THE UNIVERSITY OF SYDNEY

Prostate cancer screening in primary care:

Doctors' perspectives on prostate-specific antigen (PSA) screening of asymptomatic men in Australia and the United Kingdom

Kristen Pickles

Centre for Values, Ethics & the Law in Medicine

School of Public Health

University of Sydney

A thesis submitted in fulfilment of the requirements for the degree of DOCTOR OF PHILOSOPHY

2017

Candidate's Declaration

I, Kristen Pickles, hereby declare that the work described in this thesis is my own. I am the principal researcher of all work contained in this thesis, including work conducted in association with my PhD supervisors. This thesis does not contain written or published materials prepared by others except where acknowledged within the text and has not been submitted to any other university or institution as a part or whole requirement for any higher degree.

I, Kristen Pickles, understand that if I am awarded a higher degree for my thesis entitled Prostate cancer screening in primary care: Doctor's perspectives on prostate-specific antigen (PSA) testing of asymptomatic men in Australia and the United Kingdom being lodged for examination, this thesis will be lodged in the University Library and be available immediately for use. I agree that the University Librarian (or in the case of a department, the Head of Department) may supply a photocopy or microform of the thesis to an individual for research or study or to a library.

Kristen Pickles

Date: 8 May 2017

Abstract

Background:

Screening for prostate cancer is a highly debated public health issue. The evidence base is contested, the prostate-specific antigen (PSA) test as a screening technology is limited, no medical body recommends a population screening program for prostate cancer screening, local authorities differ in the advice they offer on the value of PSA screening in clinical care, and the substantial harms associated with PSA screening are well documented. Decisions about PSA screening most commonly occur in consultation with a general practitioner (GP). This qualitative study was designed to explain how GPs understand, reason about, and use the PSA test to screen men for prostate cancer risk in primary care. Australia and the United Kingdom draw on the same evidence base for prostate cancer screening yet have notably different rates of PSA screening; they are the two locations of this research study. In this thesis I report on GP perspectives on PSA screening.

Methods:

This is an empirical study using grounded theory methodology. Data were generated from in-depth interviews with GPs in Australia and the United Kingdom, who make decisions about using or not using the PSA test as a screening tool. Analysis was developed through transcript coding and detailed memo writing, using constant comparison to develop insight and connections between concepts. The overall aim of the study was to gain an in-depth understanding of how and why clinicians use the PSA test to screen for prostate cancer in primary care.

Main findings:

This grounded theory study found that for Australian GPs on the frontline, decision making about PSA screening is extremely difficult and complex. There was extensive variation in the clinicians' accounts of their screening behaviour. Different motivations (values and goals) of GPs, context of the clinic and specific clinical interactions, opportunity to trust, and responses to uncertainty, were central explanations for varied practice. GPs intuitively and/or explicitly drew from multiple, potentially

conflicting, types of knowledge (including that from the research evidence) - developed over time – to guide their screening decisions. The study included UK GPs as a comparison case to examine the place of past and present screening policy, and healthcare system structure and organisation in influencing and incentivising particular ways of practicing. The UK experience demonstrates that Australian screening practices are not inevitable – things can be done differently. Some Australian clinicians in this study experienced significant emotional and cognitive burden, as a result of making screening decisions under challenging conditions. The empirical chapters of the thesis focus on four key issues: managing the potential for overdiagnosis, responding to uncertainty, practice and policy context, and communicating about PSA screening. The Discussion chapter draws these findings together into a new explanatory model of GPs' decision making about PSA screening.

Conclusion:

This research provides an in-depth comparative analysis of important drivers of prostate cancer screening reported from the perspective of GPs in two locations with diverse screening rates. The model produced provides an explanation of the complex and varied process of PSA screening in the two jurisdictions. Policy continues to evolve and attract substantial debate in this field in Australia. Given that past attempts to intervene in PSA screening practice in Australia seem to have had limited effect, a new approach that better reflects the complexity of this issue, including the range of drivers of current practice, seems warranted. These findings offer useful empirical guidance for future policy and practice, grounded in the experiences of clinicians.

Table of contents

List of acronyms

DRE Digital rectal examination

EBM Evidence based medicine

ERSPC European Randomized Study of Screening for Prostate Cancer (trial)

FDA [US] Food and Drug Administration

GP General Practitioner

IDM Informed decision-making

MBS Medicare Benefits Schedule

NEJM New England Journal of Medicine

PCRMP Prostate Cancer Risk Management Programme (UK)

PLCO Prostate, Lung, Colorectal, and Ovarian Cancer Screening (trial)

PSA Prostate-specific antigen (test)

RCT Randomised Controlled Trial

SDM Shared decision-making

UK United Kingdom

USA United States of America

List of organisations

ACP American College of Physicians

ACS American Cancer Society

AFP American Academy of Family Physicians

AHMAC Australian Health Ministers' Advisory Council

AHTAC Australian Health Technology Advisory Committee

AIHW Australian Institute of Health and Welfare

AUA American Urological Association

CCA Cancer Council Australia

EAU European Association of Urology

NCI National Cancer Institute

NHMRC National Health and Medical Research Council

NHS National Health Service

NICE National Institute for Health and Care Excellence

PCFA Prostate Cancer Foundation of Australia

PHE Public Health England

RACGP Royal Australian College of General Practitioners

RCGP Royal College of General Practitioners

UK NSC United Kingdom National Screening Committee

USANZ Urological Society of Australia and New Zealand

USPSTF United States Preventive Services Task Force

Contributions, Publications, and Presentations

Associate Professor Stacy Carter was my primary supervisor. Associate Professor Lucie Rychetnik was my associate supervisor. Both made conceptual, analytic, and editorial contributions to the work in this thesis and co-authored publications. Professor Vikki Entwistle and Professor Kirsten McCaffery were co-authors on two of the published papers and made conceptual, analytic, and editorial contributions to those papers.

This is a thesis by publication. Some components of the work presented in this thesis have been published and/or presented at academic conferences or seminars. Each chapter that contains a publication (Chapters 3-5) or a manuscript that is in-press (Chapter 6) is prefaced by a statement outlining the specific contributions of each author. The citation details are as follows:

Publications:

Pickles K, Carter SM, Rychetnik L, Entwistle VA. Doctors' perspectives on PSA testing illuminate established differences in prostate cancer screening rates between Australia and the UK: A qualitative study. *BMJ Open,* 2016*.* 6:e011932-e011932

Pickles K, Carter SM, Rychetnik L, McCaffery K, Entwistle VA. General Practitioners' Experiences of, and Responses to, Uncertainty in Prostate Cancer Screening: Insights from a Qualitative Study. *PLoS ONE*, 2016, 11(4): e0153299.

Pickles, K, Carter, S, Rychetnik, L. Doctors' approaches to PSA testing and overdiagnosis in primary healthcare: a qualitative study. *BMJ Open,* 2015; 5:e006367

Pickles K, Carter SM, Rychetnik L, McCaffery K, Entwistle VA. Primary goals, information-giving and men's understanding: A qualitative study of Australian and UK doctors' varied communication about PSA screening. *BMJ Open.* 2017. In press.

I also contributed to three additional co-authored papers. In the first paper I drafted and revised the sections on prostate cancer screening. In the second I contributed to interpretation of the data and drafting and revising of the article. In the third I contributed to drafting and revising of the article. In the case where I am not the corresponding author, permission to include the published material has been granted by the corresponding author. These publications are replicated in Appendix I-III.

Additional publications:

Carter SM, Williams J, Parker L, **Pickles K,** Jacklyn G, Barratt A. Screening for Cervical, Prostate and Breast Cancer: Interpreting the Evidence. *American Journal of Preventive Medicine,* 2015 49(2): 274-85

Degeling C, Rychetnik L, **Pickles K,** Doust J, Gardiner R, Glasziou P, Newson A, Thomas R, Carter S. "What should happen before asymptomatic men decide whether or not to have a PSA test?" A report on three community juries. *Medical J Aust,* 2015; 203(8):335

McCaffery, K, Jansen, J, Scherer, L, Thornton, H, Hersch, J, Carter, S, Barratt, A, Moynihan, R, Waller, J, Sheridan, S, Brodersen, J, **Pickles, K**, Edwards, A. Walking the tightrope: communicating overdiagnosis in modern healthcare. *BMJ,* 352:1348, 2016

I gave several oral presentations during my candidature that presented material from this thesis. The details of these presentations are as follows:

Presentations:

Pickles, K, Carter, S, Rychetnik, L, McCaffery, K, Entwistle, V. How doctors experience and respond to uncertainty in prostate cancer screening. *International Shared Decision Making (ISDM)/International Society for Evidence Based Healthcare (ISEHC) conference.* 19-22 July 2015. Sydney University (oral presentation)

Pickles, K, Carter, S, Rychetnik, L. Overdiagnosis in prostate cancer screening: An Australian GP perspective. *Preventing Overdiagnosis conference: Winding back the harms of too much medicine',* 15-17th September 2014. University of Oxford, Oxford UK (oral presentation)

Pickles, K, Carter, S, Rychetnik, L. Overdiagnosis in prostate cancer screening: An Australian GP perspective. *Seminar Series, Health Services Research Unit,* 19th September 2014. University of Aberdeen, Scotland (oral presentation)

Pickles, K, Carter, S, Rychetnik, L. Overdiagnosis in prostate cancer screening: An Australian GP perspective. *STEP Seminar Series, Sydney School of Public Health,* 19th August 2014. University of Sydney (oral presentation)

McCaffery, K, Edwards, A, Hersch, J, **Pickles, K**, Scherer, L, Sheridan, S, Waller, J, Jansen, J. Workshop: Communicating about Overdiagnosis: A Symposium of Current Research. *Preventing Overdiagnosis conference: Winding back the harms of too much medicine',* 15-17th September 2014. University of Oxford, Oxford UK (oral presentation - Pickles: Approaches to PSA testing in Australian general practice: A GP perspective on communicating overdiagnosis information)

Pickles, K, Carter, S, Rychetnik, L. Overdiagnosis in prostate cancer screening: An Australian GP perspective. *Preventing Overdiagnosis conference: Winding back the harms of too much medicine',* 10-12th September 2013. Dartmouth University, Hanover, USA (poster presentation)

Pickles, K, Carter, S, Rychetnik, L. PSA testing of asymptomatic men in General Practice. *Prostate Cancer World Congress,* 6-10th August, 2013. Melbourne Convention and Exhibition Centre, Melbourne, Australia (poster presentation and abstract published British Journal of Urology International)

Some findings of this study have been reported in the Australian medical media. The details of these publications are as follows:

Cited in *Australian Doctor*. 7 December 2016. Call for co-pays, cooling-off periods to curb PSA testing. Author: Clare Pain. http://www.australiandoctor.com.au/news/latest-news/call-for-co-pays-cooling-off-periods-to-curb-psa

Cited in *MJA Insight*. 8 February 2016. New guidelines but prostate testing still complex. Author: Nicole MacKee. https://www.mja.com.au/insight/2016/4/new-guidelines-prostate-testing-still-complex

Cited in *Medical Republic*. 4 November 2015. Damned if you do. Damned if you don't. Author: Mic Cavazzini. http://www.medicalrepublic.com.au/damned-if-you-do-damned-if-you-dont/

Acknowledgements

Many people collectively contributed to the completion of this research and thesis. I would most importantly like to express my gratitude to the clinicians who agreed to participate: their contributions and thoughtful reflection made this study possible.

I particularly wish to thank my primary supervisor Stacy Carter, whose expertise, calming presence, and patience added considerably to my experience. I had the great privilege of accessing and absorbing Stacy's vast knowledge, creativity, and writing proficiency over the years. Thanks also to my associate supervisor, Lucie Rychetnik, for continuing to share her wisdom and providing guidance and encouragement from afar, and to Vikki Entwistle and Kirsten McCaffery for their ongoing support.

Thanks to the staff and students at VELiM for hosting me and to those who generously provided casual employment during my candidature. I am grateful to have had the opportunity to be a member of the cancer screening project team and wish to thank the University of Sydney and the NHMRC for their financial support. I will be forever indebted to the many colleagues who have become friends, for their incredible generosity, and endless encouragement and reassurance throughout this process. This thesis would never have been possible without that connection.

To the special ones in my inner circle, past and present. Mum and Dad, Lauren, Jenna, and Chris, I cannot even begin to find the words to express the extent of my appreciation for your support, for always keeping me grounded, and for having an unwavering belief in me. I hope at some point I am able to fully express how I feel.

It is to Wesley James Bonny that I dedicate this thesis, whose love and encouragement started me on this path and whose memory continues to inspire me every day.

Preface

This thesis describes a qualitative study that investigated how general practitioners (GPs) understand, reason about, and use the prostate-specific antigen (PSA) test to screen men for prostate cancer risk in primary care. Screening for prostate cancer is a complex and notably controversial public health issue (1, 2), regularly encountered by a large number of men and GPs, particularly in Australia. Internationally, no clinical guideline recommends a population-screening program for prostate cancer screening. This is because current epidemiological evidence about populations indicates that the harms associated with PSA screening, such as false positive tests and overdiagnosis, likely outweigh any benefits (3, 4). Yet PSA screening rates remain high (5). Little was known about GPs' views and experiences of PSA screening. I wanted to find out how GPs approach this challenging topic. Are they concerned about PSA screening? What are they prioritising? My purpose in asking these questions is to better understand those factors that are contributing to the current state of PSA screening practice.

How this thesis is organised

This thesis is presented in seven chapters, and written so that each chapter can be read independently. Chapter One is the introductory chapter. It is divided into three parts: Part I introduces prostate cancer and the PSA test as a screening tool. I briefly discuss the complexities of the evidence base for PSA screening and conclude with an overview of current policy and recommendations. Part II is a review of the literature on how and why primary care clinicians use the PSA test as a screening tool in their clinical practice. Part III details the structure of primary care in Australia and the United Kingdom to provide context for this study. I conclude Chapter One with my study aims and research questions. In Chapter Two, I describe grounded theory methodology and its application in practice in this study. Each of the published or submitted papers in this thesis contain some information about methods; this chapter presents the methodology and methods for this empirical study as a whole.

Chapters Three to Six report the findings of my empirical work. Chapter Three is a study of General Practitioners' approaches to PSA screening and reasoning about overdiagnosis and underdiagnosis in

primary healthcare. Chapter Four is an analysis of General Practitioners' experiences of, and responses to, uncertainty in prostate cancer screening. Chapter Five is a comparative study of General Practitioners' perspectives on established differences in prostate cancer screening rates between Australia and the United Kingdom. Chapter Six presents findings about differences in communication accounted for by General Practitioners' primary goals and practice situations. Chapter Six is in press at and replicates the version accepted for publication. Chapter Seven is a discussion paper.

Published papers are as they appear in the journal. Each chapter contains its own reference list. The journal papers vary from one another in formatting and referencing style, reflecting the requirements of the publishing journal. Chapters One, Two, and Seven were written specifically for this thesis rather than for journal submission.

A note on terminology:

The terminology used to describe prescribing an asymptomatic male a PSA test to screen for prostate cancer risk is contentious. In the majority of this thesis I use 'screening' to refer to PSA testing of ostensibly healthy men who are not considered to be at high risk of prostate cancer for their age, and 'testing' to describe PSA tests prescribed for men who have a diagnosis of prostate cancer or are experiencing acute symptoms that may suggest prostate disease. In general, I have used the word 'screening' wherever possible. In the empirical chapters (chapters 3-5), which were published in the peer-reviewed literature before this thesis was consolidated and submitted, there is more variation in terminology. Regardless of whether the term 'testing' or 'screening' is used, this analysis focuses on the GPs' use of the PSA test in men who do not appear to be at higher than population-average risk for prostate cancer, as specified in the introduction.

References:

1. Boyle P, Brawley OW. Prostate cancer: current evidence weighs against population screening. CA: a cancer journal for clinicians. 2009;59(4):220-4.
2. Barry MJ. Screening for prostate cancer—the controversy that refuses to die. Mass Medical Soc; 2009.
3. Moyer VA. Screening for prostate cancer: US Preventive Services Task Force recommendation statement. Annals of Internal Medicine. 2012;157(2):120-34.
4. Ilic D, Neuberger MM, Djulbegovic M, Dahm P. Screening for prostate cancer. Cochrane Database Syst Rev. 2013;1.
5. Drazer MW, Huo D, Eggener SE. National prostate cancer screening rates after the 2012 US Preventive Services Task Force recommendation discouraging prostate-specific antigen–based screening. Journal of Clinical Oncology. 2015;33(22):2416-23.

CHAPTER ONE.

Introduction

Part I: Introduction

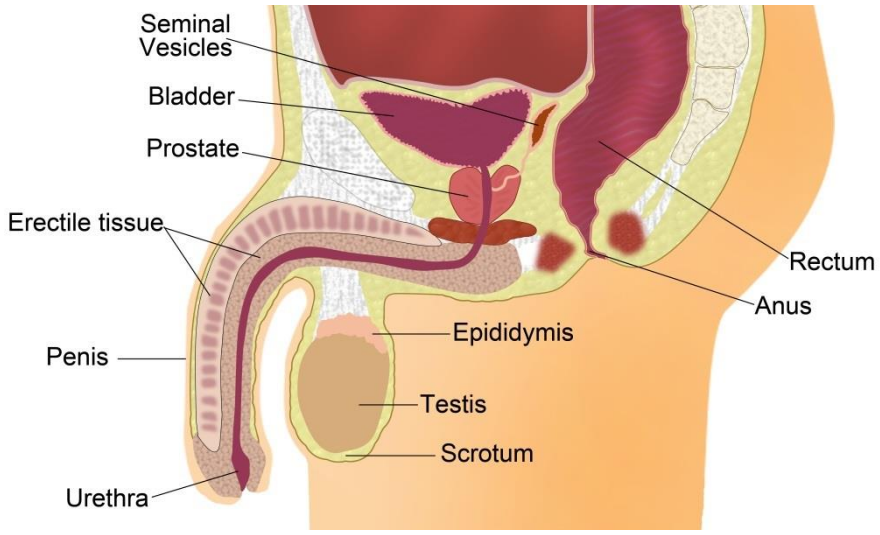
1. Overview of this chapter

There are three parts to this chapter. Part I introduces prostate cancer and prostate-specific antigen (PSA) screening for prostate cancer risk. I describe how the PSA test works as a screening tool and the diagnosis and treatment of prostate cancer. I trace the development of the evidence base for PSA screening and discuss the complexities of that evidence base. Part I concludes with an overview of the current state of prostate cancer screening policy and practice. Part II reviews the published international literature on how and why primary care clinicians use the PSA test as a screening tool in their clinical practice. Part III details the structure of primary care in Australia and the United Kingdom - the two locations of focus for this research project - and concludes with my study aims and research questions.

1.1 Prostate cancer

The prostate is a gland in the male reproductive system. It is about the size of a small apricot and sits at the base of the bladder and in front of the rectum. The prostate gland produces a fluid that forms part of semen and the muscles of the gland help propel this seminal fluid into the urethra during ejaculation (1). Prostate cancer occurs when abnormal cells in the prostate grow in an uncontrolled way. Prostate cancer can put pressure on or obstruct the bladder or urethra (the tube that allows urine to be released from the bladder) and cause problems with urination and sexual function.

Figure 1: Location of the prostate gland



ducu59us/www.shutterstock.com (2)

Prostate cancer is an important cause of death. It was the third most common cause of cancer deaths in Australia in 2014. The age-standardised mortality rate in Australia is 26 deaths per 100,000 males (2014) (3), and 48.1 deaths per 100,000 males in the United Kingdom (2014) (4).

Prostate cancer incidence ranges widely between population groups. Prostate cancer is the most commonly diagnosed cancer in developed countries (5): a six-fold difference in prostate cancer incidence has been reported in more developed countries (56.2 cases per 100,000 population) compared to less developed countries (9.4 cases per 100,000 population)(6). Internationally, prostate cancer incidence is highest in Australia, North America, Northern and Western Europe, and the Caribbean, and lowest in Asia (5). Within Australia, prostate cancer incidence is highest among males living in the least disadvantaged and inner regional areas of the country and lowest among males living in the most disadvantaged and remote areas (2004-8) (7). Similarly in the UK, the incidence of prostate cancer is highest in the least deprived areas (and lowest for males living in the most deprived area)(8).

Prostate cancer mortality ranges widely between population groups. (9). Just as prostate cancer incidence varies widely between groups, so does prostate cancer mortality. Prostate cancer mortality rates are highest in the Caribbean and lowest in South Central Asia (10). This may partly reflect varying data quality worldwide. Within Australia, the age-standardised mortality rate was higher

among those living in inner regional and outer regional areas compared to those in major cities in 2006-2010. There is little difference in mortality between the least and most disadvantaged (26.9 and 27.7 per 100,000 males, respectively)(7). In the UK, there is some regional variation in prostate cancer mortality: in 2007-2009, mortality was higher in the East Midlands and lower in London when compared to the England average (11). Mortality rates did not show any difference between deprivation groups.

As discussed later in this chapter, incidence and mortality figures are complicated by the effect of PSA screening rates on incidence rates, with contestable effects on mortality.

The factors that determine the risk of developing prostate cancer are not well known. There are three well-established risk factors for prostate cancer:

1. *Age.* Prostate cancer is rare in men under 50 years (6). The average age of a [US] man diagnosed with prostate cancer is approximately 67 years. 71% of prostate cancer deaths occur in men older than 75 years (12).
2. *Family history.* A man's risk for developing prostate cancer is higher than average if a brother (2.5-3 times higher) or father and two brothers (9-10 times higher) are diagnosed with prostate cancer, particularly if they are younger than 60 years at diagnosis (13).
3. *Ethnicity.* Men of African and Caribbean descent have a greater risk of developing prostate cancer and more advanced disease upon diagnosis compared to white men (14, 15). US studies have found little difference in PSA uptake between black and white men (16, 17).

Prostate cancer is a clinically heterogeneous disease with a variable natural history. This means that tumours can range from small, slow growing lesions to very aggressive tumours. Early, localised prostate cancers are confined within the prostate and usually do not produce symptoms; some men may experience changes in urinary and sexual function. Locally advanced cancer affects nearby tissues, such as the bladder and rectum. Metastatic cancer affects other areas in the body, usually the lymph nodes or bone. Locally advanced and metastatic cancers can have a significant effect on morbidity, mortality, and quality of life (18).

The general population harbours a large pool of predominantly latent prostate tumours. These microscopic or indolent tumours progress so slowly that the individual generally dies from other causes (e.g. heart disease) before the prostate cancer progresses. Autopsy studies have demonstrated a high rate of undiagnosed, asymptomatic prostate tumours in men (19). Welch and Black conducted a review of evidence from autopsy studies and estimated that men aged over 60 years have a 30-70% lifetime risk of dying *with* prostate cancer but only a 4% lifetime risk of dying *from* prostate cancer or metastatic disease (20). This is arguably the central problem in prostate cancer early detection and management, and I will return to it repeatedly throughout this thesis.

1.2 Screening for prostate cancer

Screening for cancer or cancer risk is a well-established feature of secondary preventive medical care in high-income countries. The purpose of screening programs is to reduce suffering and mortality by enabling early intervention. Cancer screening involves the systematic use of a test to find asymptomatic disease or disease risk in healthy populations (7).

Screening for prostate cancer, accordingly, involves testing men to identify early-stage prostate cancers so as to enable early (and effective) intervention. The main goal should be to ensure that men live longer and experience less suffering. Because so much prostate cancer is latent and relatively indolent, however, the challenge is to find those men whose cancer might otherwise have progressed to advanced disease, and distinguish them from the many men who harbour a latent prostate cancer that would never have become symptomatic.

Prostate cancer screening mostly uses the prostate-specific antigen (PSA) test. The PSA test is a common blood test that measures the total concentration of PSA protein in a man's blood. PSA is prostate-tissue specific but not prostate cancer-specific; it is found in the epithelial tissue of the healthy prostate, in benign hyperplastic tissue, and in prostate cancer. Elevated PSA levels may indicate an increased risk for the presence of prostate cancer, but can also be caused by conditions such as benign prostatic hyperplasia (BPH) (enlargement of the prostate) and prostatitis (inflammation of the prostate). There is no evidence that these benign prostate conditions lead to

prostate cancer (21). There are no symptoms that can differentiate early prostate cancer from benign prostate conditions such as BPH (22).

Digital rectal examination (DRE) has sometimes also been used for prostate cancer screening.[1] A digital rectal examination involves manual examination of the prostate gland through the rectum to check any abnormality in size, shape, or texture. Irregularities such as a swelling, hardening or lumps on the surface of the prostate may be signs of prostate cancer (23). Use of the DRE as a screening tool is limited due to poor reliability, sensitivity, and the inability to feel the entire prostate and small cancers (24). As the focus of this study is the PSA test, rather than DRE, DRE will not be considered in any further detail in this thesis.

In the following section I present the key features of the PSA test when used as a screening tool.

How does the PSA test work?

PSA is measured in nanograms/millilitre (ng/ml). Because the PSA test is a biomarker, a cutoff or threshold value must be set at which a result will be considered 'abnormal'. However these threshold values have varied considerably in the literature and practice. The traditional cut-off level of PSA concentration in the blood to be considered an abnormal PSA level has ranged from 2.5ng/ml – 4.0ng/ml in the major screening studies. It is most commonly recommended that patients be referred to specialist services for further investigation if their blood PSA concentration is greater than 4.0ng/ml (25), though there is some variation in clinical practice. Some practices use a more stringent level of 2.5ng/ml. Under these conditions, either a PSA result above 4.0ng/ml, or a PSA result above 2.5ng/ml, respectively, would be referred to as a positive or abnormal PSA result to guide further clinical investigation.

[1] Guidelines vary in relation to whether DRE should be performed alongside PSA. The combination of DRE and PSA testing may improve prostate cancer detection rates compared to either test used alone; the USPSTF reports that screening programs including DRE alone have not been adequately evaluated in controlled studies. In Australia, the NHMRC does not recommend DRE as a routine addition to PSA testing of asymptomatic men in the primary care setting. In the United Kingdom, following a recent modification to policy, GPs are advised to consider DRE findings in conjunction with PSA results.

Any choice of PSA cut-off involves a trade-off between sensitivity and specificity. With a cut-off point of 4.0ng/ml, the PSA test is reported to have sensitivity - the ability to detect cancer if it is there - of approximately 21% for detecting any prostate cancer and 51% for detecting high-grade cancers. The estimated specificity - the ability to give a true negative test result - is 91% (26). While lowering the PSA cut-off would improve test sensitivity and therefore lower the chance of missing clinically significant cancers, a lower PSA cut-off would reduce specificity, leading to more false-positive tests and unnecessary biopsies (27). This has been the source of considerable disagreement, and will be discussed in Section 1.5.

Age-adjusted PSA values were introduced in 1993 to improve the clinical impact of PSA. Different 'normal' reference ranges may be a means of improving specificity of the PSA test. PSA levels are influenced by the size of the prostate. As men age, it is common for the prostate to become larger, leading to higher levels of PSA in the blood and therefore impacting on the diagnostic performance of the test. Different normal reference ranges may be appropriate based upon a man's age (27). Age-defined PSA levels consider the impact of age on the diagnostic performance of the test. They also aim to reduce unnecessary investigation of older patients (28). The usefulness of age-specific PSA ranges remains controversial (29).

Table 1: Upper limits of "normal" serum PSA concentration at different age groups (ng/ml)(30)[2]

Age range	Upper limit of normal (ng/ml)
40-49	2.5
50-59	3.5
60-69	4.5
70-79	6.5

In Australia, the National Health and Medical Research Council (NHMRC) and Royal College of Pathologists (RCPA) recommend that PSA results be interpreted with reference to age-related

[2]Oesterling et al were among the first to establish age-specific normalised serum PSA values. They found serum PSA concentrations strongly correlated with age and prostatic volume. To define reference ranges, the authors condensed PSA values in a set of 471 reference individuals per decade. Using a regression method, the 95th percentile was determined as the upper limit of normal (reference range)

cut-offs (31). This level is quoted on the patients' results by the pathology laboratory undertaking the analysis (32). In contrast, the UK National Health Service (NHS) has recently set PSA >3.0ng/ml for all men, regardless of their age (33). Other variations have been suggested to improve detection of clinically important cases of prostate cancer, including the use of age-adjusted PSA cut-offs, free PSA, and PSA density, slope, and doubling time. No evidence has so far demonstrated that any of these testing strategies improve health outcomes (12) and I will not consider them in any detail here. Regardless of the threshold chosen, an "abnormal" PSA result does not indicate ill health in a clinical sense; PSA levels are an indicator of the possible existence of prostate disease, rather than being a reliable indicator of the presence or absence of prostate cancer.

Some, mostly urological societies, advocate for baseline PSA screening at or after age 40. Measuring PSA levels in younger men (45-49 years) may predict long-term risk of developing metastatic prostate cancer (34, 35). It is suggested that PSA levels at midlife can be used to stratify the intensity of screening over the next two decades of life (36, 37). In Australia, the 2013 Melbourne consensus statement recommended baseline PSA screening of men in their 40s to predict the future risk of prostate cancer and its aggressive forms (38). Advocates suggest that this risk-adapted approach may reduce the cost of screening, decrease over-detection of inconsequential tumours, and maintain detection of potentially lethal cancers (39).

1.3 Diagnosis of prostate cancer

If a screening test suggests higher than average risk, the next step is generally to refer the person for more testing, possibly a repeat of the screening test, and if concerns persist, diagnostic testing.

A prostate biopsy is the only method by which prostate cancer can be definitively diagnosed. TRUS-guided (i.e. under ultrasound guidance) or transperineal biopsy are currently the most common follow-up investigative procedures for asymptomatic men with an elevated PSA test result. Both procedures use a biopsy gun to collect tissue samples from regions of the prostate through the rectum. Generally there is no obvious lump to remove so urologists sample cells from different portions of the prostate. In Australia, different providers take different numbers of core samples. Historically, six

needle biopsy samples were taken; now, many urologists are advocating 12 or more, noting that the more samples that are taken, the more cancer is found (40). In the UK, a TRUS-guided biopsy involves taking 10-12 cores of prostatic tissue (41). Some researchers advocate for 'saturation biopsy', whereby 32 to 38 needle biopsy samples are taken, arguing that these increase the detection rate for microscopic cancers when compared with repeated normal biopsy procedures (42).

