[ORIGINAL RESEARCH]

Title: CIRGEN, Development of a Surgical Guidelines System.

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Abstract

Over the past decade, clinical guidelines became a familiar part of clinical practice. The Cuban Guidelines for Diagnosis and Treatment in Surgery were introduced 30 years ago as the right tool to improve the quality of medical care. During these years shortcomings such as low availability, poor integration to practice, and obsoleteness have arisen, leading to rare use in daily practice; therefore we attempted to develop a new framework where quidelines become more usable in daily practice.

We expose difficulties in the current organisation related to lack of standard structure in the Cuban guideline. We present a structure to normalise the contents of the guideline, allowing the introduction of information technology. We develop a system to handle the information of the guidelines relying on the new formal structure of the guideline. The system CIRGEN (stands for general surgery in Spanish) provides a web-based interface with features to allow quick browsing through the contents, including technical references and on-line bibliographic support. The system is complemented with a reporting tool to integrate the guideline system at daily practice. It produces compliant surgical reports and allows constant interaction with the guideline.

CIRGEN provides a new environment where the surgical guidelines can be used as continuing education tool integrated to practice.

Keywords: Clinical guidelines; Surgery; Reporting system.

CIRGEN. Sistema Automatizado para las Normas Quirurgicas de Diagnostico y Tratamiento.

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Resumen

Hace mas de 30 anos fueron introducidas las Normas Cubanas para el Diagnostico y Tratamiento en Cirug a como instrumento para mejorar la calidad de la atencion medica. Con el transcurso de los anos algunas dificultades se han presentado y han provocado su uso infrecuente en la practica quirurgica diaria, quedando solo para fines educativos. En este estudio proponemos un nuevo formato organizativo para las normas donde se aplica una estructura formal para el contenido de la edicion vigente tomando como punto de partida para este prototipo, tres problemas medicos: Enfermedades quirurgicas del tiroides, Litiasis vesicular y Hernia Inguinal. Se diseno una base de datos relacional para almacenar la informacion y se construyo una interface en Hypertext Markup Language (HTML) para permitir una facil interaccion con los usuarios; se incluyeron aditamentos especiales para permitir un rapido acceso a los contenidos del programa y ademas se agregaron nuevas opciones para consulta de informacion tecnica ampliada, imagenes didacticas y soporte bibliografico. Con el proposito de lograr una mayor integracion a la practica quirurgica diaria el sistema se complementa con una aplicacion que permite la generacion automatica de informes quirurgicos en el momento de la operacion. Esta aplicacion fue disenada para un ambiente Windows®; utiliza una interface de facil manejo con un formato similar al informe tradicional que se basa en la información de las normas. Este nuevo instrumento permitira contar con informes legibles, organizados. completos y almacenados en formato electronico, a la vez que optimiza el tiempo en el salon y suministra informacion inmediata sobre el proceder. Para la evaluación el nica del prototipo se propone su aplicación de forma local y a pequena escala.

Introduction

Over the past decades, clinical guidelines increasingly became a familiar part of clinical practice. Guidelines may offer concise instructions on which diagnostic or screening test to order, on how to provide medical or surgical services, on the length of stay of patients in hospitals, or on other details of health care. Guidelines based on a critical appraisal of scientific evidence (evidence based guidelines) clarify which interventions are of proved benefit. They alert clinicians to interventions unsupported by science and call attention to ineffective, dangerous, and wasteful practice [1-3].

In Cuba national groups in every speciality were created along the country 30 years ago, with the mission to develop guidelines for clinical practice to improve the quality of medical care. In 1969 the first edition of the Cuban Guideline for Surgical Diagnosis and Therapeutics was published [4]. They were received with enthusiasm among the surgical community, as they were seen as the first attempt to standardise surgery applying an evidence-based concept. The guideline provided the new generation of practitioners with an educational tool, spreading novel international trends and the best legacy of the Cuban surgical school.

