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AUSTRALIAN CLINICAL PRACTICE GUIDELINES

WORKING TO BUILD A HEALTHY AUSTRALIA

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Executive summary

Background

Clinical practice guidelines represent a significant financial and intellectual investment for both government and the health sector. At any given time there are between five- and six-hundred guidelines in circulation in Australia, covering a wide range of clinical topics and settings and of varying quality and currency.

Clinical practice guidelines have the potential to translate findings from medical research into clinical practice, and when properly implemented have been shown to improve health outcomes.[1]

Users of clinical practice guidelines have an expectation that they will be of high quality, free from commercial and intellectual bias and fit for purpose. The National Health and Medical Research Council (NHMRC) has throughout this century been at the forefront of international efforts to improve the quality, transparency and usability of these guidelines.

Methods

Since establishing the national clinical practice guidelines portal in 2010 NHMRC has published annual reports on Australian clinical practice guidelines, reporting on a database established in 2006 and now numbering 1046 guidelines. Each guideline in this report was independently assessed by two reviewers using a 37 point data collection tool. More than a quarter of these guidelines had referenced NHMRC documents in their development process.

Findings and discussion

This report, the fourth and most comprehensive, confirms ongoing serious and systemic problems in the way guidelines are funded and developed in Australia.

Governments have funded 22% of the guidelines in this report, yet there remains a demonstrable lack of coordination in the way guidelines are prioritised and commissioned in key clinical areas. Current guidance is lacking or expired in many clinical areas with high Australian burden of disease such as dementia, schizophrenia, adult depression, musculoskeletal pain, and ischemic heart disease.

A number of guideline quality indicators are reported here, but perhaps the most concerning of these are that 60% are published with no acknowledgement of funding. Poor documentation also extends to the evidence review process, suggesting that government funding is supporting guidelines where the evidence base is unknown. Only 11% of government funded and developed guidelines are published with documented evidence of a full systematic literature review: more than half of these have been approved by NHMRC.

Effective implementation of guidelines still remains a key challenge for guideline developers and funders, with continued debate on how to ensure effective implementation. The failure to document key information for guideline users may continue to hamper implementation efforts. For example, identification of the intended users and settings is a key step in effectively implementing a guideline, but is often not specified in Australian guidelines.

Despite these problems this report identifies some important areas of improvement, most notably in the rates of conflict of interest declaration which are steadily improving, albeit from a low base. The report also shows that state and territory governments continue to invest in important guideline work which, with some additional effort, could be made applicable to the national health system.

It is hoped that this report will assist ongoing efforts to better prioritise clinical practice guidelines in Australia to ensure that more of the guidelines that are developed are of high quality, independent, fit for purpose and represent a better return on the significant financial and intellectual investment used in their development.

1. Introduction

This is the fourth annual National Health and Medical Research Council (NHMRC) report on clinical practice guidelines in Australia. The guidelines in this report have all been assessed for inclusion on the NHMRC's national clinical practice guidelines portal (the portal) (www.clinicalguidelines.gov.au), which was established in 2010 as a single access point for clinical guidelines. The portal was established to address two reported problems with Australian guidelines – they are difficult for users to locate, and they are of variable quality.

1.1 Scope of this report

This report presents an analysis of the key characteristics of 1046 clinical practice guidelines published between 2005 and 2013 for use in clinical practice in Australia. It reports:

- who develops guidelines in Australia, and who pays for them
- who guidelines are developed for
- which areas of clinical practice are supported by guidelines, and which are not
- the influence of NHMRC on guideline development
- trends in the quality of Australian guidelines based on a number of indicators.

This report does not discuss the appropriateness or otherwise of guideline recommendations drawn from clinical evidence, nor does it report on the use or adoption of guidelines in clinical practice, as these data are not available.

Public health, environmental health and ethical guidelines, which are significant components of NHMRC's research translation work, are outside the scope of this report.

It is hoped that this report will inform decisions about the prioritisation of guidelines in Australia.

1.2 Why is this important?

Clinical practice guidelines can be expensive. While the overall cost of guideline development to the Australian health system is difficult to quantify, some of the sentinel national clinical practice guidelines currently in use have cost between $1 million and $1.6 million to develop and distribute.

Much of the labour used in the development of these guidelines is contributed on a voluntary basis. For guidelines with effective lifespans of five years this represents a significant investment of financial and intellectual capital. It is important that scarce public and private funds are effectively directed to areas where clinical practice guidelines are needed, and that guideline development activity is not unnecessarily duplicated.

Guideline development in Australia has been characterised as 'bottom up' in nature, and while this may offer the advantage of allowing guidelines to be developed in response to local need and consumer demand, there is a danger that guidance in key areas of importance to Australia, such as the National Health Priority Areas (NHPA), may be underserved.

Finally there are ongoing questions about the place of guidelines in modern clinical practice. The traditional disease encompassing guideline model which was common at the beginning of this report period has in many cases been supplanted by guidelines focussed on clinical questions defined by clinical equipoise, and often supported by single Cochrane reviews.

Recent examples include the *Australian and New Zealand guideline for hip fracture care* (2014) and the *Antenatal magnesium sulphate prior to preterm birth for neuroprotection of the fetus, infant and child guidelines* (2010).

