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Internal quality control indicators of cervical cytopathology exams performed in laboratories monitored by the External Quality Control Laboratory

Avaliação de indicadores de controle de qualidade interno de exames de citopatologia cervical realizados em laboratórios monitorados pelo Laboratório Externo de Controle de Qualidade

Original Article

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Palavras-chave
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Abstract

PURPOSE: To evaluate the impact of continued education provided by an external quality control laboratory on the indicators of internal quality control of cytopathology exams. **METHODS:** The internal quality assurance indicators for cytopathology exams from 12 laboratories monitored by the External Quality Control Laboratory were evaluated. Overall, 185,194 exams were included, 98,133 of which referred to the period preceding implementation of a continued education program, while 87,061 referred to the period following this intervention. Data were obtained from the Cervical Cancer Database of the Brazilian National Health Service. **RESULTS:** Following implementation of the continued education program, the positivity index (PI) remained within recommended limits in four laboratories. In another four laboratories, the PI progressed from below the limits to within the recommended standards. In one laboratory, the PI remained low, in two laboratories, it remained very low, and in one, it increased from very low to low. The percentage of exams compatible with a high-grade squamous intraepithelial lesion (HSIL) remained within the recommended limits in five laboratories, while in three laboratories it progressed from below the recommended levels to >0.4% of the total number of satisfactory exams, and in four laboratories it remained below the standard limit. Both the percentage of atypical squamous cells of undetermined significance (ASC-US) in relation to abnormal exams, and the ratio between ASC-US and intraepithelial lesions remained within recommended levels in all the laboratories investigated. **CONCLUSION:** An improvement was found in the indicators represented by the positivity index and the percentage of exams compatible with a high-grade squamous intraepithelial lesion, showing that the role played by the external quality control laboratory in providing continued education contributed towards improving laboratory staff skills in detecting cervical cancer precursor lesions.

Resumo

OBJETIVOS: Verificar o impacto da educação continuada realizada pelo Laboratório de Monitoramento Externo da Qualidade nos indicadores de monitoramento interno da qualidade dos exames citopatológicos. **MÉTODOS:** O estudo avaliou os indicadores de monitoramento interno da qualidade dos exames citopatológicos de 12 laboratórios monitorados pelo Laboratório de Monitoramento Externo da Qualidade, totalizando 185.194 exames, sendo 98.133 referentes ao período antes da educação continuada e 87.061 após a educação continuada. Os dados para avaliar os indicadores foram obtidos por meio do Sistema de Informações do Câncer do Colo do Útero disponibilizados pelo Departamento de Informática do Sistema Único de Saúde. **RESULTADOS:** Verificou-se que, após a educação continuada, quatro laboratórios mantiveram o índice de positividade (IP) dentro do recomendado, quatro que estavam abaixo passaram a ter o IP dentro do recomendado, um permaneceu baixo, dois permaneceram muito baixo e um passou de muito baixo para baixo. Em relação ao indicador percentual de exames compatíveis com lesão intraepitelial escamosa de alto grau, cinco laboratórios mantiveram o índice dentro do recomendado, três que estavam abaixo do recomendado passaram a ter esse índice acima de 0,4 e quatro permaneceram abaixo do recomendado. Os indicadores atipias de significado indeterminado/alterados e razão atipias de significado indeterminado/lesões intraepiteliais mantiveram-se dentro do recomendado em todos os laboratórios. **CONCLUSÃO:** Observou-se melhora nos indicadores de positividade e percentual de exames compatíveis com lesão intraepitelial de alto grau, mostrando que o papel desempenhado pelo Laboratório de Monitoramento Externo da Qualidade contribui para o aprimoramento dos profissionais na detecção de lesões precursoras do câncer do colo do útero.

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Introduction

Efforts have been made by the Brazilian Ministry of Health to improve strategies to reduce the incidence of cervical cancer and its resulting mortality, both of which can be decreased through organized, active and well-managed screening programs[1-5]. The process of screening for cervical cancer is based on the natural history of the disease and on the detection and treatment of its precursor lesions, preventing their progression to cancer[1,6].

The objective of a quality control program in cytopathology is to improve the ability of exams to detect epithelial abnormalities and, consequently, reduce false-negative results[7]. Therefore, internal and external quality control measures that would guarantee excellence at all the different stages of the exams need to be implemented as routine practice in laboratories[8-11].

Internal quality control allows laboratories to identify any nonconformity, from the moment the material arrives at the laboratory until the results are issued. Methods of reviewing cytopathology exams need to be well defined by laboratories according to the relevant recommendations of the Ministry of Health. In addition, laboratories need to ensure that the cervical cytopathology team is qualified and sufficiently dimensioned to deal with the volume of examsperformed[1]. Internal quality control indicators are very important, since they permit processes to be monitored by analyzing, quantifying and registering data at all the different stages, enabling results to be compared at different moments. It is essential for the laboratory to monitor its results continuously, evaluating both the overall performance and the individual performance of staff members[1].

