J Bras Patol Med Lab. 2018 Dec; 54(6): 401-406.

10.5935/1676-2444.20180066

Patient safety by analyzing the information not provided in the requisition orders of cervical cytology test

Segurança de pacientes pela análise de informações não preenchidas nas requisições dos exames citopatológicos

Dayane B. Costa[1]; Analine Rosa B. A. Carvalho[1]; Michele Ana F. Chaves[1]; Jacqueline Plewka[1]; Maurício Turkiewicz[2]

1. Universidade Estadual do Oeste do Paraná (UNIOESTE), Paraná, Brasil. 2. Labcell Citologia Diagnóstica, Paraná, Brasil.

ABSTRACT

Introduction: Cervical cancer is a serious public health problem because of its high incidence and mortality in developing countries and is, therefore, a priority in global health. Organized screening programs can reduce the incidence and mortality of cervical cancer due to the early detection of precancerous lesions. **Objective:** To evaluate the incomplete information from cervical cytology test requisitions of the National Cancer Control Programme of the Brazilian Ministry of Health (MoH), verifying the percentage of non-completion in a municipality in western Paraná, Brazil. **Methods:** A retrospective and quantitative study was carried out, based on data from cervical cytology test requisitions, from women attended by the Unified Health System [Sistema Único de Saúde (SUS)] in a municipality in western Paraná from May 2014 to May 2015. **Results:** The failure to provide the information occurred in 9,010 (40.9%) requisitions. The information not provided is mandatory for the health team responsible for collecting this exam in accordance with MoH guidelines. **Conclusion:** There is a need for professional training about filling in the information on requisitions, because they collaborate with the increase of the sensitivity and specificity of the cytology test, thus allowing more reliable results that aid in patient safety.

Key words: cervix; patient safety; Pap smear test.

INTRODUCTION

Cervical cancer is a serious public health problem due to its high incidence and mortality and is, therefore, a priority in global health[1]. The combination of prevention of human papillomavirus (HPV) infection and the oncotic cytology screening is one of the main measures to reduce the morbidity and mortality of the disease. According to the World Health Organization (WHO), 85% of cervical cancer deaths occur in developing countries, accounting for 13% of all female cancers[2].

In Brazil, this pathology is still a serious public health problem, since it affects mainly women with greater difficulty in accessing health services[3]. It is classified as the third type of cancer with a higher incidence in the female population, with 16,370 new cases estimated for each year of the 2018-2019 biennium[4].

Organized, efficient and effective screening programs can reduce the incidence and mortality of cervical cancer due to the early detection of precancerous lesions. With a coverage of the population of at least 80% and the guarantee of diagnosis and treatment of altered cases, there may be a 60% to 90% reduction in the incidence of this cancer[5].

Developed countries such as France and Italy, which implemented cervical cancer prevention programs in 1991 and 1989, respectively, and used the same strategy adopted in Brazil, according to the WHO report on cancer screening in the European Union, presented in 2012 the incidence of cases of cervical cancer of approximately 7.9 cases and a mortality of approximately 2.4 cases per 100,000 women[6].

On the other hand, East African countries have a mortality rate of 27.6 cases per 100,000 women[6]. In 2015, Brazil had a mortality rate of 5.7 deaths per 100,000 women[7].

First submission on 07/11/18; last submission on 07/11/18; accepted for publication on 10/22/18; published on 12/20/18

Based on the above, the main screening method used worldwide for the disease is cervical cytopathology tests examination, known as Pap test, as it is an effective, safe and a low cost strategy for the early detection of this pathology. In Brazil, the National Cancer Control Programme for Cervical Cancer of the Brazilian Ministry of Health (MoH) was created with the objective of reducing the mortality, physical, psychological and social impact of cervical cancer. This program is targeting women in the age group of 25 to 64 years[4] and women who have already started sexual activity, according to the Law no. 11,664, dated April 29, 2008, which provides for the implementation of health actions that ensure the prevention, detection and treatment of this cancer in the Unified Health System [Sistema Único de Saúde (SUS)][4, 8].

