

Organizing Guidelines Models and Clinical Practice Guidelines

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Improving the access to healthcare, the quality and effectiveness of the services is the main goal of healthcare strategies all over the world. By the use of the information and communication technologies support and according with the international and national trends in developing of an equitable, efficient and cost effective health care systems, the fundamentals and methodologies of three guidelines models and an original model were integrates into a tool for assisting creation of guideline models and clinical practice guidelines. The application, created by the used of the MySQL as database server and PHP as programming language, offer an interactive computer-assisting creation of guideline models and clinical practice guidelines and theirs management. The GUIDELINES proved to be friendly and easy to use application, being a useful tool in creation and implementation of guideline models and clinical practice guidelines in any languages. The application offer a real solution to any countries which are interested in creation and implementation of national clinical practice guidelines.

Keywords

information management, information storage and retrieval, online system, clinical practice guideline (CPG)

1. Introduction

Information and Communication Technologies (ICT) are entering nowadays in all aspects of our life and in all sectors of activities [1], opening in medicine a new dimension of communication [2]. As was remarked by Ho K. & all [3] the *"information and communication technologies can be effective tools to help in the collection, processing, and targeted distribution of information from which clinicians, researchers, administrators, policy makers in health, and the public can benefit"*.

At the international level, the clinical practice guidelines, defines as *"systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances"* [4], proved to improve physician's knowledge [5], healthcare outcomes [6], and useful in reducing the costs of healthcare services [7].

The trends in development of clinical practice guideline are moved from the unstructured paper based to electronic structured guidelines [8]. Structuring the clinical practice guidelines and including the information into electronic databases allows: facile information-sharing across developers and institutions [9], prompt dissemination of CPGs [10], and real time updating of CPGs information [11]. A series of structured language were developed in order to create electronic guidelines and to facilitate searching and retrieving CPGs information

(Arden syntax [12], Asbru language [13], Guideline Interchange Format [14], Guideline Element Model [15], Guideline Acquisition, Representation and Execution [16]).

In Romania, as in all developing countries the access of physicians to up to date, valid and relevant medical information is restricted by many factors: the absence of information in national languages, the inadequate information finding in books, the inadequacy of continuing medical education proposals (not in accordance with physicians need and desires, expensive courses, et cetera), and so one. The primordial source of medical information in these countries remain the books which have the disadvantages of containing inadequate information, and of presenting the information on a didactical manner, being obtained just by the physicians which afford it. In these conditions, medical decisional process is in most of the cases based on the physician expertise and/or national expert's opinions. The creation of an electronic database with evidence-based CPGs could be the optimum solution in opening the access to valid, relevant and up-to-day medical information.

According with the international trends in creating the equitable, efficient and cost effective health care systems [17] and in creation of methodological standards of guidelines [18,19], the fundamentals and methodologies of three guideline models and an original methodology were documented and integrated into a tool for assisting creation of guideline models and clinical practice guidelines.

First purpose of our research was to integrate three from the most representative formal guideline models existing at international and national level, to integrate them into a friendly easy-to-use interface and to facilitate the collaboration in the development of CPGs between countries which have experiences and countries which need expertise. The second purpose was to propose an evidence-based clinical practice guideline model in native language, model which to allow creation of clinical guideline based on evidence rather than national expert's opinions and/or physician expertise.

2. Materials and Methods

2.1 Materials

After a comprehensive study of specialty literature and analyzes of guideline methodologies existent at international and national level, we decide to integrate two world recognized methodologies (the Canadian Medical Association [21] methodology - see table 1, and the National Guideline Clearinghouse [20] methodology - see table 2) and a national recognized one (the methodology propose by the Romanian College of Physicians [22] - see table 3).

Table 1 Characteristics of the Clinical Practice Guidelines.

Item	Remark
Aim	Supporting guideline retrieval
Type of guideline	Evidence based clinical practice guidelines
Publication	Online
Provider	The Canadian Medical Association's – Quality of Care Program
Developed by	Canadian national, provincial/territorial or regional medical or health organization, professional society, government agency or expert panel
Guidelines language	● English and French
Major components	● Structured abstracts); ● Ultra short summary; ● Full text; and ● Patient guide
Submission	By regular mail, fax or email
Access	Free

Table 2 Characteristics of the National Guideline Clearinghouse.

