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ELECTRONIC BASE OF CLINICAL DATA OF STOMACH DISEASES

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ABSTRACT

***Background*:** Prospective epidemiological studies have more quality results than reviews of literature and meta-analysis. Today, a computer database is the best form to collect clinical information. The creation of one database for storing prospective patient information would result in high quality and trustful scientific studies. ***Objectives*:** To create a gastric disease clinical database; Creation of the software called electronic protocol of gastric disease to store this information in a computer database; To incorporate this protocol to SINPE® © (Electronic Protocols Integrated System). ***Methods*:** First, the clinical database of gastric diseases was made. Textbooks and journal articles were used to collect the specific information about thirteen gastric diseases: gastric bezoar/foreign body, acute gastric dilatation, dyspepsia, peptic ulcer disease, gastric motility disorders, gastric diverticulum, gastritis, upper digestive hemorrhage, gastric tumor, gastric polyp, gastric perforation, postoperative gastric syndromes, and gastric volvulus. After, the database was stored in the software developed in the Multimedia and Informatics Laboratory in the Health Studies Sector of the Federal University of Parana. During the database storage, two kinds of electronic protocols were created: the master and the specific protocol. The main clinical data that refers to gastric diseases was stored in the master one. The specific protocols were created from the master one, considering the characteristics of each disease. To complete, this electronic database was incorporated into SINPE® ©. This program is registered on INPI (National Institute of Industrial Property) under nº 00051543, from Prof. Dr. Osvaldo Malafaia's intellectual property. ***Results*:** This electronic protocol allows the patients collected data to be used to produce scientific studies. After registering the patient, the collector chooses one disease in the specific protocol. Then, the selection of clinical data based on direct questions is made to the respective patient. This data to be recovered and statistical information becomes possible. ***Conclusions*:** The creation of a clinical database was completed; It was possible to store the clinical data in a computer by the creation of specific software; The electronic database of gastric diseases is now incorporated to SINPE®.

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INTRODUÇÃO

The creation of new knowledge is a constant challenge for medicine. The spectrum of clinical research is broad, ranging from studies of disease pathogenesis to normal human physiology, clinical epidemiology, prevention, health status, intervention studies, evidence-based medicine, and clinical trials (Chan, 2002). As clinical research is carried out on human beings, with all the limitations that this research context offers, the epidemiological method represents a basic source of methodological support for this enterprise (Rouquayrol, 1994). The quality of scientific information in the medical field is related to the methodology applied in clinical epidemiological studies. The design of the study, the reliability of data collection, and its subsequent analysis influence the accuracy of the results and their conclusions (Pereira, 1995). According to Blettner, the main lines of conduct of an epidemiological study currently used are literature review, meta-analysis, re-analysis of individual data, and prospective study (Blettner, 1999). The traditional literature review evaluates a specific subject in a qualitative way, not considering the methodology, trends, and errors in the articles consulted. It has the advantages of less time and reduced cost (Dickersin, 1990 and 1997). The meta-analysis is a quantitative summary of the main data studied on a given topic, based on bibliographic reviews. It uses previously established protocols to select the studies consulted, making the publication more reliable (Friedenreich, 1993). There is also a need to tabulate the relevant elements of each study, such as sample size and

homogenization, available variables, study design, year of publication, and other data considered relevant. The objective is to cancel trends and avoid errors that limit the quality of the information generated (Stewart, 1995). Data re-analysis emerged in an attempt to minimize the possibility of errors. They are used mainly in the study of rare events, where a significant number is not reached in individual studies. In addition to the mandatory agreement of the authors of the original works, it is expensive and time-consuming than the review and meta-analysis (Lubin, 1995).Estudos prospectivos de coleta de dados apresentam o melhor nível de evidência científica. The main difference of this form of work, in relation to the meta-analysis, is in its planning of collection and subsequent analysis of the data. Thus, they have a higher cost than other forms of study and need more time to obtain the results (Boffeta, 1997). The systematic literature review, meta-analysis, and data re-analysis are considered sources of high-quality scientific information, however, the prospective study is considered superior to the others (Goodacre, 2003).

