Quality of Australian clinical guidelines and relevance to the care of older people with multiple comorbid conditions

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ABSTRACT

Objective: To assess the quality of Australian clinical guidelines for chronic diseases and their relevance to older people with multiple comorbid conditions.

Design: Selection and assessment of national clinical guidelines for chronic conditions listed as National Health Priority Areas: cardiovascular health, diabetes mellitus, mental health, asthma, arthritis and musculoskeletal conditions, and cancer.

Main outcome measures: Standardised mean scores obtained with the Appraisal of Guidelines Research and Evaluation (AGREE) instrument (criteria grouped into six domains: scope and purpose; stakeholder involvement; rigour of development; clarity and presentation; applicability; and editorial independence). Relevance of guidelines for older people with multiple comorbid conditions.

Results: 17 guidelines were included in the study. Guidelines approved by the National Health and Medical Research Council (NHMRC) scored significantly better than those not approved by the NHMRC in all domains except for editorial independence and clarity and presentation. The mean quality of guidelines not approved by the NHMRC was below 50% in all domains except clarity and presentation. Half of the guidelines addressed treatment for older patients or for patients with one comorbid condition, but only one addressed treatment for older patients with multiple comorbid conditions.

Conclusions: Professional societies and charities should be encouraged and supported to develop clinical guidelines in compliance with NHMRC requirements. Future guidelines should place more emphasis on the management of older people with multiple comorbid conditions.

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Clinical guidelines have been developed to improve health care by increasing the uptake of evidence-based treatments and reducing the use of unnecessary, ineffective or harmful interventions.[1] However, several recent studies have found that the methodological quality of clinical guidelines was highly variable.[2-5] Guidelines developed by professional societies were of poorer quality than guidelines produced by governmental agencies.[6-8] Researchers and commentators have noted that most guidelines for chronic diseases do not modify or discuss the applicability of their recommendations to older patients with multiple comorbid conditions, and that they provide limited guidance on combined use of treatments for different diseases.[9,10]

In Australia, the National Health and Medical Research Council (NHMRC) has adopted standards with which guideline developers need to comply if they want NHMRC approval. NHMRC standards require strong methods, the involvement of a multidisciplinary working panel and a public consultation process.[11,12] In practice, many Australian clinical guidelines are produced by professional societies and charities without seeking NHMRC approval.

We aimed to assess the quality of selected Australian national clinical guidelines and their relevance to older people with multiple illnesses. We also compared the quality of NHMRC-approved guidelines with those that were not NHMRC-approved.

METHODS

Guideline search and selection

National guidelines for the chronic conditions listed as National Health Priority Areas (cardiovascular health, diabetes mellitus, mental health, asthma, arthritis and musculoskeletal conditions, and cancer) were selected, including guidelines for the most prevalent cancers in Australia, colorectal, breast and lung cancers. When several guidelines had been published by the same organisation on the same topic, only the most comprehensive and/or the latest version was included. Position or consensus statements that had not been developed by a systematic approach to the retrieval and the analysis of the literature were excluded.

Guidelines were identified through searches in the MEDLINE database for 2000–2006 ("guideline" [publication type or text word] and "Australia" as keywords) and on the Internet by means of the Google search engine. Additionally, the following Australian websites were searched: Australian Government Department of Heath and Ageing; NHMRC; National Institute of Clinical Studies; Royal Australian College of General Practitioners; National Heart Foundation of Australia; Cardiac Society of Australia and New Zealand; Australian Resuscitation Council; Cancer Council of Australia; Arthritis Foundation; Diabetes Australia; Osteoporosis Australia; *Medical Journal of Australia*; and the *Internal Medicine Journal*. International guideline websites (New Zealand Guidelines Group and the National Guideline Clearinghouse) were also searched for Australian guidelines.

Assessment of guidelines

All guidelines were assessed independently by two reviewers. The quality of guidelines was assessed by using the Appraisal of Guidelines Research and Evaluation (AGREE) instrument (Box 1).[13] The AGREE instrument has been validated and tested in several countries,[3,5] and is considered the best current tool for assessing the quality of a guideline.[14-16] It includes 23 items within the six theoretical domains shown in Box 1. A four-point Likert scale was used to score each item. Agreement between the two reviewers for quality scores was measured by means of linear weighted κ statistics. Scores of the two reviewers were then summed and standardised domain scores were calculated as the percentage of the maximum possible score. The mean domain scores for guidelines that were and were not NHMRC-approved were compared by means of the Mann–Whitney U test.