Item	Remark
Aim	Supporting guidelines retrieval
Type of guidelines	Evidence based clinical practice guidelines
Publication	Online
Providers	The Agency for Healthcare Research and Quality (AHRQ) in partnership with the American Medical Association and the American Association of Health Plans
Developed by	National, provincial/territorial or regional medical or health organization, professional society, government agency or expert panel
Guidelines language	English
Major key components	● Structured abstracts; ● Links to full-text guidelines; ● Guideline comparison; ● Complete NGC Summary for PDA; ● Guideline Syntheses; ● The National Guideline Clearinghouse electronic discussion list; ● The National Guideline Clearinghouse Annotated Bibliographies
Classification axes	● Five major classification axes (clinical area, guideline category, use of the guideline, development information, and implementation) with a specific purpose; ● Twenty-one sub-axes, seven of them with predefined values
Submission	Mail or e-mail submission
Type of access	Free

Table 3 Methodological characteristics of the Diagnostic and Treatment Guidelines.

Item	Remark
Aim	Creating national clinical guideline
Type of guideline	Diagnostic and treatment guidelines
Publication	● Book – Diagnostic and Treatment Guideline- 1 st volume (1999); ● Available as *.PDF files at http://www.cmr.ro/index.php?option=com_content&task=view&id=77&Itemid=27
Provider	The Romanian College of Physicians
Developed by	Romanian professional organizations and association with counsel of the Specialty Commissions of Romanian Ministry of Health
Language	Romanian
Major components	● Structured guideline (seventy items); ● Full text
Access	Free

A structured methodology of an evidence-based guideline model, in Romanian language, was developed and proposed. Its characteristics are described in table 4.

Table 4 Methodological characteristics of propose evidence-based guideline.

Item	Remark
Aim	Creating national evidence-based guidelines
Guidelines	Evidence-based guidelines
Publication	Online
Guidelines language	Romanian
Major components	● Structured evidence-based guideline; ● Full text; ● Grading the recommendation based on evidence; ● Scaling the evidence
Submission	Online, protected by encrypted password
Access	Free

2.2 Implementation method

Starting with the necessity of creation an interactive online environment useful in medical practice, the GUIDELINES application was been created by the use of MySQL [23] as database management system, PHP [24] as the programming interface and Apache [25] as http server. MySQL is the most popular open source relational database system that allows creation of multi-user secure databases. The interface of the application was implemented by the use of PHP, which has the unique distinction of being an open-source scripting language used to create interactive and dynamic applications. Apache, open-source software originally developed in 1995, become the world's most popular Web server being fast, secure, efficient and extensible.

The above presented methodologies were integrated into the application and the assay and evaluation of it was performed by including a number of nine guidelines and by applying a survey at which participate forth-year medical students from "Iuliu Hatieganu" University of Medicine.

The survey consisted of six questions and evaluates the following aspects about the GUIDELINES application: the feature offered by the application, the easiness of use the application; its usefulness, its utility, and its usefulness in training as well as in medical practice.

3. Results

The created GUIDELINES application is host by AcademicDirect domain, and is available via the address: http://vl.academicdirect.org/medical_informatics/guidelines/.

The main features of the application are:

- Assisting creation of new guideline models;
- Assisting creation of new clinical practice guidelines;
- Management of guideline models and clinical practice guidelines.

3.1 Assisting creation of new formal guidelines models

In creation of a new formal guideline model are imposed five fields (see table 5).

Table 5 Fields imposed in creation of a new standardized guideline model.




Field	Description
Model abbreviation	The abbreviation of a new model must has maximum three characters The field is used in queries and interrogations
Name	The name of the guideline model must suggest the provider The field is used in searching and filtering the database
Name of field which store guideline title	The title field is used in searching and filtering processes
Description of the model	A short description of the guideline model appears as information when the model is use in creation of new guideline

The GUIDELINES application integrates two models in English language (the National Guideline Clearinghouse™- at which abbreviation is *ngc*, and the Canadian Medical Association - Clinical Practice Guidelines - *cma*) and two models in Romanian language (the Romanian College of Physicians – Diagnosis and Treatment Guideline - *cmr*, and the proposed Evidence-Based Guideline - *gbe*).

By the use of the GUIDELINES application, the author's of a new standardized guideline model can create as many fields as consider opportune by specifying the name of the field, its

description, as well as its type (two predefined types are allowed in GUIDELINES application: a unclassified field, or a classified field - see table 6). For the classified fields, the author must specify the possible values. For example, the evidence-based guideline model implemented in Romanian language has twelve out of thirty-nine classified fields.

