Development of an electronic protocol for uterine cervical cancer

Criação de protocolo eletrônico em câncer do colo do útero

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A B S T R A C T

Objective: Development of an electronic protocol for cancer of the cervix. **Methods**: We collected data through a literature review and formatted them to build a theoretical base for cancer of the cervix for inclusion in the protocol. The computerized database used the SINPE © (Integrated Electronic Protocols) developed at the Federal University of Parana by the Graduate Program in Surgery, Department of Health Sciences, with the help of the Laboratory of Computer and Multimedia. **Results**: We created 2,687 items, grouped into seven main categories: history, physical examination, laboratory tests, diagnosis, final pathology, treatment and monitoring. We added items on socio-demographic indicators, contraceptive use, smoking, gynecological and obstetrical histories, staging, the most widely accepted classifications and nomenclatures, diagnostic methods, treatments and follow-up. **Conclusion**: It is possible to develop an electronic protocol with low cost, little space and minimal staff training. The use of computers avoids limitations and the subjective character of written records. With the data collected in an appropriate manner it is possible to determine, through statistical analysis, the importance of each factor in cancer development and progression and prognosis.

Key words: Uterine cervical neoplasms. Informatics. Clinical protocols. Electronic health records. Software.

INTRODUCTION

In daily practice, approaches used in patient care are usually based on the conscious application of the provided information, which is evaluated by explicitly defined rules. This is called the principle of evidence-based medicine. There is a national imperative to increase activities in the area of research in Brazil, aiming to develop a knowledge base for the practice of evidence-based medicine and health policies [1,2].

Data are collected from surveys, mostly through questionnaires and interviews, the validity of results depending on the quality of these instruments [3]. The use of information technology is vital to assure adequate access to these data [4].

Through the creation of electronic protocols, Information technology makes the capture and storage of clinical data possible, allowing the conduction of prospective studies.

The use of informatics in research depends on the type of clinical information and how it is collected, stored and interpreted. For this, there is a need to formulate tools to organize information generated from clinical observations. The advantages of an electronic medical record system are easily distinguishable, since all available information is digitized and becomes easy to handle [5].

In 1999, the line of research called "Electronic Computerized Protocols" was established by the Post-graduation Program in Surgery, Department of Health Sciences, with the aid of the Laboratory of Computer and Multimedia Industry located in the Health Sciences Division, Federal University of Paraná, which is currently incorporated into the Electronic Protocols Integrated System (SINPE ©) [6].

Cancer of the cervix is the second most common cancer among women, with approximately 500,000 new cases per year worldwide, being responsible for the deaths of approximately 230,000 women per year. Its incidence is about two times higher in less developed countries when compared to developed countries. The number of new cases of cervical cancer expected for Brazil in the year 2010 is 18,430, with an estimated risk of 18 cases per 100,000 women, making it the second most frequent cancer in Brazilian women, exceeded only by breast cancer [7].

It is known that, for the development of high grade squamous intraepithelial lesions and invasive cancer of the cervix, Human Papillomavirus (HPV) is a necessary cause, though not sufficient alone [7]. Therefore, there is a need for research other factors that may contribute to study

the etiology of cervical cancer in the clinical history of women. We then decided to develop an electronic protocol to be used in research on cancer of the cervix.

METHODS

The development of the electronic protocol was didactically divided into two stages: creation of the theoretical basis of clinical data of cervical cancer and computerization of it, using the Electronic Protocols Integrated System (SINPE ©).

The development of the theoretical basis was carried out with literature review for cervical cancer, collecting data in the literature and its format for inclusion in the master protocol.

The literature review was conducted in textbooks, specific literature review through web search in the databases *pubmed*, *medline* and *lilacs*. Information was crossed with the following terms terms, in Portuguese and in English: epidemiology, risk factors (HPV, smoking, contraception etc.), treatment, imaging and quality of life related to cervical cancer.

The date range of the search of selected articles was between 2005 and 2010. The purpose of this research was to horizontally look for epidemiological, etiopathogenic, clinical and diagnostic data about cervical cancer.

The database consists of two protocols: master and specific. The master protocol is the result of any information provided after the literature review of cervical cancer. The specific protocols are formed by the selection of the folders contained in the master protocol, allowing further studies without using all the data contained in the master protocol.

