

Cervical Cancer Screening in Women Aged 25 to 64 Years: Indicators of the First Cytopathological Examination Registered at Siscolo, 2007-2013

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Rastreamento do Câncer do Colo do Útero em Mulheres de 25 a 64 anos: Indicadores do Primeiro Exame Citopatológico Informado no Siscolo, 2007-2013

Tamizaje Masivo de Câncer de Cuello Uterino en Mujeres de 25 a 64 años: Indicadores de la Primera Vez de Examen Citopatológico en Siscolo, 2007-2013

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ABSTRACT

Introduction: Cervical cancer has high rates of incidence and mortality in women in Brazil. Monitoring of control actions has been limited to the number of tests performed and not to the women examined due to the lack of a unique identifier in the information system. **Objective:** To analyze indicators of cervical cancer screening actions among women aged 25-64 years with a record of the first cytopathological examination reported at Siscolo from 2007 to 2013. **Method:** Study of time series of indicators of cervical cancer screening actions were calculated for women aged 25-64 years who had their first cytopathological exam identified at Siscolo between 2007 and 2013. Trend analysis was performed using Prais-Winsten regression. **Result:** The uptake indicator showed an increasing trend only in the South ($p=0.038$) while overall positivity (any cytopathological alteration) remained stationary in the country ($p\geq 0.108$). Representativeness of the transformation zone sampling rate showed a decreasing trend in all regions ($p<0.05$), while the ratio between high-grade intraepithelial lesion and squamous cell carcinoma showed an increasing trend in the Northeast (10.3 in 2007 to 13.3 in 2013), Southeast (17.5 to 20.2) and South (20.2 to 30.4) regions. **Conclusion:** The increasing ratio between high-grade lesions and cancer in three regions representativeness of the country indicates a good screening performance in these locations. Indicators with a stationary trend and a decreasing trend in the transformation zone need monitoring.

Key words: health information systems; uterine cervical neoplasms; papanicolaou test; mass screening; time series studies.

RESUMO

Introdução: O câncer do colo do útero apresenta elevadas taxas de incidência e mortalidade em mulheres no Brasil. O monitoramento das ações de controle tem sido limitado ao número de exames realizados e não às mulheres examinadas em razão da falta de um identificador único no sistema de informação. **Objetivo:** Analisar indicadores das ações de rastreamento do câncer do colo do útero entre mulheres de 25-64 anos com registro do primeiro exame citopatológico informado no Siscolo no período de 2007 a 2013. **Método:** Estudo de séries temporais dos indicadores das ações de rastreamento do câncer do colo do útero, calculados para mulheres de 25-64 anos que tiveram o primeiro exame citopatológico identificado no Siscolo entre 2007 e 2013. A tendência temporal foi avaliada usando a regressão linear generalizada pelo método de Prais-Winsten.

Resultado: O indicador de captação mostrou tendência crescente apenas na Região Sul ($p=0,038$), enquanto a positividade geral (qualquer alteração citopatológica) manteve-se estacionária no país ($p\geq 0,108$). A representatividade da zona de transformação apresentou tendência decrescente em todas as Regiões ($p<0,05$), enquanto a razão entre lesão intraepitelial de alto grau e carcinoma epidermoide apontou tendência crescente nas Regiões Nordeste (10,3 em 2007 para 13,3 em 2013), Sudeste (17,5 para 20,2) e Sul (20,2 para 30,4). **Conclusão:** A razão entre lesão de alto grau e câncer crescente em três Regiões do país indica bom desempenho do rastreamento nessas localidades. Indicadores com tendência estacionária e tendência decrescente da representatividade da zona de transformação necessitam de acompanhamento.

Palavras-chave: sistema de informação em saúde; neoplasias do colo do útero; teste de papanicolaou; programas de rastreamento; estudos de séries temporais.