The relevance of the guidelines to the care of older people with multiple illnesses was assessed by means of a specific instrument developed in a previous study (Box 2).[9] This instrument includes 14 items assessing whether guidelines address treatment for older people and for people with several comorbid conditions, as well as patient-centred aspects such as patients' preferences and quality of life. Agreement between the

1 Overview of the AGREE criteria, and agreement between the two reviewers

Theoretical domains and criteria	Weighted κ
Scope and purpose	
1. The overall objective(s) of the guideline is (are) specifically described.	0.81
2. The clinical question(s) covered by the guideline is (are) specifically described.	0.72
3. The patients to whom the guideline is meant to apply is (are) specifically described.	0.70
Stakeholder involvement	
4. The guideline development group includes individuals from all the relevant disciplines or stakeholders.	0.91
5. The views and preferences of patients have been sought.	0.92
6. The target users of the guideline are clearly defined.	0.74
7. The guideline has been pilot-tested among target users.	0.84
Rigour of development	
8. Systematic methods were used to search for evidence.	0.88
9. The criteria for selecting the evidence are clearly described.	0.81
10. The methods used for formulating the recommendations are clearly described.	0.56
11. The health benefits, side effects and risks have been considered in formulating the recommendations.	0.61
12. There is an explicit link between the recommendations and the supporting evidence.	0.76
13. The guideline has been externally reviewed by experts before publication.	0.78
14. A procedure for updating the guideline is provided.	0.47
Clarity and presentation	
15. The recommendations are specific and unambiguous.	0.60
16. The different options for management of the condition are clearly presented.	0.58
17. Key recommendations are easily identifiable.	0.61
18. The guideline is supported with tools for application.	0.72
Applicability	
19. The potential organisational barriers in applying the guideline have been discussed.	0.85
20. The potential cost implications of applying the recommendations have been considered.	0.83
21. The guideline presents key review criteria for monitoring and/or audit purposes.	0.64
Editorial independence	
22. The guideline is editorially independent from the funding body.	1.00
23. Conflicts of interest of guideline development members have been recorded.	0.81

AGREE = Appraisal of Guidelines Research and Evaluation instrument.[13] ◆

two reviewers for quality scores was measured with κ statistics. Any disagreement was then resolved by discussion.

RESULTS

Seventeen national guidelines were selected, including five for cardiovascular health, four for cancer, four for mental health, two for respiratory health, one for musculoskeletal conditions and one for diabetes mellitus (Box 3).[17-33] No national Australian guideline for the management of arthritis was identified. All guidelines were developed by professional or disease-oriented charity organisations. Only two received governmental funding. Six had been approved by the NHMRC, including four for cancer, one for cardiovascular health and one for diabetes.

AGREE instrument

Box 1 shows that the agreement between the two reviewers was excellent for 10 items (weighted $\kappa > 0.8$), good for 10 items (weighted $\kappa > 0.6$–0.8) and moderate for three items (weighted $\kappa = 0.4$ to < 0.6). The mean and individual standardised AGREE domain scores are presented in Box 4 and Box 3, respectively. Clarity and presentation provided the highest mean score of 71.3%. The six NHMRC-approved guidelines had significantly higher domain scores than the guidelines not approved by the NHMRC for all domains except editorial independence and clarity and presentation, where no difference was observed (Box 4).

Relevance for older people with comorbid conditions

The agreement between the two reviewers was excellent for 10 items and good for 4 items (data not shown). Box 2 shows that eight guidelines (47%) addressed treatment for older patients, nine (53%) addressed treatment for patients with multiple comorbid conditions and one (6%) addressed treatment for older patients with multiple comorbid conditions

DISCUSSION

This study showed that the quality of Australian guidelines for chronic conditions listed as National Health Priority Areas was average (around 50%) in three domains, low in two domains and good in one domain. The mean quality of guidelines not approved by the NHMRC was below 50% in all domains except clarity and presentation. Only a few guidelines not approved by the NHMRC described the methods used for selecting the evidence or formulating the recommendations. Our findings are consistent with the results of other studies which showed that quality of guidelines produced by specialist societies was low,[6] and that high-quality guidelines were more likely to be produced by government-funded agencies or developed within a structured and coordinated program to produce clinical practice guidelines.[5,7,34]

Compared with an international study that assessed the quality of 86 guidelines in 10 European countries and Canada,[5] mean scores achieved by Australian guidelines in our study were higher for stakeholder involvement (45.8% v 33.6%), rigour of development (40.9% v 36.9%), clarity and presentation (71.3% v 57.2%), and lower for scope and purpose (54.3% v 66.1%), applicability (21.6% v 31.3%) and editorial independence (11.8% v 47.8%). This was mainly owing to the high mean scores for NHMRC-approved guidelines, which were higher than mean scores observed in all other international studies that have used the AGREE instrument, in all domains except scope and purpose, and editorial independence.[2-5,34-39]

