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IMPLEMENTATION AND VALIDATION OF THE INTEGRATED SYSTEM OF ELECTRONIC PROTOCOLS (SINPE ©) ON DISEASES OF THE DIGESTIVE APPARATUS IN THE HOSPITAL OF CLINICS: A BRAZILIAN STUDY FROM THE FEDERAL UNIVERSITY OF PARANÁ

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ABSTRACT

***Introduction*:** Electronic protocols for prospective data collection tend to stand out with regard to the quality of the results obtained. Standardized and computerized data are considered reliable, highly accurate, and of great scientific value. With the creation of computerized protocols in the various diseases of the digestive system and its incorporation into the Integrated Electronic Protocols System (SINPE©), it became necessary to verify the functioning, applicability, and validation of the system. ***Objective*:** 1 - The implantation of SINPE © related to diseases of the digestive system at Hospital de Clínicas da UFPR; 2 - Application of these computerized protocols through prospective data collection; 3 - Validation of SINPE through research on the database. ***Material and Method*:** Eight electronic protocols developed on digestive diseases were used: Esophagus, Stomach, Small intestine, Colon, Rectum and anus, Liver, Extrahepatic bile ducts, and Pancreas. The system was installed and implemented in June 2005. In the following 18 months, training and systematization of collections were completed. The preparation of the database, with prospective collections, was carried out between January 2007 and July 2008 in patients admitted to the Digestive System Surgery Service of Hospital de Clínicas - UFPR. For data research, SINPE©'s own research tools and the Analyzer software were used. The research was carried out on each of the eight protocols to test the versatility and functioning of SINPE© and, subsequently, the preparation of scientific works. ***Results*:** There were 490 collections, 59.8% of which were female patients. The specific protocol for chronic lithiasis cholecystitis presented the largest number of collections (116 cases), followed by gastro-oesophageal reflux disease (94 cases). The median age ranged from 34.7 to 58.2 years, depending on the studied protocol. The research carried out showed in detail the data on each disease. These data were structured in prospective scientific studies that were sent, accepted, and presented at the VIII Week of the Digestive System (2008), which are: Postoperative complications and recurrence of gastroesophageal reflux in the first year of surgical treatment: the study of 400 cases; Diabetes and acute cholecystitis in the age of video laparoscopy: pre-and postoperative complications among diabetic and non-diabetic patients undergoing cholecystectomy; Early symptom recurrence in patients with gastroesophageal reflux disease (GERD) with typical and atypical symptoms submitted to video laparoscopic fundoplication (VFL); and Electronic database of clinical data on stomach diseases. ***Conclusions*:** 1- The implantation of SINPE © related to diseases of the digestive system was successfully carried out; 2- Prospective application of computerized protocols for diseases of the digestive system was possible; 3- The validation of SINPE © was obtained through research on the database, showing its adequate functionality and versatility in the elaboration of quality scientific publications.

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INTRODUCTION

Carrying out quality scientific research is essential for the continuous development of medicine, especially in the surgical area. This initiative allows doctors and students to have secure access to new information and, consequently, improve their knowledge. A relevant aspect of the medical field is that the quality of scientific information 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). Prospective data collection studies show the best level of scientific evidence. The main difference of this form of work 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 results (Boffeta, 1997). The development of the computer started more than 5000 years ago, with the invention of the oriental abacus, a rudimentary calculus instrument. The first machine with characteristics similar to a computer was designed in 1836 by Babbage, considered by some authors as the first computer. Hollerith, at the beginning of the 20th century, built the first data collection machines employing automatic card perforation (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 & Noyce and the microprocessor by Ted Hoff. The first generation of computers had an electronic valve as a basic component. The second used transistors and then printed circuits. The third, appeared in the mid-60s, bringing the integration of circuits (chips), which increased the speed and decreased the volume of the machines. The advances continue today, but in smaller and more frequent jumps, with great improvement in the processing and storage capacity of data available in today's versatile and highly complex computers (Holland, 1971; Covvey, 1978; Martinez, 1982). Initially, they were created for military purposes and later for space racing. 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. 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 1983, in Brazil, Rocha Neto described the importance of the computerized Medical File System (SAME) due to the ease of retrieving stored data, which would assist in the development of health sciences, facilitating medical teaching through scientific research, or even for better management of the hospital structure. 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. Computerized and multicentric databases were recently created and applied by several authors with the ratification of the effectiveness of this type of platform in scientific research (Sigwalt, 2004; Druszcz, 2006; Lima, 2007). 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). In 2002, there were more than 70,000 pages are available on the Internet on medical matters (Bereczki, 2002).