RESUMEN

Introducción: El cáncer de cuello uterino tiene altas tasas de incidencia y mortalidad en mujeres en Brasil. El seguimiento de las acciones de control se ha limitado al número de pruebas realizadas y no mujeres examinadas debido a falta de un identificador único en sistema de información. **Objetivo:** Analizar indicadores de acciones de tamizaje de cáncer cervicouterino en mujeres de 25-64 años con registro del primer examen citopatológico reportado en Siscolo en período 2007 a 2013. **Método:** Estudio de series temporales de indicadores de acciones de tamizaje masivo del cuello uterino calculado para mujeres de 25-64 años a las que se les identificó su primer examen citopatológico en Siscolo entre 2007 y 2013. La tendencia temporal se evaluó mediante regresión lineal generalizada mediante el método Prais-Winsten. **Resultado:** El indicador de captación mostró tendencia creciente solo en Sur ($p=0,038$) mientras que la positividad general (cualquier alteración citopatológica) se mantuvo estacionaria en el país ($p\geq 0,108$). La representatividad de la zona de transformación mostró una tendencia decreciente en todas regiones ($p<0,05$), mientras que la relación entre lesiones intraepitelial de alto grado y carcinoma células escamosas mostró una tendencia creciente en regiones Noreste (10,3 en 2007 a 13,3 en 2013), Sudeste (17,5 a 20,2) y Sur (20,2 a 30,4). **Conclusión:** La relación entre lesiones de alto grado y aumento de cáncer en tres regiones indica buen desempeño de detección en estos lugares. Los indicadores con tendencia estacionaria y tendencia decreciente en representatividad de la zona de transformación necesitan monitoreo.

Palabras clave: sistemas de información en salud; neoplasias del cuello uterino; prueba de papanicolaou; tamizaje masivo; estudios de series temporales.

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INTRODUCTION

Although an avoidable disease, cervical cancer has high rates of incidence and mortality in women, especially in developing countries. The disease is preceded by pre-malignant lesions that if detected and treated timely will not progress to cancer. Studies about the natural history of the disease estimate that the progression time of the malignant neoplasm and cellular changes caused by the Human Papillomavirus (HPV) persistent infection is around 10 to 15 years¹.

Cervical cytology by Pap smear is adopted in Brazil for cervical cancer screening. The Brazilian Guidelines for Cervical Cancer Screening recommend cytology testing every three years after two consecutive annual negative results². The World Health Organization (WHO) recommends at least 70% of coverage of the target-population for effectiveness in reducing cervical cancer morbimortality³.

In the decade of 1980, cervical cancer control actions started with the creation of the Women's Health Care Integrated Program (Paism). In the next decade, in 1997, the project *Viva Mulher* started out to organize the National Program for Cervical Cancer Management (PNCCCU)². The Information System for Cervical Cancer Management (Siscolo)⁴ was developed and began to be adopted nationally in 1999.

Siscolo registers the cytopathological and histopathological exams performed at the National Health System (SUS). The data are forwarded by all the Brazilian federation states and Federal District to the Department of Informatics of the Unified Health System (DATASUS) which collects them into the national system. It also encompasses a set of relevant information for the management of the cervical cancer screening, nevertheless, limitations as register of exams and not of the women, national information consolidation system depending on the routine of sending and monitoring the database by the municipalities and States still exist⁴. Because of these issues, the calculation of indicators utilized in cancer screening programs and comparability with other countries to monitor its effectiveness is compromised⁵⁻⁹. At best, national-based studies eventually stick to proxy indicators which have important limitations¹⁰⁻¹³. Strategies of probabilistic linkage among databases to identify and follow-up women appear to be an alternative for an improved approach to the reality¹⁴⁻¹⁶.

This article has the objective of analyzing the indicators of cervical cancer screening in women in the age-range of 25-64 years old with first cytology exam registered in Siscolo from 2007 to 2013 and its evolution along of the time.

METHOD

This is a time series study of cervical cancer screening program indicators in Brazil. Data of women from 25 to 64 years of age first cytopathological exam were collected from Siscolo database between 2007 and 2013. The study period was based in the year of implementation of the first version of Siscolo with the nomenclature updated (2007) until its discontinuation (2013).

The data were collected from Siscolo national database that does not have a variable which can be used as identification-key of the women. A probabilistic linkage was established among the databases containing exams registered in the period to identify the first exam registered for each woman.

The software R¹⁷ version 3.5.3 and packages RecordLinkage and SoundexBR were utilized, having as blocking key the woman's name, mother's name and date of birth. The date of the exam was utilized as criteria to identify the woman's first exam.