2 Relevance of Australian clinical guidelines for the treatment of older patients with comorbid conditions[9]

Relevance	No. of guidelines
Issues addressed	
Guideline addressed treatment for older patients	8 (47%)
Guideline addressed treatment for patients with multiple comorbid conditions	9 (53%)
Guideline addressed treatment for older patients with multiple comorbid conditions	1 (6%)
Quality of evidence	
Quality of evidence discussed for older patients	6 (35%)
Quality of evidence discussed for patients with multiple comorbid conditions	7 (41%)
Quality of evidence discussed for older patients with comorbid conditions	1 (6%)
Recommendations	
Specific recommendations for patients with one comorbid condition	9 (53%)
Specific recommendations for patients with several comorbid conditions	2 (12%)
Burden of treatment	
Time needed to treat to benefit from treatment in the context of life expectancy discussed	3 (18%)
Guideline discussed burden of comprehensive treatment on patients or caregivers	5 (29%)
Guideline discussed patients' financial burden	5 (29%)
Guideline discussed patients' quality of life	11 (65%)
Patient preferences	
Guideline discussed patients' preferences	8 (47%)
Guideline discussed patients' preferences for end-of-life treatment	5 (29%)

All the Australian guidelines we studied, regardless of whether they were approved by the NHMRC, performed poorly in the domain of editorial independence. Disclosure of conflicts of interest of guideline development members was not a requirement of the NHMRC until a recent update of its standards in October 2007.[11]

The applicability domain evaluates issues that are pertinent to guideline implementation, such as organisational barriers, cost implications and monitoring criteria. The mean score for the Australian guidelines was low, suggesting implementation barriers were not sufficiently overcome in Australian guidelines. However, it should be noted that the AGREE instrument does not assess the actual implementation of guidelines.

Low-quality scores in the rigour of development domain raise concern about guideline validity. This needs to be addressed as the promotion of invalid guidelines may result in ineffective or unsafe treatments, or inefficient use of resources. The costs involved with the development of rigorous guidelines based on systematic reviews of the evidence may be a barrier for a single Australian professional society or charity. There is a limited amount of public funding for guideline development. Only two guidelines in our sample were funded by state or federal government departments. Increased resources for developing of guidelines may be required to overcome this barrier.

Another reason for not following the NHMRC process is that several professional organisations have chosen to adapt existing international guidelines for use in Australia rather than develop their own. This option avoids duplicating efforts when high-quality international guidelines are already available on similar topics. However, there is no validated process for adapting guidelines produced in one cultural and organisational setting for use in another.[40] NHMRC guidance in this area would be welcome to support the efforts of professional societies.

Only half of the guidelines studied covered treatment for older patients and for patients with a single comorbid condition. Only one discussed issues of older people with multiple conditions. These results are consistent with a previous American study.[9] The 2004–05 Australian National Health Survey reported that 80% of Australians aged 65 years or older had three or more chronic conditions,[41,42] and the absence of guidance on how to manage older patients with multiple chronic conditions means that treatment decisions are left with individual practitioners. It has been proposed that meta-guidelines should be developed for the most common patterns of chronic conditions, which would define how to prioritise the many interventions that could be undertaken in people with multiple conditions.[43]

The AGREE instrument and the instrument used to assess relevance examined different aspects of patient-centred care. A minority of guidelines reported having involved at least one consumer in part of the guideline development (35%), discussed patients' preferences (47%) and considered the burden of comprehensive treatment on patients or caregivers (29%). The revised NHMRC standards for externally developed guidelines require that consumers should be involved early in the development process.[11] However, "effective" patient involvement in the development process is still being debated.[44] Research on how patient preferences can be integrated into an evidence-based model of care is also still in its infancy.[44]

Our study has several limitations. The selection criteria allowed the inclusion of a wide range of important health conditions and of guideline producers. However, our results may not be generalisable to all Australian guidelines on chronic diseases or to guideline producers. We used the generally agreed definition of a guideline as "a set of systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances".[45] Because of the definition adopted and the format of the AGREE instrument, we did not include documents produced by the Royal Australian College of General Practitioners (RACGP) or Therapeutic Guidelines Limited in our analysis.

Poor quality of guidelines could also be the result of poor reporting of the methods used during guideline development rather than actual poor process. However, guideline readers should be able to assess the reliability of guidelines for themselves. Clear documentation of how guidelines were developed may also enhance their acceptance by clinicians.