Laboratories are expected to have a positivity index (PI) ≥3.0%. In addition, the percentage of atypical squamous cells should be less than 60% of abnormal exams; the percentage of exams compatible with high-grade squamous intraepithelial lesion (HSIL/satisfactory) should be ≥0.4% of the total number of satisfactory exams; and the ratio between atypical squamous cells and squamous intraepithelial lesions (the ASC/SIL ratio) should be ≤3[1]. It was recently shown that in the majority of Brazilian laboratories the PI and HSIL/satisfactory percentage were below recommended levels, possibly indicating false-negative results and highlighting the need to implement internal quality control measures. Additionally, all laboratories should participate in the external control programs conducted by the External Quality Control Laboratories (LabMEQ)[12,13].

This facility promotes continued education for professionals performing cytopathology exams with the aim of standardizing cytomorphological criteria, improving accuracy in the detection of early precursor lesions, reducing the percentage of false-negative results, and consequently, improving internal quality control indicators[14]. To guarantee the quality of cytopathology exams ensures the effectiveness of cervical cancer screening programs. Since the internal quality control indicators were below recommended levels in the majority of laboratories, it is crucial that the professionals working in this area participate in continued education programs to update their knowledge, improve their performance and standardize cytomorphological criteria. Therefore, the objective of this study was to evaluate the impact of a continued education program on the internal quality control indicators of cytopathology exams in cervical cancer screening.

Methods

This intervention study was conducted by LabMEQ at the School of Pharmacy of the Universidade Federal de Goiás, Brazil. It was approved by the university's internal review board under approval #343/10. Cytopathology exams carried out between 2007 and 2012 at 12 laboratories accredited with the Brazilian National Health System (SUS). They were evaluated by calculating the internal quality control indicators. Data were obtained using the tabnet function of the Cervical Cancer Database, available at the SUS website[15].

The sample consisted of 185,194 cytopathology exams, 98,133 pertaining to the period preceding implementation of the continued education program (2007 and 2008) and 87,061 referring to the period following implementation of the continued education program (2011 and 2012). All the laboratories evaluated in this study participate in an external quality control program conducted by LabMEQ in compliance with the Ministry of Health recommendations. Therefore, all the reports and slides of all cases considered positive or unsatisfactory and 10% of those considered negative and selected through the Cervical Cancer Data System are referred to LabMEQ on a monthly basis.

Upon receipt, the slides and reports were checked and sent for an initial review. If the results were in agreement with those of the initial evaluation, this cytopathology result was considered final. Discordant results were sent to a second reviewer to define the final cytopathology result. If an agreement was reached, this was considered the final cytopathology result. If results continued discordant, then the result was defined at a consensus meeting that included the participation of at least three professionals. The final result of the cytopathology exams was classified in accordance with the Bethesda system[16]. Cases were considered discordant when the results led to a change in the woman's clinical

management in accordance with the criteria established by the Ministry of Health[5].

The laboratories were provided with monthly reports informing them of any nonconformity, providing them with an evaluation of the pre-analytical phase, and communicating any results considered by LabMEQ to be discordant. If the laboratories agreed with the result, they forwarded the amended report to the healthcare center responsible for locating the woman and defining the clinical management to be implemented in her particular case. If they disagreed, a consensus meeting was held at LabMEQ to define the final cytopathology result.

The continued education program consisted of theoretical and practical classes held every two months with 18 professionals from the laboratories involved in this study, including the technicians responsible for the pre-analytical technical stage and the trained professionals responsible for analyzing the exams. These classes included practical training, with a review of slides and a discussion of clinical cases, and theoretical classes on topics of interest. The continued education program enabled any discordant cases detected during external quality control to be reviewed and discussed, including false negative and false positive results and delayed management. This measure was aimed at improving accuracy with regard to cytomorphological criteria and the quality of the exam, principally in detecting precursor lesions. In accordance with the needs of each laboratory, individual meetings were held with the staff to discuss the nonconformities detected and the discordant cases.

Four internal quality control indicators were used to evaluate the cytopathology tests as recommended by the Ministry of Health[1]. The PI is an indicator of positivity that expresses the prevalence of cell alterations and characterizes the sensitivity of the screening process in detecting lesions, defined in accordance with the Bethesda system, in the population examined[16]. It is calculated according to the total number of cytopathology exams with abnormal results in any given place and period divided by the total number of satisfactory cytopathology exams conducted in the same place and over the same period of time, multiplied by 100. A PI<2.0% is considered very low, 2.0–2.9% low, 3.0–10.0% within the expected range and >10% better than expected[1].

