The regulation of non-invasive medical devices in Australia: a case study of breast cancer imaging devices marketed direct-to-consumer

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Table of contents

Thesis summary

Background

The premarket assessment of medical devices by an independent regulator is necessary to ensure that devices are safe and effective before they are made available to consumers in Australia. This responsibility is further necessitated by the practice of direct-to-consumer advertising (DtCA), whereby devices can be promoted to, and accessed by consumers without the involvement of a registered healthcare practitioner. An increase in the number of complaints against medical device advertising in Australia has raised questions around the effectiveness of the current regulations at ensuring that devices and their advertising material are adequately supported by evidence.

Aims

The aim of this thesis is to explore the relationship between scientific evidence and DtCA in the policy context of medical device regulation in Australia. This aim is investigated using a case study of three emerging breast cancer imaging devices: digital infrared thermal imaging (DITI), electronic impedance scanning (EIS) and electronic palpation imaging (EPI). In this thesis, the evidence supporting the safety and effectiveness of these devices is evaluated, the nature and frequency of claims presented in online advertisements for these devices are assessed and compared against the available evidence, and stakeholders are engaged in a discussion around options to reform the regulation of medical devices and medical device advertising.

Methods

A mixed methods approach was undertaken, involving three interrelated studies. The first study presents a systematic review of the available evidence for the safety and effectiveness of DITI, EIS and EPI. Following the systematic review, a quantitative content analysis was used to investigate the evidentiary basis of advertising claims made on websites that promote DITI, EIS and EPI in Australia. Finally, the results of the first two studies were used to inform stakeholder engagement around options to reform the regulation of medical devices and medical device advertising. Thematic analysis was used to synthesise stakeholder preferences in relation to a series of reform options proposed by Australia's principal therapeutic goods regulator, the Therapeutic Goods Administration (TGA).

Results

Study 1

As no direct effectiveness data were identified, the surrogate outcome measure of diagnostic accuracy became the primary focus of the systematic review. Significant heterogeneity was present among all three device classes, limiting the potential for meta-analyses. There was insufficient evidence to support the use of DITI, EIS or EPI for breast cancer screening, and the reported estimates of the sensitivity and specificity in symptomatic populations varied greatly for DITI (Sens 0.25-0.97, Spec 0.12-0.85) and EIS (Sens 0.26-0.98, Spec 0.08-0.81), while only two poor quality studies were identified for EPI.

Study 2

Thirty-nine Australian websites promoting DITI, EIS or EPI were identified. Despite a lack of primary evidence identified in the prior systematic review, the devices were advertised for diagnosis (n = 22 websites), screening (n = 20), prevention (n = 13) and risk factor identification for breast cancer (n = 13). Similarly, advertising claims of diagnostic accuracy (Sens 0.78-0.99, Spec 0.44-0.91) did not reflect the evidence base. Direct comparisons with conventional imaging were highly prominent (n = 31), and one third of websites explicitly promoted their device as a suitable alternative to conventional imaging (n = 12).

Study 3

Sixteen stakeholders representing breast cancer research, patient advocacy and screening provided input into reforms to premarket medical device regulation and advertising proposed by the TGA. Participants highlighted important benefits and limitations of the proposed options. Differences between the TGA's options for reform and stakeholder views indicated a need to update the current model for regulation that allows consumer choice and supports innovation, but within a more tightly regulated, safety-oriented framework.

Conclusion

Online advertising claims made for DITI, EIS and EPI extend the indications and efficacy of these devices beyond the available research evidence. This disconnect suggests the regulatory framework tasked with ensuring the safety and efficacy of these devices and their promotion is in need of reform. Extending the current regulations for advertising pre-approval to include medical devices, assessing diagnostic imaging devices for efficacy prior to market, and monitoring the use of a device in practice compared to its approved use on the Australian Register of Therapeutic Goods (ARTG) will help close the gap between DtCA and the evidence for emerging breast imaging devices.

Declaration

I certify that this work contains no material which has been accepted for the award of any other degree or diploma in my name, in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission in my name, for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint-award of this degree.