The AGREE criteria provide a well validated assessment instrument, and the inter-rater agreement was excellent or good for most items in our study. However, ratings can be influenced by the reviewer's background knowledge of the guideline topic or the method of guideline development. In our study, one reviewer had significant

3 Individual standardised AGREE domain scores for the 17 guidelines studied

Name of guideline	Published	Developed by	NHMRC approved	Scope and purpose	Stakeholder involvement	Rigour of development	Clarity and presentation	Applicability	Editorial independence
Asthma management handbook[17]	2006	National Asthma Council	No	39%	17%	21%	88%	28%	0
Clinical practice guidelines for the management of early breast cancer[18]	2001	National Breast Cancer Centre	Yes	78%	96%	62%	92%	72%	0
Clinical practice guidelines for the prevention, early detection and management of colorectal cancer[19]	2005	Australian Cancer Network	Yes	89%	38%	76%	67%	33%	17%
Clinical practice guidelines: evidence-based information and recommendations for the management of localised prostate cancer[20]	2003	Australian Cancer Network	Yes	33%	50%	67%	79%	11%	0
Guidelines for the management of acute coronary syndromes[21]	2006	National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand	No	39%	63%	21%	88%	33%	50%
The COPD-X plan: Australian and New Zealand guidelines for the management of chronic obstructive pulmonary disease[22]	2007	Australian Lung Foundation and Thoracic Society of Australia and New Zealand	No	67%	42%	50%	58%	0	8%
Guidelines for preventing cardiovascular events in people with coronary heart disease[23]	2007	National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand	No	0	0	0	71%	0	8%
Hypertension management guide for doctors[24]	2004	National Heart Foundation of Australia	No	22%	4%	27%	75%	6%	0
National evidence-based guidelines for the management of type 2 diabetes mellitus (Part 4)[25]	2005	Australian Centre for Diabetes Strategies	Yes	100%	71%	90%	75%	33%	0
Guidelines for the management of postmenopausal osteoporosis for GPs[26]	2004	Osteoporosis Australia	No	67%	25%	12%	8%	0	0
Clinical practice guidelines for the psychosocial care of adults with cancer[27]	2003	National Breast Cancer Centre and National Cancer Control Initiative	Yes	72%	75%	57%	88%	56%	0
Care of patients with dementia in general practice[28]	2003	New South Wales Department of Health	No	67%	75%	5%	33%	6%	0
Australian and New Zealand clinical practice guidelines for the treatment of depression[29]	2004	Royal Australian and New Zealand College of Psychiatrists	No	22%	33%	38%	42%	11%	25%
Royal Australian and New Zealand College of Psychiatrists clinical practice guidelines for the treatment of schizophrenia and related disorders[30]	2005	Royal Australian and New Zealand College of Psychiatrists	No	22%	29%	10%	79%	0	50%
Clinical guidelines for stroke rehabilitation and recovery[31]	2005	National Stroke Foundation	Yes	89%	71%	76%	100%	67%	8%
Guidelines for the prevention, detection and management of chronic heart failure in Australia[32]	2006	National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand	No	61%	42%	38%	92%	11%	8%
Treating depression: the *beyondblue* guidelines for treating depression in primary care[33]	2002	*beyondblue*	No	56%	50%	45%	79%	0	25%

AGREE = Appraisal of Guidelines Research and Evaluation instrument. NHMRC = National Health and Medical Research Council. ◆

4 Overall mean domain scores for the AGREE instrument, and a comparison of mean scores for guidelines that were and were not approved by the National Health and Medical Resarch Council (NHMRC)

Domain	Mean	SD	Mean: NHMRC-approved	Mean: Not NHMRC-approved	*P*
Scope and purpose	54.3%	28.3%	76.9%	41.9%	0.009
Stakeholder involvement	45.8%	26.7%	66.7%	34.5%	0.021
Rigour of development	40.9%	27.6%	71.4%	24.2%	0.001
Clarity and presentation	71.3%	23.9%	83.3%	64.8%	0.157
Applicability	21.6%	24.2%	45.4%	8.6%	0.003
Editorial independence	11.8%	16.7%	4.2%	15.9%	0.181

AGREE = Appraisal of Guidelines Research and Evaluation. ◆

experience in guideline development, while the other had not been involved in guideline development. The high κ scores suggest the background knowledge of the reviewers did not significantly influence the results.

Our results show that the quality of Australian clinical guidelines is low when they have not been approved by the NHMRC. Professional societies and charities should be encouraged and supported to adopt NHMRC standards and procedures for developing guidelines. Future Australian guidelines should also provide more guidance on the management of older people with multiple comorbid conditions.

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COMPETING INTERESTS

None identified.

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