Title:	**Digital mammography for breast cancer screening, surveillance and diagnosis**
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AIM

To carry out a structured evaluation of digital mammography (DM) for (1) breast cancer screening in the general population, (2) surveillance of women at potentially high risk of breast cancer, and (3) diagnosis in women with signs or symptoms of breast cancer.
To determine whether DM is an *alternative* to film mammography (FM), should *replace* FM, or whether it should be used as an *additional* method to identify breast abnormalities that have not been identified with FM (ie, used only in those women who test negative on FM).

CONCLUSIONS AND RESULTS

DM allows the processes of image acquisition, processing and display to be managed (and optimised) more separately than is possible in conventional FM. In FM, an image of the breast is generated by converting the energy from the x-ray beam (which has passed through the breast) into light via a phosphor screen, which then exposes a film (hard copy) held within the screen. The film is processed chemically and an image is developed. DM also uses x-rays to produce images of the breast tissue, but the x-ray photons encounter a solid-state detector that converts the absorbed energy into electrical signals. These electrical signals are used to produce images of the breast that can be displayed on a computer monitor (soft copy) or be printed on laser film (hard copy).

Safety

Three studies have compared radiation exposure levels between DM and FM. They suggest that radiation exposure is very similar between the two. However, phantom studies using more recently developed mammography units suggest that the radiation dose from DM is likely to be lower than that from FM. It can therefore be concluded that DM is at least as safe as FM in regards to radiation dose.
The best-quality evidence on false positive rates suggests that DM may produce slightly more unnecessary further investigations than FM. The statistical significance or clinical relevance of this difference could not be determined from the data provided, and these results were contrasted by a second large screening trial that reported lower false positive rates from DM. False positive rates are likely to depend on familiarity and experience with interpreting digital mammograms. Overall, DM appears to be as safe as FM.

Effectiveness

Screening (asymptomatic women)

Good quality evidence indicates that DM is as accurate as FM in screening asymptomatic women. The case for replacing FM is not obvious overall, given the similar accuracy and cancer detection rates of the two methods. DM would, however, appear to be a reasonable alternative to FM on the basis of the population-based effectiveness data alone. The relative impact of DM and FM on interval cancer rates has yet to be properly established. Given the similar diagnostic accuracy of DM and FM in an asymptomatic population, it is likely that the health benefits from FM versus no screening would apply to a population screened with DM.

In the largest good quality screening trial to date, DM was found to be more accurate at detecting breast cancer in women who are conventionally difficult to image with FM, specifically women aged under 50 years, those who are pre- or perimenopausal, or those with heterogeneously dense or extremely dense breast tissue. As such, DM should replace FM for these women. If DM were used for screening asymptomatic women aged under 50 years, women who are pre- or perimenopausal, or women with radiographically dense breasts, it is likely that the mortality reduction from screening would be higher in these subgroups than with FM.

Surveillance (women at potentially high risk) and diagnosis (symptomatic women)

For the diagnosis of women at potentially high risk of breast cancer or symptomatic women, it is unclear whether DM is as effective as FM. Although no significant differences in the diagnostic properties of the two methods have been reported in the literature, it is difficult to make any strong conclusions from the available evidence. It appears likely that as women at high risk present for surveillance at a younger age than the general population, and thus are more likely to be pre- or perimenopausal with dense breasts, the improved diagnostic accuracy of DM in these subgroups would be applicable – probably leading to increased benefits over FM, given that these women are starting at a higher baseline risk for breast cancer than the general population. Benefits from breast cancer treatment for symptomatic women are well known and should remain the same if DM replaces or is used as an alternative to FM for diagnosis – assuming that similar diagnostic accuracy between the two methods is confirmed by a larger evidence base in a diagnostic population.

There is currently no evidence to suggest that DM should be used in addition to FM in either a symptomatic or a surveillance population.