Figure 1 shows identified women with first exam registered at Siscolo annually in the study period. Follow-up exams were not included in the scope of the study.

Several indicators are used in screening programs to monitor and evaluate the performance of the initiatives^{5,9}. In the present study, the following indicators were analyzed: proportion of women capture, positivity rate, transformation zone (TZ) sampling rates and high-grade lesion cancer ratio.

The indicator of capture allows to measure the number of women who did the exam for the first time in their lives among those who were examined. Although the database investigated included women from 25 to 64 years of age registered for the first time in the period, it was used the information available in the variable "previous preventive exam" to calculate "women recruited" because the women could have been examined at younger ages or in non-approved health services by SUS.

Formula: Number of women examined for the first time (previous preventive exam = no) in the target population/number of women in the target population=examined.

The positivity rate evaluates how many women had cytopathological abnormal exam in comparison with the population screened¹². When restricted to women screened for the first time this indicator shows the abnormal exams rate for women who had never been submitted to cytopathological exam before. The women who presented at least one of the following results are defined as having abnormal results: atypical squamous

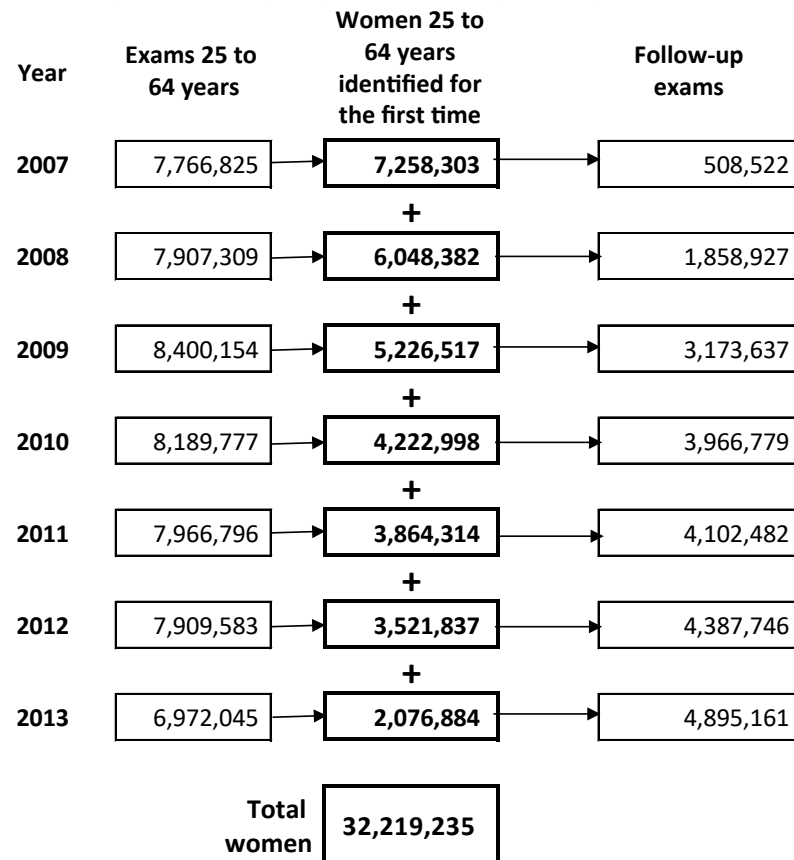


Figure 1. Data Flow chart showing women identified by probabilistic linkage of cytopathological exams annually, Brazil, 2007-2013

cells of undetermined significance (ASC-US and ASC-H); low-grade squamous intraepithelial lesion (LSIL); high-grade intraepithelial lesion (HSIL); invasive epidermoid carcinoma (IEC); atypical glandular cells of undetermined significance (AGUS); adenocarcinoma *in situ* (AIS) and invasive, atypical cells of undetermined origin and other neoplasms². This indicator was calculated for the group of women from 25 to 64 years of age (overall positivity) and for those who informed not submitted to preventive exam previously (positivity in women recruited).

a. Positivity rate in women examined in the period

Formula: Number of women of the target-population with abnormal exam/number of women examined in the target-population, year and region multiplied by 100.

b. Positivity rate in women of the target-population recruited

Formula: Number of women of the target-population recruited with altered exam/number of women recruited in the target-population, year and region multiplied by 100.

