Performance of diagnostic centers in the classification of opportunistic screening mammograms from the Brazilian public health system (SUS)*

Avaliação do desempenho dos centros de diagnóstico na classificação dos laudos mamográficos em rastreamento oportunista do Sistema Único de Saúde (SUS)

Danielle Cristina Netto Rodrigues¹, Ruffo Freitas-Junior², Rosangela da Silveira Corrêa³, João Emílio Peixoto⁴, Jeane Gláucia Tomazelli⁵, Rosemar Macedo Sousa Rahal⁶

Abstract Objective: To evaluate the performance of diagnostic centers in the classification of mammography reports from an opportunistic screening undertaken by the Brazilian public health system (SUS) in the municipality of Goiânia, GO, Brazil in 2010. Materials and Methods: The present ecological study analyzed data reported to the Sistema de Informação do Controle do Câncer de Mama (SISMAMA) (Breast Cancer Management Information System) by diagnostic centers involved in the mammographic screening developed by the SUS. Based on the frequency of mammograms per BI-RADS[®] category and on the limits established for the present study, the authors have calculated the rate of conformity for each diagnostic centers performed mammographic studies for SUS and reported 31,198 screening mammograms. The performance of the diagnostic centers concerning BI-RADS classification has demonstrated that none of them was in conformity for all categories, one center presented conformity in five categories, two centers, in three categories, two centers, in two categories, four centers, in one category, and three centers with no conformity. Conclusion: The results of the present study demonstrate unevenness in the diagnostic centers performance in the classification of mammograms reported to SISMAMA from the opportunistic screening undertaken by SUS. Keywords: Breast cancer; Screening programs; Mammography; Information systems; Health services.

Resumo Objetivo: Avaliar o desempenho dos centros de diagnóstico na classificação dos laudos dos exames de mamografia em rastreamento oportunista do Sistema Único de Saúde (SUS), no município de Goiânia, em 2010. **Materiais e Métodos:** Trata-se de estudo ecológico, em que foram analisadas informações reportadas ao Sistema de Informação do Controle do Câncer de Mama (SISMAMA) pelos centros de diagnóstico que realizavam mamografia de rastreamento para o SUS. A partir da frequência de exames por categoria BI-RADS[®] e os limites estabelecidos para este estudo, foram calculados os percentuais de conformidade de cada centro de diagnóstico. Consideraram-se como centros de diagnóstico realizavam mamografia para o SUS, e estes reportaram 31.198 exames de rastreamento. O desempenho dos centros de diagnóstico com relação às categorias BI-RADS mostrou que nenhum centro apresentou conformidade para todas as categorias, um apresentou conformidade em cinco categorias, dois em quatro categorias, três em três categorias, dois em duas categorias, quatro em uma categoria e três não apresentaram conformidade. **Conclusão:** Os resultados deste trabalho mostraram que houve desigualdade no desempenho dos centros de diagnóstico no que se refere à classificação dos laudos dos exames de mamografia reportados ao SISMAMA do rastreamento oportunista realizado pelo SUS.

Unitermos: Câncer de mama; Programas de rastreamento; Mamografia; Sistemas de informação; Serviços de saúde.

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 PhD, Professor at School of Medicine, Coordinator for the Program of Mastology, Hospital das Clínicas da Universidade Federal de Goiás (UFG), Goiânia, GO, Brazil. Fellow PhD degree in Collective Health, Epidemiologist, Coordination of Strategic Actions, Instituto Nacional de Câncer (INCA), Rio de Janeiro, RJ, Brazil.

6. PhD, MD, Professor, School of Medicine – Universidade Federal de Goiás (UFG), Goiânia, GO, Brazil.

Mailing Address: Danielle Cristina Netto Rodrigues. Programa de Mastologia, Hospital das Clínicas da UFG. 1ª Avenida, s/nº, Setor Universitário. Goiània, GO, Brazil, 74605-050. E-mail: daniellepsinetto@yahoo.com.br.