Quality clinical studies are essential for continuous scientific development, as it 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 area (Khan, 1994). In the medical area, electronic collection through standardized protocols has become widespread due to the reduction of collection errors and the reduction of physical means for storage, such as paper and spaces (Coeira, 1997). 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 (Afrin, 1997). The use of these electronic protocols for clinical research centers brings, as a result, inserted in the collected data, an indispu table control of scientific quality (Siegel, 1987; Sigwalt, 2001). The constant evolution of information technology with the possibility of better collection and archiving of information, as well as its immediate sharing with the scientific community, has made medical information technology one of the main foundations of modern medicine, where electronic collections are its fundamental pillars. In 1999, the line of research called "Integrated System of Electronic Protocols" was developed at the Informatics and Multimedia Laboratory of the Postgraduate Program in Surgical Clinic of the Health Sciences Sector of the Federal University of Paraná. The system uses C # programming language, Windows © operating system, Access © database manager and Excel © data analysis system. This computer program and this system are the intellectual property of Prof. Dr. Osvaldo Malafaia and registered at the National Institute of Industrial Property (INPI) under number 00051543. SINPE © made it possible to carry out several master's and doctoral theses at the Federal University of Paraná and at the Federal University of São Paulo (Borsato, 2005). In 2001, Sigwalt developed the first computerized protocol called "Electronic Database of Clinical Data on Esophageal Diseases". Since then, other electronic protocols have been created, totaling more than 100 registered diseases and 10,000 stored data. Eight electronic protocols on diseases of the digestive system have been developed and incorporated into SINPE ©: Esophagus, Stomach, Liver, Pancreas, Extrahepatic Bile Ducts, Small Intestine, Colon, Anorectal. After its creation and individual application of each protocol, the integrated implantation of the entire system, in the case directed to digestive diseases, became necessary for definitive testing of its practical applicability and subsequent validation. The practical applicability consists of using electronic protocols in the hospital routine, conducting prospective collections of clinical data. Validation is about the research itself, with the preparation of quality scientific papers and their presentation as a way of proving the value of the database obtained and its operational versatility. Therefore, the present study aimed to carry out the implantation of SINPE © related to diseases of the digestive system at the Hospital de Clínicas of the Federal University of Paraná-UFPR. Application of computerized protocols for diseases of the digestive system contained in SINPE © through prospective data collection. Validation of SINPE © by conducting research on the database obtained to test its functionality and versatility.

METHODS

The methodology applied in the development of this work can be divided into 5 phases:

- installation of the computer program: an integrated system of electronic protocols (SINPE ©);
- training of users and systematization of collections;
- creation of the computerized database;
- interpretation of the information collected;
- validation of the integrated system of electronic protocols (SINPE ©).

Instalação do programa de computador: sistema integrado de protocolos eletrônicos (SINPE©): SINPE © is software implemented in the Informatics and Multimedia Laboratory of the Health Sciences Sector of the Federal University of Paraná (UFPR) and is registered with the National Institute of Intellectual Property (INPI), under number 00051543, as intellectual property of Professor Dr. Osvaldo Malafaia, with use rights assigned to carry out this work.Eight computerized protocols referring to diseases of the digestive system incorporated into SINPE © at the end of their confections were used, namely: Esophagus, Stomach, Small intestine, Colon, Rectum and anus, Liver, Extrahepatic bile ducts, and Pancreas. The initial step was the installation of a computer program containing these protocols at the Department of Surgery of the Digestive System (CAD) of the Department of Surgery, Hospital de Clínicas, UFPR. For this installation, the minimum equipment required was a computer with a Windows 98 © operating system,

with 64 megabytes of RAM and a 500-megabyte hard disk available. The program, once installed, allows only the registration of patients and the collection of data necessary for research. The program has been installed and available for use at the institution referred to since June 2005. Possibility of collections via the Internet through the website www.sinpe.com.br were made available as of February 2006.

User training and systematization of collections: For the training of data collector users, training sessions were held between June 2005 and January 2006, to learn about the program and provide guidance for future collections. Meetings were also needed before and after training to learn about the difficulties faced by users. The systematization of data collection was defined according to the usual flow of patients admitted to the Digestive System Surgery Service at Hospital de Clínicas da UFPR, storing the data daily during the hospital stay of these patients. After hospital discharge, outpatient collections were performed at subsequent consultations. Thus, the registered patients had their data stored in the system, avoiding failures and loss of information. The database was reviewed quarterly to verify the quality and consistency of the collections performed.Patients in which the collection cannot be carried out completely during hospitalization or in subsequent returns were removed from the present study, as well as those with retrospective data stored.

Creation of the computer database: For the knowledge of SINPE © numbers on diseases of the digestive system, the existence of:

- 8electronicprotocols(masters):
  Esophagus, Stomach, Intestinethin, colon, anorectal, liver, extrahepatic bile ducts, and pancreas;
- 135 specific protocols: correspond to each of the diseasesrelated to the original master protocols;
- 35401 items: referring to the total number of data available for collections.

Data collection was performed on patients admitted to the CAD of Hospital de Clínicas - UFPR between January 2007 and July 2008 using the systemimplanted, including the entire electronic database of clinical data on digestive diseases and their specific diseases. Using the software, data were collected based on the diseases (specific protocols) that motivated the patients' hospital admission. Approximately 1377 collections were made in patients admitted to the Hospital de Clínicas, Universidade Federal do Paraná, started in 2001 during the multicenter application of the computerized protocol on gastroesophageal reflux disease and, later, with the use of the other protocols for specific diseases. Despite the collaboration in these collections, it was decided to exclude retrospective data and without a complete record of outpatient follow-up. Thus, the prospective collection of clinical data was totaled in 490 patients hospitalized and undergoing surgical treatment. Eight digestive disease protocols were contemplated, except liver transplantation, as previously mentioned. Available outpatient follow-up information was also recorded for patients registered and seen on a postoperative return at the clinic of the discipline itself. To start the collections, it is necessary to select SINPE © to open the program, easily identifiable on the desktop.