The proportion of the women with cytopathological exam with representation of the TZ is an indicator that allows to qualify the discussion on the abnormal results, when evaluated together with the positivity rate, because the presence of epithelium in the TZ increases the likelihood of identifying a lesion¹⁸. The presence of endocervical cells, metaplastic cells and squamous cells on a smear reflects the quality of sample collection^{2,18}.

Formula: Number of the women in the target-population whose TZ is present in samples divided by the number of women of the target-population examined multiplied by 100.

High-grade intraepithelial lesion and epidermoid carcinoma ratio allows the evaluation whether the program is being able to identify more precursor lesions than cases of cancer among the diagnosed squamous atypia indicating effectiveness of the screening¹⁹.

Formula: Number of women of the target-population with high-grade intraepithelial cytopathological result divided by the number of women of the target-population with cytopathological result of epidermoid carcinoma.

The generalized linear regression method of Prais-Winsten to analyze the trend was applied and Durbin-Watson statistic to evaluate the serial autocorrelation, that is, the dependence of a measurement with its own values prior to the series^{20,21}. When the trend was statistically significant and the Durbin-Watson statistic was left in the zone of indecision, it was classified as undetermined. It was calculated the annual percent change – APC of the indicators for the regions with confidence interval of 95% (CI_{95%}). Additionally, the Pearson correlation was calculated between the indicator of general positiveness and representativeness of the TZ and classified as proposed by Callegari-Jacques²²: $r = 0$, null; $0 < r \leq |0.3|$, weak; $|0.3| < r \leq |0.6|$, moderate; $|0.6| < r \leq |0.9|$, strong; $|0.9| < r < |1|$, very strong; and $r = 1$, classified as perfect. It was considered the level of significance of 5% for all the statistical analyzes.

This study is part of a project approved by the Institutional Review Board of the National Cancer Institute José Alencar Gomes da Silva (INCA), CAAE: 68203117.1.0000.5274.

RESULTS

From 2007 to 2013, 71,527,653 screening satisfactory cytopathological exams were identified in Siscolo, of which 55,112,489 (77%) in the 25-64 years target-population. The study identified 32.3 million women in the target age group, a ratio of 1.71 exams/women. The North region presented the lower ratio of exams per women examined (1.59) while in the Southeast and Mid-West regions, the ratio was 1.82 (Table 1).

Throughout the years, there was gradual reduction of the women identified for the first time at Siscolo. Between 2007 and 2010, the reduction was approximately one thousand women/year with higher percentage of 19% between 2010 and 2009, diminishing in the following years (less than 9%). However, in 2013, the reduction was approximately 41%, corresponding to 1.4 thousand women less than the year before.

Table 2 shows the trend of the indicators analyzed in the period. The indicator of capture had raising trend only in the South Region ($p=0.038$) with annual growth of 6.83 (CI_{95%} 0.83;13.48), ranging from 6.1 in 2007 to 7.8 in 2013.

The proportion of general positivity indicated stationary trend in all regions ($p \geq 0.108$). The proportion of positivity in women recruited, however, increased 4.10 (CI_{95%} -0.18; 8.56) in the Midwest although with borderline statistical significance ($p=0.066$), while in the other regions they remained stationary ($p \geq 0.327$). Nonetheless, the Midwest region stands out with a higher proportion of positivity in women recruited than the general positivity in the whole period, similar to the South Region.

The indicator of representativeness of the TZ had raising trend in all regions. The highest reduction was in the North region with annual increase of -2.71 (CI_{95%} -3.61; -1.81), ranging from 77.5 in 2007 to 64.0 in 2013. The lower occurred in the South region (APC=-1.47; CI_{95%} -1.95; -0.99) ranging from 67.1 in 2007 to 58.9 in 2013. The most extreme values of APC were in the North (-2.71, CI_{95%} -3.61;-1.81) and Southeast (-1.86; CI_{95%} -3.12;-0.59) regions. The Southeast region indicated potential serial autocorrelation (indecision zone) according to the Durbin-Watson statistic and the trend although decreasing and statistically significant ($p=0.016$) was deemed undetermined. All the other regions presented significant and decreasing trend ($p < 0.001$).

