A unique framework for the Persian clinical guidelines: addressing an evidence-based CDSS development need

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Abstract
Background and aim One of the prerequisites to develop Computerised Decision Support Systems is Clinical Practice Guidelines (CPGs) which provide a systematic aid to make complex medical decisions. In order to provide an automated CPG, it is needed to have a unique structure for the CPGs. This study aims to propose a unique framework for the Persian guidelines.

Methods and materials 20 Persian CPGs were selected and divided into the creation and validation sets (n=10 for each). The first group was studied independently and their headings were listed; wherever possible, the headings were merged into a new heading that was applicable to all the guidelines. The developed framework was validated by the second group of the guidelines.

Results Studied guidelines had a very heterogeneous structure. The number of original headings was 249; they were reduced to 14 main headings with 16 subheadings in a unique developed framework. The framework is able to represent and cover 100% of the guidelines.

Conclusion The heterogeneity of guidelines was high as they were not developed based on the unique framework. The proposed framework provides a layout for designing the CPGs with a homogeneous structure. Guideline developers can use this framework to develop structured CPGs. This will facilitate the integration of the guidelines into electronic medical records as well as clinical decision support systems.

Background
Clinical Practice Guidelines (CPGs) are important tools that integrate the evidence-based information with the medical practice in favour of improving diagnostic accuracy, enhancing effective treatment and reducing variations in medical decisions.1–4 These tools could improve healthcare processes and patient outcomes by providing a systematic aid to support complex medical decision-making and prioritising the healthcare.5

Adaptation of CPGs to the local context of use may increase their application1 and this adaptation should be considered in the development phases of guidelines.5 The compliance rate of the clinicians to the CPGs is not satisfying and this can lead to inappropriate application of CPGs.1 In some countries such as USA and Netherlands, around 30%-40% of patients do not receive evidence-based healthcare.5 In Iran, only 31.8% of physicians are aware of the CPGs. Therefore, there is a gap between available medical knowledge and routine medical practice.6

There are different factors that affect physician guideline adherence including awareness, familiarity, agreement, self-efficacy and outcome expectancy.7–8 Also, the high volume of the contents, and finding the specific content in the unstructured guidelines are some obstacles to physicians’ compliance with the CPGs.6 Clinicians typically need the right information at the right time according to the patient’s context, but this demand is challenged with the conventional textual format of CPGs.9–10 The use of Computerised Decision Support System (CDSS) could be the solution for these problems.10 A CDSS can support the physicians by providing the guideline-based and patient-specific recommendations, and overcomes obstacles in the use of traditional paper-based guidelines and improve physicians’ adherence to recommendations.11 In fact, using structured CPGs is an important stage in developing a rich CDSS.12

In the past recent years, the development of evidence-based CPGs is followed systematically and seriously in Iran.6 Based on our knowledge, there is no study assessing the variety of CPGs’ structure in Iran. The main aim of this study was assessing the contents of Persian CPGs published by the department of health in Tehran University of Medical Sciences in order to propose a unique framework for them that could be used in CDSS development.

Methods and materials
In order to develop a framework for the Persian clinical guidelines, a comprehensive three-phase protocol has been followed (figure 1). In the first phase, the 20 evidence-based CPGs published by the department of health of Tehran University of medical sciences in Iran were selected and randomly divided into two groups. The first group was used to develop the framework and the second for validation of the framework. The first group of CPGs was reviewed by the authors (five medical informatics PhD candidates). All subject headings were extracted separately by the authors.
Summary

**What is already known about this subject?**
- Adaptation of Clinical Practice Guidelines (CPGs) to the local context of use may increase their application.
- The compliance rate of the clinicians to the CPGs is not satisfying and this can lead to inappropriate application of CPGs.
- In some countries, around 30%–40% of patients do not receive evidence-based healthcare.

**What are the new findings?**
- Reviewed CPGs did not have a homogeneous structure and were established in different formats.
- A framework for design new guidelines or restructuring existing CPGs was proposed in this study.
- The proposed framework provided 14 main headings and 16 subheadings that can be used as a template for designing the CPGs with a homogenous structure.

