Original Research Article

The Quality of Malaysian Clinical Practice Guidelines and Relevance to The Care of Older People

Nadzihah Mohd Nawi[1], Shubashini Gnanasan[1, 2], Mohd Shahezwan Abd Wahab[1, 2], Mahmathi Karuppannan[1, 2*]

[1]Faculty of Pharmacy, Universiti Teknologi MARA (UiTM), 42300 Bandar Puncak Alam, Selangor, Malaysia.
[2]Department of Pharmacy Practice, Faculty of Pharmacy, Universiti Teknologi MARA (UiTM), 42300 Bandar Puncak Alam, Selangor, Malaysia.

Abstract

Clinical Practice Guidelines (CPGs) are key instruments in providing the most appropriate decision in the treatment of any disease. CPG was developed to improve health care by increasing the incorporation of evidence-based treatments to reduce the use of unnecessary, ineffective or harmful interventions. This study assessed 5 Malaysian CPGs using Appraisal of Guidelines Research and Evaluation II (AGREE-II) instrument which could help the stakeholders to decide if further improvement or modification is needed. AGREE-II is an international instrument that aids in CPG development. It comprises of 23-items under 6 different domains. The κ statistics was used to look for agreement between 3 appraisers across these domains. The relevance of the Malaysian CPG to the care of older people in this study was also assessed using an instrument that have been developed by a previous study (Quality of Australian clinical guidelines and relevance to the care of older people with multiple comorbid conditions). This instrument evaluated if the guidelines addressed the treatment for older people, the burdens to the patients and caregivers as well as patient-centered aspects such as patients' preferences and their quality of life. This study showed that all 5 Malaysian CPGs are of good quality and acceptable to clinical settings according to the AGREE instrument. However, it was found that none of the CPG considered patients' preferences in developing CPGs. In terms of the CPGs' relevance to the care of older people, our results showed that there is poor relevance on the patients' burden of treatment. Only two CPGs (Management of Type 2 Diabetes Mellitus and Management of Hypertension) had a higher agreement between the appraisers compared to other CPGs in relation to management of medical conditions in older patients. As a conclusion it was found all 5 Malaysian CPGs evaluated were in good quality but need improvement in terms of involving stakeholder in the development of CPGs at par with other developed countries.

Keywords: Quality, Malaysian CPGs (CPG), older people, Appraisal of Guidelines Research and Evaluation II (AGREE II), management, CPG development

Corresponding author

Dr. Mahmathi Karuppannan
Level 11, FF1 Building, Faculty of Pharmacy,
UiTM Puncak Alam, Bandar Puncak Alam, 42300,
Selangor, Malaysia
mahmathi@uitm.edu.my

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1.0 Introduction

CPGs are important tool for decision makers to determine the effectiveness and cost-effectiveness of practice, and also make treatment recommendations to patients (1). In order to improve the health care service quality, many strategies have been taken and the reduction of unnecessary, ineffective and harmful interventions in CPGs are some of the strategies (2). Donatus *et al* (3) reported that CPGs have been criticized as being "disease driven rather than patient driven". This statement refers to the difficulty in finding CPG that can be applied to elderly patients with multiple comorbidities. Final CPG produced must comply to strong methods and include a multidisciplinary working panel as well as public consultation process (2). However CPG should be consistently evaluated as to ensure their quality (1). An instrument produced by AGREE Enterprise in 2003 called Appraisal of Guidelines for Research and Evaluation (AGREE) is a useful and reliable instrument to evaluate CPGs. It has been utilised in many countries to aid in the CPG development so that it will be cost-effective and also improve their quality (4–6).

Malaysia has undergone a rapid change in the last two decades, including the health care system which is gradually improving to make sure that people are served with the most efficient treatment., Most of the available CPGs in Malaysia focus on the diseases and not patient-centred (3). Thus, the treatment given sometimes not on the basis of giving the right treatment to the right patient but more on the basis of giving the treatment to the right diseases that the patients have. A study in Australia assessed the quality of Australian clinical guidelines for chronic diseases and their relevance to older people with multiple comorbid conditions (2). However, there was no such study conducted in Malaysia.

In Malaysia, CPGs are developed by MaHTAS and professional societies (7). The topic for CPG developed by MaHTAS will be determined by the CPG Technical Advisory Committee (TAC) while the professional societies have the liberty of developing CPG of their interest (7). MaHTAS will brief the work process of CPG development and implementation to the latter on their request and assist them wherever possible (8). CPG development, implementation and review should be seen not as a linear process, but cycles of interdependent activities which complement each other (7).

