BUILDING THE EVIDENCE BASE FOR DISINVESTMENT FROM INEFFECTIVE HEALTH CARE PRACTICES:

A CASE STUDY IN OBSTRUCTIVE SLEEP APNOEA SYNDROME

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For my mother, father, sister and brother

~ From little things big things grow ~

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Thesis Summary

In the early 1990s claims were made that in all areas of health care, "30-40% of patients do not receive treatments of proven effectiveness",[1] and, "20-25% of patients have treatments that are unnecessary or potentially harmful".[2] Many such practices were diffused prior to the acceptance of modern evidence-based standards of clinical- and cost-effectiveness. I define *disinvestment* in the context of health care as the processes of withdrawing (partially or completely) resources from any existing health care practices, procedures, technologies or pharmaceuticals that are deemed to deliver little or no health gain relative to their cost, and thus are not efficient health resource allocations. Arguably disinvestment has been central to Evidence-Based Medicine (EBM) for well over a decade yet despite general advances in EBM, this topic remains relatively unexplored. This thesis examines the ongoing challenges that exist within the Australian context relating to effective disinvestment. Upper airway surgical procedures for the treatment of adult Obstructive Sleep Apnoea Syndrome (OSA) are used as a case study to contextualise these challenges. This thesis has six sections:

1. A review of the literature outlines developments in EBM broadly and provides a detailed background to OSA, including the numerous treatment options for the condition. This review examines evidence that highlights the importance of 'highly effective treatment' over 'sub-therapeutic treatment' as a necessity to confer improved health outcomes in OSA. It is argued that claims of surgical success inherent in most published results of surgery effectiveness fail to assimilate contemporary evidence for clinically significant indicators of success.

2. Section two comprises the first reported meta-analysis in this area. It presents the pooled success rates of surgery according to various definitions. Specifically, when the traditional 'surgical' definition of success is applied the pooled success rate for Phase I (i.e. soft palate) surgical procedures is 55% (that is 45% fail). However, using a more stringent definition (endorsed by the peak international sleep medicine body), success is reduced to 13% (that is 87% fail). Similarly for Phase II (i.e. hard palate) procedures success rates decrease from 86% to 43% respectively when moving from a surgical to a medical definition of success. That various medical specialties differentially define treatment success, I argue, creates uncertainty for observers and non-clinical participants in this debate (eg policy stakeholders and patients). This represents a barrier to disinvestment decisions.

3. Results are presented from a clinical audit of surgical cases conducted as a component of this thesis. Both clinical effectiveness and procedural variability of surgery are reported. A unique methodology was utilised to capture data from multiple centres. It is the first time such a methodology has been reported to measure procedural variability alongside clinical effectiveness (inclusive of a comparative treatment arm). The observed cohort (n=94) received 41 varying combinations of surgery in an attempt to treat OSA. Results on effectiveness demonstrate an overall physiological success rate of 13% (according to the most stringent definition; phases I and II combined). This demonstration of procedural variability combined with limited effectiveness highlights clinical uncertainty in the application of surgical procedures.

4. Section four outlines how a qualitative phase of enquiry, directed at exploring the perspectives and experiences of surgery recipients, was approved by three independent research ethics review boards but was not supported by a small group of surgeons, resulting in the project being canceled. Potential consequences of this for impeding health services research (HSR) are discussed.

5. Two sets of results are reported from a qualitative phase of enquiry (semi-structured interviews) involving senior Australian health policy stakeholders. The first results are of policy stakeholders' perspectives on the surgical meta-analysis and clinical audit studies in 2 and 3 above. The second results are from an extended series of questions relating to challenges and direction for effecting disinvestment mechanisms in Australia. Stakeholder responses highlight that Australia currently has limited formal systems in place to support disinvestment. Themes include how defining and proving inferiority of health care practices is not only conceptually difficult but also is limited by data availability and interpretation. Also, as with any policy endeavour there is the ever-present need to balance multiple interests. Stakeholders pointed to a need, and a role, for health services and policy research to build methodological capacity and decision support tools to underpin disinvestment.

6. A final discussion piece is presented that builds on all previous sections and summarises the specific challenges that exist for disinvestment, including those methodological in nature. The thesis concludes with potential solutions to address these challenges within the Australian and international context. Systematic policy approaches to disinvestment represent one measure to further improve equity, efficiency, quality of care, as well as sustainability of resource allocation.

