# ORIGINAL ARTICLE

# Quality Assurance in Mammography: College of Radiology Survey in Malaysia

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#### Summary

Malaysia's mammography QA practice was surveyed based on the Malaysian Ministry of Health and the American College of Radiology (ACR) requirements. Data on mammography unit, processor, image receptor, exposure factors, mean glandular dose (MGD), sensitometry, image quality and viewbox luminance were obtained. Mean developer temperature and cycle time were  $34.1 \pm 1.8^{\circ}$ C and  $107.7 \pm 33.2$  seconds. Mean base+fog level, speed index and contrast index were  $0.20\pm0.01$ ,  $1.20\pm0.01$  and  $1.33\pm0.26$  respectively. Eighty-six percent of the fifty centres passed the image quality test while 12.5% complied with ACR recommended viewbox luminance. Average MGD was  $1.0\pm0.4$  mGy. Malaysia is on the right track for QA but with room for total quality improvement.

Key Words: Mammography, Quality Assurance, Survey, Malaysia

# Introduction

In 2003, there were 3738 new cases of female breast cancer diagnosed in Malaysia while in 2002; there were 4337 new cases of female breast cancer. A Malaysian woman has a 1 in 19 chance of getting breast cancer in her lifetime<sup>1, 2</sup>.

There is still no known direct cause identified for breast cancer but several risk factors have been established. These include previous history of breast cancer, biopsy confirming benign proliferative breast disease, nulliparity at age 40 years, family history, being a BRCA1 and/or BRCA2 carrier, early menarche (at 12 years or younger) and late menopause (55 years or older)<sup>3</sup>. Early diagnosis is the most effective weapon against this disease, and mammography is considered the only diagnostic tool proven for use in the early detection of non- palpable lesions.

Poor quality mammograms lower the detection rate of early breast cancer, reducing the patient's chances of survival and undermining the public's confidence in the value of mammography. Achieving high-quality studies at low dose requires vigilant attention to quality control<sup>4,5</sup>.

This paper reports the survey of the status of quality assurance in mammography practice in Malaysia using the Ministry of Health Quality Assurance Programme (QAP) requirement and the American College of Radiology (ACR) Quality Control in Mammography<sup>5, 6</sup> as the standard. The results will provide baseline information for establishing mammography accreditation and serve as the basis for total quality improvement. Interpretive accuracy and positioning factors were not evaluated in this study.

### **Materials and Methods**

#### Sample Selection

A total of 50 centres (9 government, 3 teaching and 38 private) in East and West Malaysia participated

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voluntarily in this survey. The distribution of the volunteer participating centres is as shown in Figure 1. Data on the mammography unit, processor, image receptor, exposure factors, viewbox luminance and mean glandular dose were obtained from each centre.

### Film Processing

A pre-exposed sensitometric test film (Agfa Mammoray HDR-C Plus, Agfa-Gevaert, Mortsel, Belgium) for the evaluation of the Hurter & Driffield (H & D) curve was processed at the local processor. Sufficient films to conduct the entire survey were acquired, ensuring that they were all from the same emulsion lot. The sensitometer (X-Rite, Grandville, MI, USA) used has an optical density tablet with increments of 0.15 density per step. The processed sensitometer (X-Rite 301-X, X-Rite, Grandville, MI, USA).

From the sensitometric test film, the H & D curve was plotted and the base + fog optical density (OD on Step 1), speed index (1 OD + (Base + fog)) and contrast index ((OD  $\leq 2.20D) - (OD \geq 0.45D)$ ) were obtained.

#### **Image Quality**

An image quality film was obtained using the mammographic image quality phantom (RMI 156, GAMMEX RMI, Wisconsin, USA), at 28kVp using semiauto mode. The cassette and film used clinically by each individual centre were used. To simulate a "standard breast", the RMI 156 phantom was used. This phantom, which is made of polymethylmethacrylate (Lucite), has a thickness of 3.63cm and a cavity containing an image quality insert, giving an overall thickness of 4.5cm of compressed breast consisting of 50% glandular and 50% adipose tissue for imaging with typical film-screen energies (Figure 2). The image quality insert contains 16 test objects embedded in a wax matrix. Details of the insert are shown in Figure 3. The image quality film using RMI 156 phantom is shown in Figure 4. The purpose of this test is to assure that film optical density, contrast (density difference), uniformity and image quality due to the X-ray imaging system and film processor are maintained at optimum levels.

The image quality image obtained was scored by two qualified medical physicists and a radiologist (JW, KHN, SR) according to the ACR film scoring protocols<sup>5</sup>. The images were viewed on the same viewbox (Planilux, Gerätebau Felix Schulte, Warstein, Germany). The passing criteria took into account the Ministry of Health's QAP guidelines. The MOH passing criteria are the visibility of 4 fibrils, 3 groups of specks and 3 masses as per MOH guideline<sup>6</sup>. The ACR scoring protocol includes subtractive correction for artifacts in the films when giving the score but the ACR and MOH passing criteria are otherwise the same.

#### Mean Glandular Dose

The mean glandular dose (MGD) at 28kVp was obtained from the latest H-class Quality Control (QC) report of the individual centres.