We aimed to measure the quality of Malaysian CPGs and its relevance to elderly group with multiple comorbidities in Malaysia. Our main focus in this study is on CPGs for metabolic syndromes due to the high prevalence of this problems among elderly in Malaysia i.e. 43.4% (9). The outcomes from this study could highlight the important components needed in CPGs for the management of diseases in patients emphasising on the older generation and the development of policies for CPG uses in Malaysia. Hence, this study can help to improve the quality of the CPGs in Malaysia.

2.0 Materials and methods

2.1 Guideline search and selection

Five CPGs for metabolic syndromes listed and published in official portal Ministry of Health (MoH) were included in this study. Guidelines were identified through official portal MoH where all CPGs were listed. The selected CPGs were:

i. Management of Heart Failure 3rd edition (10)
ii. Management of Dyslipidaemia 5th Edition (11)
iii. Management of Type 2 Diabetes Mellitus 5th Edition (12)
iv. Management of Ischaemic Stroke 2nd Edition (13)
v. Management of Hypertension 5th Edition (14)

2.2 Assessment of guidelines

All guidelines were evaluated independently by three appraisers. The Appraisal of Guidelines for Research and Evaluation II (AGREE-II) checklist was used to appraise the quality of the guidelines (15). The AGREE-II instrument has been validated and tested in several countries (16,17), and is perceived to be the best tool for evaluating the quality of a guideline (18,19). There are 23 items under six theoretical domains (scope and purpose, stakeholder involvement, rigour of development, clarity and presentation, applicability and editorial independence) which were rated using 7-point scale (1-strongly disagree to 7-strongly agree).

The AGREE-II is intended to be used by the following stakeholder groups (15):

- by health care providers who wish to undertake their own assessment of a guideline before adopting its recommendations into their practice;
- by guideline developers to follow a structured and rigorous development methodology, to conduct an internal assessment to ensure that their guidelines are sound, or to evaluate guidelines from other groups for potential adaptation to their own context;
- by policy makers to help them decide which guidelines could be recommended for use in practice or to inform policy decisions; and
- by educators to help enhance critical appraisal skills amongst health professionals and to teach core competencies in guideline development and reporting.

2.3 Relevance of guidelines to the care of older people

The relevance of the guidelines to the care of older people were assessed using a specific instrument developed in a previous study (2). This instrument includes 12 items assessing whether guidelines addressed treatment for older people and for people with several co morbid conditions, as well as patient-centred aspects such as patients' preferences and quality of life.

2.4 Study procedure

The distribution and collection were done through an invitation email sent to the appraisers i.e. MK, SG and MSAW. MK and SG are senior

clinical pharmacy academicians with more than 10 years of experiences while MSAW is a pharmacy academician. All the documents needed were attached in the email:

i. Invitation letter
ii. Information sheet
iii. AGREE-II manual for appraisers
iv. 5 CPGs selected
v. Two google form links i.e. Evaluation of CPGs using AGREE-II instrument (Table 1) and The Relevance of Malaysian CPGs to The Care of Older People

Data keyed in by the appraisers were collected through google form website. All the scores given by each appraiser were tabulated in the form of table before they were analysed.

Table 1: The 23 items in AGREE-II instrument (15)

DOMAIN 1. SCOPE AND PURPOSE
1. The overall objective(s) of the guideline is (are) specifically described. 2. The health question(s) covered by the guideline is (are) specifically described. 3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
DOMAIN 2. STAKEHOLDER INVOLVEMENT
4. The guideline development group includes individuals from all relevant professional groups. 5. The views and preferences of the target population (patients, public, etc.) have been sought. 6. The target users of the guideline are clearly defined.
DOMAIN 3. RIGOUR OF DEVELOPMENT
7. Systematic methods were used to search for evidence. 8. The criteria for selecting the evidence are clearly described. 9. The strengths and limitations of the body of evidence are clearly described. 10. The methods for formulating the recommendations are clearly described. 11. The health benefits, side effects, and risks have been considered in formulating the recommendations. 12. There is an explicit link between the recommendations and the supporting evidence. 13. The guideline has been externally reviewed by experts prior to its publication. 14. A procedure for updating the guideline is provided.
DOMAIN 4. CLARITY OF PRESENTATION
15. The recommendations are specific and unambiguous. 16. The different options for management of the condition or health issue are clearly presented. 17. Key recommendations are easily identifiable.
DOMAIN 5. APPLICABILITY
18. The guideline describes facilitators and barriers to its application. 19. The guideline provides advice and/or tools on how the recommendations can be put into practice. 20. The potential resource implications of applying the recommendations have been considered. 21. The guideline presents monitoring and/or auditing criteria.
DOMAIN 6. EDITORIAL INDEPENDENCE
22. The views of the funding body have not influenced the content of the guideline. 23. Competing interests of guideline development group members have been recorded and addressed.

