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A Manual for Prioritizing the Topics of Clinical Practice Guidelines for Family Physicians

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ABSTRACT

Background: Development of a manual or well-defined criterion for prioritizing the topics of clinical practice guidelines (CPGs) will help validate and organize this process evermore. This study was conducted to design an applicable manual that would prioritize the CPG topics for family physicians.

Methods: This study was a multi-stage method using a qualitative approach that was conducted for the manual developing. The manual development process took place in four steps, as follows: Literature review, interviews with ten experts, preparing a list of criteria and determining its appropriateness by applying the RAND/UCLA Appropriateness method, and development of the final draft of the manual and pilot study.

Results: Interview transcripts went under content analysis and were classified into eight main groups, 12 subgroups, and 85 themes. A comprehensive list consisting of fifty preliminary criteria were extracted. After summarizing and classifying the criteria, 12 appropriate criteria were evaluated using the RAND appropriateness method. Eventually, based on the literature review and our own results of the interview analysis, a manual consisting of five main sections and one clause on ethics was developed. Later, a pilot study was conducted on ten family physician topics, and prioritized by nine experts.

Conclusions: The manual can be eyed as a tool ensuring the quality of the process of prioritizing CPG topics for family physicians, as it takes into account the issues involved in priority-setting. Selecting informed stakeholders for rating the criteria and ranking the topics was an issue that was greatly emphasized by the experts. Eventually, the application of this manual can be the first step toward systematizing the process of prioritizing CPG topics in the country.

Keywords: Clinical practice guideline, family physician, guidelines as topics, health priorities

INTRODUCTION

Clinical practice guidelines (CPGs) are evidence-based recommendations that are presented[1] to physicians as

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appropriate models to help them better perform and deliver services at the bedside.[1] Adhering to standards and paying adequate attention to the development of CPGs is of great importance. Topic selection and prioritization of CPGs is one of the foremost steps in the development of CPGs, which is considered basic for further stages of the process. Resource Managements in various fields of the health sector often face issues such as time shortage, lack of costs, and human resources. Hence, in practice, planning, and policy-making are pushed towards priority-setting. Therefore, priority-setting on the basis of a standard method that employs well-defined criteria can increase the validity of the process more and more.[2-6]

Throughout the world, CPGs are developed for various groups delivering clinical services at national and international levels. The family physician holds a special place among these groups as it is the first-line service deliverer in the health system. The family physician is the head of the health team and is in charge of employing facilities to provide, maintain, and promote health among the populations it covers.[7] Hence, it must possess the necessary skills in the fields of screening, diagnosis, and treatment, to be able to correctly manage patients, and, in particular, those patients who need long-term care. Approximately, 80–90% of patients can be diagnosed and treated at first-line health-care, so a great proportion of health needs can be met at this level of service delivery.[8] A cross-sectional study was conducted on general physicians in Tehran in 2009 to investigate their knowledge and attitude toward CPGs. Among the 280 participants of the study, only 27.14% were familiar with CPGs. Their low level of awareness of CPGs is a significant point that can indicate weaknesses in the various steps of development, dissemination, and application of CPGs. Thenceforth, systematizing the process of development and domesticization of CPGs for family physicians can strengthen the aforementioned steps.[9]

To this day, different methods and models have been adopted for prioritizing CPG topics globally. These methods have been mostly qualitative and have been based on expert opinion. However, priority-setting for selection of CPG topics has not been undertaken as a structured and well-defined process in our country.[2,10,11] Usually, each organization sets its own priorities of topics on the basis of its own goals and agreements. This applies to the family physicians as well, who are pioneers of the health system. The development of a comprehensive and applicable manual for the family physician, keeping in mind definite criteria for priority-setting, can help better select CPG topics for this group. This study was a multi-stage method using a qualitative approach that was conducted aimed to produce a manual with clear criteria for scoring and prioritizing the topics of clinical guidelines. Hence, this manual can prove to be the first effective systematized step toward optimal priority-setting of CPGs for family physicians in the country.