The diagnosis and grading of prostate cancer is based on histopathological examination of the collected biopsy samples. When a cancer is detected, biopsies can provide information about the stage and location of the cancer within the prostate, indicate whether the cancer remains localised, and how different the tumour looks from normal prostate tissue to suggest how aggressively it is likely to behave.

A prostate cancer's *stage* refers to its extent at diagnosis. Staging is important to both estimating prognosis and selecting treatment. The most important distinction in staging a prostate cancer is whether or not it appears confined to the prostate. T1 and T2 cancers are confined to the prostate (i.e. "early stage cancers"). T3 and T4 cancers have grown beyond the prostate into adjacent tissues (i.e. "locally advanced cancers"). Prostate cancers that have spread to local lymph nodes or beyond are incurable and are referred to as metastatic cancers (22).

A prostate cancer's *grade* refers to how aggressive the cells of the tumour look under a microscope. The Gleason score is the standard method of classifying prostate cancers. The pathologist looks at the samples and assigns a score from 1 (least aggressive looking or 'low grade') to 5 (most aggressive looking or high grade) to the most common and second most common pattern they see. These grades are combined to produce the Gleason score, ranging from 2 to 10. A lower Gleason score (5 or less) indicates a slower growing cancer, less likely to progress, behaving less aggressively, and a better prognosis. A higher Gleason score (8 to 10) indicates a faster growing cancer, more likely to spread beyond the prostate, and therefore behaving more aggressively. Most men have Gleason scores in the middle range (6 or 7). In practice, it is unusual for pathologists to report a Gleason score of less than 4 (22).

1.4 Treatment of prostate cancer

Once a man is diagnosed with prostate cancer, making treatment decisions is complex.

Treatment and management options for the treatment of prostate cancer vary depending on the cancer type. There is a broad spectrum of prostatic cancer from slow growing "clinically insignificant" tumours to rapidly growing "clinically significant" tumours. Treatment varies from active surveillance alone to multimodality treatment. Active treatment options include radical prostatectomy, radiation therapy, and androgen deprivation therapy. Table 2 below presents the various treatment options available to men who are diagnosed with prostate cancer. I present potential harms associated with the various treatment options in Section 1.5.

Table 2: Treatment options available to men who are diagnosed with prostate cancer

Treatment pathway	About this treatment option
Active surveillance	• Aim: delay curative treatment until there are signs of disease progression to avoid unnecessary, potentially harmful, treatments and complications (43) • Used in younger, healthy men with low-risk/low-grade cancer • Can include PSA screening, digital rectal examination, repeated biopsies, and/or MRI (44) • Increasingly popular internationally (45)
Watchful waiting	• Aim: delay palliative treatment until there are signs of disease progression • Used in men unlikely to benefit from aggressive treatment, such as the elderly, those with limited life expectancy, or comorbid conditions (26) • A passive management strategy; monitoring may occur regularly depending on the patient
Radical retropubic prostatectomy	• Aim: to remove the prostate gland, part of the urethra, and seminal vesicles • Used in men with clinically localised cancer; the most common treatment (46) • The use of robotic-assisted prostatectomy (the "da Vinci" robotic surgery machine) has surged and has received a lot of publicity
Radiation therapy	• Aim: to kill cancer cells via high-energy rays • Used in men with earlier stage cancers (internal and external), or to help relieve symptoms such as bone pain if the cancer has spread to a specific area or bone • Two main types: external beam radiation therapy (EBRT) and brachytherapy (7)
Androgen deprivation therapy	• Aim: to keep cancer cells from getting the male hormones they need to grow. Does not cure prostate cancer • Used in men with advanced disease • Involves oral or injection medications, or surgical removal of testicles to lower or block circulating androgens (7)

Having presented the basics of prostate cancer disease, PSA screening, and prostate cancer diagnosis and treatment, I will now consider the contested evidence for using the PSA test as a screening tool in asymptomatic men.

1.5 Complexities of the evidence base for prostate cancer screening

This section presents the complexities of the evidence base for prostate cancer screening practices, beginning with a brief discussion of the history and relevance of evidence based medicine (EBM).

The rise of PSA screening and evidence-based medicine (EBM)

It is generally accepted that Richard J Ablin first observed the PSA antigen in 1970; it was taken up by law enforcement agencies to produce material evidence of sexual assault in criminal cases (47). The first commercial PSA test was approved by the US Food and Drugs Administration (FDA) in 1986 to monitor the progression of prostate cancer in men who had already been diagnosed with the disease. A landmark study by Stamey et al published in the New England Journal of Medicine (NEJM) correlated higher levels of serum PSA with advancing stages of prostate cancer – establishing PSA as a useful marker for residual and recurrent disease (48). A 1991 NEJM study of 1600 men by urologist William Catalona reported that PSA screening could increase prostate cancer detection by 20% over rectal examination (49). It was highly influential because at the time, nearly 20% of men diagnosed with prostate cancer had an advanced form, motivating clinicians towards early detection (50). Clinician and patient demand for PSA screening increased dramatically following publication of the Catalona study, and its associated publicity and enthusiastic media coverage (51). Mass media campaigns were launched nationally in the United States for the 'ignored male disease' and there were widespread gender equity arguments in support of making the PSA test available (52).

While no formal screening program existed, PSA testing of asymptomatic men became widespread between 1986 and 1994 in the United States and Australia. It was effortlessly integrated into clinical care because it was easily accessible, inexpensive, and not invasive. Public awareness of PSA was high; in the US, mobile prostate screening vans were launched at sporting events and health fairs with the purpose of recruiting asymptomatic men to be screened (53). At this time, the PSA test had not yet been approved beyond the purpose of monitoring recurrence of disease. But a market for screening had been created (54).

Public and professional belief in the value of prostate cancer screening occurred before efficacy data from randomised trials was available. Proponents of screening advised clinicians to err on the "safe" side and offer screening, with justification that many men would miss out on the benefits of screening while waiting for the generation of evidence (55). On this view, the *possibility* of benefit trumped concerns about lack of demonstrated effectiveness.

In 1994, the FDA approved the use of the PSA test in conjunction with a DRE to test asymptomatic men for prostate cancer. Other high-income countries, including Australia and the UK, provided similar approval shortly after.

The PSA has been a controversial screening test since its establishment in clinical care. Before the PSA test was approved as a screening tool in the United States, peak medical bodies including the American Cancer Society (ACS) (56), American Urological Association (AUA) (57), and the American College of Radiology (58), recommended annual PSA screening for all men aged over 50 or for men over 40 years of age with a family history or of African American descent. Other professional bodies including the American College of Physicians (ACP)(59) and American Academy of Family Physicians (AFP) (60) found the evidence questionable and explicitly called for processes of informed consent (51). In 1996 the United States Preventive Services Taskforce (USPSTF) declined to recommend in favour of PSA screening owing to the as yet unproven benefits of screening asymptomatic men, and potential harms (61). Others also declined, citing insufficient evidence, including the National Cancer Institute (NCI). In 1997 the American Cancer Society qualified its recommendation for annual PSA screening to advise that men be informed of the potential harms of PSA screening as well as the benefits prior to being screened (62).

The Australian Cancer Society (now Cancer Council Australia) consistently advised against screening, from the time of its initial policy statement for health professionals released in 1995 (63); a position at odds with the American Cancer Society. The Royal Australian College of General Practitioners (RACGP) recommended against screening with either DRE or PSA in 1994 (64), despite increasing calls for the introduction of a prostate screening program from community groups. The growth in de facto screening in Australia alongside conflicting international positions on PSA

screening prompted the Commonwealth Government to clarify the purpose of PSA testing in primary care. In 1996, the Australian Health Technology Advisory Committee (AHTAC) produced an evidence review and report recommending against prostate cancer screening, on the basis that the evidence did not meet accepted criteria for benefits, risks, and costs (65). The report did not recommend any policy action to reduce the informal screening occurring in primary care.

In the United Kingdom, policy and health professionals resisted PSA screening from its inception. Two systematic reviews commissioned by the National Screening Committee (NSC) in 1996 each concluded that the available worldwide evidence gave no suggestion that screening would do more good than harm (66, 67). However in 1998, in response to public pressure and demand for prostate screening, the UK NSC announced that, although a national screening program would not be introduced, an informed choice initiative would be developed. The Prostate Cancer Risk Management Programme (PCRMP) was subsequently launched in 2002, referred to as the 'compromise policy' (68). This programme meant that men could receive a PSA test within the NHS if they had been fully counselled on the risks and benefits.

During this period, the evidence-based medicine (EBM) movement was also gaining momentum. Evidence-based medicine first emerged in the 1990s, with the aim to improve clinical practice with better evidence (69). It represented a shift from medicine's traditional reliance on clinical judgment as the foundation for medical decision-making (70) towards using current evidence to guide the process. The stated goal of EBM was to establish a scientific foundation for medical practice and medical decision-making (71).

The EBM movement emphasised empirical evidence from formal and systematic epidemiological research (69, 70, 72). Evidence was arranged in a hierarchy, with prospective randomised controlled trials (RCTs) and systematic reviews of those trials at the top (69). Retrospective and observational studies were less-well respected as forms of evidence. When PSA screening became popular, the evidence about it was strongly dominated by observational studies and retrospective analyses, not rigorous prospective studies measuring mortality or quality of life

outcomes (73). Difficulties in calculating causation and treatment benefits on the basis of observational data are well known (74).

A well-designed randomised controlled trial (RCT) is the gold standard for evaluating whether or not screening is making a difference: RCTs allow an accurate estimate of the number of men for whom early diagnosis and treatment impact on mortality as an endpoint (12).

RCTs are necessary because the evaluation of cancer screening is prone to several biases. Evidence about screening is particularly subject to lead time and length time bias, which I will discuss in relation to PSA screening. *Lead time bias* (Figure 2) occurs when a PSA test detects the prostate cancer before the onset of symptoms but does not change the time of death from the cancer. The survival of a patient who would develop symptoms at age 60 and die at age 70 will seemingly double if he is diagnosed through screening at age 50 and dies at the same age. The only real effect is that the man is aware that he has prostate cancer for a longer time (75). PSA screening (as opposed to diagnosis on symptomatic presentation) is more likely to detect a greater proportion of slowly progressive cancers, which have a better prognosis even in the absence of screening, including longer survival (*length time bias*). This exaggerates the survival benefits of screening. Survival rates include people with non-progressive prostate cancers, who die from something other than the prostate cancer (*overdiagnosis bias,* Figure 3). Overdiagnosis is discussed below and in Chapter 3.

Figure 2: Lead-time bias. Even if the time of death is not changed by screening—and thus no life is saved or prolonged—advancing the time of diagnosis in this way can result in increased 5-year survival rates, causing such statistics to be misleading (figure based on the original) (76)

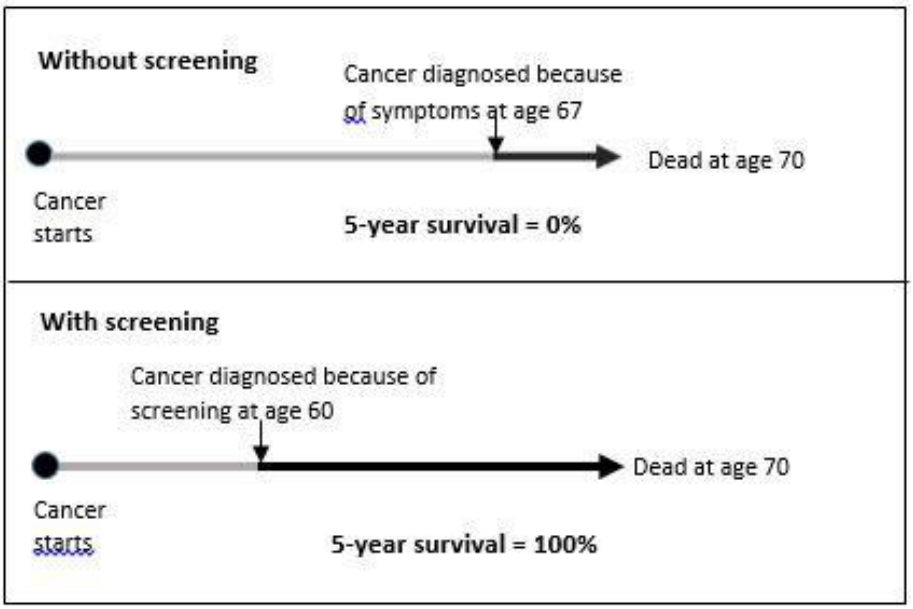
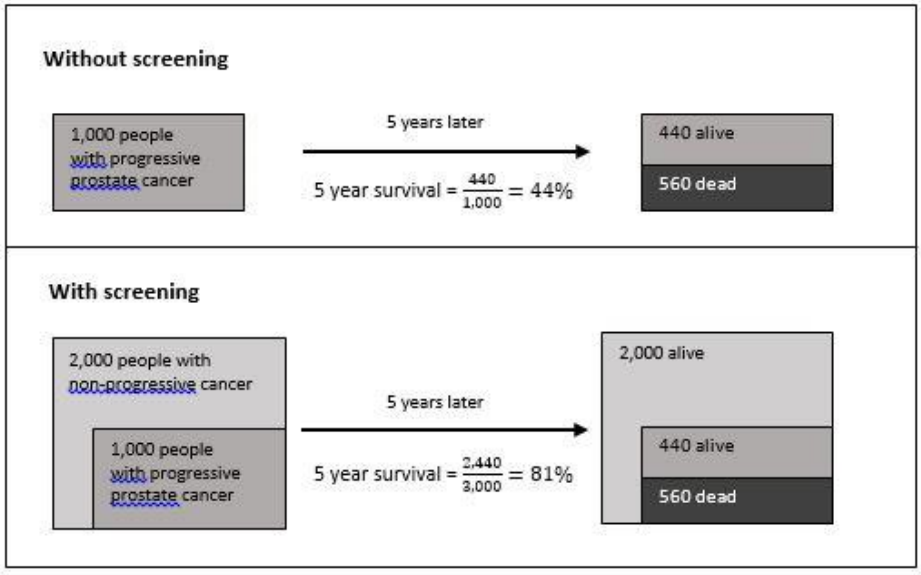
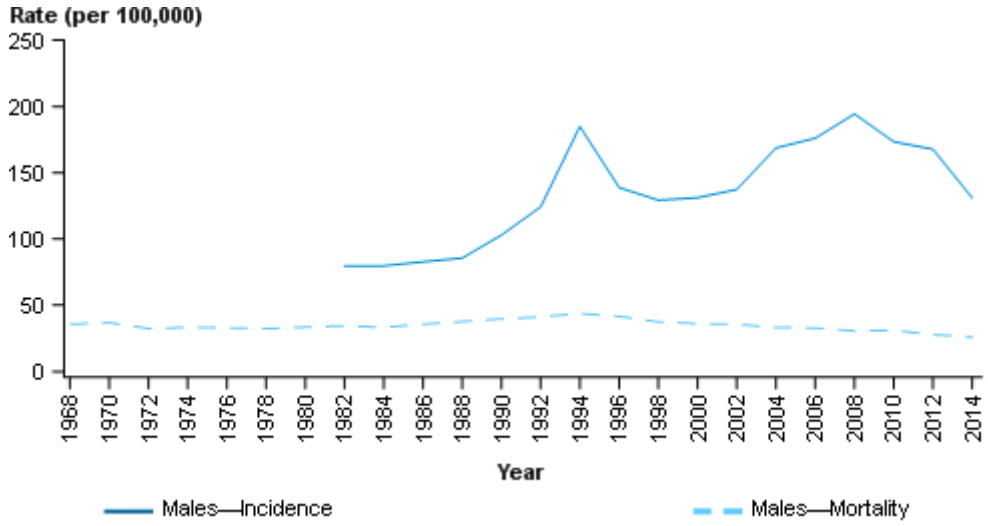


Figure 3: Overdiagnosis bias. Even if the number of people who die is not changed by screening—and thus no life is saved or prolonged—screening-detected non-progressive cancers can inflate the 5-year survival rates, causing such statistics to be misleading (figure based on the original) (76)



Detecting histological prostate cancer even though it may not cause symptoms or death has important implications for the interpretation of prostate cancer incidence data (77). Like survival rates, incidence rates include life-saving diagnoses as well as those 'screen-detected' cancers that would not have been diagnosed in the absence of screening nor threatened lives in the absence of screening (78) – so it is expected that more screening produces higher incidence (including indolent cancers). The age-standardised prostate cancer incidence rate in Australia increased from 80 cases per 100,000 males in 1982 to 163 cases per 100,000 males in 2012 (79). This is likely to have arisen, at least in part, due to the uptake of PSA screening.

Figure 4: Age-standardised incidence rates for prostate cancer 1982-2013 and age-standardised mortality rates for prostate cancer 1968-2014, males, in Australia (79)



In situations where cancer overdiagnosis through screening is occurring, the incidence of disease will tend to increase without much improvement in mortality from the disease. Many of the new cases of early-stage prostate cancer will not cause death if left untreated. Although there has been a decrease in prostate cancer mortality over time in Australia, from 36 deaths per 100,000 males in 1968 to 26 deaths per 100,000 males in 2014 (Figure 4), the rate has remained relatively stable for nearly 50 years (22), despite dramatic increases in prostate cancer incidence. Whether mortality trends can be ascribed to PSA screening is debated and difficult to determine.

A major development in the evidence base regarding PSA screening was the publication of two major RCTs.

The development of an evidence base for prostate cancer screening

Although RCTs are necessary to rigorously evaluate screening, conducting them is extremely resource intensive, generally taking at least 10-15 years (80). As previously discussed, the popularisation of PSA screening ran well ahead of any plans to conduct an RCT.

The continued debate over PSA screening in the 1990s prompted the initiation of a large, randomised controlled trial in the United States (the Prostate, Lung, Colorectal and Ovary (PLCO) screening trial) and another in Europe (the European Randomized Study of Screening for Prostate Cancer (ERSPC) (Table 3). The trials sought to answer the question of whether screening leads to an improvement in overall mortality – Will men over 50 years be likely to live longer, and/or be less likely to die of prostate cancer, if they have regular PSA tests? The aim was to enable definitive conclusions about the value of PSA screening.

The two RCTs had different control arms. ERSPC in Europe compared mass PSA screening for prostate cancer to no screening. PLCO in the US compared PSA screening to men following their *usual* medical care. However widespread promotion of PSA screening in the US before its effectiveness was proven was problematic for the PLCO trial. There was a high contamination rate: 52% of men in the control group (no screening) underwent screening, because 'usual care' for control group participants was opportunistic screening by the time the PLCO trial had begun (81).

A difference in the rate of deaths from prostate cancer was the most important endpoint in both trials. Additional reported outcomes included prostate cancer diagnosis, all-cause mortality, clinical stage, Gleason score, and treatment follow-up. The studies also provided some data on harms associated with screening. Given the controversy, the results of the RCTs were much anticipated (51).

Both study results were published simultaneously in the New England Journal of Medicine (NEJM) in 2009, and were among the 15 most frequently cited medical reports of 2009. This attention was attributable largely to the intense confusion they created, as their results were apparently contradictory. There were major differences between the trials with respect to recruitment procedures, screening interventions, PSA cut-off values, and screening intervals. I briefly summarise the design, findings, and limitations of the two trials in Table 3. The primary point to note is that the ERSPC trial reported a reduction in risk of death from prostate cancer as a result of screening with the PSA test while the PLCO trial did not.

Table 3: My summary of the PLCO and ERSPC clinical trials

The Prostate Lung Colorectal and Ovarian Trial (PLCO)	**The European Randomized Study of Screening for Prostate Cancer (ERSPC)**
• Men from 10 study centres across the USA • Trial conducted 1993 – 2001 • 76,685 men aged 55-74 years • Men randomised 1:1 to either the screening or control group. Men received either annual screening as the intervention or usual care as the control (usual care sometimes included screening) • Men with a previous history of prostate cancer and men currently receiving cancer treatment were excluded from participation • The methodological approach was uniform across all sites • Men in screening group were offered an annual PSA test for 6 years, of which 4 of the years also included an annual digital rectal examination • A PSA value greater than 4.0ng/ml was considered to be a positive screening result • Compliance: 85% and 86% of men randomised to the screening group complied with the screening protocol for PSA screening and digital rectal examination, respectively • Contamination: 52% of men assigned to the control group (no screening) underwent screening (82)	• Men from sites in 7 European countries (Belgium, Finland, Italy, Netherlands, Spain, Sweden, Switzerland) • Began in 1991, France joined 2001 • 182,160 men aged 50-74 years • Men randomised 1:1 to either the screening or control group, with the exception of Finland where randomisation was 2:3 • Men with a previous diagnosis of prostate cancer were excluded • Each country used different recruitment procedures, resulting in variations in the selection of participants with respect to age and length of follow-up plus different screening interventions, PSA cut-off values, and screening intervals • Most countries conducted screening every 4 years with the PSA test alone • A PSA value greater than 3.0ng/ml was considered to be a positive screening result; this differed between sites • Compliance: Rates varied across countries, but overall 82.2% of men in the screening group received at least one PSA test • Contamination: In the control arm, the contamination rate was 30.7% (86)
RESEARCH QUESTION • Does screening with digital rectal examination plus prostate-specific antigen reduce mortality from prostate cancer in men aged 55-74?	**RESEARCH QUESTION** • Does prostate-specific antigen screening reduce the risk of death from prostate cancer in men aged 50-74?
PRIMARY OUTCOME • Prostate cancer mortality	**PRIMARY OUTCOME** • Prostate cancer mortality in a core age group (55-69 years)
FINDINGS • Did not identify a significant reduction in prostate cancer-specific mortality (RR 1.15, 95% CI 0.86 to 1.54) in the screened group, with results at 10 years of follow-up	**FINDINGS** • Reported a significant reduction in prostate cancer-specific mortality (RR 0.79, 95% CI 0.69 to 0.92) in the screened group over a median follow-up duration of 11 years • Reported a significant 21% relative reduction (95% CI 31% to 8%) in prostate cancer mortality in the core age group • All-cause mortality did not differ between the screening and control groups

LIMITATIONS	LIMITATIONS
• Did not exclusively evaluate a screening program for prostate cancer. Men with a history of any of the cancer types under investigation (lung, colon, or prostate) were excluded from participation • High rate of contamination in the control group because the trial occurred in an already heavily-screened population. Data indicate that contamination substantially limited the ability of the PLCO to identify a clinically significant screening benefit (83) • A high rate of men had also already been screened prior to entering the study (84). This is likely to have eliminated some cancers detectable on screening, which lowers the power of the trial to detect a mortality difference (13) • Low rate of compliance for prostate biopsy following a positive screening result (85) • Detected cancers were treated according to standard (variable) practice. The decision to perform a biopsy was at physician discretion.	• Contamination rate not as high as PLCO but still considerable, which may introduce a bias towards not finding a benefit of screening • The European population was not as quick to adopt PSA screening as the US, and so there were fewer people that had been screened prior to study participation • It is difficult to assess the level of homogeneity in screening within the control group because the study centres were in different countries • The variations in the screening and follow-up methodologies employed across the eight participating sites may influence the results (82). Each country in the study adopted different recruitment procedures, screening interventions, PSA cut-off values, and screening intervals • The prostate cancer-specific mortality outcome of the trial was affected more by Sweden than any other country (87). This centre included younger participants, a lower PSA threshold, shorter screening intervals, and a longer follow-up, all of which may have affected the outcome • Biopsies of men in the screened group were carried out within the screening centres within academic institutions, strictly following defined biopsy indications. This raises the question of whether those men received better treatment (88). Compliance with biopsy indications was high.

Strong criticism of both the ERSPC and PLCO studies and their methodological limitations were and remain at the centre of public and professional debate (89). Despite this, results from both have been included in major reviews for the development of international policy on PSA screening. The Cochrane Collaboration - internationally recognised as the leading evidence synthesis resource – conducted a 2013 review and meta-analysis that included data from the PLCO and ERSPC. The authors concluded that prostate cancer screening did not result in a statistically significant reduction in all-cause mortality compared with no screening (RR 1.00; 95% CI 0.96-1.03) (82).

Table 4 below presents the summary of the evidence prepared by the RACGP for its members post-ERSPC and PLCO [2] (90). It illustrates the complex balance between benefits and harms that GPs and men need to consider when making decisions about screening for prostate cancer. Supporting people to understand these benefits and harms – which is typically the role of a GP - is no small task (91).

Table 4: Risks and benefits of PSA screening; adapted from Harding Centre for Risk Literacy 1000 men graph[3]

1000 men aged 55-69 years

WITHOUT annual PSA screening over 11 years	WITH annual PSA screening over 11 years
5 men **die** from **prostate cancer**	**4** men **die** from **prostate cancer**, **1** man is **possibly saved through screening**
190 men **die** from **other causes**	**190** men **die** from **other causes**
55 men alive with symptomatic prostate cancer	55 men alive with symptomatic prostate cancer
782 men alive with no prostate cancer	715 men alive with no prostate cancer
	87 men learned after biopsy their PSA result was a false positive
	28 men have side effects that require healthcare or hospitalisation after a biopsy
	25 men will choose to have treatment due to uncertainty about which cancers need to be treated. Many of these men would do well without treatment (i.e. they are **over-treated**)
	37 men with an elevated PSA were found to have slow-growing cancers (i.e. harmless and therefore **over-diagnosed**)
	7-10 men who have treatment will experience impotence and/or urinary incontinence or bowel problems. 0.5 men have a heart attack due to treatment.

Potential benefits and harms from screening for prostate cancer

Recommendations against screening for prostate cancer derive from the conclusion that the associated harms may outweigh any likely benefits (92). Decision making about PSA screening involves weighing up a wide range of potential benefits and harms.

The primary reported benefits of screening for prostate cancer include:

- *Decreased prostate cancer mortality:* PSA screening may have prostate cancer-specific mortality benefit among some age groups: the most recent data from the ERSPC trial reports a difference in

[3] This fact sheet was developed by Professor Lyndal Trevena, University of Sydney; Professor Paul Glasziou, Bond University; Adjunct Associate Professor Leanne Rowe, University of Sydney; and Dr Evan Ackermann, RACGP National Standing Committee – Quality Care. Published August 2015. © The Royal Australian College of General Practitioners

prostate cancer-specific mortality of 1.3 deaths per 1000 men over 13 years of follow-up (93); no data demonstrate a reduction in all-cause mortality (82).

- *Decreased incidence of metastatic prostate cancer*: PSA screening may decrease the risk of developing metastatic disease; the ERSPC showed that PSA screening almost halved the risk of metastatic prostate cancer presentation (82, 94).
- *Reassurance* provided by a PSA test result.

The primary reported harms of screening for prostate cancer include:

- *False positives*: About three-quarters of positive PSA test results are false-positives, when cut-offs between 2.5 and 4.0ng/ml are used (95). However there is no clear threshold at which prostate cancer can be conclusively diagnosed or ruled out from the results of a PSA test (96, 97).
- *Overdiagnosis*: The extent of overdiagnosis of indolent nonlethal prostate cancers, combined with the frequency and severity of treatment for such cancers, is arguably the most relevant harm limiting the acceptability of population screening for prostate cancer (26). Data from the ERSPC show approximately 35 overdiagnosed cases per 1000 men screened (27 additional cases per prostate cancer death averted) (93).
- *Overtreatment*: Treatment of overdiagnosed cases is considered both unnecessary because it does not improve disease outcome and is needlessly harmful because the treatments that follow are associated with substantial costs, increased risk of morbidity and compromised quality of life (98). Urinary incontinence, and erectile and bowel dysfunction are common harms of treatments (12, 82) and may be long lasting (99).

Limiting estimates of the harms of PSA screening to the harms of having a blood test alone, without considering other diagnostic and treatment harms, does not reflect current clinical practice because of the propensity by clinicians and patients to treat screen-detected cancer (12). In men diagnosed with cancer, 50 to 75% have low-grade disease (Gleason score <6), posing minimal

symptomatic or metastatic threat during their lifetime (100). Yet high numbers of men with PSA-detected prostate cancer opt to receive early treatment (101).

There is ongoing debate in the medical and broader community as to the value of PSA screening at both the population level and to the individual, with particular concern about the high [over]diagnosis rate and overtreatment of prostate cancer, especially low-risk cases (102, 103). The decision to engage in or offer PSA screening is almost always made by clinicians in primary care, in consultation, or not, with patients. In the following section I summarise explanations for why prostate cancer screening is such a challenge for GPs and policymakers.

1.6 The cultural context for PSA screening

PSA screening has been heavily debated in healthcare literature and mainstream media. The USPSTF decision recommending against screening for prostate cancer in 2012 was widely criticised in the media and in the scientific literature (104, 105), including by the American Urological Association (AUA), who accused the USPSTF of doing a great disservice to American men (106).

Figure 5: A snapshot of responses: a number of groups discredited recommendations by the USPSTF against PSA screening

Urologists Outraged over Government Panel's Recommendation to Stop Life-Saving Prostate Cancer Testing (107)

Prostate Cancer, to Screen or Not to Screen: What a Stupid Question or How the USPSTF Got it all Wrong (108)

The USPSTF position "condemns tens of thousands of men to die this year and every year going forward" (109)

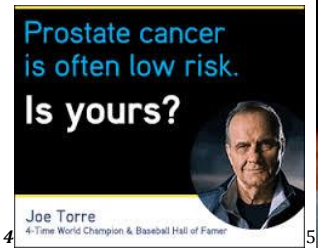
Advocates of screening have been aggressive towards those who have expressed reservations about the value of PSA screening. For example, in Australia in 2003, Alan Coates – a senior cancer-control authority - at 59 years, publicly declared that he personally would not seek PSA screening. Coates' position generated a widespread negative response, despite none of Australia's key cancer or public health bodies endorsing prostate screening at the time (110, 111). Coates was referred to as 'the apostate professor'. It was alleged that it was 'completely inappropriate for the chief executive of the Cancer Council, which runs a message that early detection is the best protection, to say that in his personal case he doesn't believe in it' [sic] (110, 112).

GPs are faced with patient demand and medical industrial support for PSA screening within and outside of the clinical setting (51). The commercial interests of test manufacturers and urologists have likely driven the spread of, and enthusiasm for screening. In 2010, Richard Ablin, the scientist who discovered the PSA test in 1970, argued against routine PSA screening, calling it a 'profit-driven public health disaster' (54).