SINPE © starts with the connection selection screen, where two types of connection can be selected: local or remote.The local connection is selected to access the hard disk (HD) of the computer in use, and the connection is predominantly used in the study. It was shown to be fast and safe because it does not depend on the access available to the internet and the speed of the provider, in addition to enabling bedside data collection with the use of notebooks. The remote connection is used to archive the data via the internet and depends on the available data transmission capacity. It has the advantage of storing the information in a central database with less risk of loss of collections, and the possibility of multicentric and simultaneous data collections. After selecting the connection type, user authentication is required. Two levels of authentication to the system are highlighted: one that verifies the user's classification (common or superuser) and another that verifies the type of permission granted to the user for each protocol, individually. The user classified as common needs the authorization previously granted by a superuser, who, in turn, has unrestricted access to the information and operation of the software. There are four types of permission that can be addressed by the superuser (Malafaia; Borsato; Pinto, 2003):

1. administrator: has unrestricted access; can access the master and specific protocols, collect information and conduct clinical data research;
2. viewer: visualizes the computerized protocol as a whole, however, it is not allowed to change the data implicit in the protocol or change the data referring to the collection of medical record information;
3. collector: only has permission to access the data collection item;
4. researcher: has permission to access the item “research”, being able to search only collected data.

Figure 3 demonstrates this SINPE © security system, where each user has their own login and password so that access to the same information can be made effective. It is also important to define the institution to access the program, as the type of authorization may vary depending on the institution to which the user belongs. After authentication, the user selects the protocol they want to perform data collection. The list of protocols displayed to the user will be relevant to the protocols for which the user is granted permission to access. Note that only the “super user” is allowed to register institutions, users and new permissions. As already mentioned, the administrator user has unrestricted access to the electronic protocol, which is not possible for other types of users. In this way, the administrator can activate any of the five items present in the upper left corner of the protocol screen: "Protocols", "Data", "Patients", "Parameters" and "Help". The bottom margin shows information about the user and the master protocol being used.

The "Protocols" icon allows the administrator user access to the master and specific protocols (sub-items: "Master" and Specific "). These options are not accessible to the average user (collector, researcher and viewer). The application of these sub-items allows the administrator additions or changes in the databases of the master protocol, as well as making changes to specific protocols.The last option, common to all users, is the subitem "Exit" used to close the program. The item "Data" is also accessible to common user allowing collection and research, depending on your permission. The item "Patients" is for registering patients included in the protocol. The item "Parameters", accessible only to super-users and administrators, is related to the registration of users and the permissions described above, as well as the registration of institutions and configuration of units. For a better understanding of the methodology used to collect data in the defined electronic protocols, below is a simulation of the collection of a patient. To start filling out a specific protocol, it is necessary to register the patient to be filed. To do this, you must select the “Patients” icon in the main options bar, where the “Registration” option appears, which must be adopted. Through this sequence, a screen that allows the insertion of registration data will be highlighted, allowing the filling in of new information and also the correction of previously registered data. After the inclusion of the new patient, data collection begins through the sub-item "Collect" linked to the item "Data" in the options bar. This new screen makes it possible to continue a collection that has already started, displayed in a selection list, using the item "View / Edit Collection", or use the command "New Collection" that allows the selection of a new patient, his specific protocol (disease) and the name of the professional responsible for collection. With this procedure, the program becomes an objective questionnaire. At the end of the collection, the user must click on the "Save" command to store the information in the database, being able to edit it later. The use of the item "Finalize collection" will mean that no data can be added in future collections for this patient. In the main options bar of SINPE © there is also the sub-item "Simulate collections" in which the collector can simulate a collection of the

specific protocol of interest. The evaluation of the collected data can be done by accessing the "Search" sub-item linked to the "Data" item in the same options bar. The specific protocol to be researched, the institutions of origin of the patients and the options for delimiting the research are selected: joint, disjoint or exact data and the period in which the collections were performed. The screen provides the characteristics of the data in evidence (Parameters of the Selected Item), absolute and relative values of the occurrence of the researched data with average value when it comes to numerical values (Statistics Results) and the list of patients and their institutions that generated these Dice. The search can be performed using the program itself. After selecting the institution (or institutions), the specific protocol, and the objective data desired in the research, just click on "Start Research". The results appeared on the right on the SINPE © screen itself in absolute and percentage values. There is the possibility of transporting the data to a Word® spreadsheet, using the item "View HTLM", at the bottom of the screen.