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INTRODUCTION

Currently, two models of mammographic screening are utilized for early detection of breast cancer, as follows: an organized screening program where there is an active planning for pre-established age groups invited to undergo screening mammography on a pre-established periodicity;

^{*} Study developed by the Program of Mastology, Hospital das Clínicas da Universidade Federal de Goiás (UFG) – Rede Goiana de Pesquisa em Mastología, Goiânia, GO, Brazil.

^{1.} Fellow PhD degree of Health Sciences, Psychologist, Capes scholar, Member of Rede Goiana de Pesquisa em Mastologia – Program of Mastology, Hospital das Clínicas da Universidade Federal de Goiás (UFG), Goiânia, GO, Brazil.

PhD, Senior Technologist, Comissão Nacional de Energia Nuclear/Centro Regional de Ciências Nucleares do Centro-Oeste, Goiânia, GO, Brazil.

PhD, Medical Physicist, Consultant, Instituto Nacional de Câncer (INCA)/Serviço de Qualidade em Radiações Ionizantes, Rio de Janeiro, RJ, Brazil.

and an opportunistic screening program to meet a spontaneous demand $^{(1-4)}$.

In Brazil, despite investments and improvements in health efforts, with breast cancer management being one of the priorities in health policies, what one actually observes is an opportunistic mammographic screening limited by logistical and economic factors as well as by socio-cultural barriers^(5–10). A study undertaken in the city of Taubaté, São Paulo State, Brazil, demonstrates such situation, as a substantial proportion of women is not screened or does not comply with received recommendations. Many of the women fail or delay to attend the ensuing screening steps⁽¹⁾.

The recommendations for breast cancer screening in Brazil were consensually defined and published in April 2004 by Instituto Nacional de Câncer (INCA) with the title "Controle do câncer da mama – Documento de consenso" (Breast Cancer Management – Consensus Document)⁽¹¹⁾. Such document, in association with other government actions, demonstrates changes in the strategies for management and prevention of breast cancer in Brazil⁽¹¹⁾.

In order to guide strategies governing the Consensus Document⁽¹¹⁾ and meet the need for implementation of management tools to evaluate the performance of Sistema Único de Saúde (SUS)^(12,13), a breast cancer management system (Sistema de Informação do Controle do Câncer de Mama – SISMAMA) was implemented to provide computerized data on procedures performed in health centers for screening and diagnostic confirmation of breast cancer⁽¹⁴⁾.

And in order to improve the quality of data for monitoring and assessment of the National Program for Breast Cancer Management, it is necessary to implement results audits at each breast diagnostic center, and such centers must also have the quality assurance instruments, both for the imaging procedure as well as for the forwarding of data⁽¹⁴⁾.

With such purpose in view, and based on the Brazilian Ministry of Health Ordinance No. 531 dated March 26, 2012 establishing the method for calculating the indicators utilized for monitoring mammographic studies results in the breast cancer screening, the Programa Nacional de Qualidade em Mamografia – PNQM (National Program for Quality in Mammography) was instituted along with the Quality Requirements for Mammographic Studies and Reports applicable to imaging diagnostic centers performing mammography in the whole Brazilian country⁽¹⁵⁾.

Thus, considering the scarcity of studies on opportunistic mammographic screening for breast cancer, particularly those studies performed by SUS, besides the need for data on the audits performed at breast diagnostic centers for SUS, the present study was aimed at evaluating the performance of the diagnostic centers in the classification of mammographic reports in opportunistic screening performed in 2010 by SUS in the city of Goiânia, state of Goiás, and also at describing the production of imaging studies on a monthly basis, clinical indication, age group and diagnostic conclusion, according to the type of network the diagnostic centers belong to.

MATERIALS AND METHODS

The present ecological study analyzed data reported to the SISMAMA by diagnostic centers involved in the mammographic screening developed by the SUS in the period from January to December 2010, involving the female population of the city of Goiânia, state of Goiás, Brazil.