The indicator of the ratio high-grade lesion and cancer presented raising trends only in three regions. Of these, the highest variation occurred in the South region (7.02; CI_{95%} 5.22; 8.86), ranging from 20.3 in 2007 to 30.4 in 2013 and the lowest in the Southeast region (2.50; CI_{95%} 0.22; 4.83) ranging from 17.5 in 2007 to 20.2 in 2013.

Figure 2 shows the distribution of the indicators of representativeness of the TZ and general positive results from 2007 to 2013 per region. It was found negative correlation between these indicators for most of the regions. Southeast region had strong negative correlation

Table 1. Distribution of the number of cervical cancer cytopathological exams and women examined from 25 to 64 years of age registered at Siscolo. Brazil. Regions, 2007-2013

Regions	Women	Exams	Ratio exams/women examined
North	2,048,233	3,250,933	1.59
Northeast	8,953,714	14,391,609	1.61
Southeast	13,721,588	24,925,959	1.82
Midwest	2,167,592	3,942,451	1.82
South	5,328,108	8,601,537	1.61
Brazil	32,219,235	55,112,489	1.71

Table 2. Indicators in women of 25 and 64 years of age, variation and trends per Regions. Brazil, 2007-2013

Indicators	2007	2008	2009	2010	2011	2012	2013	Annual variation	Value-p	Trend
								%(CI _{95%})		
Capture										
Midwest	11.7	9.3	12.9	13.8	15.5	11.8	10.9	0.08 (-7.24; 7.97)	0.981	Stationary
North	16.8	16.7	17.7	18.7	19.1	18.8	15.6	-0.60 (-5.37; 4.41)	0.778	Stationary
Northeast	12.8	12.8	12.9	14.2	14	14.1	13.2	1.11 (-0.64; 2.89)	0.219	Stationary
Southeast	7.1	6.2	5.6	6.7	7.6	7.2	7.5	2.61 (-2.03; 7.48)	0.231	Stationary
South	6.1	4.7	7.9	8	6.8	8.1	7.8	6.83 (0.83; 13.18)	0.038	Raising
General Positivity										
Midwest	3.2	3.1	3	2.8	3	3.4	3.3	0.76 (-3.12; 4.80)	0.656	Stationary
North	2.9	2.6	2.2	2.1	2.5	2.7	2.8	0.36 (-6.92; 8.20)	0.912	Stationary
Northeast	2	2	1.8	1.9	2	1.9	2.2	0.92 (-1.82; 3.74)	0.453	Stationary
Southeast	2.9	2.8	3.1	3.4	3.2	3.1	3.3	2.10 (-0.52; 4.79)	0.108	Stationary
South	1.7	2	1.7	1.9	2	1.9	1.9	1.11 (-0.42; 2.67)	0.136	Stationary
Positivity in women recruited										
Midwest	3.5	4.4	4.2	3.8	4	4.7	5.0	4.10 (-0.18; 8.56)	0.066	Stationary
North	2.7	2.6	2.5	2	2.3	2.5	3.1	1.46 (-6.73; 10.37)	0.691	Stationary
Northeast	1.8	1.8	1.6	1.7	1.8	1.6	2.1	0.87 (-1.31; 3.10)	0.377	Stationary
Southeast	2.8	2.5	2.8	3.2	3.3	3.2	2.8	1.75 (-3.44; 7.23)	0.453	Stationary
South	2.2	2.4	2.2	2.3	2.5	2.2	2.0	-1.37 (-4.40; 1.75)	0.327	Stationary
Representativeness of the transformation zone										
Midwest	69.3	67.9	66.5	66	64.5	63.1	62.0	-1.80 (-1.94; -1.66)	<0.001	Decreasing
North	77.5	72.7	70.5	68.5	66.2	67.6	64.0	-2.71 (-3.61; -1.81)	<0.001	Decreasing
Northeast	64.3	63.3	61.4	60.8	60	59.8	55.3	-1.67 (-2.01; -1.33)	<0.001	Decreasing
Southeast*	66.9	63.9	61.6	60.5	59.5	59.3	59.7	-1.86 (-3.12; -0.59)	0.016	Undetermined
South	67.1	65	63	62.1	61.2	60.9	58.9	-1.47 (-1.95; -0.99)	<0.001	Decreasing
Ratio high-grade and cancer										
Midwest	16.5	14.5	15.7	14.5	14.4	17.1	22.6	4.65 (-3.15; 13.07)	0.21	Stationary
North	11.2	13.8	10.2	9.7	14	15.8	22.1	10.49 (-1.81; 24.34)	0.094	Stationary
Northeast	10.7	10.4	11.9	11.4	11.8	11.9	13.3	3.14 (2.00; 4.29)	0.001	Raising
Southeast	17.5	18.1	19.2	20.1	21.2	19.8	20.2	2.50 (0.22; 4.83)	0.043	Raising
South	20.2	21.6	20.5	26.1	23.4	28.4	30.4	7.02 (5.22; 8.86)	<0.001	Raising
Women with first register of exam	7,258,303	6,048,382	5,226,517	4,222,998	3,864,314	3,521,837	2,076,884	-	-	-