Manuscripts Contributing to This Thesis

Published
Elshaug AG, Moss JR, Southcott A and Hiller JE. Redefining success in airway surgery for Obstructive Sleep Apnea: A meta analysis and synthesis of the evidence. **Sleep** 2007;30(4):461-467. [2006 ISI Impact Factor: 5.126]

Published
Elshaug AG, Moss JR, Southcott A and Hiller JE. An analysis of the evidence-practice continuum: Is surgery for Obstructive Sleep Apnoea contraindicated? **Journal of Evaluation In Clinical Practice** 2007;13(1):3-9. [2006 ISI Impact Factor: 1.263]

Letter of acceptance received July 19, 2007 (see appendix four)
Elshaug AG, Moss JR, Maddern GJ and Hiller JE. Upper airway surgery should not be first-line therapy for adult obstructive sleep apnoea (OSA)**. British Medical Journal** Accepted July 19, 2007. [2006 ISI Impact Factor: 9.245]

To be submitted to the Journal of Evaluation in Clinical Practice
Elshaug AG, Hiller JE and Moss JR. Exploring policymakers' perspectives on a clinical controversy: airway surgery for adult OSA. To be submitted to the **Journal of Evaluation In Clinical Practice** [2006 ISI Impact Factor: 1.263]

Letter of acceptance received September 21, 2007 (see appendix four)
Elshaug AG, Hiller JE and Moss JR. Exploring policymakers' perspectives on disinvestment from ineffective health care practices. **International Journal of Technology Assessment in Health Care** Accepted September 21, 2007. [2006 ISI Impact Factor: 1.151]

Under editorial review: resubmitted on advice from editorial board (with revisions)
Elshaug AG, Hiller JE, Tunis SR and Moss JR. Challenges in Australian policy processes for disinvestment from existing, ineffective health care practices. Resubmitted to **Australia & New Zealand Health Policy** September 22, 2007. [no official impact factor]

Statements

This PhD 'by publication' thesis exceeds the minimum standards for PhD by publication set down in the Academic Program rules outlined in the Adelaide Graduate Centre's postgraduate program rules (PhD rule 9.3 and specifications), and the Faculty of Health Sciences PhD by publication guidelines specific to the School of Population Health and Clinical Practice, available at (web link accessed October 1, 2007):
http://www.adelaide.edu.au/health/research/higher/code/SchoolPhDThesisbypublicationGuidelines.pdf

Choice of journals in this portfolio of publications is justified as follows. *SLEEP* is the official journal of the American Academy of Sleep Medicine (AASM) and is considered the leading international subject-specific journal in sleep medicine (2006 impact factor: 5.126). The *Journal of Evaluation in Clinical Practice* (2006 impact factor: 1.263) was the first and preferred choice for the second research publication (clinical audit), and for the report of stakeholder perspectives on the surgery case study (to be submitted). This is a highly regarded international journal of health policy, evidence based medicine and health services research. The *BMJ* (impact: 9.245) paper was commissioned by a BMJ editor (based on an idea by A/Prof John Moss and a subsequent submission by me) for their *Change Page* series. The *International Journal of Technology Assessment in Health Care* (impact: 1.151) was a strategic choice (first and preferred choice) for publication of the stakeholder engagement regarding disinvestment. It is the official journal of Health Technology Assessment International (HTAi) and addresses a diverse international audience of health care providers, decision makers in government, industry and health care organisations as well as diverse scholarly disciplines such as economics, psychology, ethics, sociology, law etc. Finally, *Australia and New Zealand Health Policy* (no impact factor) also represents a strategic choice for the final publication. It is a BioMed Central, peer-review, online open access journal aiming to improve interaction between policy practitioners and academics, and to promote debate and understanding about contemporary health policy developments in the Australasian region, while maintaining international relevance. There are no other Australian or New Zealand journals with this focus.

Signed:	_____	_____	_____
	Adam Elshaug (Candidate)	A/Prof John Moss (Principal Supervisor)	Prof Janet Hiller (Co-Supervisor)
Dated:	_____	_____	_____

This work contains no material which has been accepted for the award of any other degree or diploma 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.

I give consent for this copy of my thesis, when deposited in the University of Adelaide Library, being available for loan or photocopying.

Signed: _____
Adam Elshaug (Candidate)

Dated: _____

Conference Presentations Arising Out of This Thesis

Forthcoming - Abstract accepted for oral presentation: 5th Health Services Research Association of Australia and New Zealand (HSRAANZ) conference. December 2-5, 2007, Auckland, New Zealand. **Elshaug AG**, Hiller JE and Moss JR. *Exploring Policymakers' Perspectives on Disinvestment from Ineffective Health Care Practices.*

Forthcoming - Abstract accepted for oral presentation: The Menzies Centre for Health Policy, Emerging Health Policy Research Conference. Canberra, Australia, October 12, 2007. **Elshaug AG**, Hiller JE and Moss JR. *Disinvestment from Ineffective Health Care Practices: An Exploration of Policymakers' Perspectives.*

Invited panel member (one of four), Surgery for OSA. 2-hour symposium. WorldSleep07 – International Congress of the World Federation of Sleep Research and Sleep Medicine Societies (WFSRSMS), Cairns, Australia, September 6, 2007.

