Implementation of a Clinical Quality Control Program in a Mammography Screening Service of Brazil

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Abstract. Aim: To evaluate the effect of a clinical quality control program on the final quality of a mammography screening service. Materials and Methods: We conducted retrospective assessment of the clinical quality of 5,000 mammograms taken in a Mammography Screening Program between November 2010 and September 2011, following the implementation of a Clinical Quality Control Program based on the European Guidelines. Results: Among the 105,000 evaluated quality items, there were 8,588 failures (8.2%) - 1.7 failures per examination. Altogether, 89% of the failures were associated with positioning. The recall rate due to a technical error reached a maximum of 0.5% in the early phase of the observation period and subsequently stabilized (0.09%). Conclusion: The ongoing education and monitoring combined with personalized training increased the critical thinking of the involved professionals, reducing the technical failures and unnecessary exposure of patients to radiation, with substantial improvement in the final quality of mammography.

Breast cancer remains the leading cause of cancer mortality among women worldwide (1), with the highest incidence in developed countries. However, mortality rates in developing countries also show an increased trend due to a lack of resources for implementation of organized screening programs, accurate diagnosis and effective treatment (2).

Mammography is the only radiological examination that allows for systematic detection of breast cancer, as early detection remains one of the cornerstones in the fight against breast cancer mortality (3). The quality of mammography is directly related to the capacity for detecting an abnormality. While screening mammography without adequate quality control reaches a sensitivity of 66%, an adequately controlled screening mammography has sensitivity up to 85-90% (4, 5).

Optimal quality of the mammography image is essential for successful diagnosis of breast cancer (6, 7). This includes both the (i) technical criteria associated with the assessment of the mammography and workstations through well-established periodic tests (8), and (ii) clinical criteria involving the review of the produced films, mammographic compression, exposure, artifacts and image definition (5, 6, 8, 9), all affecting the accuracy of mammography (5, 6). Thus, correct positioning as well as physical and technical parameters, like adequate contrast, are absolutely necessary to obtain high-quality mammographic images. In consequence, the radiography technician must follow the positioning standards to maximize the amount of tissue covered by the image (10).

The evaluation of the clinical criteria of mammography image quality is controversial and subjective, being hampered by variations in the individual perception of the observers (11). As an attempt to develop a rigorous standardized system, several models have been proposed, including the American College of Radiology (ACR) (12) and the European Commission (European Guidelines) (13). According to the World Health Organization (WHO), developing countries display an array of difficulties when it comes to access radiological services like large gaps in image quality and also deficiencies in radiological services (14). In 2006, the Brazilian press reported that 60% of the mammographic examinations conducted by the National Cancer Institute of Brazil (INCA) (including public health systems and private clinics) exhibited some degree of failures, such as errors in the radiation dosage, equipment calibration, positioning of the patients and image interpretation (15).
With desire to improve the quality of the services and expertise based on the European model of population-based organized screening, the Barretos Cancer Hospital acquired knowledge about European screening and especially the quality assurance program and training of its screening professionals. These experiences encouraged us to start in 2009 a clinical quality control program of their screening mammography based on the European Guidelines.

The aim of this study was to evaluate the quality of the mammographic images produced in one mammographic screening service, during the implementation of a clinical quality control program.

Materials and Methods

**Materials.** We conducted an observational study based on retrospective data collection on the clinical quality of mammograms performed in a Mammography Screening Program at the Pio XII Foundation - Barretos Cancer Hospital between 2010 and 2011. The study sample comprised a series of 5,000 mammograms performed by the same group of radiology technicians during implementation of the Clinical Quality Control Program. Excluded from the study were all tests performed for women with very large breasts, those who underwent breast-conserving surgery or mastectomy, as well as the images with limitations in the evaluation of the proposed indicators.

The authors ensure that this study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. This project was evaluated by the Ethics Committee in Research of the Barretos Cancer Hospital and assessment was approved under protocol number 573/2012.

**Methods.** The target group undergoing re-education since November 2010 comprised of 33 radiography technicians who performed mammographies for women participating in the Mammography Screening Program at the Pio XII Foundation - Barretos Cancer Hospital.

