GRADE, Grading of Recommendations Assessment, Development and Evaluation.

Guideline 3: Women who are pregnant or breastfeeding

Confirming a priority issue

Is the problem a priority?

Yes (see the Rationale for Guideline 3)

Benefits and harms

How substantial are the harms and benefits of alcohol consumption for pregnant and breastfeeding women?

There are substantial net benefits in not drinking alcohol, as advised by this guideline, when pregnant and while breastfeeding, as opposed to drinking alcohol.

A more precautionary approach has been taken for these recommendations than for Guideline 1 because of the potential for lifelong harm for babies and the need for additional clarity in the wording of the guideline.

Please see Sections 6.1 and 6.2 of the guidelines for more details on the associations between maternal alcohol consumption during pregnancy and while breastfeeding, and various health outcomes.

Certainty of the evidence

What is the overall certainty/quality of the evidence?

Part of the evidence supporting this recommendation comes from a systematic review of systematic reviews evaluating the evidence on the health effects of alcohol consumption during pregnancy and while breastfeeding, in relation to the following health conditions:

- preterm birth
- low birth weight
- small for gestational age
- child motor function
- developmental delay, communication (language) delay and communication development.

The evidence base for this recommendation included a systematic review evaluating the association between alcohol consumption during pregnancy and adverse pregnancy outcomes or birth defects and behavioural problems in babies and children, and a systematic review of the association between alcohol consumption while breastfeeding and selected outcomes.

The quality of the evidence included in these systematic reviews varied across the critical outcomes. GRADE rates epidemiological evidence typical of public health as low to very low; hence, the certainty in the overall evidence was rated accordingly as very low.

Higher 'quality' study designs more typical for clinical practice guidelines — such as randomised control trials — are not appropriate for most public health research. *Well-designed observational studies are often the best source of evidence on public health issues*, but they would be attributed a GRADE rating of low to very low.

Preference and values

Is there variation in how much value women (and their partners) place on the desirable and undesirable effects of alcohol consumption when they are pregnant, planning pregnancy or breastfeeding?

It is expected that most Australian women who are pregnant, might become pregnant or are breastfeeding (and men or women as fathers or co-parents) would value minimising harm to fetuses and babies in the context of alcohol consumption. It is expected that Australians value being able to make informed choices.

Equity

What would be the impact on health equity if Australian women consumed alcohol according to the advice in this guideline?

'Health equity is the notion that everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential if it can be avoided' [163].

It is expected that health equity would be increased if these recommendations were implemented and adopted by Australian women who are pregnant, planning pregnancy or breastfeeding.

The recommendation should not create new health inequities or worsen any current inequities; however, if it is not effectively implemented, the opportunity to reduce inequities will be missed.

Information about the associations between maternal alcohol consumption and certain infant outcomes is detailed in the guideline. Drinking alcohol within the guideline recommendation would minimise the risk of alcohol-related harm for all infants and children. In keeping to this guideline recommendation, those currently disadvantaged by not being aware of these risks to the unborn child will give their unborn child a better chance of realising their full health potential.

Acceptability

Would recommending not drinking for pregnant and breastfeeding women in order to minimise harm to the fetus, unborn child or infant be acceptable to these women (and their partners)?

As the recommendations are consistent with the 2009 recommendations, it is expected that they will also be generally acceptable to Australian women who are pregnant, planning pregnancy or breastfeeding (and to men or women as fathers or co-parents).

Feasibility

Is the option realistic and practical (feasible) to implement?

The recommendations are considered feasible to implement given that they are consistent with the 2009 recommendations.

The success of the guidelines in improving health outcomes is entirely dependent on their successful dissemination, public communications and ongoing community awareness-raising about the guidelines (including to health professionals), for which the Australian Government is responsible.

Resources and other considerations

Does this proposed recommendation have resource implications (costs)?

It is expected that if Australian women who are pregnant, might become pregnant or are breastfeeding consume alcohol in line with these recommendations, there would be the following resource implications:

- Health and health system savings owing to:
 - reduced hospital admissions caused by alcohol-related harm to the fetus, baby or child
 - reduced visits to allied health and medical professionals about alcohol-related harm to the fetus, baby or child (e.g. to diagnose and manage infants and children with FASD)
 - reduced impact on other areas of the health system related to this issue.
- Savings for the early intervention and education sector, owing to a reduced need for services to work with infants and children with FASD. In Australia, FASD rates have been reported at 0.01–0.68 per 1000 births in the total population; however, this is considered to be an underestimate [165]. There would also be a reduced demand on social services and care-giving services.
- Improved productivity and economic benefit from improved health and quality of life through the prevention of FASD.
- Savings for the criminal justice sector, given research evidence indicating over-representation of children with more severe FASD [131, 132].

FASD, fetal alcohol spectrum disorder; GRADE, Grading of Recommendations Assessment, Development and Evaluation.

Appendix 4: Practical information

How to apply the Australian Guidelines to Reduce Health Risks from Drinking Alcohol

This section helps to put the guidelines into action and includes links to further information. The information is based on the expertise of the NHMRC's Expert Committee. It has not gone through the evaluation process applied to the guidelines themselves.

Guideline 1: Adults

To reduce the risk of harm from alcohol-related disease or injury, healthy men and women should drink no more than 10 standard drinks a week and no more than 4 standard drinks on any one day.

The less you drink, the lower your risk of harm from alcohol.

This guideline aims to reduce the risk of alcohol-related harm, injury, illness or death for healthy adult men and women. It is not a recommendation for minimum consumption. If you are a non-drinker, the guideline does not suggest that you can benefit from drinking alcohol.

How to reduce my risk of harm from drinking

There are several strategies you can use. For example:

- eat food before and while drinking alcohol
- · for every drink of alcohol, have one non-alcoholic drink
- · check the label on your drink to see how many standard drinks it contains
- keep in mind drinks served in pubs, bars and restaurants are often served in larger glasses and can contain more than one standard drink
- set limits for yourself and stick to them
- if you are thirsty, drink water before alcohol
- avoid using alcohol to deal with stress, anxiety or poor sleep. Although it may give short-term relief, drinking alcohol to deal with these problems may make them worse
- develop a range of alternative approaches to deal with stress and anxiety. Consult with your GP or other health professional for some possible solutions.

When should I drink less?

There are some situations in which even small amounts of alcohol increase risk. These include:

- driving a vehicle
- riding a motorbike or bicycle
- using machinery or other activities that need concentration
- boating, fishing, swimming or other activities on and around the water
- supervising children or when you are responsible for the safety of others
- using certain medicines or drugs.

Risks associated with these activities increase when alcohol is added and continue to increase with every drink.

How can I manage safety among friends and family?

If you meet with friends or family in situations where drinking alcohol is likely, you can reduce the risk for the whole group by, for example:

- deciding on a nominated driver or agreeing to travel by public transport
- ensuring children are under safe supervision by a non-drinking adult
- being aware of potential risks in the environment, such as nearby roads or bodies of water
- looking out for the safety of others.

