Hong Kong College of Radiologists
Mammography Statement

Hong Kong College of Radiologists would like to give the following comments concerning mammography.

Mammography screening:

- Breast cancer is the most common cancer in Hong Kong women since 1994 and the incidence is increasing every year.
- Diagnosis and treatment of breast cancer at its earliest detectable stage results in dramatic improvement in the outcome of the patient. As a screening tool on a population basis, mammography has been proven in randomized control trials and population studies to be effective in the early detection of breast cancer and to reduce mortality (1-6).
- Randomized controlled trials, population studies and meta-analyses have shown that mammographic screening can reduce mortality in breast cancer in women 40 years or older (7-14). The American Cancer Society recommends annual mammography screening starting at the age of 40 and continuing for as long as women are in good health (15). The American College of Radiology and Society of Breast Imaging also recommend women with average risk for breast cancer to start annual screening from age 40 (16). In Sweden, the breast cancer screening programme covers women between 40 and 74 years of age with mammography every two years. In the UK, the NHS Breast Screening Programme covers women between the ages of 47 and 73. For Australia, the BreastScreen Australia programme offers two-yearly mammogram screening to women starting from 40 years of age. In Asia, many countries such as Japan, Singapore, Korea are providing breast screening programmes to women starting at the age of 40. Whilst there is evidence of a mortality reduction from mammographic screening in women between the ages of 40-50 years, it should be acknowledged that there is no good quality evidence of a mortality reduction from screening women over the age of 70 and the risk of overdiagnosis is substantially greater.
- In Hong Kong, the incidence of breast cancer is less than that of the Western population but a significant percentage of women with breast cancer in Hong Kong are younger than 45 years (27% based on 2001 to 2005 data) (17). There is so far no population screening for breast cancer in Hong Kong. However, screening by self-initiation through medical consultation or referral from clinicians (opportunistic screening) is practiced. With opportunistic screening, advice from clinicians and shared decision making with the women are important. Benefits and risks of screening should be discussed between the women and the clinician. The decision whether “to screen or not” should be taken together according to the woman's values and the clinician’s advice, after consideration of the presence or absence of known risk factors.
- There has been significant advancement in the technology of mammography since the classic randomized controlled trials, such as the introduction of Digital Mammography (18); in women under the age of 50, in whom breast parenchyma is more likely to be dense, full field digital mammography is the standard of care. Advanced technology such as Digital Breast Tomosynthesis (DBT) may have an effect on detection rate and reduction in recall rate and false positive rate (19-24). The factor of improved technology should also be included in the benefit versus risk discussion with the patient.

- Other breast imaging modalities are complementary to mammography. Breast ultrasound characterisation of mammographic and palpable abnormalities is indicated in the evaluation and management of breast disease. On its own, it is not an effective imaging method for routine screening. If used as an adjuvant to screening mammography especially in women with dense breasts, it is associated with an increase in detection of early breast cancer and a reduction in the interval cancer rate but has a poor specificity (25). Breast MRI may be useful in screening of individuals with greater than 20% lifetime risk of cancers in addition to mammography and is also a valuable tool used in diagnosis/problem solving, staging and treatment monitoring (26).

Standards in mammography:

- It is most important that the mammography service is of good quality in order to maximize its benefit and to reduce the risk of ineffective radiation exposure and every effort has to be paid to ensure such high standard is maintained through a robust quality assurance programme. The clinician in charge of the mammographic service should be responsible for the overall standard of the mammography service and there must be clear lines of accountability.