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Conference presentations resulting from this thesis

1. **Vreugdenburg TD**, Willis C, Mundy L, Hiller JE. Direct-to-consumer breast cancer imaging devices: A systematic review of their effectiveness in diagnostic and screening settings. [Oral] 29th Annual Meeting, The International Society for Quality in Health Care. Geneva, Switzerland, October 21-24, 2012.

2. **Vreugdenburg TD**, Laurence CO, Willis CD, Mundy L, Hiller JE. Content analysis of advertisements for emerging breast cancer imaging devices. [Poster] Faculty of Health Sciences Postgraduate Research Conference. Adelaide, Australia, August 31, 2012.

3. **Vreugdenburg TD**, Willis CD, Mundy L, Hiller JE. Direct-to-consumer breast cancer imaging devices: A systematic review of their diagnostic and screening effectiveness. [Oral] 9th Annual Meeting, Health Technology Assessment International (HTAi). Bilbao, Spain, June 25-27, 2012.

4. **Vreugdenburg TD**, Willis CD, Mundy L, Hiller JE. A systematic review of thermography, electrical impedance, and elasticity imaging for breast cancer screening and diagnosis. [Poster] BreastScreen Australia Conference, Melbourne, Australia, October 28-30, 2011.

5. **Vreugdenburg TD**, Willis CD, Mundy L, Hiller JE. Emerging breast cancer imaging devices: a systematic review of their diagnostic and screening effectiveness. [Poster] 7th Health Services and Policy Research Conference. Adelaide, Australia, December 5-7, 2011.

Peer-reviewed journal articles resulting from this thesis

1. **Vreugdenburg TD**, Laurence CO, Willis CD, Mundy L, Hiller JE. Content analysis of online direct-to-consumer advertising for emerging breast cancer imaging devices. *The Medical Journal of Australia,* 2014: 201(1); 289-294.

2. **Vreugdenburg TD**, Willis CD, Mundy L, Hiller JE. A systematic review of elastography, electrical impedance scanning, and digital infrared thermography for breast cancer screening and diagnosis. *Breast Cancer Research and Treatment,* 2013: 137(3); 665-676.

3. **Vreugdenburg TD**, Willis CD, Mundy L, Hiller JE. 2013. Pre-market approval and post-market direct-to-consumer advertising of medical devices in Australia: a case study of breast cancer screening and diagnostic devices. *Internal Medicine Journal,* 2013: 43(1); 53-58.

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List of tables

List of figures

List of terms

ACCC	Australian Competition and Consumer Commission
AIMD	Active Implantable Medical Device
ARTG	Australian Register of Therapeutic Goods
ASMI	Australian Self Medication Industry
ANZHSN	Australia and New Zealand Horizon Scanning Network
AusPAR	Australian Public Assessment Report
CAM	Complementary and Alternative Medicine
CBE	Clinical Breast Examination
CHC	Complementary Healthcare Council of Australia
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CRD	Centre for Reviews and Dissemination
CRP	Complaints Resolution Panel
Cth	Commonwealth
DALY	Disability Adjusted Life Year
DITI	Digital Infrared Thermal Imaging
DM	Digital Mammography
DtCA	Direct-to-Consumer Advertising
EBM	Evidence Based Medicine
EIS	Electrical Impedance Scanning
EPI	Electronic Palpation Imaging
FDA	Food and Drug Administration
GHTF	Global Harmonization Task Force
GMDN	Global Medical Device Nomenclature
HTA	Health Technology Assessment
LOS	Level of Suspicion
MRI	Magnetic Resonance Imaging

NHMRC	National Health and Medical Research Council
OTC	Over-The-Counter
PRL	Proportional Reduction in Loss
QD	Qualitative Description
QUADAS	Quality Assessment of Diagnostic Accuracy Studies
TGA	Therapeutic Goods Administration
US	Ultrasound
USA	United States of America
USE	Ultrasound Elastography
YLD	Years Lost to Disability
YLL	Years of Lost Life