



Original Article

Cervical cancer: state of laboratories to conduct tests in Alagoas

Câncer de colo de Útero: situação dos laboratórios em Alagoas
Cáncer de cuello uterino: situación de los laboratorios en Alagoas

Heloisa Helena Motta Bandini¹, Orcid Id nº 0000-0002-7320-2637
Carmen Silvia Motta Bandini¹ Orcid Id nº 0000-0002-4731-5785
Rodrigo Japur Duarte Tavares² Orcid Id nº 0000-0001-8511-7520
Rozangela M. Almeida Fernandes Wyszomirska³ Orcid Id nº 0000-0003-0066-8927

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Corresponding Author:
Rozangela M. A. F. Wyszomirska
jrantoniasassi@hotmail.com

¹State University of Health Sciences of Alagoas, Maceió, AL, Brazil.

²Órgãos University Center, Teresópolis, RJ, Brazil.

³Federal University of Alagoas, Maceió, AL, Brazil.

Abstract

Cervical cancer has a high incidence among Brazilian women and the cytopathological exam of the uterine cervix (Pap test) is an important tool in its combat by identifying the precursor lesions of the disease. OBJECTIVE: evaluate the internal quality of the laboratories that perform cervical cytopathology tests for the UHS in Alagoas in order to allow the monitoring of the services provided. METHOD: To do so, we used the internal quality control indicators of the laboratories (positivity index, percentage of tests compatible with ASC among satisfactory tests, percentage of ASC among altered tests, ASC/SIL ratio, percentage of tests compatible with HSIL and percentage of unsatisfactory samples), for the triennium 2011-2013, based on data available in SISCOLO. RESULT: the quality of the laboratories investigated is below that recommended by the health organizations and Alagoas has a lower coverage of exams than the population needs. CONCLUSION: the results suggest failures in the health system and the need for redesigning the entire cycle of cervical cancer prevention and control in the state.

Descriptors: Papanicolaou Test; Uterine Cervical Neoplasms; Cancer.

Resumo

O câncer de colo de útero tem alta incidência entre as mulheres brasileiras e o exame citopatológico de colo de útero (Teste de Papanicolaou) é uma importante ferramenta para o seu combate por identificar as lesões precursoras da doença. Avaliar a qualidade interna dos laboratórios que realizam os exames citopatológicos de colo de útero para o SUS em Alagoas de modo a permitir o monitoramento dos serviços prestados. Para tanto, foram utilizados os indicadores de controle interno de qualidade dos laboratórios (índice de positividade, percentual de exames compatíveis com ASC entre os exames satisfatórios, percentual de ASC entre os exames alterados, razão ASC/SIL, percentual de exames compatíveis com HSIL e percentual de amostras insatisfatórias), para o triênio 2011-2013, com base nos dados disponíveis no SISCOLO. A qualidade dos laboratórios investigados está abaixo da recomendada pelas organizações de saúde e Alagoas apresenta uma cobertura de exames inferior à necessária para a população. Os resultados sugerem falhas do sistema de saúde e a necessidade de replanejamento de todo o ciclo de prevenção e controle do câncer de colo de útero no Estado.

Descritores: Teste de Papanicolaou, Neoplasias de colo do útero, Câncer.

Resumen

El cáncer de cuello uterino tiene una alta incidencia entre las mujeres brasileñas y el examen citopatológico del cuello de útero (Prueba de Papanicolaou) es una herramienta importante para su combate, ya que identifica lesiones precursoras de la enfermedad. Evaluar la calidad interna de los laboratorios que realizan exámenes citopatológicos de cuello de útero para el SUS en Alagoas a fin de permitir el monitoreo de los servicios prestados. Para ello se utilizaron indicadores de control interno de calidad de los laboratorios (índice de positividad, porcentaje de pruebas compatibles con ASC entre pruebas satisfactorias, porcentaje de ASC entre pruebas alteradas, relación ASC / SIL, porcentaje de pruebas compatibles con HSIL y porcentaje de muestras insatisfactorias) para el período 2011-2013, con base en los datos disponibles en SISCOLO. La calidad de los laboratorios investigados está por debajo de la recomendada por las organizaciones de salud y Alagoas tiene una cobertura de exámenes por inferior a la necesaria para la población. Los resultados sugieren fallas del sistema de salud y la necesidad de rediseñar todo el ciclo de prevención y control del cáncer de cuello de útero en el Estado.