The system used to load the theoretical basis of clinical data in the master protocol is based on a set of data arranged in a hierarchical way, in items and subitems, distributed in different input generations, created by two simple commands: *Add sibling* command and *Add son* command , which define their information content.   On a clinical order, the master protocol configuration begins with the item *History* and follows by adding the siblings: physical examination, laboratory tests, diagnosis, treatment and outcome.

The subsequent step is the insertion of subitems named sons, which belong to a later generation. The SINPE © allows the display of items in a tree structure that is represented by the plus sign (+) to the left of the item, indicating that one item has one or more sons (subitems). The items included in the master protocol can be modified at any time by the user through the admin commands *Remove* and *Update*.

Although the software requests identifying data, these are not amenable to statistical analysis. Thus, important socio-demographic items, such as age, race, household income and years of study, were included in the tree. We used the concepts of the Brazilian Institute of Geography and Statistics (IBGE) regarding minimum social indicators [8].

The concept of "Years of study" is the period between the start first school year and the last grade successfully completed. The "monthly income" is defined as the sum of the monthly income of working with income from other sources. The definition of "Color or Race" is the characteristic declared by persons in accordance with the following options: white, black, yellow, brown or Indian [8].

The complaints listed under "complaints" were obtained in textbooks on cervical cancer and the items of the interrogation on the various body systems were based on clinical workup and general gynecology textbooks [9-12].

In personal background, for the assessment of tobacco, alcohol and diet, we used data from the Household Survey on Risk Behavior and Morbidity from Non-contagious Diseases and Conditions, developed by the Brazilian National Cancer Institute [13].

In gynecological history, we placed items that are considered risk factors for cervical cancer, such as number of pregnancies and number of partners[14]. We also added items to assess data on how many cytology exams patients had collected in their lives and how many years had passes since the last cytology [15].

It has been shown an increased risk of cervical cancer with oral contraceptive use. Thus, items were added relating to the use of these medications. We chose to classify the time of use in five-year intervals, the same way the reviewed studies did [16].

In family history, we added items related to cancer of the cervix and cervical dysplasia. Some studies suggest that cancer of the cervix can cluster in families [17].

For items of physical and gynecological examination, we used textbooks devoted to clinical and gynecology as references, devoting great attention to staging [18-20].

For cervical cytology, we used the Brazilian nomenclature for reporting Cervical cytopathology, published in 2006 by the Brazilian National Cancer Institute, a Bethesda-based system modified for use in Brazil [7].

The classification of the vulvoscopic findings was based on publications of the societies of pathology of the lower genital tract. The colposcopic classification was based on the nomenclature of colposcopic aspects published by IFCPC - Barcelona 2002 and ratified by the Brazilian Association of Colposcopy and PTGI [18,21].

As for imaging studies, we listed the more important exams for the diagnosis, staging and monitoring of cancer of the cervix.

Special attention was given to nuclear magnetic resonance, which has been widely studied as an important diagnostic tool, assisting in staging and lymph node evaluation [22].

We listed all the treatments for cervical cancer, including some experimental, such as neoadjuvant

chemotherapy. For each treatment modality we considered the most frequent acute and chronic complications.

We use the hysterectomy classification proposed by Piver *et al.* [23], and for research purposes, we added the new classification proposed by Morrow and Querleu [24], which has been well explored.

For the anatomic classification we used to the WHO classification, and for staging, the FIGO classification, considering the changes proposed in 2009 [25-27].

RESULTS

There were 2687 created items, divided into seven main categories: interview (895 items), physical examination (381 items), exams (606 items), diagnosis (28 items), treatment (217 items), final pathology analysis (57 items) and monitoring (503 items).

Figure 1 displays the data master protocol, creation date and last update, health care area to which it belongs, all items of this master protocol and the items that comprise this protocol.

At the bottom of the screen there are also the bottoms Add Sibling (add a main item), Add Son (add subitems), Remove (remove items) and Update (update items). On the right side of the screen there are spaces for the details of the previously selected item, such as a description and explanation of the item type of selection, value associated with, sound, image or video (Figure 1).

The sub-items of the main item physical examination are: General, Cardiovascular, Respiratory, Abdomen, Extremities, lymph node chains and gynecological examination. The main item of the subitem Gynecological examination are divided as follows: inspection of the vulva, anus inspection, vaginal examination, bimanual examination and rectal examination (Figure 2).

