Research Article
AMERICAN JOURNAL OF PHARMACY AND HEALTH RESEARCH
www.ajphr.com
2017, Volume 5, Issue 5
ISSN: 2321–3647(online)

Applicability Magnitude of Clinical Practice Guidelines for Diagnosis, Prevention & Treatment of Osteoporosis in Internal Medicine Practice

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ABSTRACT

Main objective and aim of prospective, cross sectional research is to evaluate the magnitude of applicability of International Osteoporosis Foundation Guidelines for diagnosis, prevention and treatment of Osteoporosis in Asia for Pakistani population. Study was conducted during December 2015 to January 2017 in Karachi, Pakistan. Primary data has been collected from 30 internists working in private and government sector hospitals and clinics. Six main domains scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, editorial independence and overall quality of IOF guide for Asia are evaluated. Data was analyzed through SPSS 20 by using descriptive statistics. Among 30 internists, number of practitioners from hospital (57%), clinic (43%), private sector (73%), government sector (27%). Magnitudes of six domains are scope and purpose 71%, stakeholder involvement 62%, rigour of development 86%, clarity of presentation 88%, applicability 85%, and editorial independence 74%, all these domains are significantly ($p<0.003$) lower compares to ideal score. Examination of the overall assessment by the appraisers revealed that guideline was not rejected by a majority of medical practitioners. 43.33% appraisers are interested to use or recommend guideline without any changes. Almost 53.33% rated the guidelines as being in need of modifications, while 3.33% are not interested to practice these guidelines.

Keywords: Guidelines, magnitude, applicability, osteoporosis, medicine

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Received 18 April 2017, Accepted 30 April 2017

Please cite this article as: Khaliq SA *et al*., Applicability Magnitude of Clinical Practice Guidelines for Diagnosis, Prevention & Treatment of Osteoporosis in Internal Medicine Practice. American Journal of Pharmacy & Health Research 2017.

INTRODUCTION

Guidelines for clinical practice are systematically developed statements. Guidelines can focus key clinical thoughts for choosing effective strategies, reduce unnecessary costs and avoid inaccuracies. The best quality guidelines frequently review the medical literature and summarize the best existing evidence. This upturns the validity of guidelines[1]. High variability is possible in the quality of clinical practice guidelines. It has been noted that some guidelines does not contain basic standardization and[2] thus show variability in quality[3-5]. In order to determine the variability in quality of guideline, *Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument*[6]is developed. AGREE – II instrument evaluates the methodologies and transparencies for development of guidelines[6].

Population of Pakistan is growing and elderly population is increasing, that is why osteoporosis is becoming a threat. The ratio among female: male is 2:1 for hip fracture in a 5 year analysis with average age of fracture 61 years[7], which is comparable to India but lower than North America and Europe[8]. The prevalence of osteopenia and osteoporosis was found to be 16 and 34% respectively in 45-70 years aged women[9]. Study of North West Frontier Province have prevalence of 29 and 42% respectively[10]. Risk of osteoporosis was found to be 75% in women of Peshawar [11].

Most of the guidelines like; National Osteoporosis Foundation (NOF), American Academy of Orthopedics (AAO), North American Guidelines of Osteoporosis, World Health Organization (WHO), International Osteoporosis Foundation (IOF) are made, evaluated and appraised for the patients of western world. Ideally Pakistan should have local guidelines; however scarcity of resources is a major reason for non-availability. It is therefore necessary to evaluate the application of above mentioned guidelines by using AGREE-II instrument in Pakistani population.

MATERIALS AND METHOD

A descriptive cross sectional study was conducted in Karachi from December 2015 to January 2017. The data was collected from validated and reliable questionnaire`[12,13] after detailed discussion of IOF (International Osteoporosis Foundation) guidelines recommended for Asian countries [14] to diagnose, prevent and treat osteoporosis to Internists (Internal medicine and Rheumatologists). A minimum sample size of 26 internists was determined by power analysis technique, where effect size was high (0.50), level of significance ($\alpha = 0.05$), power of study ($\beta = 0.80$)[15], however, 30 practitioners were included in the study.

The questionnaire focused on six main domains; (scope & purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence) (BOX). The appraisal of guidelines for research & evaluation (AGREE-II) Instrument [16] was used to address the issue of variability in guideline quality. Internists were also asked to rate the overall quality of guideline for its applicability in medical practice system of Pakistan. The questionnaire included data in ordinal scale which is evaluated by calculating domain scores by formula in AGREE – II instrument [12,13]. Mathematical computation of domains scores are made according to the following method:

- Maximum possible score = strongly agree (7) X questions (3) X # of internists (30) = a
- Minimum possible score = strongly disagree (1) X questions (3) X # of internists (30) = b
- Scaled domain score = (obtained score – minimum possible score) / (maximum possible score – minimum possible score) = c X 100 = Z%

SPSS 20 version software was used to evaluate descriptive, inferential statistics and mathematical evaluation was done on Microsoft Office Excel. Verbal inform consent was taken by the physicians and approved by the University of Karachi.