Descriptor: Prueba de Papanicolaou, Neoplasias de Cuello de Útero, Câncer.

Introduction

Cervical cancer is the fourth most common cancer among women worldwide¹. The mortality rate for this type of cancer, in the country, is much higher than in developed countries², indicating a probable failure of early detection.

Since 1941, the cytopathological exam has been considered an important tool for detecting cervical cancer because it identifies cancer precursor lesions while still in their treatable stage³. However, the test has some limitations, such as low sensitivity and a large number of unsatisfactory samples, as well as false negative results caused by problems in material collection, smear fixation and preparation, and even examiner training⁴⁻⁵. Collection errors are responsible for 20% to 39% of false negative results due to screening errors³, when neoplastic cells are represented on the smear but are not recognized by the examiner; or the non-representativeness or the scarcity of neoplastic cells in the sample and the presence of necrotic background or inflammation on the smears, which impair the analysis⁶.

To ensure the quality of the examinations, both internal and external control is necessary⁷. External control is performed by a second laboratory that blindly reanalyzes 10% of the normal slides and all the altered slides from the initial laboratory. This parameter has been used in Brazil since the end of 2013⁸. Internal control must be performed by the laboratory itself and is defined as a set of systematic actions regularly performed in order to monitor sample suitability, scrutiny time, scrutinizer workload control, hierarchical review of smears, and review of negative smears⁹.

It is up to the state and municipal managers to supervise the quality of the services provided to the population that uses the Unified Health System (UHS), whether the service provider is public or private⁷. The Cervical Cancer Information System (SISCOLO) was a valuable management tool for states and municipalities in monitoring the quality of cytology laboratory services, and SISCAN was discontinued and implemented. However, the new system is experiencing operational difficulties, and the 2013 data from SISCOLO are the last

that can give evidence of the quality of cytology services offered to the SUS user population so far.

Some studies have been conducted with the aim of verifying the quality of cytopathological exams performed in the public network in the country. In 2012, for example, Bortolon *et al.*¹⁰ conducted a national survey evaluating four indicators of internal quality of laboratories that performed the test (positivity rate, percentage of tests compatible with high-grade intraepithelial lesion, percentage of tests compatible with squamous cell atypia of undetermined significance, and ratio of squamous atypia of undetermined significance to squamous intraepithelial lesions). The study used SISCOLO data from January to December 2010 and found a high percentage of laboratories with positivity rates considered very low, especially in the North, South, and Northeast regions of the country (54%, 57%, and 59%, respectively). For the authors, these data may indicate the non-identification of positive samples, thus generating the issuance of many reports with false negatives.

Despite the importance of mapping the effectiveness of laboratories that provide services to UHS by performing cytopathological tests, it is verified that there are no recent publications on the subject in Brazil. Despite the recent discussion on evaluation and planning in the field of Public Health¹¹⁻¹³, it is necessary that the evaluation of laboratories, occurring prior to or together with the service planning, can be a source of guidance for public management in an attempt to solve the constant problems of serving the population. The state of Alagoas has no research covering the network as a whole and that evaluates the internal quality indicators, thus evidencing a gap in the literature and, mainly, an extra difficulty for the state health management.

In view of the above, the objective of this study was to evaluate the internal quality of cytology laboratories that provide services for the UHS for the State of Alagoas in order to allow the monitoring of the services provided, as well as to assist in the planning of structuring actions to fight cervical cancer in the State.

This study included data collected in SISCOLO for the years 2011, 2012, and 2013 from laboratories

Methods

accredited to perform cytopathological tests by UHS in the State of Alagoas. To avoid distortions in the sample, the data were evaluated year by year and together.

From the data available in SISCOLO, five Internal Control indicators were analyzed, detailed below.

Positivity Index (PI)

The PI (*no. of altered tests in a certain place and year/total of satisfactory tests x 100*) aims to determine the prevalence of cellular alterations in cytological exams and indicate the sensitivity of the exam in screening to detect lesions in the evaluated population. It is considered very low the PI categorization below 2.0%; low, the one located between 2.0% and 2.9%; expected, the one located between 3.0% and 10% and above the expected, the one above 10%¹⁴.