2.5 Data analysis

Domain scores for each guideline were calculated by summing scores across the three appraisers and standardising them as a percentage of the possible maximum score a guideline could achieve. Using the scores, Fleiss's kappa coefficient was calculated to measure internal consistency of each domain across the guidelines assessed. For the relevance of the guidelines to the care of older people, numbers of guidelines that were relevant to the issue addressed were counted and presented as percentage.

3.0 Results

The domain-standardized scores for Malaysian CPGs are presented in Table 2. The mean score for the scope and purpose domain was 98% (range 96–100%). The overall objectives of the guidelines, their health questions as well as target populations were described in detail in the guidelines.

The overall mean score for the stakeholder involvement domain was 67.6% (range 65–70%). The guidelines description of guideline development group, target's preferences and target description were discussed in this domain. Among five guidelines evaluated, none of them considered the target populations' views and preferences.

The mean score for the rigour of development domain was 87% (range 83–92%). This domain discussed about the guideline's development process from searching for evidence process until the description process of updating the guidelines. None of the guidelines described their procedures for updating the guideline.

The mean score for the clarity of presentation domain was 95.2% (range 94–98%). All guidelines scored above 50%. Most guidelines provided specific, unambiguous and easily identifiable recommendations.

The mean score for the applicability domain was 79.4% (61–94%). Management of Heart Failure CPG had the lowest mean scores among all with 61%. Only a few guidelines systematically described the facilitators and barriers of its applications very well. Most guidelines did not sufficiently consider the costs of applying their recommendations.

The mean score for the editorial independence domain was 92.8% (73–100%). This high mean score shows that competing interests of guideline development group members have been recorded and addressed and external funding support from other sources have not influenced the content of the guideline.

Table 3 shows that the agreement between the three appraisers was acceptable in most of the items but poor in rigour of development domain for Management of Heart Failure ($\kappa = 0.28$) and Management of Dyslipidaemia ($\kappa = 0.34$)

Table 4 shows the review from three appraisers based on the items they chose. The agreement between the three appraisers were excellent in 3 domains i.e. issue addressed, quality of evidence and recommendations. Yet, our result showed a poor agreement in the burden of treatment domain. Only 1 or no reviewer at all selected most of the items under the burden of treatment domain. Comparing all five CPGs, only two CPGs (Management of Type 2 Diabetes Mellitus and Management of Hypertension) had a higher agreement between the appraisers in relation to management of medical conditions in older patients.

4.0 Discussion

This study showed that the quality of Malaysian (CPGs) for heart failure, dyslipidaemia, type 2 diabetes mellitus, ischaemic stroke and hypertension was good in five domains but low in one of the domains (stakeholder involvement = 67.6%). All 5

Table 2: Individual standardised AGREE-II domain scores for the 5 guidelines

Name of guideline	Published	Developed by	Scope and purpose	Stakeholder involvement	Rigour of development	Clarity and presentation	Applicability	Editorial independence
Management of Heart Failure 3rd edition (10)	2014	Ministry of Health	98%	67%	85%	94%	61%	100%
Management of Dyslipidaemia 5th Edition (11)	2017	Ministry of Health	100%	69%	90%	94%	82%	97%
Management of Type 2 Diabetes Mellitus 5th Edition (12)	2015	Ministry of Health	96%	65%	83%	98%	94%	94%
Management of Ischaemic Stroke 2nd Edition (13)	2012	Ministry of Health	98%	70%	85%	94%	89%	73%
Management of Hypertension 5th Edition (14)	2018	Ministry of Health	98%	67%	92%	96%	71%	100%
Mean percentage of maximum possible score			98%	67.6%	87%	95.2%	79.4%	92.8%

Table 3: Overview of the AGREE-II domains, and the agreement between the three appraisers