Besides, for technical and educational consultation, the guideline was also used to evaluate clinical decision-making within the surgical departments. The guideline was the standard to measure the quality in diagnostic protocols, surgical procedures, and the management of hospitalised patients.

After several years of use, difficulties inherent to paper-based guidelines became apparent in the Cuban version, such as, a delay in updating and especially, poor integration into daily practice. Furthermore, they were affected by national economical problems, resulting in insufficient amount of copies with low availability. The sum of all these limitations led to almost no use in practice and, in our opinion, remained just for educational consultation. In this study we explore the limitations that lead to improper use, and will propose a new framework for improvement of the guideline. Throughout this paper we will use the term 'guidelines', although several (not always) interchangeable terms such as recommendations, standards, protocols, practice parameters, practice policies and clinical algorithms are used in other publications.

In the following, we analyse the shortcomings of the Cuban surgical guideline, making a distinction between those related to international guidelines and local conditions operating in Cuba. Furthermore, we introduce and discuss a computer system design to provide a new environment for the guideline, where these problems could be solved.

Limitations of the Cuban guideline.

As the surgical guideline diffused into practice surgeons had the feeling that indeed, improvement of quality of care could be accomplished. Soon, important limitations arose; limitations shared by most guidelines implemented in paper format.

Limited browsing: The Cuban guidelines are indexed by diagnosis or medical problems. They present trees of information under every major diagnostic category (concepts, classifications, diagnostic, treatment, etc). This familiar organisation does not support multiple views on information or specific searches (e.g. "a list of all diseases sharing the same diagnostic procedure or the same surgical technique"); the authors choose to use internal referrals between separate chapters instead, making consultations even more tedious.

Delay in updating: Keeping guidelines up-to-date is difficult especially when they are based on published scientific evidence. The high frequency and variety of publications appearing in related journals overcome established guidelines editions, making them relatively 'out-of-date' at the moment of implementation [5-7].

Poor integration into daily practice: The development of good guidelines does not ensure their use in practice [8]. The Cuban surgical guideline used passive methods of dissemination and implementation -by publication-, which is proven to be rarely effective [8].

From 1989 Cuba has faced serious economical problems, with repercussion to the health care sector. Guidelines were specifically affected by low availability of materials to produce new editions. These difficulties compromised even more the performance of the document, by an increase of the delay for updating and a limited availability for surgeons. To illustrate this; the first author used in his own practice the latest edition of the surgical quideline, published more than 15 years ago.

Towards electronic guidelines.

Guidelines do not escape from the general trend present in all contemporary science towards increasing use of computers and information technology (IT). Several systems have been developed to improve the use of guidelines in all medical areas, showing favourable known results [9-12]. Therefore we decided to start an investigation to design and implement a prototype of a computerised system with a new framework for the Cuban guidelines. The system would be used as a research instrument and should answer the following questions:

- Can the computer-based guideline overcome the limitations of the paper version?
- Can the system produce additional benefits in daily practice?

We started by extensively reviewing the structure of the guidelines to get insight in the current organisation, which ranged from brief expositions to extended ones. An example can be seen in table 1, where 'Surgical diseases of the thyroid' show a large subdivision with several items explained under every category; compared to 'Groin hernia', where the information is compacted in few categories. Moreover, we found that the method to present the information on every disease was not always the same, raising doubts about missing aspects (e.g. the post-operative care, which was inconsistent throughout the guideline compendium). We designed a new organisation where all the information could be contained and presented, following a standard structure (figure 1). The new framework could be applied to the guideline allowing normalisation of the contents, and preparing the field for the introduction of IT.

[Insert table 1 about here]

To build a prototype we selected three diseases within the guidelines to concentrate the efforts in. These were Surgical Diseases of the Thyroid, Gall Bladder Lithiasis and Groin Hernia. They were selected because of their relatively high frequency in surgical practice, for the heterogeneity in their contents and also because of their straightforward management. A relational database was built containing the new formal structure, which would function as a knowledge base for the future system.