The Computer in Medicine: It can be said that the development of the computer began more than 5000 years ago, with the invention of the oriental abacus, a rudimentary calculus instrument. Only in the 17th century did the mechanical adder created by Pascal appear. At the same time, Leibnitz designed a mechanical multiplier. The first machine with similar characteristics to a computer was designed in the middle of the 19th century by Babbage, followed by Hollerith who at the beginning of the 20th century built the first data collection machines by means of automatic card drilling (Ashurst, 1983). You can also divide the evolution of the modern computer into 4 periods: until 1940 - with the creation of machines analogous to computers; 1940 to 1947 - first-generation; 1947 to 1960 - second generation; and after 1958- third generation, with the invention of the microchip by Kilby and Noyce and the microprocessor by Ted Hoff. The first generation of computers had an electronic valve as a basic component. The second-generation used transistors and then printed circuits. The third generation appeared in the mid-sixties, bringing the integration of circuits (chips), which increased the speed and decreased the volume of the machines. Advances continue today, but in smaller and more frequent jumps, with great improvement in data processing and storage capacity available in today's versatile and highly complex computers (Holland, 1971; Covvey, 1978; Martinez, 1982). Despite the widespread advancement and use of the computer in the various areas of economic activity, its initial use in medicine was restricted to the administrative aspect (Barnett, 1984).

In 1958, LIPKIN published an article for clinical use on an electronic system of perforated cards, with basic computer principles, to make the differential diagnosis of hematological diseases. Schenthal (1960) reported a pilot study initiated in 1959, in which he created an archive of patient data. In the surgical area, the first description of data collection using a computer was in 1971 by BLACKBURN and HOLLAND, followed by LISTER who, in 1974, used information technology to create a file system for classifying diseases in plastic surgery. In Brazil, Rocha Neto (1983) described the importance of the Medical File System (SAME) to be computerized, as it facilitates the recovery of stored data, which will contribute to the development of health sciences, facilitating medical teaching through research scientific research, or even for better management of the hospital structure. Subsequently, Blumeinstein (1995) reported the need to create a system of interconnected computers, for the collection and storage of reliable data, highlighting the importance of the quality of the information obtained. The benefits of technology were described by NAKAMURA in 1999, highlighting the important contributions of the computer in laboratory diagnostics and health care. Computerization in data collection is of fundamental importance not only in improving the quality of information but also in the possibility of interconnecting computers and institutions, which would enable the expansion of data collection and storage in a more reliable and multicentric way.

Computer Science in Scientific Production: With the evolution of information technology in recent years, easier access to computers and especially to the Internet, which eliminated geographical limitations and information restrictions, immediate access to the latest clinical research results became possible (Clayton, 2001). There are more than 70,000 pages available on the Internet on medical matters (Bereczki, 2002). Doctors use it for three main purposes: quick access to information, assistance in clinical and diagnostic decisions, and electronic communication with their patients (Kerse, 2001). Hence the importance of quality clinical studies so that there is continuous scientific development in the field of medicine, especially in the surgical area. This initiative allows doctors and students to have secure access to new information with the consequent improvement of their knowledge. Most large hospitals in the United States of America have numerous databases directly linked to the administrative, operational, and financial areas (Khan, 1994). However, most electronic databases focused on clinical activity are related to laboratory, pharmacy, or radiology exams (Dick, 1992). There are still few protocols developed for exclusively clinical purposes, and databases with this profile are, to a large extent, installed in medical-academic centers. The use of these electronic protocols for clinical research centers brings, as a result, inserted in the collected data, and indisputable control of scientific quality (Siegel, 1987). The constant innovations of science and the interaction of the world medical community have raised the level of quality of research in the most diverse areas of medicine. Currently, it seems that the best way to collect data prospectively is based on the creation of electronic protocols, due to the ease of data collection, organization, and archiving.Medical informatics makes it possible, through the making of an application (software) connected to a data storage source, to carry out prospective clinical studies with the same format.

The Computerized Protocol: In 1999, the line of research called "Computerized Protocols" was implemented by the Informatics and Multimedia Laboratory of the Postgraduate Program in the Surgical Clinic of the Health Sciences Sector at the Federal University of Paraná. Today, this line is incorporated into SINPE® (Integrated System of Electronic Protocols). This computer program and this system are the intellectual property of Prof. Dr. Osvaldo Malafaia and registered with the National Institute of Industrial Property (INPI) under number 00051543. The proposal to manage an electronic means of creating and filling out protocols is well-founded on scientific work, presented at the International Symposium on Knowledge Management, which took place in 2003 (Malafaia; Borsato; Pinto, 2003a).The present study is part of this line of research and is aimed at stomach diseases. This organ is affected by several diseases of high prevalence and incidence (motility disorders, ulcerative disease, benign and malignant neoplasms, acute and chronic inflammatory diseases, among others) and is considered a rich source of study by digestive tract surgeons. The prevalence of peptic ulcer disease is 5.0% of the studied populations, with an incidence of 0.02 to 0.15%, considering gastric and duodenal ulcers. In our country, it has a higher prevalence in men, and it can lead to complications of varying severity and death (Coelho, 2004). Another relevant disease worldwide is gastric cancer, despite the decrease observed in its incidence. Japan still has a high incidence and mortality, despite efforts in early diagnosis and the various surgical and adjuvant treatment modalities. Other diseases of universal distribution that affect this organ are gastritis, volvuli, polyps, diverticula, and motility disorders, among others of lesser relevance. Due to the high prevalence of stomach diseases in the various tertiary hospitals in the country, and to better take advantage of a large amount of information obtained with the admission of these patients, the creation of a database in electronic and computerized form for the collection was idealized. continuous prospective. This protocol aims to encompass gastric diseases in the adult population. So it is to be considered that despite the high prevalence of some of them, there will be rare diseases and that, even with time, they will not have covered a sufficient number of data for credible research. Specifically considering this situation, the solution seems to be the interaction of several centers with these clinical databases. Thus, the sum of several medical institutions in the contribution of completing the same protocol would, in less time, lead to a more expressive and significant number of data. The objectives of this work were to create a clinical