Such study is part of the investigation named "Sistema de informação, monitoramento e emissão de laudo em mamografia" (System of information, monitoring and data reporting in mammography) approved by the Committee for Ethics in Research Dr. Henrique Santillo, State of Goiás Secretary of Health, without the need for a term of free and informed consent.

Study area

The area covered by the analysis in the present study was the municipality of Goiânia, capital city of the state of Goiás, located in the Mid-western region of the country. The municipality comprises an area of approximately 732,801 km² and a population of 1,302,001 inhabitants, with 681,144 being women⁽¹⁶⁾.

Data acquisition and processing

According to the SISMAMA operational flow $^{(17)}$, the data were acquired from

the "data export" file of the state coordination module, based on the period from January to December 2010. From the "General Routines" menu of SISMAMA, the files were imported, and from then on, databases were generated and the variables were tabulated with the TabWin tool⁽¹⁸⁾.

The frequencies for the following variables were calculated: mammograms production per diagnostic center (service provider); monthly mammograms production; mammograms per clinical indication (screening or diagnosis); screening mammograms per age group (< 40 years; 40 to 49 years, 60 to 69 years and > 70 years); and screening mammograms per diagnostic conclusion.

The radiological classification at SISMAMA followed the classification proposed by the Breast Imaging Reporting and Data System (BI-RADS[®]) published by the American College of Radiology (ACR) and translated into Portuguese by Colégio Brasileiro de Radiologia and Imaging Diagnosis (CBR). Such a system utilizes categories from zero to six in the description of imaging findings and provides approach recommendations for each category, with the purpose of minimizing the differences inherent to intraobserver variability or disagreement, as described on Table 1⁽¹⁹⁻²¹⁾.

The diagnostic centers were classified into two types of networks: the SUS network and the service providers network. The SUS network comprises public services, while the services providers network comprises philanthropic and private services accredited by SUS for rendering mammography services.

Performance evaluation

Initially, the performance was evaluated according to the compliance of each diagnostic center with the BI-RADS in the classification of mammographic reports.

Taking into consideration the absence of data in the literature regarding the frequency of mammograms per BI-RADS category in the mammographic screening performed by SUS in the city of Goiânia, an arbitrary variation threshold of \pm 30% of the relative frequency presented by all diagnostic centers for each BI-RADS category was established to evaluate the diagnostic centers conformity. The centers that

BI-RADS category	Diagnostic conclusion	Recommended management strategy Supplementary ultrasonography		
0	Further assessment with ultrasonography			
1	No mammographic finding	Routine screening in one year		
2	Benign mammographic findings	Routine screening in one year		
3	Probably benign mammographic findings	Radiological follow-up in six months		
4	Suspicious mammographic findings	Histopathology		
5	Highly suspicious mammographic findings Histop			
6	Mammographic findings and biopsy with diagnosis of cancer	Specific therapy		

 Table 1
 Recommendation for management strategy according to BI-RADS category.

were within such threshold were considered as being compliant.

The calculation of the conformity score for each diagnostic center was based on the established threshold. A score 1 was attributed for compliance and score zero was attributed for non-compliance, for each BI-RADS category. Thus, for the six BI-RADS categories (0 thru 5), the total score for each diagnostic center ranged from zero to six. Based on the score for each diagnostic center, the respective rate of compliance was calculated.

Later, by means of the rate of compliance, the equality in the diagnostic centers performance was evaluated. For such a purpose, one considered centers with equal performance those with equal rates of compliance.

Data analysis

For the statistical data analysis, the Statistical Package for Social Sciences 17.0 (SPSS) (SPSS Inc.; Chicago, IL, USA) software was utilized, and the absolute and relative frequencies of the variables were calculated.

RESULTS

According to the data reported to SISMAMA, 15 diagnostic centers performed mammography for SUS in the city of Goiânia in the year of 2010. Of those centers, two were public services belonging to SUS and 13 were private service providers.

