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Effectiveness of a quality control program in mammography for the Brazilian National Health System

ABSTRACT

OBJECTIVE: To assess the effectiveness of a quality control program in mammography services of the Brazilian National Health System (SUS).

METHODS: A prospective study using temporal analysis of a health surveillance action was conducted. A total of 35 service providers that had mammography equipment in operation and regularly performed exams between 2007 and 2009 in the state of Goiás, Central-Western Brazil, participated in this study. Services were assessed during three site visits by performance testing of mammography equipment, film processors, and other materials, and image quality and entrance surface dose in a phantom were also assessed. Each service was scored according to the percentage of tests that conformed to standards.

RESULTS: The mean percentage for compliance among the participating service providers were 64.1% (± 13.3%) in the first visit, 68.4% (± 15.9%) in the second, and 77.1% (± 13.3%) in the third (p < 0.001). The main improvements resulted from adjustments to the breast compression force, the automatic exposure control system, and the alignment of the compression paddle. The doses measured were within the conformity range in 80% of the services assessed.

CONCLUSIONS: The implementation of this program in the mammography services was effective at improving the operational parameters of the mammography machines, although 40% of the services did not reach the acceptable level of 70%. This result indicates the need to continue this health surveillance action.

DESCRIPTORS: Mammography, standards. Effectiveness. Evaluation of the Efficacy-Effectiveness of Interventions. Quality Assurance, Health Care. Brazilian Public Health System. Breast Neoplasms, diagnosis.

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INTRODUCTION

The main objective of mammography as a screening method for breast cancer is to reduce the mortality rate through the increase of cases detected at early stages of the disease.[5] Randomized trials show statistically significant reduction in mortality rates for women undergoing mammography screening.[9,14,16,17] However, screening effectiveness is directly related to the quality and performance of equipment, materials and procedures employed.[8] As a result, reference documents were drawn up for the implementation of quality control programs in mammography.[6,a,b]

The Brazilian College of Radiology created in 1992 the Quality Certification Program in Mammography on a voluntary basis, in order to initiate an action plan for quality control in mammography in Brazil.[10] Radiological protection guidelines in medical and dental radiodiagnosis were established by the Brazilian Ministry of Health, in 1998.[c]

The National Cancer Institute (INCA) recommended in 2004 the creation of quality control guidelines to the Brazilian National Health System (SUS), as part of the criteria for accreditation and monitoring of mammography services.[d] This recommendation was aimed at implementing quality control programs in the accredited network. Thus, the services became responsible for conducting periodic performance tests in mammography units, film processors and other materials, as well as verifying the image quality and the radiation dose applied to patients.

Screening programs for breast cancer are aimed at improving public health. Quality control actions for achieving satisfactory imaging by exposing patients to acceptable radiation doses constitute a major component of such programs. Thus, the objective of this study was to evaluate the effectiveness of the quality control program in mammography for continuous monitoring of services that integrate the SUS network.

METHODS

A prospective temporal analysis of a health surveillance action was carried out. The unity of the research was the mammography service, and data collection was performed by site visits in three periods: 2007, 2008 and 2009. Service providers that had equipment with conventional processing system (screen/film) and performed mammograms through the SUS from July 2007 to March 2009, in the state of Goiás, Central-Western Brazil, were included in this research. Data collection was divided into two stages: service provider registration and performance assessment of mammography units, film processors and other materials, as well as evaluation of image quality and radiation doses applied.

Of the 45 mammography service providers caring for SUS patients in the state of Goiás between 2007 and 2009, 35 participated in this study. The following service providers were excluded: two were banned from performing mammography on the SUS, four were closed (during the research period) for not having the technical conditions required, two were not involved in all stages of the research, and two were excluded at the end because they replaced their conventional image processing for a digital system.

An evaluation report was sent to each service provider after the visits, containing the measured and the acceptance value (or value range) for each parameter. Upon delivery of the report, the service provider received a deadline from the health surveillance organ of the State of Goiás for the completion of nonconformities.