The Menzies Centre for Health Policy, Emerging Health Policy Research Conference. Sydney, Australia, October 13, 2006. **Elshaug AG**, Hiller JE and Moss JR. *Stuck with the old and overwhelmed by the new: challenges in the policy process for the disinvestment of non-efficacious health care practices in Australia.*

The 6th International Conference on Priorities in Health Care. Toronto, Canada, September 20-22, 2006. Abstract #P-01, page 49. **Elshaug AG,** Hiller JE, Southcott AM and Moss JR. *When clinical practices vary, best practice is one of multiple variations: need for a formal mechanism to monitor effectiveness.*

Canadian Association for Health Services and Policy Research (CAHSPR) Annual Conference, Vancouver, Canada, September 17-19, 2006. **Elshaug AG**, Hiller JE, Southcott AM, Moss JR. '*When clinical practices vary, best practice is one of multiple variations: a practical analysis of the 'know-do-gap'.*

Health Technology Assessment International (HTAi) 2006 Annual Meeting, Adelaide, Australia, July 2-5, 2006. **Elshaug AG**, Hiller JE, Southcott AM, Moss JR. '*An Audit of Surgical Intervention for Obstructive Sleep Apnoea: Questions of Efficacy and Improved Health Outcomes'.*

4th Health Services and Policy Research Conference (Health Services Research Association of Australia and New Zealand). Canberra, Australia 2005. **Elshaug AG,** Hiller JE and Moss JR. '*When clinical practices vary, best practice is only one of multiple variations: need for a formal mechanism to monitor effectiveness'.*

Public Health Association of Australia, Australasian Faculty of Public Health Medicine and Australian Health Promotion Association joint conference 'Public Health in the Community', Adelaide, Australia, October 22, 2005. **Elshaug AG,** Hiller JE and Moss JR. '*The need for a formal mechanism to monitor effectiveness in health care: questions of efficacy and improved health outcomes'.*

Invited Addresses Arising out of This Thesis

Government/Policy - International

4-hour Round Table Forum on *Disinvestment* (with 8 senior government health policy advisors). Strategic Policy and Research Branch, Ministry of Health, Victoria, British Columbia, Canada. September 15, 2006.

Strategic Policy and Research Branch, Ministry of Health, Victoria, British Columbia, Canada. *Stuck with the old and overwhelmed by the new: challenges in the policy process for the disinvestment of non-efficacious health care practices in Australia*. September 15, 2006.

Institute of Health Economics, Edmonton, Alberta, Canada. *Disinvestment from ineffective health care: challenges for Australian health policy processes*. September, 2006.

Government/Policy - Australia

Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S), Australasian College of Surgeons. *Building the evidence base for disinvestment from ineffective or inappropriately applied health care practices.* September 27, 2007.

TRACsa Trauma and Injury Recovery, Government of South Australia. *Disinvestment from ineffective health care: barriers, carriers and stakeholder engagement*. July 31, 2007.

Adelaide Health Technology Assessment (AHTA) Retreat and Planning Day. "Disinvestment from ineffective health care: barriers, carriers and stakeholder engagement". July 27, 2007.

South Australian Government Department of Health, Adelaide, Australia. *Stuck with the old and overwhelmed by the new: challenges in Australian policy processes for the disinvestment of ineffective health care practices*. May 14, 2007.

National Institute of Clinical Studies (NICS), Melbourne, Australia. *Stuck with the old and overwhelmed by the new: challenges in Australian policy processes for the disinvestment of ineffective health care practices*. February 13, 2007.

Invited discussion with advisors to the Australian Medical Services Advisory Committee (MSAC). Australian Department of Health, Canberra, Australia. November, 2005.

Clinical Medicine

Forthcoming: Medical Grand Round presentation. The Repatriation General Hospital, Adelaide. *Reporting on a clinical controversy: upper airway surgery for obstructive sleep apnoea (OSA) – results from a meta analysis and South Australian based surgical audit*. October 10, 2007.

Royal Adelaide Hospital multidisciplinary meeting (FRACP/FRACS), Adelaide. *Utilizing patient perspectives in the planning of clinical programs and health policy: a research study*. 2006.

Royal Adelaide Hospital multidisciplinary meeting (FRACP/FRACS), Adelaide. *The fourth hurdle: Cost-effectiveness and efficacy in the regulation of medical services.* 2006.

Invited Addresses Arising out of This Thesis, Continued

Academia

Forthcoming – Discipline of Public Health, The University of Adelaide. *Towards quality and sustainability: building the evidence base for disinvestment from ineffective health care.* Invited Seminar Series Presentation.

Centre for Health Economics Research and Evaluation (CHERE), University of Technology, Sydney. *Health services research and the proliferation of sleep medicine: questions of resource allocation, treatment efficacy & health outcomes?* 2006.