Such 15 centers reported to SISMAMA the information on 36,253 mammograms performed in 2010. According to place of residence, 31,474 (86.8%) mammography was performed in individuals living in Goiânia, with 31,454 (99.9%) of those procedures being performed in women and 20 (0.1%) in men.

Of the 31,454 mammograms performed in women living in the Goiânia municipality, 8,268 (26.3%) were reported by the diagnostic centers of the SUS network and 23,186 (73.7%) were reported by the private service providers. The monthly mammograms production per the network type is presented on Figure 1. Considering 200 working days, the daily average number of mammograms at the SUS network diagnostic centers was 21 (variation from 18 to 23) per day, while at the private centers the average number of mammograms was 9 (variation from 1 to 21 exams) per day.

Of the total of 31,454 mammograms, 31,198 (99.2%) had clinical indications for screening, and 256 (0.8%) for diagnosis. No significant difference was observed with respect to the proportion of mammograms performed for clinical indications between the SUS network and the service providers network (Table 2). However, of the 13 service providers, six (46.1%) reported to SISMAMA only mammograms with clinical indication for screening.

The distribution of screening mammograms per age group shows that, of the to-

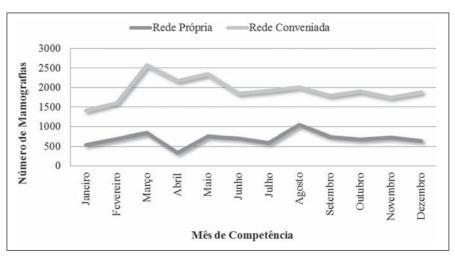


Figure 1. Production of mammograms per month and according to the type diagnostic center network, in the municipality of Goiânia, in 2010.

Table 2Distribution of mammograms per clinical indication according to type of diagnostic centernetwork, as per the data reported to SISMAMA on mammography studies performed in the female population of the municipality of Goiânia in 2010.

	SUS network ($n = 8,268$)		Private network (
Clinical indication	n	%	n	%	p-value*
Diagnosis	27	0.3	229	1.0	0.395
Screening	8,241	99.7	22,957	99.0	0.999

* Test: Proportion difference.

tal, 7.4 % of the procedures were performed in the age group < 40 years, 43.3 % were performed in the age group between 40 and 49 years, 31.6% in the age group between 50 and 59 years, 13.2% in women between 60 and 69 years, and 4.5% in women \geq 70 years. The stratification according type of diagnostic centers network (Figure 2) shows that the age range was not associated with the type of network where the mammography was performed (p = 0.998).

The frequency of screening mammograms per diagnostic conclusion according to BI-RADS categories show that 3,122 (10%) mammograms were category 0, 17,410 (55.8%) were category 1, 9,494 (30.4%) were category 2, 761 (2.4%) were category 3, 376 (1.2%) were category 4, and 33 (0.1%) were category 5. The diagnostic conclusion was not reported for two mammograms. Table 3 presents the percentage of mammograms per by BI-RADS category stratified by type of network and minimum and maximum percentages observed at the services. It is important to highlight that the SUS' diagnostic centers classified mammograms into all categories, while one of the private centers reported all mammograms (n = 474) as category 1.

In order to evaluate the compliance of the diagnostic centers with respect to the BI-RADS classification of mammograms, Table 4 shows the thresholds within a variation of \pm 30% of the mammograms with indication for screening.

On Table 5, it is possible to observe that, among the 15 diagnostic centers performing mammography for SUS in the municipality of Goiânia in 2010, seven were within the thresholds established for compliance in category 0, seven for category 1, six for category 2, three for category 3, four for category 4, and three centers were within the thresholds for category 5.

The performance of the diagnostic centers regarding compliance with BI-RADS categories demonstrated that none of the centers complied in all categories: one center was compliant in five categories, two centers were compliant in four categories, three centers were compliant in three categories, two centers in two categories, four centers in one category and three centers did not comply with any category (Table 5).