Identification of services was performed using data from the National Registry of Health Care Services (CNES/DATASUS/MS).[e] Background information on the equipment and materials used in mammography was collected. Participating services were coded by the acronym GO (state of Goiás), followed by a three-figure numerical sequence starting at the code GO001, to preserve the mammography services identity.

Mammography quality was established according to the degree of compliance shown in performance tests applied to the equipment and materials used. The evaluation of the performance parameters for equipment and materials, image quality and radiation dose was

[a] OIEA. Organismo Internacional de Energía Atómica. Control de calidad en mamografía. Protocolo elaborado en el marco de dos proyectos regionales ARCAL/OIEA. Viena; 2006. (IAEA-TECDOC-1517). [cited 2011 Sept 12] Available from: http://www.pub.iaea.org/MTCD/publications/PDF/te_1517s_web.pdf

[b] Wolf CJM, Perry NM, editors. European guidelines for quality assurance in mammography screening. Luxembourg: European Commission, Europe Against Cancer Programme; 1993.

[c] Ministério da Saúde (BR), Agência Nacional de Vigilância Sanitária. Portaria/MS/SVS nº 453, de 1º de junho de 1998. Aprova o Regulamento Técnico que estabelece as diretrizes básicas de proteção radiológica em radiodiagnóstico médico e odontológico, dispõe sobre o uso dos raios-x diagnósticos em todo o território nacional e dá outras providências. *Diario Oficial Uniao*. 2 jun 1998. [cited 2011 Sept 18]. Available from: http://www.anvisa.gov.br/legis/portarias/453_98.htm

[d] Ministério da Saúde (BR). Instituto Nacional de Câncer (INCA). Controle do câncer de mama: documento de consenso. Rio de Janeiro; 2004. [cited 2011 Sept 12]. Available from: http://www1.inca.gov.br/publicacoes/Consensointegra.pdf

[e] Ministério da Saúde (BR). Cadastro Nacional de Estabelecimentos de Saúde – CNES. Brasília, DF; 2007. [cited 2011 Sept 12]. Available from: http://cnes.datasus.gov.br

carried out according to the technical regulation by MS/SVS,[c] the European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis[15] and the Protocol on Quality Assurance in Mammography of the International Atomic Energy Agency (IAEA).[a] Such documents provided the measurement processes used in the evaluations of performance parameters and their acceptance limits.

Radiation dose and image quality were assessed through a mammographic phantom[3] (Figure 1A). It simulates a 5.3 cm compressed breast made of 50% fat and 50% fibroglandular tissue. It consists of three acrylic sheets (10 mm x 120 mm x 160 mm) and one acrylic plate (20 mm x 120 mm x 160 mm), which contains a wax insert (5 mm x 70 mm x 140 mm) and a five-step scale that produces areas of different optical densities, used for the assessment of image contrast (Figure 1B). The wax insert contains four metal grids for evaluating the spatial resolution of the image, five groups of Al_2O_3 microspheres simulating microcalcifications, eight polyester disks simulating low contrast areas, six nylon strands simulating fibrous tissues and five spherical nylon caps simulating tumor masses.

The images were generated under the same conditions in each mammography unit, with the phantom positioned on the breast support platform, aligned with the cassete on the edge of the chest wall and the sensor for automatic exposure control (AEC) activated and positioned under the phantom's main body. The strain selected for the exposure was held constant at 28 kV at all mammography services. After exposure, the film was developed at the service's processor, in normal use conditions (Figure 1B).