[Insert figure 1 about here]

Since physicians are not all experienced computer users it was evident that the system had to be user-friendly [13]. Hyper Text Mark-up Language (HTML) format appeared to be one of the most attractive and popular interfaces format, because of its multiple graphic and linking advantages. Still some features needed to be kept in mind at the developmental phase:

- The system needs to include elements to facilitate dynamic browsing throughout the contents.
- The system needs to provide active technical references (not included in the paper version), regarding the surgical techniques mentioned in every chapter.
- The system needs to be linked to on-line bibliographic sources to support the information provided.

After these considerations we built a Microsoft Access® database and developed a web-site using HomeSite4.0® as web editor and included some resources to comply with the previous considerations such as: an *Anatomical menu* (figure 2), *Information access menu* (figure 3) and *Bibliographic reference hyperlinks* (figure 4).

[Insert figure 2, 3 and 4 about here]

Guidelines into practice.

Once the web-based system is ready and available [14] many of the shortcomings previously mentioned would be overcome. The computer-based guideline provides dynamic and easy browsing, allows faster updating, connects with on-line references and publications, and increases availability by using existing computer infrastructure at surgical departments. Still, one of the most important limitations remain unsolved, the new guideline would not be actively used into daily practice. Thus we decided to study whether it was possible to integrate the system into the main activity of the surgical department: surgery, by means of a practical application to assist while reporting. This reporting tool would use the guideline's knowledge base as information source to provide with the required standards in a fast and friendly

fashion. Both programs, the electronic guideline and the reporting tool will be integrated into a single system, CIRGEN (standing for general surgery in Spanish).

A reporting system.

The main activity in a Surgical Department is surgery itself and it comprises paperwork where the surgical report plays a significant role. This document is an important element within the patient record in the Department, it contains a description of the findings and procedures performed on a patient during a certain operation; therefore it is a determinant information to be used in the post-operative stage [6]. During the elaboration of such documents some problems may occur, especially those related to illegibility, poor organisation and lack of information.

Several systems have been developed to aid in reporting, specially in Radiology [15,16], Echography [16,17], Cardiology [16], Cytology [18,19], Endoscopy [16,20,21] and Gynecology [22] although there has been a trend lately to introduce computers in operation rooms too [23-25]. During clinical trials the results of such systems have been diverse, but the overall analysis indicates that indeed, positive outcome can be achieved; such as: legibility, completeness, electronic-storing, etc.

Trying to overcome the difficulties on reporting and based on the positive results achieved by these systems we designed a computerised tool to assist during reporting using data provided by the surgeon and information stored in the knowledge base. Analysing the current format of the surgical report we identified the aspects directly related to the information contained in the guideline and the ones highlighted in table 2 were the ones established to be compliant. Information concerning: 'Preoperative diagnosis', 'Performed operation', 'Incision', 'Main procedure', 'Drainage', 'Complementary procedures', "Anaesthesia', and 'Definitive diagnosis' are retrieved from the guidelines.

[Insert table 2 about here]

The reporting system should be as user-friendly as the guideline and users should be able to familiarise themselves with it in a short time. Limited data input by keyboard and an easy-to-control interface should enhance the acceptability of the system. The program will retrieve the information about the compliant aspects from the guideline's knowledge base, merging both programs into one single system.

This reporting tool was built as a Windows® application designed in Delphi4® with various data entry windows, reassembling the current paper form (figure 5) currently used at operation theatres.

[Insert figure 5 about here]

Use of the system

In a typical scenario CIRGEN could be used in two different ways: strictly for consultation or at the operation theatre while reporting surgery. The first comprises access to the on-line guideline where physicians can browse dynamically through its contents, retrieving specific medical indications, technical information on surgical procedures, related publications and information provided by other international guidelines. In the second variant the user would log in by supplying a username and password to secure patient information. Patient's identification data is entered and previous surgical reports can be consulted. Once the diagnosis is chosen from a list the system generate options of surgical techniques advised by the guidelines and contained in the knowledge base for the specified disease. The system also generates information about the advised incisions, additional tests during surgery, drainage placement and other surgical details. When all the information about the current procedure is entered a preview of the final report is shown, containing the data entered and a proposal of the procedure description provided by the guideline's database. A new feature was added to the reporting system to allow surgeons reviewing the related post-operative measures. These measures are currently contained in the guideline and are retrieved from the system's database.

