Original Article

# APPLICABILITY MAGNITUDE OF CLINICAL PRACTICE GUIDELINES FOR DIAGNOSIS, PREVENTION AND TREATMENT OF OSTEOPOROSIS AMONG FAMILY PHYSICIANS: A CROSS SECTIONAL STUDY

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**ABSTRACT:**

**BACKGROUND:** Clinical Practice Guidelines are developed by professional groups. Guideline development process should be strategically rigor and methodologically appropriate; otherwise, resulting recommendations will not be implemented successfully. Variability in guidelines quality and deviations from basic standards are possible. Main aim of study is to evaluate the magnitude of applicability of International Osteoporosis Foundation Guidelines for diagnosis, prevention and treatment of Osteoporosis in Asia for Pakistani population by family physicians.

**SUBJECTS AND METHODS:** Cross sectional study was conducted during December 2014 to January 2017. Data has been collected from 50 family physicians practicing in Karachi. Sample size was determined by power analysis technique. Six main domains provided by AGREE – II instrument were evaluated; scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence in addition to overall quality of guideline. Data was analyzed through SPSS 23 using descriptive statistics.

**RESULTS:** Among 50 family physicians, practitioners from private hospital are 10 (20%),private clinics are 40 (80%). Magnitudes of six domains were 66% scope and purpose, 65% stakeholder involvement, 84% rigour of development, 86% clarity of presentation, 84% applicability and 61% editorial independence, all these domains are significantly ($p<0.003$) lower compares to ideal score.

**CONCLUSION:** Examination of the overall assessment of guideline revealed that majority of family physicians did not reject the guideline.

**KEY WORDS:** Guidelines, domains, magnitude, applicability, osteoporosis

## INTRODUCTION:

Guidelines for clinical practice are statements that are systematically developed for healthcare providers to help make decisions about patient in specialized or specific clinical situation. These guidelines frequently review the clinical literature and summarize the best existing evidence for choosing effective strategies, reducing unnecessary costs and avoiding in accuracies hence, up turns its validity[1]. Guidelines emphasis on a precise clinical problem, articulate relevant matters when treating the patients with that problem, assemble the medical literature, allocate values

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to the evidence and produce clinical recommendations. Guidelines development group members are multidisciplinary. Multidisciplinary member may include pharmacists, physicians and other allied health professionals.

High variability is possible in the quality of clinical practice guidelines. For this reason, it is important that healthcare professionals understand how to assess the quality of such resource. Clinical studies are basis for the best evidence based guidelines and are thus more objective than opinion or consensus guidelines. Nevertheless, guidelines that are peer reviewed and that present recommendations and evidence relevant to patient care are considered to be both relevant and valid [2,3].

Family physician plays a highly active and an important role in practicing evidence based management. Medical practitioners in specific clinical circumstances may need to take decisions for the patient based upon systematically developed clinical practice guidelines [4]. It has been observed that some guidelines does not contains basic standardization[5] and thus show variability in quality [6,8]. In order to determine the variability in quality of a guideline, *Appraisal of Guidelines for Research & Evaluation (AGREE-II) Instrument* [9] was developed. This instrument evaluates the methodologies and transparencies for development of guidelines[10].

In Pakistan, there is rapid increase in elderly population and osteoporosis is a big threat among them. Estimates based on study suggested 9.91 million people (7.19 million women, 2.71million men) are suffering from osteoporosis'[11]. The female:male ratio was 2:1 for hip fracture in five year analysis of single center with average age of fracture is 61 years [1]. In another study risk of osteoporosis was found to be 75% among women in Peshawar [12].

Since most of the guidelines are prepared, evaluated and apprised for the patients in west, due to scarcity of resources there is nonexistence of local guidelines in Pakistan. Therefore, the objective of this study is to evaluate the application of International Osteoporosis Foundation (IOF) guideline for Asia among family physician by using AGREE-II instrument.