The image quality assessment considered the possibility of visualizing the following groups of structures: four metal gratings (spatial resolution), four microcalcifications (high contrast details), seven disks (low contrast threshold), four fibers (linear low-contrast details) and four spherical caps (tumor masses). The contrast index and the background optical density were also measured in the phantom image, the presence of artifacts and image uniformity being observed. Image reading was carried out in a dimly lit room by at least two reviewers, using masks to cover the unused clear area of the negatoscope.
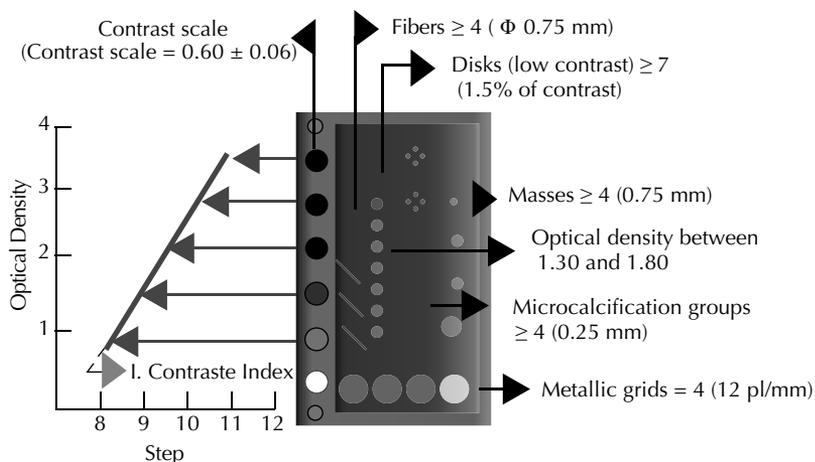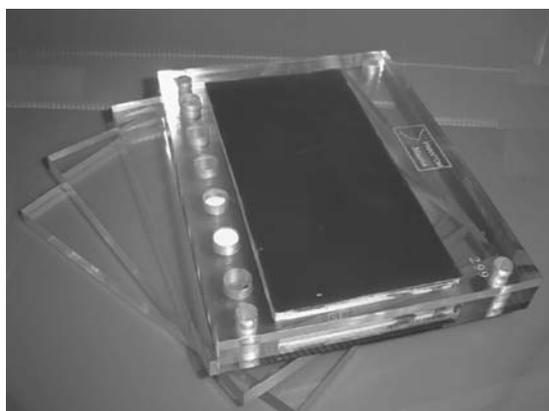
Figure 1. A. Mammographic phantom ; B. Image of the breast phantom produced in the mammography services.

The performance of the devices and accessories that directly and indirectly influenced image quality was tested by collimation system, AEC's performance, compression force, alignment of thecompression paddle, cassete integrity and processing system.

The radiation dose at the entrance surface of the phantom was determined by measuring the air-kerma, established by MS/SVS,[c] with a solid state dosimeter (model Multi-O-Meter L 535, Unfors, Billdal, Sweden) calibrated for mammography. The measurements were performed with the same radiographic techniques selected for image processing of the phantom. The compliance range of 7 to 13 mGy was adopted, considering the reference value of 10 mGy (± 30% for this study), established by the SVS/MS.[c]

One point was awarded for compliance and zero for non-compliance of each parameter, at each assessment. Thus, considering 16 parameters, the total score of the service varied from zero to 16. The percentage of compliance for each service and their average

percentage (2007, 2008 and 2009) were calculated. The t-test for comparison of means for paired data samples was used to verify the statistical differences between the mean compliance percentages between the services at each year. The McNemar's test was applied to compare the parameters between two years (2007 and 2008, 2007 and 2009, and 2008 and 2009). The significance level of 0.05 was used in the statistical tests.

This study was approved by the Dr. Henrique Santillo Ethics in Research Committee at the State Department of Health of Goiás (Protocol 0007.1.177.000-5).