The second indicator is the percentage of high-grade squamous intraepithelial lesions (HSIL) in relation to the number of tests with satisfactory results: this indicator measures the capacity of a laboratory to detect precursor lesions. HSIL are the true lesions precursor of cervical cancer, i.e. those with an actual potential for progression, rendering their detection the prime objective in the secondary prevention of cervical cancer[17]. It is calculated from the total number of exams defined as HSIL divided by the total number of satisfactory exams, multiplied by 100. Recommendations state that this indicator should be ≥0.4%.

The percentage of exams defined as atypical squamous cells (ASC) in relation to the total number of abnormal exams should be analyzed together with the PI, since an apparently adequate PI may nonetheless include a high percentage of exams compatible with ASC, and recommendations are that ASC should be <60% of abnormal exams. This index is calculated from the total number of exams defined as atypical squamous cells of undetermined significance (ASC-US) or atypical squamous cells — cannot exclude high-grade squamous intraepithelial lesion (ASC-H) divided by the total number of abnormal exams, multiplied by 100.

The fourth criteria is the ASC-SIL ratio which indicates technical difficulties in identify in low- and high-grade squamous intraepithelial lesions (LSIL and HSIL). This ratio is calculated based on the total number of exams defined as ASC-US or ASC-H divided by the total number of exams defined as LSIL or HSIL. Recommendations are that this ratio should be no greater than 3.

Results

Of the 12 laboratories evaluated, the PI remained within recommended parameters in four. In another 4 cases, the PI progressed to within specifications (PI≥3%) following implementation of the program, with 66.7% of the laboratories now complying with these specifications compared to 33.3% prior to intervention. In one laboratory, however, the PI remained low (2.0–2.9%) and in another two cases, it remained very low (<2.0%). In one laboratory, the PI progressed from very low to low. In the general evaluation of the laboratories, the PI that was considered very low came within the recommended standards following implementation of the continued education program (Table 1).

The HSIL/satisfactory index remained within the recommended parameters in five laboratories, while in three it progressed from below the recommended limit to above 0.4% following the continued education program. The number of laboratories within the recommended limits rose from 50 to 66.7%. Nevertheless, this indicator remained below recommended levels in four laboratories. In the general evaluation of the laboratories, this indicator, which was below the recommended levels, came within specifications following implementation of the continued medical education program (Table 1).

In relation to the ASC/abnormal index (<60%) and the ASC/SIL ratio (<3), all the laboratories remained within the recommended parameters (Table 1).

Table 1. Internal quality control indicators of cytopathology exams in participating laboratories prior to and following a continued education program conducted by the External Quality Control Laboratory

LAB	Performed (n)		Abnormal (n)		Positivity Index (%)		HSIL/Satisfactory (%)		ASC/Abnormal (%)		ASC/SIL ratio	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
1	4,541	4,212	175	128	3.8	3.0	0.5	0.7	46.8	40.5	1.1	1.1
2	6,978	6,413	232	172	3.3	3.0	0.4	0.5	54.2	33.3	1.1	0.7
3	29,216	29,358	823	1,254	2.7	4.4	0.6	0.8	30.5	48.7	0.4	1.0
4	3,953	1,159	12	41	0.3	3.5	0.0	0.3	18.1	39.2	0.6	1.1
5	14,955	6,831	20	128	0.1	0.9	0.1	0.5	52.7	40	1.3	1.3
6	5,740	3,940	141	80	2.4	2.1	0.2	0.3	54.6	39.7	1.8	0.9
7	2,018	2,620	114	190	5.8	7.2	0.9	0.7	50.5	50.2	1.2	1.8
8	1,519	3,932	14	210	0.8	5.2	0.1	1.4	40.0	33.5	1.3	0.7
9	2,356	2,064	94	112	3.7	5.6	0.6	1.0	31.3	50.9	0.6	1.0
10	14,786	13,012	300	626	2.0	5.0	0.4	1.1	40.6	46.7	0.7	0.9
11	3,997	4,332	29	32	0.7	0.8	0.1	0.1	24.0	27.2	0.4	0.4
12	8,074	9,188	31	210	0.3	2.3	0.1	0.2	5.0	19.1	0.1	0.3
T	98,133	87,061	1,985	3,183	2.1	3.6	0.3	0.6	37.3	30.1	0.9	0.9

LAB: laboratory; HSIL/satisfactory: percentage of detection compatible with high-grade squamous intraepithelial lesion; ASC/abnormal: percentage of exams compatible with atypical squamous cells among abnormal exams; ASC/SIL ratio: ratio between atypical squamous cells and squamous intraepithelial lesions; T: total.