When do the effects of alcohol end?

Time is the only antidote to alcohol. The average healthy adult needs at least one hour - and often longer - to process the alcohol in a single standard drink.

Activities such as showering, exercise, or drinking coffee after consuming alcohol do not speed up its removal from the body.

What if it's too hard to limit my intake?

Some people find it hard to limit their drinking. Once they start, it is difficult to stop.

For people in this situation, there are professional and community-based approaches that can provide support and help. Options include making an appointment with your GP, and learning more about effects of alcohol by reading the expert advice presented on the Australian Government Department of Health website: <u>https://www.health.gov.au/health-topics/alcohol</u>

Where can I get help?

The Australian Government Department of Health recommends the services of a number of research and community organisations, such as:

- Alcohol and Drug Foundation: 1300 858 584 or visit: <u>www.adf.org.au</u>
- Alcohol. Think Again: 1800 198 024 or visit: <u>www.alcoholthinkagain.com.au</u>
- Alcoholics Anonymous: 1300 222 222 or visit: <u>www.aa.org.au</u>

For a full list of organisations, visit: <u>https://www.health.gov.au/health-topics/alcohol/</u><u>alcohol-contacts</u>

This document contains links to other websites which are external to the Australian Government National Health and Medical Research Council. Views or recommendations provided in linked sites may include the views or recommendations of third parties and do not necessarily reflect those of the Commonwealth or indicate a commitment to a particular course of action.

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What is a standard drink?

A standard drink is 10 grams of pure alcohol. The type of alcohol makes no difference, 10 grams of alcohol is 10 grams of alcohol, whether it is in beer, wine or spirits. It does not matter whether it is mixed with soft drink, fruit juice, water or ice.



Guideline 2: Children and people under 18 years of age

To reduce the risk of injury and other harms to health, children and people under 18 years of age should not drink alcohol.

Why not drinking is important for young people

Human brains continue to develop until around the age of 25 years and are particularly sensitive to alcohol. Drinking is a contributor to the leading causes of death among adolescents, including road accidents, injuries and suicides. It also contributes to risk-taking. For these reasons, children and adolescents should not drink.

Parental supply of alcohol

There is evidence that early drinking increases the risk of behaviour and health problems in later life. There is no evidence that giving children or teenagers alcohol under parental supervision helps protect them against risky drinking.

How can I reduce the chances of my children drinking alcohol?

- Work on good, open communication. Talk to your child or adolescent about alcohol; listen as well as share information. Explain the risks and harms from drinking alcohol.
- Spend regular one-on-one time with them, doing activities you both enjoy.
- Help them feel they belong in their family, school or sporting club.
- Help them feel good about themselves. Praise their efforts or achievements. Make them feel respected and loved.
- Be aware of the influence of friends and peers. Talk with your teenager about pressure they may experience, and how to respond.
- Encourage positive friendships. Maintain communication with other parents if you have a united approach to alcohol, it can make life easier.
- For detailed expert advice, please visit <u>www.health.gov.au/health-topics/alcohol/alcohol-throughout-life/alcohol-and-young-people#how-to-reduce-your-risk</u>

How can I be a role model?

- If you drink, do so within the guidelines.
- Don't drink every time you see friends, celebrate or relax.
- Find ways to cope with stress that do not involve alcohol.

Parties

- Contact the host to check that a parent will be there. Ask if alcohol will be present and, if so, how they will ensure children don't access it.
- Encourage your adolescent to call you if or when they want to leave.
- Consider providing travel cards and phone credit as lower risk alternatives to cash.

Where can I get help?

More information about alcohol and young people can be found on the Australian Government Health Department website: <u>https://www.health.gov.au/health-topics/</u><u>alcohol/alcohol-throughout-life/alcohol-and-young-people</u>

The Department of Health website also offers advice for parents and children: www.health.gov.au/health-topics/alcohol/alcohol-contacts

A wide range of articles, apps and videos on issues around alcohol, children and young people can also be found at: <u>https://raisingchildren.net.au/</u>

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Guideline 3: Women who are pregnant or breastfeeding

- A. To prevent harm from alcohol to their unborn child, women who are pregnant or planning a pregnancy should not drink alcohol.
- B. For women who are breastfeeding, not drinking alcohol is safest for their baby.

Pregnancy

- No safe level of drinking during pregnancy has been identified.
- The risk of harm to a developing baby increases the more, and the more frequently, the mother drinks. The risk reduces the earlier the mother ceases drinking.
- If a woman drinks alcohol before she finds out she is pregnant, it does not automatically mean the baby will be harmed.
- Women who stop drinking when they find out they are pregnant reduce the risk of harm to the developing baby.
- If you are a heavy drinker, seek medical support to stop safely. Withdrawal syndromes are bad for developing babies.
- Partners of pregnant women play an important role, supporting the decision not to drink.
- Talk to your GP or women's health professional.

For more advice on alcohol and pregnancy, please visit the Alcohol and Drug Foundation: <u>https://adf.org.au/insights/alcohol-and-pregnancy/</u>

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Breastfeeding

For women who are breastfeeding, not drinking alcohol is safest for their babies.

- If a mother drinks when she is breastfeeding, the alcohol crosses into the breastmilk.
- If a mother breastfeeds her baby while there is still alcohol in her breastmilk, the baby also drinks the alcohol.
- When a mother drinks alcohol while breastfeeding, the baby can have problems feeding and sleeping.
- A baby's brain keeps developing after it is born. This means an infant's brain is more sensitive to damage from alcohol than an adult brain.

But what if I decide to drink alcohol?

- Not drinking is always the best option for you and your baby, but if you do decide to drink, you can reduce the risk to your child by planning ahead.
- Breastmilk expressed and stored before you have a drink will not contain alcohol. This can be used to feed the baby afterwards.
- Only time removes alcohol from breastmilk, and it takes at least an hour for a healthy adult body to process one standard drink. Breastmilk won't be free of alcohol until the level in the mother's bloodstream returns to zero. If a woman drinks several drinks, she will not be able to safely breastfeed for multiple hours. "Pump and dump" does not do the trick!

Where can I get help?

Seek professional advice if you have questions about this information.

More information about alcohol, pregnancy and breastfeeding can be found on the Australian Government Health Department website: <u>https://www.health.gov.au/health-topics/alcohol/alcohol-throughout-life/alcohol-during-pregnancy-and-breastfeeding</u>

Download the free <u>Feed Safe</u> app to help know when breastmilk should be free of alcohol. Created by the Australian Breastfeeding Association, Reach Health Promotion Innovations and Curtin University, it is available for Apple and Android devices.

<u>Call a breastfeeding counsellor</u> on the Australian Breastfeeding Association Helpline, available 24/7, 1800 686 268.