RESULTS AND DISCUSSION

Evaluation of 23 questions/items determines the magnitude of applicability of six key domains of IOF (International Osteoporosis Foundation) guidelines for Asia [14]. Score of these domains are mentioned in Table – I ($t= -5.297$, $p<0.003$, SD: 10.327, SE: 4.216, H_o; rejected). Response of question/item 24 regarding overall quality of guideline is 83.89%.

Table I: (Domain Scores & Rate of Overall Quality of Guideline)

Domain (Items)	Domain Description	Magnitude*	Significance
Domain 1 (Q1 - Q3)	Scope & Purpose	71%	t= -5.297
Domain 2 (Q4 - Q6)	Stakeholder Involvement	62%	p<0.003
Domain 3 (Q7 - Q14)	Rigour of Development	86%	
Domain 4 (Q15 - Q17)	Clarity of Presentation	88%	
Domain 5 (Q18 - Q21)	Applicability	85%	
Domain 6 (Q22 - Q23)	Editorial Independence	74%	
Q 24	**Overall Quality of Guideline**	**83.89%**	

***Calculated by mathematical valid & reliable formula [12,13] provided by AGREE - II instrument [17]

Internist's responses for the item of rate of overall all quality of guideline from 1 = fully disagree to 7 = fully agree **(Table – II)**.

Table II: (Rate the overall quality of this guideline)

(Fully Disagree) 1	2	3	4	5	6	(Fully Agree) 7
0.00%	0.00%	3.33%	0.00%	16.67%	50.00%	30.00%

Internist's response for question/item 25. **(Table – III)**

Table III: (IOF guideline for Asia would be recommended for use)

Yes	Yes with Modification	No
43.33%	53.33%	3.33%

DISCUSSION:

Main objective of current study is to evaluate the applicability magnitude of IOF (International Osteoporosis Foundation) guideline recommended for Asian countries[14]through profession of internal medicine and rheumatology. Guidelines are having wide ranging implications that may include improvement of quality of care, resolve the issue of malpractice claims, aiding evidence for the development of clinical decisions or for health policy makers [18].

Current study determined the magnitude of applicability of overall quality of International Osteoporosis Foundation guidelines recommended for Asian countries to manage Osteoporosis. Guideline which is recommended for Asia by IOF comprises the data of Hong Kong and China [14]. South Asian populations living in SAARC (South Asian Association for Regional Co-operation) countries like India, Bangladesh, Pakistan, Sri Lanka, Afghanistan, Nepal, Bhutan, and Maldives are having different pharmaco-genetic characteristics in many clinical circumstances, in order to make appropriate clinical decisions it is therefore necessary to have data from local population.

Internists and rheumatologists in Pakistan working either in government or private sector believe that magnitude of applicability of scope and purpose of guidelines is 71%, so more than two third of guidelines is meeting the overall aim pertaining to Pakistani population. Internists and rheumatologists have opinion that despite clear objective of IOF guide for Asia, local population, patients, and public is not considered. Every society has their own norms and values, so guidelines development members have their own societal norms and values that may affect the choice and interpretation of evidence which may affect their recommendations for disease state management [19-25].

During development of guideline, views of main stakeholders must be considered. A quality clinical practice guidelines must have inputs of all these stakeholders. Stakeholder should also have comprehension about population for whom guideline is addressing. Internists and rheumatologists of Pakistan believe that applicability magnitude of this domain is 62% and target

patients and population of Pakistan have not been considered, however, users of guideline and all relevant professionals were part during development process. Many authors believe that patient should be part of the team who develop the guideline, which is not found in many currently available standards [18,26].

Applicability magnitude score of rigour of development is 86%. Rigour of development is related to the processes used to gather and synthesized the evidence, methods to formulate the recommendations, and to update them. Regarding this domain, internists and rheumatologists are in more agreement but not full that during synthesis of evidence systematic methods were applied, consideration was done for strength and limitations of evidences, appropriate methodology was followed for formulating the recommendations, consideration was done for side effects, risks, health benefits, review of guideline was done before publication and perpetual update criteria is mentioned. Strategy was applied up to maximum extent to avoid the possibility of biases.

Clarity of presentation deals with language, structure and format of the guideline. It has the highest applicability magnitude i.e. 88%, which represents that internists and rheumatologists are convinced that recommendations of IOF for Asian countries provide concrete and precise description of different options. There is no ambiguity in recommendations and key recommendations are clearly presented after consideration of all health issues, however, if local population data is provided, that could further improve the score of this domain.

