UNDER PEER REVIEW

Review paper

Development or adaptation of clinical guidelines in the health system of developing countries: a review article

Abstract

Clinical guideline is one of the best attemps to improve clinical care. The content of this study is part of a database review which is been developed by reviewing and studying the world's most renowned organizations' approaches in guideline development. This study, attempts to point out the importance of development or adaptation of clinical guidelines in developing countries such as Iran. This study will look at; benefit and characteristics of clinical guidelines, identification and refinement of subjects in a guideline, the world's approaches in the use of clinical guidelines, and preparation and adaptation of clinical guidelines in Iran.

In developing countries such as Iran, adaptation of clinical guidelines is very important and is considered as a top priority. Because in the development of original guideline, in addition to a deep knowledge about the desired subject, developer should have in-depth and comprehensive knowledge and metrological sciences expertise.

Keywords: Clinical guideline, Adaptation, Development, Iran

Introduction

Inefficiency in the transfer or interpretation of knowledge into clinical field has been recognized as one of the main obstacles in the use of research in medical sciences. It is estimated that, up to 40% of patients do not receive clinical care and interventions consistent with the best scientific evidence, and 20% of the care provided is unnecessary or even harmful. The best approach to evidence-based care is the development and implementation of clinical guidelines[1, 2].

UNDER PEER REVIEW

Clinical guideline is one of the best attempts to improve clinical care. Guidelines are systematic non-mandatory sentences that help physicians and patients to make an appropriate decision on the specific clinical conditions. Guidelines also help to improve quality of health care for patients and provide correct information for specific diagnosis, conditions or treatment, which consequently improve health and prevent additional costs[2].

In fact, these developed and ordered sentences have been designed to help patients and the health care providers to organize an appropriate team in specific clinical situations.

In the definition, the two words of “help and appropriate”, should be noted. Appropriate care should consider special circumstances, the view of patients to treatment and risk factors [3].

Clinical guidelines are an inseparable part of the clinical governance. They help healthcare professionals in developing, tracking, measuring and improving standards[3]. The development of clinical guidelines is the most important part of a comprehensive approach to evidence-based medicine and nursing (EBM), because the end result of gathering, synthesizing and decision making based on the best evidence available in regard to local issues and problems, is its main foundation. Efforts to provide better care, based on the best scientific evidence and enhancing the quality of care, have drawn the attention of healthcare providers to the use of clinical guidelines. Therefore, the development of national and international clinical guidelines is on the rise [4].

Although, the developers of guidelines repeatedly need to include a range of evidences in their guidelines, yet, there is not enough information and guidance to achieve that goal. To develop the guidelines, formal consensus rather than informal consensus is crucial[5]. Developers need to act clearly and rationally regarding the methods and integration of patients' experiences and research. This study, attempts to point out the importance of development or adaptation of clinical guidelines in developing countries such as Iran.

Mathods

UNDER PEER REVIEW

This study is part of a nursing PhD thesis titled “developing clinical guideline for resuscitation of dying patients” which is been developed in two phases and approved by Tehran University of Medical Sciences. The first phase was the review of resources which has been completed. The content of this study is part of resource review at phase one which is been developed by reviewing and studying the world’s most renowned organizations’ approaches in guideline development. This review was conducted between September 2014 and December 2015.

The study had no time limitation, and focused on the study evidence base medicine, clinical guideline, guideline development, guideline adaptation, To search for these studies, electronic bibliographic data sources and online databases such as Medline, EMBASE, Springer, Blackwell Sengery, Elsevier, Scopus, Cochran Library as well as databases, including SID, Iran Medex and Magiran were used. In addition, a manual search was done on articles references. The criteria for being included in the research were: using the terms specified in the title, research design, quantitative or qualitative methods of research, and the criteria of exclusion were the studies limited to abstracts and the ones which had a language other than English or Farsi. The repeated researches were excluded by software Endnote. In the first step, only studies using quantitative methods were included, but since the researcher encountered qualitative studies during the search, which had valuable information, they were also included in the study. A total of 100 articles were found, which 19 articles met the inclusion criteria and were entered in the study.

This study will look at; benefit and characteristics of clinical guidelines, identification and refinement of subjects in a guideline, world’s approaches in the use of clinical guidelines, and preparation and adaptation of clinical guidelines in Iran. All over the world, there are programs for development and adaptation of clinical guidelines according to each country’s national approaches. In this regard, Scotland, England and Australia have had validated programs and can be used as reference. Therefore, in this study, their approaches have been used.

