The Importance of Computing Systems in Chronic Pelvic Pain Research

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Abstract — **Chronic pelvic pain is a common clinical condition with negative consequences for many aspects of women's life. The clinical presentation is heterogeneous and the involvement of several body systems impairs the identification of the exact etiology of the problem. At the same time, a clinical treatment of good quality depends on the professional and the learning process is slow. Besides, biomedical aspects predominate in the educational process during the graduation in health sciences, which are inadequate due to the biopsychosocial approach that this condition requires. It is believed that the acquisition, storage and adequate processing of information related to the different aspects of the clinical history of these women may help professionals to better understand this disease. Objectives: 1- to evaluate the appropriate filling out of the form regarding the clinical variables and identification of the professional responsible for patient care; 2- to evaluate the satisfaction of the user regarding free and manual filling out or the new electronic and structured method for a new case along time. Methods: the project was approved by the Research Ethics Committee of HCFMRP and the implantation of the system was approved by the Committee for the Analysis of Medical Records and Deaths of HCFMRP. The process of development and implantation of the system was based on the principles of software engineering, with the adoption of the classical life cycle starting with analysis of the problem, survey of requisites, project, codification, tests, and maintenance. The Filemaker Pro software was used for the development of the form, together with the Filemaker Server 11 for database management. One-hundred new cases were evaluated in a first phase in an alternate manner: 50 of them elaborated with the manual system and 50 with the electronic system. The number of data that were not provided, the number of erasures or inadequately filled out data, the time of execution of a new case and the final identification of the professional responsible were determined. A structured questionnaire was also applied for an objective evaluation of user satisfaction, with analysis and implantation of suggestions for an adequate layout. In a second phase, 50 new cases were elaborated using the new electronic system and were also evaluated by the users. Results: As important as usability were the significant results obtained in terms of the reduction of consumables since the reports to be inserted in the medical records of the patients were reduced by 50%. The mean time needed to fill out the traditional (manual) form was less than the mean time needed to fill out the electronic form, although this difference can be considered to be of little significance from a clinical viewpoint. Conclusion: The electronic form is filled out within a time similar to that needed for a traditional form, it generates a completely legible report of fewer pages, without erasures or missing information, and contains the precise identification of the professional in 100% of cases. The users also stated that they were satisfied with the system.**

Keywords-component; Pelvic Pain; Computing; Medical; Research.

I. INTRODUCTION

A. General considerations

Chronic pelvic pain is a common clinical condition worldwide and is defined as a pain in the lower abdomen and/or in the pelvis, persisting for at least six months and intense enough to cause functional incapacity, demanding clinical or surgical treatment [1].

This condition is difficult to control because frequently the primary cause is not identified. The etiology is not clear and, usually results from a complex interaction between the gastrointestinal, urinary, gynecological, musculoskeletal, neurological, psychological and endocrine systems, also influenced by sociocultural facts [2].

The disease implies a direct expense exceeding two billion dollars per year in the United States and has a considerable impact on the socioeconomic national scenario, directly due to elevated expenses and secondarily due to the incapacity caused by this condition [3].

At the same time, the importance of computing has been increasing over the years in a wide variety of fields, including medicine, in which the use of computational systems in extensive. Ranging from X-ray scanners to computerized robotic surgeries, computing has been used in many tasks in medicine. One of these tasks is the possibility to enable the acquisition and reliable storage of selected clinical data that can be very useful for scientific research, including the field of chronic pelvic pain, by the creation of systems that record and

manage structured forms [4]. Another important task would be to obtain artificial intelligence systems that would help with the diagnosis of the real cause of this condition.

On this basis, the present paper presents a discussion about computing systems and their importance for chronic pelvic pain research, showing what they can do to improve the reliability of acquired data, enabling the interaction between different databases and systems and also leading to more reliable investigations based on clinical data.

By discussing these questions the goal of this paper is to promote reflection among clinical professionals and researchers about the benefits of computing systems, such as the structured forms and artificial intelligence systems described here, for supporting the development of good quality research.

B. Structured forms

The use of structured forms in medicine as stated in [5] "reduces the ambiguity of natural language format reports and enhances the precision, clarity and value of clinical documents", and having a precise and clear data is essential to research in a manner that the results depends on the data that is being studied. Other studies as [6], [7] and [8] also reinforces the idea that by using structured reports the data acquired by it is more precise and clear that regular natural language format reports.

Structured forms are computer forms that can be configured to request any type of information, and all data that are inputted into them are controlled and can be easily manipulated allowing, among other features, searching, storing and comparing with other similar elements. These features facilitate clinical research and teaching.

Other benefits of the use of structured forms are cost reduction since the storage of electronic data is cheaper and involves a reduction of the amount of paper needed [5], and improved communication, with the possibility of obtaining better replies to questions that really matter [7]. There is also the possibility of accessing these data anywhere, enabling easy sharing of information [8], which is an important feature when thinking about geographically distant research contributors.