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Appendix 5: Administrative report

Introduction

In March 2009, the National Health and Medical Research Council (NHMRC) released the *Australian guidelines to reduce health risks from drinking alcohol* [4], providing policymakers, health professionals and the Australian community with evidence-informed advice concerning the health risks of drinking alcohol. At its 203rd session in March 2015, the <u>Council of NHMRC</u> considered the status of the 2009 alcohol guidelines as part of its routine process of considering whether current clinical practice and public health guidelines that were produced more than 5 years ago required revision. Council recommended to NHMRC's Chief Executive Officer that the 2009 alcohol guidelines be updated.

Contributors

The guidelines were developed with the expertise of the Alcohol Working Committee (or Expert Committee, see below). The Office of NHMRC managed the process, and representatives from the Australian Government Department of Health participated as observers at committee meetings.

Current NHMRC Project Team

- Cathy Connor: Director Public Health Team
- Jennifer Savenake: Director Public Health Team (from Feb 2020)
- Catherine King: Assistant Director Public Health Team
- Melanie Grimmond: Senior Project Officer Public Health Team

Previous NHMRC Project Team

- Zeinab Bazzi
- Heather Kirk
- Tanja Farmer
- Rebecca Rees
- Elaine Stone

Contractors

- University of Adelaide, systematic reviewers
- Cochrane Australia, systematic reviewers
- Cochrane Australia and South Australia Health and Medical Research Institute, systematic reviewers
- Clinical Trials Centre, University of Sydney, methodological reviewers
- Sheffield Alcohol Research Group, Sheffield University, mathematical modellers

Governance

The Australian Government Department of Health commissioned NHMRC to update the 2009 guidelines, and contributed funding to the comprehensive evidence evaluation and other project costs. NHMRC provided funding for staffing, committee costs and mathematical modelling. NHMRC sought input from the Australian Government Department of Health, NHMRC's Consumer and Community Advisory Group and its Principal Committee Indigenous Caucus to finalise the draft guidelines before public consultation.

All draft research protocols and evidence evaluation reports were considered and advised on by the Alcohol Working Committee in line with its terms of reference (see below). The Committee advised on the development of the guidelines as described below. The Council of NHMRC considered the draft guidelines on 6 December 2019 and recommended to the NHMRC Chief Executive Officer that they be released for public consultation. The NHMRC Chief Executive Officer agreed to release the guidelines for public consultation on 16 December 2019.

Following this the Expert Committee met to consider public consultation submissions and advise on revisions to the guidelines. The revised guidelines underwent independent expert review from 20 July to 28 September 2020 as described below.

At their meeting on the 29 October 2020 the Council of NHMRC advised the Chief Executive Officer to issue the Guidelines. The Chief Executive Officer agreed to issue the Guidelines under section 7(1)(a) of the *National Health and Medical Research Council Act 1992.*

Guideline development

Since 1987, NHMRC has published evidence-based guidelines to help Australians reduce the risk of harm associated with drinking alcohol. The previous edition, *Australian guidelines to reduce health risks from drinking alcohol*, was published by NHMRC in 2009 [4]. Research on the health effects of alcohol is continuously evolving, and new studies are published regularly. For this reason, NHMRC reviews its guidelines to ensure that the advice is up to date and reflects the latest body of evidence.

In 2015, the Council of NHMRC, in consultation with the Australian Government Department of Health, requested that the guidelines be revised. The Alcohol Working Committee was appointed to guide this revision. This independent expert committee comprises expertise in clinical and public health, alcohol policy, alcohol research, consumer advocacy, epidemiology and biostatistics (see terms of reference and membership below).

The 2009 guidelines took a novel approach to reporting on the health risks of drinking, providing new information about the risks of alcohol-related harm over a lifetime. Specifically, the 2009 guidelines conveyed to the Australian public and policymakers a new concept of the risk of harm progressively increasing as the amount of alcohol consumed increases. In these revised guidelines, NHMRC has retained this approach but has simplified the messages further by separating the guidelines into three distinct categories: adults, children and young people, and pregnant or breastfeeding women.

An internationally recognised approach — Grading of Recommendations Assessment, Development and Evaluation (GRADE) — was used to synthesise the evidence and translate this into guideline recommendations and accompanying text. In developing the recommendations, quality evidence from a range of sources was considered, as detailed below.

NHMRC has started to use an electronic approach for publishing guidelines. For these guidelines, NHMRC has presented the recommendations and other information in the MAGICapp platform (which incorporates templates for GRADE and integrated reference management) in addition to the PDF format. As a publishing platform, MAGICapp makes it

possible to update elements or modules of a guideline and display a 'version history' for any updates. NHMRC will manage any changes to the synthesis of the body of the evidence or the wording of the recommendations in line with the *National Health and Medical Research Council Act 1992*. This will usually include establishing an expert committee and having a public consultation process. Minor typographical errors or broken links can be amended through scheduled maintenance.

The evidence base for the guidelines

A range of inputs was considered in revising the guidelines that included:

- the 2009 guidelines guideline elements were retained in the updated version unless there were compelling reasons to change them
- the current worldwide evidence on the effects of alcohol relevant to the Australian community, including data from 42 systematic reviews and additional supplementary evidence (reports available at www.nhmrc.gov.au/alcohol)
- data on health indicators, alcohol consumption, sociodemographic and other features of the Australian community
- for Guideline 1, modelling of the relationship between alcohol and a range of outcomes, including cause-specific and all-cause mortality (report available at <u>www.nhmrc.gov.au/alcohol</u>)
- public health and implementation considerations for effective, evidence-based policy and guidance, including for important populations within Australia
- trends in international alcohol consumption guidance
- the shared expertise of the Expert Committee
- NHMRC and international best practice for guideline development.

For further information see section 1.5 The evidence base for the guidelines.

Assessing the evidence

The methods used to analyse and interpret the evidence align with international best practice. They are summarised below, with further information available within each of the systematic review and modelling reports. Since the publication of the previous edition of the guidelines, there have been substantial advances in the methodology for guideline development and formatting, and these have been used for this revised guideline. This includes the use of the GRADE methodology and the MAGICapp platform for publication.

Scoping

NHMRC undertook a scoping activity to help the Alcohol Working Committee to determine whether all or part of the 2009 guidelines needed to be updated, and to identify any gaps in the existing guidelines.

NHMRC scanned the published literature for new scientific evidence that had emerged since the 2007 systematic review that underpinned the 2009 guidelines. The purpose of this search was to assess the volume of evidence published since 2007, to identify priority areas for the revision of the 2009 guidelines. This search encompassed literature published from 1 January 2007 until May 2016, and was restricted to systematic reviews or meta-analyses (or both). In addition, references listed in the report from the United Kingdom Committee on Carcinogenicity — *Statement on consumption of alcoholic beverages and risk of cancer* (2015) [167] — which was published alongside the draft guidelines from the United Kingdom, were included. No thorough assessment of the evidence or quality of the systematic reviews was performed at this point in the process; only abstracts were retrieved. The results of the literature search indicated where evidence on the health effects of alcohol has grown and areas where the evidence is still lacking. The search was structured around the four guideline recommendations included in the 2009 guidelines.