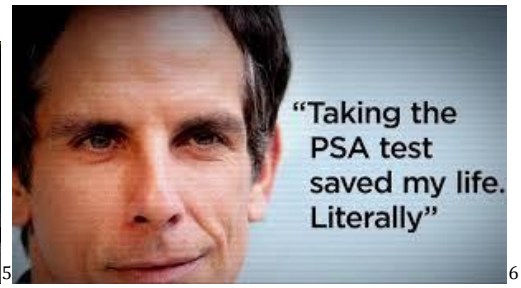
Highly publicised, sometimes misleading messages, have created a screening culture. Many mass campaigns urging men to 'get tested' have played out over the years in Australia and overseas. Men who have had their prostates removed become committed advocates for screening, 'living proof' that screening can save lives. The websites of advocacy groups that promote the benefits of screening commonly list a range of commercial sponsors in the pharmaceutical, medical equipment, and pathology industries, who could benefit financially from large numbers of men being screened and treated.

Figure 6: Examples of ads and campaigns promoting PSA screening

[4]



[5]



[6]

[7]

[8]

[4] *Everyman Cancer* campaign, The Institute of Cancer Research. Image available at https://charityuknews.wordpress.com/tag/fumblefriday-prostatecancer-patricksedgwick-balls/#jp-carousel-25509. Accessed May 08, 2017.
[5] *Your Prostate Your Decision* campaign, Zero – The End of Prostate Cancer, Prostate Health Education Network and Men's Health Network with support from Genomic Health. Image available at *http://www.multivu.com/players/English/7322251-your-prostate-your-decision-joe-torre-talks-about-prostate-cancer-genomic-testing-treatment-options-psa/*. Accessed May 08, 2017.
[6] *Ben Stiller Reveals Prostate Cancer Diagnosis, Advocates PSA Tests*, NBC Nightly News. Video available at http://www.nbcnews.com/nightly-news/video/actor-ben-stiller-reveals-he-had-prostate-cancer-advocates-routine-psa-tests-779195459673. Accessed May 08, 2017.
[7] *What's Your Number?* campaign, Prostate Cancer Canada. Image available at http://marketingmag.ca/brands/prostate-cancer-canada-wants-to-talk-numbers-2395/. Accessed May 08, 2017.
[8] *Stand By Your Man* campaign, ITV and Prostate Cancer UK. Image available at http://www.itv.com/news/calendar/2013-06-11/stand-by-your-man-prostate-cancer-awareness-campaign/. Accessed May 08, 2017.

Campaigns target men as consumers of health care, encourage individual decisions about screening, and thereby add to demand for the test. Messages contained in the ads and slogans can also be false and misleading (Figures 6, 7). For example, an Australian campaign featuring young, healthy male sporting and acting celebrities, claiming that prostate cancer kills men *just like me.* Mortality data shows there were no cases of men *just like them* in their 30s who died of prostate cancer in Australia (7, 22).

Figure 7: Examples of persuasive slogans that campaigns have used to encourage men to undergo or talk to their GP about PSA screening

- *"Man Up!"* [9,10]
- *"Do it for Dad"* [11]
- *"Fight for your man"* [12]
- *"The stats that every real man knows"* [13]

To complete part 1 of this chapter I present the current state of PSA screening policy and practice.

[9] *Blue September* campaign, Prostate Cancer Foundation of New Zealand. http://blueseptember.org.nz/. Accessed May 08, 2017.
[10] Man Up! Australia. http://manupaustralia.org.au/. Accessed May 08, 2017.
[11] *Do It For Dads* walk run, Prostate Cancer Canada. https://secure.e2rm.com/registrant/LoginRegister.aspx?eventid=213563&langpref=en-CA&Referrer=https%3a%2f%2fwww.google.com.au%2f. Accessed May 08, 2017.
[12] *Fight For Your Man* campaign, Janssen Phils. and Healthway Medical Clinics. http://lifestyle.inquirer.net/133143/women-urged-fight-for-your-mans-prostate/. Accessed May 08, 2017.
[13] *STATS* campaign, The Prostate Cancer Charity UK. https://www.coloribus.com/adsarchive/prints/the-prostate-cancer-charity-stats-7891855/. Accessed May 08, 2017.

1.7 The current state of practice

Because population PSA screening is not generally supported (unlike population screening programmes such as those for bowel or cervical cancer) prostate cancer screening is not centrally organised, there is not a population register or invitation system, and recruitment is primarily via clinicians in a primary care setting. In Australia and the United Kingdom, prostate screening is largely opportunistic – incorporated as part of a medical consultation and request initiated by the person being screened and/or his physician. Routine screening is common, especially in the Australian context, and occurs almost always in primary care settings (113).

GPs are the first point of contact for men wanting to know whether to undertake screening or not in Australia and the UK. An important starting point is to understand what the peak medical bodies advise GPs to do in their role as gatekeepers to the PSA screening test, and to specialist services. PSA screening is a particular case study for which new evidence has prompted the withdrawal of previous recommendations; this occurred several times over the course of this thesis (2012-2016). Table 5 summarises the position of the main relevant health authorities advising GPs on what to do about screening men for prostate cancer, in the absence of a national screening programme.

Most authoritative bodies currently support the concept of patient-informed, shared decision-making, regardless of whether they support or reject screening for prostate cancer. There is also general agreement that (1) PSA screening of older men (>70-75 years) and those with limited life expectancy (i.e. <10-15 years) is of limited or no benefit, (2) there are significant downstream harms associated with the clinical response to PSA test results, and (3) overtreatment of low-grade tumours is problematic (73).

While issues with PSA screening are universally acknowledged, some medical bodies have taken different positions in terms of the way they advise GPs to approach the issue. For example, while both the USPSTF and the AUA acknowledge that existing screening strategies lead to overdiagnosis and overtreatment, the USPSTF response is to recommend against screening in all men while the AUA recommends limiting screening to specific age ranges and increasing screening intervals. No policy position excludes or prohibits PSA screening as an informed choice taken by men in consultation with their doctors.

Table 5: USA, Australia, and UK recommendations for prostate specific antigen (PSA) screening of asymptomatic males for prostate cancer
(Note: the USPSTF issued a draft version of updated recommendations shortly before this thesis was submitted; the latest advice, pending public comment, is included in italics)

PROFESSIONAL BODY	ADVICE FOR HEALTH PRACTITIONERS	SOURCE OF EVIDENCE	CONCLUSION ABOUT EVIDENCE
USA **United States Preventive Services Task Force (USPSTF)** (12, 114) An independent volunteer panel of experts supporting primary care practitioners to provide evidence-based services	• If men raise PSA screening, or individual circumstances warrant, discuss PSA thoroughly • If men do not raise/request PSA screening, do not feel obligated to offer • Do not offer PSA without shared decision making • If patient understands benefits/harms, respect his preference for screening • *April 2017: Inform men ages 55 to 69 years about the potential benefits and harms of PSA-based screening for prostate cancer. Individualise decision making following discussion*	• PLCO and ERSPC trials plus comprehensive review of the evidence examining benefits and harms • *April 2017: commissioned reviews of the evidence of screening and treatments, and of existing decision analysis models*	• The very small mortality benefit of PSA-based screening for prostate cancer does not outweigh the risk of harms • *April 2017: The potential benefits and harms of PSA-based screening for prostate cancer in men ages 55-69 years are closely balanced*
USA **American Urological Association (AUA)** (23) A leading advocate for urology	• If men raise PSA screening, or individual circumstances warrant, make individualised decision • If 55-69 yo man requests PSA screening, use shared decision-making • Do not routinely screen men aged 40-54 years, men >70 years, or with <10-15 year life expectancy	• ERSPC and PLCO trials plus systematic review and meta-analysis of the published literature 1995-2013	• Screening should still occur, but only for certain patients
USA **American Cancer Society (ACS)** (115) The largest private, not-for-profit funder of cancer research. A single Board of Directors sets policy and related resource allocation	• Provide men with information about PSA screening from 50 years; at 40-45 years for men at higher risk • Use discretion to make screening decision for men unable to decide • DRE may be included	• A series of systematic evidence reviews of published literature 1950-2009. Results evaluated by ACS Prostate Cancer Advisory Committee	• It is not clear if the benefit of screening all men for prostate cancer outweighs the risks
USA **American College of Physicians (ACP)** (116) The second-largest physician group in the United States	• Discuss PSA screening thoroughly with men 50-69 years • Do not screen patients who do not express a clear preference for screening • Do not screen average-risk men under 50 years, over 69 years, or with a life expectancy of less than 10 to 15 years	• Rigorous review of existing prostate cancer screening guidelines developed by other organisations	• It is important to balance the small benefits from screening with harms and other side effects that result from certain forms of aggressive treatment

AUSTRALIA **National Health and Medical Research Council (NHMRC)** (13) Australia's leading health expert body comprising teams of specialists providing and promoting evidence-based public health standards	• If men raise PSA screening, offer evidence-based decisional support • Discuss PSA screening thoroughly before making screening decisions • If informed man requests PSA screening, offer PSA test every 2 years from age 50-69 years, and offer further investigation if total PSA is greater than 3.0 ng/ml • Do not offer DRE as routine addition to PSA	• Appraised 7 systematic reviews, including PLCO and ERSPC trials, plus supplementary non-systematic review of the literature describing benefits and harms	Compared with no PSA screening: • There is no effect of PSA screening on all-cause mortality • Present evidence is inconsistent as to whether there is an effect of PSA screening on prostate cancer mortality • PSA screening reduces the risk of prostate cancer metastases at diagnosis • It is unknown if PSA screening affects quality of life due to advanced prostate cancer
AUSTRALIA **Royal Australian College of General Practitioners (RACGP)** (117) Australia's largest professional general practice organisation; supports GPs in patient care	• Endorsed NHMRC guideline • If men do not raise/request PSA screening, do not raise this issue • If men raise PSA screening, discuss PSA thoroughly • Do not offer PSA without shared decision making • If a man chooses screening, both PSA and DRE should be performed	• ERSPC and PLCO trials plus two systematic reviews (103, 118)	• Evidence shows the harm of a false positive vastly outweighs the possible benefit
AUSTRALIA **Urological Society of Australia and New Zealand (USANZ)** (119) Peak professional body for urological surgeons in Australia and New Zealand; works with advocacy and support groups such as the Prostate Cancer Foundation of Australia (PCFA)	• Endorsed NHMRC guideline. In addition: • If younger men (<55yo) are interested, offer single PSA test and DRE; individualise follow-up PSA tests • If confident, offer DRE to men 55-69 years	• ERSPC and PLCO trials	• PSA-based screening, and subsequent treatment where appropriate, has been shown to reduce prostate cancer mortality in large randomised studies and should be offered to appropriately selected patients

UNITED KINGDOM **National Health Service (NHS)** (120) The public health services of England, Scotland, and Wales; provides a comprehensive range of health services The National Institute for Health and Care Excellence (NICE) advises the NHS on effective, good value healthcare	• Do not offer systematic PSA screening • GPs should not proactively raise the issue with asymptomatic men, but PSA can be provided at patient request	• Systematic reviews of the best available evidence and explicit consideration of cost effectiveness • When minimal evidence is available, recommendations are based on the Guideline Development Group's experience and opinion of what constitutes good practice (121)	• Currently there is no evidence that the benefits of a PSA-based screening programme would outweigh the harms • More research is needed to determine whether a screening programme would provide men with more benefit than harm
UNITED KINGDOM **The National Screening Committee (NSC)** (33) The UKNSC reviews screening policies every 3 years and makes recommendations to ministers in the 4 UK countries about whether or not a screening programme should be set up. Published the Prostate Cancer Risk Management (PCRMP) material for GPs	• Do not offer systematic PSA screening • GPs should not proactively raise the issue with asymptomatic men, and GPs should use the Prostate Cancer Risk Management (PCRMP) materials to counsel asymptomatic men aged 50 and over who ask about PSA screening • Any man over the age of 50 years, who asks for a PSA test, after careful consideration of the implications, should be given one	• Evidence used to support the response: PLCO, ERSPC, Goteburg subgroup of the ERSPC, ProTecT, PROBASE Trial • Reviewed the evidence published between 2010 and 2014	• Evidence shows a benefit of prostate screening to reduce prostate cancer deaths by 21%. However the evidence is not yet sufficient to justify introducing a national screening programme using PSA as the harms still outweigh the benefits
UNITED KINGDOM **The European Association of Urology (EAU)** (122) Leading authority within Europe on urological practice, research, and education	• Offer early baseline PSA screening to men at elevated risk for prostate cancer (over 50 years, men over 45 years with family history, African-Americans) • If man is informed, offer PSA screening and DRE	• Reviewed the public literature 1990-2013 • Included information from the ERSPC and PLCO trials, and the 2013 Cochrane review	• Based on the evidence, an individualised risk-adapted strategy for early detection might be offered to a well-informed man with at least 10-15 years of life expectancy. • The long term benefit for survival and QOL of an early baseline screening approach remains to be proven at a population level

PSA screening in general practice

Since primary care providers play a critical role in screening, it is paramount to examine their perspectives on prostate cancer screening in this context of significant controversies and conflicting guidelines. GPs in primary care order the majority of PSA screening tests; they have implicitly been given the responsibility for guiding men's decisions about whether or not they should have a PSA test.

In Part II of this chapter I present a review of the literature about PSA screening in general practice, to illustrate existing research interest in this topic and to illuminate gaps in our current understanding of these issues.

Part II: A review of the literature

The following section reviews the international literature on how and why primary care clinicians engage with, reason about, or use the PSA test for prostate cancer screening in their clinical practice.

Literature Search

The review was based on a search of three databases (Medline, Embase, Web of Science). Articles published from inception to June 2016 were considered for inclusion. The literature search was performed by one researcher (KP). The search was limited to English language. The reference lists of all selected articles were also reviewed.

Search Strategy

The search strategy, including variations of relevant keywords, was devised with the assistance of a university librarian[14].

[14] Medline and Embase:
1 exp Prostatic Neoplasms/
2 prostate cancer.mp.
3 (cancer adj2 prostate).tw.
4 exp Prostate-Specific Antigen/
5 prostate specific antigen.mp.
6 (PSA and (test* or screen*)).mp.
7 exp Primary Health Care/
8 general practi*.tw.
9 GP.tw.
10 ((family or internal or general) and (doctor or physician or internist)).tw.
11 (health care and (clinician or professional or provider)).tw.
12 1 or 2 or 3
13 4 or 5 or 6
14 7 or 8 or 9 or 10 or 11
15 12 and 13 and 14
Web of Science:
(prostate cancer) and (prostate specific antigen or PSA) and (screen or screening) and (general practice or primary) and (doctor or physician or clinician)

Inclusion and Exclusion Criteria

A study was considered eligible for inclusion if the study participants included primary care providers (general practice and/or family practice and/or internal medicine); it reported factors implicated in or influencing the use of the PSA test as a screening tool for detecting prostate cancer risk in general practice; and it was published in English. Articles were excluded if they were editorials, opinion pieces, reviews, or guidelines; focused on patient variables or patients' point of view; studies on diagnosis, treatment and management of prostate cancer; incidence and prevalence studies; and clinical/pathology outcome studies. The review was limited to peer-reviewed papers.

Study Selection and Review Procedure

The initial selection of papers was based on titles and abstracts using the inclusion and exclusion criteria, and was performed by one reviewer (KP). At this stage, all potential studies were included for consideration pending full text review. For the next stage, the same criterion was applied to the full texts of the studies. Two additional reviewers (my thesis supervisors) applied the criteria to a subset of the studies separately; the team discussed and resolved any disagreements.

Data Extraction and Analysis

Data was abstracted and recorded in a standardised template by one reviewer (KP), including information on author; country of origin; sampling technique; sample size; methodologies; and findings. The research question was: *What factors explain PSA screening practices in primary care?* Data was initially coded to encompass all potentially relevant factors involved in PSA screening decision-making and clinical practice. Initial codes were collapsed into a shorter list of more inclusive codes. A taxonomy of factors was developed based on these revisions. The two additional reviewers applied the codes to a subset of studies to clarify and confirm usability of the codes.

Findings of the review

57 studies were identified reporting on prostate cancer screening in general practice, from the GP perspective. The majority of studies reported on practice in the United States (n=30). 6 studies were conducted in Australia, 5 in the United Kingdom. Four of the studies used qualitative methods (n=1 UK, n=3 US). Most data in the quantitative studies was collected via the use of questionnaires alone or questionnaires with vignettes. The questionnaires included questions using a Likert scale, questions that asked respondents to "choose one of the following", and yes/no questions.

11 studies were published in the 1990s, when PSA screening was still relatively new (but being enthusiastically adopted), advice to GPs about PSA screening was highly conflicted, and potential harms were largely unknown. Less than one-third of the studies were published after 2009, the year that ERSPC and PCLO reported preliminary results. In addition, many of the studies published post-2009 report on data collected in the years preceding 2009.

The variations in screening policies and within and between jurisdictions discussed earlier in this chapter are relevant to interpretation of these studies. Differences in the epidemiology of prostate cancer between populations, and variation in screening modalities (e.g. use of DRE) are also reflected in the study designs. For example, two of the included studies focused on African American clinicians (123, 124). The studies collectively illustrate the complexity of influences on the PSA screening practice of GPs around the world.

In this section I present the findings of the international quantitative findings under four broad categories reflecting the content of the included literature: determinants of screening practice, PSA screening in the clinic, communicating with men about PSA screening, and the place of evidence and guidelines. I then present findings from the subset of quantitative work specifically conducted in Australia and the United Kingdom, to highlight the most relevant background to this study. I conclude this section with the findings of the four qualitative studies and describe the different types of research questions that have been investigated using qualitative methods.

1.8 Findings of the quantitative literature

Overall, the quantitative studies confirm the central and influential role of GPs in directing and managing decisions and discussions in the clinic about PSA screening. Although patient request was a common driver, GP knowledge, beliefs, characteristics, and practice context strongly shaped screening decisions and outcomes.

Determinants of screening practice

A number of quantitative studies identified, mostly via surveying clinicians, those factors associated with higher or lower rates of PSA screening. These studies were of two kinds. Some asked GPs to report the characteristics of patients that changed their practice. Others looked for correlations between GPs' screening practices and their personal or practice characteristics (Table 6).

Table 6: Factors associated with higher or lower rates of PSA screening, as reported in the quantitative literature (n=53 studies)

	Factors associated with *higher* likelihood that an individual patient will be screened	Factors associated with *lower* likelihood that an individual patient will be screened
Patient characteristics	• Patient requests PSA screening (125-136) • Age, specifically men >45-50 years (125, 126, 129, 136) • Higher risk patients: Family history of prostate cancer (125, 129, 130, 135, 137-141); African American (139, 142) • Anxiety about prostate cancer (140) • Lower urinary tract symptoms (132, 134, 137, 142-144)	• Age, specifically men > 75-80 years and < 40 years (138, 145, 146)
Clinician characteristics	• Less knowledgeable about prostate cancer and/or prostate cancer screening (125, 135, 136, 142, 147-149) • Attitude towards screening or the PSA test (125, 126, 149) • Beliefs (that prostate cancer screening represents standard of care) (126, 133); belief in PSA test or prostate cancer screening efficacy to improve survival (125, 126, 129, 138, 139, 150-155); • Older age (126, 131, 133, 144, 148, 152, 154, 156-158) • Male gender (126, 130, 147, 148, 156); not associated (129, 159) • More years in practice (130, 133, 147, 148, 159) • African American (123, 146, 160) • Previous experiences, personal and professional (130, 141, 148) • Personal screening behaviour (GP has had PSA test, or reports he would have the test) (147, 148, 161) • Malpractice concerns (149, 150, 162, 163); anticipated regret for not ordering • Discomfort with uncertainty (134, 163)	• More knowledgeable about prostate cancer and/or prostate cancer screening (125, 135, 136, 142, 147-149, 164) • Attitude towards screening or the PSA test (125, 126, 149) • Beliefs (lack of scientific evidence, question efficacy of the PSA test, concern about treatment side effects)(125, 126, 129, 137, 139, 150, 162) • Younger age (126) • Female gender (126) • Academic or teaching affiliation, membership in a professional association (130, 133, 144, 147, 148, 150, 152, 158, 162) • Fewer years in practice (148) (130)
Contextual characteristics	• Urban or rural practice location (126, 130, 155, 165) • Routine health examinations (127, 130, 138, 143, 148) • Practice environment: local urology service available (130, 159); high volume practice (129, 160); solo practice (rather than multi-specialty) (160); private practice (166) • Form of GP remuneration (fee-for-service) (129, 159)	• Urban or rural practice location (126, 130, 152, 155) • Insufficient time (139, 150, 151) • Practice environment: group or multi-specialty (not solo) practice (167); academic setting (152) • Affiliation with GP College (158) • Longer consultations (168) • Recommendations from professional organisations (163) • Form of GP remuneration (salaried) (129, 159)

Patient request was the most consistently reported factor prompting prostate cancer screening. Two-thirds of the studies reporting on patient request as a primary factor sampled clinicians in North America, where PSA screening was quickly adopted in clinical practice and consequently has a significant public profile. A patient's request for screening is reportedly difficult to decline in the United States (134). GP participants in New Zealand and the United Kingdom reported not feeling pressured to perform PSA screening (153, 130). These findings may reflect differences in policy environments (as presented in Part I of this Chapter) and public attitudes towards screening.

Clinician knowledge about prostate cancer and belief in the utility of the PSA test were important factors. As would be expected, clinicians who tested routinely were more likely to accept that the PSA test is a good screening tool offering substantial mortality benefit. Clinicians who did not test regularly were more likely to question the test's value and evidence-base, and less likely to believe it offered a mortality benefit.

In many studies, those clinicians who scored higher on tests of knowledge about prostate cancer and PSA screening epidemiology screened less frequently or more age-selectively, while lower knowledge scores were associated with a higher propensity to screen. Shared decision making (SDM) —generally recommended when making PSA decisions—appeared more likely from GPs who had greater knowledge scores (147). Physicians in one US study reported low confidence in their knowledge about PSA screening and felt uncomfortable with their ability to answer patients' questions about it, despite recording high knowledge scores (135). Knowledge alone may be insufficient to help GPs to make confident recommendations.

GPs more likely to recommend a PSA test were of older age, male gender, and had more years in practice. Male GPs who would have a PSA test themselves were up to eight-times more likely to screen men than GPs who would not have a test (148). Nearly all GPs 50 years or older in one US study had personally received a PSA test (147). Prior professional experiences were also relevant: clinicians who reported having an asymptomatic patient diagnosed with prostate cancer following a PSA test were more than

three times more likely to screen asymptomatic men compared with their colleagues with no such experience (130, 148).

Lastly, as shown in Table 6, several contextual factors have been associated with prostate screening patterns, such as urban clinicians being more likely to screen than rural clinicians. This may be partly due to limited access to resources—including urological services—in rural areas. In Australia, GPs in metropolitan practice were more likely to discuss PSA screening opportunistically than those GPs in rural locations (158). Other studies conducted in the UK and US reported PSA screening highest among GPs in rural practices and lowest in urban practices (e.g. (130). These findings likely reflect different structures of social demographics in the respective locations.

PSA screening in the clinic

A number of studies reported on clinician PSA screening behaviour in the clinic. In most studies, a high percentage of clinicians (up to 95% in US studies, 75% in Australia) offered PSA screening routinely or recommended screening for prostate cancer using the PSA test (123, 126, 128, 129, 131, 132, 135, 138, 144, 145, 148-151, 154, 159, 168-171). There was a comparatively low rate of GPs actively arranging appointments for PSA testing of healthy men in the United Kingdom (21%) (132) and Denmark (14%) (143).

Several studies reported on clinicians routinely ordering PSA screening for men outside of policy recommendations (e.g. >75 years) (145, 146, 149, 172).

Patient expectation for clinicians to continue screening was the most frequently cited barrier to discontinuing PSA screening in the US context, reported by three-quarters (74%) of respondents (146, 163).

Communicating with men about PSA screening

Because of the complexity of PSA screening decisions, excellent clinical communication is necessary to ensure men have the opportunity to make informed screening decisions. Yet comparatively few studies have focused on this specific component of the screening process.

The existing literature suggests considerable variation in whether clinicians communicate with men about, or prior to, PSA screening, and also in the nature of that conversation. Overall, the included studies suggest that most clinicians at least informed men that their PSA was being checked, but there were exceptions. Between 20 and 25% of US physicians surveyed did not engage in pre-screening discussions (139, 162, 163); these physicians were more likely to attempt to persuade a reluctant man to be tested (139).

Clinicians who did communicate with men prior to PSA screening took different decision-making roles. Some clinicians shared the decision about screening or not screening with the patient (147, 150). Some clinicians had a discussion with the patient, and then expected them to decide (137, 139). Some clinicians encouraged screening, or attempted to talk patients into having a PSA test (123, 160, 167). These studies were of US physicians, except for one from the UK (137). There is an absence of literature exploring the views and communication practices of Australian GPs and their role in that process.

Some studies asked clinicians about barriers to communicating with men about prostate cancer screening. Clinicians reported that dissuading patients from having a PSA test consumes precious consultation time (168); patients have difficulty understanding the issues despite the clinician's best efforts; and most patients will elect to get the PSA test anyway (153). GPs in a New Zealand study reported needing more knowledge to advise patients, and more than half (56%) felt it was difficult to give a balanced view to patients regarding PSA screening (153). Further exploration of these issues is warranted to understand communication challenges, and to ascertain whether they can be remedied via clinician education, training, or resource development.

The place of evidence and guidelines

Studies have investigated whether clinicians refer to clinical guidelines, whether guidelines influence screening decisions and practice, and which guidelines are most influential. Findings relating to agreement with guidelines and use in practice need to be interpreted in the context of time and place. For example, Lawson et al reported that most clinicians agreed with published guidelines (166); but this study was conducted in the USA in 1993, when the American Cancer Society recommended routine screening, so cannot be generalised to contemporary clinicians. Similarly, Drummond et al reported that high screening GPs were less inclined to apply 'evidence-based' information in favour of trusting their salient experience and 'gut feelings' (148); but this study was reported from Ireland in 2009 when there was no national policy or guidelines on prostate cancer screening.

Most studies included in this review were US-based and referred to the recommendations of the United States Preventive Services Task Force (USPSTF), which has advised against prostate cancer screening of men of all ages since 2012. Most (93%) US physicians surveyed in 2012 were familiar with the USPSTF recommendation (163) and many considered it the most influential clinical guidance (135). However, fewer than half (41%) of physicians who agreed with the recommendation (against screening) would no longer order routine PSA tests (163).

> The USPSTF recently (April 2017) released an updated draft recommendation statement for public comment, from which a final version will be developed. The Task Force now recommends offering or providing PSA screening to selected patients depending on individual circumstances, rather than discouraging all PSA-based screening as was previously recommended (114).

A large number of physicians practicing in the US and Australia disagreed with the 2012 USPSTF recommendation (155, 163). I present studies that have specifically investigated Australian GPs' views on Australian policy and recommendations in the following section.

The nature of the guideline environment may be reflected in screening behaviour. I explained in Part I of this chapter that guidelines in the USA have been notably contradictory since the PSA test was introduced; for instance, the USPSTF recommendations were in direct opposition to those published by the American Cancer Society in the 1990s and 2000s. In contrast, a single national agency is responsible for formulating practice guidelines for all physicians in France and has opposed routine prostate screening since 1998 (173). A study comparing practice in the USA and France in 2000 identified avoiding regret about anticipated 'bad outcomes' (i.e. not ordering a PSA test for a patient who was subsequently found to have advanced prostate cancer) as the strongest predictor of ordering PSA tests in US physicians. This was not a concern for French physicians (134). Clear guidance from one authority may offer GPs important support for less frequent screening.

Next I present quantitative research that has been conducted in Australia and the United Kingdom, because this is particularly relevant to the context of this thesis. These studies are a subset of those already discussed.

Quantitative studies conducted in Australia

There have been six quantitative studies conducted in Australia (128, 144, 155, 158, 165, 174). Two of the studies were published in 2015 (128, 155), after publication of the two trials (ERSPC and PLCO) and significant international policy changes that ensued (the USPSTF's D recommendation was made in 2012, as was the RACGP's policy against PSA screening unless specifically requested). The other four studies were older: one published in 1995, two in 1998, and one in 2003. No Australia-based research published between 2003 and 2015 was identified. All studies concluded significant variation in practice.

Almost half (43%) of Australian GPs surveyed in 1996 indicated that PSA screening was effective in reducing premature mortality from prostate cancer, and more than half (57%) would recommend a PSA test during a health check (158). Twenty years later, three-quarters (74%) of Australian GPs surveyed indicated that PSA screening is at least 'somewhat effective' in reducing prostate cancer mortality in an

average risk male (155), and more than half (57%) always or usually offered prostate screening: opportunistically (56%) and at patient request (39%) in 2012 (128). So despite significant policy changes over the years both within Australia and internationally, GP beliefs in screening and screening behaviour may be relatively unchanged.

In the earlier study, GP awareness of relevant Australian guidelines on prostate cancer screening was low: almost half were unable to recall publications from the RACGP or Australian Cancer Society (the two existing relevant guidelines at that time). About 40% of the GPs who were familiar with the guidelines indicated that they were useful, but most still advocated screening (158), despite that not being the recommendation of any of the available guidelines. In the more recent research, GPs were familiar with a wide range of Australian guidelines, but most (80%) reported the guidance not clear (128, 155). One-quarter (28%) did not refer to any guideline (128).

One study included in this review reported specifically on the concept of overdiagnosis, and it was from Australia in 2012. There was clear variation in GP opinion about whether prostate cancer is overdiagnosed: one-third of GPs surveyed believed that prostate cancer is overdiagnosed while nearly two-thirds (61%) believed prostate cancer is a disease that needs to be diagnosed (128). There are ongoing mixed attitudes about overdiagnosis and PSA screening more broadly in the Australian context.

Quantitative studies conducted in the United Kingdom

Four studies conducted in the UK context used questionnaires for data collection. Three of the four studies were based in Northern Ireland or Ireland (130, 132, 148). Although Northern Ireland has the NHS, it is organised differently to the NHS in England and Scotland. As I noted previously, the one study from Ireland was conducted at a time when there were no national policy or guidelines for prostate cancer screening. These studies are not discussed in any further detail here because they are less relevant to the findings of my study.