There are many systems that allow the assembly of structured forms, such as Oracle RDC and Medidata Rave. One of these systems, called Filemaker, is the worldwide leader in easy-to-use database software that can be easily operated by non-technical people [9]. This software was used by the Center for Epidemiological Research in Women's Health (NUPEM) of the University of São Paulo to create a structured form for medical consultation of patients with chronic pelvic pain. This software has enabled a better control of the information for these patients and has provided more precise data [10], as can be seen in the "Methods" section. It has also provided the basis for the creation of another system, which uses artificial intelligence to help with the diagnosis of the cause of chronic pelvic pain.

Traditionally, the paper form used by the medical service contains 4 pages of questionnaire. Erasures, inadequate information and even incomplete filling out of the form were constant occurrences. The development of a form that would guide a correct filling out within an acceptable period of time for the conditions of the hospital service, as well as the reduction of the amount of paper in the records, and mainly an easier later investigation of the database were the major reasons for the development of the new system. The objectives of the present study were: 1- to evaluate user satisfaction with the utilization of this new proposal as opposed to free and manual recording of the data of the first medical visit, and 2- to describe the eventual benefits of the use of the electronic structured form compared to the traditional model employed thus far.

II. MATERIALS AND METHODS

The study was conducted at the Chronic Pelvic Pain and Gynecologic Video-endoscopy Center of the Department of Gynecology and Obstetrics, Faculty of Medicine of Ribeirão Preto, University of São Paulo. The project was approved by the local Ethics Committee and by the Committee for the Analysis of Medical Records and Deaths (protocol nº 6694/2010).

A. Development and implantation of the structured form

For the development and implantation of the multicenter system we adopted the cascade life cycle of software engineering, justified by the high degree of detailing of the entry, processing and exit requisites [11]. In order to obtain better acceptance of the technology by the users, we developed a software with an intuitive interface that would facilitate the search for information. In parallel, we insured safety of the information by defining access rules though virtual private networks (VPN) and users and passwords with privileged access to the system. The Filemaker Server 11 solution of Filemaker Co. was used as the database management system (DBMS)..

A five point Likert scale, where 1 = unsatisfied and 5 = highly satisfied, was used to assess the quality of the software and to compare the traditional method (paper form) to the electronic method (structured form). We analyzed user satisfaction regarding screen layout, flow of form filling out, menu organization, clarity of the information requested, and software operationality. We also evaluated user preference for one of the systems based on the guidelines contained in the form and the legibility of the report generated. We described and compared the mean time for the filling out and general feasibility of the information. All professionals were informed about the installation of the new system but no meeting was offered before its implementation. Access support was provided daily by the persons responsible for the development of the system at the place where the clinical activities were performed.

In a first phase, 100 new cases were evaluated between August 2011 and March 2012 in an alternate manner: 50 of them elaborated with the manual system and 50 with the

electronic system. All cases were the responsibility of gynecology and obstetrics medical residents, particularly of those in the 3rd and 4th year of specialization. The professional was supposed to fill out the information of a new case obligatorily using the electronic system to answer the questionnaire. Preferentially, the same professional processed a new case using the traditional system (manual filling out of a form printed by the print shop of the Hospital) and the subsequent one using the electronic system (finally generating a report pre-formatted by the persons responsible for the outpatient clinic, printed and attached to the medical records of the patient). In this phase we determined the number of data not provided, the number of erasures or of improperly filled out data, the time of processing of a new case, and the presence of the final identification of the professional responsible. We also applied a structured questionnaire in order to evaluate in an objective manner the satisfaction of the users with the filling out methods, with analysis and implantation of suggestions regarding adequacy of the layout. This questionnaire and its pertinent results are presented in Table 1.

In a second phase, after the implantation of suggestions for layout adequacy and functionality, 50 additional new cases were processed from April to July 2012 using only the electronic system. At that time, we also reevaluated user satisfaction using the same questionnaires.

B. Statistical analysis

The Agostino and Pearson test was used to determine the normality of numerical variables. Variables with a normal distribution were then analyzed by the Mann-Whitney test and variables with non-normal distribution were analyzed by the Kolmogorov-Smirnov test. The curve of user satisfaction was represented by sigmoid dose-response graphs. The level of significance was set at α=5%. All analyses were performed with the aid of the GraphPad Prism 5® software.