Name of guidelines / **Theoretical domains**	**Management of Heart Failure 3rd edition**	**Management of Dyslipidaemia 5th Edition**	**Management of Type 2 Diabetes Mellitus 5th Edition**	**Management of Ischaemic Stroke 2nd Edition**	**Management of Hypertension 5th Edition**
Scope and purpose	0.86	1.00	0.94	0.86	1.00
Stakeholder involvement	0.57	0.97	0.90	0.58	0.99
Rigour of development	0.28	0.34	0.84	0.62	0.71
Clarity and presentation	0.75	0.97	0.75	0.75	0.86
Applicability	0.74	1.00	0.75	0.75	0.75
Editorial independence	1.00	0.75	0.67	0.67	1.00

*Fleiss's kappa coefficient

Table 4: Relevance of Malaysian CPGs for the treatment of older patients based on three appraisers

Relevance	**Review of the items by three appraisers**					
	Name of the guidelines*/ Number of appraisers					
Issue addressed	**HF**	**DYS**	**T2DM**	**ISCS**	**HYP**	**Total %**
Guideline addressed treatment for older patients	1	3	3	1	3	11 (73%)
Guideline addressed treatment for patients with multiple comorbid conditions	2	3	3	2	3	13 (87%)
Guideline addressed treatment for older patients with multiple comorbid conditions	0	0	3	0	3	6 (40%)
Quality of evidence						
Quality of evidence discussed for older patients	1	3	3	1	3	11 (73%)
Quality of evidence discussed for patients with multiple comorbid conditions	2	2	3	3	3	13 (87%)
Quality of evidence discussed for older patients with comorbid conditions	1	2	3	1	3	10 (67%)
Recommendations						
Specific recommendations for patients with one comorbid condition	2	3	3	3	3	14 (93%)
Specific recommendations for patients with several comorbid conditions	2	2	3	2	3	12 (80%)
Burden of treatment						
Time needed to treat to benefit from treatment in the context of life expectancy	1	1	1	1	1	5 (33%)
discussed	0	1	2	0	2	5 (33%)
Guideline discussed burden of comprehensive treatment on patients or	0	0	2	0	1	3 (20%)
caregivers	3	0	2	0	1	6 (40%)
Guideline discussed patients' financial burden						
Guideline discussed patients' quality of life						

***Name of the guidelines:**
HF: Management of Heart Failure 3rd edition (6) **DYS: Management of Dyslipidaemia 5th Edition (7)**
T2DM: Management of Type 2 Diabetes Mellitus 5th Edition (8) **ISCS: Management of Ischaemic Stroke 2nd Edition (9)**
HYP: Management of Hypertension 5th Edition (10)

CPGs evaluated in this study have been approved and currently being used by all health institutions under MOH currently. Thus, their mean quality is shown to be as good as expected. In this study, their quality will be further discussed in depth according to their domains.

4.1 Scope and purpose

In this scope, the description of the overall objectives should be in detail. Plus, specification of expected health benefits from the guidelines should be well elaborated and stated (15). Normally, this domain would have the highest score across other domains (6,20). The scope and purpose for management of dyslipidaemia was calculated to be 100% while CPG for heart failure, ischaemic stroke and hypertension were 98%. It showed that the overall objectives of the guidelines are specifically described. Although CPG for type 2 diabetes mellitus has a lower percentage compared to other CPGs, it is still considered as a good value thus showing that this CPG also describes its whole objectives.

Our findings are consistent with other studies assessing international guidelines which showed that CPGs for type 2 diabetes mellitus have a lower percentage in this domain compared to other CPGs but this finding is not significant (21). Development team has clearly stated that the objective for Management of Type 2 Diabetes Mellitus 5th Edition CPG is to detect pre-diabetes and diabetes among the general as well as high-risk populations, whilst ensuring timely appropriate intervention (12). In this domain, the population to whom the guideline is meant to be applied need to be specifically described. All guidelines have described and stated in detail the type of patients and public that should be screened for the respective medical conditions (10–14).

4.2 Stakeholder involvement

Three items were evaluated under stakeholder involvement domain: the guidelines' development group included individuals from all relevant professional groups, the views and preferences of the target population were sought and the target users of the guidelines were clearly defined. This domain scored low percentage due to poor participation of the patients or their representatives during the development of these five CPGs.

According to Broerse et al, this domain is considered important as it completes the scientific evidences (22). Individuals from all relevant professional groups can assist in deciding the scientific evidences and whether or not the evidences are suitable to be included in the CPG (22). Many guidelines development groups have advised that this item should be included in every step throughout the development of CPGs as patients preferences and views are highly related with their adherence thus lead to an increase in the health outcomes (23). The involvement of patients in CPG development has now been acknowledged internationally as an important feature to ensure the production of more patient-centred and trustworthy guidelines (24,25). In the future process of development of CPGs, improvement on these features should be given more importance.