The one remaining study, reported in 2005, used a combination of direct questions and patient vignettes (137). Most UK GPs expressed support for policy recommending against routine screening. In contrast to the Australian GPs' reports – which suggested PSA screening is a common feature in primary care – it appeared that routine screening in the UK context was rare. The majority of GPs (65%) in this study had discussed PSA screening with fewer than 5 men in the past 3 months; one-quarter had not conducted any PSA tests for asymptomatic men in this time (137). 83% of the GPs preferred to engage patients in thorough discussion of the issues, in comparison to the findings presented earlier regarding US-based physicians not engaging in pre-screening discussions (one-quarter of US-based GPs surveyed ordered PSA tests without first discussing it with patients).

1.9 Findings reported in the qualitative literature

The findings of four qualitative studies (124, 157, 175, 176) are presented separately here to contextualise my own qualitative study. Three qualitative studies have been conducted in the United States and one in the United Kingdom, reported between 2004 and 2007 (note again no studies post-2009). One US study collected data only from African American clinicians (124). The qualitative studies have focused on determinants of screening practice and GPs' discussions with men about PSA screening.

Determinants of screening practice

In 2001 and 2002, Cooper et al conducted telephone focus groups with US primary care physicians about their PSA screening practice and factors influencing those practices. The authors identified two distinct practice patterns: "routine screeners", who recommended and encouraged regular PSA screening for asymptomatic men, and "non-routine screeners". *Non-routine* screeners were a minority group: they neither recommended for or against PSA screening, but rather discussed the implications of PSA screening before offering it. *Non-routine screeners* practiced to guidelines derived from the scientific evidence. *Routine* screeners typically based their practice on their professional and personal experience, rarely discussed the test prior to screening, and uniformly believed that PSA screening saves lives (176).

Interestingly, both groups reported high screening rates, despite describing considerably different practice patterns. One possible explanation is the strength of patient expectation: non-routine screeners reported that pre-screening discussions rarely dissuaded patients from having a PSA test.

Two studies emphasised the powerful influence of personal and professional experiences on PSA screening practices (124, 176). Clinicians explained vigilant screening by recounting the diagnoses or deaths of family members or friends, deaths of patients who were not screened, survival of patients who were screened, or their own personal experience with prostate cancer. Other clinicians reported instances of patients undergoing repeated biopsies with no cancer ever found, which served to deter over-screening (176).

Communicating with men about PSA screening

The discussions that clinicians reported having with asymptomatic men about PSA screening varied widely, depending on the personal views held by the clinician about the value or lack of value of the PSA test: they placed different emphasis on certain key points, provided different degrees of detail, and were more or less impartial in presenting information.

Some GPs in a UK-based study, where PSA screening is strongly discouraged, emphasised the drawbacks of screening to counter men's primarily positive views of the test. The authors noted that GPs gave relatively little attention to the potential benefit of screening for prostate cancer (175). All UK GPs that were interviewed in this study said they had some degree of discussion with all men prior to ordering a PSA test.

In contrast, most physicians in Cooper et al's US-based study routinely recommended that men be screened and believed opportunistic screening important. Some reported only having in-depth discussions with patients who declined the test, to persuade them to change their mind and agree to be screened (176). A number of physicians preferred to avoid in-depth discussions altogether (157, 176), reasoning that it would cause patients unnecessary anxiety: one physician likened a discussion about the

implications of PSA screening to telling his children there was a possibility that they would be in a car accident every time they left home (176).

African American men have a documented greater burden of prostate cancer than white men, which appeared to influence communication approaches: African American physicians described pre-screening discussions (with racially mixed patient populations) as typically directed towards explaining the reasons the patient should have a PSA test and reported little patient involvement in the screening decision (124). These GPs' were most influenced by evidence highlighting mortality in African American men, and higher personal risk for prostate cancer.

Overall, the literature reviewed provides an array of determinants of screening practice and diversity in approaches to PSA screening. These findings highlight the guiding role of the clinician in directing screening decisions and action, and the importance of context in explaining screening approaches. However there is still little known about doctor's perspectives on prostate cancer screening in primary care, particularly the experiences of Australian GPs. I present the context, rationale, and aims of the study in Part III of this Chapter.

Part III: Context, Rationale and Aims

1.10 The context of this study

Primary health care in Australia and the United Kingdom

This study was undertaken in primary health care in two jurisdictions: Australia and the United Kingdom. Some observations about the structure of these two systems, particularly their differences, are necessary to frame the methodology and results chapters of this thesis. Detailed information regarding sampling of clinicians practicing in the two locations is provided in the methodology section, Chapter 2.

Primary health care in Australia serves as a gateway to the health system. Australia's primary health care service delivery system has been described as complex, fragmented, and often uncoordinated (177). Healthcare in Australia is provided through interdependent public and private sectors, providing both equivalent and complementary services. Australia's health system is funded and administered by several levels of government (national, state/territory, and local); in addition 55.6% of the population over 18 years has private health insurance (2013) (178), encouraged by taxation penalties on those without private health insurance who earn over $90,000/year (179).

Public health care is funded under Medicare, a national public health insurance scheme funded by taxation, which provides all Australians with access to free or subsidised healthcare. The Medicare Benefits Scheme (MBS) governs the tests, procedures and services that are, or are not, subsidised by the Australian government, allocating a Medicare Benefits Schedule number to those services that are subsidised. PSA testing is included on the schedule (item 66655), which allows payment of a benefit for a PSA test once in a 12 month period for men who do not have previous prostate disease (180). Additional item numbers (66656, 66659, 66660) code for patients who have prostatic disease, including follow-up testing for previously diagnosed prostate cancer. Up to 4 PSA tests are permitted in a 12-month period (180), depending on the purpose of the test and the PSA value.

In Australia, general practices essentially operate as private businesses. Most primary health care providers charge fee-for-service, including via the MBS. Doctors bill for each item of service they provide, and different GPs can charge different fees; any 'gap' between the MBS rate and the GP's fee is paid by the patient. Billing policies vary between practices: some practices 'bulk bill', where the GP bills Medicare directly for the service provided at no cost to the patient, while others bill the patient directly. In the period 2012-2013, 82% of GP attendances were bulk-billed (177).

The United Kingdom has a long-established and highly developed system of generalist, primary care delivered by GPs (181), with strong continuity of care (182). Health care in the United Kingdom has been centrally funded through the National Health Service (NHS) since 1948. The NHS provides both primary and specialist health care which is largely free at the point of delivery. The NHS is generally highly regarded by the British public and core features of UK primary care have been constant since its inception (182).

NHS GPs are responsible for a defined population. There is universal registration with a single practice of the patient's choice. Patients may select a GP, but their choice is restricted within geographical areas. The incidence of people changing their GPs – other than for reasons of changed residential location – is low. Most people have a long-standing relationship with their GP (181). As in Australia, GPs act as gatekeepers to specialist care. Specialists work largely in public hospitals. GPs work in practices, which they usually own, in partnerships, typically of 4-6 self-employed physicians (182).

Primary and specialist care is provided by a single payer and is funded nationally from general taxation. Practices derive most of their income from contracts to provide NHS care. Approximately 75% of practice income comes from capitation, that is, allocation of funding among GPs is determined by patient registrations. The remainder is from pay-for-performance fees and contracts for more specialist care. GPs' take-home pay is the practice's profit. Currently, the average net pay of a GP is slightly more than the average NHS income of a specialist (182). All appointments and treatments are free at the point of care, paid through taxes. A minority of patients opt out of the NHS system and receive private care.

Specific aspects of the respective health care systems are presented in more detail in Chapter 5, a detailed empirical analysis of GPs' perspectives on PSA screening between Australia and the UK, with a particular focus on the influence of historical and current organisational and funding structures and rules. The next section presents the rationale, aims, and research questions for this study.

1.11 Rationale for this study

I have now discussed relevant controversies and uncertainties in PSA screening of asymptomatic men for prostate cancer. These concern the PSA test, the evidence base, and the associated harms, and are reflected in the inconsistency between numerous guidelines and recommendations. As demonstrated, there is substantial variation in screening practice. The quantitative evidence, involving large cohorts of GPs from around the world, has shown that certain characteristics of GPs, patients, and contexts can partly explain screening behavior, and provided insights into screening patterns and potential drivers of PSA screening in general practice. In this study I aimed to produce new knowledge to complement this existing evidence base.

We know from the literature and anecdotally that PSA screening is occurring opportunistically and informally in Australian general practice, despite there being no organised prostate cancer screening program in this country. We also know that screening rates, and relative screening rates, differ between different groups of patients and GPs. At least 20% of Australian men aged 45-74 years have a PSA screening test each year, as well as 19% aged over 74 years (183). Recent population-based analyses indicate that men undertaking a Medicare-subsidised PSA test decreased by 6% between 2011 and 2014 (79). One UK study analysed data from patient electronic records in primary care for men aged 45–84 years and reported that for every 100 men enrolled with a GP for one year, 5.03 (asymptomatic men) were tested in 2010, and the rate increased by 8% in 2011 to 5.45 per 100 (184).

What is less well understood is why these differences might exist. To understand this requires knowledge of the PSA screening experience, from the GP perspective. Qualitative research methods are best suited to

developing such understanding. The four qualitative studies identified in the literature review reported on potential facilitators and barriers to prostate screening and GP-reported discussions with men about the PSA test. However these studies provide limited insight into GPs' reasoning: how and why do GPs decide to provide or not provide PSA screening, given the complexities in the evidence base and historical contention. I was unable to locate any qualitative research conducted in Australia, and only one qualitative study was situated in the UK.

GPs have primary responsibility for guiding men's decisions about whether or not to be screened for prostate cancer. As I presented earlier in this Chapter, discussions and decisions about PSA screening can be complicated due to the complex balance between the benefits and harms of screening, diagnosis, and treatment, the mixed advice from professional organisations, and the central controversies.

This project aimed to generate a rich empirically grounded understanding of what happens in the clinic when the topic of PSA screening arises, as explained by GPs. I specifically sought to understand the decision-making and screening process and the complexities arising in consultations with asymptomatic men about PSA screening, from the GP perspective. I used grounded theory methodology to investigate GP explanations of how the PSA test is used for screening purposes in primary care in Australia and the United Kingdom, including their reasoning for practicing in this way.

1.12 Aim of this thesis

The broad aim of this thesis is to gain an in-depth understanding of how and why general practitioners screen for prostate cancer in primary care consultations.

1.13 Research questions

Three core research questions were the starting point for this thesis:

1 How do GPs approach PSA screening?

2 What factors influence GP approaches to PSA screening?

3 What are the consequences of this process?

I added more refined sub-questions over the course of the project as my understanding about the screening process evolved, and theoretical frameworks to explain some of the findings began to develop. This is the way of a grounded theory study. I present a full explanation of grounded theory methodology and its application to this study in Chapter 2.

Initially my goal was to identify, understand, and report on the range of positions taken by GPs, and the influence of these positions on screening practice.

1 How do GPs approach PSA screening?

1.1 How and why do GPs provide, or not provide, the PSA test to their asymptomatic male patients?

1.2 How do GPs describe their communication with men about prostate cancer screening?

As data collection and analysis developed and progressed, I identified several core concepts from the GP accounts.

2 What factors influence GP approaches to PSA screening?

2.1 How does concern about under- or over- diagnosis influence GPs' approaches to PSA screening?

2.2 How does uncertainty influence GPs' approaches to PSA screening?

2.3 How do GPs in Australia and GPs in the UK explain their PSA screening practices? What do any similarities or differences suggest about the influence of health systems on GPs' PSA screening practices?

2.4 What reasons do GPs give for communicating with men about PSA screening as they do?

3 What are the consequences of this process?

3.1 How do GPs describe the consequences of their PSA screening practices?

3.2 How do these described consequences vary?

Each empirical chapter of this thesis (Chapters 3-6) offers a focused explanation of the core concepts – under and over- diagnosis, uncertainty, organisational differences, and communication practices - drawn from the developing analysis. The next chapter, Chapter 2, presents the methodology and methods used in this study.

Chapter References

1. How does the prostate work? PubMed Health: US National Library of Medicine [Available from https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072475/].
2. Male reproductive tract [Available from: https://www.shutterstock.com/image-vector/male-reproductive-system-useful-education-schools-94324789.
3. Australian Institute of Health and Welfare 2016. Australian Cancer Incidence and Mortality (ACIM) books: Prostate cancer.: Canberra: AIHW.
4. Cancer Research UK. Prostate cancer mortality statistics United Kingdom [Available from: http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer/mortality#ref-0].
5. Jemal A, Bray F, Center MM, Ferlay J, Ward E, Forman D. Global cancer statistics. CA: a cancer journal for clinicians. 2011;61(2):69-90.
6. Ferlay J, Bray F, Pisani P, Parkin D. IARC cancer base no. 5 Version 2.0. Lyon: IARC Pr. 2004.
7. AIHW. Prostate cancer in Australia Australian Institute of Health and Welfare; 2013 [Available from: http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129545133.
8. Public Health England. Cancer by deprivation in England: Incidence, 1996-2010, Mortality, 1997-2011 London: NCIN2014 [Available from: http://www.ncin.org.uk/about_ncin/cancer_by_deprivation_in_england].
9. Ferlay J, Steliarova-Foucher E, Lortet-Tieulent J, Rosso S, Coebergh J, Comber H, et al. Cancer incidence and mortality patterns in Europe: estimates for 40 countries in 2012. European journal of cancer. 2013;49(6):1374-403.
10. Ferlay J SI, Ervik M, et al. . GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 Lyon, France: International Agency for Research on Cancer [Available from: http://globocan.iarc.fr]
11. National Cancer Intelligence Network (NCIN). Mortality from Prostate Cancer Urological Cancers SSCRG. UK; 2012.
12. Moyer VA. Screening for prostate cancer: US Preventive Services Task Force recommendation statement. Annals of Internal Medicine. 2012;157(2):120-34.
13. NHMRC. PSA testing for prostate cancer in asymptomatic men: Information for health practitioners. 2014 [https://www.nhmrc.gov.au/guidelines-publications/men4].
14. Jemal A, Siegel R, Xu J, Ward E. Cancer statistics, 2010. CA: a cancer journal for clinicians. 2010;60(5):277-300.
15. Ndubuisi SC, Kofie VY, Andoh JY, Schwartz EM. Black-white differences in the stage at presentation of prostate cancer in the District of Columbia. Urology. 1995;46(1):71-7.
16. Mariotto AB, Etzioni R, Krapcho M, Feuer EJ. Reconstructing PSA testing patterns between black and white men in the US from Medicare claims and the National Health Interview Survey. Cancer. 2007;109(9):1877-86.
17. Scales CD, Antonelli J, Curtis LH, Schulman KA, Moul JW. Prostate-specific antigen screening among young men in the United States. Cancer. 2008;113(6):1315-23.
18. Chou R, Croswell JM, Dana T, Bougatsos C, Blazina I, Fu R, et al. Screening for Prostate Cancer: A Review of the Evidence for the U.S. Preventive Services Task Force. Annals of Internal Medicine. 2011;E-375
19. Sakr W, Grignon DJ, Haas G, Heilbrun L, Pontes JE, Crissman J. Age and racial distribution of prostatic intraepithelial neoplasia. European urology. 1995;30(2):138-44.
20. Welch HG, Black WC. Overdiagnosis in cancer. Journal of the National Cancer Institute. 2010;102(9):605-13.
21. Prostate-Specific Antigen (PSA) Test: NIH National Cancer Institute US Department of Health and Human Services; [Available from: https://www.cancer.gov/types/prostate/psa-fact-sheet.

22. Chapman S, Barratt A, Stockler M. Let sleeping dogs lie? What men should know before getting tested for prostate cancer. Sydney: Sydney University Press; 2010. Available from: http://ses.library.usyd.edu.au/bitstream/2123/6835/3/Let-sleeping-dogs-lie.pdf.
23. American Urological Association. Early Detection of Prostate Cancer: AUA Guideline. 2013.
24. Gambert S. Prostate cancer. When to offer screening in the primary care setting. Geriatrics. 2001;56(1):22-6, 9-31.
25. Welch HG, Schwartz LM, Woloshin S. Prostate-specific antigen levels in the United States: implications of various definitions for abnormal. J Natl Cancer Inst. 2005;97(15):1132-7.
26. Wolf A, Wender RC, Etzioni RB, Thompson IM, D'Amico AV, Volk RJ, et al. American Cancer Society guideline for the early detection of prostate cancer: update 2010. CA: a cancer journal for clinicians. 2010;60(2):70-98.
27. Adhyam M, Gupta AK. A review on the clinical utility of PSA in cancer prostate. Indian journal of surgical oncology. 2012;3(2):120-9.
28. Rochester M, Donaldson P, McLoughlin J. Perception of abnormal serum prostate-specific antigen (PSA) test results amongst family practitioners. The Annals of The Royal College of Surgeons of England. 2008;90(5):398-402.
29. Luboldt H-J, Schindler JF, Rübben H. Age-specific reference ranges for prostate-specific antigen as a marker for prostate cancer. EAU-EBU update series. 2007;5(1):38-48.
30. Oesterling JE, Jacobsen SJ, Chute CG, Guess HA, Girman CJ, Panser LA, et al. Serum prostate-specific antigen in a community-based population of healthy men: establishment of age-specific reference ranges. JAMA-J Am Med Assoc. 1993;270(7):860-4.
31. McKenzie P, Delahunt B, Ross B, Tran H, Sikaris K. Prostate specific antigen testing for the diagnosis of prostate cancer. Pathology-Journal of the RCPA. 2011;43(5):403.
32. Ranasinghe WK, Kim SP, Lawrentschuk N, Sengupta S, Hounsome L, Barber J, et al. Population-based analysis of prostate-specific antigen (PSA) screening in younger men (< 55 years) in Australia. BJU international. 2014;113(1):77-83.
33. Louie KS. UKNSC Screening for prostate cancer review. Queen Mary University of London; 2015.
34. Fleshner NE, Lawrentschuk N. Risk of developing prostate cancer in the future: overview of prognostic biomarkers. Urology. 2009;73(5):S21-S7.
35. Vickers AJ, Ulmert D, Serio AM, Björk T, Scardino PT, Eastham JA, et al. The predictive value of prostate cancer biomarkers depends on age and time to diagnosis: Towards a biologically-based screening strategy. International Journal of Cancer. 2007;121(10):2212-7.
36. McKenzie PR, Delahunt B, Kench JG, Ross B, Lam Q, Tran HA, et al. Prostate specific antigen testing: age-related interpretation in early prostate cancer detection. Pathology-Journal of the RCPA. 2013;45(4):343-5.
37. USANZ. Urological Society of Australia and New Zealand PSA Testing Policy 2009.
38. Murphy DG, Ahlering T, Catalona WJ, Crowe H, Crowe J, Clarke N, et al. The Melbourne Consensus Statement on the early detection of prostate cancer. BJU international. 2014;113(2):186-8.
39. Gelfond J, Choate K, Ankerst DP, Hernandez J, Leach RJ, Thompson IM. Intermediate-Term Risk of Prostate Cancer is Directly Related to Baseline Prostate Specific Antigen: Implications for Reducing the Burden of Prostate Specific Antigen Screening. The Journal of urology. 2015;194(1):46-51.
40. Arnold PM, Niemann TH, Bahnson RR, editors. Extended sector biopsy for detection of carcinoma of the prostate. Urologic Oncology: Seminars and Original Investigations; 2001: Elsevier.
41. Burford DC, Kirby M, Austoker J. Prostate cancer risk management programme. NHS Cancer Screening Programmes. 2009.
42. Fleshner N, Klotz L. Role of “saturation biopsy” in the detection of prostate cancer among difficult diagnostic cases. Urology. 2002;60(1):93-7.
43. Dahabreh IJ, Chung M, Balk EM, Yu WW, Mathew P, Lau J, et al. Active surveillance in men with localized prostate cancer: a systematic review. Annals of Internal Medicine. 2012;156(8):582-90.
44. Parker C. Active surveillance: towards a new paradigm in the management of early prostate cancer. The lancet oncology. 2004;5(2):101-6.

45. Cooperberg MR, Carroll PR. Trends in management for patients with localized prostate cancer, 1990-2013. JAMA-J Am Med Assoc. 2015;314(1):80-2.
46. Stanford JL, Stephenson RA, Coyle LM, Cerhan J, Correa R, Eley J, et al. Prostate Cancer Trends 1973-1995, SEER Program, National Cancer Institute. NIH pub. 1999(99-4543).
47. Hara M, Koyanagi Y, Inoue T, Fukuyama T. Some physico-chemical characteristics of"-seminoprotein", an antigenic component specific for human seminal plasma. Forensic immunological study of body fluids and secretion. VII. Nihon hōigaku zasshi= The Japanese journal of legal medicine. 1971;25(4):322.
48. Stamey TA, Yang N, Hay AR, McNeal JE, Freiha FS, Redwine E. Prostate-specific antigen as a serum marker for adenocarcinoma of the prostate. New England Journal of Medicine. 1987;317(15):909-16.
49. Catalona WJ, Smith DS, Ratliff TL, Dodds KM, Coplen DE, Yuan JJ, et al. Measurement of prostate-specific antigen in serum as a screening test for prostate cancer. New England Journal of Medicine. 1991;324(17):1156-61.
50. Sohn E. Screening: Diagnostic dilemma. Nature. 2015;528(7582):S120-S2.
51. Mandelson MT, Wagner EH, Thompson RS. PSA screening: a public health dilemma. Annual review of public health. 1995;16(1):283-306.
52. Rathore SS, McGreevey JD, Schulman KA, Atkins D. Mandated coverage for cancer-screening services: whose guidelines do states follow? American journal of preventive medicine. 2000;19(2):71-8.
53. Justman S. How did the PSA system arise? J R Soc Med. 2010;103(8):309-12.
54. Ablin RJ. The Great Prostate Mistake. New York Times. 2010 New York edition(March 10):A27.
55. Frankel S, Smith GD, Donovan J, Neal D. Screening for prostate cancer. Lancet. 2003;361:1122-28.
56. Mettlin C, Jones G, Averette H, Gusberg S, Murphy GP. Defining and updating the american cancer society guidelines for the cancer-related checkup: Prostate and endometrial cancers. CA: a cancer journal for clinicians. 1993;43(1):42-6.
57. American Urological Association . Early detection of prostate cancer and use of transrectal ultrasound. Baltimore, Md: Williams & Wilkins; 1992. In: American Urological Association 1992 Policy Statement Book.
58. American College of Radiology. 1991. Resolution #36, approved October 1991. In Mandelson MT, Wagner EH, Thompson RS. PSA screening: a public health dilemma. Annual review of public health. 1995;16(1):283-306.
59. Screening for prostate cancer. American College of Physicians. Ann Intern Med 1997;126:480-84.
60. American Academy of Family Physicians. Appendix F—periodic health examination. In AAFP Reference Manual, 1997–1998, p. 62. Kansas City, MO. 1998.
61. USPSTF. Guide to clinical preventive services: report of the US Preventive Services Task Force: Lippincott Williams & Wilkins; 1996.
62. Von Eschenbach A, Ho R, Murphy GP, Cunningham M, Lins N. American Cancer Society guideline for the early detection of prostate cancer: update 1997. CA: a cancer journal for clinicians. 1997;47(5):261-4.
63. Prostate cancer screening: guidelines for health professionals. Australian Cancer Society. Cancer Forum. 1995(19):47-50.
64. Royal Australian College of General Practitioners. Guidelines for preventative activities in general practice. Melbourne: RACGP, 1994.
65. Prostate cancer screening: summary of the review prepared by the Australian Health Technology Advisory Committee. Canberra: Department of Health and Community Services; 1996.
66. Chamberlain J, Melia J, Moss S, Brown J. Report prepared for the Health Technology Assessment panel of the NHS Executive on the diagnosis, management, treatment and costs of prostate cancer in England and Wales. British journal of urology. 1997;79:1-32.
67. Selley S, Donovan J, Faulkner A, Coast J, Gillatt D. Diagnosis, management and screening of early localised prostate cancer. Health technology assessment (Winchester, England). 1996;1(2):i, 1-96.
68. Raffle A, Gray M. Screening: evidence and practice. Oxford: Oxford University Press; 2007.
69. Sackett DL, Rosenberg WM, Gray JM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. British Medical Journal. 1996;312(7023):71-2.

70. Guyatt G.JC, Churchill, D et al Evidence-Based Medicine Working Group Evidence-based medicine. A new approach to teaching the practice of medicine. J Am Med Assoc. 1992;268(17):2420.
71. Shah HM, Chung KC. Archie Cochrane and his vision for evidence-based medicine. Plastic and reconstructive surgery. 2009;124(3):982.
72. Davidoff F, Haynes B, Sackett D, Smith R. Evidence based medicine. BMJ: British Medical Journal. 1995;310(6987):1085.
73. Wilt TJ, Scardino PT, Carlsson SV, Basch E. Prostate-specific antigen screening in prostate cancer: perspectives on the evidence. Journal of the National Cancer Institute. 2014;106(3):dju010.
74. Egger M, Schneider M, Smith GD. Spurious precision? meta-analysis of observational studies. BMJ: British Medical Journal. 1998;316(7125):140.
75. Durham JA. Population screening for prostate cancer: a systematic review: Department of General Practice, Wellington School of Medicine, University of Otago; 2002.
76. Gigerenzer G, Gaissmaier W, Kurz-Milcke E, Schwartz LM, Woloshin S. Helping doctors and patients make sense of health statistics. Psychological science in the public interest. 2007;8(2):53-96.
77. Parker C, Muston D, Melia J, Moss S, Dearnaley D. A model of the natural history of screen-detected prostate cancer, and the effect of radical treatment on overall survival. British journal of cancer. 2006;94(10):1361-8.
78. Mistry M, Parkin D, Ahmad AS, Sasieni P. Cancer incidence in the United Kingdom: projections to the year 2030. British Journal of Cancer. 2011;105(11):1795-803.
79. AIHW. Cancer in Australia 2017. Cancer series no. 101. Cat. No. CAN 100. Canberra: AIHW.; 2017.
80. Bretthauer M, Kalager M. Principles, effectiveness and caveats in screening for cancer. British journal of surgery. 2013;100(1):55-65.
81. Andriole GL, Crawford ED, Grubb RL, Buys SS, Chia D, Church TR, et al. Prostate cancer screening in the randomized Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial: mortality results after 13 years of follow-up. Journal of the National Cancer Institute. 2012.
82. Ilic D, Neuberger MM, Djulbegovic M, Dahm P. Screening for prostate cancer. Cochrane Database Syst Rev. 2013;1.
83. Gulati R, Tsodikov A, Wever EM, Mariotto AB, Heijnsdijk EA, Katcher J, et al. The impact of PLCO control arm contamination on perceived PSA screening efficacy. Cancer Causes & Control. 2012;23(6):827-35.
84. Andriole GL, Crawford ED, Grubb RL, 3rd, Buys SS, Chia D, Church TR, et al. Mortality results from a randomized prostate-cancer screening trial.[Erratum appears in N Engl J Med. 2009 Apr 23;360(17):1797]. New England Journal of Medicine. 2009;360(13):1310-9.
85. Andriole G, Djavan B, Fleshner N, Schroder F. The case for prostate cancer screening with prostate-specific antigen. European Urology Supplements. 2006;5:737-45.
86. Roobol MJ, Kerkhof M, Schroder FH, Cuzick J, Sasieni P, Hakama M, et al. Prostate cancer mortality reduction by prostate-specific antigen-based screening adjusted for nonattendance and contamination in the European Randomised Study of Screening for Prostate Cancer (ERSPC). European Urology. 2009;56(4):584-91.
87. Schröder FH, Hugosson J, Roobol MJ, Tammela TLJ, Ciatto S, Nelen V, et al. Prostate-Cancer Mortality at 11 Years of Follow-up. New England Journal of Medicine. 2012;366(11):981-90.
88. Azvolinsky A. Prostate cancer study: update to PSA screening data renews controversy. 2012.
89. Catalona WJ. Prostate-cancer screening. N Engl J Med. 2009;361(2):202.
90. RACGP. Prostate cancer screening: Patient information sheet. Should I have prostate cancer screening? The Royal Australian College of General Practitioners; 2015. [Available at http://www.racgp.org.au/your-practice/guidelines/prostate-cancer/]
91. Schwartz PH, Meslin EM. The ethics of information: Absolute risk reduction and patient understanding of screening. J Gen Intern Med. 2008;23(6):867-70.
92. Pinsky PF, Prorok PC, Kramer BS. Prostate Cancer Screening-A Perspective on the Current State of the Evidence. The New England journal of medicine. 2017;376(13):1285-9.