database referring to stomach diseases through the standardized collection of information, to computerize this base in the form of software for the systematic collection of data from patients with stomach disease, to incorporate this electronic protocol into the Integrated Electronic Protocols System (SINPE®).

METHODS

The "Electronic Database of Clinical Data on Stomach Diseases" is a descriptive study and respects the rules for the presentation of scientific documents from the Federal University of Paraná in 2000.The methodology applied in the development of the electronic protocol can be didactically divided into three phases:

Creation of the protocol and clinical data collection process for stomach diseases: The development of a theoretical database of clinical data aims at its future inclusion in the computerized electronic protocol. The general aspects of the research were pre-established for stomach diseases, considering only the population over the age of fourteen, consequently excluding congenital and childhood diseases. This first stage could be subdivided: bibliographic review of the chosen subject, collection of data from the specific literature and formatting of the protocol before computerizing it. After choosing the topic to be worked on in the preparation of the future database of stomach diseases, five textbooks with an extensive approach to the subject were selected. Two of them covering general surgery: Sabiston Textbook of Surgery: The Biological Basis of Modern Surgical Practice (SABISTON, 2002) and Principles of Surgery (Schwartz, 2001); two for digestive tract surgery: Digestive Tract Surgery: A text and Atlas (BELL, 1996) and Digestive Apparatus - Clinical and Surgical, (COELHO, 2004) and one for gastroenterology: Sleisenger & Fordtran's Gastrointestinal and Liver Diseases (Sleisenger, 2002).

After a horizontal study of these books was carried out, it was possible to divide thirteen diseases related to the stomach. Since then, extensive research has started in search of scientific articles published in medical journals referring to each of the nosological entities in question with the intention of deepening the theme and its specific data. This research was carried out through an active search on the Internet at the addresses:http//:www.periodicos.capes.gov.br and http//:www.bireme.com.br,in the databases MEDLINE E LILACS. The following sites were also used: http//:www.medscape.com, http//:www.mdconsult.com and http//:www.gastronews.org.brwith their respective search tools and database. Information was collected in articles published about each disease from 1999 to 2004. The research was based on literature review articles, scientific articles focused on data collection and published clinical cases. The articles published before 1999 and used in this work were found from references in textbooks or initial articles. After the search for the different data sources, the information was organized. Considering the future applicability of the protocol in relation to the collection of clinical information for quality scientific research, it was necessary to establish in advance some work guidelines in the making of the database. Firstly, the need to create something with vast literary content, but that was simple for the user to fill it quickly and effectively. It was then decided to make the questionnaire direct and objective.

Only the patient's personal identification data were considered, in part, of a subjective character. They are: name, date of birth, sex, identification (through medical record number and personal record), date of hospitalization, in addition to the date of discharge or death of the patient. From this basic information, the entire protocol was formulated in a closed manner, that is, with direct options. This also facilitates the future comparison of results after the introduction of clinical cases. The 13 stomach diseases selected followed the same assembly line, respecting their individualities and characteristics. The diseases studied were arranged and related, as far as possible, according to the International Statistical Classification of Diseases and Related Health Problems-ICD-10 (World Health Organization, 1997). The following are the 13 diseases, in alphabetical order, and their correlation to ICD-10:

1 Bezoar / Gastric foreign body (ICD: T18.2)
2 Acute gastric dilation (ICD: K31.0)
3 Dyspepsia (ICD: K30)
4 Peptic ulcer disease (ICD: K25 and K 26)
5 Disorders of stomach motility (ICD: K30) 6- Gastric diverticula (ICD: K31.4)
7 Gastritis (CID: K29)
8 Upper gastrointestinal bleeding (ICD: K92.2)
9 Gastric neoplasia (Malignant - ICD: C16; Benign - ICD: D13.1)
10 Gastric polyp (ICD: D 13.1)
11 Gastric rupture (ICD: K31.8)
12 Syndrome after gastric operations (ICD: K91.1) 13-Volvo gastric (ICD: K31.8)