Table 6 Types of fields used in creation of a new guideline model.

Type of field	Remarks
Free text fields	Allows to write the text for a new guideline or to drag-and-drop the text from a previous created guideline
Choosing a text from a predefined list	Associate to this type of fields there was defined a button  which allows deleting the selected information
Selecting one or more predefined options	<p>: including a selected predefined keyword</p> <p>: deleting the information from the keywords field</p> <p>These ca applied to the fields which are used in indexing the guidelines (<i>Disease/Condition</i>, and <i>Treatment/Intervention</i>)</p>



3.2 Assisting creation of new clinical practice guideline

Based on the guideline models included in the database, the users with the suitable rights can create new CPGs. The evaluation of the GUIDELINES application was done by implementing the above described models and for each model one or more than one CPGs. The titles of the guidelines and the abbreviation of corresponding model are in table 7.

Table 7 Titles of guidelines included into the application.

No.	Guideline title	Model
1	Thromboembolism in pregnancy	ngc
2	Screening for glaucoma: recommendation statement	ngc
3	ASGE guideline: the role of endoscopy in the diagnosis, staging, and management of colorectal cancer	ngc
4	Clinical practice guidelines for the care and treatment of breast cancer: 9. Follow-up after treatment for breast cancer (2005 update)	cma
5	Clinical practice guidelines for the care and treatment of breast cancer: 5. Management of ductal carcinoma in situ (DCIS)(2001 update)	cma
6	Spontaneous Intracerebral Haematoma	cmr
7	Acute Haematogen Osteomyelitis	cmr
8	Sub acute Haematogen Osteomyelitis	cmr
9	Deep venous thrombosis	gbe

Two distinct features are allows in assisting creation of a new CPGs:

- First feature is available to all users and allows dragging the information from a previous created CPG stored into the application that (by selection of the text from the rolling window - left side of the application interface) and dropping it in the predefined fields of the choused model. The creation of a new standardized CPG is interactive and the application display at the end of CPG creation, associated with the name of the field, the  icon when the field contain the correct information and the  icon if the field contain a wrong information.
- Second feature, allows to the user that has the right to save the information into the database to create a new clinical practice guideline base on a choused model. In order to protect the information from database this feature is protected by encrypted password.

3.3 Management of guideline models and clinical practice guidelines

Searching features are available for the field of guideline models, for the guideline models and for the clinical practice guidelines.

GUIDELINES application searching interface allows to the user to choose one or more than one out-of-five defined criterions (see table 8).

Table 8 The searching criterions available on GUIDELINES application.

No.	Criterion	Remark
1	Guideline model	The application displays the name of the model as it is present in table 6 and the user must to choose from the list a model which is interested in
2	Predefined fields of the guideline model	Display the contents of all the guidelines which has the name of the specified field
3	Indexing terms	The user must specify the name of the MeSH (Medical Subject Headings) descriptor (for example: aortography)
4	The author of a guideline	The user must write the name of an author
5	Keyword	The user can specified a keyword The keywords are search anywhere in all guidelines fields

The search can be restricted at exact specified criterion(s) (by selecting the *strict* option: *strict*) or can be performs taking into consideration any criterion(s) (by selecting the *any* option: *any*).

Browsing for a field of a specific guideline model or for a clinical practice guideline it is also possible. If the user is interested to visualize the content of a field of a specific guideline, it will be necessary to specify the number of the guideline and the name of the field that it is interested in. For example, if a user wants to see the target population for the guideline entitled “ASGE guideline: the role of endoscopy in the diagnosis, staging, and management of colorectal cancer” the following information are necessary to be added into the address bat: ...[medical informatics/guidelines/guideline field.php?gno=3&field=Target Population](#)

The displayed information is:

3 (the number of the guideline, gno)
Target Population (the name of the field requested, `Target Population`)
Patients with suspected or confirmed colorectal cancer (CRC) (the content of Target Population field for the guideline number 3)

Browsing feature is also available and the application display the name of guideline models and theirs associated titles for every CPG stored into databases, as below:

- Models
 - + National Guideline Clearinghouse TM
 - The Romanian College of Physicians - Diagnostic and Treatment Guideline
 - [Spontaneous Intracerebral Haematoma](#)
 - [Acute Haematogen Osteomyelitis](#)
 - [Sub Acute Haematogen Osteomyelitis](#)
 - + Canadian Medical Association - Clinical Practice Guidelines
 - + Evidence-Based Guideline

3.4 The results of the survey

Fifty-four fourth-year medical students were participating to the survey. The average of the students' age was 21.89 with a 95%CI (confidence interval) [21.74, 22.03]. Almost sixty-three percent of participants of survey were female (95% CI [48.18, 75.89]).