93. Schröder FH, Hugosson J, Roobol MJ, Tammela TL, Zappa M, Nelen V, et al. Screening and prostate cancer mortality: results of the European Randomised Study of Screening for Prostate Cancer (ERSPC) at 13 years of follow-up. The Lancet. 2014;384(9959):2027-35.
94. Schröder FH, Hugosson J, Carlsson S, Tammela T, Määttänen L, Auvinen A, et al. Screening for prostate cancer decreases the risk of developing metastatic disease: findings from the European Randomized Study of Screening for Prostate Cancer (ERSPC). European Urology. 2012;62(5):745-52.
95. Schroder FH, Hugosson J, Roobol MJ, Tammela TL, Ciatto S, Nelen V, et al. Screening and prostate-cancer mortality in a randomized European study. N Engl J Med. 2009;360(13):1320-8.
96. Loeb S, Chan DW, Sokoll LJ, Kan D, Maggiore J, Catalona WJ. Differences in PSA measurements due to assay standardization bias. The Journal of Urology. 2008;179(4):721.
97. Thompson IM, Pauler DK, Goodman PJ, Tangen CM, Lucia MS, Parnes HL, et al. Prevalence of prostate cancer among men with a prostate-specific antigen level < or =4.0 ng per milliliter. N Engl J Med. 2004;350(22):2239-46.
98. Pron G. Prostate-Specific Antigen (PSA)–Based Population Screening for Prostate Cancer: An Evidence-Based Analysis. Ontario Health Technology Assessment Series. 2015;15(10):1.
99. Smith DP, King MT, Egger S, Berry MP, Stricker PD, Cozzi P, et al. Quality of life three years after diagnosis of localised prostate cancer: population based cohort study. Bmj. 2009;339:b4817.
100. Loeb S, Carter HB, Berndt SI, Ricker W, Schaeffer EM. Complications after prostate biopsy: data from SEER-Medicare. The Journal of urology. 2011;186(5):1830-4.
101. Welch HG, Albertsen PC. Prostate cancer diagnosis and treatment after the introduction of prostate-specific antigen screening: 1986–2005. Journal of the National Cancer Institute. 2009;101(19):1325-9.
102. Bray F, Lortet-Tieulent J, Ferlay J, Forman D, Auvinen A. Prostate cancer incidence and mortality trends in 37 European countries: an overview. European journal of cancer. 2010;46(17):3040-52.
103. Ilic D, O'Connor D, Green S, Wilt TJ. Screening for prostate cancer: an updated Cochrane systematic review. BJU international. 2011;107(6):882-91.
104. Carlsson S, Vickers AJ, Roobol M, Eastham J, Scardino P, Lilja H, et al. Prostate cancer screening: facts, statistics, and interpretation in response to the US Preventive Services Task Force Review. Journal of Clinical Oncology. 2012;30(21):2581-4.
105. Brett AS, Ablin RJ. Prostate-Cancer Screening — What the U.S. Preventive Services Task Force Left Out. New England Journal of Medicine. 2011;Perspective(10.1056/NEJMp1112191).
106. American Urological Association. News center: AUA speaks out against USPSTF recommendations. 2011 [Available at http://auanet.mediaroom.com/2015-05-17-Impact-of-U-S-Preventive-Services-Task-Force-Guidelines-Raise-Concerns?articleNo=419].
107. Urologists Outraged over Government Panel's Recommendation to Stop Life-Saving Prostate Cancer Testing [Internet]. NewsRX LLC, 2012 June 9. 2012.
108. Prostate Cancer, to Screen or Not to Screen: What a Stupid Question or How the USPSTF Got it all Wrong. Patient Advocates for Advanced Cancer Treatments Inc PAACT; 2013.
109. The new PSA report: Understand the controversy. Harvard Health Publications; February 2012.
110. MacKenzie R, Chapman S, Holding S, McGeechan K. 'A matter of faith, not science': analysis of media coverage of prostate cancer screening in Australian news media 2003-2006. Journal of the Royal Society of Medicine. 2007;100(11):513-21.
111. The prostate and the apostate. Sydney Morning Herald. 7 March 2003.
112. Montgomery B. Doctor 'trivialising'prostate cancer. The Australian. 2003:26-03.
113. Vedel I, Puts MTE, Monette M, Monette J, Bergman H. The decision-making process in prostate cancer screening in primary care with a prostate-specific antigen: a systematic review. Journal of Geriatric Oncology. 2011;2:161-76.
114. USPSTF. Draft Recommendation Statement: Prostate Cancer: Screening. U.S. Preventive Services Task Force. April 2017 [Available from: https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prostate-cancer-screening1.

115. American Cancer Society. American Cancer Society recommendations for the early detection of prostate cancer 2014 [Available from: http://www.cancer.org/cancer/prostatecancer/moreinformation/prostatecancerearlydetection/prostate-cancer-early-detection-acs-recommendations.
116. Qaseem A, Barry MJ, Denberg TD, Owens DK, Shekelle P. Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. Annals of internal medicine. 2013;158(10):761-9.
117. RACGP. Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice 2012; Redbook 8th edition.
118. Djulbegovic M, Beyth RJ, Neuberger MM, Stoffs TL, Vieweg J, Djulbegovic B, et al. Screening for prostate cancer: systematic review and meta-analysis of randomised controlled trials. BMJ. 2010;341.
119. Urological Society of Australia and New Zealand PSA Guidelines [Available from: http://www.usanz.org.au/psa-guidelines/.
120. Prostate cancer - PSA screening United Kingdom: National Health Service (NHS) Choice; [Available from: http://www.nhs.uk/Conditions/Cancer-of-the-prostate/Pages/Prevention.aspx.
121. Graham J, Kirkbride P, Cann K, Hasler E, Prettyjohns M. Prostate cancer: summary of updated NICE guidance. BMJ : British Medical Journal. 2014;348.
122. Bolla M, van Casteren N, Cornford P, Culine S, Joniau S, Lam T, et al. Guidelines on Prostate Cancer. European Association of Urology; 2015.
123. Ross LE, Hall IJ. African American Primary Care Physicians' Prostate Cancer Screening Practices. Journal of primary care & community health. 2014;5(1):36-43.
124. Stroud L, Ross LE, Rose SW. Formative evaluation of the prostate cancer screening practices of African-American physicians. Journal of the National Medical Association. 2006;98(10):1637.
125. Arafa MA, Rabah DM, Abdel-Gawad E, Ibrahim FK. Association of physicians' knowledge and behavior with prostate cancer counseling and screening in Saudi Arabia. Saudi Medical Journal. 2010;31(11):1245-50.
126. Austin OJ, Valente S, Hasse LA, Kues JR. Determinants of prostate-specific antigen test use in prostate cancer screening by primary care physicians. Archives of Family Medicine. 1997;6(5):453-8.
127. Bunting P, Goel V, Williams J, Iscoe N. Prostate-specific antigen testing in Ontario: reasons for testing patients without diagnosed prostate cancer. Canadian Medical Association Journal. 1999;160(1):70-5.
128. Crowe J, Wootten AC, Howard N. Prostate cancer testing: a snapshot of the attitudes and practice of Australian general practitioners. Australian Journal of Primary Health. 2015;21(1):111-4.
129. Curran V, Solberg S, Mathews M, Church J, Buehler S, Wells J, et al. Prostate cancer screening attitudes and continuing education needs of primary care. Journal of cancer education. 2005;20(3):162-6.
130. Gormley GJ, Catney D, McCall JR, Reilly PM, Gavin AT. Prostate-specific antigen testing: uncovering primary care influences. BJU international. 2006;98:996-1000.
131. Konety BR, Sharp VJ, Verma M, Williams RD, Iowa Prostate Canc Consenus P. Practice patterns in screening and managementof prostate cancer in elderly men. Urology. 2006;68(5):1051-6.
132. Little B, Ho KJ, Gormley G, Young M. PSA testing in general practice. Prostate Cancer & Prostatic Diseases. 2003;6(2):154-8.
133. Voss JD, Schectman JM. Prostate cancer screening practices and beliefs - A longitudinal physician survey. J Gen Intern Med. 2001;16(12):831-7.
134. Sorum PC, Mullet E, Shim J, Bonnin-Scaon S, Chasseigne G, Cogneau J. Avoidance of anticipated regret: the ordering of prostate-specific antigen tests. Med Decis Making. 2004;24(2):149-59.
135. Tasian GE, Cooperberg MR, Cowan JE, Keyashian K, Greene KL, Daniels NA, et al. Prostate specific antigen screening for prostate cancer: knowledge of, attitudes towards, and utilization among primary care physicians. Urologic Oncology: seminars and original investigations. 2012;30:155-60.
136. Tasian GE, Cooperberg MR, Potter MB, Cowan JE, Greene KL, Carroll PR, et al. PSA screening: determinants of primary-care physician practice patterns. Prostate Cancer and Prostatic Diseases. 2012;15(2):189-94.

137. Brett J, Watson E, Hewitson P, Bukach C, Edwards A, Elwyn G, et al. PSA testing for prostate cancer: an online survey of the views and reported practice of General Practitioners in the UK. BMC Family Practice. 2005;6(1):24.
138. Durham J, Low M, McLeod D. Screening for prostate cancer: a survey of New Zealand general practitioners. New Zealand Medical Journal. 2003;116(1176):U476.
139. Linder SK, Hawley ST, Cooper CP, Scholl LE, Jibaja-Weiss M, Volk RJ. Primary care physicians' reported use of pre-screening discussions for prostate cancer screening: a cross-sectional survey. BMC Family Practice. 2009;10.
140. Tudiver F, Guibert R, Haggerty J, Ciampi A, Medved W, Brown JB, et al. What influences family physicians' cancer screening decisions when practice guidelines are unclear or conflicting? Journal of Family Practice. 2002;51(9):760-U8.
141. van Rij S, Dowell T, Nacey J. PSA screening in New Zealand: total population results and general practitioners' current attitudes and practices. The New Zealand medical journal. 2012;126(1381):27-36.
142. Pendleton J, Curry RW, Kaserian A, Chang M, Anai S, Nakamura K, et al. Knowledge and attitudes of primary care physicians regarding prostate cancer screening. Journal of the National Medical Association. 2008;100(6):666-70.
143. Jonler M, Eddy B, Poulsen J. Prostate-specific antigen testing in general practice: a survey among 325 general practitioners in Denmark. Scandinavian Journal of Urology & Nephrology. 2005;39(3):214-8.
144. Gattellari M, Young JM, Ward JE. GP and patient predictors of PSA screening in Australian general practice. Family Practice. 2003;20(3):294-303.
145. Bowen DJ, Hannon PA, Harris JR, Martin DP. Prostate cancer screening and informed decision-making: provider and patient perspectives. Prostate Cancer and Prostatic Diseases. 2011;14(2):155-61.
146. Pollack CE, Platz EA, Bhavsar NA, Noronha G, Green GE, Chen S, et al. Primary care providers' perspectives on discontinuing prostate cancer screening. Cancer. 2012;118(22):5518-24.
147. Bell DS, Hays RD, Hoffman JR, Day FC, Higa JK, Wilkes MS. A test of knowledge about prostate cancer screening. J Gen Intern Med. 2006;21:310-4.
148. Drummond FJ, Carsin A-E, Sharp L, Comber H. Factors prompting PSA-testing of asymptomatic men in a country with no guidelines: a national survey of general practitioners. BMC Family Practice. 2009;10.
149. McNaughton D, Aiken W, McGrowder D. Factors Affecting Prostate Cancer Screening Behaviour in a Discrete Population of Doctors at the University Hospital of the West Indies, Jamaica. Asian Pacific Journal of Cancer Prevention. 2011;12(5):1201-5.
150. Davis K, Haisfield L, Dorfman C, Krist A, Taylor KL. Physicians' attitudes about shared decision making for prostate cancer screening. Family Medicine-Kansas City. 2011;43(4):260.
151. Dunn AS, Shridharani KV, Lou W, Bernstein J, Horowitz CR. Physician-patient discussions of controversial cancer screening tests. American Journal of Preventive Medicine. 2001;20(2):130-4.
152. Hicks RJ, Hamm RM, Bemben DA. Prostate cancer screening. What family physicians believe is best. Archives of Family Medicine. 1995;4(4):317-22.
153. Hodgson F, Obertova Z, Brown C, Lawrenson R. PSA testing in general practice. Journal of Primary Health Care. 2012;4(3):199-204.
154. Morris J, McNoe B. Screening for prostate cancer: what do general practitioners think? New Zealand Medical Journal. 1997;110(1044):178-82.
155. Ranasinghe WKB, Kim SP, Papa NP, Sengupta S, Frydenberg M, Bolton D, et al. Prostate cancer screening in Primary Health Care: the current state of affairs. Springerplus. 2015;4.
156. Chan EC, Vernon SW, Haynes MC, O'Donnell FT, Ahn C. Physician perspectives on the importance of facts men ought to know about prostate-specific antigen testing. J Gen Intern Med. 2003;18(5):350-6.
157. Guerra CE, Jacobs SE, Holmes JH, Shea JA. Are Physicians Discussing Prostate Cancer Screening with Their Patients and Why or Why Not? A Pilot Study. JGIM. 2007;22:901-7.
158. Ward J, Young J, Sladden M. Australian general practitioners' views and use of tests to detect early prostate cancer. Australian & New Zealand Journal of Public Health. 1998;22(3 Suppl):374-80.

159. Edlefsen KL, Mandelson MT, McIntosh MW, Andersen MR, Wagner EH, Urban N. Prostate-specific antigen for prostate cancer screening. Do physician characteristics affect its use? American Journal of Preventive Medicine. 1999;17(1):87-90.
160. Hall IJ, Taylor YJ, Ross LE, Richardson LC, Richards TB, Rim SH. Discussions about prostate cancer screening between US primary care physicians and their patients. J Gen Intern Med. 2011;26(10):1098-104.
161. Roshanai AH, Nordin K, Berglund G. Factors influencing primary care physicians' decision to order prostate-specific antigen (PSA) test for men without prostate cancer. Acta Oncol. 2013;52(8):1602-8.
162. Volk RJ, Linder SK, Kallen MA, Galliher JM, Spano MS, Mullen PD, et al. Primary care physicians' use of an informed decision-making process for prostate cancer screening. The Annals of Family Medicine. 2013;11(1):67-74.
163. Pollack CE, Noronha G, Green GE, Bhavsar NA, Carter HB. Primary Care Providers' Response to the US Preventive Services Task Force Draft Recommendations on Screening for Prostate Cancer. Archives of Internal Medicine. 2012;172(8):668-70.
164. Burton RC, Bell RJ, Thiagarajah G, Stevenson C. Adjuvant therapy, not mammographic screening, accounts for most of the observed breast cancer specific mortality reductions in Australian women since the national screening program began in 1991. Breast cancer research and treatment. 2012;131(3):949-55.
165. Ward J, Gupta L, Taylor N. Do general practitioners use prostate-specific antigen as a screening test for early prostate cancer? The Medical Journal of Australia. 1998;169(1):29.
166. Lawson DA, Simoes EJ, Sharp D, Murayi T, Hagan R, Brownson RC, et al. Prostate cancer screening - A physician survey in Missouri. Journal of Community Health. 1998;23(5):347-58.
167. Hall IJ, Ross LE, Taylor YJ, Richardson LC. Primary care physician reports of amount of time spent with male patients in prostate cancer screening discussions. Journal of primary care & community health. 2011;2(3):192-204.
168. Philips GK, Reinier K, Ashikaga T, Luebbers RA. Attitudes and beliefs of primary care physicians regarding prostate and colorectal cancer screening in a rural state. Journal of Cancer Education. 2005;20(3):167-72.
169. Hoffman RM, Papenfuss MR, Buller DB, Moon TE. Attitudes and practices of primary care physicians for prostate cancer screening. American Journal of Preventive Medicine. 1996;12(4):277-81.
170. McKnight JT, Tietze PH, Adcock BB, Maxwell AJ, Smith WO, Nagy MC. Screening for prostate cancer: a comparison of urologists and primary care physicians. Southern Medical Journal. 1996;89(9):885-8.
171. Gilfrich C, May M, Braun KP, Lebentrau S, Lehsnau M, Ecke T, et al. Evaluating the use of prostate-specific antigen as an instrument for early detection of prostate cancer beyond urologists: results of a representative cross-sectional questionnaire study of general practitioners and internal specialists. Urologia Internationalis. 2014;93(2):160-9.
172. Konety BR, Raut H, Smith BJ, Sharp VJ, Williams RD. Effect of uniform consensus recommendations for PCa screening in older population: differential effects and perceptions of healthcare providers and patients. Urology. 2009;73(3):603-8.
173. Agence Nationale d'Accréditation et d'Evaluation en Santé. Opportunité d'un Dépistage Systématique du Cancer de la Prostate par le Dosage de l'Antigène Spécifique de la Prostate. Paris: Agence Nationale d'Accréditation et d'Evaluation en Santé; 1998.
174. Sladden MJ, Dickinson JA. General practitioners' attitudes to screening for prostate and testicular cancers. Medical Journal of Australia. 1995;162(8):410-3.
175. Clements A, Watson E, Rai T, Bukach C, Shine B, Austoker J. The PSA testing dilemma: GP's reports of consultations with asymptomatic men: a qualitative study. BMC Family Practice. 2007;8(35).
176. Cooper CP, Merritt TL, Ross LE, John LV, Jorgensen CM. To screen or not to screen, when clinical guidelines disagree: primary care physicians' use of the PSA test. Preventive Medicine. 2004;38:182-91.
177. AIHW. Australia's Health: Australia's Health Series. Canberra, Australia: Australian Institute of Health and Welfare 2014.

178. Private Health Insurance Administration Council, Quarterly Statistics March 2015. Canberra.
179. Medicare Levy Surcharge: Australian Government Private Health Insurance Ombudsman; [Available from: privatehealth.gov.au]
180. Medicare Benefits Schedule MBS Book Category 6: Australian Government Department of Health; 2014.
181. Robinson R. Primary health care in the UK: policy, practice, and performance. 2000;131:83-96.
182. Roland M, Guthrie B, Thomé DC. Primary medical care in the United Kingdom. The Journal of the American Board of Family Medicine. 2012;25(Suppl 1):S6-S11.
183. Percentages calculated from data on claims for PSA tests [item number 66655] processed by Medicare Australia in 2015–16 [medicarestatistics.humanservices. gov.au/statistics] and Australian Bureau of Statistics tables of estimated resident population by age and sex at 30 June 2015 and 30 June 2016 [ABS report series 3101.0 Australian Demographic Statistics]; in Armstrong BK, Barry MJ, Frydenberg M, Gardiner RA, Haines I, Carter S. PSA testing for men at average risk of prostate cancer. Public Health Research & Practice 2017; 27(3)
184. Moss S, Melia J, Sutton J, Mathews C, Kirby M. Prostate-specific antigen testing rates and referral patterns from general practice data in England. Int J Clin Pract. 2016 Apr; 70(4):312-8.

CHAPTER TWO.

Methodology & Methods

2. Overview of this chapter

This chapter presents the methodology and methods used in this study to investigate (a) How GPs approach PSA screening, (b) factors that influence GP approaches to PSA screening, and (c) the consequences of this process.

The empirical work was entirely qualitative. Qualitative research methods are concerned with understanding phenomena through the meanings people attach to experiences, and are routinely used to study the meanings of health and illness and processes of health care (1). This work seeks to explore behaviours, processes of interaction, and experiences of individuals and groups in natural settings to understand a process or an issue as completely as possible.

A qualitative approach was appropriate because my aim was to gain in-depth understanding of how and why GPs screen for prostate cancer in primary care consultations. I was particularly interested in understanding GPs' reasoning, complexities of the process (including screening practice, communication, and decision making), and organisational structures involved in the delivery of this service. As shown in Chapter 1, this was a gap in the existing literature.

In this chapter I provide a detailed description of grounded theory methodology and its application in practice during this study.

Ethics approval and ethical issues

Study procedures were approved by the Cancer Institute New South Wales and the University of Sydney Human Research Ethics Committee [#15245]. GPs had an opportunity to discuss the study with KP prior to participation; all GPs provided informed consent to participate and were compensated for their time. Participation was voluntary, participants could withdraw at any time, and confidentiality was protected. All responses were anonymised before analysis and potentially identifying information removed.

2.1 Grounded theory

I applied a well-established methodology, grounded theory, to guide the collection and analysis of qualitative data. It is one of the oldest, most epistemologically sophisticated, and best-described methodologies in qualitative health research; and has been used across a range of disciplines since the 1980s (2). 'Grounded theory' refers to both the research product and the analytic method of producing it. In a grounded theory study, data are systematically collected and analysed using a specific method. The aim is to generate a substantive theory about human behaviour or social processes drawn directly from the research data (3). Grounded theory analysis begins inductively. The study is not designed to test pre-existing theory; rather the researcher looks for new concepts and explanations by studying the perspectives of participants within meaningful and relevant contexts, and the findings reflect patterns observed within participants' accounts. While deliberately prioritising the participants' perspectives as much as possible, as analysis progresses the researcher/s bring in conceptual resources from existing theory to contextualise and enrich the developing explanation.

Glaser and Strauss laid the foundations for grounded theory in 1967, publishing a rhetorical defense of inductive analysis in their book "The Discovery of Grounded Theory" (4). Their original conception of the theory was based on objectivist assumptions about the empirical world, with emphasis on an objective reality, neutrality, and providing explanation of a single truth. In their view, sociology had become dominated by the use of quantitative methods to operationalise and test existing theories; they argued that this was increasingly divorcing sociological research from what mattered to people in the everyday world. "Discovery" encouraged researchers to remember how to listen to participants' own perspectives, and develop social theory that adequately reflected participants' understanding of the world. Abstraction, in this original formulation, separated the completed grounded theory from the context and conditions of its data collection and analysis. The researcher's views dominated interpretation of the data.

Glaser's original framework was increasingly criticized as researchers began working with the grounded theory methodology. Many argued against the idea that the legitimacy of a theory can be determined

simply by recourse to its "emergence" from "the data." Strauss and Corbin (15) advanced the method to acknowledge the importance of multiple perspectives, with increasing recognition of the role of social constructionism – socially situated meaning, constructed in interaction with others – in knowledge production.

Kathy Charmaz developed a contemporary version of grounded theory that updated the methodology epistemologically (3). Charmaz argues that what previous researchers defined as objective data in reality reflects partial knowledge and particular perspectives, priorities, and positions. Her constructivist grounded theory prioritises the production and quality of data, with close attention to context, actors, and actions, to provide an *interpretive* understanding of the studied phenomenon. Charmaz emphasises that both the data and analysis are actively constructed during the research process, involving the work of both researcher/s and participants, and requiring careful attention to the quality of data collection and analysis processes. I attended grounded theory training with Kathy Charmaz in Melbourne in 2014 and 2015.

A longstanding point of contention in grounded theory methodology is the relationship between the theory being produced, which is 'grounded' in the data collected, and relevant theory existing in the literature. Early expressions of grounded theory methodology (4) strongly emphasized the development of new theory as opposed to the testing of existent theory and were resolutely inductive. This was likely a reflection of the local context: Glaser and Strauss attempted to establish and distinguish qualitative methods in the United States in the 1960s, where hypothesis-driven, deductive quantitative research prevailed. Contemporary mainstream grounded theorists, in contrast, strongly concur that qualitative empirical work must be conducted in the context of existing knowledge (2) and not independently of scholarly work. I drew on the theories of various scholars in my interpretive work and have referred to them directly in the empirical chapters: examples include Han's model of uncertainty in Chapter 4 and Gabbay and Le May's mindlines theory in Chapter 5.

Fundamental components of a grounded theory study

Grounded theory methodology provides a specific guiding structure for sampling, data collection, analysis, and reporting, designed to support researchers to build theory grounded in collected data. Rigor is increased if these phases are iteratively related. The twin foundations of grounded theory are the processes of constant comparison (a simultaneous and concurrent process of coding and analysis) and theoretical sampling (sampling with the aim of developing the properties of a developing theory). Other key features include coding for actions and memo-writing. These methods together guide the systematic development of emerging theory, theory construction, and theoretical integration.

2.2 Sampling

Initial, purposive sampling

Grounded theory studies begin broad in scope and researchers presume that they may know little about the meanings that drive the actions of participants (5). I began with broad, open research questions: How do GPs approach PSA screening? (*What is the process, the conditions of practice?*), and: What factors influence GP approaches to PSA screening? (*Why do GPs practice in that way? How is variation explained?*).

Sampling in a grounded theory study begins purposively, that is, recruitment is guided less by traditional quantitative concepts of representativeness, and more by the purpose of the study. The researcher seeks to recruit those people who are most likely to be able to provide relevant and *diverse* perspectives on the central research questions. I identified GPs as being in the best position to provide insight on my research questions, but required a strategic sampling strategy within the population of GPs. The purposive component of the sampling was driven by existing quantitative evidence on characteristics of GPs, patients and practice contexts associated with higher or lower screening rates (see Section 1.1. Chapter 1). I aimed to recruit a set of GPs likely to have diverse practices (especially, frequent versus infrequent testers) and to begin to observe how statistically demonstrated variation might work in practice.

For the first few interviews, I aimed to gather data from those GPs most likely to face the question of PSA screening as part of everyday practice. To begin to understand the process, I wanted to find informants who experienced it often and would be able to speak about it readily. I contacted local men's health clinics in Sydney, Australia, particularly in higher socioeconomic suburbs. My background research and literature review presented in Chapter 1 indicated that socioeconomic status might be associated with higher rates of PSA screening. I broadened my sampling to any GP practicing in Sydney - in regular family practices, and in all areas of Sydney. Existing datasets also suggested that PSA screening rates in Australia are higher in capital cities than in rural areas (6, 7). To begin to understand this distinction, I targeted the newsletters and email lists of regional GP organisations (Medicare Locals) to compare accounts from urban areas with those from regional areas. Further advertising in mass and social media, and in medical journals (Medical Observer, the Australian Medical Association's GP Network News, and the 6minutes newsletter) extended sampling beyond NSW to other states and territories. This allowed more extensive comparison of the influence of different contexts, such as practice location and local culture.

My evolving research questions continued to drive the process throughout, I constantly returned to these questions and asked what extra material I needed to answer my questions more effectively and comprehensively.

Theoretical sampling

Theoretical sampling is conceptually driven sampling specifically for theory construction. New targets for data collection are directed by the results collected from the preceding sample (8). A theoretical sampling strategy is only possible as analysis and sampling evolves, informed by coding, comparison, and memo writing (5). Questions are raised and gaps in the data set become evident.

The emphasis of this study evolved as I became increasingly aware of what was important to GPs or issues raised by them that alerted me to consider and explore further. For example, I discovered that avoiding under-diagnosing prostate cancers was highly valued by some GPs, despite guidelines and the evidence

suggesting otherwise. I selected new GPs based on their ability to answer specific analytical questions. My interview schedule was modified accordingly. See Section 2.3 for a description of the progression of the interview questions. The aim was to clarify uncertainty, test (and attempt to disprove) my interpretations of the data, develop the properties of my emerging concepts which were not yet clear, and to better support the integrity, focus, and explanatory power of my continuing analysis, including the final product (9).

I scrutinized how issues and processes evident in my analysis might be considered in different contexts and under potentially different practice conditions, to refine the scope of my explanations. I invited rural and interstate GPs in Australia to answer specific analytical questions; for example, was the variable screening practice evident in my initial interviews widespread? What was contributing to variability? Did evidence of issues relevant to the first few GPs interviewed appear elsewhere? Regional and rural GPs were accessed by phoning practice managers, through colleagues, and advertising with rural Medicare Locals. When I encountered GPs whose routine care was divergent from previously-interviewed GP norms, I invited more GPs from that practice to attempt to distinguish between personal and institutional influences on their practice. Sampling rural GPs also allowed me to test specific provisional explanations, that is, that location is relevant to divergent screening patterns.

For the final phase of theoretical sampling, I interviewed GPs in the United Kingdom. The decision to extend my sample to the UK was for a number of reasons, based on my developing analysis of data collected from Australian GPs, and in conjunction with information gathered from the existing literature. I became interested in exploring whether and how GPs operating under conditions of a contrasting health care system may influence PSA screening decisions and behaviour and considerations of the evidence. I wanted to find out if screening decisions are any easier for GPs in the UK. I looked for whether uncertainty was a common experience, for example (as a provisional explanation of variation in screening practice); and how screening guidelines work in UK practice (to further explore possible explanations in conditions of practice). I recruited GPs throughout England, Scotland, and Wales. The initial sample of GPs responded

to an invitation distributed by academic colleagues through professional networks. I then broadened the sample by advertising via email to members of the Royal College of General Practitioners (RCGP), primary health care departments, university academic departments, and general practice and research mail lists. I also advertised via newsletter including the Society for Academic Primary Care (SAPC) and RCGP Scotland's eBulletin.

GP demographics

GPs who received the flyer inviting them to participate in the research were instructed to contact the researcher (KP) if they were interested and willing to take part. I included all GPs who expressed interest in participating in the research study. Overall, I recruited a sample of 69 GPs, 40 GPs in Australia and 29 GPs in the UK. Participants were of varying ages, clinical experience, gender, and patient populations.

	Australia n=40	United Kingdom n=29	Total
Gender			
Male	28	16	44
Female	12	13	25
Years in practice			
Mean	19	12	
Range	1-40	1-39	
GP location			
Metropolitan	16	16	32
Regional, rural	24	13	37

I continued to sample until I reached theoretical saturation. In a grounded theory study, theoretical saturation is the point at which gathering more data ceases to yield any further insights about the process being studied, so cannot develop the theoretical explanation any further (10). I ceased recruitment once I had (1) developed a clear picture of the rationale and practice of GPs in Australia and the UK; (2) felt well enough informed to generate an appropriate explanation of specific aspects of that process; and (3) all concepts that were important in my developing theories could be substantiated from the data.

2.3 Data collection - Interviews

My aim was to explore how a specific process (prostate cancer screening) occurs in a social context (primary care), from a specific perspective (general practitioners). I wanted to know how doctors interact with that process, with that medical technology (PSA screening test), in that context, under those conditions, and identify patterns and explanations that participants might or might not be aware of.

I generated data via in-depth semi-structured interviews. Interviewing is the most frequently used form of data collection in grounded theory studies (10). I interviewed Australian GPs between March 2013 and June 2014 and UK GPs between September and December 2014. I conducted all interviews, primarily by telephone or Skype. They ranged in duration from 18 to 70 minutes.

Interview questions

A semi-structured interview guide was prepared to provide general direction and an overview of potential question routes. There was sufficient scope for participants to raise issues the interviewer had not anticipated. The guide was loosely based on the research questions as well as what I had learned from the existing literature on the topic, and covered a broad range of topics, including GPs' recent clinical encounters involving PSA screening decisions; communicating information about PSA screening to patients; screening pathways; and overdiagnosis of prostate cancer. I did not rigidly adhere to the interview guide when interviewing the GPs; ordering and wording of the questions was contextual and responsive to the particular GP and their ability to inform the developing analysis. Questions were open-ended to encourage in-depth and detailed responses, range and diversity, and to allow for prompting.

All GPs in Australia and the United Kingdom were asked to think back to their most recent consultation involving a discussion about PSA screening or to describe a typical consultation where the topic was raised, and were invited to tell the interviewer as much as they could about what happened in the consultation (without disclosing patient personal details). The aim of this approach was to open the discussion about, and provide context for, conversations about PSA screening, and to use this as a

platform to guide prompts and to focus subsequent questions. It also established that the interview was about use of the PSA test as a screening tool for asymptomatic men, rather than as a tool to assist in the diagnosis or monitoring of prostate cancer. Terminology regarding PSA screening is often difficult to interpret. This is in part because similar medical technology is used for both a screening test and a diagnostic test. I wanted to make it clear from the outset that this analysis was concerned with the use of the PSA test as a tool for screening only.

The overall initial interview schedule for Australian GPs was very broad; examples of questions from the initial schedule included:

- How did you come to approach prostate screening in this way? Has this changed over time?
- How do you decide when to refer a man to a urologist?
- How well do you think men understand PSA screening?