Considering the high incidence and mortality rates of cervical cancer in Brazil, it is necessary to know the prevalence of cervical cytopathologic alterations in a population and to correlate them with the clinical data of the patient, for an appropriate follow-up and treatment of the precursors lesions of cervical cancer in these women[9].

According to the Brazilian Guidelines for Cervical Cancer Screening of the Ministry of Health (2016), data of the pap smear cytology requisition are mandatory for the health team responsible for collecting this exam, since they help in the interpretation of the cytomorphological criteria observed in the laboratory analysis[4]. Therefore, Ordinance no. 176, dated January 29, 2014, which amends provisions of Administrative Rule no. 3,388 GM/MS published on December 30, 2013, redefined the National Qualification in Cytopathology for Cervical Cancer Prevention (QualiCito), which consists of establishing norms and evaluating the quality of cytopathology tests by monitoring service providers for the SUS, through Internal Quality Monitoring (IQM) and External Quality Monitoring (EQM)[10].

The quality monitoring indicators of cervical cytopathology tests allows to contribute in the implementation of corrective strategies and improvements, as well as to monitor and evaluate the impact of these actions and the inclusion of new practices[10].

In the IQM, the provider laboratory only performs in the pre-analytical phase the checking and the inspection of the received material, besides the preparation, staining and assembly of the slides, which must be properly registered by the laboratory; the personal information records are completely filled in the health units[10].

Appropriate completion of the women's identification data and anamnesis data, such as the date of the last menstrual period, previous examinations, any previous treatments, symptoms and changes in the cervix are essential for the traceability of patients and also for the identification of a high-risk patient[10].

In the analytical phase, in the IQM, the main objective of the laboratory is the reduction of false negative and false positive results, caused mainly by errors of scrutiny or interpretation of the result. Therefore, the analytical phase fully cooperates with the pre-analytical phase, and the integration of both phases performed properly is one of the tools for the success of the prevention program[10].

WHO estimates that thousands of individuals suffer unnecessary harm each year due to unsafe health services[11]. In this regard, health systems that reduce the risk of harm to the patient to an acceptable minimum are increasing the quality of their services. Patient identification and data on specimens and requisition forms are required in any attempt to prevent laboratory errors[12].

Quality monitoring contributes to patient safety, stimulating change and reformulation in care processes, identifying failures before causing harm to patients[13]. Thus, the objective of this study is to evaluate the incomplete information of the cervical cytopathology test requisitions of the National Cancer Control Programme of the MoH for this cancer, checking the quality of the pre-analytic phase in cervical cancer prevention in a municipality of western Paraná, Brazil.

METHODS

A retrospective and quantitative study was carried out based on the data from the cervical cytopathology tests requisitions from women attended by SUS in a municipality in western Paraná, from May 2014 to May 2015. These data were collected in an accredited cytopathology laboratory, service provider to SUS as from May 2014. The work was approved by the ethics committee under protocol number 892.452.

The cervical cytopathology tests were collected by the health team, according to the protocol established by the MoH, in the 36 Basic Health Units [Unidades Básicas de Saúde (UBS)] and Family Health Units [Unidades de Saúde da Família (USF)] of referred municipality and districts and five agencies of specialized services, totaling 41 units.

Twenty-two thousand and fourteen requisitions for cervical cytopathology tests were evaluated, and the completeness of data information on anamnesis and the clinical examination (visual inspection of the cervix) was included in this study.

RESULTS

The absent information demonstrated in this study are required by the health team responsible for collecting this exam, according to MoH guidelines, however they occurred in 9,010 requisitions (40.9%) out of a total of 22,014.

The reason for the test (screening, repetition or follow-up) was the information with a higher percentage of non-completion, followed by visual inspection of the cervix, bleeding after menopause, and bleeding after sexual intercourse. Regarding the other parameters, these are shown in the **Table**.