Despite the individuality of each disease, there were many options common to all. This occurred because data such as clinical picture, most commonly associated diseases, associated chronic diseases, diagnostic tests, treatment, and post-treatment complications are necessarily inserted in the clinical context of any patient with stomach disease. The 2173 data collected from the survey were grouped into 11 main items: Signs and Symptoms, Risk factors, Morbid history, Laboratory tests, Endoscopic examination, Radiological tests, Anatomopathological examination, Staging and classification of gastric neoplasms, Differential diagnosis, Therapeutics, and Evolution post-treatment, respecting the clinical form and natural chronology of related diseases. As a final result of this phase, the theoretical base of clinical data on stomach diseases was created.

***Development of the computer program until the integrated system of electronic protocols* (SINPE®):** The second step consisted of choosing the methodology for computerization as well as its development. The data computerization process was developed at the Informatics and Multimedia Laboratory of the Graduate Program in the Surgical Clinic of the Health Sciences Sector at UFPR based on the intellectual property software of Prof. Dr. Osvaldo Malafaia and registered with the National Institute of Industrial Property - INPI under number 00051543. With the creation of the medical informatics research line, it was possible to implement the computerization of the logical model of the protocol that has been constantly improved by technicians in data processing Dice. The latest version, developed in 2003 and called the Integrated Electronic Protocols System (SINPE®), is currently in use.

The software makes it possible to transform the theoretical basis of clinical data, developed with the bibliographic review, into a computerized data collection system. This database was computerized, using an Access gerencia database manager program. The computer program was programmed with the C # computer language, using Microsoft's .net technology, which organizes, feeds, and manipulates the data that is stored. This computerized system allows the distribution to be on CD-ROM, facilitating access to the program and also with possible collections and research of multicentric data in an online way. The installation of this program on CD-ROM is simple, requiring computers configured, at least, with the Microsoft Windows 98 operating system with 32 megabytes of RAM and a 500-megabyte hard disk available. Once installed, an icon called “SINPE® 2003” will appear on the monitor screen (Desktop). It should be noted that the Windows system must be correctly updated with Microsoft products called .net Framework 1.1 and Microsoft Data Access Component 2.7.To facilitate your training and later use of this CD-ROM, two protocols were created: the master and the specific. The master protocol is the result of all the information made available after the bibliographic review in textbooks and internet searches for stomach diseases. Specific protocols are formed based on the selection of folders contained in the master protocol directed to each of the thirteen main gastric diseases previously selected. Once installed, SINPE® will ask the user for the access code (login and password), and the institution that the user belongs to. If the access

code is valid, SINPE® checks and releases the system according to the user's permissions.Four types of permissions can be granted to users for each protocol, which are:

- **Administrator:** allows the user to define the items of a master protocol and specific protocols; collect patient data for diseases registered in specific protocols; research the data collected and change protocols when necessary;
- **Viewer:** allows viewing of items from the master protocol and specific protocols only;
- **Collector:** allows the user to only collect data for diseases registered in specific protocols;
- **Researcher:** allows the user to perform data searches on the collections made.

To facilitate installation, user control, and their respective access, the SINPE® User Manual (Integrated Electronic Protocols System) (MALAFAIA, BORSATO; PINTO, 2003b) is available for consultation.

Computerization of the theoretical base of clinical data - master protocol and confection of specific protocols: After selecting the master protocol, the option to enter is accessed, placing a new protocol name (Electronic Protocol for Stomach Diseases), and its respective area of activity (Medicine). The system used to load the theoretical database of clinical data in the master protocol is based on a set of data, arranged hierarchically, on items and sub-items distributed in different generations and created using two simple commands: the Add brother command and the command Add child, which define your information content. Respecting the clinical order of stomach diseases, the configuration of the master protocol started with the item Signs and Symptoms and later adding the following sibling items: Risk factors, Morbid history, Laboratory tests, Endoscopic examination, Radiological examinations, Anatomopathological examination, Staging and classification of gastric neoplasms, Differential diagnosis, Therapeutics, and post-treatment evolution. The next step was the insertion of the sub-items, called children, which belong to a later generation. SINPE® allows the visualization of the items in a tree structure in which it is represented by the positive sign (+) to the left of the item, indicating that it has children (subitems).