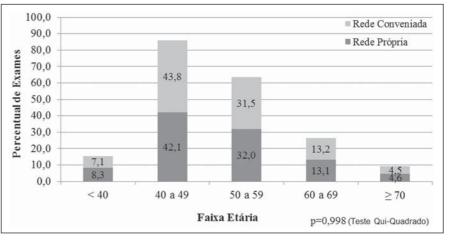


Figure 2. Relative frequency of mammograms reported to SISMAMA according to diagnostic center network type and age group of SUS users in the municipality of Goiânia, in 2010.

Table 3Distribution of mammograms according to BI-RADS category and type of diagnostic centernetwork, as per data reported to SISMAMA regarding mammography studies performed in the femalepopulation of the municipality of Goiânia in 2010.

	SUS network ($n = 8,239$)*		Private ne	Private network ($n = 22,957$)		
BI-RADS category	%	(min – max)	%	(min – max)		
0	11.3	(7.8 – 14.8)	9.1	(0.0 – 22.6)		
1	51.9	(42.9 - 61.0)	67.9	(14.4 - 100.0)		
2	41.6	(36.8 - 46.4)	29.5	(0.0 - 84.2)		
3	2.8	(0.7 - 4.9)	1.9	(0.0 - 5.8)		
4	3.5	(1.4 – 5.6)	0.6	(0.0 - 1.5)		
5	0.2	(0.1 - 0.3)	0.1	(0.0 - 1.3)		

* For two mammograms, the diagnostic conclusions were not reported.

Table 4Percentage of mammograms according BI-RADS category and thresholds for evaluating thediagnostic centers performance in the classification of screening mammograms by diagnostic conclusion,according to data reported to SISMAMA on mammography studies performed by SUS in the femalepopulation of the municipality of Goiânia in 2010.

BI-RADS category	Number of mammograms per category	Percentage per BI- RADS category	Minimum threshold [†]	Maximum threshold [†]
0	3,122	10.01	7.01	13.01
1	17,410	55.81	39.07	72.55
2	92,494	30.43	21.30	39.56
3	761	2.44	1.71	3.17
4	376	1.21	0.84	1.57
5	33	0.11	0.07	0.14
Total	31,196*	_	—	—

* For two mammograms, the diagnostic conclusions were not reported. [†]The thresholds were established with basis on the percentage of mammograms per BI-RADS category, with a variation of \pm 30%.

As regards the diagnostic centers performance, Table 5 also demonstrates that the diagnostic centers of the SUS network presented uneven performance. The centers in the private network 4, 5 and 6 presented equality in their performance, with 50% compliance. The centers 10 and 11 also presented equality with 33.33% compliance. Centers 8, 13 and 14 presented equality with 16.67% compliance. And finally, centers 2, 3, and 9 were not compliant in any category.

As the mammograms were stratified into inconclusive, normal, requiring radiological follow-up, and altered, the authors observed that 10.01% (3,122) of the

Diagnostic center	Number of	Percentage of mammograms per diagnostic conclusion					Data of	
	mammograms (31.196)	BI-RADS 0	BI-RADS 1	BI-RADS 2	BI-RADS 3	BI-RADS 4	BI-RADS 5	Rate of compliance
1*	2,871	9.68	55.66	30.58	3.76	0.24	0.07	66.67
2*	474	_	100.00	_	_	_	_	_
3*	731	1.50	94.25	3.83	0.14	0.27	_	_
4*	3,378	17.41	36.23	40.32	4.77	1.18	0.09	50.00
5*	4,084	11.95	59.70	23.04	4.43	0.73	0.15	50.00
6*	3,318	1.42	71.64	25.14	1.78	0.03	_	50.00
7*	1,223	8.83	48.08	38.51	3.03	1.31	0.25	83.33
8*	1,139	7.37	13.35	77.96	0.70	0.44	0.18	16.67
9*	1,031	5.63	88.75	5.33	_	0.29	_	_
10*	2,165	8.59	74.97	14.97	0.09	1.34	0.05	33.33
11*	1,271	9.83	63.81	25.89	0.31	0.16	_	33.33
12 [†]	4,611	7.76	56.28	33.92	0.63	1.30	0.11	66.67
13*	888	22.64	38.96	35.47	2.36	0.56	_	16.67
14*	384	13.80	66.41	18.75	_	0.78	0.26	16.67
15†	3,628	14.80	36.52	39.50	4.13	4.77	0.28	16.67
Number of compliances	_	7	7	6	3	4	2	_