As NHMRC and others look to find different ways to maximise the results of government investment in Cochrane, and to find more efficient ways to keep guidelines updated and current, it is hoped that this report will help to inform decisions about what guidelines are needed, and what form they should take.

1.3 Methods

The report draws on data from Australian clinical practice guidelines published between 2005 and 2013 that are currently either active (that is currently linked to from the portal), updated, rescinded or expired.

The guidelines used in this report have been systematically sourced through a number of avenues. These include structured literature searches and journal updates, invited and unsolicited developer submissions, NHMRC's guidelines in development register, systematic website searches, media monitoring, NHMRC's guideline approval program and hand searching.

Each of the 1046 guidelines used in this report have been independently assessed by at least two assessors using a 37 point data collection tool. This is used to determine if the guidelines meet the criteria for inclusion on the portal, and to identify quality indicators discussed in section eight of this report.

The selection criteria exclude guidelines developed by pharmaceutical companies and guidelines developed for use in local health services, except in cases where the health service serves an entire jurisdiction (for example, nationally funded centres and some state-wide children's services).

Because of the relative paucity of evidence based guidelines in many areas of clinical practice in Australia, the portal (and its parent database which provided the data for this report) has, since its inception, contained links both to guidelines that have been systematically developed ('evidence documented'), and those that have not. Each type of guideline is clearly identifiable as such on the portal.

Guidelines are removed from the portal five years after publication, unless they are updated or rescinded earlier.

Since NHMRC's last annual report on guidelines (2013) a further 109 guidelines have been added to the dataset.

2. Australian investment in guidelines

2.1 Who funds guidelines in Australia?

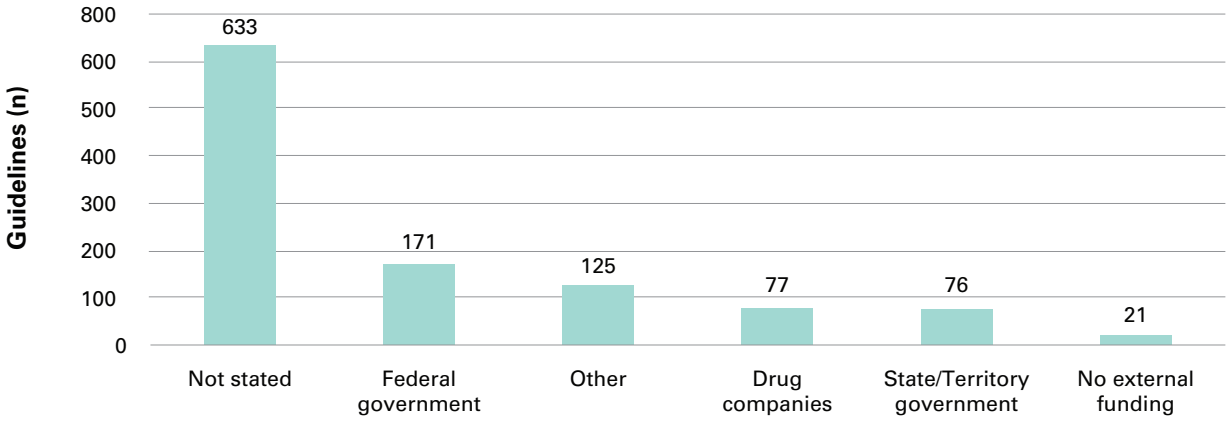
The Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines[2] (2011 NHMRC Standard) require that 'sources of funding for guideline development, publication and dissemination are stated' (requirement A2).

More than half of the 1046 guidelines developed in Australia between 2005 and 2013 contain no explicit statement of funding: from these guidelines it is not possible to ascertain where the funds for their development came from.

Of the remaining guidelines that were published with an explicit funding statement, half of these were funded by either federal, state or territory government. A number of these guidelines cite multiple funding sources, which include the federal departments of Health, Defence and Veterans Affairs.

Figure one below illustrates the breakdown of funding sources of Australian guidelines.

Figure 1: Funding sources of Australian guidelines



Note: Multiple funders may have contributed to the development of a single guideline. Hence the total (n=1103) is greater than the total number of guidelines (n=1046).

The 'other' category contains 125 guidelines funded by a variety of groups including national condition groups, professional societies, charities, trust funds and benefactors.