Interpretation of the information collected

Use of the SINPE© analysis module - Analyzer software©: Despite allowing direct research, SINPE © does not support data crossing or improved statistical analysis. The process is in charge of another application, the SINPE Analyzer ©. This new program provides the results in a structured way, being able to generate graphs, print and save these results, in addition to exporting data, still allowing a complete view of the researched clinical database. The SINPE Analyzer © was used to analyze the database obtained from the prospective collection performed.As previously mentioned, the SINPE © data analysis module, known as Analyzer ©, was developed for research of direct and percentage objective parameters, providing analytical statistical data on digestive system diseases contained in the computerized protocols under study. Once installed, it is presented as an executable file. Its selection allows for opening the initial screen of the program. Once connected to the database, it is possible to view all the protocols available for analysis at SINPE ©, as well as their respective specific protocols. Then, you can select a specific protocol for the full view of its items, which is obtained through the "View Protocol" button. Then, you can select the "Analysis Form" that shows the data of the protocol under analysis, which are part of the research results:

I Item under analysis: name of the protocol and date of the analysis;
II General characteristics: creator of the protocol, institution, date of creation and revision of the protocol, as well as number of data of the same;
III Data collections: number of collections and dates, collection institutions and demographic data;
IV Graphics: distribution by sex, age and race; distribution by age group and number of collections per month.

In data analysis, it is also possible to research the incidence of items collected in absolute terms, percentages, and their graphical representation, as will be seen in the results. To exit the program, simply execute the "Exit" command on the "File" icon.

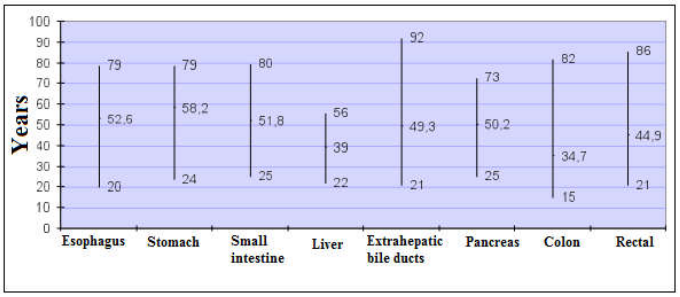
Use of the SINPE© research tool: To start the search, it is necessary to open the program, opening the main search screen. In this screen, it is possible to select the specific protocol to be studied, as well as the institution and the type of research (joint items, disjoint items, or exact items). The data of specific interest are selected directly, and objectively, in the chosen protocol. Afterward, click on "Start Research" to obtain the statistical results, such as the number of collections that satisfy the research, the percentage values related to the items under study, and the list of patients who have the data investigated in their protocol.

Validation of the integrated electronic protocols system (SINPE©): In order to validate the system as a whole, after its implementation and collection phase, researches were developed to test the ease of use, versatility and functionality of the program.The specific protocols on gastro-oesophageal reflux disease and calculous cholecystitis were the most explored at this stage, due to the significant number of collections, including the preparation of scientific works elaborated from this database. Subsequently, the data obtained with the validation was structured and scientific works were developed. The objective was to analyze the ease of use of this data and its reliability. Thus, they were sent for selection and submitted to analysis by the scientific committee of the VIII Brazilian Week of the Digestive System, being approved for presentation. The use of SINPE © in research was also the subject of presentation at a medical congress showing the facilities of this computerized tool.

General results of collections

In the 18 months of collections, 490 prospective collections were carried out in the computerized protocols related to diseases of the digestive system. Most of the patients were female, totaling about 59.8%. The electronic database with the highest number of collections was on diseases of the extrahepatic biliary tract with about 180 collections performed. The specific protocol of chronic lithiasic cholecystitis (116 cases) was the one that obtained the largest number of patients incorporated, followed by gastroesophageal reflux disease (94 cases). The analysis of the median of age, maximum and minimum ages distributed by computerized protocol are observed in Graph 1.

Graph 1. Analysis of the median of age, maximum and minimum ages.



Results of collections by computerized protocol

Esophagus: The electronic database of clinical data on esophageal diseases consists of 26 specific protocols and included 114 patients, corresponding to 23.3% of all collections. There was a predominance of females in 57.9% of cases. The average age was 52.6 years (20 to 79 years). Gastroesophageal reflux disease (GERD) had 94 patients (82.5%), followed by megaesophagus (7.9%), idiopathic achalasia (3.5%) and esophageal cancer (3.5%). Some non-surgical or less prevalent diseases, present in the protocol, did not present records, such as: foreign body, epiphrenic diverticulum, infectious, eosinophilic or medication-induced esophagitis, non-infectious granulomatosis, esophageal membranes, benign neoplasms, esophageal perforations, Mallory syndrome Weiss, esophageal varices, pseudodiverticulosis and esophageal manifestations of systemic diseases.The data regarding the number, sex, race and age are shown in Table 1 and in graphs 5 and 6.

Table 1. Demographic data of esophageal diseases, as a generic example

Disease	Cases	Gender		Age (years) (min. – max.)
		Female	Male	
Idiopathic achalasia	4	2	2	49 (28-60)
Schatzki's Ring	1	1	0	70
Zenker's diverticulum	2	0	2	74 (72-76)
GERD *	9	5	3	51 (20-77)
	4	6	8	
Chagasic megaesophagus	9	3	6	58 (31-79)
Malignant neoplasm	4	2	2	66 (48-77)

* GERD - Gastroesophageal reflux disease.