DISCUSSION

Most medical centers and university hospitals use computer technology to collect data only in financial, operational and administrative fields.

The application of electronic questionnaires or electronic protocols is still limited due to equipment costs, lack of skilled labor for their maintenance or possible resistance to the use of computers. However, it is nowadays possible to develop an electronic protocol with low cost, little space and minimal staff training.

The clinical history of patients incompletely filled by different professionals and the delay in collection of clinical data hamper the correct evaluation of data, preventing the conduction of quality research.

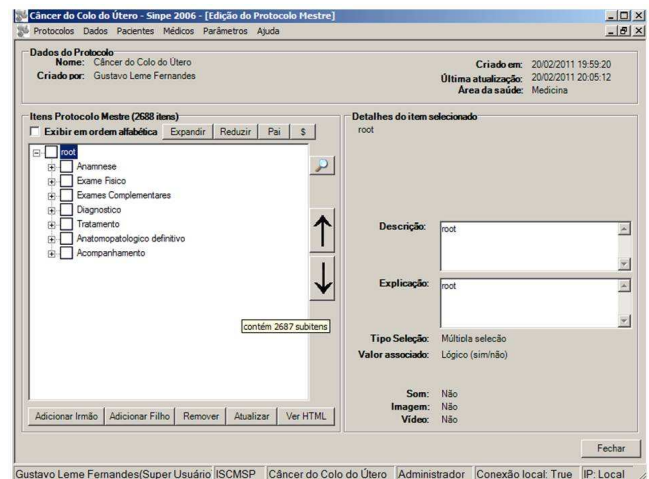It is often the quality of information obtained that compromises the results of a well-designed study. The use

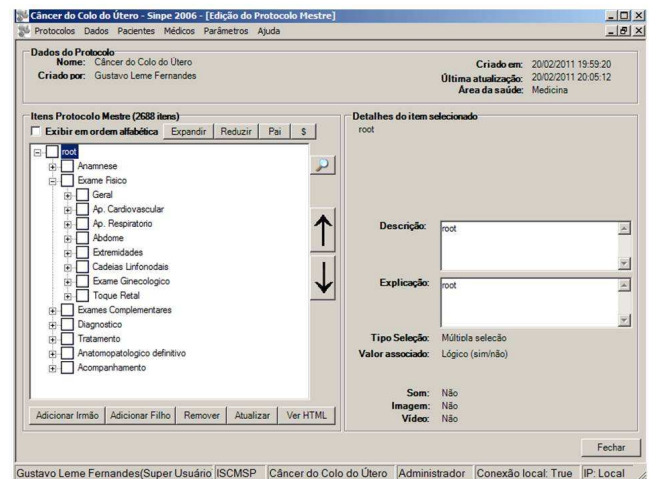**Figure 1** -   *View of the items in the master protocol.*

Figure 2 -   *Subitems "clinical assessment" and "physical examination".*

of computers avoids limitations and the subjective features of medical records.

These protocols for electronic clinical data collection are not designed to replace medical records, which are unreplaceable records of doctor-patient relationship, but to serve as a source of information for future medical research.

The availability of reliable information enables the production of research studies based on large series of patients, particularly meta-analyzes and guidelines available through the Internet [28]. Also, they are not intended to replace the Population-based Cancer Registries, a service already performed in Brazil by the Brazilian National Cancer Institute and the São Paulo Oncocenter Foundation – FOSP.

For the preparation of this protocol, renowned textbooks of the field have been consulted [9-12,18,20], and research on the internet has been carried out, looking at updates and further knowledge on the matter. The Internet search was restricted to the last five years because we believe that relevant previous publications are included in textbooks.

The development of this protocol aimed at clarity, simplicity, careful writing and neutrality to an appropriate tabulation. We relied on closed questions that, though may limit the collection of data, are more objective, providing answers more susceptible to analysis. Open questions generate subjective information, hampering data analysis. The main difficulty in creating this protocol has been gathering and organizing the information on cervical cancer. After conducting the study in textbooks [9-12], we determined the most relevant themes within the research of the disease and its risk factors [13-15] and from then, an extensive search of scientific articles related to each topic was carried out.Users of electronic protocol must first be registered with password and login, both for collection of data and for their use.