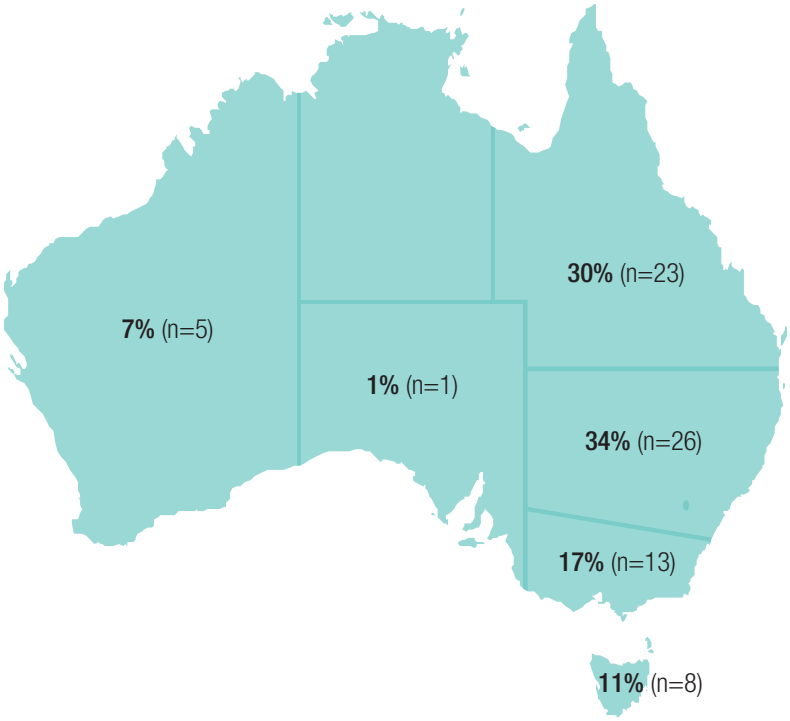
Private benefaction for guideline development is relatively uncommon but may prove to be an important source of funding in the future. Individual benefactor funding has already been used to develop national guidelines on brain cancer, diabetes and mesothelioma. Charitable trusts and foundations have funded the development of a number of guidelines including mental health first aid, tuberculosis, neonatal care and hip fracture.

2.2 Australian government funding

Of the 1046 guidelines, 235 were fully or partially funded by government. While 81% (n=191) of these were funded by a single federal or state government entity, 5% (n=11) received a combination of federal and state funding. The remaining 14% (n=33) were funded by government in conjunction with other funding groups, including pharmaceutical and device companies.

State funding contributed to the development of 76 guidelines from organisations including cancer organisations, motor traffic accident authorities, insurance groups and health bodies. Figure two below illustrates the state government breakdown by number of guidelines and as a percentage of funded guidelines by state.

Figure 2: State government funding of guidelines



Note: the Australian Capital Territory and Northern Territory governments did not fund any guidelines between 2005 – 2013.

3. Australian guideline development

More than 130 guideline developers have produced guidelines for use in Australia between 2005 and 2013. They range from *ad hoc* collaborations formed to provide guidance on a single issue to complex organisations with long-term work plans.

Table one below groups guideline developers by category and numbers of guidelines produced. The table includes guidelines developed by multiple developers.

Table 1: Guideline developers in Australia

Guideline Developer	Number	%
Other*	464	40%
State and territory government health departments	257	22%
Specialty societies	161	14%
National condition groups	131	11%
Medical colleges	90	8%
Australian Government Department of Health	22	2%
Other federal government departments	22	2%
Other state and territory government departments	13	1%
National Health and Medical Research Council	8	<1%
Total	**1168**	**100%**

* The 'other' category includes the Joanna Briggs Institute; Therapeutic Guidelines, collaborating authors, etc.

Of note is the 23% (n=270) of Australian guidelines developed by state and territory governments. These are produced not only by health departments themselves, but by a range of other government departments and statutory organisations. The government agencies responsible for guideline development during the previous nine years are shown in table two overleaf.

Table 2: Government guideline development agencies

Government	
Federal Government	**52 guidelines**
• Australian Commission on Safety and Quality in Health Care • Australian Council for Safety and Quality in Health Care • Cancer Australia • Civil Aviation Safety Authority • Australian Government Department of Health	• Department of Veterans Affairs • Ministerial Council on Drug Strategy • National Blood Authority • National Breast and Ovarian Cancer Centre • National Health and Medical Research Council • National Drug Strategy • National Mental Health Strategy
Australian Capital Territory Government	**3 guidelines**
• ACT Health	
New South Wales Health	**124 guidelines**
• EnableNSW • Institute of Trauma and Injury Management • Lifetime Care and Support Authority • Motor Accidents Authority of NSW • NSW Agency for Clinical Innovation • NSW Clinical Excellence Commission	• NSW Health • NSW Statewide Spinal Cord Injury Service • NSW Therapeutic Advisory Group • NSW Cervical Screening Program • NSW State Spinal Cord Injury Service Psychosocial Strategy Steering Group
Northern Territory Government	**12 guidelines**
• NT Department of Health and Community Services/ Department of Health and Families	
Queensland Government	**50 guidelines**
• Queensland Ambulance Service • Queensland Clinical Guidelines	• Queensland Health
South Australian Government	**28 guidelines**
• Drug and Alcohol Services SA • SA Centre for Trauma and Injury Recovery	• SA Health • WorkCover SA
Tasmanian Government	**19 guidelines**
• Tasmanian Department of Health and Human Services	
Western Australian Government	**18 guidelines**
• WA Department of Health	• WA Therapeutic Advisory Group
Victorian Government	**16 guidelines**
• Ambulance Victoria • Victorian Department of Health • Victorian Department of Human Services	• Victorian Department of Justice • Victorian Surgical Consultative Council • Western and Central Melbourne Integrated Cancer Service
Total	**322 guidelines**

Note: the organisations listed above reflect only a selection from the dataset

4. Guideline formats in Australia

Guidelines are selected for inclusion on the portal using four selection criteria, one of which is the 1990 Field and Lohr definition[3] adopted by the Institute of Medicine and subsequently modified by NHMRC:

> *The clinical practice guideline contains statements that include recommendations, strategies, or information that assists health care practitioners and patients make decisions about appropriate health care for specific clinical circumstances.*

One characteristic of the current 1046 guideline dataset is the wide diversity of formats by which clinical advice is presented. The dataset demonstrates a bewildering array of descriptions, yet all offer one or more recommendations or strategies for health care.