METHODS

This study was a multi-stage method using a qualitative approach that was conducted to develop a manual for prioritizing guideline topics.The manual development process took place in 4 steps, as follows:

Literature review

Literature review was conducted in PubMed, Google Scholar and five databases specific to CPGs, i.e. SIGN, NICE, G-I-N, "National Guideline Clearinghouse," and "Clinical Practice Guidelines Portal" to identify the criteria and issues involved in CPG topics' prioritization. The time limit for the search was 2014, and the following keywords were used: Priority setting/s, topic selection, clinical guideline, criteria, and family physician.

Interviews with experts and stakeholders

Based on a qualitative study using content analysis approach, ten in-depth interviews were held with stakeholders such as service producers – providers and receivers. They included: Family physicians, specialties, and policymakers who were familiar with the process of guideline development. Interviewees were selected through purposeful sampling and sampling procedure continued up to data saturation. The average duration of the interviews was 45 min each. They were recorded upon obtaining permission from the participants. The interviewers were guided by some open questions to explore the appropriateness of criteria, stakeholders, the common problems, and recommendations for priority-setting. The interviews revolved around such topics as important priority-setting criteria, stakeholders, and issues involved in priority-setting. The interviews were transcribed ad verbatim. After carefully reading them, the themes were extracted, and the results were content-analyzed. Member check was conducted for ensuring trustworthiness of the findings.

Preparing the list of criteria and determining the appropriateness of the criteria

Based on the interview results and literature review relevant to priority-setting criteria a preliminary list of fifty criteria was prepared (literature review: Forty criteria; interviews: Ten criteria). Many of the criteria had similar meanings or fell into the same groups, so the duplicate cases were excluded. After combining and classifying them, we developed 14 criteria with well-defined definitions [Table 1]. To determine the criteria's appropriateness from the experts' perspectives the RAND/UCLA Appropriateness Method was applied.[12] Two rating rounds were held wherein the agreement on the criteria, and their appropriateness were determined.

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Table 1: Determining agreement on each criterion in the second round*

Criterion number	Criterion definition	Median score	Agreement**
1. Magnitude/frequency of the problem	Prevalence: Existing cases of disease (old and new cases) in a specific time period Incidence: New cases of disease in a specific time period Burden of disease: taking into account Mortality and morbidity: Average numbers of deaths from disease in a year QOL: QOL of patients with disability (chronic pain, depression and the likes) Fertility and capacity of production: Reduction of production capacity Complexity of the problem (respectively, from uncomplicated to complicated problem) At the level of prevention: To promote patients' health At the patient level: Patients with a single chronic uncomplicated problem At the patient level: Patients with an acute problem and limited time At the patient level: Patients with multiple complicated problems along with social worries	9	+
2. Variation in problem management techniques	Variation in clinical practice in problem-solving	8.5	+
3. The capacity to improve health outcomes	Improvement of health outcomes, on the basis of the patient's performance and experience, and taking into account the following Effectiveness: Care should be provided to the population in a correct manner, avoiding error Efficiency: Achieving a desirable effect of care by spending minimum effort and cost Efficacy: Care should have the capacity to meet relevant demands in ideal settings	8	+
4. The capacity to improve costs	Estimating the positive economic effects on the health system and society, taking into account Cost: Reducing the direct medical costs for specific patients annually/balancing indirect high costs Cost-efficiency: Costs and outcomes should simultaneously improve	7.5	+
5. Significance of the main population affected by the CPG	Population groups: Children, working-age adults, pregnant women, society's vulnerable/low-income groups	7	+
6. Risk capacity	The possible occurrence of serious side-effects of treatment, risks of using technology	8	+
7. Physicians' interest	Preferences of the professional community and high acceptability of the topic	7	?
8. The society's demands/worries	The population's concern/high demand of the society	7	?
9. Necessity and urgency	National health plan (meeting national demands), national health priorities, the risk of waiting and postponing the problem, newfound issues	8.5	+
10. Need for evidence'	The need for new information/modification of evidence, significance/added value of new information, lack of high-quality CPGs, the need to domesticize CPGs, the need to update national CPGs (on the other hand, avoid reworking	7.5	+
11. Feasibility and applicability (the system's capacity to implement)	The ease of developing recommendations and the feasibility to disseminate them, the socio-political feasibility, insurance and facilities, commitments and ethics, environmental health, human rights (e.g., is the process politically doable and does it comply with governmental policies?) The ease of applicability: Availability of resources, financial support and sufficient time for application (resources should not be too sought after and there should be no significant barriers in applying changes), availability of scientific data for evaluation	7.5	+
12. Persistence of the problem	Persistence of the problem for at least 3 years	8	+