RESULTS

About 20% of mammography units were owned by public institutions, 11% by charities and 69% by private health services. Mammography units from eight different manufacturers were identified: 80% were imported and 20% were Brazilian units. Among the film processors, 69% were imported, 20% were made

Table 1. Assessment and statistical comparison between mammography services, according to performance parameters for equipment and materials in compliance with the standards. Goiás, Central-Western Brazil, 2007 to 2009.

| Performance parameters | Services in compliance with the standards | | | | | | Statistical comparison (2007 to 2009) |
| | 2007 | | 2008 | | 2009 | | p |
	n	%	n	%	n	%	
Compression force	17	48.6	25	71.4	27	77.1	0.013
Field alignment	25	71.4	27	77.1	32	91.4	0.092
Exposure automatic control	13	37.1	22	62.9	24	68.6	0.007
Alignment of the compression paddle	19	54.3	28	80	30	85.7	0.003
Chassis integrity	21	60.0	23	65.7	30	85.7	0.035
Processing	13	37.1	13	37.1	16	45.7	0.581

Tabela 2. Assessment and statistical comparison between mammography services, according to parameters of quality for phantom image and dose in compliance with the standards. Goiás, Central-Western Brazil, 2007 to 2009.

| Parameters of quality for phantom image and dose | Services in compliance with the standards | | | | | | Statistical comparison (2007 to 2009) |
| | 2007 | | 2008 | | 2009 | | p |
	n	%	n	%	n	%	
Optical density	20	57.1	21	60.0	25	71.4	0.302
Spatial resolution	30	85.7	30	85.7	30	85.7	1.000
Microcalcifications	31	88.6	29	82.9	30	85.7	1.000
Fibers	35	100.0	35	100.0	35	100.0	*
Masses	35	100.0	35	100.0	35	100.0	*
Low contrast disks	22	62.9	15	42.9	17	48.6	0.302
Contrast index	21	60.0	24	68.6	21	60.0	1.000
Image uniformity	23	65.7	23	65.7	32	91.4	0.035
Image with no artifacts	14	40.0	10	28.6	24	68.6	0.021
Dose	20	57.1	23	65.7	26	74.3	0.210

*The test was not applied because the variable did not show dichotomy.
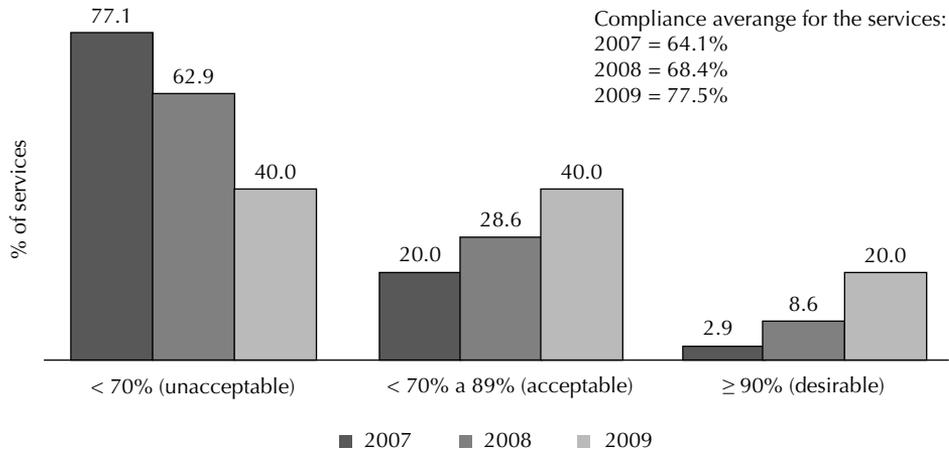
Figure 2. Percentage of compliance of the performance parameters for equipment and materials related to phantom image quality and dose in mammography services, according to year of assessment. Goiás, 2007 to 2009.

in Brazil and 11% were made by other national and foreign manufacturers. A total of 69% of the processors were used exclusively for mammograms.

