Australian Government

Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network

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National Horizon Scanning Unit
Horizon scanning prioritising summary

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Computer Aided Detection Systems in Mammography: A breast cancer detection tool for women attending screening and/or diagnostic mammography services.

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PRIORITISING SUMMARY

REGISTER ID:	**0000068**

NAME OF TECHNOLOGY:	**COMPUTER AIDED DETECTION SYSTEMS IN MAMMOGRAPHY**

PURPOSE AND TARGET GROUP:	**BREAST CANCER DETECTION TOOL IN WOMEN ATTENDING SCREENING AND/OR DIAGNOSTIC MAMMOGRAPHY SERVICES**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes		ARTG number
☒	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
USA	✓		
Australia	✓		
Singapore	✓		

IMPACT SUMMARY:

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 1998 a total of 739,345 women attended a BreastScreen service with 493,946 aged 50-69 years (AIHW 2004). In two calendar years (1998-1999), approximately 1.4 million Australian women were screened by BreastScreen Australia.

The AIHW reported 11,400 new cases of breast cancer in Australia with a crude mortality rate of 26.1 per 100,000 in the year 2000. Breast cancer is the most common registered cancer and the leading cause of mortality for women in Australia. In 1998 breast cancer comprised nearly 30% of all cancers in women.

Computer aided detection (CAD) systems assist radiologists with the diagnostic process in mammography screening for breast cancer. These systems have been approved in the USA for clinical use and are funded both through U.S. Medicare and private health insurance. CAD systems for breast mammography are not yet used in Australia although they are being trialled in St.Vincents Hospital, Melbourne.

Computer-aided detection systems for mammography are intended to identify and mark regions of interest on standard mammographic views to bring them to the attention of the radiologist after the initial reading has been completed. Thus, the systems assist the radiologist in minimising observational oversights by identifying areas on the original mammogram that may warrant a second review. The technology uses image processing and pattern recognition algorithms hosted on a personal computer to detect potential areas of concern.

Results, from studies submitted to gain FDA approval, suggest that the use of computer-aided detection systems can potentially increase breast cancer detection rates by approximately 20% without substantially increasing recall rates (Warren et.al 2000, Wagner et.al. 2002, Brem R.F. 2001). These studies examined retrospective data of select groups of patients in laboratory settings.

A study (level 1b diagnostic evidence, see Appendix A) of CAD systems applied to 294 breast mammograms in Singapore found that radiologists not specifically trained in mammography increased their ability to correctly identify mammographic abnormalities (sensitivity) from 74% without CAD to 87% with CAD (Quek et. al. 2003) However, CAD systems failed to detect suspicious abnormalities in 24% (71) of mammograms (false negatives).

A prospective cross-classification study (level 1b diagnostic evidence) of 12,860 patients over a 12-month period in a community mammographic centre involved interpreting mammograms initially without the assistance of CAD, followed by a re-evaluation of mammograms with areas marked by a CAD system (Freer & Ulissey 2001). The study outcomes were the measure of effect of CAD on the recall rate, positive predictive value for biopsy, cancer detection rate and stage of malignancies at detection. A comparison of the two radiologists performance with and without CAD indicated the following: an increase in recall rate from 7% to 8% with CAD; no change in the positive predictive value for undergoing biopsy (38%); a 20% improvement in sensitivity, i.e. the proportion of tumours correctly identified; and an increase in the proportion of early stage malignancies detected from 73% without CAD to 78% with CAD.

A diagnostic case-control study (level 3b diagnostic evidence) compared single and double reading of mammograms with a CAD system compared sensitivity and recall rates (Ciatto et al 2003). A set of 89 negative mammograms was compared to 31 mammograms reported as negative but developing interval cancer in the following 2 year interval (there were 11 false negatives and 20 cases with minimal signs in this group). Compared to single mammogram readings, CAD was found to be more sensitive although it had reduced specificity. Compared to double readings of mammograms, CAD was almost as sensitive and significantly more specific, for the detection of breast cancer.

A study (level IV evidence) assessing the effect of implementing CAD, reported no difference in breast cancer detection and recall rates between periods when mammograms were read with computer aided detection and periods when 24 radiologists interpreted mammograms without CAD (Gur et al. 2004). All screening mammography examinations performed in the six imaging clinics during 2000, 2001 and 2002 were included in this study. The recall and cancer detection rates for 56,432 screening mammograms interpreted before the CAD system was implemented and 59,139 screenings interpreted after the CAD was installed, were presented.

The cost of CAD mammography is partly funded through federal and private health insurance companies in the USA. American Medicare pays approximately $US18.00 each for diagnostic and screening CAD mammography (FDA 2004). Elmore et al suggest that CAD has been adopted rapidly in clinical practice (Elmore et. al. 2004).

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The cost of a CAD system would cost approximately AUD $300,000 to purchase in Australia. However, it can be incorporated into existing digital mammography systems as a standard feature. The MBS fees for diagnostic mammography in item numbers 59300 and 59303 are currently $82.00 and $49.45 (MBS 2004). Screening mammography is provided free of charge by BreastScreen Australia.

Ethical concerns regarding the introduction of CAD mammography have been raised (Elmore et al. 2004). The test costs more and yet the evidence of improved detection rates or long-term outcomes for patients with breast cancer may be lacking. Long term data observing the possible effects on mortality are not available to date as this requires many years of follow-up after screening. There is some concern that radiologists may begin to rely too heavily on CAD and risk becoming less vigilant in their own assessments (Elmore et al. 2004).

CONCLUSION:

There is the potential for rapid uptake of this high-cost technology in Australia based on the speed of uptake of CAD mammography in the USA.

HEALTHPACT ACTION:

Therefore it is recommended that a Horizon Scanning report be conducted.

SOURCES OF FURTHER INFORMATION:

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SEARCH CRITERIA TO BE USED:

Breast Neoplasms/ radiography
Calcinosis/radiography
Mammography/methods
Radiographic Image Interpretation, Computer-Assisted
Diagnosis, Computer-Assisted/ instrumentation/trends
Diagnostic Imaging/ instrumentation/trends