Source: SISCOLO/DATASUS. Accessed on June 20, 2013.

Discussion

The results of the present study show that, after the implementation of LabMEQ's continued education program, the PI was within the recommended range in the majority of the participating laboratories. In countries such as the United States and the United Kingdom, in which screening has successfully reduced the incidence of cervical cancer and its resulting mortality, the percentage of positivity has been reported as 6.8[18] and 6.4%[19], respectively.

The results of this study show an increase in the number of laboratories in which the percentage of HSIL/satisfactory results was ≥0.4%. In the United States[20] and in Canada[21], the percentage of HSIL/satisfactory results has been reported as 0.5 and 0.6%, respectively. When this indicator is below the recommended level, this may be a sign of false-negative results that would consequently delay clinical management and treatment of the lesion. Correctly identifying these abnormalities, confirming diagnosis, initiating treatment in a timely fashion and monitoring the patient appropriately may avoid progression of the precursor lesion to invasive cancer[19].

It appears reasonable to assume that the improvement in PI and in the detection of HSIL found in this study is a direct consequence of the participation of the professionals in the continued education program conducted by LabMEQ. The program improved the definition and standardization of the cytomorphological criteria and consequently improved staff skills, principally with respect to their ability to detect cervical cancer precursor lesions.

In addition to identifying non conformities at all the stages of the exam, continued education highlighted the need for the laboratories to implement internal quality control measures. This initiative would enable them to monitor errors in the daily routine of the laboratory, reducing false-negative and false-positive results and guaranteeing the best possible service. Such measures would also provide the means by which to evaluate the staff's skills[22-25]. Nevertheless, following implementation of the continued education program in this study, the PI and HSIL/satisfactory indicators still failed to meet the recommended standards in some laboratories. This may have occurred due to the high turnover of professionals in some of the laboratories, resulting in some of them missing some of the continued education classes held at LabMEQ. This may have had a detrimental effect on the standardization of the cytomorphological criteria proposed in the continued education program.

In cytopathology, quality control is based on techniques for detecting, correcting and reducing deficiencies in the laboratory's production process[26]. The participation of laboratories in external quality control programs contributes towards improving the quality of the exams; however, the implementation of internal quality control measures as routine practice in all the laboratories represents an essential step towards guaranteeing quality, since this improves procedures and minimizes the occurrence of diagnostic errors, in addition to providing guidance on how to improve sample collection and supplying educational material[12]. Cytopathology involves professionals with different types of training and different levels of experience; therefore, it is a subjective method that depends

on the skill and experience of the examiner[27]. The Pan American Health Organization (PAHO) recommends a production volume of at least 15,000 exams annually to enable the professional to develop the required skills[28]. This will result in an improvement in the PI and in the identification of cases of HSIL, since the examiner will be more familiar with suspect alterations[12].

In Brazil, the majority of laboratories perform fewer than 15,000 cytopathology exams annually. A study conducted to evaluate the profile of the cytopathology laboratories working within the Brazilian National Health network showed that only 18.9% of the laboratories were in compliance with recommendations in that they processed more than 15,000 exams annually[29]. In the majority of the laboratories evaluated, the volume of production was low, which may have affected the skill of the professionals performing the exams, thus partially explaining the lack of improvement in the PI and HSIL/satisfactory index. Furthermore, the small number of exams performed, resulting in less financial gain for the laboratory, may in part explain the reluctance of the laboratories to implement routine internal quality control measures.

In relation to the ASC/abnormal percentage and ASC/SIL ratio indicators, the results of the present study show that they remained within the recommended parameters in all the laboratories evaluated. These indicators are important, since they are able to identify those professionals who need to review the ASC and SIL criteria. The ASC/abnormal indicator should be analyzed together with the PI, as an apparently adequate positivity index may conceal a high percentage of exams compatible with ASC[1]. High percentages of ASC suggest problems with the quality of the sample, problems with the laboratory analysis or problems in both steps; however, it is impossible to evaluate the quality of the process separately[1]. Another concern is that, in the case of ASC-US, more exams need to be repeated to improve diagnostic investigation.

The role of laboratories in cervical cancer screening programs is decisive; therefore, concerns respect to the quality of the results of cytopathological exams has led to the implementation of actions aiming to assure its quality. All efforts to reduce the proportion of incorrect results should be encouraged, since these actions will contribute towards improving health conditions and for consolidate screening strategies.

Therefore, it is reasonable to assure that the continued education program conducted by LabMEQ contributed towards improving the performance of the professionals carrying out cytopathological exams, since following implementation of the continued education program, the indicators represented by the PI and HSIL/satisfactory percentage came within the recommended limits.

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