NHMRC also compared the existing 2009 guidelines with other national and international guidelines.

Public call for evidence

NHMRC conducted a public call for evidence between 25 November 2016 and 13 January 2017, to capture relevant studies and issues of public concern. To be considered, publications had to meet certain quality criteria, set by the Expert Committee:

- high-quality studies based on scientific research (systematic reviews, randomised controlled trials and observational studies including cohort, case-control or nested case-control studies)
- published after the search of the literature for the evidence evaluation report was conducted
- assessing the health effects of varying levels or patterns of alcohol consumption alcohol only, not in combination with other drugs – that were generalisable to the Australian population
- publicly available and published in the English language in peer-reviewed journals.

Evidence from the public call was used to support and update the content within the guidelines. A summary of the evidence used to develop each recommendation and the accompanying information is included in each of the guideline sections.

Systematic reviews

Two systematic review activities were used: systematic review of systematic reviews, and commissioning of systematic reviews. These activities are described below.

Systematic review of systematic reviews

An overview of systematic reviews was completed to consider the short-term and long-term health risks and benefits associated with various levels and patterns of drinking alcohol (exposure). The analysis focused on identifying systematic reviews and meta-analyses published since 2007, to identify areas where the evidence has grown since the 2009 guidelines. The Clinical Trials Centre from the University of Sydney was engaged to do this evaluation. The evidence review team completed a declaration of interest process before being appointed by NHMRC, and no conflicts of interest were identified. The report of this overview was finalised in January 2018 and can be found at <u>www.nhmrc.gov.au/alcohol</u>.

Commissioning of systematic reviews

Four systematic reviews were commissioned by NHMRC to address identified gaps in existing review evidence. These included evidence on the association of alcohol exposure with mental health and long-term cognitive impairment through pregnancy and breastfeeding. The evidence review teams completed a declaration of interest process before being appointed by NHMRC, and no conflicts of interest were identified.

The independent evaluations of the evidence were undertaken in accordance with research protocols approved by the NHMRC Project Team, based on advice from the Alcohol Working Committee. For each review, the research protocols outlined the scope, scientific question and methodology. The methods and results of the review are detailed in the Evidence Evaluation Reports and Technical Reports finalised in November 2018, found at <u>www.nhmrc.gov.au/</u> <u>alcohol</u>. They include the research questions using the PECO approach (population, exposure, comparator, outcomes); the search strategy; and the methods used to select, appraise and summarise the evidence, results and evidence profiles.

The contracted reviewers were:

- Adelaide Health Technology Assessment, the University of Adelaide reviewing the association between alcohol consumption and mental health disorders
- Cochrane Australia reviewing the association between alcohol consumption and long-term cognitive impairment
- Cochrane Australia and the South Australia Health and Medical Research Institute reviewing the association between different levels and patterns of:
 - alcohol consumption during pregnancy and birth defects and behavioural problems in fetuses, babies and children
 - maternal alcohol consumption while breastfeeding and health outcomes for breastfed babies and children (up to 5 years of age).

The Evidence Evaluation Reports and Technical Reports were published on the NHMRC website in December 2019, to coincide with the public consultation on the draft guidelines.

Mathematical modelling

Guideline 1 is informed by mathematical modelling, which estimates the risk of dying from alcohol-related disease and injury from different levels and patterns of drinking. The model simulates the relationship between any given level of alcohol consumption and the risk of disease and death for different age groups in Australia. The risk threshold chosen for this guideline corresponds to a 1 in 100 chance of dying from alcohol-related disease or injury for an average, healthy adult person who drinks alcohol (see the Rationale for Guideline 1), and is consistent with the threshold used in the NHMRC 2009 alcohol guidelines [4]. The analyses from the modelling are outlined in more detail in the modelling report (see <u>www.nhmrc.gov.au/alcohol</u>).

The Sheffield Alcohol Research Group, based at Sheffield University in the United Kingdom, was commissioned by NHMRC to complete this work. Modelling was undertaken using an adaptation of the Sheffield Alcohol Policy Model v2.7, which is a mathematical simulation model that has previously been used to assess alcohol policy options in the United Kingdom and internationally. For more information about the modelling and how it was used to develop the guideline recommendation, see Appendix 2.

Quality assurance step: independent methodological review

An independent methodological review of the five systematic reviews described above was completed to ensure that the reviews followed the systematic and rigorous approach specified in the respective research protocol. The methodological review of the overview was completed by Ms Lisa Jones, Reader in Public Health, Liverpool John Moores University, Liverpool, United Kingdom.

The Clinical Trials Centre from the University of Sydney was engaged by NHMRC to methodologically review the four systematic reviews.

Public consultation

Public consultation is a core feature of the guideline development work of the NHMRC, contributing to the accountability of the agency and the independence of the advice. For the draft guidelines, public consultation was undertaken from 16 December 2019 to 24 February 2020. The process was conducted in accordance with Section 13 of the *National Health and Medical Research Council Act 1992*.

Public consultation was advertised on the NHMRC website, NHMRC Tracker and social media platforms. Invitations were also sent to a large number of key stakeholders.

The Alcohol Working Committee met on 30 April and 6, 7, 12 and 22 May 2020 to consider all submissions. Table A5.1 summarises the main suggestions and key actions taken.

Table A5.1 Summary of main suggestions and key actions taken by the Alcohol Working Committee

DRAFT ALCOHOL GUIDELINES PUBLIC CONSULTATION: SUMMARY OF KEY ACTIONS TAKEN		
Note: Alcohol Working Committee guiding principle for making changes: edits are made to the draft guideline only if there is compelling evidence to do so.		
Consultation comment or suggestion	Edits/changes made	
General, structural or formatting	changes	
General typographical or grammatical errors	Numerous grammatical, formatting and typographical edits were made to improve consistency and clarity of the text.	
	They included using 'adolescent' instead of 'young people' in Guideline 2, and clarifying use of 'fetus' and baby' for Guideline 3.	
Some statistics in graphs and text queried	Statistics, citations and graphs were updated and improved throughout.	
GRADE steps and how evidence	Relevant text on evidence was clarified in each guideline section.	
was used could be clarified	The three GRADE 'Evidence to Decision frameworks' were moved to a new appendix (Appendix 3), which clarifies the importance of this step in the GRADE process and how it was used to develop the strength and wording of the guideline recommendations.	
	A schema was developed to illustrate evidence sources (see Figure 1.1 in Section 1).	
One submission queried adequacy of consumer engagement	Nil edits were required. NHMRC had consumer representation on the Expert Committee, and consulted with two of NHMRC's Principal Committees that represent consumer issues. NHMRC also invited the public to participate in providing evidence (on two separate occasions), and in providing public comment on the completed draft guideline.	
Plain English summary		
Requires simplifying	The document was comprehensively edited to simplify the language; only the main guideline recommendations were included, together with the reasons why they were developed.	
Standard drink needs defining	The definition and illustration of a standard drink were included.	
Plain English summary or executive summary?	A new guideline summary was created, in addition to the Plain English summary. It articulates the guideline recommendations and key messages.	
Introduction		
References to aims across the document are not aligned	The aims and scope of the guideline were clarified. The aims of the individual guidelines were edited to align with the overarching guideline aim.	
Queries about the challenges for NHMRC in maintaining a 'living' guideline	The section about how NHMRC plans to monitor its 'living' or 'sustainable' guidelines was edited.	
Many questions asked and suggestions provided across the guidelines about the importance of implementation	The text was edited to reinforce that implementation is critical to the success of the guidelines, and to extend responsibility for implementing the guidelines from just the Australian Government Department of Health to state and territory health departments and other nongovernment organisations.	