The items entered in the master protocol can be modified at any time by the administrator user using the Remove and Update commands.In the end, 2173 data from the theoretical basis of clinical data on stomach diseases were inserted in the master protocol, that is, items related to all gastric diseases.Specific protocols were created using the Select a Specific Protocol command, making a total of thirteen: Bezoar/Gastric foreign body, Acute gastric dilation, Dyspepsia, Peptic ulcer disease, Stomach motility disorders, Gastric diverticula, Gastritis, Upper gastrointestinal bleeding, Gastric neoplasia, Gastric polyp, Gastric rupture, Post-gastric syndrome, and Gastric Volvo. From the master protocol, it was possible to create the items of the specific protocols, using the command of an arrow directed to the right, selecting the items and sub-items contained in the master protocol. Similar to the master protocol, these items can be modified at any time.The eleven items contained in the master protocol are common to all specific protocols, and the distribution of the sub-items depends on the specific issues related to each disease. The data collected by the collector user begins with the registration of the patient, through the command Patient, located at the top of the screen, presenting the main data for registration. Also at the top of the screen is the Data command, used to collect clinical data on stomach diseases and also for future research, even allowing options for delimiting the research, with the data collected from specific protocols.

Implementation of the electronic protocol of diseases of the stomach in sinpe® (integrated system of electronic protocols): All items and sub-items (2173) of stomach diseases were computerized and incorporated into SINPE®, through a computer program developed for the creation and manipulation of the master protocol and the specific protocols. This program was created to enable researchers, who define protocols (master and specific), to perform these tasks remotely through local networks or over the internet. To allow the system to work independently of the network, it is also possible to build protocols, using a database of the program itself (local connection). In addition to the manipulation of protocols, SINPE® allows data to be collected for the diseases defined in specific protocols. This collection can be done in a multicenter environment (several health service institutions) and all data stored in a central database. With the collection of data from several institutions, SINPE® allows for the conduct of prospective multicenter researches online. Surveys can be carried out using parameters (such as the period of collection, items collected, etc.) defined by the researcher/specialist himself. The product of these surveys is the statistical survey of data items collected for a specific protocol.

It can be seen that SINPE® allows researchers/specialists in the health field great flexibility, as they are the ones who will inform the system which data items should be considered in a collection and, later, their research. Also, it is possible to increase data collections only by inserting new data items in the protocols already defined. Therefore, SINPE® allows an upgrade in its operation but is performed only by the administrator user. For ethical reasons, SINPE®, because it can be multicentric, does not allow patient identification data (from a specific institution) to be viewed by users who do not belong to the institution where the patient is registered. Therefore, a user access control system and the respective permissions of these users are integrated into SINPE®.

RESULTS

The results were demonstrated using the Electronic Stomach Disease Protocol. They can also be accompanied by the CD-ROM. After installing the stomach disease clinical data CD-ROM, the program runs the initial screen with the presence of the SINPE® icon. After clicking on the SINPE® icon, the figure that defines the type of connection the user wants will appear on the screen. If it is local, the connection will be based on local data; if it is remote, there will be a need for the internet (under development). To exit the program, just click the Exit button. After clicking the Next button, the system will ask for user login information. The login (name) of the user, his respective password, and the institution he belongs to presented, defining, then, what type of user he is (Administrator, Viewer, Collector or Researcher).

Then, the selection of the master protocol with the user's permission type, previously selected in the previous item. Remembering that only the administrator user has access to the master protocol. The main screen of SINPE®, with its respective menu bar (Protocols, Data, Patients and Help), appears at the bottom the name of the user, which institution he belongs to, the name of the protocol, what type of user, and connection information. By selecting the Protocols option in the menu bar, the administrator user will have access to the master protocol or specific protocol. The data of the master protocol, date of creation and last update, health area to which it belongs, total items of this master protocol (2173), and the eleven main items that make up this protocol are displayed: Signs and Symptoms, Risk factors, Antecedents morbid, laboratory tests, endoscopic examination, radiological examinations, anatomopathological examination, staging and classification of gastric neoplasms, differential diagnosis, therapeutics, and post-treatment evolution. Also appears at the bottom of the screen, keys for Add brother (add the main item), Add a child (to add subitems), Remove (remove items), and Update (update items). On the right side, there are spaces for the details of the selected item, such as description and explanation of the item, type of selection, associated value, sound, image, or video. The sub-items of Signs and Symptoms are data referring to clinical history, listing all symptoms, signs, and other findings pertinent to stomach diseases, such as abdominal pain, abdominal distension, vomiting, weight loss, and others. The sub-items of the Risk Factors of stomach diseases are Dietary factors, Environmental factors, Hereditary factors, Ethnic factors (ethnicity), and Psychosomatic factors. The sub-items related

to the main item Morbid history are Personal history and Family history. The sub-items of laboratory tests are as follows: blood count and biochemistry, liver function test, blood culture, occult blood in the stool, the culture of intra-abdominal secretion, tumor markers, acid secretion tests, and research on molecular changes / genetic markers.The Endoscopic Examination item issubdivided into Normal upper gastrointestinal endoscopy, Altered upper gastrointestinal endoscopy, Ecoendoscopy, and Technetium-90 endoscopic injection for lymph node mapping.