**How might it impact on clinical practice in the foreseeable future?**
- The proposed framework provides a layout for the CPGs with a homogeneous structure.
- Compliance with the CPGs may be facilitated through structured format of guidelines.

In the second phase, the extracted subject headings were discussed and refined by the authors in six 1-hour sessions. In these sessions, if possible the subject headings were merged together so new headings and subheadings that are applicable to all guidelines have been created. For example, the guidelines contained four subject headings including ‘methodology’, ‘main objective’, ‘target population’ and ‘level of evidence’. These headings were merged to a new subject heading entitled ‘about the clinical guideline’. This step was continued for all guidelines of the first. Discrepancies between the authors were discussed and finally resolved by two experts (the general practitioner and PhD of medical informatics). Finally, the prototype of the framework had been developed based on the new list of subject headings and subheadings.

In the third phase, the proposed framework was evaluated by the second group of the guidelines to validate it. For this purpose, six 1-hour sessions were held by the authors and two experts and the generalisability and applicability of the subject headings and subheadings of the framework for the content of the second group of CPGs had been checked. It assumed that if any subject heading founded in the second group of CPGs that had not been covered by the proposed framework, it adds to the framework. Finally, the frequency of each subject heading in the reviewed guidelines was determined to represent the importance of them. The proposed framework that was designed by Mind View software V. 7.0 is shown in figure 2.

**Results**

Totally, 20 CPGs related to various disease contexts were reviewed (10 for development and 10 for validation of the framework). The title of used guidelines listed in table 1. The first 10 guidelines in table 1 were used for creation and the remaining 10 were used for validation of the framework. Totally, 249 subject headings were extracted from 10 CPGs in the first phase and validated by the guidelines of the second group. The proposed framework consists of 30 subject headings including 14 main headings and 16 subheadings. These subject headings created by the merging related ones together. For instance, seven headings including ‘audit indicators’, ‘screening recommendations’, ‘medium risk screening schedules’, ‘bone mineral density measurements’, ‘who should be screened’, ‘pregnancy screening’ and ‘screening for gestational diabetes’ were replaced with one new main subject heading entitled ‘screening’.

There was no need to add any new subject heading to the framework in the validation phase. The list of the main subject headings, subheadings and their frequency in the reviewed guidelines is presented in table 1. As shown in table 1, ‘rehabilitation’ (n=2), ‘events’ (n=2), ‘abbreviations’ (n=3), ‘infant and children’ (n=4) and ‘pregnancy and breastfeeding’ (n=5) had the minimum frequency in all guidelines. On the other hand, some headings including ‘a title of the clinical guideline’, ‘about the clinical guideline’, ‘clinical guideline profile’, ‘preface’ and ‘contributors’ were at 100% CPGs. The frequency of the other subject headings was less than 50%.

At the end of the third phase of the study, a unique framework was finalised based on the 14 main subject headings and 16 subheadings. Figure 2 presents the final proposed framework for Persian CPGs.

**Discussion**

Approximately two decades have elapsed from the appearance of the related activities to evidence-based medicine in Iran. However, there is not any unique framework or instruction in CPG development and no consistent structure was used to develop a guideline that results in Persian CPGs in variant formats and structures. It appears that the format and content of the guidelines are the main factors in the implementation and consequently, the use of them. The structured guidelines have a greater chance to be utilised. The free text format challenges the accessibility of care providers to CPGs. The results of this study revealed that Persian CPGs have not a homogeneous structure so that the same subjects were titled by the various headings. On the other hand, the same subject headings had different contents. Furthermore, the contents of reviewing guidelines were presented in various formats including free text, flowcharts and tables. These heterogeneities may be due to variations in guidelines’ topics and that they were written by different experts from various research centres.

We used 20 CPGs with various medical domains to develop and validate a unique framework for them. Some headings appeared in the majority of guidelines, whereas others were only in a few numbers of guidelines. Furthermore, some important headings for medical practice were not appeared in some guidelines. For example, nutrition is an important factor in any CPG, while only six guidelines considered this heading.