Caption: CI = Confidence Interval.

(*) Durbin-Watson statistic indicating possible serial autocorrelation.

(- 0.75) but without statistical significance ($p=0.055$). From 2009, the North region had very strong correlation (-0.95 , $p=0.014$) and the Midwest, strong negative correlation (-0.84), but without statistical significance ($p=0.072$). Only the South region presented positive correlation from 2010 although weak (0.21) and without statistical significance ($p=0.790$).

DISCUSSION

The study herein stands out among others published because of individualized data of women and not only exams, having identified 55,112,489 cytopathological exams performed in Brazil between 2007 and 2013 in 32,219,235 women, a ratio of 1.71 exams per women

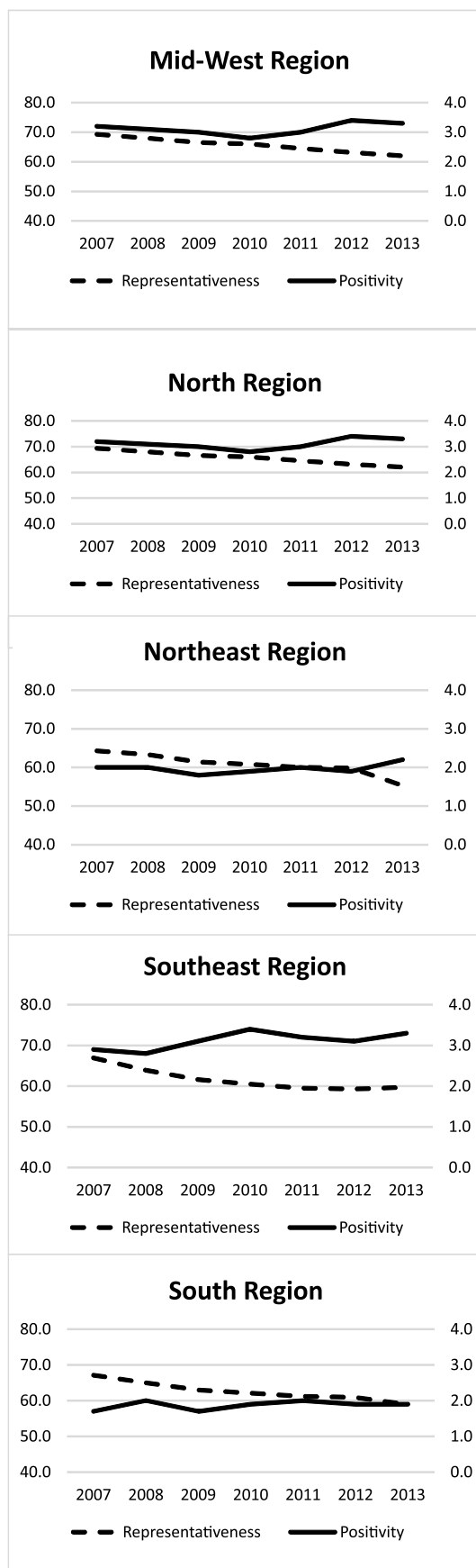


Figure 2. Representativeness of the transformation zone and general positive results per Regions, 2007-2013

examined. The results reveal the limitations of other studies published in Brazil so far where the number of exams are considered as proxy of the number of screened women. In addition, it identifies cohorts of women screened since the implementation of the cervical cancer information systems, which is critical to evaluate the screening actions until today because it is a continuous action, calling for follow-up and several screening rounds through many decades of women's lives.