## MATERIALS AND METHODS:

A descriptive cross sectional study was conducted in Karachi from December 2014 to January 2017. Current study is a part of large research on different specialties. The data was collected by validated and reliable questionnaire [13,14] after detailed discussion of IOF (International Osteoporosis Foundation) guidelines recommended for Asian countries[15] to diagnose, prevent and treat osteoporosis to family physicians (general practitioners). A minimum sample size of 46 family physician was determined by power analysis technique, where effect size was moderate (0.35), level of significance however, 50 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[17]was used to address the issue of variability in guideline quality. Family Physicians were also asked to rate the overall quality of guideline for its applicability in general 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[13,14]. Mathematical computation of domains scores are made according to the following method:

- Maximum possible score = strongly agree (7) X questions (3) X # of family physicians (50) = a
- Minimum possible score = strongly disagree (1) X questions (3) X # of family physicians (50) = b
- Scaled domain score = (obtained score – minimum possible score) / (maximum possible score – minimum possible score) = c X 100 = Z%

SPSS 23 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:**

Out of total, 10 (20%) and 40(80%) family physicians work in hospital and clinics respectively (Table – I).

**Table – I**
**Clinical Setting of Family Physician/General Practitioner**

| Hospital | **Clinic** |
|---|---|
| 20% | 80% |

The evaluation of 23 questions/items (BOX) explained the magnitude of applicability for six key domains of International Osteoporosis Foundation guidelines for Asia (t= -5.483, p<0.003, 95% CI, SD: 11.465, SE: 4.680, $H_o$; rejected)(Table – II).

**Table – II**
**Domain Scores and Statistical Significance**

| Domain (Items) | **Domain Description** | **Magnitude (Score)*** | **Significance** |
|---|---|---|---|
| **1 (Q1 - Q3)** | Scope & Purpose | 66% | t=-5.483 p<0.003 95% CI |
| **2 (Q4 - Q6)** | Stakeholder Involvement | 65% | |
| **3 (Q7 - Q14)** | Rigour of Development | 84% | |
| **4 (Q15 - Q17)** | Clarity of Presentation | 86% | |
| **5 (Q18 - Q21)** | Applicability | 84% | |
| **6 (Q22 - Q23)** | Editorial Independence | 61% | |
| Q/Item 24 | Overall Quality of Guidelines | 81.67% | |

*Calculated by mathematical valid & reliable formula (13, 14)provided by AGREE – II instrument (18)

Family physician's response for the item of rate of overall all quality of guideline from 1 = fully disagree to 7 = fully agree and agreement for implementation (Table – III).

**Table – III**
**Response for Question/Item 24 and 25**

| **The overall quality of IOF guideline for Asia (15)** | | | | | | |
|---|---|---|---|---|---|---|
| (Fully Disagree) 1 | **2** | **3** | **4** | **5** | **6** | **(Fully Agree) 7** |
| 0.00% | 0.00% | 4.00% | 0.00% | 24.00% | 46.00% | 26.00% |
| **Recommendation to use IOF guideline for Asia** | | | | | | |
| Yes | | Yes with Modification | | | No | |
| **30.00%** | | **60.00%** | | | **10.00%** | |

## DISCUSSION:

The main objective of this study was to evaluate the applicability magnitude in Pakistani family physicians for six main domains of International Osteoporosis Foundation guideline for Asia [15]. Unfortunately, guideline which is recommended for Asia by IOF comprises of the data of population from Hong Kong and China [15]. South Asian populations living in SAARC (South Asian Association for Regional Co-operation) countries like Pakistan, India, Bangladesh, Sri Lanka, Bhutan, Nepal, and Maldives are having different pharmaco-genetic characteristics in many clinical situations, it is therefore necessary to have data from local population in order to make appropriate clinical decisions.