#### Viewbox Luminance

The recommended luminance level of viewboxes is  $3000 \text{ cd/m}^2$  or more. The luminance of the viewbox was measured using a calibrated luminance meter (Mavo monitor, GOSSEN Foto-und Lichtmesstechnik GmbH, Germany). The luminance of the centre (Q<sub>0</sub>) and the four quadrants (Q<sub>1</sub>, Q<sub>2</sub>, Q<sub>3</sub>, Q<sub>4</sub>) of the viewbox (Figure 5) were measured as follows:

The mean luminance was calculated as follows:

Mean Luminance=
$$\frac{(Q_0+Q_1+Q_2+Q_3+Q_4)}{5}$$
(cd/m<sup>2</sup>) ---- (Eq.1)

The uniformity of the viewbox luminance in percent was calculated as follows:

Uniformity=
$$\frac{\left|\frac{Q_{0} - \left[\frac{(Q_{1} + Q_{2} + Q_{3} + Q_{4})}{4}\right]}{Q_{0}}\right|}{Q_{0}} x 100(\%) -\dots (Eq.2)$$

#### Results

### **General Facility Information**

Forty eight of the centres used conventional mammography while two centres used computed radiography mammography. Amongst the centres surveyed, 3 leading makes of mammography units were in use (44% brand A, 18% brand B, and 14% brand C). There were two popular processors used. Each was used in 38% of the centres surveyed. The most popular type of film and screen used were from one manufacturer, 47.9% and 66.7% respectively.

#### Film Processor

Twenty (40%) of the centres had dedicated mammography processors. Sixty percent of the centres did not have dedicated mammography processors due to financial constraints, lack of space and the investment-returns consideration.

The mean developer temperature and cycle time was  $34.1 \pm 1.8$ °C and  $107.7 \pm 33.2$  seconds respectively.

#### **Film Processing**

The mean base + fog level, speed index and contrast index were  $0.20\pm0.01$ ,  $1.20\pm0.01$  and  $1.33\pm0.26$ respectively. The H & D curve was plotted for all the centres and a national H & D curve was obtained (Figure 6).

#### Image Quality

Forty-three (86%) of the centres passed the phantom image quality test. The national mean, passing criteria according to MOH guideline and individual passing rate for the visibility of each of the objects in the RMI 156 phantom are shown in Table I.

For the background optical density and density contrast of the image quality test, the national mean, passing criteria according to MOH guideline and the passing rate of the centres are shown in Table II.

#### Mean Glandular Dose

The mean glandular dose for all the centres was below the 3mGy limit with the mean at  $1.0\pm0.4$  mGy.

#### Viewbox Luminance

A total of 96 viewboxes were measured, out of which only 12 (12.5%) viewboxes complied with the recommended luminance level of greater than 3000  $cd/m^2$ . The mean luminance for 96 centres was 1827.8  $cd/m^2$  and the mean percentage luminance uniformity was 14%.

# Table I: National mean, passing criteria according to MOH guideline and individual passing rate for the visibility of each of the objects in the RMI 156 phantom<sup>5</sup>.

	National Mean	MOH criteria	Centres Passed (%)
Fibrils	$4.2 \pm 0.3$	4	90
Specks	$3.8 \pm 0.2$	3	100
Masses	$3.1 \pm 0.3$	3	94

# Table II: National mean, passing criteria according to MOH guideline and the passing rate of the centres for the background optical density and density contrast<sup>6</sup>.

	National Mean	MOH criteria	Centres Passed (%)	
Background OD	$1.34 \pm 0.32$	1.10 - 1.50	60	
Contrast Density	0.45 ± 0.11	≥ 0.40	82	







Fig. 2: RMI 156 Image Quality phantom with 1 cm-diameter, 4mm-thick-acrylic disc for contrast measurement (arrow)

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Fig. 3: RMI 156 phantom insert showing fibrils, specks and masses.



Fig. 4: Image Quality Image using RMI 156 phantom. The very "white" circle (arrow) between 2 fibrils corresponds to the 1cm-diameter, 4mm-thick-disc for contrast measurement shown in Fig 2. The score is 5 fibrils, 4 speck groups and 4 masses, thus passing the MOH criteria.



Fig. 6: Family H & D curve for all the centres.

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#### Discussion

Quality mammograms within acceptable glandular dose limits have been attained in the majority of centres. This shows Malaysia is on the right track to international QA standard but there is room for improvement of good clinical mammography practice with dedicated processors and viewboxes. Interpretive accuracy and positioning factors were not evaluated in this study.

Although the majority of the centres passed the image quality test, the image quality film was not reviewed at the respective centres but instead on a high luminance viewer by three reviewers. Having good image quality does not translate to accurate interpretation of actual mammograms but is a prerequisite to more accurate interpretations and detection of cancers at an earlier stage.

Despite the fact that only 40% of the processors were dedicated to mammography, the image quality was acceptable in more than 90% of centres. Many facilities may face administrative setbacks when requesting for QC test tools and for extra time to perform the QC tests. No doubt, cost-benefit analysis and returns have to be balanced with optimum quality to ensure the public is deriving maximum benefit from performing mammography. Administrators should therefore not be excluded from courses on why QAP is vital and not an

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option in any centre wishing to set up and maintain a mammography facility. Thus far, the focus has been on the radiographers, medical physicists, and radiologists – it is time for administrators and managers who make the financial decisions to be part of the team.

Accreditation of centres should be a positive move to and more encourage compliance sustained commitment to OAP in mammography. It will complement licensing and legal requirements but the difference is that accreditation is a voluntary process of peer review. Centres which undergo accreditation make a public statement that they are committed to ongoing evaluation and improvement. This in return can give the public confidence, may favourably influence liability insurance premiums, influence choice of appointments by healthcare organizations and provide the necessary feedback to the mammography team on their strengths and weaknesses.

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