The sub-items of Radiological Examinations are Abdominal X-ray, Chest X-ray, Contrast esophagus-stomach-duodenal radiography (SEED), Transabdominal ultrasound examination, Computed tomography examination, Abdomen magnetic resonance examination, Examination for emptying study gastric, Biliary scintigraphy with HIDA / Tecnécio-99 and Enterogastric scintigraphy with DISIDA / Tecnécio-99. The main item Anatomopathological Examination is subdivided into Benign primitive gastric tumors, Malignant primitive gastric tumors, Gastritis, Peptic ulcer disease, Gastric polyp, Helicobacter pylori, Intestinal metaplasia, Other forms of metaplasia, and Dysplasia. The subitems of Staging and classification of gastric neoplasia are as follows: Staging not determined / Not described, TNM system for staging gastric cancer (WHO), Staging by the Japanese Society for Gastric Cancer Research, Staging of primary gastric lymphoma (LGP), Classification macroscopic analysis of gastric cancer, Histological (microscopic) classification of gastric cancer, Description of surgical margin, Description of vascular invasion and Perioperative freezing. The item Differential Diagnosis refers to the subtypes and classifications of different stomach diseases. Its subitems are: Gastric motility disorder, Dyspepsia, Gastritis, Peptic ulcer, Upper digestive hemorrhage, Gastric diverticulum, Acute gastric dilation, Gastric rupture, Gastric Volvo, Gastric gouging, Foreign body, Gastric tumors and Gastric tumors. When accessing the Specific option of the Protocols item, the screen for registering and accessing specific diseases on the stomach will appear. Selecting this option, the next screen will appear that shows the specific protocols already registered and allows the registration of new ones.

The registration of new specific protocols starts with the Insert option, then the name of the chosen disease is entered and then the Record key is used. Consequently, the name of this new registered disease will appear in the lower space of the screen and in the item Specific registered protocols. After registering the new specific protocols and selecting the Specific item again, one of the protocols can be chosen in the selection box on the right side of the figure. In total, thirteen specific protocols were developed: Bezoar / Gastric foreign body, Acute gastric dilation, Dyspepsia, Peptic ulcer disease, Stomach motility disorders, Gastric diverticula, Gastritis, Upper digestive hemorrhage, Gastric neoplasia, Gastric polyp, Gastric rupture - gastric operations and gastric Volvo. After elaborating the specific protocols, one of them, in the case Peptic ulcer disease, was chosen to incorporate the items that will compose the demonstration of the functioning of this protocol. This is done by selecting the item in the master protocol (left side of the figure), clicking the selection command (arrow) to the right, where the selected item will appear on this side of the figure. In this case, the selected item was Signs and Symptoms of stomach diseases. Following the same rules as in the previous figure, the items Risk factors, Morbid antecedents, Laboratory tests, Endoscopic examination, Radiological examinations, Anatomopathological examination, Differential diagnosis, Therapeutics and post-treatment evolution of the master protocol were selected to subsequently incorporate the specific protocol on the right of the screen.

This program allows the administrator user to remove, when deemed necessary, any item of the specific protocol for the master protocol. In this figure, the sub-item of the Laboratory exam called Research of molecular changes/Genetic markers, was removed from the specific protocol, through the arrow on the left. All items of the master protocol and consequently of the specific protocols can be modified at any time by the administrator user, using the commands contained in this Remove program. To start the registration of a patient, it is necessary to access the Patient icon in the main menu and then the Registration command. A figure will appear on the screen, which will allow you to fill in the patient's data (code, name, race, sex, profession and others). Then, the data is saved using the Save command. The list of registered patients appears at the bottom of the screen with the items: Name of the patient, Institution to which he belongs, Date and User identification. After registration, data collection begins with the option Data and then the command Collect. Then, using the View/Edit Collection command, a figure will appear containing the list of Data Collections already performed, the Identification of the collection in the protocol, the Number and Name of the patient, Name of the specific protocol and the User, as well as the date. There is also the New Collection command on this screen, which, if accessed, will start a new data collection as will be shown below.For a new data collection, it is necessary to select the specific protocol (disease) and the registered patient; then select the Next option.