If the user agrees with the proposal the report becomes final, the information is stored to a patient database and paper copies are produced for attachment to the paper-based patient record. At any moment of the session surgeons can access the guideline interface by activating hyperlinks (figure 6), providing extra information on the procedure they are about to perform.

[Insert figure 6 about here]

Future projections

CIRGEN will be evaluated in Cuba to study the impact of such system on medical practice. The study group would include surgical specialists and residents measuring a baseline without the system. An evaluation period will be assessed in both possible uses (guideline consultation and reporting aid) and finally, results would be measured again addressing the two original questions:

- Did the computer-based guideline overcome the limitations of the paper version?
- Did the system produce additional benefits in daily practice?

If the project shows improvements, further efforts will be aimed to generalise the structure for the entire guidelines, based on updated information. For this purpose the National Group could provide the new version following the proposed scheme, to allow its integration to the electronic format.

Discussion

Clinical guidelines are increasingly part of current practice and will become more common over the next decade [8]; access to pertinent and valid information is demanded by the doctor, in principal, the correct information at the appropriate time [26]. The Cuban Guidelines for Diagnosis and Treatment is a positive initiative, which could provide several benefits in case of active use at surgical departments; however, problems mainly related to lack of organisation have caused misuse. In this paper we described a standard structure to handle the information from the guideline in a more efficient fashion. We presented the project CIRGEN as a prototype system to provide a new electronic format for the Cuban Guidelines for Diagnosis and Treatment in Surgery, based on this new structure. The system allows overcoming many of the problems present in the current paper version and integrates the guidelines into daily practice by means of a useful application, a reporting tool. This reporting aid will incorporate new benefits, such as:

- Surgeons can be able to save time by just filling blanks in a pre-elaborated report, based on standard steps to follow in an operation.
- We eliminate the illegibility problem by producing a print out of the report.
- We diminish the "lack of information problem" by reminding practitioners the aspects to be mentioned and filled in the surgical report on mandatory basis.
- Compliance to the guidelines will increase, by producing reports based on techniques suggested in the document, and at the same time will provide with reference information by means of explicit hyperlinks.

Still we think that certain aspects must be discussed within the surgical community to allow full implementation of the system. Specifically aspects related to the flexibility of the guideline in certain conditions where the lack of compliance could be justified. The reporting tool of the system guarantees fast reports by retrieving information from the guideline's knowledge base. Nonetheless the system remains rigid and does not allow flexibility because that is the current conception of the Cuban guideline. CIRGEN presents the user a fix list of procedures to be described, not allowing new decisions unsupported by the guideline. This attitude comprises a danger for the information to be recorded, especially for the truthfulness of the data in comparison with what actually happened during the operation.

Medicine can eventually be an inexact science and even the most complete guideline cannot cover all the possible conditions to be found during practice [7]. That's why mandatory guidelines have always been polemic issues among clinicians because of their restricting nature. It is advisable to review the compulsiveness of the Cuban guideline, based on current international experiences and local needs and get a consensus about the most convenient approach to this issue. The result of such discussion would be a crucial aspect for the project conception, and would comprise the development of a new version with the possibility for alternatives based on supervised freedom.

CIRGEN provides an overview of the management of a condition or the use of an intervention. Clinicians may use it to answer specific clinical questions arising out of their day-to-day practice. They may also use this computerbased guideline as an information source for continuing professional education.