- Mammography should be performed with a dedicated mammography machine, operated by a trained radiographer and reported by a trained radiologist. The following standard of mammography service is recommended by the College:

- <u>The Equipment</u>
  - Only dedicated, purpose-designed mammographic apparatus should be used.
  - The apparatus should be capable of being set at least as low as 24 kVp and should be adjustable in 1-kVp increments.
  - X-ray tubes with tungsten, molybdenum or rhodium targets and molybdenum, rhodium or silver filters should be the combination of choice for mammography.
  - Material type of the detector of full field digital mammography (FFDM) should be Caesium Iodide (CsI) or Amorphous Selenium or equivalent.
  - Pixel size of the detector (FFDM) should not be higher than 100 micron
  - Acquisition bit depth should not be less than 14 bits
  - Pre-sampling Modulation Transfer Function (MTF) of 60% or greater at 4 lp/mm
  - Detective Quantum Efficiency (DQE) of 30% or greater at 4.0 lp/mm
  - The following image quality is recommended for digital mammography:
    - High contrast spatial resolution > or = 5.8 lp/mm for line-pair bars
    - Minimal detectable contrast (approximately)
      - 1.2% on 5-6mm details
      - 5% on 0.5mm details
      - 8 % on 0.25mm details
  - The following radiation dose is recommended
    - Mean Glandular Dose (MGD) per image (set of images for 3D) 3mGy when using grid for a 5cm 50/50 (50% adipose, 50% glandular) breast (preferably 2mGy for a 4.2cm 50/50 breast).

A quality assurance programme for equipment should be in place. A suggested programme is listed below:

Frequency	Test	Purpose
Daily	Visual check on electrical and mechanical moving parts	Ensure mechanical and electrical safety to both patient and staff.
Weekly	Detector flat field calibration for Full Field Digital Mammography (FFDM)	To ensure correct digital image acquisition
	Artifact evaluation of detector for FFDM	To eliminate artifact
	Phantom imaging for FFDM	To ensure proper image processing
	Contrast to noise ratio (CNR) and signal to noise ratio (SNR) measurement test for FFDM	To ensure image quality
Monthly	Compression thickness indicator test for FFDM	To ensure correct automatic exposure
	Repeat analysis for equipment	To ensure equipment's reliability
	Phantom test on both large and small focus : - Evaluate visibility of test objects inside; image density and contrast. System's resolution shall be measured. - Image quality scoring method can be used depending on the number of calcifications, fibres, masses details seen unambiguously with good definition and measure the contrast of the phantom image. Minimum requirements: • For Full field digital Mammographic machine:- a. 5 fibers, 4 specs, 4 masses. b. 4 fibres, 4 specs, 3.5 masses if SNR and resolution tests both pass	Evaluate system's image quality (any degradation), uniformity and resolution - both spatial and contrast (assessed for high-contrast resolution and low-density contrast).

Frequency	Test	Purpose
	Comprehensive Visual Checklist test for the equipment and all the accessories	To ensure safety for both patients and staff
	QA pattern test for Laser printer	To ensure proper function of the laser printer according to manufacturer's specification
Semi-annually	Preventive Maintenance for the equipment, review workstations, laser printer and all the accessories	To ensure proper and safe function of the equipment according to manufacturers' specification
	Compression force test for both powered and manual mode	To ensure adequate compression and ensure the force indication is exact and within range.
Annually	Service engineer carried out test on focal spot, half value layer, dose calculation, kVp interlock, light/X-ray field alignment, compression device, output reproducibility, output linearity, timer accuracy, timer reproducibility, kVp accuracy, kVp reproducibility.	Ensure safety, reliability, consistency of machine according to manufacturer's specification.
	Medical physicist performs check on electrical and radiation safety for equipment and exam room according to Radiation Ordinance. Mean Glandular Dose (MGD): - 3mGy when using grid for a 5cm 50/50breast (preferably 2mGy for a 4.2cm 50/50breast). - 1mGy when a grid is not used.	Ensure safety to all personnel. Minimize radiation dosage to Patient and public

Accuracy of biopsy unit should be tested and calibrated every time before start of examination.

NB:

- An error and fault record on equipment should be kept to look for trends of machine performance and degradation.
- Quality assurance process should be regularly reviewed.

