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Digital Mammography: A screening modality for breast cancer.

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PRIORITISING SUMMARY

REGISTER ID: **000179**

NAME OF TECHNOLOGY: **DIGITAL MAMMOGRAPHY**

PURPOSE AND TARGET GROUP: **SCREENING MODALITY FOR BREAST CANCER**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☒	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	Numerous
☐	No		
☐	Not applicable		

There are several digital mammography systems registered on the Australian Register of Therapeutic Goods, supplied by Siemens Ltd, Medi Consumables Pty Ltd, Alltech Medical Engineering Pty Ltd, GE Medical Systems Australia Pty Ltd, Sectra Pty Ltd and Insight Oceania Pty Ltd. In addition, FUJIFILM Australia Pty Ltd provides Fuji CR Console Lite with DICOM software for mammographic images (ARTG number 100250).

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Norway	✓		
United States	✓		
Canada	✓		
United Kingdom	✓		
Japan	✓		

IMPACT SUMMARY:

Several companies in Australia provide both stationary and portable digital mammographic systems with the aim of providing digital x-ray mammography. The technology is currently available in Australia through some private and public pathology service providers for diagnostic, not screening purposes.

BACKGROUND

Digital mammography takes an electronic image of the breast, which is then stored in a computer. Like standard film mammography, digital mammography uses x-rays to produce images of breast tissue. However, with digital mammography, an electronic x-ray detector—a phosphor screen—replaces the film cassette and converts the x-ray photons to light, which in turn passes through a fiberoptic cable to a device that converts the light to a digitised signal for display on a computer monitor. Digital mammography uses less radiation than

conventional mammography. In digital mammography the process of image acquisition, display and storage of images are separated, allowing for the optimisation of each step.

The main advantage of digitising mammographic images is that they can be stored and sent electronically, which may have implications for rural and remote settings in Australia. Once the image is stored, computer aided detection programs, or a radiologist, may be used to interpret the image (ACRIN 2005). The main advantage of digital systems is the scope for image processing after image acquisition. The radiologist can alter the orientation, magnification, brightness and contrast of the images as desired, allowing for improved detection of low contrast lesions.

A number of differently processed versions of the same mammogram may be used to identify mass lesions or micro-calcifications. Therefore, although both soft copy (viewed via computer monitor), or hard copy (laser printed) images can be produced, many readers prefer a soft copy allowing immediate manipulation of the image. Concerns have been raised that soft copy reporting may slow reporting times due to the number of possible manipulations (James 2004).

There are four types of digital mammography systems being manufactured, three of which may be described as full-field digital (FFD) mammography systems (flat-panel phosphor system, scanning phosphor-charge-coupled device (CCD), selenium flat-panel system) or computed radiography systems, such as the Fuji (Pisano and Yaffe 2005). All of these systems have their advantages and disadvantages, however only the computed radiography systems can be used in any mammography unit, have multiple plate sizes and are relatively cheaper when compared to other systems.

The Fuji system allows for multiple users. For example, if a screening facility currently operates four rooms simultaneously, this would require only one Fuji CR Console Lite system, whereas with other digital mammography systems, four separate units would be required (personal communication Fuji Australia representative).

CLINICAL NEED AND BURDEN OF DISEASE

In Australia free mammographic screening is offered on a biennial basis to all asymptomatic women aged 50 to 69 years. Screening is also available to women aged over 40 on an annual basis if there is a strong family history of breast cancer. In the period 2000-2001 a total of 1,567,544 women attended a BreastScreen service with 1,063,479 (68%) in the target population, aged 50-69 years. Between the periods 1999-2000 and 2000-2001 the proportion of women in the target population (women aged 50 to 69 years) participating in the BreastScreen Australia program rose from 56% to 57% (AIHW 2003).

In Australia, breast cancer is the most common registrable cancer in females. There were 11,314 new cases of breast cancer and 2,521 deaths from breast cancer, with a crude mortality rate of 26.1 per 100,000, reported in Australia for the year 2000. Australian women have an approximate life time risk of one in eleven of developing breast cancer before the age of 75 years. In 1998 breast cancer comprised nearly 30% of all cancers in women (AIHW and AACR 2003; NHMRC 1999).

