

First steps towards an Italian clinical guideline database.

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INTRODUCTION

In the last twenty years, clinical guidelines became an essential component of clinical practice. Every day clinical decisions, hospital procedures, and government health expenditure are being influenced by guidelines, which are constantly developed in order to assist decisions about appropriate health care. A clinical guideline has been defined as “a systematically developed statement for practitioners and patients about appropriate health care for specific clinical circumstances” (1). According to the scope note of the MeSH term *Practice Guidelines as topic*, they are defined as “directions or principles presenting current or future rules of policy for assisting health care practitioners in patient care decisions regarding diagnosis, therapy, or related clinical circumstances”.

Clinical guidelines are based upon a systematic review of the literature, their role being recognized as useful for clinicians and patients as well.

At an international level there is a large guideline production by governmental agencies, health institutions, and professional societies, to improve patient safety and quality healthcare.

In recent literature, a debate has risen on the effective importance of guidelines. Considering that the evidence based medicine has led to a proliferation of guidelines, some authors are concerned that many of them are of poor quality, while other colleagues argue that guidelines are important for improving health care.

On the one hand, therefore, guidelines detractors conclude that “Guidelines may thus be important for improving patient care, but changes are needed to make them more relevant and effective. Collaboration between all stakeholders—relevant clinicians, scientists, patients, policy makers, quality improvement experts, and others—is essential to identify clinical questions, assess the evidence, draw up workable recommendations and develop related indicators of improved quality of care and programmes for implementation.”

On the other hand, guidelines supporters discuss about “What are the arguments against guidelines? Firstly, there is concern that many guidelines are based on expert opinion rather than firm evidence. We agree this is a problem, but the solution is to develop more evidence, not to ignore existing evidence and expert consensus. The process used for developing guidelines is also not always perfect—that is, not all guidelines are created equal. However, various groups have set out recommendations that lead to sound and effective guidelines, as the US cardiovascular disease example shows.” (2)

The Italian experience

The Italian National Guideline System (SNLG) (3), set up by the Ministry of Health, is coordinated by the Istituto Superiore di Sanità (ISS), the Italian National Institute of Health, which is the leading technical and scientific public body of the Italian National Health Service, its activities including research, control, training and consultation in the interest of public health protection.

The SNLG produces, updates and disseminates clinical guidelines, consensus conferences and technology assessment in the public health field. Clinical guidelines are produced by a multidisciplinary panel, which has the task of formulating clinical questions, collecting available

evidence and suggesting recommendations. The SNLG guidelines, addressed to doctors, citizens and public health administrators, are based on sound and best evidence, collected and retrieved by searching a large number of specialized scientific databases. Specific tasks of SNLG are:

- producing information useful to address the decisions of health personnel towards a greater effectiveness and appropriateness, and towards a greater efficiency in the use of available resources;
- making the clinical practice guidelines easily accessible;
- evaluating guidelines impact, in terms of results and organization (4).

AIM

Many institutions in Italy are currently developing clinical guidelines, both at a national and a regional level. At present, a national easily-accessible database of guidelines produced in Italy is still missing. Considering that this area could be explored and developed, it was decided to develop a new tool giving access to all guidelines produced in Italy. The tool was developed by the Documentation Service and the Data Management Service of the ISS within the framework of the Italian National Guideline System. The database was specifically intended and designed for the use of health care professionals, although, in the near future it will be free on the Internet for patients, carers and the general public as well.

METHODS

Over the last year, a database collecting the Italian clinical guidelines, produced not only by the Italian National Guideline System, but also by hospitals, local health units, and professional societies has been developed by the ISS. The purpose of the database is to provide a tool addressed to health personnel who needs to identify and consult existing guidelines. Guidelines were searched on the Web, analyzed for their quality, and recorded in an in-house-developed archive. A guideline should meet the following criteria in order to be included in the ISS database:

- to be produced by a government agency, a hospital, a local health unit or a professional society;
- to be produced in Italy;
- to be developed, reviewed or updated as from 2003;
- to be written in Italian language;
- to be available on the Internet free of charge.

These criteria have been inspired by those adopted by the UK database of clinical guidelines (5).

RESULTS

For each selected guideline the title, the corporate and personal authors, the publication date, the revision date, the link to the full-text of the document, and the Italian MeSH terms are provided. Furthermore, it is clearly indicated if the guideline is addressed to the health professional or to patients and care-givers.

All of these fields will be searchable in the Web interface.

Moreover, the following characteristics are outlined:

- presence of a bibliography;

- presence of a list of databases searched for developing the guideline;
- explicit search strategies;
- presence of a grading system to classify the levels of evidence and the strength of recommendations;
- development of monitoring indicators;
- presence of a multidisciplinary panel for the guideline production.

If a grading system of the recommendations expressed by the guideline is present, the adopted schema is reported in the database.

If the guideline complies with the criteria adopted by the Italian SNLG (database searched, declared search strategies, multidisciplinary panel, monitoring indicators) it will be declared in the database that the guideline matches the SNLG criteria.

The database contains at present over two hundred clinical guidelines published since 2003.

It is distributed on the Intranet of the ISS but, in the near future, it will be available to general public on the Web, through an *ad hoc* developed interface.

CONCLUSIONS

Guideline development is a time-consuming and expensive process. In a previous paper by the authors of this contribution (4) it was estimated that the expenditure for a guideline on “Early Intervention in Schizophrenia” (produced in 2006) was more than nine thousand Euros, considering only the costs for documentary work.