 Table 5
 Rate of compliance in the classification of screening mammograms according diagnostic conclusion and BI-RADS category, as per data reported to SISMAMA on mammograms performed by SUS in the female population of the municipality of Goiânia, in 2010.

* Private network diagnostic centers. [†] SUS network diagnostic centers.

mammograms were classified as inconclusive. Normal results were found in 86.24% (29.904) of the mammograms, while those requiring radiological follow-up reached 2.44% (761). Alterations were found in 1.31% (409) of the mammograms.

DISCUSSION

The Brazilian radiological literature has recently been preoccupied with the relevant role of imaging methods in the improvement of breast diseases diagnosis⁽²²⁻³¹⁾. With the consolidation of data at SIS-MAMA, the evaluation of indicators based on national standards and proposed targets became possible by means of a contextualized observation of mammographic results reported by the SUS' diagnostic centers, allowing greater swiftness in the processing of data necessary for the planning and implementation of public health policies and better allocation of resources in this area⁽¹³⁾.

In 2010, 45 mammography apparatuses⁽³²⁾ were available for SUS in the state of Goiás. The present study allows inferring that one third of such apparatuses were installed in the Goiânia municipality. As the production of mammograms by SUS is analyzed, Figure 1 suggests that the production curve between the SUS network diagnostic centers and the private service providers presents an oscillation. When there is a decrease in the mammograms production at the SUS network centers, the production at the service providers network increases. Such a fact corroborates other studies which indicate a possible deficiency in the production of mammograms at the SUS services, with such deficiency being compensated and/or suppressed by the service providers network, thus showing a probable dependence of the public sector on private institutions^(33,34).

The following formula is suggested by INCA to follow-up the productivity of mammography centers: 4 mammograms/ hour \times 8-hour work shift \times 22 days \times 12 months \times 80% performance. With basis on such formula, the estimated production would be 6,758 mammograms/year, with a mean daily production of 25 mammograms⁽¹⁹⁾. As the present study results are compared with the results from the calculation proposed by INCA, one observes that the mean number of mammograms per day performed at the public mammography centers is close to the expected number (21/ day), but the two apparatuses available at the SUS network are not enough to perform biennial mammography in the female population in the age range between 50 and 69 years (111,127) since, according to the INCA parameters⁽¹⁹⁾, 38,894 mammograms/ year would be necessary to reach a coverage of $70\%^{(3)}$ of the target population.

A consensus is still to be reached with respect to the age range indicated for performing mammography as well as on the mammographic screening periodicity^(35,36). Such a fact is also observed in Brazil, as while the Sociedade Brasileira de Mastologia (Brazilian Society of Mastology) recommends that women above the age of 40 undergo mammography every year⁽³⁷⁾, INCA recommends that women in the age range between 50 and 69⁽¹¹⁾ years undergo the examination every other year. Since 2009, the Federal Law No. 11,664 dated April 29, 2008 provides that all women in the age of 40 years or more are entitled to undergo mammography at SUS⁽³⁸⁾.