In New Zealand, in the period 1 January to 30 June 2004, 57,808 women were screened in BreastScreen Aotearoa, representing 18.1% of eligible women, resulting in a biennial screening rate of 64.6% of the eligible population. The 6-monthly coverage for three BreastScreen Aotearoa eligible age groups (50-54, 55-59 and 60-64 years) has increased compared to the previous period, resulting in an increase in the biennial rate (63.0%, 64.9% and 66.4% respectively). The biennial rate increased in each major ethnic group compared to the previous period although there is a disparity of Maori and Pacific Islander (45%) compared to others (67%) (BreastScreen Aotearoa).

In the year 2000 the mortality and incidence rates were 21 and 89 per 100,000 respectively from breast cancer in New Zealand (New Zealand Health Information Service 2005).

DIFFUSION

In Australia digital mammography is currently used for diagnostic, not general screening purposes and there are numerous hospitals and private radiology practices that have digital systems installed (personal communication, 26th October, Fuji Australia).

COMPARATORS

The current gold standard in Australia for breast cancer detection is the mammogram, which consists of a set of two-dimensional X-rays of the breast. The patient's breasts are placed between two plates, which firmly compress the breast, flattening and pulling the breast tissue away from the chest wall. The standard mammographic examination includes two sets of low-dose X-rays, one taken from the side (medio-lateral oblique) and one from the top view (cranio-caudal) resulting in a two-dimensional radiographic representation of the breast. The procedure takes approximately 20 minutes. Double reading of screening mammograms is mandatory in Australia (Forrest & Anderson 1999; President and Fellows of Harvard College 2003).

While screen-film mammography provides a powerful tool for early breast cancer detection, there are some reported fundamental limitations (D'Orsi 2002). These limitations relate to contrast characteristics, or the ability to discern subtle soft tissue density differences, and decreased sensitivity in detecting early malignancy in the dense breast.

EFFECTIVENESS AND SAFETY ISSUES

At the time of preparing this summary two randomised, controlled trials were identified (level II screening evidence), which compared the efficacy of screening asymptomatic women for breast cancer with screen-film (SFM) versus full-field digital mammography (FFDM) (Lewin et al 2002 and Skaane et al 2004). In both studies digital images were interpreted with soft copy readings. The sensitivity for detecting malignancy showed no statistically significant difference between the two modalities in both studies.

In the study by Lewin et al (2002), patients underwent both screen-film mammogram and digital examination by the same technologist, within 3 days of each other. Of the total 4,945 paired examinations, 91% of digital examinations (4,523) were performed immediately following standard mammography and 9% (422) within three days of the initial mammography examination. Both SFM and the FFDM mammograms were interpreted by a different radiologist for a given patient. Discrepancies between the reading were reviewed and reasons for the discrepancy recorded. Twenty two cancers were detected with SFM and 21 with FFDM. The recall rate was significantly lower for the digital versus the screen-film examination (12% vs 14% respectively, $p<0.001$).

Two studies (level IV screening evidence) compared soft copy versus hard copy digital mammography readings for accuracy of malignant lesions detection (Obenauer et al 2003, Pisano et al 2002). Both studies reported no significant difference between the two methods, however it was noted that experience and training of the radiologist in reading soft copy versions is crucial to accurate interpretation.

The recently published multi-centre Digital Mammographic Imaging Screening Trial (DMIST) with 49,528 asymptomatic women (level III-2 screening evidence) was designed to measure differences in diagnostic accuracy between digital mammography and film mammography (Pisano et al 2005). Five digital systems were used; General Electric Medical

Systems, Fuji Medical Systems, Fischer Imaging, and two Hologic digital mammography systems were tested in the study. Women participating in the study underwent both digital and film mammography, each with a minimum of two views of each breast. Two different radiologists interpreted the conventional and digital mammogram exams for each individual patient.