DRAFT ALCOHOL GUIDELINES PUBLIC CONSULTATION: SUMMARY OF KEY ACTIONS TAKEN

Note: Alcohol Working Committee guiding principle for making changes: edits are made to the draft guideline only if there is compelling evidence to do so.

Consultation comment or suggestion	Edits/changes made
Suggestions to link more to the recently published National Alcohol Strategy	The National Alcohol Strategy is now referred to in Sections 1-3.
Clarify what is different from the 2009 version of the guideline	The document reports what has been retained from the 2009 guideline, and what is different.
Background	
Specify burden of disease information as it relates to alcohol consumption	The text was amended to clarify information on burden of disease, including that it relates to death, disability and injuries caused by drinking alcohol.
Immediate and cumulative effects section requires editing. Many submissions provided edits as if this section was the main information about the effects of drinking alcohol, rather than giving an overview or background to how alcohol affects the body.	Descriptions of the immediate and cumulative effects of alcohol were improved. This section was comprehensively edited given its intended purpose of simply listing these effects of alcohol, rather than providing detailed information on the pathophysiology.
Understanding the concepts of ris	k
This section only refers to Guideline 1	The explanations of concepts of risk were expanded to refer to all three guidelines, not just Guideline 1.
'Acceptable risk' is difficult for the average person to understand	The explanation of what is an 'acceptable risk' for Australian society was improved.
This section should more strongly refer to the 'precautionary principle'	Reference to the precautionary principle being considered in developing the advice in Guideline 2 and Guideline 3 was included. This principle is based on the idea that it is better to take preventive or cautionary steps now, rather than have to deal with any alcohol-related harms later in life.
Definitions of risk could be improved	Definitions of risk were revised, including lifetime risk, and distinguishing between lifetime risk and lifetime risk of alcohol-related harm.
Explain why the Expert Committee chose to set the risk threshold for dying from an alcohol-related disease or injury at 1 in 100 over a lifetime	An explanation was provided showing that different risk thresholds were considered, including 1 in 50, 1 in 100 and 1 in 1000. The risk threshold of 1 in 100 for lifetime risk of death from an alcohol-related disease or injury was the basis of the previous version of the guideline (2009). It equates reasonably well with other voluntary risks such as driving a car and the Expert Committee identified no compelling evidence to change this.
Guideline 1	
Edits to recommendation wording. Comments provided on the wording and syntax.	The recommendation was edited to: 'To reduce the risk of harm from alcohol-related disease or injury, healthy men and women should drink no more than 10 standard drinks a week and no more than 4 standard drinks on any one day. The less you drink, the
Several comments on the use of 'safest' in the last sentence ' <i>For</i>	lower your risk of harm from alcohol'.
some people, not drinking at all is the safest option'.	The last sentence of the draft recommendation was discussed and the Expert Committee advised that it be deleted. The last sentence in the revised recommendation (see above) clearly states the relationship between drinking alcohol and alcohol-related harm.

DRAFT ALCOHOL GUIDELINES PUBLIC CONSULTATION: SUMMARY OF KEY ACTIONS TAKEN

Note: Alcohol Working Committee guiding principle for making changes: edits are made to the draft guideline only if there is compelling evidence to do so.

Edits/changes made
The text was amended to highlight that the modelling was only one of a number of inputs used to develop the guideline recommendation.
A new infographic (Figure 1.1) was added to the Introduction section to illustrate all the inputs used to develop the recommendation, and this figure is referred to throughout the guideline.
The guideline retains the same advice for men and women because physiological differences are minimal for the level of alcohol consumption advised in the recommendation. This issue has been revised in Section 3 and in Guideline 1.
The 1 in 100 risk threshold used to interpret the modelling results was retained because there was no compelling reason to change this 2009 threshold, and it equates reasonably well with other voluntary risks such as driving a car.
The average drinking frequency of 3 days per week was retained because this is sourced from the best data Australia currently has for estimating average drinking frequency. Appendix 3 was revised for clarity.
A new dot point was added to the key messages stating that not drinking at all is the best way to reduce the risk of harm from alcohol.
Additional text about the purported protective effects of alcohol was included. The current evidence regarding protective effects is uncertain and, if such effects exist, they are compatible with the guideline. Additional text was included to explain that the modelling was only one of a number of inputs used to develop the guideline
recommendation.
To clarify that the modelling is just one of many inputs, and that the tables in the modelling report are not to be interpreted as an individual guide to drinking alcohol, the draft Tables 5.5.1 and 5.5.2 and the explanatory text were moved to a new appendix (Appendix 2) called 'Guideline 1 modelling results'. Also, a new schema (Figure 1.1) was added to the Introduction, to illustrate all inputs.
The key message was retained that there is no clear safe or no-risk level of alcohol consumption for children and people under 18 years. The text referring to the precautionary principle was re-confirmed.
Text was included noting that parental supply of alcohol to their children does not protect against alcohol-related harm.
The top four causes of burden of disease for people 15-24 years of age (as reported in the AIHW 2019 Burden of Disease Study) were included in Section 3.

DRAFT ALCOHOL GUIDELINES PUBLIC CONSULTATION: SUMMARY OF KEY ACTIONS TAKEN

Note: Alcohol Working Committee guiding principle for making changes: edits are made to the draft guideline only if there is compelling evidence to do so.