Department of Public Health, The University of Adelaide. *A clinical and policy investigation to support the disinvestment of ineffective health care services in Australia*. PhD progress presentation. 2005.

Department of Public Health, The University of Adelaide. *A clinical and policy investigation to support the disinvestment of ineffective health care services in Australia*. PhD establishment presentation. 2004.

Awards and Merits Arising Out of This Thesis

Merit Award from the World Federation of Sleep Research and Sleep Medicine Societies (WFSRSMS). $1,500 prize, invited address and symposia panellist at WorldSleep07, the 5th World Congress of the WFSRSMS, 2007.

The University of Adelaide (Faculty of Health Sciences) Travelling Fellowship Award (competitive). $2,000 travel award for international conferences and institutional visits. 2006 (Canada)

Best Presentation by a New or Emerging Researcher: 4th Health Services and Policy Research Conference (Health Services Research Association of Australia and New Zealand). Canberra, Australia, 2005

Best Presentation (Respondent's Prize): 'Public Health in The Community' Joint Conference of the Public Health Association of Australia, Australasian Faculty of Public Health Medicine and Australian Health Promotion Association. Adelaide, Australia, 2005

Acknowledgements

"*Free should the scholar be – free and brave.*"

Ralph Waldo Emerson

I would like to acknowledge and thank all who have contributed to the production of this thesis. First, to my supervisors, A/Prof John Moss and Prof Janet Hiller - their unwavering support throughout this difficult, often politically sensitive project has been the difference between its viability and demise. As individuals, and as a team, their intellect and expertise has provided a solid foundation for my work. Their cool headed pragmatism has ensured project viability and their knack for comic relief at times where cool heads were needed, has made this PhD a pleasurable, collegial experience. Above all, they willingly, amply and promptly dedicated valuable time from their busy schedules to help me achieve my own goals throughout this candidature. They are gratefully acknowledged.

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To Emily, a very special thank you for your support, encouragement, motivation and kindness. I will remember it always – and hope to return the favour.

Finally, I dedicate this thesis to my family, who I moved from to attend University. As the first and only family member to have done so, this submission represents an achievement for us all. To my father, who sold personal belongings to pay for my first-ever semester fees, and who sat and helped me choose my first semester subjects – I'm not sure who was more daunted? To my beautiful mother, whose inner force, love and encouragement have strengthened my development from child to adult. To my big brother, my oldest friend. As a long-distance truck driver travelling through Adelaide he would stop in for a cuppa and to shoot the breeze. Later that night, as he would be half way home on a dark country road I would happen upon a twenty dollar note stuffed hastily into my toothpaste jar, or under my pillow, 'just to see me through'. And to my baby sister, whose tear-filled eyes I still remember gazing back at me from the car as they drove away, leaving me for the first time, alone in a new city. If successful with this submission I will become the first Dr Elshaug in Australia. I now have two nieces and three nephews - may this accomplishment light their way.

Glossary of Acronyms

AHI	apnoea/hypopnoea index (Note US spelling: apnea/hypopnea)
AI	apnoea index
ART	assisted reproductive technologies
BMI	body mass index
BP	blood pressure
CI	confidence interval
CPAP	continuous positive airway pressure
CVD	cardiovascular disease
EBM	evidence-based medicine
ENT	ear, nose and throat
GA	genioglossus advancement
GAHM	genioglossal advancement with hyoid myotomy and suspension
GBAT	genial bone advancement trephine
HREC	Human Research Ethics Committee
HRQL	health related quality of life
HRQoL	health related quality of life
HS	hyoid suspension
HSR	health services research
HTA	health technology assessment
ICU	intensive care unit
IVF	in vitro fertilisation
LAUP	laser-assisted uvulopalatoplasty
MAD/S	mandibular advancement device/splint
MI	myocardial infarction
MMA	maxillomandibular advancement
mmHg	millimetres of mercury
MSAC	medical services advisory committee
NHMRC	national health and medical research council
NICE	national institute for clinical excellence
NICS	national institute for clinical studies
OA	oral appliance
OSA	obstructive sleep apnoea syndrome (Note US spelling: apnea)
PBAC	pharmaceutical benefits advisory committee
PBMA	Program Budgeting and Marginal Analysis
PSG	polysomnography
RCT	randomised controlled trial
RFVR	radiofrequency volume reduction of soft tissue
SaO2	oxyhaemoglobin saturation
SAQLI	sleep apnoea quality of life index
SD	standard deviation
SDB	sleep disordered breathing
SE	standard error
SF-36	short-form – 36
SAHS	sleep apnoea hypopnoea syndrome
TCRF	temperature-controlled radiofrequency volumetric reduction
UK	united kingdom
UPPP	uvulopalatopharyngoplasty
US/USA	united states of america
WMD	weighted mean difference