This study reported no statistically significant difference in the overall accuracy of digital mammography compared to film mammography (difference between methods in the area under the receiver operating curve 0.03, 95% CI [–0.02, 0.08]; p=0.18) according to the digital system used, race, or breast cancer risk (Pisano et al 2005). However, digital mammography accuracy was significantly higher in women under 50 (p=0.002), women with heterogeneously dense and extremely dense breasts (p=0.003), and the pre- and peri-menopausal women (p=0.002).

During the course of this study (including initial screening and follow-up), 335 women were diagnosed with cancer. In general, the cancers detected by either film or digital mammography were similar in histology and stage. The cancers detected by digital mammography and *missed* by film included many invasive medium and high grade in situ malignancies confined to the breast at diagnosis.

COST IMPACT

In Australia, the MBS fees for diagnostic mammography in item numbers 59300 and 59303 are $82.00 and $49.45 (MBS, 2004). Screening mammography is provided free of charge to women by BreastScreen Australia and is funded through joint Commonwealth and State/Territory agreements.

Digital systems currently cost approximately one and a half to four times as much as standard film systems (Pisano et al 2005). Full-field digital mammography systems are estimated to cost $AUD 650,000 and the Fuji system with all components $AUD 200,000.

A cost impact study conducted in the United Kingdom estimated and compared the cost of full field digital mammography with standard mammography for screening and assessment (Legood and Gray 2004). The direct costs associated with the different systems of equipment, consumables, storage and differences in staff workload were estimated. The estimate of the total *annual* cost of conventional mammography equipment, consumables and storage for screening 10 000 women per year was $AUD 270,000. With hard copy printing, the cost of the FFDM system, consumables and storage, after adjustment for potential staff savings from film processing and display, for screening 10 000 women was $AUD 555,000. Without hard copy imaging, the cost of an FFDM system was substantially reduced, an annual cost for screening 10 000 women was $AUD 374,400. These costs were estimated for the short-term. The study suggests that in the long-term, the use of soft copy digital mammography and a possible reduction in the number of digital systems required compared to standard mammography could result in similar costs for both modalities (Legood and Gray 2004).

The DMIST authors are currently preparing a cost-effectiveness analysis for both film and digital mammography

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

Digital mammography may facilitate information sharing, as soft copy readings can be viewed, read and assessed by multiple parties in different locations simultaneously through telemedicine. This may provide an appealing and cost-effective option for patients in rural and remote settings. Similarly, clinicians in these settings may consult with other clinicians for evaluations by specialists and coordination of further treatment.

The DMIST study demonstrated that digital mammography was more accurate in specific subgroups of women. The types of lesions detected by digital mammography for these subgroups of women but missed by standard film mammography are those that need to be detected early to prevent mortality. Given that the premise underlying breast screening is for early detection and treatment to prevent mortality, it may be argued that employing digital mammography screening for these subgroups is justified.

OTHER ISSUES The purpose of population screening for breast cancer is to increase detection of early cancer and reduce breast cancer mortality. Although digital mammography may be at least as accurate as standard mammography, to date it has not been demonstrated to affect mortality.

CONCLUSION:

If digital mammography proves more effective at detecting early breast cancer than standard screen film and improving survival, the public health benefits could be significant. Similarly, if digital imaging technologies prove to have the same level of efficacy as standard film, benefits could include more convenient, cost effective and reliable storage of images relative to standard screen film. In addition, digital images facilitate information sharing, since they can be viewed, read and assessed by multiple parties in different locations simultaneously through telemedicine. This has the potential to improve the quality of services while enhancing efficiency and reducing health care expenditures.

HEALTHPACT ACTION:

Given the substantial number of studies, the recent findings of the DMIST study and after consultation with the jurisdictions it is recommended that this prioritising summary be referred to the MSAC for a full HTA.

SOURCES OF FURTHER INFORMATION:

ACRIN (2005) *Digital vs. Film Mammography in the Digital Mammographic Screening Trial (DMIST): Questions and Answers* American College of Radiology Imaging Network. [Internet]. Available from: http://www.acrin.org/dmist_qa.html [Accessed 26th October 2005].