Discussions

UNDER PEER REVIEW

Benefits and applications of clinical guidelines

Diversity in clinical evidences may affect treatments' outcomes of the patients, and clinical guidelines can help healthcare professionals to deliver appropriate and effective care and intervention. However, this does not mean that, professional diagnosis and decisions can be replaced by guidelines. Clinical guidelines determine clinical decisions and patient's preferences in exceptional cases[6,7]. In fact, these guidelines facilitate clear understanding of decision making models in puzzled and complicated health issues for all healthcare providers [8]. Clinical guidelines can lead to an increase in quality of health and reduce unnecessary, useless and harmful interventions by providing useful guidance for healthcare professionals through the development and implementation of standard procedures. Clinical guidelines can provide useful information for the education of health care providers and, as a reference, help patients and families to make informed decisions [9].

Clinical guidelines help physicians and nurses to choose the most appropriate and effective interventions with minimum side effects. Therefore, using guidelines based on the best evidence available result to; the development of healthcare standards, better clinical outcomes and even reduction of healthcare costs [10]. A change in performance helps to reduce the costs without compromising the benefit of the treatment. Therefore, clinical guideline is inseparable part of the health governance which helps physicians and nurses in the development, continuation, observation and improvement of the standards[11].

Design, development and implementation of clinical guidelines in a country or region can lead to a change in healthcare performance and behavior at large scale that result in efficacy and improvement of healthcare quality[12]. Most experts believe that, use of clinical guidelines has revolutionized healthcare process and can be used for evaluation of healthcare professionals' performance as well as help patients to make informed decisions. Changing healthcare processes improves clinical outcomes for patients and leads to more efficient use of resources [13].

UNDER PEER REVIEW

Characteristics of clinical guidelines

Clinical guidelines are collection of clinical recommendations. However, they are not responsible for the process of diagnosis and treatment.

- Clinical guideline, is the process of systematic development based on evidence, and should be developed according to valid research evidences and local circumstances [14].
- Clinical guideline is a tool for decision making. Therefore, it is necessary to first, determine the situations that healthcare team needs help to make decision, and then develop clinical guidelines.
- In the process of clinical guideline's development, it is crucial to know that, developed guidelines should be able to play a key role in clinical decision making.
- Extracting the performance of clinical standards, policies of strategic purchase of services, development of payment criteria on the basis of performance and scientific reference in legal cases, are among applications of this product in clinical policy making [15].

Identification and refinement of a guideline's subjects

Guidelines can be developed for a wide range of subjects. Subject of a clinical guideline must be refined and precisely determined. Often, refinement of a subject is done by talking to healthcare providers, patients, potential service users and guidelines' evaluators. If the subject is not refined, the domain of the clinical situation or question will be extensively wide and it would be impossible to find a precise answer for it. To determine the domain of a guideline, it is necessary to consider the time and financial resources. Although, existing evidence and clinical trial can be used to determine the domain of a guideline, in some cases, it is necessary to consider people's particular and individual needs [14].

UNDER PEER REVIEW

How to use the best evidence for a particular illness is one of the challenges of today's medicine. It seems that, the best way to make a decision about a clinical condition is to use three types of evidences:

1. Derived knowledge from research findings
2. Derived knowledge from clinical experiences and expert opinions
3. Patients' specific information which include; patients' preferences and acceptance of the interventions

These three types of evidences can be used for the development of clinical guidelines [4]. There are limited ways to adapt expert opinions to scientific researche and even less ways to use patients' experiences in the process of guidelines' development. A formal consensus is preferred than an informal ones for the development of guidelines. Guidelines which have been developed by informal consensus do not use scientific evidences. Therefore, they are developed by speculation and there is a greater possibility of bias in them [16].

In ideal world, clinical guidelines are developed based on detailed evidences of practical researche, but in reality, there are few research-based evidences which guidelines could be developed based on. When the evidences are limited, inevitably, physicians and experts' opinions are used to develop guidelines[17].

In the development of guidelines based on judgment and consensus, it is almost impossible to find an expert who has all the information and knowledge. Therefore, it is suggested to use group consensus as direct knowledge, experience and interaction between group participants as it leads to a wide range of ideas[18].

Group as a whole is more efficient than a person. Care should be taken in the selection of participants in order to prevent the dominance of a person on the team or when, there are opposing views about a treatment (for example: how a decision must be made, what are the methods of

UNDER PEER REVIEW

organizing theoretical views and opinions?). Despite the widespread use of consensus method, there are very few methodological subjects in this area. In behavioral science, technology and society, this method is used, but it had little effect on the health sciences. However, it should be noted that the consensus process, is for the policy of decision-making and not a scientific method for creating new knowledge[19].