Consultation comment or suggestion	Edits/changes made
Given the recommendation advised not drinking, the <i>Practical information</i> section should not refer to harm reduction strategies.	The practical information section now includes practical advice that is in line with the recommendation as well as links to resources provided by the Expert Committee. This is now presented as a separate appendix, Appendix 4, which combines practical information for all three guidelines.
Guideline 3	
This recommendation aims to prevent, not reduce harm	The pregnancy recommendation and key message were clarified to refer to 'preventing alcohol-related harm'.
Several submissions queried the statement: <i>The risk from low-level</i> <i>drinking (e.g. one standard drink</i> <i>a day) is likely to be low</i>	The sentence that states ' <i>the risk from low-level drinking</i> (e.g. 1 standard drink a day) is likely to be low' was edited to include that ' <i>there is not enough evidence to say that it is safe</i> '. This more accurately represents the evidence.
Some submissions commented that many women do not know about the potential harms for the	The guideline was amended to include some information on the proportion of women who are unaware of the risks associated with alcohol consumption during pregnancy.
unborn child when a pregnant woman drinks alcohol	This advice was also provided as part of ideas to improve implementation of the guidelines.
Several submitters asked for a strengthening of the information about the potential risks to the unborn child and later as a child	The text was amended to include information about evidence for the association of maternal alcohol consumption and fetal craniofacial abnormalities, and that the developing infant brain is more vulnerable to damage from alcohol than the adult brain.
or adolescent	Information on FASD was expanded to recognise that the impacts of FASD on behaviour are lifelong; for example, by referring to interactions with juvenile detention and the justice system.
Appendixes	
Appendix 1: Drinking frequency	This appendix was redrafted to more clearly explain how the average drinking frequency of 3 days per week was derived and how it relates to the development of the Guideline 1 recommendation.
Appendix 2: Guideline 1 modelling results	This new appendix contains information from the modelling report. Tables and figures as well as relevant text from Guideline 1 were included, to more clearly explain the results.
Appendix 3: GRADE Evidence to Decision frameworks	This new appendix captures the GRADE step that is important for determining the strength and wording of the recommendations.
Appendix 4: Practical information	This new appendix contains practical advice from the Expert Committee on how to use the three guidelines. It Includes some services and their contact details.

FASD, fetal alcohol spectrum disorder; GRADE, Grading of Recommendations Assessment, Development and Evaluation.

Quality assurance step: independent expert review

How expert reviewers were nominated

Expert reviewers were nominated by members of the Council of NHMRC, the Australian Government Department of Health, the Alcohol Working Committee and others. Acceptance criteria for nominations for individuals who could undertake expert review of the draft guidelines following public consultation were similar to those for previous NHMRC guideline development projects; they included the reviewer:

- having appropriate knowledge of the evidence base underpinning public health guidelines about alcohol consumption
- being familiar with the translation of public health evidence into advice or guidelines
- having familiarity with GRADE process being highly desirable
- declaring interests according to NHMRC policies, and any interests being deemed either not in conflict with the guideline development process, or manageable through an appropriate strategy.

Independent expert review was completed between 20 July to 28 September 2020. Expert reviews were completed by:

- Emeritus Professor Bruce Armstrong, University of Sydney
- Dr Jacqueline Bowden, South Australian Health and Medical Research Institute
- Ms Heather D'Antoine, Menzies School of Health Research
- Emeritus Professor Jake Najman, University of Queensland.

A joint expert review of the modelling was completed by:

- Professor Karen Canfell, Cancer Council NSW
- Dr Michael Caruana, Cancer Council NSW
- Ms Clare Kahn, Cancer Council NSW
- Professor Dianne O'Connell, Cancer Council NSW
- Dr Peter Sarich, Cancer Council NSW
- Dr Marianne Weber, Cancer Council NSW.

How expert review comments were used

The Council of NHMRC and the Chief Executive Officer determined how the expert review feedback was actioned, and sought the advice of the Alcohol Working Committee where required.

Table A5.2 Summary of expert review feedback and key actions taken

SUMMARY OF EXPERT REVIEW FEEDBA	ACK AND KEY ACTIONS TAKEN
Feedback	Action
General feedback	
Expert reviewers provided positive feedback and overall support for the Guidelines. Reviewers noted that the Guidelines were highly appropriate for the Australian community, were written in accessible language and aligned with other high quality international Guidelines.	No edits required.
Evidence base	
Expert reviewers agreed that the Guidelines are supported by a strong and appropriate evidence base.	No edits required.
Expert reviewers agreed that the evidence used to develop the Guidelines was appropriately considered and translated in line with the GRADE process.	No edits required.
It was noted that Guideline 2 for Children and people under 18 years of age and Guideline 3 for women who are pregnant and breastfeeding, are precautionary in orientation and the evidence provided to support them is limited due to the lack of literature in this space and more research is needed to support recommendations for these population groups.	No edits required.
One expert reviewer noted that the modelling report provided a comprehensive description of how the model was constructed and used. But recommended a separate expert review to critically evaluate the model and the manner of its use in formulating the Guidelines.	A separate expert review of the modelling was completed.
Modelling review	
An expert review of the modelling undertaken for the revision of the Guidelines was completed.	No edits required.
The reviewers concluded that the modelling underpinning the Guidelines appeared to be a comprehensive and robust evaluation of the health impacts of alcohol consumption in Australia.	
The report developed as part of the expert review is available at <u>www.nhmrc.gov.au/alcohol</u> .	

SUMMARY OF EXPERT REVIEW FEEDBA	ACK AND KEY ACTIONS TAKEN	
Feedback	Action	
Guideline recommendations and key messages		
One reviewer discussed the following points in formulating the Guideline 1 recommendation and key messages:	An additional key message was added to Guideline 1 which says 'Drinking alcohol increases the risk of many cancers. The level of risk increases as more alcohol	
 Concurred with the Expert Committee's decision to formulate a single recommendation for both men and women, despite small differences in their risk profiles, given that the gender differences are not substantial and the guideline has a public health focus with the aim of providing a more effective approach to reducing alcohol-related harms. The Guidelines could be developed for specific populations, but noted that such exercise may not be useful at a community level. 	is consumed'.	
 Recommended making more explicit the link between alcohol consumption and cancer. 		
One reviewer queried whether to add an additional point to the Plain English summary for Guideline 3, that as alcohol crosses into the breastmilk, it could affect brain development.	An additional key message was added to the Plain English summary, Guideline 3 key messages and the Practical information sections of the Guideline which says 'A baby's brain keeps developing after it is born. A growing infant brain is more sensitive to damage from alcohol than an adult brain'.	
Public consultation		
Expert reviewers considered the issues raised during public consultation were appropriately considered where evidence supported them, but raised minor comments regarding:	 'Harms and benefits' is GRADE terminology. This is the name of one of the factors of the Evidence to decision framework. 	
• One submission received during public consultation which commented on the language used in the Guideline around 'harms and benefits' of alcohol consumption.	Throughout the Guideline 'harms and benefits' has been used to clearly communicate that both the harms and benefits of alcohol consumption were	
The public consultation feedback recommended that the language be revised to avoid implying	considered in the evidence evaluation activities.	
that there are potential benefits from drinking alcohol, despite the lack of evidence to support this, particularly for Guideline 2 and Guideline 3	Text in section 1.11 has been revised to clarify 'harms and benefits' is GRADE and MAGICapp terminology.	
where not drinking is the safest option for these population groups.	 Guideline 3 specifically focuses on the risk of harm from prenatal alcohol 	
The expert reviewer acknowledged that this language is often used in the context of search terms for evidence and the search needed to be unbiased. The expert reviewer suggested removing the mention of 'benefits' where it was used at the start of the Guideline and was not necessary.	exposure to the developing fetus and not the harms of alcohol consumption to the mother. Therefore a separate evidence search was not completed for the harms of alcohol consumption to women during pregnancy.	
• One submission received during public consultation which raised concerns about Guideline 3 for pregnant and breastfeeding women focusing only on the harms of prenatal alcohol exposure to the fetus and not the harms of alcohol consumption to the mother. The expert reviewer indicated that this		

comment had not been addressed in the Guidelines.