*All 12 criteria were considered appropriate, **+=Agreement, ?=Indeterminate, CPGs=Clinical practice guidelines, QOL=Quality of life

Determining appropriateness and agreement

The rating range for each criterion was 1–9. A score of 1–3 was considered inappropriate, 4–6 was considered uncertain, and 7–9 was considered appropriate. Consensus was reached on the basis of number of panelists and the agreement shown in Table 2.

To determine the final appropriateness of each criterion, criteria with median scores of 7–9 and those without disagreement were considered appropriate. Those with median scores of 1–3 and with disagreement were considered inappropriate. Moreover, those with median scores of 4–6 and/or criteria whose medians fell in either

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Table 2: Determining agreement on each criterion

Agreement	Disagreement	Number of panel members
≤2	≥3	8-9-10
≤3	≥4	11-12-13
≤4	≥5	14-15-16

score range but with disagreement were considered uncertain.

Based on the RAND method, the following steps were followed:

- Defining each criterion: The definitions of the criteria were specified on the basis of available literature and expert opinion. To create a mental picture of the concept of each criterion, its various aspects were objectively and subjectively taken into account
- The first round of rating: This round was held to gather expert opinion (16 individuals, namely: Health system managers and policy-makers, family physicians, experts familiar with CPG development, and a methodologist). Their rating (for appropriateness) of each criterion took place through face-to-face interviews. Then, the scores collected from each participant and other members (anonymous) were E-mailed to each individual in new forms. The second round was held in the form of a face-to-face meeting wherein the criteria were discussed among the panelists
- The second round of rating: In this round, the experts' opinions were expressed in a face-to-face meeting and the second rating was done. A panel of ten experts (six could not participate because of their heavy schedules) and a moderator (a methodologist acquainted with the procedure) were present at the meeting. The criteria were re-examined in this round and rating was repeated. In the end, those criteria that were appropriate and had garnered complete or relative agreement were considered as the final criteria.

Prioritizing manual and pilot study

Different sections of the manual were developed on the basis of our qualitative findings and literature review. To resolve potential problems, ten family physician CPGs that were developed by research centers in Tehran University of Medical Sciences were randomly selected and rated by nine experts.

RESULTS

Content analysis of interviews

Eighty-five themes were extracted from the ten interviews held with experts and stakeholders. These themes were classified into eight main groups and 12 subgroups.

Eight main groups

The eight main groups included the significance/necessity of priority-setting, determining the fields of priority-setting, criteria, stakeholders, challenges of priority-setting, solutions for priority-setting, priority-setting experiences, and priority-setting methodology.

Twelve subgroups

The 12 subgroups included severity and magnitude of the problem, variation in clinical practice, effectiveness and applicability, health service receivers, health service producers and deliverers, limitations in documentations, difficulties in stakeholder collaboration, solutions for documentations, solutions for stakeholders, solutions for criteria development, approaches toward priority-setting, the use of models/methods for quantifying the process.