III. RESULTS AND DISCUSSION

No absence of information was detected in the electronic form since the variables were configured as obligatory fields, so that a visit could not be completed without a completely filled out form. In contrast, with the manual method there was a median number of 9 absent data (range: 3-18) out of a total of 107 data considered essential (8.4%) (P<.0001). No inadequate, or erasured data or data incoherent with the field were detected in the electronic form since all fields of the form had previously defined values and, when necessary, pertinent information was provided for guidance. With the manual method, there was a median of 15 occurrences (range: 9-23) of erasured data or data provided in inappropriately filled out fields out of a total of 107 data considered essential (14.0%) (P<.0001). In the present study, we did not determine the reliability of the information obtained.

The mean time needed to fill out the traditional (manual) form was less than the mean time needed to fill out the electronic form, i.e., 44.6±4.7 minutes versus 48.7±5.4 minutes (P<.0001), although this difference is of little significance from a clinical viewpoint. The reports consisted of two printed pages, whereas the standard form (free text) previously used consisted of 4 pages, with a consequent 50% reduction of the number of pages inserted in the medical records of the patients. We observed that in 24 new cases processed in the first phase using the free and manual text (48%, 24/50) it was necessary to let the professional know at the end of the process that he had forgotten to identify himself or had done so in an illegible manner, a fact that did not occur with the electronic system since identification was the first condition required to authenticate the use of the system (P<.0001).

The degree of user satisfaction with the system was directly dependent on the time of exposure to the system and presented an important inflexion of the curve soon after the implantation of the suggestions made by the users themselves (Fig.1). According to the technology acceptance model (TAM), what determines the utilization of the system by an individual is an easy use and mainly the positive results provided by this new technological method [12].

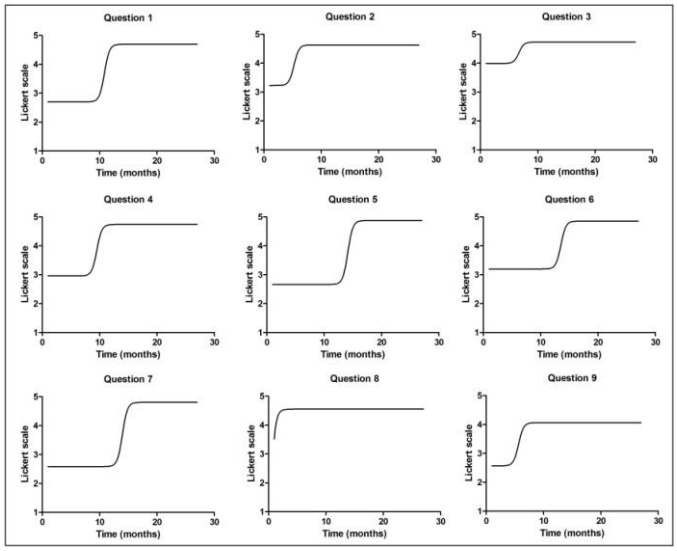

Figure 1: Curve for the degree of satisfaction with screen layout and flow of system filling out (question 1), organization of menus and of list of information(question 2), system with clear and understandable information (question 3), learning with the new system (question 4), operationality of the system (question 5), satisfaction with the performance of the application (question 6), interest in the system (question 7), possibility of reporting all the desired information in the system (question 8) and preference for the manual method or the informatized method (question 9). The legibility of system was investigated in questions 10 and 11, but the eletronic form was absolutely superior. Because of this, they are not presented at Figure.

The subjective item considered to be most relevant by the professional was the fact that the structured electronic form not only permits the digitization of the information by the users, but also provides guidance for the correct filling out of each variable and its indexing according to previously stipulated requisites. Additional benefits are the economy of paper and the reduced number of sheets attached to the medical records of the patients, which used to be four and are now a maximum of two. Clarity and reliability of the final reports printed in the medical records are also observed since there is control of the

complete recording of all the variables considered essential for a precise diagnosis.

The information acquired with this structured form is also being used to create another system that uses artificial intelligence to help diagnose the real cause of chronic pelvic pain in these patients. The information acquired with this form is stored in the FileMaker database and is accessed by the artificial intelligence system that handles these data, in an attempt to help diagnose the cause of this condition.

A. Future perspectives: Artificial Intelligence

The goal of artificial intelligence (AI) is the development of paradigms and algorithms that require machines to accomplish cognitive tasks for which humans are currently better. AI systems have to be capable of doing three things [13]:

- Store knowledge;
- Apply the stored knowledge to solve problems;
- Acquire new knowledge through experience.

Besides the capacity of doing such things, AI systems must have three fundamental components: representation, reasoning and learning [14]. Representation is used to represent the knowledge about a problem's domain, reasoning is the ability to solve problems, and finally, learning is the process of change of behavior obtained through experience built by emotional, neurological, relational and environmental factors [15].

According to Mitchell [16], to say that a machine can learn it should, from an experience E, regarding a class of tasks T and performance measure P, enhance its performance in T, measured by P, with the acquired experience E.