TABLE – Data from anamnesis and clinical examination (n = 22,014)

Variables	Not provided	%
Anamnesis		
Reason for examination	4947	22.5
Has already take preventive exam	436	2
Uses IUD	220	1
Is pregnant	252	1.1
Use of birth control pills	290	1.3
Use of hormone therapy	349	1.6
Has already be treated with radiation therapy	367	1.7
Has or had had any bleeding after sexual intercourse	533	2.4
Has or had had any bleeding after menopause	580	2.6
Clinical examination		
Visual inspection of the cervix	662	3
Symptoms suggestive of STD	374	1.7

IUD: intrauterine device; STD: sexually transmitted disease.

DISCUSSION

Failure to complete the requisition for the cervical cytology test reflects on the quality of the screening program, which may prevent the registration of women in the Cancer Information System [Sistema de Informação do Câncer (SISCAN)] or change their information in the system and the identification of the women who are in the group of precancerous lesions, in addition to compromising the statistical data of the Program[14]. Furthermore, these data assist the cytologist in the laboratory IQM, as well as in the patient clinical-laboratory correlation and the interpretation of the cytomorphological criteria observed in the cytological evaluation (scrutiny), may also interfere with the sensitivity and specificity of this test.

False negative results occur when neoplastic cells are recognized but are mistakenly classified as benign or underestimated as benign. These results in cytological evaluations are mainly due to the interpretation error, which is attributed to the cytologist's inexperience and mainly to inappropriate and not provided clinical information[15].

The information regarding the reason for the test was the index with the highest percentage of non-completion (22.5%). This information provides the cytologist with the cytomorphological follow-up of the lesions, by the regression or evolution of the cellular atypia observed, in addition to allowing the identification of the cytological slides that should be reviewed by the Internal Quality Monitoring, since the cytology obtained from women with repetition or follow-up are classified as high risk[14].

The Quality Management Manual for Cytopathology Laboratories suggests that screening selected smears based on clinical risk criteria consists of re-evaluating smears classified as negative on routine scrutiny, but having clinical indications, such as bleeding, evidence of sexually transmitted disease (STD), macroscopic alterations to the speculum examination, pelvic radiotherapy and altered anterior cytopathology test[10, 15]. For women considered to be at high risk based on clinical criteria, a review of negative results may detect a greater number of false negative results, increasing the sensitivity of the cytopathology test. An important clinical information causes this test to be re-evaluated in the laboratory's IQM program, which enables a reduction of false-negative rates[15]. It is known that one of the complications that can affect patients using intrauterine device (IUD) is infection of the female genital tract with *Actinomyces* spp. In a study by Discacciati *et al*. (2005)[16], 7% of women who used IUD were colonized with this microorganism, which is the main cause of acute pelvic inflammatory disease. The IUD use information was not provided in 0.9% of the requisitions in this study, and in the study by Amaral *et al*. (2014)[14] the percentage found on not completing this information was 3.2%.

In our study, there was a percentage of 1.1% on not provide to the question "if the woman is pregnant". During pregnancy, there is imbalance of the vaginal microbiota, and the development of infectious processes is possible. Vaginal discharge from infections can cause serious damage to the pregnant woman and newborn health, such as prematurity and low-birthweight, chorioamnionitis, postpartum endometritis, and post-cesarean section wound infection[17]. Therefore, this information is very important so that there is a screening of pregnant women at risk. Another point to consider in pregnancy is the cellular changes present in this phase known as hormonal karyomegaly or the presence of *Arias-Stella* cells, which express atypical characteristics and can be interpreted with neoplastic cells, and therefore, caution is required in relation to the possible diagnosis of adenocarcinoma in pregnancy[17].