To start the search, it is necessary to open the program, opening the main search screen. In this screen, it is possible to select the specific protocol to be studied, as well as the institution and the type of research (joint items, disjoint items, or exact items). The data of

specific interest are selected directly, and objectively, in the chosen protocol. Afterward, click on "Start Research" to obtain the statistical results, such as the number of collections that satisfy the research, the percentage values related to the items under study, and the list of patients who have the data investigated in their protocol.

***Stomach*:** The computerized protocol for stomach diseases consists of13 specific protocols. Sixteen collections were made (3.3% of the total), the majority being male (87.5%) with a mean age of 58.2 (24-79) years.As most of the related diseases are for non-operative treatment, only malignant gastric neoplasia totaled a significant number of 10 cases. The 3 cases of hospitalized and collected gastritis were initially included due to suspected acute abdomen. The patient diagnosed with gastric polyp (1 case) was admitted due to suspected malignancy. The 2 cases of gastric ulcer disease were related to complications, such as hemorrhage and pyloric stenosis. The other specific protocols did not show collections: bezoar, foreign body, acute gastric dilation, dyspepsia, stomach motility disorders, gastric diverticula, upper digestive hemorrhage, acute gastric rupture, post-gastrectomy syndrome, and gastric volvulus.Below are the other demographic data from the collection. Other data can be obtained using the SINPE© and Analyzer© systems, similar to the example cited.

Small intestine: The electronic database for the small intestine consists of 24 specific protocols with approximately 8256 items for collection. There were 40 collections, corresponding to 8.2% of all collections. There was a predominance of males in 65% of cases (n = 26). The average age was 51.8 years (25 to 80 years). Almost all of the collected cases, 38 of the 40 collected, were related to obstructive small intestine disease, whose main causes were: inguinal hernias (16 cases); incisional hernias (12 cases); umbilical hernias (6 cases) and epigastric hernias (4 cases). The other two cases corresponded to an abscess after endarterectomy (performed for reasons other than the specific disease of the small intestine), and one case of Meckel's diverticulum with an inflammatory process. All other specific protocols did not present any records: postoperative complications, such as fistulas and short bowel; other causes of obstructive diseases, such as bandages, intussusception, foreign body, inflammatory bowel disease, malignancy, endometriosis, femoral hernia and irradiation; vascular diseases; benign and malignant neoplasms; and trauma.

Liver: The computerized liver disease protocol consists of 8 specific protocols and 4587 data. Only 2 collections were made (0.4% of the total), all of them belonging to the female sex, with an average age of 39 (22-56) years.Both cases were related to liver tumors. The first was a giant adenoma in the right hepatic lobe in a 22-year-old patient who underwent a right lobectomy. The second was a case of hepatocarcinoma, which also underwent liver resection. Direct and crossed analytical data can be studied in detail using the software Analyzer © and by SINPE ©, respectively.

Extra-Hepatic Bile Ducts: The electronic database on diseases of the extrahepatic biliary tract consists of 25 specific protocols, with a total of 2717 items and included 180 patients, corresponding to 36.7% of collections. It was the protocol with the largest number of patients and data collected in the period. There was a predominance of females in 80% of cases and the average age was 49.3 years (21 to 92 years). Chronic lithiasis cholecystitis represented 116 patients (64.4%), followed by acute lithiasis cholecystitis and choledocholithiasis.Some diseases present in the protocol were not recorded, such as gallbladder adenomyomatosis, recurrent pyogenic cholangitis, acute emphysematous cholecystitis, gallbladder cholesterol, gallbladder fistulas, hemobilia, gallbladder ileus, malignant gallbladder neoplasms, gallbladder trauma or gallbladder, bile duct verminous and calcified gallbladder.

Pancreas: The electronic protocol on pancreatic diseases consists of 5 specific protocols and 5816 collection items, the largest protocol in terms of the number of storage data. 23 collections were made (4.7% of the total), with a balanced distribution between the sexes (52.2% male x 47.8% female). The average age was 50.2 (25-73) years.All 5 specific protocols (cysts and pseudocysts; acute pancreatitis; chronic pancreatitis; endocrine tumors and exocrine tumors) had collections in the period.The highest prevalence was in patients with acute pancreatitis (52.2% of collections), followed by cases of pancreatic cysts/pseudocysts (30.4%). The other diseases had a lower occurrence.

Colon: The computerized base of colon diseases consists of 16 specific protocols and 3737 items. 59 collections were made, corresponding to 12% of all collections. There was a predominance of males in 55.9% of cases. The average age was 34.7 years (15 to 82 years). The specific protocol for appendix diseases responded to 47 patients (79.7%). The other collections obtained were performed in the protocols on malignant colon neoplasia, chagasic megacolon, colonic diverticular disease, and benign colon neoplasia (adenoma). Some non-surgical or less prevalent diseases, present in the protocol, did not present records: non-infectious colitis, ulcerative colitis, foreign body, Crohn's disease, lower digestive hemorrhage, intestinal pseudo-obstruction, irritable bowel syndrome, functional disorders of the colon, colon vascular diseases, and trauma/colonic perforation.