AI systems are present in many fields of medicine, such as image processing, therapy planning, medical database mining, disease diagnosis, etc, and, as stated in Section III, there is another system that helps research on chronic pelvic pain in the NUPEM. This system uses AI to help diagnose the real cause of chronic pelvic pain. The purpose of the system is not to replace the doctor or any other professional, but to help doctors to diagnose the cause of this complex condition, especially resident doctors, because, as mentioned earlier, this systems is being used in the University of São Paulo. The system can also be used to teach; e.g. with this type of system medical students can be asked to diagnose a situation and then compare their diagnosis to that made by the system and check whether they made a wrong diagnosis and why.

Chronic pelvic pain causes a lot of direct expenses and incapacitates women for work. Therefore it is extremely important to find the cause of this condition as soon as possible, and this type of AI system can help with this task.

IV. CHRONIC PELVIC PAIN RESEARCH

There are two basic research methods: quantitative research and qualitative research, which are defined by [17] as follows.

Qualitative research is based on a process of inquiry whose goal is the understanding of a social or human problem from different perspectives. The qualitative research is conducted in a natural setting and involves a process of building a complex scenario of the phenomenon of interest.

In contrast, quantitative research is the investigation of a known problem, based on testing a theory, measured with numbers, and analyzed using statistical techniques. The goal of this method of research is to determine whether the predictive generalizations of a theory hold true.

The chronic pelvic pain research carried out by NUPEM is a quantitative type of research and therefore is based on experiments conducted on a collection of data. On this basis, it is clear that the results of this type of research depend on the quality of the acquired data, and database systems together with structured forms provides the tools for the acquisition of more precise, good quality data.

Computing systems also provide a set of tools to handle these data. Imagine searching for a single characteristic among a large number of patients who filled out a regular paper form. It is easy to see that this task would be more difficult than searching a computer database that can be easily queried for specific data. In addition a computer system that handles these characteristics for a purpose can be set up to help the researchers.

As said before, this system also simplifies the sharing of information. With the advent of the World Wide Web the structured forms and the databases can be accessed from anywhere safely, breaking geographic barriers [18] and permitting the exchange of information among researchers over the world, democratizing research.

V. CONCLUSIONS

The electronic form is filled out within a time similar to that needed for a traditional form, it generates a completely legible report of fewer pages, without erasures or missing information, and contains the precise identification of the professional in 100% of cases. The users also stated that they were satisfied with the system, despite some initial signs of resistance. The best evaluations were obtained after the more significant considerations of the users were inserted in the system.

As could be seen, the use of computing enhances research by enabling the acquisition of better quality, more reliable data. It also improves the sharing of information and the handling of acquired data, providing tools for all of these purposes.

We showed here a successful case of the use of structured forms together with database systems in the University of São Paulo, with great improvement of filling time, data quality and interaction between systems.

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Table 1. User satisfaction degree (medical professional) according to Lickert scale.

Question								Score		P
Screen layout, flow, and ease of operation								1st phase	2nd phase	
1. Were you satisfied with the layout and sequence of presentation?	Dissatisfied	1	2	3	4	5	Very satisfied	3.1±0.9	4.8±0.4	<.0001
2. Were you satisfied with the organization of menus and lists of information?	Dissatisfied	1	2	3	4	5	Very satisfied	3.8±0.9	5.0±0.2	<.0001
3. Did you think that the information contained in the system is clear and understandable ?	Very difficult	1	2	3	4	5	Very easy	4.3±0.7	4.8±0.4	<.0001
4. How do you rate your learning of the new system ?	Very difficult	1	2	3	4	5	Very easy	3.4±1.0	4.9±0.3	<.0001
5. Would you be able to operate the system by yourself without help ?	Very difficult	1	2	3	4	5	Very easy	2.7±0.8	4.6±0.6	<.0001
System performance										
6. Were you satisfied with the performance of the system ?	Dissatisfied	1	2	3	4	5	Very satisfied	3.3±0.7	4.9±0.4	<.0001
General assessment										
7. Are you interested in this information system ?	Not interested	1	2	3	4	5	Very interested	2.7±0.8	4.8±0.4	<.0001
8. Do you think that the system permits you to report everything you want or need ?	Dissatisfied	1	2	3	4	5	Very satisfied	4.3±0.7	4.7±0.5	.0192
9. Which method do you prefer to process a new case ?	Free text	1	2	3	4	5	This method	3.0±1.2	4.5±0.6	<.0001
10. Were you satisfied with the legibility of the free text ?	Dissatisfied	1	2	3	4	5	Very satisfied	2.0±0.9	---	---
11. Were you satisfied with the legibility of the electronic report ?	Dissatisfied	1	2	3	4	5	Very satisfied	4.5±0.6	4.9±0.3	.0004

Note: The results are presented by mean±standard deviation. Mann Whitney test was performed since some variable not presented normal distributi