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I-Surgical Diseases of the thyroid:

- 1. Ethiological classification:
 - -Congenital abnormalities.
 - -Simple colloidal goiter.
 - -Grave-Basedow disease.
 - -Nodular Goiter.
 - -Thyroiditis.
 - -Malignancies.
- 2. Functional classification.
- 3.TNM staging.
- 4. Diagnosis & Therapeutics:
 - -Congenital abnormalities.
 - . Diagnosis.
 - . Surgical treatment (indications and techniques).
 - -Simple colloidal Goiter.
 - . Diagnosis.
- . Surgical treatment (indications and techniques). -Substernal goiter.

- . Diagnosis.
- . Medical treatment.
- . Surgical treatment (techniques).
 - -Graves Basedow disease.
 - . Diagnosis.
- . Medical treatment (indications and procedures).
- . Surgical treatment (indications pre-operative, techniques and post-operative).
 - -Nodular goiter.
 - . Classification.
 - . Diagnosis.
- . Medical treatment (indications and procedures).
- . Surgical treatment (indications and techniques). *Plummer Disease.
 - i idililici Bisca
 - . Diagnosis.

- . Medical treatment (indications and procedures).
- . Surgical treatment (preoperative and techniques).
- -Thyroiditis.
 - . Infectious.

Table 1. Current distribution of the guidelines [4].

- Acute.
- . Diagnosis.
- . Treatment.
- Specific chronic.
 - . Treatment.
- Unknown cause (idiopathic).
 - Quervain.
 - . Treatment.
 - Hashimoto.
 - . Diagnosis.
- . Surgical treatment (indications, techniques and post-operative).
 - Riedel.
 - . Diagnosis.
- . Surgical treatment (indications and techniques). -Malignancies.
 - . Diagnosis.
- . Treatment according class.

II-Gall bladder Lithiasis.

- 1.Classification.
- Stones.
- Organic disorders.
- 2.Diagnosis.
 - History.
 - Clinical findings.
 - Complementary tests.
- 3.Treatment.
 - Medical treatment (indications and

procedures).

- Surgical treatment (indication and techniques).

III-Groin hernia.

- Classifications (5).
- Diagnosis.
- Medical treatment.
- Surgical treatment (indications, pre-operative, techniques according stage and post-operative).

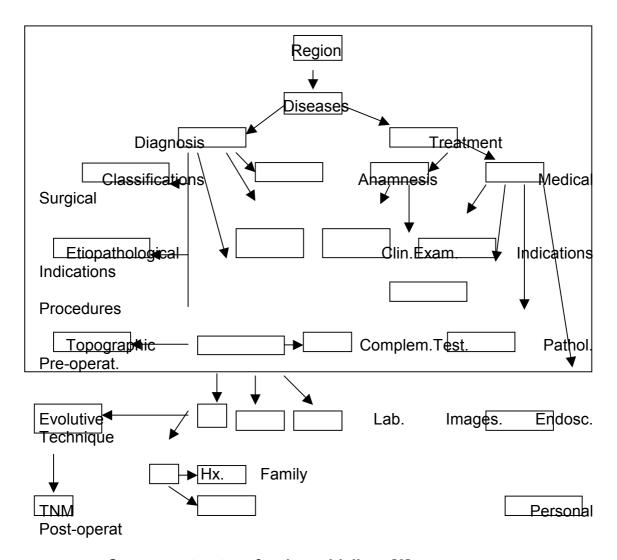


Figure 1: Common structure for the guidelines [6].

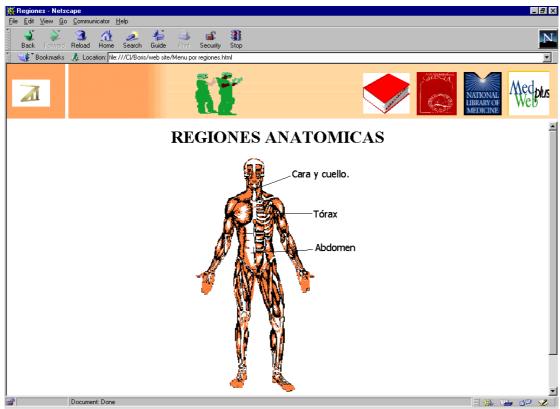


Figure 2. Anatomical menus in guidelines interface. (CIRGEN).