Global approach to the use of clinical guidelines

all over the world**,** clinical guidelines are developed to improve health care quality. Along with the advances of evidence-based medicine in 1990, the approach for development of clinical guidelines shifted from expert consensus to science-based, use of scientific review and meta-analysis. Different countries and organizations use different approaches to develop, use and evaluate clinical guidelines. Currently, there are varieties of approaches worldwide for the development of clinical guidelines which are responsible for evidence-based medicine in clinical settings[20].

Usually, clinical guidelines are developed in two ways, “Original or Adaptation”. Many developed countries develop and use original guidelines as they have access to the vast spectrum of knowledge, methodology skills, rich background of epidemiological studies, meta-analysis, systematic review studies and most importantly clinical trials.

Development and adaptation of clinical guidelines

In regard to the development of clinical guidelines, programs such as “National Institute for Health and Clinical Excellence in England”, “Scottish Intercollegiate Guidelines Network” and “National Institute of Health and Medical Research in Australia” have the best approaches. In all these programs, there are following similarities:

• The process of development and evaluation of clinical guidelines should focus on outcomes.

UNDER PEER REVIEW

• Clinical guidelines should be based on the best evidence, and must include a statement about the strength of their recommendations.

• The method used to assess the evidence must be the best option.

• The process of developing clinical guidelines should be multidisciplinary and should laso involve service users.

• It must be flexible and tailored to local conditions.

• Resource limitation must be considered and there should be an economic assessment.

• Clinical Guidelines are developed for the use of audience, therefore should be published in such a way that users can easily understand.

• The applications and impact of clinical guidelines should be measured.

• There should be a review period.

• Development process must be continuous and there should be a strategy for the development, publication, and a program for evaluation and review of them[6,18]. Adaptation of clinical guidelines, is taking place following the development of different guidelines in various medical fields. To develop the guidelines, original guidelines which exist around the world are selected based on the most similarity to the local area, and they will be adapted by developer to be used in the area. Most use of the guidelines is in under-developed and developing countries[21].

adaptation of clinical guidelines is very important and has top priority. Because, in the development of original guideline, in addition to a deep knowledge about desired subject, developers should also have in-depth and vast knowledge as well as metrological sciences expertise. Many experts believe that, in order to consider the important issues, all guidelines relarding that issue should be found. The similarity of desired guidelines is crucial and for guidelines' users and targeted population,

UNDER PEER REVIEW

should be similar in regard to; geography, economic and ….etc. In the adaptation of clinical guidelines, a consensus by local experts is crucial[22].

Development and adaptation of clinical guidelines in Iran As a developing country

It is believed, in developing countries like Iran, adaptation of clinical guidelines is very important and has been a top priority. Because, in the development of original guideline, in addition to a deep knowledge about desired subject, developers should also have in-depth and vast knowledge as well as metrological sciences expertise[25]. More importantly, development of original guideline relevant to a particular area, requires rich background of; epidemiological studies, clinical trials, systematic reviews and meta-analysis, that should already exist in that area. On the other hand, technological knowledge and other required skills for the development of original guidelines are very limited in those countries and have not been generalized yet. Currently, it is impossible to develop original guidelines in Iran. Therefore, adaptation of guidelines is a more efficient option[23, 24].

Accordingly, since 2010 in Iran, the Office of Technology Assessment, Standards Development and tariff Ministry of Health, Treatment and Medical Education has provided a detailed process for the development of clinical guidelines at the national level in accordance with;

- Legal documents for healthcare reform based on Islamic-Iranian model of progress (articles 36,45,56 and 73).
- The Fifth Development Plan Program, particularly paragraph (d) of article 32 regarding the development of clinical guidelines in a form of national health system as well as the goal of equitable access to comprehensive, continuous and high-quality care.
- Strategic objective No. 75, of the Ministry of Health and Medical Education to increase the use of clinical guidelines, standards development and the creation of evidence-based health care services and health care system.

UNDER PEER REVIEW

Leading medical guidelines based on the best available evidence, has been adapted by the help and collaboration of multidisciplinary teams through a scientific approach based on two models; Standard ACPG (proposed national structure for development of standard clinical approaches), and Short APG (proposed national structure for development of short clinical approaches).

Conclusion

Of course, it is important to consider that, in order to optimize the use of available resources and avoid unnecessary duplication of work, clinical guidelines that are appropriate to our country with some adjustments and modification, can be used. This modification process requires a regular and continuous process that is appropriate and consistent with the best available evidence. The collaboration of multidisciplinary teams and a scientific approach to continuous quality improvement of health services can also be helpful.