Family medical practice is more common in private sector rather than hospital however, family physicians in Pakistan working either in hospitals and community believe that magnitude of applicability of scope and purpose of guidelines is 66%, so two third of guidelines is meeting the overall aim. Probable reason for not achieving near to 100% score is that most of the physicians have opinions that despite clear objective of IOF guide for Asia, local population, patients and public are not considered and most of the epidemiological extrapolations are from Chinese and Hong Kong data. Every society has their own norms and values, so guidelines development members have their own societal norms and values that may affect the choice, interpretation of evidence as well as their recommendations for disease state management[19,20].

When guidelines are developed, views of their main stakeholders must be considered. Because of this reason development of clinical practice guideline is a team work, this team usually comprises of physicians of different specialties of healthcare system. Stakeholder also means that these individuals have comprehension about population for whom guideline is meant. Family physicians of Pakistan believe that applicability magnitude of this domain is 65%, probably views of target patients and population of Pakistan have not been sought which are also important stakeholders. Many authors believe that patient should be part of the team who develop the guideline, which is not found in many currently available standards [21,22].

Applicability magnitude score of rigour of development is 84%, rigour of development relates to the process used to gather and synthesized the evidence, the methods to formulate the recommendations, and to update them. Regarding this domain, family physicians in Pakistan are in more agreement but not full, that during synthesis and search of evidence systematic methods were applied, it is clearly described that how selection of evidence was done, consideration was done for strength and limitations of evidences, appropriate methodology was followed for formulating the recommendations, side effects, risks, health benefits were focused when formulating the recommendation, sound evidences are supporting almost all the recommendations, review of guideline was done before publication and perpetual update criteria is mentioned.

Clarity of presentation deals with language, structure and format of the guideline. This domain has highest applicability magnitude i.e. 86%, which represents that family physicians in Pakistan are convinced that recommendations of IOF for Asia provides concrete and precise description of different options in particular situation of patient. There is no ambiguity and key recommendations are clearly presented after consideration of all health issues, however, if local population data is provided, that could further improve this domain score.

As far as concerned with domain of applicability, on an average more than 45% family physicians are in full agreement that guideline has provided the facilitators and barriers of application in Pakistani population despite certain barriers especially financial barriers and limited resources, however, physicians are not in full agreement that criteria for audit and monitoring of guideline is clearly presented. By evaluating all these parameters, magnitude of applicability of this domain is 84%.

Domain of editorial independence is concerned with the competing interest of all the members contributed in the development of guideline. Member's opinions and views may be biased if not addressed appropriately and guideline quality will be compromised. Pharmaceutical companies, government or charity organizations, professional associations

sometimes provide funds for the development of guidelines. This funding may be as financial contribution as whole or may just part like printing of guideline. Decisions in any healthcare system may influenced by conflict of interest[23,24], it also influences the development of guidelines[25-27], therefore, in order to avoid such issues, new stringent policies should be developed and implemented[22,28-31]. Magnitude of applicability of this domain is 61% and majority of family physicians are moderately agree that development and recommendation of guideline is not influenced by funding bodies. Competing interests of guideline development group members have been addressed and interests of the funding body have not influenced the final recommendations.

Independent sample t-test explored that domain scores are significantly lower compares to ideal score ($p<0.003$, 95%CI), that is why, found magnitude of overall quality of guideline is 81.67% and 30% physicians are ready to implement guideline in their practice without any modifications and changes, however, maximum number (60%) physicians mentioned that they would use IOF guideline of Asia in their practice of medicine but with some modifications as per requirements of Pakistani patients and population. 10% of physicians mentioned that he/she would not use or implement international Osteoporosis Foundation guideline for Asia in their clinical practice.

## CONCLUSION:

After assessing six main domains and quality of IOF guidelines by questionnaire of AGREE II instrument (Table BOX), unexpected findings of this appraisal were noted for the quality and applicability of guideline. Score regarding quality of editorial independence was found to be lowest and for clarity of presentation highest. Despite significantly lower scores of domains compare to standard, majority of physicians did not reject the IOF guideline for Asia.

**Table BOX**

**Questionnaire of Agree – II Instrument (18)**

| 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** |

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