The indicators of capture and abnormal results presented stationary trend in the period while representativeness of TZ had decreasing trend. Although the results showed no statistical significance, they deserve to be investigated since initiatives to expand the offer and qualification of exams were adopted in the end of the period analyzed^{23,24}.

The study presented the number of women registered for the first time at Siscolo, without checking the periodicity of the screening which revealed an unexpected reduction of the number of women along the period. 2013 was the year with greater reduction of the number of women, reflecting the beginning of the implementation of the web-based Cancer Information System (Siscan) replacing Siscolo²⁵.

The capture of women in the target age-range varied positively along the period in most of the regions but was stationary even in a group registered for the first time at Siscolo. The authors noticed high percentage of capture in the North, Northeast and Midwest regions after analyzing the exams registered at Siscolo between 2006 and 2009²⁶. In this study, the North region was the only one with negative variation in the period among women analyzed, despite the stationary trend.

An unexpected result is the low positivity rate in the first screening group (women recruited) comparison with general positiveness, because it is expected high positiveness in women who are screened for the first time. As the general positivity is referenced to the first exam of women examined and registered at Siscolo, it is possible that errors in the field "previous preventive exam" had interfered in the result, including women already examined among the recruited, which would lead to an artificial reduction of the positivity of the group.

Representativeness of the TZ on samples improves the detection of cellular atypia as identified in the study of Bastos et al.²⁷, where the likelihood of identifying lesions was 5-fold higher among exams with representativeness of TZ (odds ratio = 5.19) in the age-range of 25-59 years old, based in Siscolo data from 2006 to 2009.

The representativeness of the samples among the examined women showed a decreasing trend in all regions, and the same decrease was not observed in relation to positivity in some regions, as concluded by this study. The

possible explanation for this unexpected result is ageing since older women tend to have low representativeness of the TZ. The correlation between representativeness of the TZ and general positivity was negative and strong or very strong for almost all regions. From 2010 in the South region, the correlation was positive and weak although not statistically significant, probably influenced by the reduction of years of observation.

In 2013, after the implementation of Siscan²⁵, the number of exams registered at Siscolo had an important drop in comparison with the past year mainly in the Southeast (about one third) and South (50%) regions. The results for 2013 for Brazil, consequently, impacted more the North, Northeast and Midwest regions, possibly changing the pattern.

Cervical cancer screening aims to identify precursor lesions that, if treated, will not progress to cancer, and reduce the incidence consequently. In the South, Southeast and Northeast regions, the raising trend of high-grade lesion/epidermoid carcinoma ratio revealed efficacy of the screening actions..

The cutoff to start the process of database cleaning in 2007 is possibly a limitation when it was implemented a version of the system with a new cytopathological nomenclature, which most likely included some women registered in the previous version of the system.

CONCLUSION

The relevance of the study relies in the analysis of screening program indicators for women of the target-population examined by SUS and point out the trend of these indicators in the country by regions. The time stationary trend of capture and positiveness in nearly all regions needs to be followed-up wisely like the decreasing trend of representativeness of the TZ. The ratio between high-grade lesion and cancer had favorable performance with raising trend for three country regions. It is expected that the results may contribute for the discussion of cervical cancer management, moving from exam-based analyzes towards women examined by States and municipalities to improve local and focused actions to control this neoplasm.

CONTRIBUTIONS

Maria Beatriz Kneipp Dias, Vania Reis Girianelli, Arn Migowski, Caroline Madalena Ribeiro AND Jeane Tomazelli contributed substantially for the study conception and/or design, acquisition, analysis and/or interpretation of the data, wording and critical review. Luciana Leite de Mattos Alcântara contributed

substantially for the study conception and/or design, acquisition, analysis and/or interpretation of the data. All the authors approved the final version to be published.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interests to declare.

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