Percentage of ASC compliant tests among satisfactory tests (ASC/Sat)

ASC-US and ASC-H are acronyms to identify atypical squamous cells of undetermined significance. This indicator represents that the cytological findings are not sufficient for the diagnosis of intraepithelial lesion. It was calculated using the formula *nº of tests with ASC-US and ASC-H/total of satisfactory tests x 100*. The recommendation is that the percentage of ASC is no more than 5% of satisfactory examinations¹⁴.

Percentage of ASC among altered tests (ASC/Alt)

The purpose of this indicator is to assess the percentage of atypical squamous cells of undetermined significance (ASC) among the altered tests. In conjunction with the PI, this indicator can demonstrate cytological ambiguity, since an adequate PI value may contain a high percentage of tests compatible with ASC. It was calculated using the formula *nº of tests with ASC-US and ASC-H/total of altered tests x 100*. The percentage of atypical squamous cells of undetermined

significance among the altered examinations should be less than 60%¹⁵.

ASC/SIL ratio (ASC/SIL)

The ASC/SIL ratio (*no. of excisions compatible with ASC-US and ASC-H / no. of examinations with LSIL and HSIL x 100*) evaluates the technical quality of the laboratory in verifying the differential diagnosis of squamous intraepithelial lesions (SIL and HSIL). The recommendations are to maintain a ratio of no more than 3:1¹⁴.

Percentage of tests compatible with (HSIL)

This indicator, *no. of HSIL screenings/total of satisfactory screenings x 100*, measures the ability to detect cancer precursor lesions and should have a percentage equal to or greater than 0.4% of satisfactory screenings¹⁵. This is the main indicator in this set of indicators, because high grade intraepithelial lesions are those that have a high potential for progression to cervical cancer.

All data used were public and available in the DATASUS/SISCOLO database for the period and processed by Microsoft Excel software, version 2016.

The nomenclature of smears adopted in the study was the Bethesda System¹⁶. In this case, ASC corresponds to the nomenclature for atypical squamous cells; ASC - US, for atypical squamous cells of undetermined significance; ASC- H means the presence of atypical squamous cells, which do not allow the exclusion of a high-grade lesion; SIL indicates a squamous intraepithelial lesion; HSIL means high grade squamous intraepithelial lesion and, finally, LSIL corresponds to the nomenclature for low grade squamous intraepithelial lesion. The formulas used to calculate the indicators and the descriptions of each indicator were the same used by Plewka *et al.*¹⁷.

found that in 2011, only two laboratories (8.6%) met the parameter recommended by the Ministry of Health, which establishes a minimum of 15,000 exams/year. In the two following years, only one laboratory (4.1% for 2012 and 3.5% for 2013) reached the parameter in question.

Results

In the three-year period studied, the evaluated laboratories performed 276,738 exams, totaling 86.4% of the exams performed in the state. When the quantity of tests performed by each laboratory was observed, it was

Tables 1, 2 and 3 present the results of the analysis of the variables studied. The PI showed that in the year 2011, approximately 20% of the laboratories had indexes within the expected. For the year 2012, the results were slightly higher, with 25% of the laboratories with PI considered within or above the expected. The year 2013 showed the best results for the triennium: about 30% of the services had PI within the expected.

Table 1- Internal quality indicators of the laboratories in Alagoas in 2011.