Table three below gives a breakdown of guideline formats. Where relevant the format nominated by the developer has been used, based on intent. For example, much of New South Wales Health guidance is based on guidelines but is designated 'policy directive', and adherence is mandatory for NSW Health funded services.

Table 3: Formats of clinical practice guidelines

Format	Number	%
Guideline	515	49%
Journal article	208	20%
Summary guideline	76	7%
Policy directive	54	5%
Protocol	56	5%
Review with recommendations	53	5%
Position statement	44	4%
Poster or flowchart	16	2%
Evidence review	11	1%
Website	12	1%
Standard	1	<1%
Total	**1046**	**100%**

Of note, 20% (n=208) of Australian guidelines are published in peer-reviewed journals. This is a format which is more likely to contain publication of author conflict of interest, particularly where the journal has adopted the use of the International Committee of Medical Journal Editors conflict of interest disclosure form.[4]

This format may also be less likely to accommodate comprehensive documentation of methods however, due to word limit constraints imposed by most print journals.

5. Relevance of guidelines in Australia

5.1 National Health Priority Areas

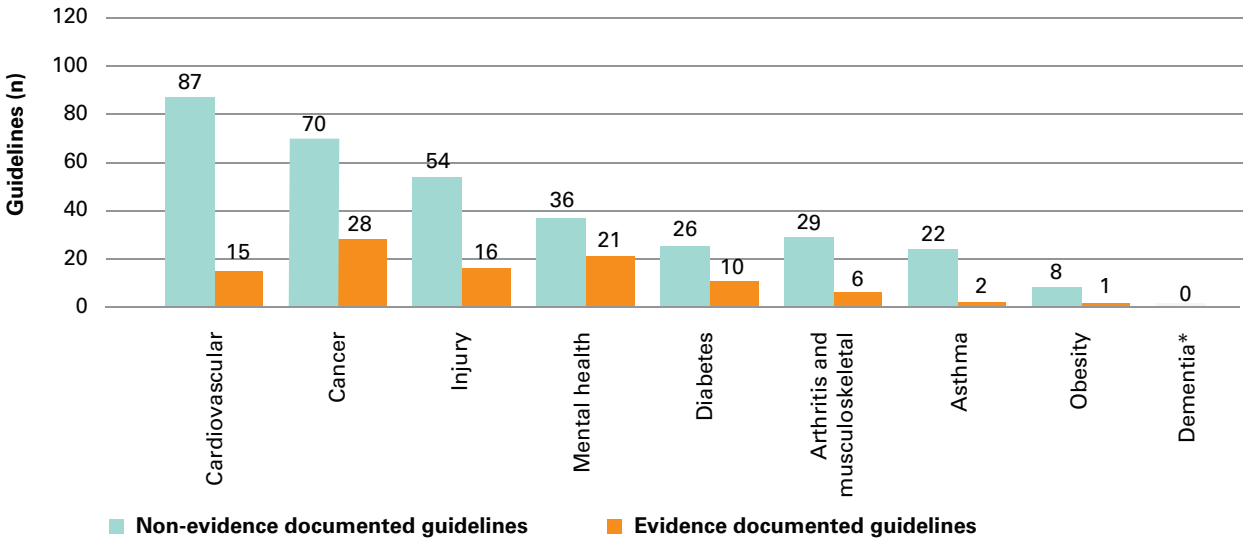
The first National Health Priority Areas (NHPA) were nominated in 1996 and represent conditions that Australian governments have chosen for focused attention because of their burden of disease on the Australian community.[5]

Seven NHPA were in place when the first guidelines in this study cohort were published, with an additional two (obesity and dementia) added in 2008 and 2012 respectively.

During the period 2005 to 2013, 41% (n=431) of published guidelines had a NHPA as their main topic. Of these 31% (n=134) had received some form of government funding for their development, however 51% of these guidelines (n=221) did not contain any funding statements at all.

Figure three below illustrates the proportion of 'evidence documented' and non-evidence documented guidelines published in each NHPA. The significance of evidence documentation is discussed further in section 8.2.

Figure 3: National Health Priority Area guideline coverage



* a dementia guideline was under development at the time that this report was written

As NHPA were established as a collaborative action program of federal, state and territory governments, a subset of guidelines covering NHPA were analysed for funding sources.

A number of national condition groups have ensured continuity of guidance in the following NHPA:

- Asthma – National Asthma Council (National Asthma Handbook)
- Cancer – Cancer Australia, Cancer Council Australia, Prostate Cancer Foundation Australia and Asbestos Research Institute (solid tumour guidelines including breast, colon, mesothelioma, prostate and lung)
- Cardiovascular – National Stroke Foundation (stroke guidelines), National Vascular Disease Prevention Alliance (absolute risk guidelines)
- Mental health – Beyond Blue (perinatal and youth depression guidelines), Australian Centre for Posttraumatic Mental Health (posttraumatic stress guidelines)
- Diabetes – Diabetes Australia, Diabetes Society and Baker IDI (diabetes guidelines)

In other NHPA, guidelines have been developed by organisations without a direct primary interest in the NHPA condition, and in conjunction with relevant national condition groups:

- Arthritis and musculoskeletal – Royal Australian College of General Practitioners (arthritis guidelines)
- Obesity – NHMRC (obesity guidelines)
- Mental health – NHMRC (borderline personality disorder guideline)

It is significant that a number of conditions that sit within NHPA, and which carry a significant burden of disease in Australia, are unsupported by current national clinical practice guidelines. These include:

- Mental health – anxiety, schizophrenia and adult depression
- Cardiovascular – ischaemic heart disease
- Arthritis and musculoskeletal – musculoskeletal pain
- Dementia (the first national guideline is currently under development)
- Injury prevention

There are no national clinical practice guidelines on injury prevention, with the exception of falls prevention. The probable reason for this is that many of the causes of injury in Australia, such as drowning, farm accidents, suicide, poisoning, assault and motor vehicle accidents, lie outside the scope of clinical practice guidelines and are more likely to lie within the scope of population health advice and guidance.

5.2 Other (non-NHPA) guidelines

There were 59% (n=615) of guidelines developed during the study period that have no direct relationship to the NHPA. These are summarised in table four below.

Table 4: Guideline topics not categorised under National Health Priority Areas

Guideline Topics	Number	%
Diagnostic, therapeutics and techniques	96	16%
Pregnancy, childbirth and neonatal care	91	15%
Infectious disease control and management	87	14%
Respiratory	45	7%
Kidney and urogenital disease	43	7%
Drug and alcohol	41	7%
Neurological disease	36	6%
Palliative care	28	5%
Gastroenterological disorders	22	4%
Paediatric care	21	3%
Andrology	21	3%
Haematology	17	3%
Emergency care	11	2%
Aged care	11	2%
Oral and dental health	7	1%
Endocrinology	7	1%
Skin disorders	6	1%
Preventive care	4	1%
Allergy	4	1%
Additional topics*		
Total	**615**	**100%**

*There are 8 additional topics that each individually represent less than 1% of the non-health priority area topics. These are: nutrition (n=3); first aid (n=3); developmental disorders (n=3); women's health (n=2); primary care (n=2); organ donation (n=2); gambling (n=1) and eye disease (n=1). Total (n=17)

Many of the pregnancy and childbirth guidelines were developed under the auspices of a single program: the Queensland Clinical Guidelines Program.

6. Users of guidelines

6.1 Who are guidelines written for?

Requirement B3 of the 2011 NHMRC Standard requires that 'the intended end users of the guideline are clearly defined, and any relevant exceptions are identified'.

The 1046 guidelines in this study were assessed to confirm whether or not the developers had established the intended users of the guideline, and whether they were clearly identifiable in the guideline, either by direct statement or inference. It should be noted that many guidelines cite multiple target users.

Target user specificity is a key element in ensuring that guidelines are used in practice. If intended users are not identifiable, this may impact on the effective implementation of a guideline, which is known to depend (in part) on clinicians being convinced that the recommendations in a guideline apply to them. Specificity also applies if a guideline clearly states who they are not intended for, as exemplified in the 2011 NHMRC *Consensus-based Clinical practice guideline for the management of volatile substance use in Australia*, which states it is not intended for use by police officers or teachers.

Thirty-one different health professions have been identified as target users of guidelines. Sixty-one percent of guidelines where the target users are identifiable are written for health care disciplines registered by the Australian Health Practitioner Regulation Agency (AHPRA) (table five below). For 369 guidelines, the intended user could not be identified.

Of note is the 29% (n=501) of guidelines where target users have been grouped together as second order users with an imprecision that makes it difficult to determine who should use the guideline, for example by use of statements such as 'this guideline is intended for use by medical specialists and other relevant clinicians'. These are represented as 'clinicians (not otherwise stated)' in table 5 below.

Table 5: Intended users of guidelines

Intended User	Registered?	Number	%
Clinicians (not otherwise stated)	Unknown	501	29%
Medical (excluding General Practitioners)	Yes	347	20%
General Practitioners	Yes	320	18%
Nursing & Midwifery	Yes	252	14%
Allied Health (registered)	Yes	126	7%
Allied Health (unregistered)	No	94	5%
Allied Health (not otherwise stated)	Unknown	52	3%
First Aiders	No	45	3%
Dentists	Yes	17	1%
Total		**1754***	**100%**

* Some guidelines specify more than one target user

6.2 Where are guidelines to be used?

Requirement B2 of the 2011 NHMRC Standard requires guideline developers to describe the health care system, level and stage where guideline recommendations apply.

The 1046 guidelines were assessed to determine whether the intended setting for use was identified or could be inferred. Table six below shows the number and percentage of guidelines across health settings. It should be noted that the denominator in the table reflects the fact that many guidelines are developed for use across multiple settings of care.

Table 6: Intended health care settings for guidelines

Health Care Setting	Number	%
Primary and community care	490	30%
Tertiary care	418	26%
Secondary care	193	12%
Not stated	191	12%
Emergency care	189	12%
Preventive care	104	6%
Homes for the aged	41	2%
Total	**1626**	**100%**

6.3 What is known about guideline use?

Clinical guidelines are produced to improve quality of care, but it has been difficult to systematically research guideline use or uptake in practice. A 2004 systematic review of 235 studies documented a 10% improvement in provider behaviour and/or patient outcomes associated with implementation and dissemination of guidelines.[6]

Assessed against quality indicators specified in guidelines, the Caretrack study (Runciman et al, 2012) found that of a sample of Australian adults, only 57% received appropriate care at eligible health care encounters.[7] This suggests that even when guidance is available, barriers still remain to the adoption of recommendations in practice.