Evolution of interview questions

Responsive and flexible data collection is the methodological standard in qualitative inquiry (11-14). The interview guide was reviewed and modified between interviews based on the developing analysis to ensure I continued to get the data I needed to inform the ongoing data collection, analysis, and developing theory, and to align with the progressing research questions.

Questions included in the interview guide evolved throughout the entire data collection process as new issues arose, driven and informed by theoretical sampling, and as I began to learn what was most important to participants. For example, early in the study I identified perceptions of the risk of underdiagnosis as a key issue underlying varied clinical practice. In subsequent interviews following this discovery, I asked GPs whether this was relevant to them, if they had experienced situations where a potentially screen-detected cancer had not been detected in their clinic, and how they reasoned about this issue. The interview guide was modified to enrich the quality of the data available to answer my research

questions. A flexible and evolving guide also enabled me to continue questioning until each point made by each interviewee was fully explained and understood.

Table 7 demonstrates additional examples of issues that emerged throughout analysis and which were further explored in the GP interviews when deemed relevant.

Table 7: The evolving interview schedule

Examples of analytic questions arising from analysis	Empirical evidence that prompted further exploration or interest in this question	Examples of questions used to follow-up issues of potential interest and relevance
• Is the cost of a PSA test relevant to screening decisions?	• Interview data indicating varied awareness of Medicare coverage of the PSA test	• How often do you order a PSA test for an asymptomatic man? • Does Medicare coverage of the PSA test have any impact when you are making decisions about ordering a PSA test?
• Do perceived medico-legal implications influence screening behaviour?	• Interview data indicating defensive practice due to concerns about potential litigation • Reported attendance at a conference in which this issue was discussed amongst GPs as being a driver of screening practice	• Do you feel there are any medico-legal considerations around PSA screening? • If yes, how is that relevant to your screening practice? • If no – other GPs have suggested this might be an issue, why is that not a consideration for you?
• Do guidelines and the information environment contribute to variability in PSA screening practice?	• Interview data indicating confusion and frustration with mixed guidance advising on PSA screening • Recent update (2012) of RACGP Red Book	• Which guidelines (if any) do you refer to when making decisions about PSA screening? • Why that guideline? • Are you familiar with the recent RACGP recommendations? What do you think of them?
• Do GPs in rural locations explain and use the PSA test as a screening tool differently to GPs located in urban practices?	Interview data indicating: • Urban and rural GPs use the PSA test differently • The potential influence of the availability of urologists on screening and referral decisions • Rural GPs self-manage abnormal PSA test results more frequently and for longer than rural counterparts, attributed to urology backlog	• What guides your referral decisions, and why? • What is your PSA threshold for urology referral? • Do you access fly-in urologists? What is their role in PSA screening and in your screening decisions? • Who or what is your preferred source of information about PSA screening?
• Is practice protocol relevant to GP screening behaviour? (in these cases, I tested emerging theories by interviewing several GPs in the same general practice to distinguish individual GP approaches, practice conditions, and context)	Interview data indicating: • Some practices have an automatic recall system for PSA tests (i.e. a man can access PSA screening without a GP consultation) • Some UK GPs said their practice nurses ordered PSA tests without the man having a GP consultation	• Does your practice have a practice protocol for PSA screening? • Does your practice have a recall system? Why? • If yes, how do you use that in your practice? • What role do practice nurses play in PSA screening of asymptomatic men? [UK GPs only]
• What is the role of the health care system in creating particular conditions of practice?	• Interview data indicating significant variation in Australian GP approaches to PSA screening, not entirely explainable. Data from a different context required to confirm, disconfirm, enrich, or extend conceptual understanding and emerging theory	• How does PSA screening fit into the care of male patients over 40 years in your clinic? • Who initiates conversations about prostate cancer screening?

Specific reasons for the inclusion of UK GPs was outlined in Section 2.2. To develop the interview guide used in the UK context, I consulted a health services expert in the UK to gain background information and identify the most relevant interview questions to that context. The resulting guide began with me asking UK GPs to think about the way they typically manage male patients over 40 years and how does PSA screening fit into their care, to obtain a general picture of how things worked in the new context. Follow-up questions included:

- What do you include in your discussions with men about PSA screening?
- Is overdiagnosis of prostate cancer considered an issue in PSA screening in your practice / the UK?
- How does referral to urologists work in your practice (i.e. high PSA)?
- Are you familiar with the Prostate Cancer Risk Management Programme? What effects has the PCRMP had on your practice?

Initial interviews indicated that unlike in some general practices in Australia, PSA screening did not appear to be the norm or an accepted standard of care. Following analysis of the initial interviews, I added further areas for exploration:

- What would happen if a GP was screening all asymptomatic men? (to ascertain whether GPs felt any pressure to practice in a particular way)
- What is the place of health checks in the UK? (to ascertain scope for opportunistic screening, as was common in Australian practice)
- Where do GPs access advice about PSA screening in the UK? Why that source?
- Why do you think the UK has lower PSA screening rates than other localities? (to ascertain broader, possibly unexplored, social and political influence)

In the following section I describe how I analysed the interview data collected from GPs in Australia and the UK, guided by the principles of grounded theory methodology.

2.4 Data Analysis

With GP permission, the interviews were digitally recorded. Interview data were transcribed verbatim by a professional transcribing service to produce data for analysis. I led the analysis, with support from my supervisors. Grounded theory methodology stipulates that data analysis should occur in parallel with data collection (10). Analysis begins immediately and is ongoing, and continues in parallel with data collection to allow for theoretical sampling (as described in the previous section). Analysis looks for patterns in the data that support a comprehensive explanation of the social process being studied (in this case, PSA screening). Analysis is conceptual rather than focusing on individual cases. Contexts, contingencies, consequences, and conditions are examined (15) to better understand the patterns and relationships among these elements and develop an explanation of the social process.

Developing codes

Coding data (10) shapes the analytic frame and direction of analysis. Coding is a process of breaking data down into small components and labelling the components with a descriptive meaningful label which represents key concepts being conveyed in that data. Codes distil and define what the data are about. The coding process allows researchers to define what is happening in the data and to begin to grapple with what it might mean, to eventually make analytic distinctions.

Initial coding

I coded the transcripts. A subset of transcripts were also read and coded by my supervisors independently to ensure interpretive rigor; this coding was compared and discussed to inform the development of the central concepts in the study.

I adopted Charmaz's method of coding for actions and processes, rather than topics, by using gerunds as codes, that is, verbs ending in "ing". Gerunds are used to code in a way that actively captures people's

intentions and concerns, and anchor the analysis. Charmaz recommends coding as quickly and actively as possible, keeping codes as similar to the data as possible and preserving event and context (3).

In my initial coding I worked by principles of inductive reasoning: entire transcripts were coded to generate as many ideas as possible from the early data. At this stage, it was not possible to determine which concepts would be most important, so I systematically read and considered all GP descriptions. This initial or open coding was an important early stage of the analytic process because it focused my attention onto things that might otherwise be missed. It also informed my theoretical sampling by highlighting areas where data was still needed, shaped the progression of my research questions and the interview schedule, and facilitated the emergence and subsequent saturation of an identified core category. I coded initially to capture the range of variation and for the conditions that could explain that variation, to be built on later in memos.

Table 8 below is a good example of the type of data I coded as 'being stuck in a catch-22'. GPs described in many different ways being caught in a difficult paradoxical situation, feeling conflicted, but unable to escape the dilemma because of conflicting or contradictory rules or conditions. This code, and its various iterations, progressively informed the focused code, 'being uncertain' which eventually formed the backbone of one of my empirical chapters, presenting an analysis of GP experiences of uncertainty (see Chapter 4). The example provided in Table 8 of the *being stuck in a catch-22* code is from a single GP - a very reflective and articulate GP communicating the frustrations of working within the current limitations of the evidence and consequent recommendations; and experiencing significant personal conflict as a result.

Table 8: Example of 'being stuck in a Catch 22' code

But I think that it's – I do feel that I've got men who've been treated who need not have been treated and –I don't know that I can weigh up – look, as I said, one – one other factor that I haven't mentioned is that my men who do have – who have been treated for prostate cancer and who now have erection difficulties and incontinence, very few of them have very much regret about that. I mean, that most of them see it as, I've been cured of cancer and I don't really mind, I guess – the price you pay for being cured of cancer. So what's interesting is, as a doctor, I think, well how terrible that you might not be able to have sex again or that you have to wear a nappy for the rest of your life, but I'm not sure that that's as much of a burden for them as it is for me – and so – and clearly, a premature death from a horrible cancer is a terrible disaster for a patient and for their doctor and so whether, you know, over-diagnosis and over treatment, I mean, I don't know how you weigh up that against saving – and so what if maybe – maybe 43 incontinent men is worth it for saving one man from a premature death, but I – I don't – I can't make that choice, you know, but I – I guess that's a question that I, sort of, contemplate at times.

Focused coding

Focused coding is more directive, selective, and conceptual (3) and occurs only after open coding has allowed the researcher to alight on a set of analytically important categories. Focused codes were used to synthesise, integrate, and organise the large amounts of data in the transcripts; only that data directly relevant to the analysis are coded at this stage. I decided which initial codes appeared to be most salient or important to the GPs and could usefully contribute most to my analysis, and tested them against more extensive data relevant to that code. For example, one of my focused codes – 'being uncertain' – was abstracted from various versions of this overarching concept evident in my initial coding, such as 'being stuck in a catch-22', 'worrying' and 'making difficult decisions'. Another example of a focused code from my analysis is 'avoiding underdiagnosis'. The refined focused codes were eventually treated as tentative conceptual categories, and were developed and tested in further memos.

Using constant comparison

The constant comparative method is an iterative analytic process involving simultaneous and concurrent coding and analysis. Data is compared with data, data with codes, codes with codes, codes with categories and so on, looking for similarities and differences, confirmation and disconfirmation. The purpose of this method is to generate theory systematically and inductively derived directly from the data (4). I compared the coded data from my first few interviews with data within the same interviews and between

interviews. Selections of data were compared to each other and to existing codes and categories so I could gauge their similarity and dissimilarity, including their fit or conflict with my developing explanations of the PSA screening process.

This strategy was an ongoing process maintained for the duration of the research study. It effectively ensured active interaction with the data, and helped to identify and clarify variation in the data. Provisional explanatory theories were developed, re-developed, and tested with new data, old data, and existing knowledge via repeatedly moving to and fro between the collection of data, coding, and memo writing. Constant comparison continues until the researcher arrives at the most plausible interpretation of the process under study (2).

Theoretical coding

Theoretical codes are conceptual connectors, developed through constant comparison. Glaser first introduced theoretical coding in grounded theory when he presented a series of theoretical coding families that the researcher could draw on to develop conceptual analysis. In his classic version, one theoretical code eventually 'emerged' that integrated all substantive categories with a core category. Charmaz argues that coding in such a way imposes a forced framework on the analysis. I followed Charmaz's variation and used theoretical coding to add precision to relationships between my focused codes and to begin theorising about what was actually happening during the PSA screening process (i.e. not aiming to "discover" an ultimate theoretical code). Table 9 provides an example of the progression from initial coding (being stuck in a catch-22) to focused coding (being uncertain) to the eventual development of a theoretical code (experiencing burden). See Section 2.1 regarding using theoretical frameworks from the existing literature, such as Han's taxonomy of uncertainty in health care (applied in Chapter 4).

Table 9: Illustration of the coding process with examples of initial, focused, and theoretical coding
(note that some initial codes in this table went on to support the development of other focused and theoretical codes)

Raw data	Initial coding	Focused coding	Theoretical coding
I give that explanation to most men – to every man who I see about a PSA testing and – but I also say that, obviously, PSA testing is really the only good way we have of finding prostate cancer and I say that we also – certainly also know men who die of prostate cancer, and I've got patients who are dying of prostate cancer, and – and it's a very difficult decision as to whether you should test for it or not and I say it's a decision that you need to make and I can't make for you, and I find probably a lot of my patients choose not to do the test after I've talked to them about it and I would say the significant minority of my patients who came in asking for the test decided to do the test anyway and I suppose, I mean,– I'll talk a bit more about this, but I think my concern is that – is that the – the spiel that I give men about this leaves them with virtually no ability to make a good decision, because I don't even know what the good decision is around PSA testing and I think I – I don't make things easier for people because I think it's an incredibly difficult area.	**Explaining:** to every man; rigorous **Making decisions:** Recognising difficulty **Making decisions:** men need to decide themselves **Making decisions:** men changing mind or doing test anyway **Being stuck in a catch-22:** Not being able to make a good decision because there's no good decision to make **Explaining:** explanation does not making it any easier for men **Making decisions:** not knowing what the good decision is	Being uncertain	Experiencing personal burden
I think prostate cancer screening is, in my daily practise, is by far my biggest kind of anxiety around cancer screening; I think it just seems to – it – we battle in general practice with convincing men that they need to see the doctor and have health care and so the man is – and the man who listens to the – the media believes that good self-care is to have a prostate cancer test and then when he comes to me, I tell him that that's actually wrong and so I'm almost, sort of, turning away the person who's trying to do the right thing. So I, you know – I don't achieve a satisfactory balance for myself, really, I mean, I just think that, you know, I worry – I worry that there are men, young men who probably will get prostate cancer and die of it because I'm not doing enough screening, but I'm not prepared to not follow the evidence and I think that the evidence says you don't do it, and I recently – I saw even this week, a new guideline from the American College of Physicians, which was – which supports my view, I think, which was to say, frankly, that we should not screen men for prostate cancer, and that we should only screen those people who've been given a detailed discussion of the risks and benefits of screening – I think that that second statement is a copout, I think the idea that we should only screen those men who've been given a proper discussion of the risks and benefits, doesn't	**Framing PSA:** worst cancer screening problem **Being stuck in a catch-22:** contradicting ourselves, turning away the compliant minority **Being stuck in a catch-22:** not being able to satisfy her/himself **Being stuck in a catch-22** **Worrying:** that s/he is letting young men die **Failing as a doctor** **Justifying position:** not prepared to contradict the evidence **Justifying position:** appealing to authority **Locating responsibility:** explanation / consent is a copout – medicine(?) needs to find a solution **Being stuck in a catch-22**	Being uncertain	

get away from the fact that we're still in a mess with what we're actually advising men to do and I just think it's a – we need to know quickly, how we decide which men need treatment for prostate cancer and which men don't need treatment and until we have that answer, this is going to remain a big mess, I think, for healthcare.	**Being in a mess** **Locating solutions:** improve knowledge (re who should get treatment) **Locating responsibility:** not exactly clear but maybe the profession?		

Writing memos

Memos are informal analytic notes that detail thinking and analytic work. I used memos during coding, collecting, and analysis to document individual cases, categories, and relationships. They create space for tracking new ideas and insights, justifying interpretations, documenting outstanding questions to direct future data gathering, and for making comparisons and articulating speculations about those comparisons.

Memo writing is a crucial analytic process in grounded theory studies because it prompts early analysis. Writing successive memos throughout the research process keeps the researcher involved in the analysis and helps to increase the level of abstraction of developing ideas (3). They are an important intermediate step between data collection and writing drafts of papers.

I coded my data in word processing documents with simultaneous memo writing to organise my analysis: the memos were the most important way of keeping track of my analysis and thinking and were written during and after the data collection period. Throughout the process I asked many questions of the data. For example: Under what conditions does this practice occur? How do the GPs think, feel, and act while involved in this process? When and how do their actions change? How does this process happen in different places, for different people, for the same people at different times? Asking these questions encouraged me to examine codes and categories across their dimensions, to develop integrated explanatory frameworks, and to focus key messages for paper production and publication.

Case-based memos

Case-based memos were written as soon as convenient after each interview: about how it went, information that stood out, what seemed important to that GP, and interesting points to follow up (e.g. experiences of uncertainty, distrust, or burden, the place of guidelines). Table 10 provides an example of a case-based memo about GPs being stuck in a catch-22, written about an early interview.

Table 10: A case-based memo, illustrating code 'Being stuck in a catch-22'

This GP provided a very useful, detailed account of the difference between "chucking in a PSA test" versus the way it 'should' be done (i.e. GP explaining and having rules of thumb about appropriateness of screening for individual patients). He does quite a lot of work to position himself and his approach; he is deeply committed to being the best GP he can be: he takes his job seriously, and wants to be fully informed, to give good advice. His practice is very much in line with the current GP guidelines (Red Book), but he clearly articulates the frustration of working within the current limitations of the evidence – and that as a profession medicine has not clearly articulated the current position. There was also some important information about the emotional effect of the current situation on him as a GP, including that he has to carry a burden to protect his patients (e.g. worrying about whether he has made the right decision). The most central code for this GP was 'Being stuck in a Catch-22'. It is not just the GP in a Catch-22, the men are also stuck in a Catch-22; a place of personal conflict. This GP has tried to work out what to do about PSA screening. But it is impossible to know what to think and the experts have failed him – they cannot give him the test or the information that he needs. And if he does think about it, he ends up in an impossible situation: he ends up not knowing what to advise, the men end up having to make impossible decisions. And if he tells men not to have the test he feels like he is undermining his profession, because it is often a miracle for men to see a GP in the first place and so GPs should be offering them anything they can but instead he is telling them NOT to have the test. And even when he thinks he has consent from men, he cannot be sure that they are actually imagining what they need to imagine to make a good decision. This is why it is a Catch-22. Some GPs can deal with this by just chucking in PSA testing (i.e. do it thoughtlessly). Thoughtlessness is a highly undesirable quality in decision making. But if you think about it – you find yourself in an impossible situation. Because there is no answer, no one can tell you what to think and you cannot work it out for yourself, so maybe better off not thinking about it.

From this memo I identified new explanations to pursue and subsequently developed the interview schedule to find out more about, for example, making impossible decisions, using the evidence, thoughtless practice, and feeling burdened.

Conceptual memos

I also wrote conceptual memos, to record my thinking about the meaning of initial and focused codes and to work out categories and relationships between them in depth. I wrote a number of conceptual memos to enrich my understanding of central issues underlying the GPs' explanations of how things worked in

their practice. Table 11 presents a conceptual memo about 'being uncertain'. At this stage of analysis, researchers using this method pay particular attention to variation in the meaning of concepts – how is the identified concept different to different people, different places, how is it similar, how does it compare to similar things in the literature – to gain a full grasp of the concept and in turn generate a comprehensive explanation of its meaning and relevance to the research question. This is an important step in the move towards theory construction.

Table 11: A conceptual memo about 'Being uncertain'

Being stuck in a catch-22 + Locating responsibility + Making impossible decisions = <u>Being uncertain</u>

*Many different types of *uncertainty* are becoming apparent in different contexts and GPs seem to focus on different versions of it, some not so overtly, but overall it doesn't seem to be a particularly pleasant? welcome? experience. I think this concept might offer at least partial explanation of the data on the Catch-22 code and repetitive references about locating responsibility, making decisions, and feeling burdened by it. Some uncertainties being talked about by GPs: uncertain screening tool; uncertain evidence base; uncertain outcomes; uncertain guidelines, recommendations, advice; GP uncertain about what they personally would do; how to communicate; do patients know what they're asking for?; unsure what colleagues are doing about it. 'We don't know what the hell we're doing'. Also, overdiagnosis and underdiagnosis which I wrote about in a memo before this one are uncertainty. This is why the area of overdiagnosis is so uncomfortable and burdensome on GPs too – it's hard to know right from wrong. The true outcome of any screening decision will never be known at an individual level. So what's a good decision and how can you be sure?*

*GPs are managing uncertainty in really different ways, in the way they describe it (as a normal part of practice, not of concern, rely on gut instinct, very frustrated and concerned) and strategies they use to deal with it (assess relevance, seek guidance, consult guidelines, and with patients – provide information, test more, test less, ignore, disclose). Some *accept it in their clinic and don't seem particularly bothered, some *negotiate (?) and try to work with it or around it, some throw it away or *transfer it to other people, and to organisations too – it is their problem. Should it be the problem of organisations? It seems to be a major concern of GPs so needs to be explored further. Paul Han's model of uncertainty could be relevant here? Follow up – suggested by a colleague. Han writes about uncertainty arising from different sources: probabilistic, ambiguity, and complexity. These concepts seem to be a good fit here.*

*There are two main points about the uncertainty: (1) paradoxically doing PSA test with uncertainty to gain certainty, (2) ignoring the technical aspects of uncertainty that the GPs knows from medical training etc in their quest for [false] certainty. **Put everything we know about the complexity of the test aside – other values and inputs have a stronger pull; there are more compelling reasons that GPs would rather do a bad test than not do a test at all. Then there were those GPs that acknowledge the uncertainty and feel the burden: because the more you think about it the more you don't know what to do (PSA screening creates exactly the thing they want to avoid; a cascading effect of uncertainty after uncertainty). So GPs are caught in dilemma of construction of false certainty. And GPs choose different pathways around that.*

BUT, why didn't this come up in the UK interviews? What is evident in the practice of UK GPs that can explain this? I think a lot of it is about whether this is a problem of organisations or of individual GPs. More collective responsibility in the UK for what GPs do with the PSA test. I think I have another paper to write here about comparing all the conditions that GPs described as relevant to their screening practice in the two settings and how that might influence particular ways of practicing.

Mapping concepts

The mapping component of this analysis provided a visual medium to organise and connect ideas. The process helped to clarify associations and relationships between topics and developing explanations. Consistent with Charmaz, I drew clustering diagrams to visualise the key themes of each memo to see how each was connected, or not, and used these images as an outline to additional future memos and in the writing process. These conceptual maps are presented in the findings and discussion chapters.

2.5 Answering my research questions

Grounded theory focuses on creating conceptual frameworks or theories through building inductive analysis from the data: from specific description of the data to more abstract understanding of the phenomenon in its entirety. General statements are made about analyses, but are always located in the context of their construction –in time, place, and the situation of inquiry (3). At the end of my data collection and analysis I had developed a provisional model explaining some aspects of the PSA screening process, from the perspective of GPs in Australia and the UK, expressed in diagrams and memos, and built around a core set of related categories.

Generating an explanatory theory

Grounded theory was explicitly developed to guide researchers to generate new theory rather than to verify existing theory (4). The product of a grounded theory study is expressed as a substantive theory: a set of concepts that are related to one another in a cohesive whole about an issue or experience that works in a particular context; substantive theories should closely reflect what participants experience and do.

Typically a grounded theory study is intended to focus on a central social process (here, prostate cancer screening in general practice) and to arrive at a final explanatory theory that explains that process as a whole. This study is a good example of this – I have produced four empirical chapters (Chapters 3-6), each

focused on a different component of PSA screening in practice: overdiagnosis, uncertainty, context, and communication, and concluded with a final discussion cohering these components into a single explanation of the process. In Chapter 7 I present a practical working model of the PSA screening process, derived from GP accounts of how screening for prostate cancer works in their clinical practice, which draws together aspects of all the empirical papers into one model. It reflects significant variation in reasoning, practice, and experiences, and provides some explanation of how that variation works, including the influence of context.

2.6 Quality of this grounded theory study

Quality control is integral to grounded theory procedures and general principles of qualitative research. The following points describe process and procedural components of this study that ensured quality and rigor at all stages of the process.

- All interviews were digitally recorded and professionally transcribed
- Interview transcripts were analysed as soon as possible to focus the progressing data collection, particularly theoretical sampling
- Sampled theoretically, to develop the emerging theoretical categories and make them robust
- Writing regular, detailed case-based and conceptual memos enriched data analysis and further guided focused data collection
- An evolving interview guide and responsive and flexible data collection ensured that gaps in knowledge could be addressed
- Use of the constant comparative method, described in Section 2.4, ensured the developing theory was an accurate and thorough reflection of the process
- All researchers involved in this project supported analysis activities and attended regular meetings to discuss the analysis and emerging interpretations.

Quality appraisal similarly applies to the credibility of the final product: the grounded theory. Charmaz suggests four characteristics that a grounded theory study should have to be considered a good-quality study. These are: credibility, originality, resonance, and usefulness (3). I briefly describe how the criteria apply in my study, below.

Credibility: Charmaz describes research 'credibility' as achieving intimate familiarity with the setting or topic. My sampling of a large number of GPs across a range of contexts in Australia and the UK has provided a useful framework not only to understand how things work in two specific primary care contexts, but also to undertake strategic comparison, allowing insights to be generated about how different conditions influence practice.

Originality: 'Originality' refers to the social and theoretical significance of the work. This study provides a nuanced analysis of how and why GPs test the way they do. I identified what matters to GPs and issues that encourage, prevent, and justify practicing in particular ways. Throughout, I compare my analyses with relevant theoretical and research literatures, including Han's taxonomy of uncertainty, Gabbay and le May's mindlines theory, Entwistle et al.'s Consider an Offer framework, and traditional models of evidence-based medicine.

Resonance: In Charmaz's text, 'resonance' is about whether the grounded theory makes sense to the participants or people who share their circumstances. I have presented components of this study at local and international academic conferences and seminars. Several GPs, academics, and professional organisations contacted me following these events to commend the work, and to confirm its relevance and applicability to their practice.

Usefulness: 'Usefulness' is achieved if the analysis offers interpretations that people can use in their everyday worlds. My conceptual model provides a new way of understanding this complex and controversial clinical and public health problem, and has important practical utility. An academic representative on the recent Australian PSA guidelines panel advocated for findings from this study to be

brought into conversations during the development process. The four empirical chapters were published in the peer-reviewed literature, have been cited in academic journals and at international conferences, and in Australian medical media, as I noted earlier in the thesis.

This chapter has provided a detailed explanation of how this study evolved using grounded theory methodology. The following chapter is the first of four presenting my empirical work. A summary table on the following page orients the reader to the place of each of the following four empirical chapters (Chapters 3-6) in relation to components of the final grounded theory, which will be explained in full in Chapter 7.

Components of the final grounded theory	**Chapter 3. Overdiagnosis** (n=32 Australian GPs only)	**Chapter 4. Uncertainty** (n=69 Australian & UK GPs)	**Chapter 5: Organisational context** (n=69 Australian & UK GPs)	**Chapter 6: Communication** (n=69 Australian & UK GPs)
Existing theory used in development of final grounded theory		Han's taxonomy of uncertainty	Gabbay and le May's Mindlines theory	Entwistle et al's Consider an offer framework
Research Question 1: How do GPs approach PSA screening?				
Three background conditions were central to GP descriptions of their screening approach: -Interpretations of the evidence (by GP or others) -Relatively stable GP values and goals -Intuitive patient typologies	GPs approached PSA screening… • Using one of four heuristics; shaped by different values and reasoning about the harms of under and over diagnosis. Considerable diversity. • By making an overall judgment about the relevance of evidence to PSA screening, for this individual man, or for all men, individually or in interaction with the patient • Sometimes, by responding to patients' individual preferences, shifting their usual screening 'rules' accordingly	GPs approached PSA screening… • With more or less uncertainty (scientific, practical, personal) about professional practice and expected standards of care • Using different strategies to manage different types of uncertainty: taking charge, engaging others, transferring responsibility	GPs approached PSA screening… • With GPs' roles, values, and corresponding goals for practice, shaped/enabled/disabled by their context: 1. According to professionally-derived, internalised values and goals of the organisation (UK) 2. According to individual values and goals, independent of their organisation (AU). • By appraising different types of evidence, with more or less guidance from their organisation	GPs approached PSA screening… • With four communication patterns: Be screened, Do not be screened, Analyse and choose, and As you wish • By communicating with men in line with their primary goals for the interaction • Sometimes, strongly influenced by patient 'types' • Sometimes, framing evidence to fit with valued outcomes • Sometimes, with little or no communication with men prior to ordering a PSA
Research Question 2: What factors influence GP approaches to PSA screening?				
Four sources of knowledge (experiential, tacit, relational, formal) influenced and shaped the background conditions	Main factors influencing GP approaches included: • The GP's experiences with PSA (e.g. missing an aggressive cancer): this provided tangible evidence; one-off experiences trumped formal evidence • Relational expectations (e.g. patient request, GP reputation): GPs discounted or re-shaped evidence to respond to these • GPs' interpretations of the research evidence (whether individually developed or received via guidelines)	Main factors influencing GP approaches included: • Three different sources of uncertainty: probabilistic, ambiguity, complexity • The GP's level of uncertainty about the PSA screening evidence base: some GPs accepted and managed on their own, some engaged others to help them make sense of the evidence, some transferred responsibility for interpreting the evidence to others	Main factors influencing GP approaches included: • History of screening policy and agendas; healthcare structures and payment models • Practice environments that encouraged (or discouraged) particular approaches, some more evidence-based than others • Institutional support and resources to apply the best available evidence in practice (or lack of) • Screening culture • GP mindlines (tacit knowledge, developed in-context)	Main factors influencing GP approaches included: • GPs' primary goals for practice (developed experientially, tacitly, relationally), influenced quality and quantity of information provision • Specific situational and relational factors (e.g. man screened by another GP) • Established norms of communicating