The Clinical Quality Control Program was supervised by a multidisciplinary team comprising (i) a radiologist specialized in mammography, responsible for assessing the clinical quality control items, (ii) a physicist dedicated to technical quality control, (iii) three technical supervisors of the practical training (to specifically correct the failures of the technical group) and (iv) a statistician.

All radiology technicians involved in the program received theoretical and practical training in mammography and executed their activities in 3 fixed units and 5 mobile units (MU) equipped with 13 mammography systems (6 digital and 7 analog systems) (Table I). Approximately 20% of the production from each unit was sampled daily through systematic random sampling. This value was defined as the sample size calculation based on the volume of the production of each unit (16).

The X-ray films from the analog units were forwarded and immediately assessed, while the digital exams were assessed using an archiving and image distribution system - PACS (Picture Archiving and Communication System) (17), within 24 hours after completion. After identification of the pattern of the breast composition, i.e., the proportion of fibroglandular tissue in relation to fat tissue, according to the BI-RADS™ classification (12), the clinical quality of the mammogram was evaluated using nominal qualitative variables according to the standardization of the European Guidelines (13), and divided into two categories: (i) failures associated with positioning or (ii) failures associated with the equipment. The collected data were compiled into a database developed within the computer system of the Barretos Cancer Hospital. The evaluation was subdivided into items associated with cranio-caudal and medio-lateral oblique views and, in the equipment category, the evaluated items included those associated with the performer equipment that could interfere with the final quality of mammography in both views (Table II).

Each item was categorized as "conformity" or "non-conformity", based on the two views in both lateral sides. Only the items in "non-conformity" were annotated using this software. The quality control program identified the unit that performed the examination, the radiology technician responsible and the committed failures. Therefore, it was possible to distinguish the types of non-conformities (technical or equipment) in each work unit, associated with each type of equipment, analog, digitized analog or digital.

The analysis of the number of errors was performed monthly. Based on the chart of the statistical process control (software R version 2.15.2, Link or Supplier) (18), which influences the individual performance relative to the group average in the period. The radiology technicians showing average failures above individual limits, calculated in proportion to the volume of the tests analyzed, were summoned to new training (Figure 1).

The failure types of the radiology technicians necessitating to repeat training were identified and personalized, and targeted corrective actions were employed in specific practical trainings with technical supervisors. The training lasted an average duration of 15 hours and the physician in charge monitored the production. After correction of the presented failures, the radiology technicians were authorized to continue their work.

The radiology technicians from the units of the Pio XII Foundation - Barretos Cancer Hospital received individualized assessments of their non-compliance and development during the period, a continuing education program and a monthly recycling in the fixed unit of Barretos was offered. When necessary, corrective intervention was performed through the dedicated physician in the mobile units; thus, any problems in these units were resolved in the

<table>
<thead>
<tr>
<th>City (State)</th>
<th>Unit type</th>
<th>Number</th>
<th>Equipment technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barretos (SP)</td>
<td>Fixed</td>
<td>3</td>
<td>Digital</td>
</tr>
<tr>
<td>Mobile (MU2)</td>
<td>1</td>
<td>Analog</td>
<td></td>
</tr>
<tr>
<td>Mobile (MU5)</td>
<td>1</td>
<td>Analog</td>
<td></td>
</tr>
<tr>
<td>Jales (SP)</td>
<td>Fixed</td>
<td>1</td>
<td>Digital</td>
</tr>
<tr>
<td>Fixed</td>
<td>1</td>
<td>Digital</td>
<td></td>
</tr>
<tr>
<td>Mobile (MU4)</td>
<td>2</td>
<td>Analog</td>
<td></td>
</tr>
<tr>
<td>Mobile (MU6)</td>
<td>2</td>
<td>Digital</td>
<td></td>
</tr>
<tr>
<td>Juazeiro (BA)</td>
<td>Fixed</td>
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<td>Analog</td>
</tr>
<tr>
<td>Mobile</td>
<td>1</td>
<td>Analog</td>
<td></td>
</tr>
</tbody>
</table>

Where: BA=Bahia State; CR=computed radiography; MU=Mobile Unit; SP=São Paulo State.