NHMRC does not routinely collect information on the use of guidelines following their release, but does assess whether or not the guidelines articulate and document a dissemination and/or implementation strategy.

6.4 Dissemination

The 2011 NHMRC Standard requires that a plan for the dissemination of the guideline is submitted as a separate document from the clinical practice guideline (requirement G1).

Of the 1046 guidelines in the dataset 9% (n=97) contained some form of documented dissemination plan.

NHMRC has been informed that for some guideline developers dissemination of print guidelines can incur considerable costs, and it is an area where pharmaceutical funding is sometimes used.

6.5 Implementation

Of the 1046 guidelines in the dataset 10% (n=108) contained information on an implementation strategy. This figure probably underestimates implementation activity given 19% (n=196) of guidelines have companion documents associated with their guidelines.

6.6 Revision

The 2011 NHMRC Standard requires guideline developers to stipulate a recommended date for future update of the guideline (requirement C9).

Of the 1046 guidelines, 37% (n=390) specified a review date, and 40% (n=418) were revised editions, partially reviewed or reissued.

Guideline developers appear to be actively reviewing their products, though it is unknown whether guidance has been reviewed within the specified timeframe.

Of note, only 11 guidelines in the dataset specified a guideline expiry date.

7. NHMRC influence on guideline development

NHMRC has been influential in Australian guideline development, with NHMRC methodological literature cited in 29% (n=301) of guidelines published between 2005 and 2013. This methodological literature[8,9,10,11,12,13,14] is now 15 years old, and is under review. Citations specifically to the 2011 NHMRC Standard are low (n=7), though it has so far only applied to guidelines seeking approval that commenced development from 1 January 2011. Four guidelines have been developed and published under the 2011 NHMRC Standard to date, with a further seven in development.

Conflict of interest

In 2012 the NHMRC released the *NHMRC Guideline Development and Conflicts of Interest - Identifying and Managing Conflicts of Interest of Prospective Members and Members of NHMRC Committees and Working Groups Developing Guidelines (2012 COI policy)*.[15]

Although this policy was primarily written for the internal NHMRC audience, it does provide guideline developers with 'principles' for the management of conflicts of interests. The dataset does not provide information on use of the 2012 COI Policy, however the declaration and management of conflicts of interest is a mandatory requirement of the 2011 NHMRC Standard (requirement A6).

Guidelines containing details of a conflict of interest management process continue to be in the minority. Only 7% (n=75) of guidelines in this dataset have documented a full conflict of interest management process, of which 47 of these were released in the last 3 years. It could be inferred that the release of the 2012 COI Policy may have played some part in the increased documentation rate.

Table seven below documents conflicts of interest declarations, illustrating the improvement in published conflicts of interest from 2% (n=2) of guidelines in 2005 to its highest level of 27% (n=21) in 2013.

Table 7: Conflict of interest declarations in guidelines by publication year

Conflicts of interest	2005	2006	2007	2008	2009	2010	2011	2012	2013
Not mentioned[i]	79	50	53	101	89	121	81	58	33
Not declared[ii]	1	4	2	19	17	25	19	10	2
Non-specific[iii]	5	8	10	11	6	4	10	10	1
None[iv]	1	2	1	7	1	7	7	8	21
Recorded[v]	1	0	1	2	3	9	14	3	1
Published[vi]	2	7	4	27	11	19	15	22	21
Total	**89**	**71**	**71**	**167**	**127**	**185**	**146**	**111**	**79**

i The guideline does not include a statement about the conflict of interest of group members.
ii Mention is made of competing interests with the statement 'none declared', 'none identified' or similar.
iii The guideline includes a general non-specific statement about conflicts of interest.
iv The guideline states that the group members have no conflicts of interest, but does not give information on how this was determined.
v The guideline includes a statement that the conflicts of interest of the group have been recorded (but they are not published in the guideline).
vi The guideline mentions the conflicts of interest of the group members and these are published in detail in the guideline or are freely available from another source such as a website.

8. Australian guideline quality

The theory and practice of evidence based health care has evolved considerably since the National Health and Medical Research Council Act was introduced in 1992. During the past 20 years, NHMRC has released guidance and operating procedures to assist Australian guideline developers improve the quality of their products.

8.1 Quality indicators in guidelines

Clinical practice guidelines housed on the portal are assessed against a number of quality criteria with regard to their process of development.

One important criterion is the degree to which the development process has been recorded, and whether the process is transparent.

Recording of the development process remains relatively poor in Australian guidelines, despite it being an important factor in user perceptions of trustworthiness.[16]

Of 1046 guidelines assessed for the portal:

- 15% (n=161) contained a fully documented development process[vii]
- 19% (n=198) provided partial information on their development process
- 66% (n=687) contained no description of the development process.

Methodological literature is cited in just over half of these guidelines (n = 530), suggesting that authors of these guidelines had reviewed or used some form of structured development process. This has not however translated to transparent reporting of guideline processes.