On the data collection screen, the name of the patient, his specific protocol and the health area he belongs to appear. With the clinical data from the medical record, the collecting user selects the items available in the electronic protocol. Example: Specific protocol: Peptic ulcer disease, with the following items selected: Risk factors: Dietary factors - Coded foods and Foods rich in salt; Environmental factors - Alcohol, Quantity, 20 to 50 grams / day, always observing the natural clinical and chronological form of any disease. The details of this collection will automatically appear on the right side of the screen and the commands Save and Finalize to file the selected data and end the collection, respectively. To perform a search for clinical data on stomach diseases, use the option Data and then Search, in the access menu. A figure will appear that allows the selection of a specific protocol, the type of research, the period of collection and the list of institutions used in this research. In the bottom left, are the research items previously selected; and at the bottom right, the parameters of the selected item, its statistical results, localized collections and the details of the item for research. After performing the previous steps, the Start Search command is used to obtain the selected collected data and statistical results. After selecting an item for analysis of results, the number of collections appears on the first screen; in the second, the statistical information of the research (number of collected collections and the percentage of occurrences); and in the third, the list of collections found in the survey.

DISCUSSION

When idealizing a descriptive scientific study, it comes up against the difficulty of obtaining quality information due to the inadequate filling of medical records, the lack of coordination and standardization of the descriptions contained and, sometimes, the illegibility of this information, characterizing subjectivity with compromising the results obtained (DICK, 1991; RIND, 1993; TANG, 1999). Most medical and hospital centers have databases focused on administrative, operational, and financial areas. The use of information technology for the collection of clinical data from patients is practically restricted to laboratory, pharmacy, and diagnostic tests, even so in a simplified way. The development and implementation of a computerized data collection would facilitate the subsequent search for information, allowing for the constant updating of data in an organized manner, and future related research. However, the greatest difficulties would be the high cost of acquiring computers and programs and the lack of human resources capable of providing adequate maintenance after their implementation. Considering that both medicine and information technology are constantly evolving, a good database should allow changes in its structure to accompany this development, step by step. In large medical centers in the United States and Europe, information technology has emerged as an alternative to solve this problem, that is, carrying out the filling of medical records in the usual way and, simultaneously, collecting relevant clinical data in a standardized way with the use of computers, avoiding the limitations and the subjective character of these records (McDonald, 1992; Sitting, 1994; Kohane, 1996). The purpose of these electronic protocols for collecting clinical data is not to replace medical records, but to create a reliable and

secure source of information. Medical research conducted with the collection of clinical data prospectively, with the use of electronic protocols in a targeted manner, in addition to the little physical space required for its operation and the possibility of analyzing these collected data, would increase the credibility and the possibility of the structuring of quality scientific studies (Weinberger, 1997; Mcdonald, 1998). Thus, descriptive studies using large electronic databases can provide greater quality and reliability to medical research (Goonan, 1995; Davidoff, 1997).

The use of a prospective data collection program in patients with Acquired Human Immunodeficiency Syndrome (AIDS), and the subsequent analysis of this information, has transformed the University of Alabama into the United States' main referral center for the respective disease (LEE, 1994). Another important point is that the use of the clinical database for study and research can serve only one institution or be multicentric. Its use by a single institution serves to determine the clinical profile of the population studied. When multicentric, the research acquires more comprehensive and reliable general and specific data. In cases of rare diseases, the use of multiple centers for the study would allow a larger sample and, consequently, more accurate information. In France, about 38 Intensive Care Units (ICUs) use standardized clinical data and are stored in a single database (LOIRAT, 1989). In 1991, COLTORTI published the results of an Italian multicentre study on liver diseases in that country. In Brazil, the Brazilian Association of Intensive Care Medicine (AMIB) maintains an online electronic database (<www.amib.com.br>) where it is possible to access information from the main Brazilian ICUs, thus allowing data exchange and also the quality analysis of each registered unit. Thus, the collection of computerized clinical data would stimulate the development of multicenter studies, increasing the number of available data and improving the quality of scientific works (Blumeinstein, 1995), also providing a reduction in research time, an increase in the population studied and faster and more accurate results (Pereira, 1995). The elaboration of the "Electronic Basis for the Collection of Clinical Data on Stomach Diseases" followed the line of research created by Professor Doctor Osvaldo Malafaia for the prospective collection of clinical data. Described by SIGWALT in his master's dissertation in 2001, the principles are related to the creation of a computerized clinical data collection protocol capable of generating, in a prospective way, a quality database, characterized by simplicity in its form and completion. generation of information (Sigwalt, 2001).