- The Radiographer

The following are the minimum requirement and quality assurance programme for mammographers:

Mammographers' requirements:
1. At least one mammographer operating the machine has acquired the local (HKCRRT Certified Mammographer) or international recognized qualification in mammography.
2. Minimum standard of each mammographer is to take mammograms of at least 500 women a year preceding being a qualified mammographer in a clinical setting.
3. Regular update of knowledge, technique and new trends (equipment, new scientific approaches) – At least 25 hours over 5 years of continued professional development (can be seminars or conference attendances).
4. Clinical involvement in breast imaging for an average of 150 hours per year.

Quality assurance programme for mammographers:
1. Regular repeat and reject analysis of every mammographer; technical repeats <3% of total images taken.
2. Film Rating of every mammographer. Criteria include
   - >75% should be in perfect or good group in PGMI rating system.
   - >97% should be in P, G, M groups.
   - <3% in inadequate group.

- The Radiologist

For imaging of symptomatic women:
1. Radiologists should be competent in reporting mammograms, performing and interpreting breast ultrasound and in supervising specialist mammography techniques. The radiologist should acquire skills in performing image-guided biopsy and localization of impalpable breast lesions, using stereotactic techniques or ultrasound.
2. Recognized and recommended descriptive terms should be used in the reporting of mammogram and breast ultrasound according to the BI-RADS or adapted BI-RADS lexicon. Details of site, imaging size and nature of any abnormality should be reported. When available, the present examination should be compared to previous studies and this should be indicated in the report. The overall impression should include the likely diagnoses, the assessment category and recommendations for any further diagnostic procedure or intervention.
3. They should regularly participate in personal breast imaging audits and multidisciplinary breast service audits.
4. Radiologists involved in breast imaging should have completed at least a 3 months training in breast radiology during their higher training period or had attended 30 hours of continuing medical education in breast imaging in the previous 3 years
5. The radiologist should read at least 300 symptomatic mammograms annually.
6. They should have regular update of knowledge in breast radiology with at least 25 hours over 5 years of CME activity with breast imaging content
7. 8 hours of training in mammographic modality (e.g. digital or tomosynthesis) before beginning to use that modality is required (27).

For involvement in screening mammography:

In addition to the above

1. The radiologist should have 15 hours of continuing medical education at a breast screening course in the previous 3 years.
2. For initial qualification, the interpreting radiologist should have interpreted or multi-read 500 mammograms within the 12-months period immediately prior to the date for interpreting screening mammogram. That means 800 mammograms for radiologists performing both symptomatic and screening mammography.
3. Biopsy results should be traced and is an important source for feedback. They should participate in personal breast imaging audits.
4. They should be involved in assessment, multidisciplinary meetings & review of interval cancers.
5. They should participate in audits and quality assurance review rounds.
6. The radiologist should read at least 500 screening mammograms annually.

- Performance standards for a mammography screening centre

A quality control program should be in place which includes the following:

(a) Radiographer's checks & equipment check as above
(b) Professional quality improvement program which should include system for reviewing outcome data from mammography screening, and audit of biopsies.
(c) Note that separate audit statistics should be maintained for screening and diagnostic examinations, as many of the audit data (e.g., cancer detection rate) are significantly different for screening and diagnostic examinations.

There have not been any objective standards for breast screening for Asians, but the desirable goals recommended in UK & USA can be used as a reference (25, 28-30).

By comparing one's practice outcomes with the desirable goal, and to compare one's own performance over time, one can provide quantifiable evidence in pursuit of the goals of screening mammography. The following are the audit data suggested for collection:

- Cancer detection rate - to maximize the number of cancers detected.
- Recall rate, positive predictive value based on abnormal findings, recommendation for biopsy & biopsy yield of malignancy - to minimize cost and morbidity.
- Minimal cancer detection rate, axillary lymph node negativity - to maximize the number of small and node-negative cancers detected, which are important for patient outcome.

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