Poorly documented processes in Australian guidelines are consistent with published evaluations of international clinical practice guideline quality.[1]

Table eight overleaf assesses the portal dataset against criteria put forward by the US Institute of Medicine (IOM) as quality indicators of guideline trustworthiness. Most of these indicators are common to the NHMRC assessment of guidelines for inclusion on the portal.

vii This includes the level of detail ascribed to the description of the development committee, the process of deriving recommendations from the literature review, and descriptions of consultation methods and decisions.

Table 8: Quality indicators of Australian guidelines

IOM quality indicators associated with guideline trustworthiness	
Who developed the guidelines?	
Developer	30% (n=316) were developed by a Government agency
Funder	22% (n=235) were funded by a Government agency
Working Committee	30% (n=309) documented relevant professionals as members of the guideline working committee
Can you trust the advice?	
Backed by scientific evidence	17% (n=176) linked their guideline recommendations to levels of evidence and references 7% (n=78) included a replicable description of the evidence review
Conflict of interest management	36% (n=381) mentioned conflict of interest 12% (n=128) published conflicts of interest 7% (n=75) articulated a conflict of interest management process
Externally Reviewed	*Data is not routinely collected for the portal. All NHMRC approved guidelines are externally reviewed (5% of guidelines)*
Endorsers	26% (n=276) of guidelines were endorsed by other agencies (range = 1 to 26 agencies)
Is it fit for purpose?	
Public consultation	*Data is not routinely collected for the portal. All NHMRC approved guidelines undergo public consultation (5% of guidelines)*
User testing	35% (n=369) of guidelines intended users were unable to be identified
Right setting	18% (n=191) of guidelines intended settings were unable to be identified
Consumers involved in development	14% (n=148) documented defined consumer involvement during the guideline development process

8.2 Quality of government funded and developed guidelines

Users look to governments for impartial health advice, with the expectation that it is free from bias, safe from harm and reflective of best evidence.

Guidelines that are issued or approved by NHMRC have met quality standards before they are publicly released, however they represent only 5% (n=52) of Australian guidelines published in the past nine years.

Interestingly, an additional 40 guidelines in the same period have been developed in such a way as to suggest they had the potential to be eligible for consideration of NHMRC approval. The barriers to eligible developers seeking NHMRC approval warrants further investigation.

While government involvement in the funding and development of clinical practice guidelines remains consistent, this investment has not ensured consistency of development methods across Australia.

Of note, only 22% of guidelines funded or developed by government have been 'evidence documented', that is published with documentary evidence that the guideline is based on a systematic or non-systematic review of the literature.

If the 'evidence documented' criteria is refined to include only guidelines published with evidence of a full systematic review, then the percentage of government funded or developed guidelines falls to 11%: over half of these are NHMRC approved/developed guidelines.

In addition only 16% of guidelines associated with government investment published a full description of their development process.

8.3 Authorship

Transparent guideline authorship is one of the main determinants of the trustworthiness of guidelines. Thirty-one percent (n=323) of the guidelines studied contained no information about guideline development group and/or authors.

In only 34% (n=358) of guidelines was it possible to fully identify the authors of the guideline because of full disclosure of names, professional affiliations and disciplines.

8.4 Clinical involvement

The 2011 NHMRC Standard requires that 'a multidisciplinary group that includes end users, relevant disciplines and clinical experts' is convened to develop the scope, purposes and content of a guideline seeking NHMRC approval (requirement A3).

Guidelines were assessed to ascertain whether there was multidisciplinary clinical involvement in the guideline development process appropriate to the guideline topic. For example, were physiotherapists included in guidelines making recommendations about physiotherapy as a modality of care? The results are summarised in table nine below.

Table 9: Disciplinary representation on the guideline development group

All relevant disciplines included?	Number	%
Yes	309	30%
No	200	19%
Unknown	537	51%
Total	1046	100%

It was not possible to identify clinical disciplines involved in over half the guidelines because of insufficient disclosure of author information.

8.5 Consumer involvement

The 2011 NHMRC Standard requires that consumers participate in the development of guidelines seeking NHMRC approval (requirement A4).

For the purposes of this report consumer involvement is defined as a documented and identifiable involvement in the guideline development process (and not post hoc consultation or endorsement). Previous reports have documented an annual rate of consumer involvement in guidelines of between 9% and 17% (mean 14%).

Of all 1046 guidelines published between 2005 and 2013,

- 14% (n=148) document consumer involvement
- 46% (n=477) did not document consumer involvement
- 40% (n=421) did not allow determination to be made on the information provided.

Poor reporting of the development process used for many guidelines makes it hard to interpret whether additional consultation methods were used to involve or engage consumers in guideline development.

8.6 Quality and the top ten guidelines

An analysis of the search results for users of the portal between January and December 2013 was conducted (table 10 below).