GPs evaluated the sources of knowledge via **two knowledge filters** -Trust -Uncertainty	Main factors influencing GP approaches included: • Lower trust in research evidence = GP guided by other sources of knowledge, like clinical experiences (which provided more certainty about the right thing to do, not necessarily evidence-based) • Higher trust in research evidence = GP guided by epidemiology, and more certain about the harms of overdiagnosis • Some GP uncertainty relating to translating overdiagnosis statistics to individual patients	Main factors influencing GP approaches included: • Type of uncertainty: GPs had more trust in their ability to engage in 'good' practice based on probabilistic uncertainty than uncertainty arising from ambiguity or complexity • Inconsistent versions of expert advice undermined Australian GPs' trust in the system and fuelled uncertainty about clinical and legal obligations	Main factors influencing GP approaches included: • Institutional trust: underpinned screening practice of GPs in the UK; strongly guiding healthcare structures were a proxy for relative certainty about the evidence and an evidence-based approach • Interpersonal trust: underpinned screening practice of GPs in Australia; ambiguity uncertainty meant GPs were more likely to perceive evidence as uncertain and thereby feel uncertain about the best approach	Main factors influencing GP approaches included: • Trust in, and certainty about, the evidence: GPs communicated epidemiological perspectives • Distrust, and uncertainty about, the evidence: GPs framed conversations according to personal judgments about the evidence
GPs engaged or did not engage others in **the screening interaction** -Communicating -Making a final decision (which mediated the final outcome)	Main factors influencing GP approaches included: • If a GP felt there was a clear 'right answer' they would advise patients to take that path, and include the patient less • If a GP was less clear, they would include patients more, case-by-case, or acted in line with patient instructions (e.g. to be screened) without question • Routine screening behaviours: some GPs habitually did not engage others (e.g. 'tick-box' approach) • GPs reported communicating about overdiagnosis was difficult (so most did not discuss it with patients)	Main factors influencing GP approaches included: • Uncertainty: some GPs took charge and managed screening decision making on their own • Uncertainty: some GPs engaged others in managing uncertainty, including the medical profession, colleagues, and patients • Uncertainty: some GPs sought to transfer to other parties the responsibility for managing or reducing some uncertainties • Some GPs felt conflicted, or guilty, about involving patients in making decisions based on uncertainty • Some GPs found talking with men challenging because of underlying uncertainty	Main factors influencing GP approaches included: • Institutional arrangements created more or less opportunity for engagement processes to occur; e.g. two-step process, written information resource in the UK (more opportunity), practice recall systems and mailed pathology forms in Australia (less opportunity)	Main factors influencing GP approaches included: • GPs' ambitions for patient understanding: some GPs aimed for comprehensive detailed information exchange, others were satisfied with 'gist' understanding of the basic concepts • Patient 'types': some GPs reverted to intuitive understandings of 'PSA patients' to help them to decide whether to involve patients in the process and if they did, how that should be done • Determining that not all patients wanted to be active participants in decision making
Research Question 3: What are the consequences of this process?				
There were relevant consequences (**outcomes**) for both GP and patient: -Screening or not screening -Patient outcomes -GP outcomes	Main consequences were: • GPs perceived there to be much at stake for them individually: easy to take 'wrong' course of action	Main consequences were: • GPs felt insufficiently supported professionally, and burdened by the complexities of their situation and responsibilities to patients	Main consequences were: • Men could receive very different care, depending on their GP: Institutional norms and infrastructure shaped what GPs	Main consequences were: • Consistent communication patterns in the UK, variation in Australia • GPs' heuristics of patient values, rather than actual patient values,

- GPs experienced cognitive and emotional burden, feeling personally responsible for the consequences of their approach
- Because of variation in GP practice, men are likely to experience unequal access to information and consent to screening
- GP anxiety arising from perceived incapacity to make good decisions without good evidence
- Continued PSA screening in the Australian context, in pursuit of certainty
- prioritised as an outcome for a patient
- Promoting a market for PSA screening: Australia's fee-for-service payment system continues to reward GPs for activity in primary care
- commonly transpired to inform decision making
- A spectrum of patient involvement: GP conceptualisations of the 'ideal' patient outcome varied

Chapter References

1. Grypdonck MH. Qualitative health research in the era of evidence-based practice. Qualitative health research. 2006;16(10):1371-85.
2. Bryant A, Charmaz K. The Sage handbook of grounded theory: Sage; 2007.
3. Charmaz K. Constructing grounded theory: Sage; 2014.
4. Glaser B, Strauss A. The discovery of grounded theory. 1967. Aldin, New York. 1967.
5. Sbaraini A, Carter SM, Evans RW, Blinkhorn A. How to do a grounded theory study: a worked example of a study of dental practices. BMC medical research methodology. 2011;11(1):1.
6. Baade PD, Youlden DR, Coory MD, Gardiner RA, Chambers SK. Urban-rural differences in prostate cancer outcomes in Australia: what has changed. Med J Aust. 2011;194(6):293-6.
7. Ranasinghe WK, Kim SP, Papa NP, Sengupta S, Frydenberg M, Bolton D, et al. Prostate cancer screening in Primary Health Care: the current state of affairs. SpringerPlus. 2015;4(1):1.
8. Sarantakos S. Social Research. 3rd. Hampshire: Palgrave Macmillan. 2005.
9. Carter SM, Little M. Justifying knowledge, justifying method, taking action: Epistemologies, methodologies, and methods in qualitative research. Qualitative health research. 2007;17(10):1316-28.
10. Charmaz K. Constructing grounded theory : a practical guide through qualitative analysis. London: SAGE Publications; 2006.
11. Pope C, Mays N. Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. BMJ: British Medical Journal. 1995;311(6996):42.
12. Britten N. Qualitative research: qualitative interviews in medical research. British Medical Journal. 1995;311(6999):251-3.
13. Mays N, Pope C. Rigour and qualitative research. British Medical Journal. 1995;311(6997):109.
14. Mays N, Pope C. Assessing quality in qualitative research. British Medical Journal. 2000;320(7226):50.
15. Strauss A, Corbin J. Basics of qualitative research: Techniques and procedures for developing grounded theory: Sage Publications, Inc; 1998.

CHAPTER THREE.

Doctors' approaches to PSA testing and overdiagnosis in primary healthcare:

A qualitative study

3. Overview of this chapter

This chapter presents an analysis of how and why GPs provide, or do not provide, the PSA test to their asymptomatic male patients (Research Question 1.1), with a focus on under- and over- diagnosis. GP considerations of under- and over- diagnosis were identified as significant sources of variation in reasoning (Research Question 2.1), and having a substantial impact on GPs, personally and professionally (Research Question 3.1, 3.2).

PSA screening has significantly increased the detection of prostate cancers. Some cancers found through PSA screening grow so slowly that they may never become clinically relevant or impact on a man's life. Men with such cancers do not benefit from detection and treatment. Overdiagnosis is thus particularly pertinent to prostate cancer. Overdiagnosis is widely considered the most concerning potential harm of PSA screening. But overdiagnosis is a complex concept to understand and explain for health care professionals and the public. Responsibility for guiding men's decisions about whether or not to be screened for prostate cancer has largely been placed in the hands of individual clinicians. A conundrum for clinicians is that it is not possible for them to know which cases represent overdiagnosis at the time of screening. Few publications have reported on clinician views on overdiagnosis.

3.1 Publication details

Pickles K, Carter SM, Rychetnik L. Doctors' approaches to PSA testing and overdiagnosis in primary healthcare: a qualitative study. BMJ Open 2015;5: e006367. doi:10.1136/bmjopen-2014-006367

3.2 Authors' contributions

KP, SC, and LR conceived the study and were involved in designing the study and developing the methods. SC & LR obtained funding and are CIs on the NHMRC funded project grant. KP conducted the interviews and led the analysis, had full access to all data in the study, and takes responsibility for the integrity of the

data and the accuracy of the data analysis. KP, SC, and LR drafted the manuscript. All authors contributed to the interpretation of the analysis and critically revised the manuscript.

3.3 Abstract

This was a qualitative study that sought to explain how PSA screening works in clinical practice. Data were analysed using grounded theory methods. We interviewed 32 Australian GPs to illuminate the issues from the GP perspective. We found significant variation in the GPs' approaches to screening for prostate cancer, which were strongly related to their personal view on how underdiagnosis and overdiagnosis should be balanced. We identified four heuristics to describe GP preference for, and approaches to, PSA screening and overdiagnosis: (1) GPs who prioritised avoiding underdiagnosis, (2) GPs who weighed underdiagnosis and overdiagnosis case by case, (3) GPs who prioritised avoiding overdiagnosis, and (4) GPs who did not engage with overdiagnosis at all. Many GPs gave considerable weight to concerns about missing cancers. Some GPs described feeling conflicted about the right thing to do which created considerable burden. We look at GP responses to navigating this complex situation. These findings offer important guidance for future efforts to address the problem of prostate cancer overdiagnosis.

3.4 Manuscript

The published version of the manuscript follows.

BMJ Open

Doctors' approaches to PSA testing and overdiagnosis in primary healthcare: a qualitative study

Kristen Pickles,[1] Stacy M Carter,[1] Lucie Rychetnik[1,2]

To cite: Pickles K, Carter SM, Rychetnik L. Doctors' approaches to PSA testing and overdiagnosis in primary healthcare: a qualitative study. *BMJ Open* 2015;**5**: e006367. doi:10.1136/bmjopen-2014-006367

▸ Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2014-006367).

Received 12 August 2014
Revised 16 February 2015
Accepted 17 February 2015

[1]Centre for Values, Ethics and the Law in Medicine, Sydney School of Public Health, University of Sydney, Sydney, New South Wales, Australia
[2]School of Medicine, University of Notre Dame, Sydney, New South Wales, Australia

Correspondence to
K Pickles;
kristen.pickles@sydney.edu.au

ABSTRACT

Objectives: (1) To explain general practitioners' (GPs') approaches to prostate-specific antigen (PSA) testing and overdiagnosis; (2) to explain how GPs reason about their PSA testing routines and (3) to explain how these routines influence GPs' personal experience as clinicians.

Setting: Primary care practices in Australia including men's health clinics and rural practices with variable access to urology services.

Participants: 32 urban and rural GPs within Australia. We included GPs of varying ages, gender (11 female), clinical experience and patient populations. All GPs interested in participating in the study were included.

Primary and secondary outcome measure(s): Data were analysed using grounded theory methods to determine how and why GPs provide (or do not provide) PSA testing to their asymptomatic male patients.

Results: We observed patterned variation in GP practice, and identified four heuristics to describe GP preference for, and approaches to, PSA testing and overdiagnosis: (1) GPs who prioritised avoiding underdiagnosis, (2) GPs who weighed underdiagnosis and overdiagnosis case by case, (3) GPs who prioritised avoiding overdiagnosis and (4) GPs who did not engage with overdiagnosis at all. The heuristics guided GPs' *Routine Practice* (usual testing, communication and responses to patient request). The heuristics also reflected GPs' different *Practice Rationales* (drawing on experience, medicolegal obligations, guidelines and evidence) and produced different *Practice Outcomes* (GPs' experiences of the consequences of their PSA testing decisions). Some of these heuristics were more responsive to patient preferences than others.

Conclusions: Variation in GPs' PSA testing practices is strongly related to their approach to overdiagnosis and underdiagnosis of prostate cancer. Men receive very different care depending on their GP's reasoning and practice preferences. Future policy to address overdiagnosis will be more likely to succeed if it responds to these patterned variations.

Strengths and limitations of this study

- Most previous research has examined which general practitioner (GP) characteristics are associated with frequent or infrequent testing, and has been predominantly quantitative. This in-depth qualitative study offers a unique examination of GPs' approaches to prostate cancer overdiagnosis, from the GP perspective. It is the first study to systematically map prostate-specific antigen (PSA) testing with GPs' reasoning and understanding of prostate cancer screening and overdiagnosis.
- We identified and interviewed highly informative participants (GPs) and have developed valuable detailed insights into how the PSA testing process works in everyday practice.
- There may be value in knowing the prevalence of the four heuristics we have discovered across the population: a next step could be a population-based survey to ascertain the prevalence of these heuristics at a population level.
- Since physicians with strong opinions may have been more likely to volunteer, some selection bias is possible. However, diverse opinions and approaches were reported, suggesting that strong selection bias is unlikely.

INTRODUCTION

Prostate-specific antigen (PSA) testing for prostate cancer in healthy men is an emotive, controversial[1] and hotly debated issue. Evidence suggests that harms of PSA testing for prostate cancer in asymptomatic men can outweigh benefits.[2–4] Most guidelines recommend against population screening;[3 5–7] however, some professional societies do recommend selective PSA testing[8–10] (table 1). In Australia, and internationally, many men continue to be tested despite guidelines advising not to screen.[16–18] This article presents an empirical qualitative study of how Australian general practitioners (GPs) reason about PSA testing of asymptomatic men for prostate cancer, who they test and why, with a particular focus on how GPs manage the risk of overdiagnosis.

Overdiagnosis and/or overtreatment are considered the main potential harms of PSA testing. Overdiagnosis occurs when people without symptoms are correctly diagnosed

Table 1 The US, UK and Australian recommendations for prostate-specific antigen (PSA) testing of asymptomatic men for prostate cancer

	Professional body	Advice for health practitioners (see original documents for exact phrasing)
Population	US Preventive Services Task Force (USPSTF)[3]	▶ Discuss PSA screening thoroughly with men who raise the issue or if the man's individual circumstances warrant consideration of PSA testing. Do not feel obligated to offer PSA testing if a patient does not raise the issue or request the test ▶ The decision to start or continue PSA screening should reflect the patient's understanding of the possible benefits and expected harms and should respect his preferences
	National Health and Medical Research Council (NHMRC)[11]	▶ Before ordering a PSA test, health practitioners should talk to men about the potential benefits and harms of PSA testing
	National Health Service (NHS)[12]	▶ Screening not recommended. An informed choice programme, Prostate Cancer Risk Management aims to provide high-quality information about the risks and benefits to men who ask about screening in order to enable them to decide whether to have the test
National	American Cancer Society (ACS)[10]	▶ Provide men the opportunity to make an informed decision; for men who are unable to decide, the screening decision can be left to the discretion of the healthcare provider ▶ Men at average risk and expected to live at least 10 more years should receive this information beginning at age 50 years. Men in higher risk groups should receive this information at age 40–45 years
	Cancer Council Australia (CCA) and Australian Health Ministers' Advisory Council (AHMAC), 2010*[13]	▶ Speak to men about the benefits and harms of testing and treatment so that they can make an informed choice
Specialist	American Urological Association (AUA)[8]	▶ Shared decision-making for men aged 55–69 years based on a man's values and preferences ▶ Routine screening is not recommended in men aged 40–54 years at average risk, or in men over 70 years or with less than a 10–15-year life expectancy; decisions should be individualised for men younger than 55 years at higher risk
	Urological Society of Australia and New Zealand (USANZ)[14]	▶ PSA and digital rectal examination (DRE) should be offered to men 55–69 years, after providing information about the risks and benefits of such testing ▶ Interested men in younger age groups (under 55 years) could have a single PSA test and DRE performed at or beyond age 40 to provide an estimate of their prostate cancer risk over the next 10–20 years, with the intensity of subsequent monitoring being individualised accordingly
Primary Care	American College of Physicians (ACP)[15]	▶ Inform men 50–69 years about the limited potential benefits and substantial harms of screening for prostate cancer ▶ Base the decision on the man's risk for prostate cancer, a discussion of the benefits and harms of screening, the patient's general health and life expectancy and patient preferences ▶ Advised not to screen patients who do not express a clear preference for screening ▶ Advised not to screen average-risk men under 50 years, over 69 years, or with a life expectancy of less than 10 to 15 years
	Royal Australian College of General Practitioners (RACGP)[6]	▶ Not recommended unless the man specifically asks for it, and he is fully counselled on the pros and cons ▶ General practitioners need not raise this issue, but if men ask about prostate screening they need to be fully informed of the potential benefits, risks and uncertainties of prostate cancer testing ▶ When a patient chooses screening, both PSA and DRE should be performed ▶ Responding to the patient's concerns and fulfilling medicolegal responsibilities are considerations in discussion with patients

with a disease that would not cause them to experience symptoms or early death.[19] It is hard to understand and explain,[20] and difficult to quantify; estimates range from 15% to more than 84% of screen-detected prostate cancers.[21–26] Overdiagnosis may lead to overtreatment:[27] treatment a person did not need. PSA testing often triggers a cascade of diagnostic tests and active treatment,[28 29] potentially compromising a well person's quality of life.[30 31] Advocates of testing argue that PSA testing may, in some cases, lower the stage and grade of cancer at diagnosis, and reduce the risk of being diagnosed with metastatic prostate cancer, for which there is no cure.[32–34] However, across the population of asymptomatic men, PSA testing does not decrease all-cause mortality, and some men will progress and develop metastatic disease even if they are screened (despite earlier diagnosis).[35]

Responsibility for guiding men's decisions about whether or not to be screened for prostate cancer has largely been placed in the hands of individual physicians. In Australia, GPs are the primary point of contact to access a PSA test. There is no organised screening programme; PSA testing is opportunistic but prevalent.[18]

Empirical work exploring prostate cancer screening in general practice has primarily focused on: (1) the reasons GPs give for ordering PSA tests; (2) the characteristics of GPs (such as age, gender, location) associated with more or less frequent testing and (3) how GPs communicate with patients about the PSA test.[36–44] The predominantly quantitative evidence provides insights into the patterns and potential drivers of PSA testing in general practice but does not illuminate the dilemmas of PSA testing from the GP's perspective, and in particular how GPs reason about overdiagnosis. To fill this gap, we conducted a qualitative study to explore how and why GPs provide (or do not provide) PSA testing to their asymptomatic male patients. We report on the significance and impact of overdiagnosis in GPs' clinical reasoning about PSA testing.

METHODS

Design

We used the well-established, systematic qualitative research methodology of grounded theory[45] to guide our sampling and analysis. We collected data via in-depth interviews. GPs had an opportunity to discuss the study, and gave consent prior to participation.

Participants and setting

We recruited 32 urban and rural GPs throughout Australia (11 female). Our initial purposive sample was of GPs working in men's health clinics in Sydney (n=2). We advertised via the newsletters and email lists of regional GP organisations (Medicare Locals) in Sydney (n=8). GPs were invited to contact KP if they were interested and willing to participate in the research. We then broadened our sampling by advertising in mass and social media, and in medical journals (*Medical Observer*, the Australian Medical Association's *GP Network News*, and the 6 min newsletter). As analysis and sampling evolved, we invited additional rural and interstate GPs to answer specific analytical questions (n=11). Rural GPs were accessed by phoning practice managers, through colleagues, and advertising with rural Medicare Locals, adding eight further GPs. When we encountered GPs whose routine care was divergent from previously interviewed GP norms, we invited more GPs from that practice to attempt to distinguish between personal and institutional influences on their practice. An additional three GPs were recruited in this final phase of theoretical sampling. GPs of varying ages, clinical experience, gender and patient populations were all included. All GPs interested in participating in the study were included. GPs were compensated for their time.

Interviews/data collection

A semistructured interview schedule was developed with a focus on GPs' current approaches to, and reasoning about, PSA testing. The schedule covered a broad range of topics, including GPs' recent clinical encounters involving PSA testing decisions; communicating information; screening pathways; and the central theme of this paper, overdiagnosis. The interview schedule was modified between interviews, informed by the developing analysis. Interviews took place between March and September 2013. They were conducted by KP, mostly by telephone, and ranged in duration from 18 min to 1 h and 10 min. All interviews were audio-recorded, de-identified and transcribed verbatim.

Examples of questions GPs were asked about overdiagnosis included the following:

- Are you familiar with the term 'overdiagnosis'?
- Do you think about the issue of overdiagnosis in your practice?
- How do you manage overdiagnosis in your practice?
- Overdiagnosis must be a challenging concept to talk about with your patients; how do you manage that challenge?

Data coding and analysis

The analysis was led by KP, who coded the transcripts and wrote detailed memos which were reviewed and discussed by the authors in analytical meetings. A subset of transcripts was read and coded by all three authors independently; this coding was compared and discussed to inform the development of the central concepts in the study. This paper focuses on how GPs dealt with the concept of overdiagnosis.

RESULTS

Most GPs felt uncertain and/or conflicted regarding what to do about PSA testing of asymptomatic men.

In the following section, we will explain overall patterns and then outline four heuristics used in practice.

GPs considered underdiagnosis as well as overdiagnosis

GPs discussed the harms of underdiagnosis (the missed opportunity to intervene in potentially preventable deaths) as much as those of overdiagnosis (the psychological and physical harms and financial costs of unnecessary diagnosis and treatment). Since both harms are salient and serious, PSA testing decisions were described as a "balancing act" (GP21) or gamble. GPs reported the difficulties of needing to choose between potential harms (eg, incontinence and impotence) and the chance of saving lives.

Testing decisions were described as a personal burden

Uncertainty about PSA testing created a 'personal burden' for some GPs; they felt personally responsible for the consequences of their PSA testing approach, and experienced guilt and self-blame as a result.

Many GPs used personal or professional experiences with the PSA test, both positive and negative, as powerful anchors for their current practice: these experiences often explained GPs' perception of personal burden. We will return to the personal burden of PSA testing throughout the following sections.

GPs' communication practices varied

GPs varied in the conversations they had with men specifically about overdiagnosis. Some deliberately avoided raising the issue, or talked men into or out of having a PSA test. GPs described several important contextualising factors.

1. Cancer is widely feared and difficult to talk about.
2. Overdiagnosis is hard to understand for GPs and for the public—and it is contradictory to many people's existing health beliefs.
3. Both doctors and patients often have a strong belief that cancer screening is, in general, a worthwhile and important strategy to combat the risk of getting cancer.

GPs employed four heuristics to manage PSA testing

GPs' responses to this difficult situation depended on how they viewed an implicit continuum between overdiagnosis and underdiagnosis. They considered which end of the spectrum would cause the greatest harm to each patient and/or their patients in general.

Four broad patterns ('heuristics') were employed.

1. Some GPs preferred to offer PSA testing to avoid underdiagnosis.
2. Some GPs were strongly oriented to avoiding overdiagnosis, and so tried to test as little as possible.
3. Some GPs made case-by-case individualised decisions.
4. Some GPs did not think about underdiagnosis or overdiagnosis at all.

These four heuristics represent observed patterns of GPs' *preferred* or *dominant practice orientations*; that is, each GP seemed to prefer one of these four heuristics as their overall approach to PSA testing. Some of these heuristics were more responsive to patient preferences than others (table 2).

The GPs' *Dominant Practice Orientation* guided their *Routine Practice* (usual testing, communication and responses to patient requests). GPs also described their *Practice Rationale* (drawing on experience, medicolegal obligations, guidelines and evidence) which influenced testing decisions and justified why they adopted their particular practice orientation. Their orientation produced a *Practice Outcome:* GPs' experiences of the consequences of their PSA testing decisions. The four dominant practice orientations (heuristics) are summarised in table 2 and described below.

Heuristic 1: GP preference to offer PSA testing to avoid underdiagnosis

GPs employing heuristic 1 thought testing was necessary because there was a *possibility* it might prevent a man's death. Overdiagnosis was perceived as (1) a natural consequence of PSA testing; (2) better than dying and (3) a justifiable source of harm (harms being a regrettable but necessary price of 'cure').

These GPs focused on cancer as life-threatening, and prostate cancer as a terrible death. They saw preventing death as the primary duty of the GP. This heightened their responsibility to do anything that may diagnose cancer early: "Because if you don't overdiagnose, the alternative is to underdiagnose" (GP28). Underdiagnosis was perceived to be a medicolegal risk, and for some GPs, legal risk was uppermost in their minds during the decision-making process. GPs concerned with missing diagnosing cancers practised more defensively; "I'm often a bit defensive…I guess that's partly that legal thing" (GP5).

GPs with this practice orientation advised men to have a PSA, emphasising benefits of early detection, and did not discuss overdiagnosis.

Some of these GPs thought decisions about postdiagnosis management (eg, active surveillance) could limit the harms of potential overdiagnosis. This allowed them to define testing without invasive procedures as inconsequential: "it's not terribly onerous to have a blood test every six months" (GP3). Although many of these GPs accepted that the PSA test was not perfect, they preferred to test because "clearly, people's lives are saved" (GP8).

These GPs anchored their practice orientation to personal experiences. Their approach was supported by stories of men still being alive following active testing and treatment.

Another anchor for this heuristic was having experienced caring for patients with metastatic cancers, "I've had two recently where their GP refused to actually test the PSA level over the last ten years and both presented with metastatic prostate cancer" (GP24), and witnessing the horrors of prostate cancer deaths: "dying from prostate cancer would probably rank amongst one of the

Table 2 Practice, conditions and consequences of the four general practitioner (GP) heuristics for dealing with prostate-specific antigen (PSA) testing

		Dominant practice orientation			
		GPs engaging with overdiagnosis			GPs not engaging with overdiagnosis
		GP prioritises avoiding underdiagnosis	GP thinks about underdiagnosis and overdiagnosis case by case	GP prioritises avoiding overdiagnosis	GP avoids thinking about overdiagnosis or underdiagnosis
Routine Practice	How did GPs approach communication?	GPs inclined not to talk about overdiagnosis. The information they provide is "next to none" (GP9). Communication style characterised by advising men to have a PSA with emphasis on benefits of early detection	GPs inclined to talk about overdiagnosis and underdiagnosis, tailored specifically to the personal circumstances of each patient and what they are perceived as being capable of understanding. GPs agreed that it is never a particularly easy discussion to have, because the information is complex and "the figures are so—are quite hard to explain" (GP16), with the discussion described by some as becoming "more complicated depending on how interested the person is" (GP4)	GPs inclined to talk about overdiagnosis and emphasise the harms of PSA testing when giving advice. Most of these GPs try to talk patients out of having the test, and many had patients who did not go ahead with a PSA test following discussion	GPs do not talk about overdiagnosis or underdiagnosis; general information about the PSA test as a screening tool sometimes provided. GPs happy to leave discussion up to the specialists; "I wouldn't go ahead, two steps ahead and discuss that they might find a cancer that they—that wouldn't have killed them; I don't go and—I don't go there. I think, I mean, that's sort of a urologist can do that" (GP7). For some, it was easiest to just do the PSA test with no explanation at all
	How did GPs approach PSA testing?	Mostly test. Testing is perceived to be an absolute obligation. These GPs feel their primary duty is to prevent prostate cancer death, and save men's lives wherever possible. "To not screen somebody, I don't know, it seems cruel, it's cruel and irresponsible… to not at least make an attempt to avoid the misery of a person getting prostate cancer, to me, seems unbelievably cruel" (GP29). "We have to diagnose them if they have a problem. What if it couldn't wait? How would you know it won't affect them?" (GP11)	Variable testing practice. Testing decisions and 'rules' shifted according to the patient, and factored in such things as the patient's risk profile (eg, age, family history), life expectancy, interest in and reason for wanting a PSA test, motivation to have the test, anxiety around cancer, understanding, and intention and ability to follow up any abnormal test results. For some GPs, *[It's]* "really one of those tests in medicine that you order with the hope that it will be low or negative, and the sort of dread that it will be positive because you know that, it being positive creates a whole lot of problems for you and the patient" (GP17)	Prefer not to test or will test only under duress because of uncertain benefit and potential harms caused by overdiagnosis. GP tries to minimise the likelihood of overdiagnosis by minimising PSA testing. Overdiagnosis described as "bad. It's like sin" (GP19), and "makes us very thoughtful about what preventive care and what screening we would recommend to patients" (GP19). These GPs believed the harms of overdiagnosis were too great to justify testing, "Even though we—in the long term you might save someone's life, if you do an awful lot of harm along the way, it's just not worth it" (GP18)	Mostly test. GPs seemed disengaged from the overdiagnosis debate and tended to default to testing, doing what they had always done without any further consideration
	How did GPs respond to patient requests for a PSA test?	GPs will test if requested. These GPs valued the knowledge produced by the test which can reassure patients and the GP. "I believe there is no case for saying you shouldn't take PSAs…how can knowledge not be a good thing?" (GP29)	GPs will test if requested. These GPs particularly emphasised being responsive to patient preferences	GPs try and talk patients out of it, but will test if requested, despite convictions that PSA is "a very concrete example of where doctors can help mess things up" (GP8)	GP will test if requested

continued

Table 2 Continued

		Dominant practice orientation			
		GPs engaging with overdiagnosis			GPs not engaging with overdiagnosis
		GP prioritises avoiding underdiagnosis	GP thinks about underdiagnosis and overdiagnosis case by case	GP prioritises avoiding overdiagnosis	GP avoids thinking about overdiagnosis or underdiagnosis
Practice rationale	Did GPs draw on first-hand experiences to reason about PSA testing?	Yes. Witnessing the horrors of prostate cancer deaths was enough to motivate GPs to do everything in their capacity to prevent further deaths. For some, having a man alive following a prostatectomy was a powerful anchor and confirmation for PSA testing; "for me that was worth it. Even his side effects are, I don't know if he thinks it, but he's still alive" (GP26)	No	Yes. It is a difficult balance for these GPs to practise according to the evidence while not being influenced by personal and professional experiences; "it's certainly a—hard to be, treating dying people who are young and not to worry about all of this and I, but I try not to change my practice based on my own personal experience of one or two people dying of prostate cancer. I have to still have confidence in the advice I get from, the population screening advice I get from bigger experts than me" (GP8)	No
	Did GPs express medicolegal concerns about PSA testing?	Yes. Many GPs were preoccupied with concern of legal risk. "I never want to get caught out really, by someone having asked for a test and you refusing it, and then in fact, they did have an abnormality" (GP15). This influenced more defensive practice; "you are so open for being sued by anything but it's very easy to want to lean towards the screening everyone because…I know it's the wrong thing to say because it's meant to be let's not do the PSA but I think if I wasn't concerned about being sued then maybe I'd say let's do it less…I definitely think it's hard not to think legally" (GP6). Some of these GPs felt legally covered putting men on their practice recall system	No. Either GPs believed their patients had made an informed choice following discussion or they felt they practised from a defensible position	No. Perceived themselves to be covered by the guidelines of their medical college. They engaged patients in detailed discussions about potential harms and resisted medicolegal fears. "If I did that…I think I would be a more paternalistic doctor who ordered a lot more tests. And I don't see that would be good medicine. I think it would do more harm to more people for practicing defensively like that" (GP30)	Varied. "It's very unclear for GPs, what it is [why there is an onus to discuss testing]. And, I mean, on one hand we are being told to, you know, to try to, you know, basically discuss the—the downside of PSA screening and things with patients…But then pretty much, they all go on and have the test anyway…and part of that is probably fuelled by my anxiety about missing something. Ah, and I guess part of that anxiety comes from medico-legal anxiety" (GP3)
	Did GPs draw on practice guidelines, recommendations or their interpretation of the evidence?	Many of these GPs were following the guidance of specialists (urologists). Many also believed they were following their medical college guidelines. They tended to be sceptical of the evidence. "it's	These GPs were likely to agree that population statistics do not, or cannot, apply to individuals, and sometimes had difficulty translating population-based information; "applying knowledge from an	GPs trusted the evidence to guide their decisions and practised according to population-level statistics and the guidance of most professional recommendations (particularly their medical college);	No

continued

Table 2 Continued

		Dominant practice orientation			
		GPs engaging with overdiagnosis			GPs not engaging with overdiagnosis
		GP prioritises avoiding underdiagnosis	GP thinks about underdiagnosis and overdiagnosis case by case	GP prioritises avoiding overdiagnosis	GP avoids thinking about overdiagnosis or underdiagnosis
		fine for the people in their… universities and stuff like that to—to give us figures and say, you know, we are only going to lose this number of individuals if we do all this testing…but those individuals, some of them are young men, with lots of productivity and stuff" (GP24)	epidemiological study to one person is not easy…it's so hard to apply" (GP28). "I don't think, a doctor should ever be guided by mathematics, you know, humans aren't machines" (GP29)	"we must stick to the epidemiological rigor behind screening" (GP23); "I worry that there are men, young men who probably will get prostate cancer and die of it because I'm not doing enough screening, but I'm not prepared to, to not follow the evidence and I think that the evidence says you don't do it" (GP8). However, it was extremely challenging for GPs to balance guidelines against anecdotal experiences; "even though you know the statistics, you are influenced by what you are dealing with at the time…if you hear the story instead of just the statistics, it makes a lot more powerful a case" (GP27)	
Practice outcome	GP experience of personal burden	Burden moderated by belief in the PSA test as life-saving. Some GPs were so convinced that testing to save lives was the right thing to do that they did not feel burdened. Other GPs were somewhat burdened by the experience of the patient's side effects but rationalised this using their belief in preventing prostate cancer death. "Oh, well, it happens. I mean unfortunately no matter how good a doctor, now and then this is going to happen" (GP19). "We all live with that fear of, kind of, missing a cancer in somebody that is clinically significant" (GP3)	Burden shared with patients."It's a difficult area for GPs because there is this debate…about what should be done. You're trying to do the best for your patients, you're trying to avoid, you know, being sued for missing something" (GP5)	Heavy personal burden reported. Many GPs carried the burden of hoping they had protected their patient from the harms of overdiagnosis while witnessing prostate cancer death. "I'm fully aware of the fact that prostate cancer kills my patients and that by not testing for it, I won't find it…it's an incredibly difficult situation" (GP8). GPs recalled cases of patients who had suffered with aggressive/metastatic cancers and spoke of how hard it is to see men suffering (from potentially missed cancers) but to continue to practise according to their own values, the evidence and recommendations. "But I did what you were meant to do and that's what's going to happen sometimes, so it's just hard to take" (GP27)	Personal struggles about what is the right approach to PSA testing were not a significant feature. GPs did not have to grapple with the 'what ifs' because they weren't engaging with issues of overdiagnosis.For some it was about performing according to 'good' GP ideals.For example, one GP's understanding was that a large majority of people would think he was neglectful if they were 45 years and above and he wasn't offering PSA testing. This GP believed patients would compare him with other GPs who were screening and think they were much better than him. Satisfying patient expectations meant no burden on the GP

worst ways to die…pain that is almost not able to be alleviated by narcotics" (GP29).