1. The features of the GUIDELINES application identify by the students express as absolute frequency, relative frequency and its associated 95%CI are:
 - Assisting creation of guideline models: thirty-eight out of fifty-four students (70.37%, 95%CI [55.59, 81.45]).
 - Assisting training in standardized CPGs creation: forty-one out of fifty-four students (74.93%, 95% CI [63, 87]).
 - Management of guideline models and CPGs (saving, searching, browsing, displaying): thirty out of fifty-four students (55.56%, 95% CI [40.78, 68.48]).
 - Assisting creation of formal guideline models: thirty-two out of fifty-four students (59.26%, 95% CI [44.48, 72.19]).
2. The usefulness of the GUIDELINES application was grade as:
 - *Indifferent* by five out of fifty-three students (9.43%, 95%CI [3.81, 20.72]);
 - *Useful* by twenty-eight out of fifty-three students (52.83%, 95% CI [37.77, 66.00]);
 - *Very useful* by twenty out of fifty-three students (37.74%, 95% CI [24.56, 52.79]).
3. The practical utility of the GUIDELINES application was grade as:
 - *Indifferent* by three out of fifty-four students (5.56% 95%CI [1.89, 14.78]);
 - *Useful* by thirty-four out of fifty-four students (62.96%, 95% CI [48.18, 75.89]);
 - *Very useful* by seventy out of fifty-four students (31.48%, 95% CI [18.55, 46.26]).
4. The easiness of the use of application was grading as:
 - *Relative difficult* by ten out of fifty-four students (18.52%, 95% CI [9.29, 31.45]);
 - *Relative easy* by sixteen out of fifty-four students (29.63%, 95% CI [18.55, 44.41]);
 - *Easy* by twenty-one out of fifty-four students (38.89%, 95% CI [25.96, 53.67]);
 - *Very easy* by seven out of fifty-four students (12.96%, 95% CI [5.59, 24.04]).
5. Twenty-nine out of fifty-four students (53.70%, 95% CI [38.92, 66.63]) consider that GUIDELINES application is a helpful instrument in medical education.
6. Thirty-four out of fifty-four students (62.96%, 95% CI [48.18, 75.89]) consider that GUIDELINES application is an instrument useful in daily activity.

4. Discussions

Nowadays, the trends in development of clinical practice guidelines is towards of creation of more rigorously evidence-based guidelines which are packaged in ways that make it easier to put them into practice [26]. All over the world were created guideline systems as *Medical Logic Modules* [27], *DeGeL* [28], and on the other hand, systems for clinical decision making able to integrate the electronic evidence-based guidelines with electronic patient management systems (*EON* [29], *GEODE-CM* [30], *ECDS* [31], *PREDICT* [32]).

First and second purposes of the presented research were reaching. Thus, the GUIDELINES application integrate into a friendly easy-to-use interface two different formal guideline models in English and two in Romanian language.

The main characteristics of the GUIDELINES application are:

- ⊕ Assisting creation: provide an interactive environment for assisting creation of guideline models and standardized clinical practice guidelines;
- ⊕ Guideline models and CPGs management: provide an environment that allows managing the guideline models and CPGs information (storing, filtering, searching, and displaying);
- ⊕ Updating: the updating of clinical practice guidelines is a effortless process, and can be done in real time and as many time as it is considers being opportune;
- ⊕ Easy to use: anyone with minimum computer skills (start up a computer, access and browse the World Wide Web, basic searching and browsing files and information in databases) can use the GUIDELINES application;

- + Flexibility: at one time that the new formal guideline model was established, the implementation of the model using the GUIDELINES application is a facile process;
- + Accessibility: the use of the GUIDELINES application is not restricted by any timetable, being open to every one who is need up-to-date, valid and relevant medical information;
- + Multi-tasking: GUIDELINES application can be use simultaneously with other applications;
- + Multi-user: GUIDELINES application can be use simultaneously by more than one user;
- + Integrity of information: the data stores into the application are protected against unauthorized modification or destruction of information through encrypted password;
- + Guidelines dissemination: the GUIDELINES application can be use as a tool of dissemination of any clinical practice guideline, being a useful tool in implementation process of a new guideline at the level of health care system.