Laboratory	Amount of tests	PI	ASC/Sat	ASC/ Alt	ASC/SIL	HSIL	Insat
1	18,468	1.61	0.78%	48.38%	1.16	0.23%	6.78
2	3,443	1.92	1.07%	56.06%	1.42	0.26%	0.03
3	3,122	0.16	0.00%	0.00%	0.00	0.00%	0.03
4	9,115	1.56	0.42%	27.14%	0.41	0.12%	1.70
5	465	0.86	0.22%	25.00%	0.50	0.43%	0.00
6	1,444	5.39	3.69%	68.42%	2.89	0.50%	2.42
7	47,438	0.54	0.33%	60.71%	1.89	0.03%	1.32
8	2,425	1.66	0.95%	57.50%	1.35	0.17%	0.54
9	1,004	1.49	1.39%	93.33%	14.00	0.00%	0.00
10	2,754	0.91	0.44%	48.00%	2.00	0.22%	0.04
11	12,616	0.03	0.01%	25.00%	0.00	0.00%	0.00
12	1,579	2.47	1.90%	76.92%	3.75	0.25%	0.00
13	126	4.81	0.96%	20.00%	0.25	0.00%	17.46
14	675	1.63	0.74%	45.45%	1.00	0.44%	0.00
15	3,530	1.79	0.99%	55.56%	1.30	0.23%	0.14
16	2,230	0.18	0.00%	0.00%	0.00	0.00%	0.13
17	199	7.07	2.53%	35.71%	0.56	0.51%	0.50
18	406	6.65	6.16%	92.59%	5.00	0.74%	0.00
19	1,477	1.83	0.81%	44.44%	0.86	0.27%	0.07
20	2,007	1.42	1.16%	82.14%	4.60	0.05%	1.49
21	119	2.52	1.68%	1.60%	2.00	0.00%	0.00

Source: SISCOLO – DATASUS.

Table 2 - Internal quality indicators of the laboratories in Alagoas in 2012.

Laboratory	Amount of tests	PI	ASC/Sat	ASC/ Alt	ASC/SIL	HSIL	Insat
1	11,777	2.22	1.16	52.08	1.44	0.22	8.19
2	3,121	2.05	1.19	57.81	1.95	0.26	0.00
3	6,695	0.21	0.03	14.29	0.22	0.00	0.13
4	8,431	1.90	0.63	33.33	0.52	0.14	0.82
5	1,401	0.07	0.00	0.00	0.00	0.00	0.14
6	1,828	5.46	3.48	63.64	2.17	0.44	0.88
7	22,047	0.50	0.33	66.36	2.70	0.05	0.26
8	2,573	3.03	2.26	74.36	3.22	0.08	0.04
9	1,569	1.34	1.21	90.48	9.50	0.13	0.00
10	2,044	0.78	0.54	68.75	2.20	0.15	0.05
11	10,070	0.05	0.02	40.00	0.00	0.00	0.00
12	1,220	1.97	1.56	79.17	3.80	0.16	0.00
13	381	0.62	0.00	0.00	0.00	0.00	15.49
14	858	1.05	0.35	33.33	0.60	0.23	0.47
15	1,567	1.09	0.89	82.35	4.67	0.19	0.06
17	1,005	3.58	2.19	61.11	1.69	0.10	0.00
18	1,794	10.14	8.53	84.07	5.67	0.00	0.00
19	1,547	1.68	0.97	57.69	2.50	0.06	0.19
21	999	4.51	3.01	66.67	2.73	0.20	0.10

Source: SISCOLO – DATASUS.

Regarding ASC/Sat, for the years 2011 and 2012, almost all services, except those performed by laboratory 18, presented ASC/Sat within the expected. Regarding ASC/Alt, the results for 2012 and 2013 show that only 50% of the services were within the standards for ASC/Alt.

The fourth indicator, ASC/SIL, showed that in the year 2011, about 81% of the services presented a result within the expected, while in the years 2012 and 2013, the results were considered within the expected in 75% and 87.5% of the laboratories, respectively. However, the results obtained by laboratory 9 for the years 2011 and

2012 (Tables 1 and 2) draw attention for the high number of ASCs for each SIL case. For 2011, laboratory 9 presented 14 ASC for each case of SIL, and in 2012, there were nine cases of ASC for each case of SIL. The same can be observed for laboratory 22, in 2013 (Table 3), with seven cases of ASC for each case of SIL.

The fifth internal quality indicator calculated was HSIL, in which only laboratory 6 achieved acceptable levels, at 0.44%, in 2012. For the years 2011 and 2013,

about 25% of the laboratories achieved adequate levels of HSIL.

The data in Table 4 present an analysis of Alagoas' overall performance for the four indexes evaluated in the 2011-2013 triennium. The state's average PI in the period was 2.29% and the HSIL, 0.18%.

Table 3 - Internal quality indicators of the laboratories in Alagoas in 2013.