To prevent a collection performed in duplicate, the system automatically checks if there is already an unfinished collection of data from the same patient. For ethical reasons, SINPE does not allow identification data of patients from one institution to be viewed by users of another institution in the case of multicenter studies.

Although the electronic protocol itself allows the analysis of certain data, statistical analysis with data crossing is facilitated with the usage of the software SINPE Analyzer. The SINPE Analyzer is an application that can interact with the clinical database and allow statistical analysis and data generation in the form of graphics, besides allowing the archiving of data, with ability to print and export the information generated.

The conduct of research is fundamental to the advancement and growth of the medical field. With the data collected in an appropriate manner it is possible to determine, through statistical analysis, the importance of each factor in cancer development and in patient evolucao and prognosis.

The created protocol for Cervical Cancer aims to be objective, comprehensive and easy to fill, being held in a structured way, based on an ample literature review.

The development of an electronic protocol of cervical cancer, by creating a theoretical basis and its incorporation into SINPE©, is feasible.

R E S U M O

Objetivo: *Desenvolvimento de um protocolo eletrônico para o câncer do colo do útero.* **Métodos:** *Coletar dados através de revisão da literatura e formatá-los para a construção de uma base teórica sobre o câncer do colo uterino para inclusão no protocolo. A informatização do banco de dados utilizou o SINPE© (Sistema Integrado de Protocolos Eletrônicos), desenvolvido na Universidade Federal do Paraná pelo Programa de Pós-graduação em Clínica Cirúrgica do Setor de Ciências da Saúde com auxílio do Laboratório de Informática e Multimídia.* **Resultados:** *Foram criados 2687 itens, agrupados em sete categorias principais: anamnese, exame físico, exames complementares, diagnóstico, anatomopatológico definitivo, tratamento e acompanhamento. Acrescentamos itens sobre indicadores sócio-demográficos, uso de anticoncepcionais, tabagismo, antecedentes ginecológicos e obstétricos, estadiamento, as classificações e nomenclaturas mais aceitas, métodos diagnósticos, tratamentos e seguimento.* **Conclusão:** *É possível o desenvolvimento de um protocolo eletrônico com baixo custo, pouco espaço físico e mínimo treinamento de pessoal. O uso de computadores evita limitações e o caráter subjetivo do prontuário escrito. Com os dados coletados de maneira adequada é possível determinar, através de análise estatística, a importância de cada fator no desenvolvimento do câncer e na evolução e prognóstico do paciente.*

Descritores: *Neoplasias do colo do útero. Informática. Protocolos clínicos. Registros eletrônicos de saúde. Software.*

REFERENCES

1. Sacket DL, Tugwell P, Guyatt GH. Clinical epidemiology: a basic science for clinical medicine. 2th ed. Boston: Little Brown; 1991.
2. Friedland DJ. Evidence-based medicine. A framework for clinical pratice. Stanford: McGraw-Hill; 1998.
3. Hulley SB, Cummings SR, Browner WS, Grady D, Hearst N, Newman TB. Delineando a pesquisa clínica – Uma abordagem epidemiológica. 2ª ed. Porto Alegre:Artmed; 2003.
4. Friedman GD. Primer of epidemiology. 4th ed. New York: McGraw-Hill; 1994.
5. Horgarth M. Informática médica: um pouco de história. Informat Med [Internet]. 1998;1(5). Disponível em http://www.informaticamedica.org.br/informaticamedica/n0105/hogarth.htm
6. Malafaia O, Borsato EP, Pinto JSP. Manual do usuário do SINPE®. Curitiba: UFPR; 2003.
7. Brasil. Ministério da Saúde. Secretaria de Atenção à saúde. Instituto Nacional de Câncer. Coordenação de prevenção e Vigilância. Incidência de câncer no Brasil 2010; 2009. Acessado em 14/02/2011. Disponível em http://www1.inca.gov.br/estimativa/2010/
8. Brasil. IBGE – Instituto Brasileiro de Geografia e Estatística. Síntese de indicadores sociais 2006 [Internet]. Acessado em 12/02/2011. Disponível em: http://www.ibge.gov.br/home/estatistica/populacao/condiçãodevida/indicadoresminimos/sinteseindicsociais2006/indic_sociais2006.pdf
9. Halbe HW. Tratado de ginecologia. 2ª ed. São Paulo: Rocca; 1993.
10. Piato S. Tratado de ginecologia. 2ª ed. São Paulo: Artes Médicas; 2002.
11. Bates B, Bickley LS, Szilagyi PG. Bates propedêutica médica. 8ª ed. Rio de Janeiro: Guanabara Koogan; 2005.
12. Massaia IFDS, Bonadia JCA, Golin V. Propedêutica médica da criança ao idoso. São Paulo: Atheneu; 2009.