Table I. The use of digital and analog mammography equipment in the mammography screening of Barretos Cancer Hospital, Fundação Pio XII.
Figure 1. *The control chart demonstrating technical performance of the radiology technicians related to the volume and compared to the group in the same period. The average failures of each technician are represented by a dot. The dotted line depicts how much each technician will fail and still maintain a technical performance within the acceptable range. The points above the dotted line indicate the radiology technicians whose performance was outside the accepted range and who were referred for further training.*

<table>
<thead>
<tr>
<th>Category</th>
<th>View</th>
<th>Evaluated item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positioning</td>
<td>Cranio-caudal</td>
<td>Nipple in profile and centered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lateral and medial portions of breasts correctly shown</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Presence of the pectoral muscle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Absence of skin folds</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Symmetry</td>
</tr>
<tr>
<td></td>
<td>Medio-lateral oblique</td>
<td>Nipple in profile and parallel to the film</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All the breast tissue clearly shown</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pectoral muscle to nipple level</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pectoral muscle relaxed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Absence of skin folds and axilla</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Absence of minor pectoral muscle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Visualization of infra-mammary angle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Symmetry</td>
</tr>
<tr>
<td>Equipment</td>
<td>Cranio-caudal and Medio-lateral oblique</td>
<td>Definition</td>
</tr>
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<td></td>
<td>Optical density</td>
<td>Contrast</td>
</tr>
<tr>
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<td>Noise</td>
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<td>Artifacts</td>
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<td>Identification</td>
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shortest possible time. During the study period, the rates of repeated examinations and recalls due to a technical error (12, 13, 19) of the units were recorded. This study was conducted using a single expert observer to avoid bias due to inter-observer variation, inherent to the subjectivity of the clinical quality assessment.

Statistical analyses. The data were subjected to exploratory analysis through descriptive statistics, using mean, absolute and percentage frequencies, and graphs.

Results

Altogether, from the 5,000 consecutive mammograms submitted to clinical quality control program between November 2010 and September 2011, 105,000 quality items were evaluated, related to both the positioning and equipment.

In total, 2,851 results were obtained from the digital exams (57.02%), 1,968 results were derived from analog exams of the radiographic films (39.36%) and the remaining 181 results represented digitized analog exams (3.62%).

Out of all failures, 7,676 (89%) were associated with the positioning of the breast during the examination and 912 (11%) failures were associated with the equipment. Fixed units of Barretos, as well as MU2 and MU5 exhibited the lowest average failure rate associated with positioning, ranging between 1.2 and 1.4 failures/exam, whereas the fixed
units of Barretos, fixed units of Jales with digital equipment (fixed Jales D) and MU6 exhibited the lowest equipment-related failures, ranging between 0 and 0.03 failures/exam. The highest rate of failures in both positioning (between 2.6 and 3 failures/exam) and the equipment (between 0.6 and 0.9 failures/exam) were observed at the units of Juazeiro, Bahia. The distribution of the failure types by the mammography units is shown in Figure 2.

Technical failures. The 912 non-conformities associated with the equipment failure were analyzed in more detail and 673 (69.9%) of those were attributed to the presence of artifacts in the image, followed by 137 (15%) variations in optical density, 58 (6.4%) losses in definition, 37 (4.1%) losses in contrast, 31 (3.4%) mis-identifications and 12 (1.3%) indications of image noise. Evaluation of these non-conformities according to the type of equipment revealed a predominance of the failures in analog equipment, with 839 (93%) non-conformities. The digitized analog equipment (CR) and digital analysis registered only 4% and 3% failures, respectively. Correlation of the type of failure with the equipment determined, using the Kruskal-Wallis test, showed the highest prevalence of failures for artifacts in analog equipment (79.6%), definition problems in digitized analog (67.7%) and digital (64.3%) equipment (Table III).

