

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

Abstract

Clinical guideline is one of the best attempts 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].

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

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

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

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

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

48 **Methods**

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

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

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

73 **Discussions**

74 *Benefits and applications of clinical guidelines*

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

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

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

99 *Characteristics of clinical guidelines*

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

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

112 *Identification and refinement of a guideline's subjects*

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

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

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

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

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

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

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

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.

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

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

170 • The process of developing clinical guidelines should be multidisciplinary and should also involve
 171 service users.

172 • It must be flexible and tailored to local conditions.

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

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

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

177 • There should be a review period.

178 • Development process must be continuous and there should be a strategy for the development,
 179 publication, and a program for evaluation and review of them[6,18].

180 Adaptation of clinical guidelines, is taking place following the development of different guidelines in
 181 various medical fields. To develop the guidelines, original guidelines which exist around the world
 182 are selected based on the most similarity to the local area, and they will be adapted by developer to
 183 be used in the area. Most use of the guidelines is in under-developed and developing countries[21].

184 adaptation of clinical guidelines is very important and has top priority. Because, in the development
 185 of original guideline, in addition to a deep knowledge about desired subject, developers should also
 186 have in-depth and vast knowledge as well as metrological sciences expertise. Many experts believe
 187 that, in order to consider the important issues, all guidelines regarding that issue should be found.

188 The similarity of desired guidelines is crucial and for guidelines' users and targeted population,
 189 should be similar in regard to; geography, economic and etc. In the adaptation of clinical

190 guidelines, a consensus by local experts is crucial[22]. Also, Updated clinical guide should be
191 performed every 4 years.

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

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

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

- 205 • Legal documents for healthcare reform based on Islamic-Iranian model of progress (articles
206 36,45,56 and 73).
- 207 • The Fifth Development Plan Program, particularly paragraph (d) of article 32 regarding the
208 development of clinical guidelines in a form of national health system as well as the goal of
209 equitable access to comprehensive, continuous and high-quality care.
- 210 • Strategic objective No. 75, of the Ministry of Health and Medical Education to increase the
211 use of clinical guidelines, standards development and the creation of evidence-based health
212 care services and health care system.

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

217 **Conclusion**

218 Of course, it is important to consider that, in order to optimize the use of available resources and
219 avoid unnecessary duplication of work, clinical guidelines that are appropriate to our country with
220 some adjustments and modification, can be used. This modification process requires a regular and
221 continuous process that is appropriate and consistent with the best available evidence. The
222 collaboration of multidisciplinary teams and a scientific approach to continuous quality
223 improvement of health services can also be helpful. The researcher hopes, In developing countries,
224 With the improvement of evidence, carried out clinical guideline development about issues of
225 culture and context-based.

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