Other relevant considerations

One of the major reasons DM is currently being considered as an option is the shortage of qualified radiologists and radiographers within Australia. This, in conjunction with the increasing demand for mammography, has created an imbalance between supply and demand. DM could reduce labour in image development, image hanging, film processing and archiving. Further, the accessibility of the same digital mammograms from different reading stations through a picture archiving and communication system (PACS) could reduce the need for radiologists to travel between centres to read films, and thus improve their work flexibility and efficiency.

As DM is replacing FM, FM is unlikely to be supported by vendors and developers in the near future. However, given DM is currently not publicly funded any out-of-pocket costs associated with this technological change are likely to be borne by the consumer.

Cost-effectiveness

This assessment determined that DM is at least as safe and effective as FM overall. DM also appears to be associated with improved diagnostic accuracy for breast cancer screening in certain subgroups of women relative to FM. Therefore, we compared the costs of DM and FM in breast cancer screening, diagnosis and surveillance of the overall population. In addition, we analysed the cost-effectiveness for the subgroups in which DM is more accurate than FM in breast cancer screening.

The cost comparison included all cost categories of importance. Given the considerable variation in costs between the two types of DM, computed radiography (CR) and digital radiography (DR), we analysed two diagnostic scenarios: one using CR without a PACS and one using DR with a PACS, as would happen in screening. The cost comparison indicates that DM is $11 more expensive per examination than FM in a screening setting, and $36 or $33 more expensive per examination in a diagnostic setting when DR or CR is used, respectively. In both settings, the average throughput of the mammography system has the most significant impact on the incremental cost per examination per year. The incremental cost per DM examination could be between $11 and $36 in a surveillance setting for women at potentially high risk of breast cancer.

In the analysis of the cost-effectiveness of screening women younger than 50 years, pre- or perimenopausal women, and women with heterogeneously or extremely dense breasts, the incremental cost per extra cancer detected is around $10 000 in each subgroup examined, suggesting that DM represents good value for money when compared with FM. However, sensitivity analyses demonstrate that the incremental cost per extra cancer detected varies widely as a result of wide confidence intervals of differences in cancer detection rates between DM and FM. This is particularly the case in the estimates for women with heterogeneously or extremely dense breasts.

Mammography is a frequently performed diagnostic procedure, and so the associated financial impact on Medicare is considerable. Should DM *replace* FM in a diagnostic setting, an additional $33 to $36 per examination would be borne by Australian society. This change in technology would represent a total additional cost of $10–$13 million per annum. The estimated incremental cost per procedure of DM is $11 in a screening setting. Thus, the incremental cost to Australian society would be $9 million per annum for screening 800 000 women. However, with the wide use of DM, the prices of DM machines and associated PACS will continue to decrease, and thus in the future the actual cost borne by society may not be as great as estimated in this evaluation.

Recommendations
'MSAC has considered the safety, effectiveness and cost-effectiveness of digital mammography when compared with conventional film mammography: as a screening test for breast cancer in asymptomatic women aged over 40 years or women at high risk; and in the investigation of women with symptoms of breast cancer.
MSAC finds that digital mammography is as safe and as effective. There may be subgroups of patients where it is more effective.
Film mammography is being superseded by digital mammography and will lose technical support.
MSAC recommends that public funding is supported for this procedure under the arrangements that currently apply to film mammography.'

The Minister for Health and Ageing endorsed this recommendation on 11 April 2008.

METHOD

A systematic literature review was conducted to assess the safety and effectiveness of DM, relative to FM, for (1) breast cancer screening in the general population, (2) surveillance of women at potentially high risk of breast cancer, and (3) diagnosis in women with signs or symptoms of breast cancer. Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched from 1990 until February 2007. Specific journals were handsearched and reference lists pearled. Studies were included in the review using pre-determined PICO selection criteria. Study quality was appraised and data extracted in a standardised manner. A linked evidence approach was used – linking evidence of DM accuracy to likely impact on patient management and ultimately patient health outcomes. Methods of economic analysis are provided in the discussion of cost-effectiveness above.