For the domain of applicability, on an average more than 40% internists and rheumatologists are in full agreement that guidelines discussed the facilitators and barriers of application of guideline, different tools and methodologies have been mentioned that how guidelines can be practiced despite certain financial barriers. However, physicians are not agreeing that criteria for audit and monitoring of guidelines are clearly presented, which resulted in 85% score of domain.

Editorial independencies concerned with the competing interest of all the members contributed in the development of guideline. Their opinions, views may be biased if not addressed appropriately and guideline quality can be compromised. Decisions in any healthcare system may influenced by conflict of interest[27,28], it can also influence the development of guidelines[29-31]. In order to avoid it, stringent policies should be implemented [26,32-35]. Magnitude of applicability of this domain is 74%. Majority of internists and rheumatologists are moderately agreed that development and recommendation of guideline is not influenced by competing interests of guideline development group members.

Independent sample t-test explored that domain scores are significantly lower compares to ideal score ($p<0.003$, 95%CI) that is why magnitude of overall quality of guideline is 83.89% and 43.33% internists and rheumatologists are ready to implement guideline in their practice without any modifications, however, 53.33% mentioned that they would use guideline in their practice but with some modification. 3.33% physicians rejected the guidelines.

CONCLUSION:

Six main domains and overall quality of IOF guide were assessed by questionnaire of AGREE II instrument (BOX). Score regarding domain of stakeholder involvement was found to be lowest and highest for clarity of presentation. Majority of physicians did not reject the IOF guideline recommended for Asian countries.

Table BOX

Questionnaire of Agree – II Instrument [17]	
Domains (Type)	Questions/Items
Scope & Purpose	The overall objective/s of the guideline is/are specifically described.
	Specific description is available in guideline pertaining to health question
	Specific description is available in guidelines for population e.g. public, patient, to whom guidelines is applicable
Stakeholder Involvement	Professional groups from relevant specialty were part of IOF guideline development group
	Population which is targeted in this guideline, their preferences & views have been taken
	The target users of the guideline are clearly defined
Rigour of Development	Systematic methods were used to search for evidence
	The criteria for selecting the evidence are clearly described
	Comprehensive detail is available for strength & limitation of body of evidence
	Clear detail are available for formulating the recommendations and their methodology
	The health benefits, side effects, and risks have been considered in formulating the recommendations
	There is an explicit link between the recommendations and the supporting evidence
	The guideline has been externally reviewed by experts prior to its publication
	A procedure for updating the guideline is provided
Clarity of Presentation	The recommendations are specific and unambiguous
	It is clearly mentioned that what are different options available for the management of osteoporosis
	Key recommendations are easily identifiable
Applicability	The guideline describes facilitators and barriers to its application
	The guideline provides advice and/or tools on how the recommendations can be put into practice
	The potential resource implications of applying the recommendations have been considered
	Auditing/monitoring criteria for IOF guide for Asia is mentioned
Editorial Independence	Recommendations and details of guidelines are not influenced by any funding body
	Members of guideline development group have competing interests (if any), that was appropriately addressed after recording

REFERENCES:

1. Field MJ, Lohr KN. Clinical practice guidelines: directions for a new program. Vol 90: National Academies Press; (1990).
2. Shaneyfelt TM, Mayo-Smith MF, Rothwangl J. Are guidelines following guidelines?: The methodological quality of clinical practice guidelines in the peer-reviewed medical literature. Jama. 1999;281(20):1900-1905.
3. Grilli R, Magrini N, Penna A, Mura G, Liberati A. Practice guidelines developed by specialty societies: the need for a critical appraisal. The Lancet. 2000;355(9198):103-106.
4. II A. Appraisal of guidelines for research & evaluation II. 2009.
5. Terrace L. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. Qual Saf Health Care. 2003;12:18-23.
6. Brouwers MC, Kho ME, Browman GP, et al. AGREE II: advancing guideline development, reporting and evaluation in health care. Canadian Medical Association Journal. 2010;182(18):E839-E842.
7. Harinarayan C. What's in a name—25 (OH) D or 25 (OH) D3. Natl Med J India. 2004;17(2):114-115.
8. Sultan A, Khan D, Mushtaq M, Hassan M. Frequency of osteoporosis and its associated risk factors in postmenopausal women in clinical practice at Rawalpindi. Pakistan J Pathol. 2006;17:115-118.
9. Lowe N, Bano Q, Bangash SA, Ellahi B, Zaman M. Dietary calcium intake and bone health in post-menopausal women in Nahaqi, North West Frontier Province, Pakistan. Proceedings of the Nutrition Society. 2008;67(OCE8):E369.
10. Habiba U, Ahmad S, Hassan L. Predisposition to osteoporosis in postmenopausal women. Journal-College Of Physicians And Surgeons Of Pakistan. 2002;12:297-301.
11. Hamilton BE, Martin JA, Ventura SJ. Births: Preliminary data for 2008. National vital statistics reports. 2010;58(16):1-18.
12. Brouwers MC, Kho ME, Browman GP, et al. Development of the AGREE II, part 2: assessment of validity of items and tools to support application. Canadian Medical Association Journal. 2010;182(10):E472-E478.
13. Brouwers MC, Kho ME, Browman GP, et al. Development of the AGREE II, part 1: performance, usefulness and areas for improvement. Canadian Medical Association