The analyses for 2007-2008 and 2007-2009 revealed statistically significant differences between the percentages of compliance for compression force (p = 0.039 and p = 0.002), AEC (p = 0.012 and p = 0.004) and alignment of the breast support platform (p = 0.004 and p = 0.002), while the integrity of the cassete (p = 0.035) showed a statistically significant difference in the 2007-2009 period. An increase in absolute numbers of services showing compliance in the alignment of the x-ray field with the film and in the processing of x-ray films (Table 1), even without statistically significant differences between the percentages.
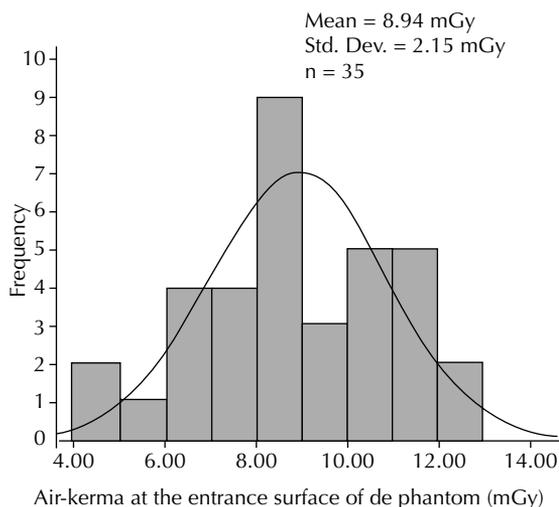
Figure 3. Radiation dose at the entrance surface of the phantom (air-kerma) at the mammography services. Goiás, Central-Western Brazil, 2009.

Regarding the assessment of the quality parameters of the phantom's image recorded on film and the radiation dose used, the two parameters that showed statistically significant differences from 2007 to 2009 were the absence of image artifacts (p = 0.021) and the image uniformity (p = 0.035) (Table 2).

Although no statistically significant differences were observed regarding the optical density of the image and the dose, the data showed an increase in the number of services that were in conformity with these parameters. In relation to the spatial resolution and the visualization of structures that mimic tumor masses and fibers, services showed compliance in the assessment for 2007, a result that was also seen in 2008 and 2009.

The other parameters of image quality (visualization of microcalcifications and contrast index) showed differences in the order of $\pm 5\%$ between the percentages, whereas the difference was $\pm 14\%$ for the low contrast disks. In such cases, no numerical increase of services in accordance with the standards was observed.

About 23% of services presented percentage of compliance equal or higher than 70% in 2007, which is considered acceptable, decreasing to 60% in 2009 (Figure 2). A mammography service (3%) achieved a desirable level of compliance in 2007, above 90%, but was rated three (9%) in 2008 and six (17%) in 2009. The average compliance of services in the first visit (2007) was 64.1% ($\pm 13.3\%$), whereas in the second (2008) and third (2009) were 68.4% ($\pm 15.9\%$) and 77.5% ($\pm 13.3\%$), respectively. The difference between the mean percentage of compliance of the services was statistically significant between the first and third visits (p < 0.001) and between the second and third visits (p = 0.004).

Approximately 20% of evaluated services in 2009 were not in compliance with the established range for the dose used, which was from 7 to 13 mGy (Figure 3).

DISCUSSION

The evaluation of the quality actions and health services is fundamental to the control of health care offered to the population[2]. Equipment emitting ionizing radiation can operate with a high degree of quality, but it is necessary to follow the rules and procedures of radiological protection and quality control.[a] The implementation of a quality control program in mammography services, which are part of the SUS network in Goiás, was more effective with the results found for 2007 and 2009, i.e., with two interventions. By continuing the program, it is possible to establish a better quality control, reducing the risks linked to mammography exams, even though 20% of services have shown desirable results in the last assessment of above 90% compliance, considering the evaluated items.