Laboratory	Amount of tests	PI	ASC/Sat	ASC/ Alt	ASC/SIL	HSIL	Insat
1	3081	1.44	0.49	34.21	0.59	0.49	14.15
2	3642	3.57	1.92	53.85	1.52	0.58	0.05
3	4235	0.80	0.28	35.29	0.55	0.07	0.05
4	5688	2.47	0.88	35.71	0.60	0.16	0.49
5	870	0.81	0.00	0.00	0.00	0.00	0.11
6	1546	7.99	3.34	41.80	1.42	0.92	1.23
7	29919	2.35	1.47	62.45	2.01	0.15	0.20
8	2331	5.83	4.59	78.68	3.96	0.30	0.00
9	881	1.14	1.14	100.00	0.00	0.00	0.00
10	3536	1.24	0.88	70.45	2.82	0.11	0.00
11	2795	0.04	0.04	100.00	0.00	0.00	0.29
12	1435	2.09	1.39	66.67	2.50	0.21	0.00
14	3134	8.39	4.09	48.67	1.03	0.54	0.03
15	1337	5.56	3.38	60.81	1.67	0.83	0.52
16	770	0.00	0.00	0.00	0.00	0.00	0.00
17	1099	5.74	2.64	46.03	3.63	0.55	0.18
18	1631	2.70	2.51	93.18	0.00	0.00	0.00
19	1786	1.24	0.68	54.55	2.00	0.06	1.01
21	1265	3.08	2.13	69.23	3.00	0.00	0.00
22	6376	0.25	0.22	87.50	7.00	0.03	0.38
23	614	0.33	0.33	100.00	0.00	0.00	0.00

Source: SISCOLO – DATASUS.

Table 4 - Average of the internal quality indicators of the laboratories in Alagoas by year and for the triennium 2011 to 2013.

Year	PI	ASC/Sat	ASC/Alt	ASC/SIL	HSIL	Insat
2011	2.21	1.25%	45.90%	2.14	0.21%	1.56%
2012	2.16	1.44	53.27%	2.31	0.12%	1.34%
2013	2.51	1.39	55.80%	1.46	0.21%	1.09%
Triennium	2.29	1.36%	51.66%	1.97	0.18%	1.33%

Source: SISCOLO – DATASUS.

Discussion

It was observed that the quantity of tests performed annually by each laboratory was below that recommended by the Ministry of Health, probably due to two factors. The first is related to the spreading of tests among the laboratories that provided services for the UHS in Alagoas. In the period from 2011 to 2013, 22¹⁸, while 17 laboratories would be enough to supply the demand in the state of Alagoas⁷. The second factor to be considered is the low coverage of cytology exams in the Alagoas population (average of 14.25%) for the period

from 2011 to 2013. Data from the Ministry of Health point out that the ratio of cytopathology exams in Alagoas for the years 2011, 2012, and 2013 was 0.49, 0.47, and 0.43, respectively¹⁹. These results are below what was expected and what was agreed upon in 2012, in the Pacto pela Saúde (Health Pact)¹⁵, whose goal for the year was a ratio of 0.75 cytopathological exams.

The first indicator evaluated was the PI. The analyses of the evaluated data indicate that, for the triennium studied, most of the tests performed in Alagoas were undertaken by laboratory units whose PI was below

the recommended one. The results are compatible with those observed by Plewka *et al.*¹⁷ and Bortolon *et al.*¹⁰ and indicate that measures need to be taken to ensure that the laboratories chosen to perform cervical cytopathology tests in the state are of higher quality. Measures, such as increasing the quality of pre-screening of all smears or including rapid review of 100% of negative smears, may be beneficial in this regard.

Observing the data on PI presented in table 1, it is possible to verify a worrisome data, which is that laboratories 1, 7 and 11 performed, together, 68.4% of the exams in 2011 and 55% of the exams in 2012. All these services had a PI considered very low. In 2013 (Table 3), about 38.6% of tests were performed by laboratory 7, which presented a PI of 2.35, considered low, but higher than the PI presented in previous years.