Preparing the complete list of criteria

Combining the criteria

At this stage the criteria obtained from literature review and interviews were re-examined. After classifying and excluding duplicate criteria a list of 14 criteria – along with their definitions was generated. These criteria included: (1) The severity and magnitude of the problem; (2) variation in problem management techniques; (3) the capacity to improve health outcomes; (4) the capacity to improve costs; (5) necessity and urgency; (6) risk capacity; (7) physicians' interest; (8) the society's demands/worries; (9) status of current evidence; (10) significance of the main population affected by the CPG; (11) equity; (12) feasibility and applicability; (13) persistence of the problem; (14) the effect of technology over time.

Determining agreement and appropriateness of criteria through the RAND method

Results of the first round of rating

Among the 14 aforementioned criteria, 11 were considered appropriate and acquired complete or relative agreement. The three criteria of "physicians' interest," "the society's demands/worries" and "the effect of technology over time" fell into the "uncertain" area with median scores of 4.5, 6 and 6 respectively. Therefore, a second round was held with experts to obtain their viewpoints, opinions, and rating once more.

Results of the second round of rating

Once again, all the criteria were reviewed in the presence of the participants. Some of the criteria were thenceforth modified. Upon experts' consensus, criterion number 11 (equity) and criterion number 14 (the effect of technology over time) were excluded. Moreover, criteria numbers 1, 5 and 10 were modified. These modifications were, respectively completing criterion number 1 (magnitude/frequency of the problem) – upon taking into account the level of complexity of the problem; criterion number 5 (significance of the main population

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affected by the CPG) – by adding the phrase "with an emphasis on society's low‑income and vulnerable groups;" and changing criterion number 10 from "status of current evidence" to "need for evidence." Regarding criterion number 11, it was expressed that equity is not a direct goal of CPGs. And with regards to criterion number 14 the panelists believed that the turnover of technology was not the reason behind writing guidelines, so there was no need to include it in the priority‑setting criteria. At this stage, 12 criteria were finalized. In the second round of rating, all 12 criteria were considered appropriate (median scores ranged from 7 to 9) and were agreed upon. Agreement on ten criteria was complete, but was relative on two cases (criteria numbers 7 and 8). Table 1 shows the second round scores.

Prioritizing manual

At this stage, the main elements of the manual were developed – consisting of five main sections and one clause on ethics.

First section: Determining the levels of stewardship for the priority‑setting process

Determining the level of stewardship for priority‑setting is the first step in priority‑setting that is done to clarify the domain of work. Here, on the basis of the interviews, two national and peripheral levels were outlined. The national level includes the ministry of health and medical education and its representatives such as national Knowledge Management Units (KMUs) and national health institutes. The peripheral level may include the university, hospital, health center, or health research center at provincial or district level – based on the center in charge of producing guidelines.

Second section: Identifying important topics for the development of clinical guidelines for family physicians

At this stage, the important topics or preliminary priorities are outlined on the basis of evidence such as: Scientific evidence, available reports and documentations, expert opinion, needs assessment and/or a combination of two of these.

Moreover, in this section the priority‑setting process is separately done for each group of clinical topics, such as: (1) Prevention, (2) diagnosis, and (3) treatment.

Third section: Identification and involvement of stakeholders

Selection of capable stakeholders with a mastery over the subject is the most important step of priority‑setting. The number of participants required for rating can be anywhere between 5 and 15 (on average, 7–10). The combination of panelists consists of experienced family physicians, manager/director of the custodian organization or representative of the management.

To raise the efficacy of the stakeholder team, the following are also present: KMU officials, representatives of the district/provincial Health Department (such as communicable and noncommunicable diseases officials), public health professionals such as epidemiologists, a specialist physician relevant to the subject at hand (as higher levels of referral), and community representatives. To ensure quality, the stakeholders are identified and selected through the stakeholder analysis technique.

Fourth section: Application of well‑defined criteria for rating and ranking important topics

The important selected topics are rated on the grounds of 12 criteria at national or peripheral level.