Table 10: Top ten guidelines searched between Jan 2013 and Dec 2013

Rank	Guideline	Date Published
1	Clinical practice guideline for the management of borderline personality disorder*+ (ID#2223)	2013
2	Working with the suicidal person. Clinical practice guidelines for emergency departments and mental health services+ (ID#1774)	2010
3	Australian consensus guidelines for the management of neutropenic fever in adult cancer patients^ (ID#1864)	2011
4	Therapeutic guidelines antibiotic version 14^ (ID#1510)	2010
5	Guidelines for the management of absolute cardiovascular disease risk*+ (ID#2079)	2012
6	Clinical practice guidelines for depression and related disorders - anxiety, bipolar disorder and puerperal psychosis - in the perinatal period. A guideline for primary care health professionals*+ (ID#1837)	2011
7	Haemochromatosis (3rd edition) (ID#1922)	2007
8	Guide to management of hypertension 2008. Assessing and managing raised blood pressure in adults (ID#1817)	2010
9	Ambulance Victoria clinical practice guidelines for ambulance and MICA paramedics (ID#1511)	2009
10	Clinical guidelines for stroke management*+ (ID#1737)	2010

* NHMRC approved or issued
+ 'Evidence documented'
^ Fee payable to access

Despite, previous studies indicating that health professionals thought it was important that a guideline be evidence based[17], only half of these guidelines in the top 10 were 'evidence documented'.

Interestingly, nine of the top ten searched for guidelines were endorsed by professional colleges. Endorsement is not necessarily recognised as a quality indicator for guidelines but may be used as a surrogate indicator of quality by portal users.

Topping the portal search was the (then) recently released NHMRC clinical practice guideline on borderline personality disorder - the only guideline in the top 10 that does not have external endorsement.

8.7 Is guideline quality improving in Australia?

Fifteen years ago, a study of guidelines found that the reporting of methodological quality was poor, but that the promotion of standards would likely bring improvements in guideline quality.[18]

Some standards appear to have made a difference to Australian guidelines. There has been a significant increase in the mention of conflicts of interest (COI) in guidelines, despite management policies and documentation not yet being fully realised. If the 36% (n=381) of guidelines that mentioned COI, provided better transparency in their documentation of COIs, this would improve the overall quality of Australian guidelines.

Though it is not a significant impost to guideline developers, reporting of the development process is still very poor across clinical practice guidelines. If the 66% of developers that did not give any detail on their development process provided a partial description, and if 19% provided some additional detail in their descriptions, this would lead to a significant improvement in the overall quality of guidelines in Australia.

Transparency of reporting should be a key area for NHMRC to invest in with guideline developers. This should also include investigation of whether technological advancements in guidelines (e.g. web based guidelines) have the potential to improve documentation of methods in guidelines.

9. Conclusion

This report provides an analysis of 1046 clinical practice guidelines published between 2005 and 2013 and included on the NHMRC clinical practice guidelines portal.

During this period a number of guidelines have been developed in new and innovative ways, challenging NHMRC's traditional models of quality assessment and approval. Examples of these include:

- rapidly updating electronic guidelines
- systematically adapting international guidelines for Australian use
- incorporating health care standards and measurable indicators into guideline recommendations
- developing focussed guidelines addressing a limited number of clinical questions
- developing guidelines through international collaborations.

While the utility and methodological quality of some of these new approaches is not yet fully established, the evolving nature of guideline development further supports the need for NHMRC to review its advice to guideline developers, which is now 15 years old.

As previous reports have highlighted, there are serious and systemic problems with the way clinical practice guidelines are developed and funded in Australia. Perhaps the biggest of these is the lack of effective and coordinated commissioning to ensure that guidelines are developed and maintained in areas where they are most needed, and for the health care professionals who need to use them.

The report has highlighted the important role of Australian states and territories in funding, commissioning and developing guidelines. While government involvement in clinical practice guidelines remains consistent, this investment has not ensured consistency of development methods across Australia, nor a guarantee of a sound evidence base for health advice.

Despite these issues there are some guidelines developed for use in specific jurisdictions that have the potential to be adapted for national use. Examples include guidelines on the management of incontinence in the community, sexual safety in in-patient psychiatric facilities, radiological imaging pathways and the management of head injuries in children, all of which are important issues throughout Australia.

The report has also identified an emerging role of private donors and charitable trusts in the funding of guidelines, both by organisations and by individual bequest. Examples of these include the BUPA Foundation, the John Burge Trust Fund and the Biaggio Signorelli Foundation. This may prove to be an important avenue for guideline funding in the future.

Consistent with other literature, this report has been unable to identify the specific impact of guidelines in the delivery of Australian health care, and this can be regarded as a major deficit in our understanding of guidelines.

Despite persisting problems there are encouraging signs of sustained improvement in some quality indicators, particularly in the areas of conflict of interest.

The increasing awareness of the importance of transparent declarations of interest is reflected in improving declaration of interest rates, albeit from a low base in 2005. This is attributed to a range of factors, including new journal publication policies and the NHMRC's COI policy.

The report suggests a number of areas that may warrant further investigation. The first of these is to identify what are the authentic barriers and enablers for guideline developers to seek NHMRC approval, particularly for the developers of the 40 guidelines based on systematic reviews and robust development methods that did not approach NHMRC for approval.

The second is to establish what would motivate guideline developers to provide more transparent documentation of their guideline development process, and what if anything could NHMRC do to facilitate this?

The third is to identify what are the characteristics of a guideline that are important to a user, such as college endorsement or user consultation, and to determine whether these characteristics are more influential than factors such as evidence or NHMRC approval.

The final area is to establish whether it is possible, and indeed desirable, to extend the life of a guideline using high quality evidence from other sources, such as Cochrane reviews. While this approach may offer a mechanism to maintain the currency and relevance of a specific clinical question, it may not extend to maintaining the currency of the full scope of a guideline.

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