The findings related to the Percentage of Exams Compatible with ASC among Satisfactory Exams (ASC/Sat), for the triennium 2010-2013 in Alagoas, demonstrate that a good part of the exams presented atypical squamous cells of undetermined significance, i.e., results for which a diagnosis of intraepithelial lesion cannot be confirmed or ruled out. If the average percentage of ASC/Alt for the triennium are evaluated together with the indicators of PI and the Percentage of Exams Compatible with High Grade Lesion (HSIL), it can be seen that 83.4% of the services evaluated in Alagoas, in the triennium 2011-2013, do not have clarity in identifying the cytomorphological criteria of intraepithelial lesions, both low and high grade. These results are similar to those of Plewka *et al.*¹⁷ and show that the diagnoses made by cytopathology laboratories in Alagoas do not present certainty of the results found and are not able to clearly identify whether the tests indicate or not precursor lesions of cervical cancer. Thus, it is feasible to infer that many of the slides with indeterminate results had a high chance of being positive, and thus the opportunity was lost to urgently intervene in precursor lesions of cancer, leaving it to be detected only when the disease was in more advanced stages.

When looking at the data related to cervical cancer mortality in Alagoas in the same period, one can see an increase in relation to the previous period. Data

from INCA²⁰, for the period 2005-2009, indicated a mortality rate of 9.78%, while in the period 2010-2014, the rate rose to 10.95%. These results are below the results found in the Northeast region for the period, however, they are much higher than those of developed countries²⁰⁻²¹.

A question should be raised regarding lab 18. The PI results for this lab were higher than expected¹⁴. Normally, results like these are obtained in specialized reference services, which is not the case in this laboratory, considering that the reference laboratories for Alagoas (type II laboratories) were two others¹⁸. In this case, the possibility that there has been some error in the feeding of SISCOLO by the laboratory cannot be ruled out, especially if one considers that the Percentage of Exams Compatible with ASC among Satisfactory Exams (ASC/Sat) for laboratory 18 was below the adequate one, indicating clear cytological ambiguity in the analysis of the slides.

Other results that point to flaws in the evaluation of the slides are the analysis of the Ratio of Indeterminate Tests to those Confirmed with High-grade Lesion (ASC/SIL) and the Percentage of Tests Compatible with High-grade Lesions (HSIL). The results indicate that for every test case without diagnostic certainty, only one case was confirmed as high-grade lesion, which is below the recommended¹⁴. To avoid the cases of doubts or false negatives from errors in the readings of the exams, Tavares *et al.*³ suggested that a 100% review of negative slides should be implemented, even though this solution consumes more resources and time.

Finally, one last question needs to be addressed: how will the constant evaluations of the system generate real changes in the provision of services to the population and in the very logic of the performance of the teams involved? As shown in the results presented here, the constant application of the internal control indicators in the laboratories and the feeding of the computerized data systems of the State Secretariats/Ministry of Health show that there is an institutionalization of the evaluation process; however, the information found there remains disconnected from the performance of the evaluated services themselves. Despite the undeniable increase in

the public power's systems of evaluation of health services, there seems to be no improvement in the services in question, neither for those who are served nor for those who are served¹¹.

Moreover, even with a considerable increase in the number of studies on the subject of evaluation and planning of public health policies in Brazil, there were few times when scientific discussions in the area served as a guide for practical decision making that went beyond a model focused only on system efficiency, in which the results are coldly analyzed in relation to the initial goals of the service¹². The fact is that the authors understand that the assessment must guide the decision making, taking into account the real commitment with the permanent training of the teams involved, the autonomy of the groups of actors in the process and the proposition of institutional support for the less able, in an attempt to correct the problems verified. In the case of cytopathology exams, these considerations seem to be of special importance, since constant training and institutional support could reduce the errors in the collection and examination of slides, as well as adequately control the amount of work of the examiner, minimizing many of the factors considered responsible for many of the false negatives found^{3,9}.

Conclusions

The results of this study show that the internal quality of laboratories that performed cytopathological exams for the UHS in Alagoas is below that recommended. The data also showed that Alagoas fails in two essential issues in the fight against cancer: it presents a coverage of cervical cytopathological exams below the necessary for the population and offers evaluation services of the exams performed with quality below that recommended by the health authorities.

In this scenario, it seems necessary an urgent intervention of the state authorities in the establishment of internal and external control of the practices established by the cytopathology laboratories, however, not only in a reductionist logic regarding the adequacy result-target, but in a model that can put the constant evaluation of the indicators as a tool in the creation of transformation strategies of the health system.

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