The performance parameters for the equipment and materials that showed improvement resulting from the quality control action in the services were related to adjustments in breast compression force, AEC system, alignment of the breast support platform and integrity of the cassete. However, some mammography units were left unadjusted in relation to the breast compression force (22.9%), AEC system (31.4%) and alignment of the compression paddle and integrity of the cassete (14.3%). In a study carried out in Minas Gerais[13], the percentage of mammography units unadjusted for the compression force was 23.9%, whereas 37.3% were unadjusted for the AEC system. The results obtained in both studies coincide and point to a situation in which it is not possible to make adjustments in these performance parameters for some mammography units. It was not possible to establish, during this research, whether this hypothesis was associated with the technology of the equipment or duration of use.

The only performance parameter that showed no improvement during the study period was the alignment of the x-ray field with the image recording system composed by the cassete and the film (p = 0.092). However, there was a progressive increase in the percentage of compliance for this parameter, result that shows the need for continuity of this type of intervention in the coming years.

Studies indicate the development of radiographic films as the process that most affects image quality in mammography.[3,11,12] The solution of non-compliance cases for film processing is not simple, involving from the change of equipment to the adoption of standardized processes for the preparation of certified solutions. The result obtained in this study showed that the percentage of compliance of film processing remained almost unchanged, and around 40% during the three years of research, which is similar to that found in the study carried out in Minas Gerais[13] (38.8%). About 31% of the film processors were not specific for mammography, which may have contributed to the relatively low percentage of compliance in film processing. The materials used, the temperature of the employed solutions and the processing time were not evaluated in this study.

The image quality parameters that showed improvement resulting from the quality control program between 2007 and 2009 were related to uniformity and reduced number of image artifacts. Those that did not show a statistically significant difference between the mean percentage of compliance services between the first and third visits can be divided into two groups. In the first group are included the mean optical density, spatial resolution, microcalcifications, fibers and masses, with percentages of compliance above 70% (minimum acceptable percentage for a set of services). In the second group are the low contrast disks and contrast index, with percentages of compliance below 70%. These groups require separate analysis. The parameters of the first group reached the minimum acceptable levels. The situation is not considered critical and requires a finer adjustment in the image production chain, in a small number of services.

The situation of the parameters in the second group is considered critical, because no improvement was observed between assessments. Their mean percentages of compliance (43% and 69%) are considered unacceptable. These parameters will require more intense effort for performance tuning of equipment and materials. The visualization of low contrast disks and the contrast index are directly associated with the performance of the automatic film processor.

On one hand, the analysis of radiation doses on the entrance surface of the phantom shows no improvement during the study (p = 0.210), but a progressive increase in the percentage of compliance of this parameter was observed. Corrective measures related to equipment and materials can improve the image quality parameters of the phantom, with a positive impact on the adequacy of the doses to a range of acceptable values.[1]

The dose of radiation to which the patient is exposed should be kept as low as possible without compromising the quality of the image.[a] The legislation[c] established 10 mGy as the reference value for applications near the skin. In this study, upon acceptance of variation of ± 30%, 80% of services showed values of 7 to 13 mGy, averaging 8.94 mGy and comparable to the results of the Minas Gerais research.[13]

A study conducted in the Republic of Macedonia showed that 50% of mammography units lacked basic quality criteria for the screening of breast cancer, in 2008-2009.[7] In an opportunistic screening performed by the SUS in 2008[4], in the state of Goiás, 62.9% services had quality standards of not acceptable compliance (< 70%), whereas 28.6% were considered acceptable (70% < 90%) and 8.6% were rated as desirable (> 90%).

The quality of services in relation to equipment and accessories was evaluated. However, it is necessary to conduct research focusing on mammography professionals, as well as image quality, for the early detection of breast cancer and the carcinogenic risk within the SUS and the supplementary health system.

Interventions in the Quality Control Program in Mammography, based on the methodology applied in this study, were effective for improving the screening quality and monitoring the services that compose the SUS in Goiás. Although the percentage of mammography services classified as unacceptable in relation to the technical criteria evaluated has decreased (from 77.1% in 2007 to 40% in 2009), doctors continued to have mammograms of inferior quality and were more prone to misdiagnosis. It is necessary to continue quality control activities, including services that are not linked to the SUS.

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