4.3 Rigour of Development

Our results show that all 5 CPGs achieved an adequate methodological quality. This means that recommendations that were suggested in the CPGs are based on the best available evidence. Although creating a high-quality CPG requires many financial resources, time, highly specialized personnel, and health system support. Malaysian development team was able to fulfil these requirements well (26–28). However,

Management of Type 2 Diabetes Mellitus CPG has lower scores (rigour of development scores = 83%) in this domain compared to other CPGs. This could be due to insufficient report of development process compared to other CPGs which were reported better. Some CPGs may fulfil an adequate rigor of development but attained a lower score in the AGREE-II instrument because the development process was not adequately reported (29). To avoid this, the guideline development groups could apply AGREE-II or another appropriate instrument to verify the adequate reporting of their CPGs.

4.4 Clarity and presentation

The mean domain scores of maximum possible scores for clarity of presentation domains was excellent (95.2%) for all guidelines evaluated. This showed that recommendation in all guidelines are specific and unambiguous. The different options for management of a condition or health issue were clearly presented while the key recommendations were easily identifiable. Furthermore, guidelines also indicated special needs of instrument in the management of certain medical conditions (30). The key recommendations were found to be bold, positioned in the table, box, typed in bold, underlined or presented as flow charts or algorithms (15). Even though this domain obtained the second highest scores across all domains, it still need improvement so that the guideline interpretation and implementation can be utilized maximally (31).

4.5 Applicability

The applicability domains mean scores suggest that Malaysian CPGs covered the implementation barriers sufficiently. Under applicability domain specifically item 18, three evaluators review the presence of the explanations of the possible facilitators and barriers that could impact the application of guideline recommendations (15). Management of Type 2 Diabetes Mellitus CPG scored the highest (applicability = 94%) across the CPGs evaluated as it clearly stated in the CPG statement that primary care may require patients followed up in diabetic clinics after treatment has been given. (12). The Management of Heart Failure CPG obtained the lowest score (61%) among five CPGs for this domain. This could be due to no mention of crucial barriers in the treatment of heart failure.

4.6 Editorial independence

The involvement of the funding body to the content of the guideline was evaluated under this domain. The editorial independence domain was highly described in all CPGs. Malaysian guidelines provided funding information and described competing interests in detail. Malaysian guidelines developers prefer disclosing their funding information. They have also acknowledged the importance of conflict of interest disclosures and management. Studies have shown that financial conflicts of interest are prevalent among CPGs in a variety of clinical areas (32,33).

In other study, one of the factors reported that may affect guideline recommendations was financial conflict of interest. (34) Therefore, guideline developers should strongly emphasize the editorial independence domain.

4.7 Relevance of Malaysian CPGs for the treatment of older patients

Three evaluators have high agreement (range from 67%-93%) on the relevance of Malaysian CPGs for older people in three domains evaluated which are the way of issue addressed, quality of evidence and recommendations suggested by the guidelines for the treatment of older people. Results showed that evaluators have a poor

agreement on the burden of treatment domain. Under this domain, only one evaluator chose each item. Improvement in this domain during next CPGs update or development should be focussed as older population is in increasing trend. Between 1990 and 2020, the population of Malaysia is expected to increase from 18.4 million to 33.3 million - an increase of 80% (35).

Our study has several limitations. Any position or consensus statements that have not been developed by a systematic approach to the retrieval and the analysis, guidelines that are still at the level of development/drafting and guidelines for paediatric, child health and adolescent were excluded in this research.

5.0 Conclusion

Our results showed that the 5 Malaysian CPGs are in good quality and acceptable to be used in the clinical settings. However, none of the CPG took into account patients' preferences. While creating a management guideline for patients, it is important to acknowledge the patients concerns and preferences to ensure that the guideline also meets their expectation. Thus, this study suggests that in future, before updating or creating a CPG, patients' view should be taken into consideration. CPGs should also give attention on the burden of treatment in older patients as higher burden could lead to poor adherence. Only two CPGs (Management of Type 2 Diabetes Mellitus and Management of Hypertension) had a higher agreement between the appraisers compared to other CPGs in relation to management of medical conditions in older patients. This reveals that CPGs should start focusing on incorporating more information about managing older patients with multiple medical conditions as the older population is in increasing trend.

Conflict of interest

Authors declare no conflict of interest in the present work.

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