Failures in breast positioning. Among the 7,676 non-conformities associated with breast positioning during mammography, 3,316 (43%) were observed in the craniocaudal view and 4,356 (57%) were found in the medio-lateral oblique view. The absence of major pectoral muscle in the craniocaudal view was the single most frequent failure, representing 2,547 (33%) of the errors. The second most frequent error was the lack of adequate opening of the infra-mammary angle, with 1,846 (24%) non-conformities, followed by incorrect positioning of the breast above the nipple line (14.2%) (Figure 3).

Also the correct positioning of each evaluated item was recorded. The major pectoral muscle was sampled correctly in craniocaudal view in 49.2% of the patients; it was properly positioned on the nipple line in 78.2% of the examinations, while the infra-mammary angle was correctly viewed in 63.1% of the mammograms (Table IV). The average number of non-conformities for each radiology technician was cyclic during the study period, showing bi-monthly or quarterly peaks, while the variation of the overall group failures leveled off along with the realized examinations.

Repetition and recall rates. The repetition rate of the examinations increased from 1.6% to 6.6% between

![Figure 3. Distribution of positioning-related failures.](image)
November 2010 and February 2011, with a decline in subsequent months, stabilizing between 3 and 4%, as shown in Figure 4. The recall rates due to a technical error ranged from 0.05% to 0.3%, showing a decline of 0.47% between November 2010 and February 2011 (i.e., a decrease from 0.5% to 0.03%), and stabilizing at an average level of 0.09% (Figure 5).

**Discussion**

Potential causes of false negative mammographies include (i) dense parenchyma obscuring the lesion, (ii) subtle features of malignancy, (iii) slow growth of the lesion, (iv) perception error, (v) incorrect interpretation of a suspect finding and (vi) failing of positioning or examination technique (20). An
adequate quality of mammography is essential for the accurate diagnosis of breast cancer (4, 5). However, controlling the quality of mammography is a greater challenge than in any other field of radiology (9) which makes it imperative to adopt a continuous and rigorous quality-monitoring process in all mammographic screening programs.

INCA (Brazil) in association with the Brazilian College of Radiology (CBR) and the National Agency for Sanitary Surveillance (ANVISA), with 53 services of the Unified Health System (SUS) conducted a pilot study on quality control in mammography between 2007 and 2008 (21). It was disclosed that the quality of 30% of the mammographic examinations was below the satisfactory standards, with an index three-times higher than the percentage of failures accepted by WHO guidelines (21). Despite its extreme importance, the quality certification of the mammography services by the Brazilian College of Radiology and Diagnostic Imaging (CBR), in which the examinations and medical reports are subjected to a rigorous evaluation, was not mandatory and is currently available in only 5.7% (183) of the 3,200 mammography services available in Brazil (22).

The availability of good-quality radiological services worldwide is worrying, particularly in low- and middle-income countries (LMC). According to WHO, 3.5 to 4.7 billion individuals worldwide have difficulties to access the radiology services due the lack of progress in LMCs (23). The medical imaging services in these countries continue facing several difficulties, most importantly the lack of resources to structure the services and a weak or inexistent infrastructure for training and education of the different professionals to improve the quality of radiography (14). A major problem in developing countries, however, is the qualification of all the professionals involved in organized radiological services.

Resources for education and training are important for implementation and sustainability of a radiological service, which can be used to educate local health care providers to improve the quality of the service (24). Furthermore, specialized and qualified labor requires time and financial investment. The training of Brazilian radiology technicians for the performance of mammography is conducted as a part of generalist training which includes 18 months of a technical course without qualification specific to mammography, as compared with the 4 years required to graduate with mammography specialization in many of the developed countries. This inadequate training of radiology technicians is well-illustrated by the results of an audit (in 2009) by an independent European organization, emphasizing that the first thing to be tackled is the high number of recalls due to technical and positioning problems.