Rectal: The electronic protocol for anorectal diseases consists of 18 specific protocols with 3926 items for collection. 56 collections (11.4% of the total) were carried out, distributed equally between the sexes, and with an average age of 44.9 (21-86) years. Most collections (50%) were performed in hemorrhoidal disease. Collections were also obtained in the specific protocols: anorectal abscesses, rectal cancer, pilonidal cyst, anal fissure, and anorectoperineal fistula. There were no cases of anal cancer, condylomatosis, anal stenosis, rectovaginal/rectovesical fistula, perianal hematoma, hidradenitis suppurativa, anal incontinence, polyps/benign neoplasms, anorectal prolapse, actinic proctitis, anal pruritus, dermatological disease, trauma, or foreign body. As a result of searching a database, it is possible to obtain the name of the protocol and date of the analysis; the general characteristics of the studied protocol such as its creator, institution, date of creation and revision of the protocol, as well as a number of data of the same; data collections with their total number and dates, collection institutions and demographic data; Also, the results can be checked in the form of graphs for better illustration, namely: distribution by sex, age and race; distribution by age group and a number of collections per month. In the data analysis, it is possible to search the “Incidence” of the collected items, as shown in figure 37. Graphs related to absolute and percentage values are also generated during this research. Obtaining percentage statistical results and collections related to the research can be performed by SINPE© itself. In the example used, it is observed that in patients with gastro-oesophageal reflux disease (n = 94), 10 collections showed an interrelation between the items Heartburn/Heartburn/ Retro-sternal burn ”and“ Weight loss ”. A 20% relationship (occurrences) between pulmonary symptoms and weight loss was obtained in this same group of patients. It is possible to verify which patients (collections) have this association.

DISCUSSION

Descriptive scientific studies that use medical records as the only source of available data represent a major challenge for research centers. The pattern of filling in these documents varies widely between institutions, which can also occur within the same establishment and thus provide inaccurate information. It is often the quality of information obtained from medical records that compromises the results of a well-designed study (Dick, 1991; Rind, 1993; Tang; Larosa; Laine, 1999). Informatics becomes an alternative to solve this problem, as currently occurs in the most advanced medical centers in the world, where there is a tendency to carry out prospective studies based on electronic data collection. This process works as if there were, in addition to the usual medical record, an electronic medical record, with the sole purpose of storing

and accessing information for scientific studies in a faster and safer way (Kohane; Greenspun; Fackler, 1996; McDonald; Tierney; Overhage, 1992; Sittig, 1994). 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. The advantages of applying a computerized clinical database are the possibility of prospectively collecting information based on a defined and objective protocol, and the little physical space necessary for its operation. The possibility of analyzing the most varied data collected in a targeted and immediate way provides the structuring of scientific studies of quality and credibility in results and conclusions (McDonald, 1994; Weinberger; Hui; Laine, 1997). Electronic databases have great potential as sources of high-quality scientific research (Davidoff, 1996). The importance of the constant use of databases in the preparation of scientific works was very emphasized by Goonan in 1995. It seems simple to understand that currently, the application of electronic protocols aimed at the clinic will provide a complete source of medical information. The speed in accessing these data, in addition to the certainty of the homogeneity of their collection (based on a standardized protocol), makes this scientific instrument an important alternative for the improvement of medicine (McDonald *et al.,* 1998). The data collection bank is not intended to replace medical records, but rather to provide information about a specific group of patients within medical research. The University of Alabama made use of a prospective data collection program in patients being treated for Acquired Immunodeficiency Syndrome (AIDS). This institution has become a reference, being considered one of the main centers of study on AIDS in the United States of America, due to the quality of the studies produced from its database (Lee, 1994).

Clinical databases can serve only one institution or be multicentric. If used in a single institution, they serve to define the clinical profile of the population studied. In cases of less common diseases, it is more interesting that the protocol is available to several centers, which would allow a larger sample with reliable information. As an example of multicenter studies, in France, there is data collection from 38 intensive care units, which are stored in a single protocol. This protocol contains information such as age, current clinical status, previous clinical status, and psychological assessment of patients (Loirat, 1989). In Italy, Coltorti, Del Vecchio Blanco, and Caporaso, in 1991, published the results of a multicenter study carried out by the liver disease group in that country. The advantages of multicentric studies are that they provide an increase in the population studied, enabling faster conclusions about rare phenomena and a reduction in the time of conducting the research (Pereira, 1995). The use of computerized protocols for prospective collection of clinical data makes it possible to carry out high-quality scientific work, since it facilitates the development of multicenter studies, and may involve smaller institutions, which would send their information to larger databases, thus obtaining relevant and quality results in less time (Blumeinstein, 1995). The creation of computerized protocols followed the same principles described by Sigwalt at the time of his master's dissertation. These principles are related to the creation of a clinical data collection protocol, capable of prospectively generating an electronic database of quality data, characterized by simplicity in its form of filling and generating objective data (Sigwalt, 2001).