Steroid hormones, in birth control pills form, for contraception, are commonly administered during the reproductive phase and appear to increase the transforming activity of HPV oncogene, and interfere with the efficient resolution of lesions caused by the virus in the cervix of young women[18]. However, there are controversial studies, since women who use contraceptive also have other promoting factors, such as early start of sexual intercourse, large number of partners and non-use of condoms, which favors the acquisition of STD, and therefore are also considered as co-factors in the cervical carcinogenesis[19, 20]. In our study, the information if the woman was using a birth control pill was not provide in 1.3% of the requisitions; whereas in the aforementioned study, 3.4% did not provide this information. We found a lower index than that in the presented study, but this information is significant for the sensitivity of the exam.

In 1.6% of the requisitions, information on hormone use was not provided. This information on the use of hormone replacement therapy helps the cytologist to identify the atrophic reactive and degenerative changes that cause cytomorphological changes that can mimic atypical squamous cells of undetermined significance (ASC-US), and also to verify if there is unnecessary repetition of the cytopathology test[10, 21].

Radiation therapy for cervical cancer can cause benign reactive or reparative cellular changes, which may lead to doubt to the interpretation of the cytomorphological criteria when not reported and may be concluded as cellular atypia, which indicates that the woman treatment to this cancer was not effective. In our study, this data was not provided in 1.6% of the requisition, which is of great importance since the cells with a radiotherapy effect are difficult to interpret and may be underestimated by a cytopathologist with little experience, not detecting an early or recurrent cancer[20].

The second highest non-completion index was bleeding after sexual intercourse (2.6%). This data is important because it may be one of the signs related to the suspected precancerous lesions or cervical cancer, as well as atypia, which, in case of severe altered cytological results identified by the clinician, should be investigated with complementary exams such as colposcopy and histology in secondary care, according to the MoH guidelines and behaviors[10].

According to the work by Almeida *et al*. (2012)[22], in the city of Vitória, Espírito Santo, Brazil, data on the completion of the requisition for cytopathology tests, such as IUD use, pregnancy, birth control pill use, hormone use, radiotherapy, bleeding after sexual intercourse, bleeding after menopause, visual inspection of the cervix and STD symptoms, were provided in 88.8% for each of the items listed above[22].

In Criciúma, Santa Catarina, Brazil, the percentage of incomplete data on cervical inspection, STD symptoms and bleeding after menopause were 25%, 22% and 12%, respectively, with the highest unreported percentage[23]. In comparison with our work, the non-completion of these data were 3%, 1.7% and 2.6%, respectively, thus lower percentages than that observed in other studies.

The Brazilian National Health Surveillance Agency [Agência Nacional de Vigilância Sanitária (Anvisa)] recommends that the patient's medical records or requisitions must contain accurate and complete information, thus allowing the efficiency in the diagnosis of different conditions and also in the selection of the correct treatment, especially cytopathology test of the cervix, which is a subjective examination, and the screening of cervical cancer[12].

In 2014, according to Anvisa, 8,435 notifications of incidents related to health care were submitted; from these, 194 refer to "symptoms, signs and abnormal findings of clinical and laboratory exams not elsewhere classified". Among the types of incidents 59 "clinic or pathology-related failures" and 254 "patient identification failures" have been described[13].

The health care field has several sources of error common to the system, such as routine, fatigue, overtime, work overload and employee turnover, therefore it is difficulty found for the prevention programs to be carried out in a promising way[13].

In basic health care, there is a technical manual for professionals who work on cervical prevention, but often the manual alone is not enough on its on, and it is necessary to carry out training or qualifications to improve the quality of care. A study by Amaral *et al*., in 2014, shows that there was a significant increase in data completeness frequency after training of the professionals who were responsible for completing the cytopathology tests requisition form[14]. For the visual inspection of the cervix, for example, this increase ranged from 86.8% to 96.6%.

The mandatory completion of these requisitions by the health units aims to allow the understanding of the pathological processes involved in the development of this cancer, as well as the inflammatory processes and STD. Furthermore, it aims to promote computerization and allow the comparability of the results, enabling the epidemiological knowledge about the pre-neoplastic and neoplastic lesions of the cervix, as well as a proper prevention and control actions planning by the competent authorities[3].