The rating process takes place in a face‑to‑face meeting, in the presence of all the stakeholders, so that individuals can share their experiences and points of view and resolve any probable discrepancies. Each criterion is rated with a 5‑point Likert scale, ranging from "very little" to "very much" (1 = very little, 2 = little, 3 = average, 4 = much, 5 = very much). Eventually, the mean of the total score is determined and ranking is done on the basis of the total score.

Fifth section: Leadership and management of the priority‑setting process

The entire process is followed with a clear well‑defined framework and management from beginning to end. To this end, 1–3 individuals are chosen as mediators to steer, follow‑up and provide feedback to the process.

Ethical clause

Conflict of interests should be kept in mind during the priority‑setting process.

It is essential to avoid any sort of conflict of interests during the entire priority‑setting procedure. Thenceforth, personal or organizational interests – be it financial or nonfinancial‑will be avoided and judgments will be completely neutral and in line with the priority‑setting goals.

Results of the pilot study

In this step, ten family physician CPG topics in the field of treatment were selected by experts for prioritization. These topics were the primary priorities of Tehran University of Medical Sciences' research centers. Then, keeping in mind the significance of each criterion (12 criteria) the topics were scored with a 5‑point Likert scale by nine experts and family physicians. A summary of the available epidemiologic data on the significance and severity/magnitude of the problem was prepared to rate each criterion and to determine its significance. Ranked on the basis of their significance/importance, the results of the topics rating, along with their means and standard deviations, are as follows: (1) Hypercholesterolemia 51.11 (3.95); (2) anemia 49.44 (2.78); (3) osteoporosis 49.22 (3.96); (4) indigestion/dyspepsia 48.33 (5.78);

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(5) pneumonia 46.55 (5.12); (6) colorectal cancer 46.11 (7.13); (7) head injury 45.22 (5.82); (8) hepatitis 43.55 (8.06); (9) epilepsy and anaphylaxis (with an equal mean score) 43.33 (4.00) and (10) 43.33 (5.33) respectively.

The topics selected in this pilot study included a wide variety of treatments for chronic and acute cases. After going over the results with experts, a complementary point was added to the second section of the manual (selection of important topics), and a specific share was considered for emergency topics separately. In fact, emergency topics hold a special place, as these measures are life-saving. Here, "head injury" and "epilepsy and anaphylaxis" were somehow emergency topics, and although they garnered lower scores in the rating, they can still be considered separately in the ranking.

DISCUSSION

Evidence-based medicine and its promotion are among the main goals of any health system in the world, including that of our country. In this regard, the systematic development of CPGs and their utilization – as evidence-based tools-have many applications that can eventually improve physicians' performance at the bedside. Among the most important of these applications is the utilization of upper-level and up-to-date scientific evidence. Furthermore, fewer differences will be seen in therapeutic approaches toward a single clinical problem, and as a result therapeutic methods will become homogenized.[13,14] The adoption of different therapeutic approaches toward the management of a specific problem is an issue that somewhat exists at all levels of treatment (the three levels of primary healthcare [PHC]). However, it appears to be a more prominent and significant issue at the initial diagnostic – therapeutic levels and in the clinical practice levels of general and family physicians. This is because their topics are more variable, more therapeutic options exist and hence more associated uncertainties.

Moreover, problems with resources management always exist, such as inadequate time and costs for different tasks in the health domain. Hence, practically speaking, planning and policy-making are driven toward priority-setting.[4,5]

This project too was conducted to develop a practical manual for prioritization of topics for family physician CPGs. Results of interviews with experts and stakeholders were classified into eight main groups, 12 subgroups and 85 themes. Furthermore, based on the RAND method, 12 specific criteria were determined for ranking the CPG topics. Eventually, based on the interview results and solutions put forth a manual comprising of 5 main sections was defined: Determining the relevant level, identifying stakeholders, determining important topics, rating and ranking topics on grounds of criteria, and leadership and management of the process through follow-up and feedback.