Other authors (2) argue that the total cost per guideline is about 150 000 € in the Netherlands, and more than £ 400 000 for a NICE (National Institute for Clinical Excellence, UK).

Therefore, the authors of this paper believe that it is very important to create and manage appropriate tools for detecting existing guidelines, in order to decide whether produce a new one or simply update or revise an already developed one.

Furthermore, the development of an Italian register of guidelines may be useful for identifying research groups working on a specific health topic.

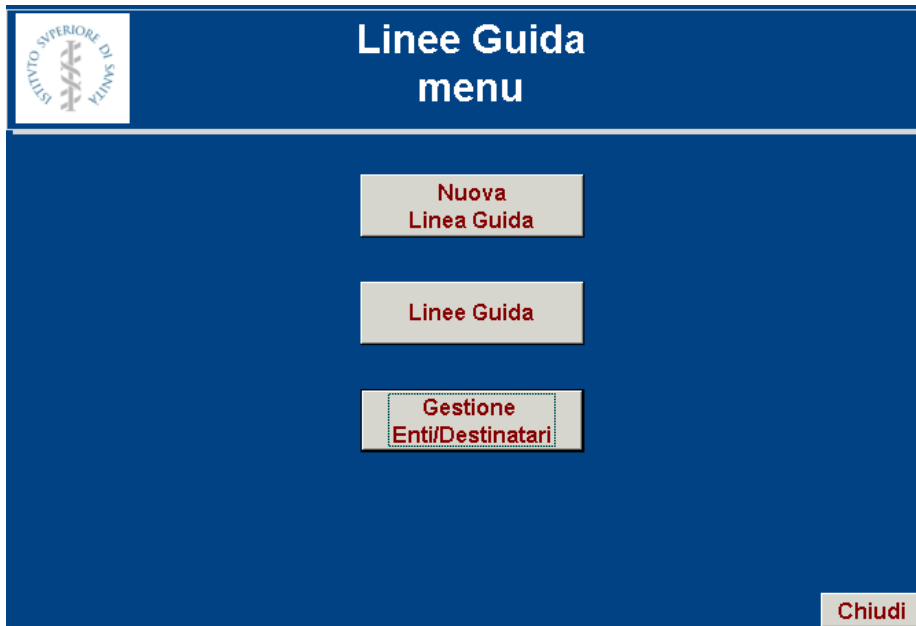


Fig. 1 The home page of the Italian Guideline Database. The interface for data-entry includes the possibility of cataloguing a new guideline, searching already recorded guidelines and managing the authority file of corporate authors and audience

CHIAVE		(Contatore)		Gestione Linea Guida	
Titolo					
Autori personali					
Publicato il		Revisionato il		WEB	<input type="checkbox"/>
URL					
Bibliografia	<input type="radio"/> Si <input type="radio"/> No	Testo completo in rete	<input type="radio"/> Si <input type="radio"/> No	Schema di grading	<input type="radio"/> Si <input type="radio"/> No
Se si specificare					
Indicatori di monitoraggio	<input type="radio"/> Si <input type="radio"/> No	Presenza Panel multidisciplinare	<input type="radio"/> Si <input type="radio"/> No	Base di dati consultate	<input type="radio"/> Si <input type="radio"/> No
Strategia di ricerca dichiarata	<input type="radio"/> Si <input type="radio"/> No			Criteri SNLG	<input type="radio"/> Si <input type="radio"/> No

File	File type
<input type="text"/>	<input type="text"/>
Record: <input type="text" value="1"/> di 1	
Ente Autore <input type="text"/>	Destinatario <input type="text"/>
Record: <input type="text" value="1"/> di 1	Record: <input type="text" value="1"/> di 1
Mesh <input type="text"/>	
Record: <input type="text" value="1"/> di 1	
Nuovo	Duplica
Salva	Chiudi

Fig. 2 The data entry form of the Italian Guidelines Database, with all available fields

CHIAVE		385	Gestione Linea Guida	
Titolo	Taglio cesareo: una scelta appropriata e consapevole			
Autori personali	Mele Alfonso; Baglio Giovanni; Donati Serena; Morciano Cristina			
Publicato il	01/01/2010	Revisionato il		WEB
URL	http://www.iss.it/binary/pres/cont/LG_cesareo_def.pdf			
Bibliografia	<input checked="" type="radio"/> Si <input type="radio"/> No	Testo completo in rete	<input checked="" type="radio"/> Si <input type="radio"/> No	Schema di grading
Se si specificare	Schema di grading LIVELLI DI PROVA*			
Indicatori di monitoraggio	<input checked="" type="radio"/> Si <input type="radio"/> No	Presenza Panel multidisciplinare	<input checked="" type="radio"/> Si <input type="radio"/> No	Base di dati consultate
Strategia di ricerca dichiarata	<input checked="" type="radio"/> Si <input type="radio"/> No	Criteri SNLG	<input checked="" type="radio"/> Si <input type="radio"/> No	
File		File type		
▶ 385		pdf		
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Record: 1 di 1				
Ente Autore		Destinatario		
▶ Sistema Nazionale Linee Guida - SNLG I:		▶ Operatori Sanitari		
▶ Ministero della Salute		▶ Cittadini		
* []		* []		
Record: 1 di 2		Record: 1 di 2		
Mesh				
▶ Taglio cesareo				
* []				
Record: 1 di 1				
Nuovo		Duplica		Salva
				Chiudi

Fig. 3 The full record of the Italian Guideline “Caesarean Section: an appropriate and aware choice” developed in 2010 by the Italian National Guideline System.

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