SUMMARY OF EXPERT REVIEW FEEDBACK AND KEY ACTIONS TAKEN	
Feedback	Action
Implementation	
Expert reviewers raised the importance of the implementation of the Guidelines and urged that they are translated into action to substantially reduce the harmful effects from alcohol on Australians.	Feedback considered and provided to the Department of Health who are responsible for the implementation of the Guidelines.
One expert reviewer recommended consumer testing for all communications related to the Guidelines to ensure they are interpreted as intended.	No edits required. NHMRC had consumer representation on the Expert Committee, and consulted with two of NHMRC's Principal Committees that represent consumer issues. NHMRC also invited the public to participate in providing evidence (on two separate occasions), and in providing public comment on the completed draft guideline.

Alcohol Working Committee

Appointment process

The Alcohol Working Committee was established by a CEO delegate, under Section 39 of the *National Health and Medical Research Council Act 1992* (NHMRC Act). The Committee was selected to ensure appropriate expertise in the key areas of clinical and public health research, and evidence-based methodologies, to oversee and provide expertise in updating the 2009 *Australian guidelines to reduce health risks from drinking alcohol* [4]. Also sought were a person with expertise in the health needs of Aboriginal persons and Torres Strait Islanders, and a person with expertise in consumer issues.

Terms of reference

The terms of reference were as follows:

- consider the process for development of the 2009 guidelines and identify priority areas for review
- guide the development of an evaluation of the evidence, including modelling, on the health effects of drinking alcohol, focusing on studies and data published since 2007
- consider the outcomes of the evidence evaluation, and use these findings to inform the update of NHMRC's Australian guidelines to reduce health risks from drinking alcohol (2009) [4]
- · consider comments received during consultation on the draft revised guidelines
- update the revised draft with consideration to comments received from public consultation and expert review.

The Alcohol Working Committee reported to the Council of NHMRC.

Membership

Appointments to the Committee were effective from 23 May 2016 until 30 March 2021. The members are shown in Table A5.3.

Name	Affiliation	Area of expertise
Professor Kate Conigrave (Chair)	Senior Staff Specialist, Drug Health Services at Royal Prince Alfred Hospital, and Conjoint Professor in Addiction Medicine at Sydney Medical School, the University of Sydney.	Clinical and public health research
	New South Wales	
Professor Emily Banks (Deputy Chair)	Epidemiologist and public health physician at the Australian National University.	Epidemiology and public health
	Australian Capital Territory	
Professor Robert Ali	Director, Community Based Treatment Drug and Alcohol Service SA (2016), Senior Research Fellow, University of Adelaide (2016) and Director, WHO Collaborating Centre.	Clinical public health
	South Australia	
Dr Rebecca Armstrong	Director of Public Health Insight, the University of Melbourne, and Joint Coordinating Editor, Cochrane Public Health.	Methodologist public health
	Victoria	
Professor Tanya Chikritzhs	Professor at the National Drug Research Institute, Curtin University.	Epidemiology biostatistics
	Western Australia	
Professor Peter d'Abbs	Academic, Menzies School of Health Research. Queensland	Research sociologist policy
Professor Mark Harris	Professor of General Practice, Scientia Professor, and Executive Director at the Centre for Primary Health and Equity, the University of New South Wales.	Primary health care and health services research
	New South Wales	
Ms Nicole Hewlett	Public Health Program Manager, Menzies School of Health Research and Queensland University of Technology.	Aboriginal and Torres Strait Islander representative and FASD prevention
	Queensland	
Dr Michael Livingston	Senior Research Fellow, Centre for Alcohol Policy Research, La Trobe University.	Research epidemiology modelling
	Victoria	
Professor Dan Lubman	Director, Turning Point, and Professor of Addiction Studies and Services at Monash University.	Clinical research and mental health
	Victoria	
Ms Anne McKenzie	Senior Manager Community Engagement Telethon Kids Institute.	Consumer advocate
	Western Australia	

Table A5.3 Membership of the Alcohol Working Committee

Name	Affiliation	Area of expertise
Dr Colleen O'Leary	Coordinator, Standards Monitoring at Western Australian Office of the Chief Psychiatrist and Adjunct Research Associate Telethon Kids.	Research policy, alcohol and pregnancy, FASD
	Western Australia	
Professor Alison Ritter	Director, Drug Policy Modelling Program, and Deputy Director, National Drug and Alcohol Research Centre (2016–18) and Social Policy Research Centre (2018 – current), both at the University of New South Wales. New South Wales	Policy research
Adjunct Associate Professor Scott Wilson	Chief Executive Officer of the Aboriginal Drug and Alcohol Council, South Australia, Adjunct Associate Professor, the University of Sydney.	Aboriginal and Torres Strait Islander representative
	New South Wales	

Disclosure of interest process

Appointees to committees of NHMRC are required to disclose their interests consistent with Section 42A of the NHMRC Act, and instructions issued under sections 16A and 16B of the *Public Governance, Performance and Accountability Rule* 2014 (made under subsection 29(2) of the *Public Governance, Performance and Accountability Act 2013*). Prospective members were specifically asked to identify, to the best of their ability, interests including:

- financial interests: an interest must be declared when benefits or losses either in money or in-kind have occurred or may occur at a level that might reasonably be perceived to affect a person's judgement in relation to fair decisions about evidence and their participation in group decision-making
- other relationships: an interest must be declared when a strong position or prejudice or familial connection or other relationship held by a person could reasonably, or be perceived to, affect a person's judgement in relation to fair decisions about evidence and their participation in group decision-making including making an effort to arrive at a consensus
- affiliations to or associations with any organisations or activities that could reasonably be perceived to be an influence due to a competing interest, either for or against the issues being considered by the committee
- any other influences that might reasonably be considered likely to affect the expert judgement of the individual, or lead to the perception by others that the judgement of the individual is compromised.

Under the PGPA Act, members have a responsibility to declare any interests to the whole committee, and members have a joint responsibility to decide on the management of any perceived or real conflict. No unmanageable conflicts were identified by the Committee or NHMRC.