Journal. 2010;182(10):1045-1052.

14. Lau E, Sambrook P, Seeman E, Leong K, Leung P, Delmas P. Guidelines for diagnosing, prevention and treatment of osteoporosis in Asia. APLAR Journal of Rheumatology. 2006;9(1):24-36.
15. Faul F, Erdfelder E, Lang A-G, Buchner A. G* Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior research methods. 2007;39(2):175-191.
16. Brouwers MC, Browman G, Burgers DJ, et al. Appraisal of guidelines for research & evaluation (AGREE - II) instrument - II May 2009:1-11.
17. Brouwers MC, Browman G, Burgers DJ, et al. Appraisal of guidelines for research & evaluation (AGREE - II) instrument - II. May 2009:1-11.
18. Steinberg E, Greenfield S, Wolman DM, Mancher M, Graham R. Clinical practice guidelines we can trust: National Academies Press; 2011.
19. Woolf S, Schünemann HJ, Eccles MP, Grimshaw JM, Shekelle P. Developing clinical practice guidelines: types of evidence and outcomes; values and economics, synthesis, grading, and presentation and deriving recommendations. Implementation Science. 2012;7(1):61.
20. Raine R, Sanderson C, Hutchings A, Carter S, Larkin K, Black N. An experimental study of determinants of group judgments in clinical guideline development. The Lancet. 2004;364(9432):429-437.
21. Pagliari C, Grimshaw J, Eccles M. The potential influence of small group processes on guideline development. Journal of evaluation in clinical practice. 2001;7(2):165-173.
22. Pagliari C, Grimshaw J. Impact of group structure and process on multidisciplinary evidence-based guideline development: an observational study. Journal of evaluation in clinical practice. 2002;8(2):145-153.
23. Fretheim A, Schünemann HJ, Oxman AD. Improving the use of research evidence in guideline development: 3. Group composition and consultation process. Health Research Policy and Systems. 2006;4(1):15.
24. Moreira T, May C, Mason J, Eccles M. A new method of analysis enabled a better understanding of clinical practice guideline development processes. Journal of clinical epidemiology. 2006;59(11):1199-1206.
25. Gardner B, Davidson R, McAteer J, Michie S. A method for studying decision-making by guideline development groups. Implementation Science. 2009;4(1):48.

26. Qaseem A, Forland F, Macbeth F, Ollenschläger G, Phillips S, van der Wees P. Guidelines International Network: toward international standards for clinical practice guidelines. Annals of internal medicine. 2012;156(7):525-531.
27. Als-Nielsen B, Chen W, Gluud C, Kjaergard LL. Association of funding and conclusions in randomized drug trials: a reflection of treatment effect or adverse events? Jama. 2003;290(7):921-928.
28. Lexchin J, Bero LA, Djulbegovic B, Clark O. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. Bmj. 2003;326(7400):1167-1170.
29. Detsky AS. Sources of bias for authors of clinical practice guidelines. Canadian Medical Association Journal. 2006;175(9):1033-1033.
30. Shaneyfelt TM, Centor RM. Reassessment of clinical practice guidelines: go gently into that good night. Jama. 2009;301(8):868-869.
31. Sniderman AD, Furberg CD. Why guideline-making requires reform. Jama. 2009;301(4):429-431.
32. Eccles MP, Grimshaw JM, Shekelle P, Schünemann HJ, Woolf S. Developing clinical practice guidelines: target audiences, identifying topics for guidelines, guideline group composition and functioning and conflicts of interest. Implementation Science. 2012;7(1):60.
33. Boyd EA, Bero LA. Assessing faculty financial relationships with industry: a case study. Jama. 2000;284(17):2209-2214.
34. Campbell EG. Doctors and drug companies—scrutinizing influential relationships. New England Journal of Medicine. 2007;357(18):1796-1797.
35. Jacobs AK, Lindsay BD, Bellande BJ, et al. Task force 3: Disclosure of relationships with commercial interests: policy for educational activities and publications. Circulation. 2004;110(16):2524-2528.