The proposed structured electronic evidence-based model is unique in Romania and was created in order to be a model for the Romanian medical associations and organizations, for the Romanian College of Physicians and for the Romanian Ministry of Health specialty commissions, the forum implied in creation and implementation of national CPGs, instruments that are necessary in order to improve the quality of health care services and in control of costs.

Creation and development of an evidence-based clinical practice guideline needed an interdisciplinary collaboration between health care professionals and programmers, being at the interface between medical practice and medical informatics. The created electronic evidence-based guideline model offers at least five advantages. First, an electronic standardized evidence-based guideline model imposes a formal structure of guidelines which can be used as template by the professional associations and organizations in development of new CPGs. Second, a formal guideline model encourages the authors to be exact in the development process, imposing creation of more rigorous CPGs. Third, development of electronic guideline library avoids duplication of medical information and knowledge, allowing guidelines-sharing between institutions and providers. Fourth, electronic format allow a prompt dissemination of CPGs as well as updating of guidelines information in real time and any time when new evidences are published. Fifth, electronic clinical guidelines databases help health care practitioners in daily activities offering a fast environment of searching and retrieving evidence-based information.

Being an online application, GUIDELINES can be accessible just for the users that have a computer connected to the Internet. The main limit of using the GUIDELINES application is seems to be for the Romanian physicians the lack of a computer in the physician's office and/or examining room and the lack of Internet connection, because in Romania there is not any network in heath care systems. The same aspect was identified by Jeannot JG & all in a study of using the World Wide Web in clinical practice guidelines implementation [33].

The results of survey show us that Romanian medical students need to be trained in concept of CPGs and in using the medical evidence in daily practice. Most of participants at the survey (more than 59%) recognized the computer-assisted creation of guideline models and of CPGs, as well as their management (saving, searching, browsing, displaying) are features of GUIDELINES application. Most o the future Romanian physicians (more than 90%) classifying the usefulness of the GUIDELINES application as *useful* or *very useful*, while 94% grade the practical utility on the scale of *useful* or *very useful*. More than fifty percent of interviewed students classified the GUIDELINES application as a helpful instrument in medical education and as an instrument useful in daily medical activity. These results demonstrate the open mind of the future Romanian physicians to clinical practice guideline and theirs electronic implementation.

Studying the specialty literature at which we had access and comparing the GUIDELINES application with similar applications (*National Guideline Clearinghouse, HSTAT - The Health Services Technology/Assessment Texts, CMA Infobase*), we can say that the main

advantage of GUIDELINES application it is represent by the possibility of computer-assisting creation of structured guideline models and CPGs in any languages. A second advantage offer by the application is represent by the possibility of comparing four guideline models, two of them recognized at international level, giving the possibility to the providers of clinical practice guidelines to have an easy access to four guidelines models. These features dignify the GUIDELINES application by existing applications, being in the same time first application of this type in Romania. In order to protect data from GUIDELINE application, the creation of guideline models and CPGs is protected by encrypted password.

The future plan of development of the GUIDELINES application includes:

- Assisting of professional organizations and associations from all over the world in implementing of new standardized guideline models and CPGs;
- Increasing the number of clinical practice guidelines stored into database;
- For Romanian guideline models, it will be useful to create a national system of indexing medical information or to translate the MeSH descriptors in national language(s) with the approval of the United States National Library of Medicine, National Institutes of Health;
- Sensitizing the Romanian forums responsible with quality in health care services and implication of Romanian experts in creation of guideline models and CPGs.

It is undoubting that the existence of a computer-assisted creation of guideline models and CPGs application is not sufficient in order to implement a standardized clinical practice guideline in health care system [34], but this is not the subject in discussion. For a country as Romania, where the reform in heath care system is undergo, GUIDELINES application can be the first step in implementation of evidence-based guidelines in health care system, offering to the medical associations and organizations, to the Romanian College of Physicians, and to the Romanian Ministry of Health the environment needful for a computer-assisted creation and management of national guideline models and CPGs.

5. Conclusions

The GUIDELINES application can be a useful tool in creation and implementation of guideline models and CPGs in any languages offering a solution to any countries which are interested in creation of national CPGs.

For Romania, the GUIDELINES application opens the pathway in creation of national guideline models and CPGs according with the cultural, social, and economical frame. The GUIDELINES application developed in accordance with its aim can become a useful tool in improving the quality and effectiveness of health care services.

6. Acknowledgement

The research was partly supported through project ET36/2005 by UEFISCSU Romania.

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