A research undertaken in Goiânia demonstrated a significant increase in the rate of incidence of breast cancer among women in all age groups and that the age group between 50 and 59 years presented a three-fold higher incidence of breast cancer in the period from 1988 to 2003^(39,40). In the present study, as the production of screening mammograms was analyzed, the authors observed that 44% of the mammograms were performed on patients in the age range between 40 and 49 years, 31.7% in the age range between 50 and 59 years, and 13.2% in the age range between 60 and 69 years. Such results demonstrate that the prevalence of mammograms is not coincident with the age group with highest breast cancer incidence, and that, like in other studies, the physician-patient relationship seems to be the most significant predictor for the performance of mammography^(10,32,41,42).

As regards the mammograms with clinical indication for diagnosis, the number reported to SISMAMA by the diagnostic centers corresponded 1.3%, much below the expected 8.9%⁽¹⁹⁾. Such difference may be related to the need for training the professionals who request the mammography, as well as the professionals who report the data from the mammograms to the SIS-MAMA. The quality of the data reported to the Sistemas de Informação em Saúde (Health Information Systems) has a direct influence on the planning of actions in the healthcare sector⁽⁴³⁾.

As regards the quality of data reported to SISMAMA, one of the private diagnostic centers which reported all mammograms as category 1 corroborates the lack of standardization of mammography reports and the importance of quality control programs. Such lack of standardization may become a factor of confusion in the interpretation of mammograms, as well as interfere in the recommendations for management strategy, with basis on ambiguous mammographic findings⁽⁴⁴⁾.

Furthermore, the variability in the performance of the diagnostic centers as regards diagnosis conclusion reinforces the findings reported by other studies indicating the need for implementation of audits in screening programs results for monitoring the quality of mammograms interpretation⁽⁴⁵⁻⁴⁷⁾.

One of the requirements included in the Brazilian Ministry of Health Ordinance No. 531/2012 which instituted the PNQM and the Quality Requirements for Mammographic Studies and Reports is the monitoring of the mammogram results reported by imaging diagnosis centers in the whole Brazilian territory⁽¹⁵⁾. With such a monitoring, an equivalent performance regarding diagnostic conclusion is expected from the part of diagnostic centers.

As the performance of the diagnostic centers is evaluated, one verifies that their performance is related to a pattern of noncompliance between BI-RADS categories and the thresholds established in the present study. Thus, considering that the SISMAMA is aimed at managing the actions for breast cancer control at different levels, the incorrect input or absence of reported data in the System represents an obstacle to be overcome by public managers as a strategy for planning in health⁽⁴⁸⁾.

Another important issue is the civil liability of the radiologist in the diagnosis of breast cancer by means of mammography. A study shows that the data transmitted to the to the assisting physician by means of a detailed report⁽²⁸⁾ with accurate location of possible lesions, as well as correct BI-RADS classification, minimize medical errors, thus avoiding civil liability lawsuits⁽⁴⁹⁾.

For relying on the utilization of secondary data, the limitations faced in the present study are inherent to the inconsistencies of information reported to SISMAMA by each diagnostic center. What is expected from imaging centers that perform mammography for SUS, is homogeneity in the reported data. The consolidated results of the present study allowed the authors to infer that there is a need to promote periodical updating training for the professionals involved in data feeding to SISMAMA, approaching the relevance of a correct filling of fields such as clinical indication, for example.

However, besides providing scientific data, the present study allowed for the monitoring of the results from the diagnostic centers, both from the public (SUS) and the private service providers networks, taking into consideration that public (SUS) diagnostic centers are scarce in the municipality of Goiânia and also in the state of Goiás. The monitoring of the results will allow the development of indicators for opportunistic mammographic screening at SUS, and such indicators will contribute with better delineation of actions and health programs on a regionalized basis, as well as will establish decision making strategies targeted at reducing breast cancer morbimortality at a population level.

CONCLUSION

The results of the present study demonstrate unevenness in the diagnostic centers performance in the classification of mammograms reported to SISMAMA from the opportunistic screening undertaken by SUS, suggesting the necessity of actions for training professionals involved in the data feeding to SISMAMA, as well as in mammography reporting.

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