The computerized protocols were developed following a single standardization: a bibliographic review of the chosen subject, data collection with specific literature, formatting of the protocol before computerizing it. The next step was based on the choice of the methodology for computerization as well as its development. The data computerization process was developed at the Informatics and Multimedia Laboratory of the Postgraduate Program in the Surgical Clinic of the Health Sciences Sector at UFPR. With the creation of the medical informatics research line, it was possible to carry out the computerization of the logical model of the protocol, which has been constantly improved by technicians in the data processing. The design of the computerized protocol is based on a database called the master protocol, which allows any possibility of crossing variables, or relevant data related to the theme. From the master protocol, specific protocols are formulated with a specific questionnaire for each disease, but they can be increased to an unlimited number, depending on the interest of the researcher and the crossing of data to be carried out. The theoretical base of clinical data digitized in the master protocol promotes logical structuring in the data, allowing the folders to be ordered in a coherent way, starting with aspects of the clinical picture, associated clinical conditions, complementary exams, treatments, and postoperative evolution. This makes the data collection to develop in a clear and objective way. O! "# $% & '(Makes it possible to transform the data collected with the bibliographic review, into a computerized data collection system. Patient information is collected objectively and stored so that its content is subject to analysis. A security system was created to restrict simple user access to the master and specific protocols, avoiding the risk of random changes in the database, with unintended consequences for the program. To be a collector you need authorization from the administrator (login and password) of the computerized protocol in question.

The navigation system is similar to * +, '"!" # $ -. + / 0 "%! Due to the familiarity of the vast majority of microcomputer users. The choice of * +,' C # (C-sharp) language ' "!" # $ - was because this lineage has the potential for your programs to run both at 0 (! 1 $ "2! 3 4 & 2 $" 2! 3 / ($ 5 "" 1 !, and on internet through the electronic address www.sinpe.com.br, and also in handheld computers (6 ", 1 ($ 67), due to using / ($ 89 '&: (%"' 1. As information technology depends on technological advances for its development, the most recent fact has been the improvement of mobile telephony, which, with the improvement of data connection, will make it possible to collect protocols from the user's own cell phone. The collections made by SINPE® are made using objective forms filled out by clicking: ";! (. Therefore, all data collected must respect the definitions of the items built in the master and specific protocols. The implementation of the 8 electronic protocols and their systematization of the collection was a reason for difficulties at the beginning of this work. The need to keep the database fully prospective has created a logistical problem in relation to the usual flow of patients in CAD. The daily obtaining of information at the bedside with the patients was hampered by the constant performance of exams, consultations, and procedures performed on them, and there was not always availability of waiting by the collectors. With the aim of improving collections and avoiding data loss with the consequent exclusion of patients, the use of residents of the service itself was attempted. However, the workload and assignments made it impossible to include collections in their routine. The next step was the employment of medical students in the final stages of training, however, due to the lack of knowledge of the hospital routine and workload, the expected success was not achieved.The initially high collection time, due to the lack of standardization existing between the protocols themselves and their deeper knowledge, led to the loss of these collaborators.

The daily collections continued to be made by the present author during all attempts to solve the problems, but a new obstacle was detected: the outpatient collections remained flawed and the loss of part of the database was inevitable, as the rescue of the medical records for completion incomplete protocols would invalidate the prospection of the study. Outpatient follow-up for included patients was the most arduous part of the study. The loss of follow-up, either due to the impossibility of the collector's attendance or the lack of patients at the clinic, brought restrictions to the expansion of the database. Also, the lack of a computerized terminal generated problems, as it was necessary to collect data from conventional medical records and later transcription and filling in their specific computerized protocols. Another point to consider was the impossibility of joining 2 or more databases, through their storage in Microsoft Access, that is, the collections made on different computers could not be compiled. The solutions were the acquisition of an exclusive laptop for the application of these protocols and the restriction of the number of people committed to the project. With the division of tasks and responsibilities, and the filling of

previously deficient schedules, it was possible to create the current database. Thus, 490 patients were collected with fully prospective information not only obtained from medical records, but also the patients themselves at the bedside, to minimize collection errors and make the data more reliable. The difficulties encountered allowed the improvement of the collection systematization and allowed the elaboration of suggestions for the continuous improvement of the system. First, the standardization of protocols is essential to reduce collection times. This is possible with the creation of a unique sequence for the making of the master protocols, to later develop its ramifications. Second, collectors must be people trained in the protocols and committed to their application and development. Probably, the use of graduate students is the best alternative for maintaining collections. Third, outpatient collections should be made, if possible, by the same collectors for greater agility and less loss of information. Also, portable computers proved to be a satisfactory alternative and should be maintained with the main collection interface.