13. Brasil. Ministério da Saúde. Secretaria de Vigilância em Saúde. Secretaria de Atenção à Saúde. Instituto Nacional de Câncer. Coordenação de Prevenção e Vigilância. Inquérito domiciliar sobre comportamentos de risco e morbidade referida de doenças e agravos não transmissíveis: Brasil, 15 capitais e Distrito Federal, 2002-2003. Rio de Janeiro: INCA; 2004.

14. International Collaboration of Epidemiological Studies of Cervical Cancer. Cervical carcinoma and reproductive factors: collaborative reanalysis of individual data on 16,563 women with cervical carcinoma and 33,542 women without cervical carcinoma from 25 epidemiological studies. Int J Cancer. 2006;119(5):1108-24.

15. Brasil. Ministério da Saúde. Secretaria de Atenção à Saúde. Instituto Nacional de Câncer. Coordenação de Prevenção e Vigilância. Nomenclatura brasileira para laudos cervicais e condutas preconizadas: recomendações para profissionais de saúde. 2ª ed. Rio de Janeiro: INCA; 2006.

16. Moreno V, Bosch FX, Muñoz N, Meijer CJ, Shah KV, Walboomers JM, et al. Effect of oral contraceptives on risk of cervical cancer in women with human papillomavirus infection: the IARC multicentric case-control study. Lancet. 2002;359(9312):1085-92.

17. Zelmanowicz Ade M, Schiffman M, Herrero R, Goldstein AM, Sherman ME, Burk RD, et al. Family history as a co-factor for adenocarcinoma and squamous cell carcinoma of the uterine cervix: results from two studies conducted in Costa Rica and the United States. Int J Cancer. 2005;116(4):559-605.

18. Martins NV, Ribalta JCL. Patologia do trato genital inferior. São Pualo: ROCA; 2005.

19. DiSaia PJ, Creasman WT. Clinical gynecologic oncology. 7th ed. St. Louis: Mosby; 2007.

20. Coelho FRG, Soares FA, Foch J, Fregnani JH, Zeferino LC, Villa LL, et al. Câncer do colo do útero. São Pualo: Tecmedd; 2008.

21. ABPTGIC – Associação Brasileira de Patologia do Trato Genital Inferior e Colposcopia. Roteiro para laudo colposcópico do colo, vagina e tratamento excisional do colo uterino [Internet]. Acesso em 12/02/2011. Disponível em: http://www.colposcopia.org.br/laudo.php.

22. Subak LL, Hricak H, Powel CB, Azizi L, Stern JL. Cervical carcinoma: computed tomography and magnetic resonance imaging for preoperative staging. Obstet Gynecol. 1995;86(1):43-50.

23. Piver MS, Rutledge F, Smith JP. Five classes of extended hysterectomy for women with cervical cancer. Obstet Gynecol. 1974;44(2):265-72.

24. Querleu D, Morrow CP. Classification of radical hysterectomy. Lancet Oncol. 2008; 9(3):297-303.

25. Tavassoli FA, Devilee P. Pathology and genetics: tumours of the breast and female genital organs. WHO Classification of Tumours series. Lyon, France: IARG Press; 2003.

26. Pecorelli S. Revised FIGO staging for carcinoma of the vulva, cervix, and endometrium. Int J Gynaecol Obstet. 2009;105(2):103-4.

27. Mutch DG:. The New FIGO staging system for cancers of the vulva, cervix, endometrium, and sarcomas. Gynecol Oncol. 2009; 115(3):325-8.

28. Aranha Júnior AA, Campos ACL, Pinto JSP, Agulham MA, Scheferbecker ME, Branco AB. Protocolo eletrônico para coleta estruturada de dados clínicos para pacientes pediátricos em terapia nutricional utilizando o SINPE© (Sistema Integrado de Protocolos Eletrônicos). Rev Col Bras Cir. 2009;36(1):73-7.

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