Results of a review study conducted in 2011 on priority-setting of health topics at the PHC level identified five processes: (1) Engaging stakeholders; (2) application of a well-defined process; (3) accurate data management; (4) decision-making in line with the current circumstances and making clear choices; (5) reviewing and specifying mechanisms.[15] We too found the following to be the main components of priority-setting: Identifying and engaging the community, having a well-defined process by specifying the level responsible for priority-setting and determining the primary priorities, ranking important topics, steering and following up the process. In our study, the first step in prioritizing guideline topics was determining the responsible domain, i.e., it must be clear which individual/s shape the procedure and follow the feedbacks. To this end, two "national" and "peripheral" levels were kept in mind, each of which can follow the priority-setting goals as need be.

As already mentioned in the manual, determining important topics is fundamental in priority-setting. It is therefore part of a well-defined process of decision-making on the basis of the status quo. According to the 2011 review study, important topics can be determined through SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis, review, and needs assessment.[15]

Although all the priority-setting components are important, it may be said that the identification and involvement of stakeholders is the most vital step.[2] Choosing informed stakeholders – with a mastery over the subject-to rate the criteria and rank the topics was an issue greatly emphasized by all experts. Two points were outlined in this section: Individual skills or scientific and practical skills, and taking into account a wide range of professionals. In fact, we must see who is most qualified for rating and ranking the topics? Which professional groups in the domains of clinical sciences, epidemiology, financial issues, and insurance and/or other relevant groups do we need? A clear and concise definition of these groups will support and ensure the implementation of the following steps, which are, the development, dissemination, and utilization of these guidelines.

Here, we rated 14 criteria on the grounds of an extensive literature review and expert opinion using the RAND method. Among the latter, 12 criteria were deemed appropriate for CPG topic priority-setting in the family physician setting, all of which fell in the score range of 7–9 (completely appropriate). A Canadian study conducted in 1995 on priority-setting and selection of CPG topics outlined the following as their main criteria: Population under study, feasibility, improvement of health status, and improvement of costs.[16] Another study

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in Columbia initially determined 21 criteria for CPG priority-setting and later finalized 9 of them: Frequency of health problems, magnitude of burden of disease, economic impact, social impact, various therapeutic performances, disease prevention and health promotion, effectiveness and side-effects of treatment, the need for new information, and status of topic application.[17] We too have developed the aforementioned criteria in our study.

The current manual has been developed on the basis of current evidence and opinions of CPG and knowledge management experts. The application of this manual could be considered the first step toward systematizing the CPG topic priority-setting process in the country.

During the study we faced limitations such as, difficulties coordinating with stakeholders and setting appointments of suitable timing for the interviews and meetings. However, through continuous planning and follow-up the desired outcome was achieved. In defining the priority-setting criteria's definitions (12 criteria) the main problem was lack of a specific and accessible database. Moreover, the importance of having well-defined criteria for priority-setting led us toward defining most of them "subjectively" and by taking into account different aspects of each criterion; this solution seemed appropriate, considering the status quo at the time. To achieve goals such as promotion of evidence-based medicine and subsequently priority-setting and development of CPGS, it is particularly important to strengthen the primary infrastructures and the existent health system structures.[13] Strengthening the registry and surveillance systems of communicable and noncommunicable diseases by including accurate statistical and epidemiologic data in a coherent and consistent manner is a major requirement. The regular collection and registration of data such as incidence, prevalence, burden of disease, effectiveness, costs, cost-effectiveness, efficiency, and efficacy of therapeutic methods are among the most essential requirements of a structured system. This structured system can in turn help achieve the goals and decision-makings in the health domain. To this end, conducting projects that are in line with these goals can prove very helpful.

CONCLUSIONS

This manual can be eyed as a tool ensuring the quality of the process of prioritizing CPG topics. Utilization of the manual by CPG development officials may prove fruitful for the process of prioritizing family physician CPG topics- as this is the first level of contact in the healthcare system.

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Conflicts of interest

There are no conflicts of interest.

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