Throughout the project, members were reminded of their obligation to consider any interest that may have arisen since the last meeting or with any particular agenda items. All disclosures and determinations about interests were recorded in the minutes of the Committee meetings. Members' relevant expertise and a summary of their disclosed interests were accessible on the NHMRC website throughout the duration of the project.

Appendix 6: Glossary

Term	Meaning
Absolute risk	The actual risk of injury and disease from drinking.
Alcohol	The term 'alcohol' describes a series of organic chemical compounds, but only one type, ethyl alcohol or ethanol, is found in drinks intended for human consumption. This is the type that is the subject of these guidelines. Other forms of alcohol, including methanol, are more toxic to humans than ethanol and are not suitable for human consumption.
Alcohol poisoning	A condition in which a toxic amount of alcohol has been consumed, usually in a short period of time. The affected individual may become extremely disoriented, unresponsive, or unconscious, with shallow breathing. Because alcohol poisoning can be deadly, emergency treatment is necessary.
Alcohol-related hospitalisation	An episode of admitted patient care, which can be a total hospital stay (from admission to discharge, transfer or death) or a portion of a hospital stay that begins or ends in a change of type of care (e.g. from acute care to rehabilitation). The episode of care is caused by or related to the patient's alcohol consumption.
Burden of disease	The impact of a disease, condition or risk factor (e.g. smoking or drinking alcohol) on the health of a population. It is measured by the number of healthy years lost due to a particular risk factor (disability-adjusted life years measure).
Confounding	Something other than what is being studied that affects the results. Confounders have the potential to influence the results because they can affect the outcomes that the researchers are studying.
Cumulative effects	The effects of many drinking occasions over time.
Dependence	Alcohol dependence refers to when a person has a strong drive to drink, which comes about after repeated, regular drinking. A person with alcohol dependence has at least two of these three features:
	loss of control over drinking
	 physiological features (tolerance or withdrawal)
	 alcohol having a higher priority than other things in the person's life.
Drinking occasion	In these guidelines, a drinking occasion refers to a sequence of drinks taken without the blood alcohol concentration reaching zero in between. This might include one or more drinks at home at the end of the day or over dinner, or at a specific event, such as a party, night out, visit to the pub, a family or business event or other function. It may also include drinking spread across more than one context or venue, for instance on a 'Friday night out'.
Fetal alcohol spectrum disorder	Fetal alcohol spectrum disorder (FASD) is a diagnostic term for a spectrum of adverse neurodevelopmental impairments or brain damage caused by alcohol exposure before birth. These effects can be seen in infants, children, adolescents and adults. People with FASD have impairments that are permanent and impact negatively on their development. FASD affects the ability to think, learn, focus attention and control behaviour and emotions. People with FASD may also be impulsive and they often have low self-esteem, and mental health problems.
GRADE	Grading of Recommendations Assessment, Development and Evaluation (GRADE) is an approach used to rate the quality of evidence and grade the strength of recommendations in health care.
Immediate effects	The effects of drinking either during or after an occasion of drinking, lasting until the blood alcohol concentration returns to zero.
Lifetime risk	The measure of risk that a certain event will happen during a person's lifetime (see Section 3).

Term	Meaning	
Mendelian randomisation	A method of using measured variation in genes of known function to examine the causal effect of a modifiable exposure on disease in observational studies. The term was first proposed by Gray and Wheatley in 1991 for a method that could obtain unbiased estimates of the effects of cancer treatment within a family-based design.	
Prenatal alcohol exposure	Any alcohol consumed by the mother during pregnancy.	
Risk	The probability (chance) that an outcome may occur (see Section 3).	
	A drink containing 10 g of pure alcohol (equivalent to 12.5 ml) (see Appendix 8).	
	As a drink, this is any of the following:	
	• 100 ml of wine	
	• 3/4 can (285 ml) of full strength beer or cider	
Standard drink	 1 can of (375 ml) of mid strength beer 	
	• 425 ml of light beer	
	60 ml port or sherry	
	• 30 ml spirits.	
	The measure is defined in the Australia New Zealand Food Standards Code — Standard 2.7.1, and is the basis for all labelling of alcoholic drinks in Australia.	
Study bias	The conscious or unconscious influencing of a scientific study and its results. This makes the results less dependable. Examples include recall, selection, publication, observation and confirmation bias.	
Teratogen	A substance that can cause permanent harm to the embryo or fetus.	
Tolerance	The immediate effects of alcohol on the brain are often less apparent in people who drink regularly, because they acquire a degree of tolerance. Tolerance occurs because the person's brain learns to cope with, and compensate for, the deficits induced by alcohol. Also, the person's liver becomes a little more efficient at breaking down alcohol.	

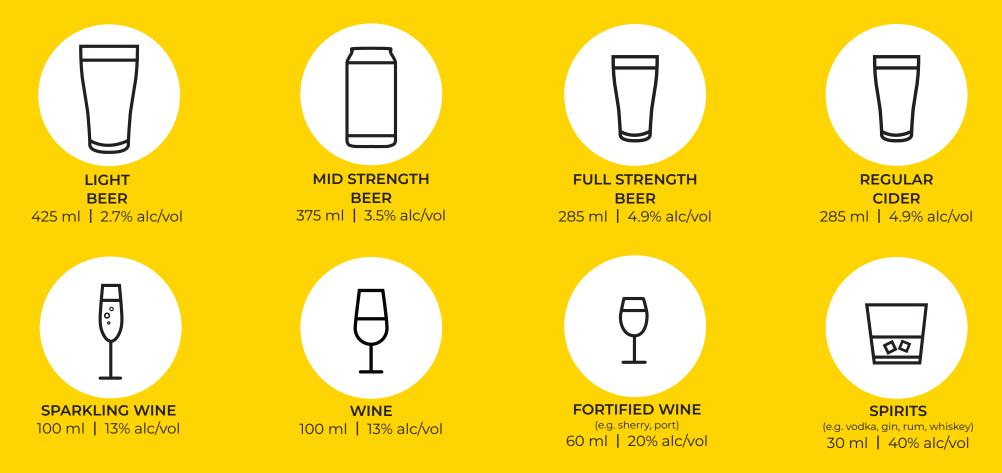
Appendix 7: Abbreviations and acronyms

Abbreviations and acronyms	Meaning
AIHW	Australian Institute of Health and Welfare
DALY	disability-adjusted life years lost due to illness or injury
EtD	Evidence to Decision (framework)
FASD	fetal alcohol spectrum disorder
GRADE	Grading of Recommendations Assessment, Development and Evaluation
NDSHS	National Drug Strategy Household Survey
NHMRC	National Health and Medical Research Council
NHS	National Health Survey
PECO	population, exposure, comparator, outcomes

What is a standard drink?



National Health and Medical Research Council



The standard drink is defined in the Australia and New Zealand Food Standards Code.



www.nhmrc.gov.au/alcohol

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