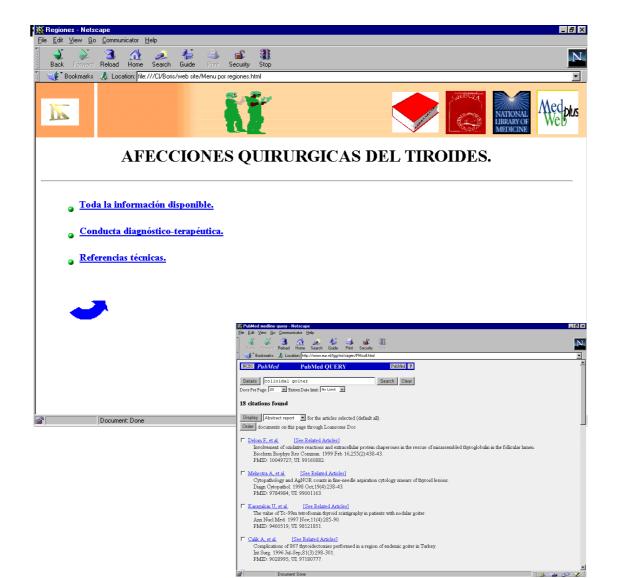




Figure 4. Bibliographic reference hyperlink in guidelines interface with MEDLINE query. (CIRGEN).

First Name.	Last Name.	Sex.		Age.	Е	Patient ID.		
) o t o	Age.	- '	atient ib.		
Ward/Bed.	Department.	Ann. [oate.					
Preoperative I	Preoperative Diagnosis.							
Main Surgeon's Name.				Code.				
First Assistant.				Code.				
Second Assistant.				Code.				
Third Assistant.				Code.				
Main Anaesthesiologist.				Code.				
Nurse.	Code.							
Performed Op	Performed Operation.							
Description								
Incision.								
Exploration.								
Main Procedure.								
Drenages								
Drenages								
Drenages Closure.								
Closure. Sutures.	y Procedures	(X-ray,	Frozen	section,	Microbiol	ogy sample,		
Closure. Sutures.	y Procedures	(X-ray,	Frozen	section,	Microbiol	ogy sample,		

Accidents.	
Anaesthesia.	
Start Time.	Finish Time.
Definitive Diagnosis.	Surgeon's Signature.
Evaluation.	Evaluator's Signature.

Table 2. A scheme of the form use to elaborate the surgical report issued by the National College of Surgeons [4]. The shadowed cells indicate information provided by the guideline.

💼 Datos Quirúrgicos			×		
Operación realizada	Tecnica				
	Cirujano	Contaminación.	Suturas empleadas		
Primer ayudante		C Limpia-contaminada.	☐ Examenes transoperatorios.		
Segundo ayudante	Sayudante <u></u>	C Sucia.	Tipe: Add		
Tercer ayudante	Tayudante	Tipo de anestesia.	:: Resultado: Resultado		
Anestesiologo principal	Anestesiologo	C GEV.			
Enfermera(o)	Enfermera 🔽	C Espinal.	Accidente(s) operatorios.		
· Incisión	Incision	C Peridural.	::::: Tipp: Acc ☑:		
Exploración	Exploracion	C Combinada.	□ Drenaje(s). Localización □ Drenalocat		
			Tipo de cierre Tipocierre		
Diagnóstico definitivo	Ddef	<u></u>	Hora de comienzo 8:30:00 AM		
		-	Hora de terminación 8:30:00 AM		
	✓ 0K	Cuidados postoperatorio	os. X CANCELAR		

Figure 5. Data entry window in reporting system. (CIRGEN).