It is known that completeness of the requisitions for cytopathology tests examination is one of the elements of the pre-analytic phase of cervical cancer prevention, and the lack of information there may reflect on the quality of the screening program. In order to perform a higher quality exam, the pre-analytical, analytical and post-analytical phases should be valued, and the integration between all of them is decisive, as well as all the professionals involved in this exam, and it should be a constant and continuous process[23].

CONCLUSION

Considering the results found in this study, it is possible to verify that there is a need for training professionals among the phases involved in order to achieve a greater data completeness for the cytopathology tests requisition form, thus increasing the specificity and the sensitivity of the cytopathology test, besides helping the cytologist in the interpretation of the cytomorphological criteria, improving quality and safety of patient care.

RESUMO

Introdução: *O câncer do colo do útero é um sério problema de saúde pública devido a sua alta incidência e mortalidade em países subdesenvolvidos, sendo, desta forma, uma prioridade na saúde mundial. Programas organizados de rastreamento podem reduzir a incidência e a mortalidade do câncer do colo do útero em virtude da detecção precoce de lesões pré-malignas.* ***Objetivo:*** *Avaliar as informações não preenchidas das requisições dos exames citopatológicos do colo do útero do Programa Nacional de Controle desse câncer do Ministério da Saúde (MS), verificando o percentual de não preenchimento em um município do oeste do Paraná, Brasil.* ***Métodos:*** *Foi realizado um estudo retrospectivo e quantitativo, com base nos dados das requisições de exames citopatológicos do colo do útero, das mulheres atendidas pelo Sistema Único de Saúde (SUS) no referido município, no período de maio de 2014 a maio de 2015.* ***Resultados:*** *Não houve preenchimento das informações em 9.010 (40,9%) requisições. As informações não fornecidas são de preenchimento obrigatório pela equipe de saúde responsável pela coleta deste exame conforme as diretrizes do MS.* ***Conclusão:*** *Há uma necessidade de treinamento profissional acerca do preenchimento das informações, pois elas colaboram com o aumento da sensibilidade e da especificidade do exame citopatológico, permitindo assim resultados mais confiáveis e que auxiliem na segurança da paciente.*

Unitermos: *colo do útero; segurança da paciente; teste de Papanicolaou.*

REFERENCES

1. Cardona-Arias JA, Valencia-Arredondo M. Prevalencia de alteraciones oncológicas en la citología cervicovaginal de pacientes de una institución prestadora de servicios de salud de Medellín 2010-2012. Ces Medicina. 2014; 28(1): 7-20.

2. World Health Organization. National cancer control programmes: policies and managerial guidelines. Geneva: WHO; 2002; 1: 1-180.

3. Teixeira LA. Dos gabinetes de ginecologia às campanhas de rastreamento: a trajetória da prevenção ao câncer de colo do útero no Brasil. História, Ciência, Saúde – Manguinhos. 2015; 22(1): 221-40.

4. Brasil. Ministério da Saúde. Instituto Nacional de Câncer. Coordenação Geral de Ações Estratégicas. Divisão de Apoio à Rede de Atenção Oncológica. Diretrizes brasileiras para o rastreamento do câncer do colo do útero. Rio de Janeiro: INCA; 2011.

5. World Health Organization. Cancer control: knowledge into action: WHO guide for effective programmes: Prevention. Geneva: WHO; 2007; 1-56.

6. Ferlay J, Soerjomataram I, Dikshit R, et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. Int J Cancer. 2015; 136(5): 359-86.

7. Brasil. Ministério da Saúde. Instituto Nacional do Câncer. Atlas on-line de mortalidade. Available at: https://mortalidade.inca.gov.br/MortalidadeWeb/pages/Modelo05/consultar.xhtml;jsessionid=82239BA2EA437B397BE174B4163AB37B#panelResultado. [Accessed on: Fev 12, 2018].

8. Brasil. Ministério da Saúde. Instituto Nacional do Câncer. Programa nacional de controle do câncer do colo uterino. Rio de Janeiro: Inca; 2011.