AIHW and AACR (2003). *Cancer in Australia 2000,* Australian Institute of Health and Welfare (AIHW) and Australasian Association of Cancer Registries (AACR), Canberra, ACT.

Australian Institute of Health and Welfare (AIHW) 2003. *BreastScreen Australia monitoring report 2000-2001*. AIHW cat. no. CAN 20. Canberra: Australian Institute of Health and Welfare (Cancer Series no. 25).

BreatScreen Aotearoa (2005). *(Internal) Monitoring Report 4: Women screened between 1 January and 30 June 2004.*

Cole, E., Pisano, E. D. et al (2004). 'Diagnostic accuracy of Fischer Senoscan Digital Mammography versus screen-film mammography in a diagnostic mammography population', *Acad Radiol,* 11 (8), 879-886.

Elmore, J. G., Armstrong, K. et al (2005). 'Screening for breast cancer', *Jama,* 293 (10), 1245-1256.

Forrest, A. P. & Anderson, E. D. (1999). 'Breast cancer screening and management', *Medical Journal of Australia,* 171 (9), 479-484.

James, J. J. (2004). 'The current status of digital mammography', *Clin Radiol,* 59 (1), 1-10.

James, J. J., Davies, A. G. et al (2001). 'Developments in digital radiography: an equipment update', *Eur Radiol,* 11 (12), 2616-2626.

Lewin, J. M., D'Orsi, C. J. et al (2002). 'Clinical comparison of full-field digital mammography and screen-film mammography for detection of breast cancer', *AJR Am J Roentgenol*, 179 (3), 671-677.

Lewin, J. M., Hendrick, R. E. et al (2001). 'Comparison of full-field digital mammography with screen-film mammography for cancer detection: results of 4,945 paired examinations', *Radiology*, 218 (3), 873-880.

New Zealand Health Information Service (2005). *Health Statistics.*[Internet]. New Zealand Health Information Service. Available from: http://www.nzhis.govt.nz/stats/cancerstats.html [Accessed 22nd November 2005].

NHMRC (1999). *Familial aspects of cancer: a guide to clinical practice*, National Health and Medical Research Council (NHMRC), Canberra, ACT.

Pisano, E. D., Cole, E. B. et al (2002). 'Interpretation of digital mammograms: comparison of speed and accuracy of soft-copy versus printed-film display', *Radiology*, 223 (2), 483-488.

Pisano, E. D., Gatsonis, C. et al (2005). 'Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening', *N Engl J Med*.

Pisano, E. D. & Yaffe, M. J. (2005). 'Digital mammography', *Radiology*, 234 (2), 353-362.

President and Fellows of Harvard College (2003). 'Update on breast imaging. New imaging techniques have led to advances in breast cancer detection. What does that mean for the annual mammogram?' *Harvard Womens Health Watch*, 10 (10), 4-6.

Skaane, P., Balleyguier, C. et al (2005). 'Breast lesion detection and classification: comparison of screen-film mammography and full-field digital mammography with soft-copy reading--observer performance study', *Radiology*, 237 (1), 37-44.

Skaane, P. & Skjennald, A. (2004). 'Screen-film mammography versus full-field digital mammography with soft-copy reading: randomized trial in a population-based screening program--the Oslo II Study', *Radiology*, 232 (1), 197-204.

Skaane, P., Young, K. & Skjennald, A. (2003). 'Population-based mammography screening: comparison of screen-film and full-field digital mammography with soft-copy reading--Oslo I study', *Radiology*, 229 (3), 877-884.

Yamada, T., Saito, M. et al (2004). 'Comparison of screen-film and full-field digital mammography in Japanese population-based screening', *Radiat Med*, 22 (6), 408-412.

LIST OF STUDIES INCLUDED

Total number of studies	
Level II screeningevidence	2
Level IV screening evidence	4

SEARCH CRITERIA TO BE USED:

Breast Neoplasms/radiography
Mammography/*methods
Mass Screening/*methods
Predictive Value of Tests
Radiographic Image Enhancement/*methods
*Radiographic Image Enhancement
Sensitivity and Specificity
Image Processing, Computer-Assisted
Mass Screening