Intercommunication between computers, either through a network or by connecting them to a central provider in the graduate computer lab, becomes necessary for the formation of a single database, maintaining the current structure of SINPE □ whose storage is done by Microsoft Access□. An alternative way would be to change the storage system using specific software, such as MS-SQL Server and Microsoft Database Engine, already successfully tested; and others like Oracle, DB2, MySQL and PostgreSQL. These programs make it possible to join 2 or more different databases. As proposed by SINPE ©, data collection was performed using the specific protocol, that is, the etiological diagnosis. Thus, the distribution of patients was able to demonstrate the main types of diseases that occurred in the studied period, as well as the prevalence of sex, race, age, symptoms and other relevant individualized data by diagnosis. Although the electronic protocol itself allows the analysis of a given data using the program <=, (4-, the statistical analysis with crossing of collected data is performed with the help of SINPE Analyzer ©. Thus, the objective results and any data obtained direct percentage can be redeemed using the Analyzer © program, while the cross data, which uses 2 or more simultaneous variables for research, are obtained within SINPE © in its research tool, as seen in the results. SINPE Analyzer © is an application capable of interacting with the clinical database and enabling statistical analysis and data generation in the form of graphs, in addition to allowing the archiving of data with the possibility of printing and exporting the information analyzed by it. It constitutes a fundamental element in the production of scientific works based on the computerized protocol. It was designed and developed by Prof. Dr. José Simão de Paula Pinto, the subject of his doctoral thesis in 2005, and is available for use by the Postgraduate Program in Surgical Clinic at the Federal University of Paraná in the research line: "Electronic Protocols" (PINTO, 2005).

SINPE© itself has a search engine that allows the analysis of the collected items. It has as an advantage, the possibility of crossing data to obtain specific results about a certain disease (eg, prevalence of acute cholecystitis in diabetics, recurrence of atypical symptoms after fundoplication, and others). The analysis tools available provide the results by specific protocol (ie, by disease). Thus, it was necessary to compile them to make their understanding easier. The technical support of programmers linked to the computer lab was of great importance for the smooth functioning of this software. Although very well structured, every program is susceptible to failures and, also, computer science is a dynamic and rapidly evolving science, requiring the constant improvement of the entire system. The differential of this thesis was the fact that it was not restricted to the application of computerized protocols through the collection of data on a specific specific protocol, with prospective collection being carried out in all 8 digestive disease protocols registered with SINPE ©. After the collections, several researches of the obtained data were proceeded. The purpose was to test the search for the information collected, analyzing the versatility and functionality of SINPE © itself and its research tools. It was possible to carry out both direct research and the crossing of data without difficulties, however the system became a little slow in analyzes containing a large number of information. New versions and updates will be extremely important in adjusting these details. Once the research on the database obtained in the study was tested and approved, scientific papers were developed and sent to the VIII Brazilian Week of the Digestive System. Two papers were sent in the form of a poster, and the other two for oral presentation as a free topic. All were analyzed and selected for presentation at the referred congress, which took place between October 5 and 9, 2008 in the city of Brasília-DF. The 2 free themes presented, present among the 35 studies selected for oral exposure among more than 400 works sent in the area of surgery, prove the quality obtained with this form of prospective collection and research provided by SINPE © and its tools. In this way, the development and presentation of studies developed at a congress with national repercussions confirm that SINPE © is a quality scientific research instrument. Thus, the application and implantation of SINPE © in the discipline of Surgery of the Digestive System at the Hospital de Clínicas of the Federal University of Paraná became a reality during the period of execution of this thesis, its implantation and validation being a landmark for the diffusion of this system as one of the main tools available for clinical research in our country.

This work illustrates the possibility of using SINPE © in institutions as a systematic part of data collection. Also, it highlights the numerous research possibilities on various aspects of the same theme. The studies generated from the analysis of these data have much more value because the collections are made prospectively, in addition to the convenience of having data stored in a standardized way, greatly facilitating clinical research. Installing the software in hospitals with an interest in research makes it possible to conduct studies with quality and time savings, serving as a stimulus to the production of studies.SINPE © was developed for incorporation into the hospital routine, without the purpose of replacing the medical record, providing a data source for quality medical research. Its easy installation, practicality of use, security in data storage and the possibility of making reliable scientific studies make this software a useful tool for the development of medical research. Considering its applicability, it has low cost and has the advantage of being able to be updated whenever necessary. The computerized protocol is filled in uniformly, using parameterized forms offering objectivity, clarity and precision to the data collected. It eliminates the bias generated from the interpretation of a subjective data, giving greater quality to the scientific research structured therein. The Integrated System of Electronic Protocols (SINPE©) was created with an improved vision and adapted to the contingencies of our time, but soon it will certainly be changing to keep up with the natural progress of medical practice. The most important will be the uniform structuring of the entire system, so that the interface becomes easier to assimilate, a fact that is already being implemented in the new protocols under development. With the technological advancement of information technology, it is essential to adapt to technology and use these tools in favor of health and the development of medical knowledge, which aims to expand research and scientific experimentation.

Conclusion

The implementation of SINPE © related to diseases of the digestive system at the Hospital de Clínicas of the Federal University of Paraná-UFPR was successful. The prospective application of computerized protocols for diseases of the digestive system was possible using the proposed methodology. The validation of SINPE © was obtained through the application of its research tools on the database, showing its adequate functionality and versatility in the elaboration of the bases for quality scientific publications.

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