Building the framework to facilitate the creation, dissemination and dynamic updating of trustworthy guidelines has been considered in other studies. Vandvik et al have developed an online application based on the conceptual framework for creating written and structured clinical guidelines. This application facilitates the accessed to the CPGs via a wide range of systems, including electronic medical record (EMR), web portals and applications for smart phones/tablets. This framework has been developed by using one guideline. The GASTON framework has been developed based on the anthologies of domain and method. This framework provides an appropriate environment for
authoring the CPGs. Although this framework helps CPGs authors in developing a new guideline, it is not possible to restructure previous guidelines with GASTON.17

Our proposed framework designed based on the various guidelines in different medical domains (diseases). The validation of the framework showed that it was compatible with the contents of the remaining 10 guidelines. So, it can be used for design any new guideline as well as improving the old guidelines. Providing a comprehensive structure for CPGs contributes to the adherence of clinicians and healthcare providers to these evidence-based documents. Restructuring current CPGs according to the proposed framework could help to design computerised clinical guideline systems that could lead to reduce complexity and increase accessibility and utilisation of guidelines. Therefore, the framework could be always in progress to be better and completer. Additionally, we used a bottom-up approach to creating our framework.
### Table 1: Results of framework validation and frequency of each heading in all guidelines

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<thead>
<tr>
<th>Heading &amp; sub-headings</th>
<th>CPG's Title</th>
<th>Frequency of headings</th>
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<tbody>
<tr>
<td>Overview of clinical guideline</td>
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<td>Assessment and evaluation</td>
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<td>Diagnosis</td>
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<td>Nutrition</td>
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<td>Rehabilitation</td>
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<td>Pregnancy and breast feeding</td>
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<td>Side effects</td>
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<td>Other</td>
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<td>Flowcharts</td>
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<td>Appendix</td>
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<td>About the clinical guideline</td>
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<td>Contributors</td>
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<td>About the diseases</td>
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<td>Screening</td>
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<td>Flowcharts</td>
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<td>Follow-up and referral</td>
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<td>Therapeutic methods</td>
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<td>Scientific evidences and documents</td>
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<td>Abbreviations</td>
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**CPG's name**

1. Diabetes
2. Anaphylaxis
3. Osteoporosis
4. Urinary Infections
5. Iron deficiency Anaemia (gastroenterology approach)
6. Colorectal cancer screening
7. Adult headache
8. Seizure in adults
9. Pneumonia (diagnosis, treatment and prevention)
10. Hypertension
11. Helicobacter infection (diagnosis and treatment)
12. Dyslipidaemia
13. Hirsutism
14. Mal digestion
15. Hepatitis-B
16. Hoarseness
17. Food allergy
18. Benign paroxysmal positional vertigo
19. Head trauma (Triage & Assessment)
20. Generalised anxiety and panic disorder

CPG: Clinical practice guideline.
means that our framework has the possibility to get complete and more. The method used to structure the framework that was both iterative and incremental.

The present study has only investigated 20 guidelines for the development of the framework. Using more guidelines to validate or improve this framework would lead to better results. However, the proposed framework can be used as a unique pattern, by developers and designers of CPGs in Persian or other languages.

Conclusion
In this study, we analysed a set of Persian CPGs and developed a framework to increase the homogeneity in their structure. This framework will be proposed to policy-makers and guideline manufacturers to develop uniformly and structured CPGs that are implementable in various electronic formats including web platforms, computers or smart phones integrating EMRs. One of the perspectives of this study is to develop and validate a web-based platform based on this framework for presentation of the content of guidelines to facilitate access to these CPGs.

Research limitation
The validity of the framework was addressed by the reviewing second group of the guidelines. So, the generalisability and applicability of the subject headings and subheadings of the framework for the content of the second group of CPGs addressed by the evaluation. However, the quality of the guidelines has not been assessed by any criteria, and we included this as a limitation of our work.

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Contributors
All co-authors have participated in developing the framework. HK and EM also have written the manuscript.

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