The elaboration of the electronic protocol for stomach diseases proceeded after a search in the world literature regarding the chosen theme. The criteria adopted for the bibliographic review were the consultation of five specific textbooks in the area of digestive system and of national and international recognition. This research was complemented and updated with the search, on the internet, of scientific articles published in the last six years (1999-2004), gathering sufficient and representative data for the elaboration of the protocol. The database was designed to cover almost all subjects related to stomach diseases, avoiding the excess of non-relevant information that could compromise the practicality of collecting this data.Since 1999, the Informatics and Multimedia Laboratory of the Postgraduate Program in Surgical Clinic of the Health Sciences Sector of the Federal University of Paraná has been developing an important project for the computerization of clinical data for research purposes. This project initially called “Electronic Protocols” was conceived and by Prof. Dr. Osvaldo Malafaia and coordinated by Professors Emerson Paulo Borsato and José Simão de Paula Pinto. This electronic database has undergone several modifications and improvements and, currently, the latest version of this program is used, which was developed in 2003 and is called SINPE® (Integrated System of Electronic Protocols). The electronic protocol was programmed in Microsoft® C + language and was executed on the .net Framework® program. This implementation allows the system to be easily adapted to other types of programs, such as the internet and handheld computers, in addition to allowing installation via CD-ROM, featuring portability and greater potential for use and evaluation of the system. An Access® data management program was used to store and organize clinical data on stomach diseases. The file created by Access® was used to allow the electronic protocol program (SINPE®) to be used independently from other computers. Access® was chosen as a management system because it is simple, facilitates data manipulation and allows it to be analyzed using the Excel® program. Naturally, after defining the master protocol and specific protocols, it is possible, with the help of IT professionals, to export this data to a server, allowing the defined protocol to be shared with other users or authorized institutions. The program can also be run on CD-ROM, which allows the information collected and stored on the computer to be transferred from one center to another. Currently, over 100 diseases are already registered with SINPE® with approximately 100,000 data items ready. These diseases cover several areas of medicine such as diseases of the digestive system, urinary tract and plastic surgery. The program structure, in which SINPE® was developed, allows other programs to be built to manipulate protocols in the short term. These other programs can be:

1- Internet Browser programs (eg Internet Explorer) that are already in use;
2- 2-Programs for mobile computing (eg Pocket PC, cell phones, etc.).

The flexibility of access to SINPE® is made possible by the program structure that was defined:

1- Database: which stores the information of the electronic database;
2- System core (Protocol Framework): which manipulates and manages the information of the protocols;Interface para o usuário: permite ao usuário (profissionais da saúde) utilizar o sistema para construir e definir a sua base eletrônica. Esta interface foi desenvolvida para sistemas operacionais *Microsoft Windows 98*® ou superior e, atualmente, já utilizando a internet para coleta dos dados (executados em *browser*). Estão sendo testas versões para os computadores de mão (*Pocket PC* e *PalmTop*).

Specifically on the electronic protocol for stomach diseases, from the creation of the master protocol to the final development of specific protocols, an attempt was made to follow a clinical and didactic order to facilitate the understanding and use of the program. As a result, when launching patient data, the user will find an electronic protocol elaborated in a coherent way, in the following order: anamnesis, history and clinical picture, complementary exams, therapy, post-treatment complications, and post-treatment evolution, is this the last filled out during the outpatient control of the patient. Due to a large amount of information, the protocol was synthesized in this dissertation in order to highlight the main steps for its use and operation, trying not to lose its scientific character at any time. It is worth mentioning that this electronic protocol cannot be modified, in its original structure, by collecting users, viewers, or researchers, with only the administrator user being able to change this database. However, due to advances and novelties in the medical field, this electronic protocol allows the insertion of new items, without changing the database already used.

The protocol in question contains only direct filling alternatives. The advantage of using this model with closed registration options, in relation to simple data entry, is that it avoids subjective information that hinders the subsequent analysis of clinical research results. As the closed questionnaire can limit or hinder the collection of some information, the ideal format would be the combination of a protocol with a predominance of direct (closed) options and some open questions for data entry (Bolling, 2000). In the future, improved versions of this software will include open-ended questions, making it more versatile and complete. It is worth mentioning that the best understanding of the installation, user control, their respective accesses, guidance on data collection and research, among other information, are available for consultation in the SINPE®® User Manual (Malafaia; Borsato; Pinto, 2003b).Finally, this electronic

protocol will be implemented for prospective data collection in the hospital routine in order to validate and continuously improve it.

CONCLUSION

The elaboration of this work allows us to conclude that the creation of the clinical database, related to stomach diseases, was possible using the methodology used in the research line. The computerization of the database was made possible in the form of a master protocol and its specific protocols on gastric diseases, providing means for collecting data from patients, as well as retrieving this information in an organized manner for use in scientific studies. With the final development of this computerized protocol, it was incorporated into the Integrated Electronic Protocols System (SINPE®).

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