9. Brasil. Ministério da Saúde. Secretaria de Assistência à Saúde. Instituto Nacional de Câncer. Coordenação de prevenção e vigilância. Nomenclatura brasileira para laudos cervicais e condutas preconizadas: recomendações para profissionais de saúde. 3 ed. Rio de Janeiro: Inca; 2012.

10. Brasil. Ministério da Saúde. Instituto Nacional de Câncer. Manual de gestão da qualidade para laboratório de citopatologia. Rio de Janeiro: Inca; 2012.

11. World Health Organization. Summary of the evidence on patient safety: implications for research. Geneva: WHO; 2008; 1-136.

12. Agência Nacional de Vigilância Sanitária (Anvisa). Assistência segura: uma reflexão teórica aplicada à prática. Brasília: Anvisa; 2017; p. 172.

13. Agência Nacional de Vigilância Sanitária (Anvisa). Boletim informativo. Segurança do paciente e qualidade em serviços de saúde. Brasília: Anvisa; 2011; 1(1): 1-12.

14. Amaral AF, Araújo ES, Magalhães JC, Silveira EA, do Nascimento Tavares SB, Amaral RG. Impacto da capacitação dos profissionais de saúde sobre o rastreamento do câncer do colo do útero em unidades básicas de saúde. Rev Bras Ginecol Obstet. 2014; 36(4): 182-7.

15. Tavares SBN, Amaral RG, Manrique EJC, Sousa NLA, Albuquerque ZBP, Zeferino LC. Controle de qualidade em citopatologia cervical: revisão de literatura. Rev Bras Cancerol. 2007; 53(3): 355-64.

16. Discacciati MG, Simões JA, Montemor EB, Portugal PM, Balys AL, Montiz DM. Avaliação microbiológica e citopatológica dos esfregaços de Papanicolaou em usuárias de dispositivo intrauterino. J Bras Doenças Sex Transm. 2005; 17(1): 28-31.

17. Murta EFC, de Souza MAH, Adad SJ, Araújo Júnior E. Infecção pelo papilomavírus humano durante a gravidez: relação com achados citológicos. Rev Bras Ginecol Obstet. 2001; 23(6): 377-81.

18. Leitão NMA, Pinheiro AKB, Anjos SJSB, Vasconcelos CTM, Nobre RNS. Avaliação dos laudos citopatológicos de mulheres atendidas em um serviço de enfermagem ginecológica. REME. 2008; 12(4): 508-15.

19. Silva FC, Boer CG, Irie MMT, Yoshida CS, Svidzinski TIE, Consolaro MEL. Avaliação da influência do uso de métodos contraceptivos sobre os resultados dos esfregaços de Papanicolaou. Acta Health. 2006; 28(1): 65-70.

20. Padilha CML, Araújo Junior MLC, Souza SAL. Cytopathologic evaluation of patients submitted to radiotherapy for uterine cervix cancer. Rev Assoc Med Bras. 2017; 63(4): 379-85.

21. Vigeta SMG, Brêtas ACP. A experiência da perimenopausa e pós-menopausa com mulheres que fazem uso ou não da terapia de reposição hormonal. Cad Saúde Pública, Rio de Janeiro. 2004; 20(6): 1682-9.

22. Almeida MVS, Amorim MHC, Thuler LCS, Zandonade E. Avaliação da qualidade dos dados do sistema de informação do câncer do colo do útero em Vitória-ES, Brasil. Rev Bras Cancerol. 2012; 58(3): 427-33.

23. Cardoso PT. Busca pela qualidade no serviço de um laboratório citopatológico de pequeno porte. [monography]. Crisciuma (SC): UNESC; 2011.

CORRESPONDING AUTHOR

Dayane Bassotto da Costa

Hospital Universitário do Oeste do Paraná; LACEPE; Avenida Tancredo Neves, 3224; Santo Onofre; CEP: 85806-470; Cascavel-PR , Brasil; e-mail: dayane_bassotto@yahoo.com.br.