To minimize the impact of the deficient technical training on mammography quality, a multi-disciplinary team comprising of radiologists, physicists and radiology technicians should be integrated to address the technical and clinical criteria of the examination. This team should immediately act in the resolution of failures with corrective actions on equipment and plan systematic activities that promote continuous quality control through personnel training, equipment renewal and monitoring the quality of the units over time for the maintenance of the established

Figure 5. Monthly variation in the recall rates due to technical error.
standards and the participation of the units in national programs of accreditation. Similar actions are taken in developed countries, such as the Netherlands (25) and Japan (26), which have training centers and mammography quality monitoring. Typically, the technical team or radiologist, who is inadequately-trained for this purpose, intuitively assesses the clinical quality of the mammography, and preventive and corrective actions are not generally endorsed. Thus, it is necessary to develop programs in which the criteria associated with the final quality of the mammogram produced are systematically analyzed to support the practical training for radiology technicians.

During this study, the analysis of the sample control charts disclosed the need for additional training only for technicians who committed an average of 2 or more failures per test. Thus, according to these criteria, the majority of the evaluated examinations (73%) did not prompt the radiographer for training. In this study, the mammography units exhibited significant changes in their average number of non-conformities. The units located more distant from the headquarters of the program and from the practical training unit exhibited nearly three-times more failures than the other units. These data suggest that the proximity to the training center is important to provide more effective correction of the failures, likely reflecting the daily opportunities to communicate with those responsible for the program as well as the possibility to participate in monthly practical training with technical supervisors, which is offered only sporadically for the more remote units.

Most of the recorded failures were associated with the positioning of the breast for examination, which is consistent with the published literature (5, 9, 27). Positioning failures are operator-dependent and closely associated with the occurrence of interval cancers (5). The cranio-caudal view showed the highest number of positioning-related non-conformities (with a number of items evaluated), of which the main item, i.e., sampling of the major pectoral muscle, was adequately performed 20% more often than reported by Cardeñosa (28) and 50% more often than in the study of Bassett (29).

The breast density is an important variable in any evaluation of the clinical quality of the picture, which potentially affects the detection of lesions and reduces the sensitivity of mammography (5, 30, 31). The pattern of the breast density might also influence the perception of the image due to the reduction of the contrast associated with variations in exposure and compression (27, 32). Further studies are required to evaluate the potential association between the quality of mammographic positioning and breast density.

Artifacts were observed in 13% of the images, but most of these errors had a characteristic, easily-detectable appearance. The units producing these failures were immediately notified for corrective measures. The low frequency of artifacts reflects the care associated with the maintenance of the cassettes, intensifying screens and processors, inherent to analog technology. The technical non-conformities represented 11% of the observed failures, primarily reflecting the use of analog mammographic equipment (93%), such as presence of artifacts in the image and changes in optical density.

The learning curve of the radiology technicians was demonstrated through the analysis of the variations in repetition and recall rates due to technical errors. During the first quarter after implementation of the program, a significant increase in the repetition rates of the radiology technicians (without request by the radiologist) was observed, indicating an arousal of a critical sense of the technical team concerning the quality items associated with positioning and equipment. In addition, there was a substantial reduction in the number of recalls by the radiologists due to technical errors that were not previously observed because these failures were corrected during the examination. In the subsequent months, a decrease in the repetition rates was observed, associated with the stabilization of the exam quality i.e., the quality standard was achieved in the first image acquisitions not requiring repositioning for correctness. At this stage, the repetition rate reached the levels acceptable by the European Guidelines (13). Moreover, the rates of recall for technical error remained low, reaching the averages acceptable by the European Guidelines (13).

These results were achieved through careful monitoring, continuous training and constant personalized technical training, because the technical performance of individual technicians oscillated over time, with the failures peaking happening again almost bi-monthly or quarterly. However, stabilization occurred in the continuous training group, with the failures of a radiology technician being compensated through the hit of another technician and, consequently, the suitability of the overall service quality.

**Conclusion**

With the apparent increase in breast cancer cases also in the developing countries, it is necessary to conduct studies to evaluate the quality of the mammography screening programs. The results presented in the present study demonstrate that continuous education and monitoring associated with personalized training promoted critical thinking of the technicians, reducing the waste of resources and unnecessary exposure of the patients to radiation, with a consequent improvement of the final quality of mammography services offered in a Breast Cancer Screening Program. The personalized education proposed in this study leads to high-quality results similar to those constantly achieved in developed countries that could also be used as a managing tool for quality in mammography in different regions of Brazil and in similar developing countries.
References