Refrencess

1. Bahramnezhad F, Cheraghi MA. Realization of Clinical Guidelines in Providing Health Services. Hayat .2015;21(3):1-4.
2. Doherty S. Evidence-based implementation of evidence-based guidelines. Int J Health Care Qual Assur. 2006;19(1):32-41.
3. Network SIG. A guideline developer's handbook. SIGN Edinburg; 2001.
4. Organization WHO. WHO handbook for guideline development: World Health Organization; 2014.(Available from: 2015.3.4)
5. McKinlay E, McLeod D, Dowell A, Marshall C. Clinical practice guidelines' development and use in New Zealand: an evolving process. The New Zealand Medical Journal (Online). 2004;117(1199).
6. Ansari S, Rashidian A. Guidelines for guidelines: are they up to the task? A comparative assessment of clinical practice guideline development handbooks. PloS one. 2012;7(11):e49864.
7. Gallery JC, Curtin F, Volunteers C. Guide to the Development of Clinical Guidelines for Nurse Practitioners.2004.
8. Philips Z, Ginnelly L, Sculpher M, Claxton K, Golder S, Riemsma R, et al. Review of guidelines for good practice in decision-analytic modelling in health technology assessment. 2004.
9. Rosenfeld RM, Shiffman RN, Robertson P. Clinical Practice Guideline Development Manual, A Quality-Driven Approach for Translating Evidence into Action. Otolaryngology--Head and Neck Surgery.2013;148(1 suppl):S1-S55.
10. 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. Implement Sci .2012;7(1):1-8.
11. Brown P, Brunnhuber K, Chalkidou K, Chalmers I, Clarke M, Fenton M, et al. How to formulate research recommendations. Bmj. 2006;333(7572):804-6.
12. Long AF. Guidelines, protocols and outcomes. Int J Health Care Qual Assur.1994;7(5):4-7.

UNDER PEER REVIEW

13. Millard A. Evidence-based clinical guidelines-implementation plans in Scotland. British Journal of Clinical Governance. 1999;4(3):98-102.
14. Rycroft-Malone J. Formal consensus: the development of a national clinical guideline. Quality in Health Care. 2001;10(4):238-44.
15. Shekelle P, Woolf S, Grimshaw JM, Schünemann HJ, Eccles MP. Developing clinical practice guidelines: reviewing, reporting, and publishing guidelines; updating guidelines; and the emerging issues of enhancing guideline implementability and accounting for comorbid conditions in guideline development. Implement Sci .2012;7(1):62.
16. Oxman AD, Schünemann HJ, Fretheim A. Improving the use of research evidence in guideline development: 8. Synthesis and presentation of evidence. Health Res Policy Syst .2006;4(1):20.
17. Makuuchi M, Kokudo N, Arii S, Futagawa S, Kaneko S, Kawasaki S, et al. Development of evidence-based clinical guidelines for the diagnosis and treatment of hepatocellular carcinoma in Japan. Hepatology Research .2008;38(1):37-51.
18. Schünemann HJ, Fretheim A, Oxman AD, Research WACoH. Improving the use of research evidence in guideline development: 1. Guidelines for guidelines. Health Res Policy Syst .2006;4(13):1-6.
19. Raine R, Sanderson C, Black N. Developing clinical guidelines: a challenge to current methods. Bmj. 2005;331(7517):631.
20. Turner T, Misso M, Harris C, Green S. Development of evidence-based clinical practice guidelines (CPGs): comparing approaches. Implement Sci. 2008;3(45):1-8.
21. Graham ID, Harrison MB, Brouwers M, Davies BL, Dunn S. Facilitating the use of evidence in practice: evaluating and adapting clinical practice guidelines for local use by health care organizations. J Obstet Gynecol Neonatal Nurs .2002;31(5):599-611.
22. Groot P, Hommersom A, Lucas P. Adaptation of clinical practice guidelines. Stud Health Technol Inform. 2008;139:121-39.
23. Harrison MB, Légaré F, Graham ID, Fervers B. Adapting clinical practice guidelines to local context and assessing barriers to their use. Canadian Medical Association Journal. 2010;182(2):E78-E84.
24. Fervers B, Burgers JS, Haugh MC, Latreille J, Mlika-Cabanne N, Paquet L, et al. Adaptation of clinical guidelines: literature review and proposition for a framework and procedure. Int J Health Care Qual Assur .2006;18(3):167-76.

25.Cheraghi MA, Bahramnezhad F, Mehrdad N,Zendehdel K. Development of the Draft Clinical Guideline on How to Resuscitate Dying Patients in the Iranian Context: A Study Protocol. Indian J Palliat Care. 2016.22(3):335-342.