Despite their convictions, GPs experienced *some* personal struggle when they witnessed side effects of prostate cancer treatment. Such cases were often recalled in detail. For example, one GP describes this as "a heavy burden if a person is left with side effects" but accepted that "that's just part of being a GP, you have to walk around with this" (GP29). They tried not to take it personally, "oh, well, it happens. I mean, unfortunately, no matter how good a doctor [I am], now and then this is going to happen" (GP19). Overall, though, the personal burden felt by this group was relatively small and did not challenge the GP's belief in PSA testing, which they said fulfilled their role as a clinician to save lives. Many also regarded testing as consistent with specialists' advice, which allowed them to reduce their personal burden; that is, the responsibility of decisions about PSA testing was shared with these specialists (but not with their patients).

Heuristic 2: GP preference to not offer PSA testing to avoid overdiagnosis

GPs employing heuristic 2 preferred not to conduct PSA testing. Their primary justification was preventing harms caused by overdiagnosis. However, while they would try to talk patients out of having the test, they would never refuse a PSA test. These GPs also recognised that PSA testing has saved lives; "we know that happens. The problem is, it just doesn't happen often enough to balance out…all the damage that we do" (GP17).

This group of GPs emphasised the harms of PSA testing (including overdiagnosis) when advising their patients; and said many patients chose not to be tested following discussion. These GPs, who fully explain overdiagnosis, described themselves as "taking the risk of doing the hard work, hard yards" (GP23). They resisted medicolegal fears by engaging in detailed discussions of benefits and harms, and felt covered from legal prosecution by the Royal Australian College of General Practitioners (RACGP) guidelines.

GPs committed to avoiding overdiagnosis particularly drew on and trusted the research evidence to guide and inform their testing decisions. However, practising accordingly could be compromised by situational factors, such as a patient who had not been tested dying of prostate cancer. GPs said it was incredibly challenging to ignore personal (anecdotal) experiences, yet some were adamant that their practice would not be influenced by these experiences.

GPs found it hard knowing some cancers would be missed because of their decision not to test: for example, one described this as "a burden that I carry" (GP8). GPs most concerned about overdiagnosis experienced the highest levels of personal burden because, although relatively rare, death as the potential consequence of not testing was seen as the worst possible outcome. Some suspected that overdiagnosis and overtreatment were not as much of a burden for the patient as they were for the doctor.

Heuristic 3: GP thinks of each patient as an individual and makes case-by-case decisions

GPs employing heuristic 3 had no preconceived attitude towards avoiding underdiagnosis or overdiagnosis. They tailored PSA testing decisions specifically for the personal circumstances of *each* patient, according to the patient's risk profile (age, family history), life expectancy, interest, motivation, reason for wanting a PSA test, cancer anxiety, or intention and ability to act on abnormal test results. These GPs were particularly responsive to patients' individual preferences, so the outcome of the consultation was largely unpredictable: "You have to try and work out what's best for the—that one particular patient that you are talking to at the time" (GP18). Testing 'rules' shifted according to the patient and the GP; "it's so easy to just learn what you do from a book but once you are actually faced with someone you know you can't—it's difficult to apply the same rule" (GP6).

These GPs approached communication in several different ways. Some made their own decision about the 'right' approach for each particular patient, and advised that patient accordingly. This could include not discussing overdiagnosis at all, on the grounds that it was irresponsible to expect patients to understand complex information; "if you start going down that road and—and to what end?" (GP7). Other GPs tailored their discussion about overdiagnosis to the needs of the individual patient, their perceived level of understanding and time pressures: "it gets more complicated depending on how interested the person is" (GP4). Thus, the GP's communication depended entirely on the individual patient in front of them.

GPs who approached PSA testing case by case generally agreed that overdiagnosis statistics do not, or cannot, apply to individuals; "those like statistical issues don't apply to the individual…because…they make their decisions on a set of complex, but perhaps irrational basis, you know, anxiety and…" (GP7). Accordingly, they tailored their testing and patient communication but expressed some difficulties in translating population-based information to individuals.

The personal burden experienced by these GPs was minimal as in most consultations the burden of decision-making was shared with their patients. GPs sought to reach a mutual understanding of PSA testing if they thought the patient was able to understand the information required, and shared the responsibility of decisions and outcomes of the consultation with the individual man. They tended to consider decisions about PSA testing as neither right nor wrong and so could be swayed either way depending on the patient and their needs. These GPs had minimal legal concern because they perceived patients to have made informed decisions based on their individual needs.

Heuristic 4: GP preference to avoid thinking about underdiagnosis or overdiagnosis

GPs not thinking about underdiagnosis or overdiagnosis did not have a preference or priority for avoiding one harm over another. For these GPs, the PSA test was considered just another form of routine screening and underdiagnosis or overdiagnosis was not an issue of concern.

The majority of GPs in this group did not engage with considering the implications of underdiagnosis or overdiagnosis and what that meant for their patients. Some of these GPs felt explaining overdiagnosis was the responsibility of urologists, and preferred to simply inform men that a PSA test may lead to them having a biopsy. These GPs also said they preferred to be guided by urologists on what to do about PSA testing overall.

Personal burden associated with underdiagnosis or overdiagnosis was therefore not a significant feature for this group of GPs. For some, their priority was being regarded as a 'good' GP by their patients: they focused on how their testing decisions might influence their reputation and rapport with their patient. They reported that a 'good' GP was in many cases deemed to be someone who actively tested.

DISCUSSION

Overdiagnosis of indolent cancers in cancer screening is now recognised as a significant problem, but solutions to this problem (eg, communication, public awareness) are as yet uncertain, including in primary care. Most previous research has examined associations between GP characteristics and frequency of PSA testing. Fewer studies have sought to explain variation in GPs' PSA testing practice. Ilic and colleagues[46] differentiated 'reactive screeners' (GPs who screened only at the patient's request) from 'proactive screeners' (GPs motivated to test, believed screening was beneficial, and feared missing cancer, including for medicolegal reasons). Our study provides a more nuanced analysis of how and why GPs test the way they do, and offers a unique examination of GPs' approaches to prostate cancer underdiagnosis and overdiagnosis. It is the first study to systematically examine the relationship between GPs' reasoning and behaviour in relation to PSA testing. We identified four distinct approaches, each associated with different practices, rationales and outcomes. Our findings explain why men so often receive different advice and clinical care: this depends on their GP's PSA testing practice orientation.

There is value in understanding the reasoning behind actual practice. GPs' reasoning makes sense of variation in practice: it explains why different GPs are making different testing decisions in similar cases. GPs' experiences with PSA testing (positive and negative), values, perceptions (of the GP role, the patient role, of the PSA test and overdiagnosis), considerations of evidence and guidelines, and their sense of personal burden (anticipated or experienced) all uniquely contribute to PSA testing patterns. Variation in practice has ethical implications, as men are experiencing unequal access to information and consent to PSA testing. Yet these GPs were not acting arbitrarily; most were simply doing the best they could in an almost impossible situation. The difficult position GPs are in should be recognised in future efforts to address the problem of prostate cancer overdiagnosis.

Policy implications

Guidance used by Australian GPs about PSA testing varies widely (see table 1). This also contributes to the diversity of practice revealed in this study. Although it would be unrealistic to expect the mere existence of a guideline to change practice,[39] it does seem reasonable for GPs to expect that expert bodies will provide clear guidance wherever possible. A community jury on PSA testing reported men's experiences of variable and inconsistent advice from GPs, and recommended programmes to support GPs to provide patients with better quality and consistent information about PSA screening.[47] The Australian Medical Health and Research Council (NHMRC) has recently produced an authoritative summary of PSA testing benefits and harms for GPs to discuss with their patients.

The findings of this study offer important guidance for the implementation of such recommendations in practice. We recommend that agencies seeking to promote the uptake of guidance for practitioners must take account of the different motivations of GPs and recognise the significant diversity in the approaches that GPs are taking towards PSA testing of asymptomatic men. GPs who employ heuristic 2, for example, were already attentive to the epidemiological evidence, and so are likely to be receptive to recent NHMRC guidance. However, GPs who are employing heuristic 1 may need very active knowledge translation strategies if they are to change their practice. These GPs were deeply concerned that by their failure to screen they might allow a man to die of prostate cancer. It seems unlikely that they will change their practice unless this concern is recognised and responded to. Communications, workshops and new incentives therefore need to consider variation in GP perspectives and the range of drivers of current practice as identified in this research (address legal concerns, the need for consent due to potential harms and acknowledge burden).

Limitations

Since physicians with strong opinions may have been more likely to volunteer, some selection bias is possible. However, diverse opinions and approaches were reported, suggesting that strong selection bias is unlikely.

Conclusions

Future strategies for addressing the problem of prostate cancer overdiagnosis in general practice should be

underpinned by empirical evidence about how GPs approach PSA testing, and the reasons they give for their actions. Explicit consideration in practice guidelines of the challenges faced by GPs when balancing underdiagnosis and overdiagnosis, including GPs experiences of personal burden, medicolegal concerns and communication strategies, will better support GPs to inform and guide men's decisions on whether or not to have a PSA test. Further public deliberation on how the inevitable trade-offs could and should be managed in primary care could also inform such discussions between clinicians and their patients.[48]

Twitter Follow Kristen Pickles at @PicklesKristen

Acknowledgements The authors thank the general practitioners for their participation in this research.

Contributors KP, SMC and LR conceived the study and were involved in designing the study, developing the methods and drafting of the manuscript. SMC and LR obtained funding and are CIs on the NHMRC funded project grant. KP conducted the interviews, had full access to all data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis. All authors contributed to the interpretation of the analysis and critically revised the manuscript.

Funding The project was funded by NHMRC grant 1023197. Stacy Carter is supported by NHMRC Career Development Fellowship 1032963. The funders had no role in the design or conduct of the study; in the collection, analysis and interpretation of the data; or in the preparation or approval of the manuscript.

Competing interests SC is supported by NHMRC Career Development Fellowship 1032963.

Ethics approval All study procedures were approved by the Cancer Institute NSW and the University of Sydney Human Research Ethics Committee [#15245].

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

REFERENCES

1. Stark JR, Mucci L, Rothman KJ, *et al*. Screening for prostate cancer remains controversial. *BMJ* 2009;339:b3601.
2. Ilic D, Neuberger MM, Djulbegovic M, *et al*. Screening for prostate cancer. *Cochrane Database Syst Rev* 2013:1–76.
3. Moyer VA. Screening for prostate cancer: US. preventive services task force recommendation statement. *Ann Intern Med* 2012;157:120–34.
4. Djulbegovic M, Beyth RJ, Neuberger MM, *et al*. Screening for prostate cancer: systematic review and meta-analysis of randomised controlled trials. *BMJ* 2010;341:c4543.
5. Mackie A. *Screening for Prostate Cancer Review against programme appraisal criteria for the UK National Screening Committee (UK NSC)*. London: National Health Service, 2010.
6. Royal Australian College of GPs (RACGP). *Guidelines for preventive activities in general practice 2012*. 8th edn. http://www.racgp.org.au/your-practice/guidelines/redbook/early-detection-of-cancers/prostate-cancer/
7. Wilt TJ, Ahmed HU. Prostate cancer screening and the management of clinically localized disease. *BMJ* 2013;346:f325.
8. Carter HB, Albertsen PC, Barry MJ, *et al*. Early detection of prostate cancer: AUA guideline. *J Urol* 2013;190:419–26.
9. Mitka M. Group now advises against routine PSA screening. *JAMA* 2013;309:2316.
10. American Cancer Society (ACS). American Cancer Society recommendations for the early detection of prostate cancer 2014. http://www.cancer.org/cancer/prostatecancer/moreinformation/prostatecancerearlydetection/prostate-cancer-early-detection-acs-recommendations
11. National Health and Medical Research Council (NHMRC). Australia. PSA testing for prostate cancer in asymptomatic men: Information for health practitioners. 2014; https://www.nhmrc.gov.au/guidelines-publications/men4, 2014.
12. National Health Service (NHS) Choice, United Kingdom. Prostate cancer – PSA screening. 2015; http://www.nhs.uk/Conditions/Cancer-of-the-prostate/Pages/prevention.aspx
13. Cancer Council Australia, Australian Health Ministers' Advisory Council (AHMAC), Australia. Position statement. Prostate cancer screening in Australia: joint key messages. 2010; http://www.cancer.org.au/content/pdf/CancerControlPolicy/PositionStatements/PS-Prostate_Cancer_Screening_Joint_key_messages_%20published_May2010.pdf.
14. Urological Society of Australia and New Zealand (USANZ). Urological Society of Australia and New Zealand PSA testing policy. 2009; http://www.usanz.org.au/uploads/65337/ufiles/PDF/psa-testing.pdf.
15. Qaseem A, Barry MJ, Denberg TD, *et al*. Screening for prostate cancer: a guidance statement from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med* 2013;158:761–9.
16. Ross LE, Coates RJ, Breen N, *et al*. Prostate-specific antigen test use reported in the 2000 National Health Interview Survey. *Prev Med* 2004;38:732–44.
17. Sirovich BE, Schwartz LM, Woloshin S. Screening men for prostate and colorectal cancer in the United States: does practice reflect the evidence? *JAMA* 2003;289:1414–20.
18. Australian Institute of Health and Welfare (AIHW). Prostate cancer in Australia. 2013; http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129545133
19. Welch G, Schwartz L, Woloshin S. *Overdiagnosed: making people sick in the pursuit of health*. Beacon Press, 2011.
20. Hersch J, Jansen J, Irwig L, *et al*. How do we achieve informed choice for women considering breast screening? *Prev Med* 2011;53:144–6.
21. Etzioni R, Penson DF, Legler JM, *et al*. Overdiagnosis due to prostate-specific antigen screening: lessons from U.S. prostate cancer incidence trends. *J Natl Cancer Inst* 2002;94:981–90.
22. Draisma G, Boer R, Otto SJ, *et al*. Lead times and overdetection due to prostate-specific antigen screening: estimates from the European Randomized Study of Screening for Prostate Cancer. *J Natl Cancer Inst* 2003;95:868–78.
23. McGregor M, Hanley J, Boivin J, *et al*. Screening for prostate cancer: estimating the magnitude of overdetection. *CMAJ* 1998;159:1368–72.
24. Telesca D, Etzioni R, Gulati R. Estimating lead time and overdiagnosis associated with PSA screening from prostate cancer incidence trends. *Biometrics* 2008;64:10–19.
25. Gulati R, Wever EM, Tsodikov A, *et al*. What if I don't treat my PSA-detected prostate cancer? Answers from three natural history models. *Cancer Epidemiol Biomarkers Prev* 2011;20:740–50.
26. Wever EM, Draisma G, Heijnsdijk EA, *et al*. Prostate-specific antigen screening in the United States vs in the European Randomized Study of Screening for Prostate Cancer–Rotterdam. *J Natl Cancer Inst* 2010;102:352–5.
27. Moynihan R, Doust J, Henry D. Preventing overdiagnosis: how to stop harming the healthy. *BMJ* 2012;344:e3502.
28. Cooperberg MR, Broering JM, Kantoff PW, *et al*. Contemporary trends in low risk prostate cancer: risk assessment and treatment. *J Urol* 2007;178:S14–19.
29. Welch HG, Black WC. Overdiagnosis in cancer. *J Natl Canc Inst* 2010;102:605–13.
30. Sanda MG, Dunn RL, Michalski J, *et al*. Quality of life and satisfaction with outcome among prostate-cancer survivors. *N Engl J Med* 2008;358:1250–61.
31. Hayes JH, Ollendorf DA, Pearson SD, *et al*. Active surveillance compared with initial treatment for men with low-risk prostate cancer: a decision analysis. *JAMA* 2010;304:2373–80.
32. Loeb S, Catalona WJ. What to do with an abnormal PSA test. *Oncologist* 2008;13:299–305.
33. Aus G, Bergdahl S, Lodding P, *et al*. Prostate cancer screening decreases the absolute risk of being diagnosed with advanced

prostate cancer—results from a prospective, population-based randomized controlled trial. *Eur Urol* 2007;51:659–64.
34. Grubb RL, Pinsky PF, Greenlee RT, *et al*. Prostate cancer screening in the Prostate, Lung, Colorectal and Ovarian cancer screening trial: update on findings from the initial four rounds of screening in a randomized trial. *BJU Int* 2008;102:1524–30.
35. Schröder FH, Hugosson J, Carlsson S, *et al*. Screening for prostate cancer decreases the risk of developing metastatic disease: findings from the European Randomized Study of Screening for Prostate Cancer (ERSPC). *Eur Urol* 2012;62:745–52.
36. Cooper CP, Merritt TL, Ross LE, *et al*. To screen or not to screen, when clinical guidelines disagree: primary care physicians' use of the PSA test. *Prev Med* 2004;38:182–91.
37. Brett J, Watson E, Hewitson P, *et al*. PSA testing for prostate cancer: an online survey of the views and reported practice of general practitioners in the UK. *BMC Fam Pract* 2005;6:24.
38. Gormley GJ, Catney D, McCall JR, *et al*. Prostate-specific antigen testing: uncovering primary care influences. *BJU Int* 2006;98:996–1000.
39. Girgis S. General practitioners' perceptions of medicolegal risk—using case scenarios to assess the potential impact of prostate cancer. *Med J Aust* 1999;171:362–6.
40. Pollack CE, Platz EA, Bhavsar NA, *et al*. Primary care providers' perspectives on discontinuing prostate cancer screening. *Cancer* 2012;118:5518–24.
41. Drummond FJ, Carsin A, Sharp L, *et al*. Factors prompting PSA-testing of asymptomatic men in a country with no guidelines: a national survey of general practitioners. *BMC Fam Pract* 2009;10:3.
42. Bell DS, Hays RD, Hoffman JR, *et al*. A test of knowledge about prostate cancer screening. *J Gen Intern Med* 2006;21:310–14.
43. Clements A, Watson E, Rai T, *et al*. The PSA testing dilemma: GP's reports of consultations with asymptomatic men: a qualitative study. *BMC Fam Pract* 2007;8:35.
44. Bowen DJ, Hannon PA, Harris JR, *et al*. Prostate cancer screening and informed decision-making: provider and patient perspectives. *Prostate Cancer Prostatic Dis* 2011;14:155–61.
45. Charmaz K. *Constructing grounded theory: a practical guide through qualitative analysis*. London: SAGE Publications, 2006.
46. Ilic D, Murphy K, Green S. What do general practitioners think and do about prostate cancer screening in Australia? *Aus Fam Phys* 2013;42:904–8.
47. Rychetnik L, Doust J, Thomas R, *et al*. A Community Jury on PSA screening: what do well-informed men want the government to do about prostate cancer screening—a qualitative analysis. *BMJ Open* 2014;4:e004682.
48. Rychetnik L, Carter SM, Abelson J, *et al*. Enhancing citizen engagement in cancer screening through deliberative democracy. *J Natl Canc Inst* 2013;105:380–6.

CHAPTER FOUR.

General Practitioners' experiences of, and responses to uncertainty in prostate cancer screening:

Insights from a qualitative study

4. Overview of this chapter

We focused on accounts generated from interviews with 69 GPs practicing in Australia and the UK about how they approach PSA screening (Research Question 1). Uncertainty about prostate screening was identified as a core issue. This chapter presents an analysis on GP experiences of uncertainty, answering: How does uncertainty influence GPs' approaches to PSA screening? (Research Question 2.2). What are the consequences of this process? (Research Question 3).

Much of the controversy described in the current prostate screening debate, presented in Chapter 1, appears to arise from prevailing uncertainty about the utility of the PSA test as a screening tool. There are unresolved tensions and disagreements amongst experts, high patient demand, complex cultural factors, and inconsistent clinical recommendations. Collectively this reflects and generates significant uncertainty about the appropriateness of screening. We explored how GPs in Australia and the United Kingdom described and responded to uncertainty in the context of PSA screening.

4.1 Publication details

Pickles K, Carter SM, Rychetnik L, McCaffery K, Entwistle VA (2016) General Practitioners' Experiences of, and Responses to, Uncertainty in Prostate Cancer Screening: Insights from a Qualitative Study. PLoS ONE 11(4): e0153299. doi:10.1371/journal.pone.0153299

4.2 Authors' contributions

All authors contributed equally to this work.

4.3 Abstract

This paper draws on our empirical data to explain the primary sources of uncertainty described by GPs in this context, and how they experience and respond to uncertainty about PSA screening. We found that Australian GPs reported experiencing substantially more uncertainty than UK GPs. This seemed partly

explainable by notable differences in conditions of practice between the two countries. Using Han et al's taxonomy of uncertainty as an initial framework, we first outline the different sources of uncertainty GPs (mostly Australian) described encountering in relation to prostate cancer screening and what the uncertainty was about. We then suggest an extension to Han et al's taxonomy based on our analysis relating to the varied ways that GPs manage uncertainties in the context of PSA screening. We consider the burden of uncertainty on GPs and the role of the health care system in supporting GPs to practice in a way consistent with evidence-based professional standards.

4.4 Manuscript

The published version of the manuscript follows.

PLOS ONE

RESEARCH ARTICLE

General Practitioners' Experiences of, and Responses to, Uncertainty in Prostate Cancer Screening: Insights from a Qualitative Study

Kristen Pickles[1☯]*, Stacy M. Carter[1☯], Lucie Rychetnik[2☯], Kirsten McCaffery[3☯], Vikki A. Entwistle[4☯]

1 Centre for Values, Ethics & the Law in Medicine, University of Sydney, Australia, **2** School of Medicine, University of Notre Dame, Sydney, Australia, **3** School of Public Health, University of Sydney, Australia, **4** Health Services Research Unit, University of Aberdeen, Scotland

☯ These authors contributed equally to this work.
* kristen.pickles@sydney.edu.au

OPEN ACCESS

Citation: Pickles K, Carter SM, Rychetnik L, McCaffery K, Entwistle VA (2016) General Practitioners' Experiences of, and Responses to, Uncertainty in Prostate Cancer Screening: Insights from a Qualitative Study. PLoS ONE 11(4): e0153299. doi:10.1371/journal.pone.0153299

Editor: Neal Shore, Carolina Urologic Research Center, UNITED STATES

Received: December 11, 2015

Accepted: March 10, 2016

Published: April 21, 2016

Data Availability Statement: Data underlying our findings cannot be made publicly available for ethical reasons; public availability would compromise our doctors' privacy. Data request may be sent to the Corresponding Author at kristen.pickles@sydney.edu.au.

Funding: The project was funded by a National Health and Medical Research Council grant 1023197 (https://www.nhmrc.gov.au/). SMC and LR obtained funding and are CIs on the NHMRC funded project grant. SMC is supported by NHMRC Career Development Fellowship 1032963. The funders had

Abstract

Background

Prostate-specific antigen (PSA) testing for prostate cancer is controversial. There are unresolved tensions and disagreements amongst experts, and clinical guidelines conflict. This both reflects and generates significant uncertainty about the appropriateness of screening. Little is known about general practitioners' (GPs') perspectives and experiences in relation to PSA testing of asymptomatic men. In this paper we asked the following questions: (1) What are the primary sources of uncertainty as described by GPs in the context of PSA testing? (2) How do GPs experience and respond to different sources of uncertainty?

Methods

This was a qualitative study that explored general practitioners' current approaches to, and reasoning about, PSA testing of asymptomatic men. We draw on accounts generated from interviews with 69 general practitioners located in Australia (n = 40) and the United Kingdom (n = 29). The interviews were conducted in 2013–2014. Data were analysed using grounded theory methods. Uncertainty in PSA testing was identified as a core issue.

Findings

Australian GPs reported experiencing substantially more uncertainty than UK GPs. This seemed partly explainable by notable differences in conditions of practice between the two countries. Using Han et al's taxonomy of uncertainty as an initial framework, we first outline the different sources of uncertainty GPs (mostly Australian) described encountering in relation to prostate cancer screening and what the uncertainty was about. We then suggest an extension to Han et al's taxonomy based on our analysis of data relating to the varied ways that GPs manage uncertainties in the context of PSA testing. We outline three broad strategies: (1) taking charge of uncertainty; (2) engaging others in managing uncertainty; and (3) transferring the responsibility for reducing or managing some uncertainties to other parties.

no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: The authors have declared that no competing interests exist.

Conclusion

Our analysis suggests some GPs experienced uncertainties associated with ambiguous guidance and the complexities of their situation as professionals with responsibilities to patients as considerably burdensome. This raises important questions about responsibility for uncertainty. In Australia in particular they feel insufficiently supported by the health care system to practice in ways that are recognisably consistent with 'evidence based' professional standards and appropriate for patients. More work is needed to clarify under what circumstances and how uncertainty should be communicated. Closer attention to different types and aspects of the uncertainty construct could be useful.

Introduction

Prostate-specific antigen (PSA) testing for prostate cancer is controversial. There are unresolved tensions and disagreements amongst experts, and clinical guidelines conflict. This both reflects and generates significant uncertainty about the appropriateness of testing, especially in asymptomatic men. The United States Preventive Services Taskforce (USPSTF) recommends physicians should not offer or order PSA screening unless they are prepared to engage in shared decision making (SDM) that enables an informed choice by the patient; this includes providing information about the associated uncertainties [1]. The Royal Australian College of General Practitioners (RACGP) advises GPs not to raise the issue of PSA testing unless men specifically ask, in which case they should provide full information regarding the benefits, risks, *and uncertainties* (about benefits and risks) [2]. The UK's National Screening Committee (UK NSC) policy similarly does not recommend universal screening for prostate cancer. Instead there is an informed choice program in place where men who request PSA testing can have it following detailed information exchange to aid shared decision making.

Primary care clinicians advise on and are gatekeepers to the PSA test. In practice, they vary in what they disclose to patients about the uncertainty and controversy that surrounds it. Recognition of uncertainty may in general be ethically preferable, facilitating more completely-informed consent [3] and promoting realistic patient expectations about medical care [4,5]. However, research from the US and UK suggests communication of uncertainties with patients in the context of PSA testing is infrequent and complex [6–8].

Uncertainty is a common but under-researched issue in general practice and clinical decision making [9,10]. Some research about communication in various clinical settings indicates that doctors can be reluctant to disclose uncertainty, preferring to present the appearance of certainty to their patients [11,12], and to avoid being judged as inadequate or ineffective [13]. There are different findings (and suggestions about the implications of) communicating uncertainty. Communicating uncertainty can have a negative effect on patients, including heightening perception of risk, causing unnecessary worry [14], and decreasing ability to make decisions about care [15]. In contrast, other research suggests honest expressions of uncertainty may improve the doctor patient relationship [13], facilitating trust [11], therapeutic effectiveness [16] and patient confidence [10], and decreasing patient interest and participation in medical screening [6,17,18].

Studies investigating doctors' experiences of uncertainty, specifically in the context of PSA testing, are scarce. The experience of uncertainty is a challenging phenomenon to explore [14]; yet it is central to much of medical practice. Some argue that tolerance of uncertainty is an essential dimension of professional competence [19]. Others have suggested that changing

professional and public attitudes towards medical error and uncertainty is key to reducing overdiagnosis and overtreatment [20].

Han's taxonomy of uncertainty [14] makes a valuable contribution to its conceptualisation in health care. As shown in Box 1 (modified), the taxonomy has three dimensions: sources of uncertainty (where uncertainty comes from), issues of uncertainty (what uncertainty is about), and locus of uncertainty (who is uncertain).

In this paper we first report on clinician perspectives and experiences of uncertainty in relation to PSA testing using Han's framework. We then add to Han's taxonomy an outline of the strategies that GPs use to manage uncertainty in PSA testing.

We use data from a qualitative study that explored general practitioners' current approaches to, and reasoning about, PSA testing of asymptomatic men. Uncertainty in PSA testing was identified as a core issue, and we draw on this data to address the following questions:

1. What are the primary sources of uncertainty as described by GPs in the context of PSA testing?
2. How do GPs experience and respond to different sources of uncertainty?

Methods

Design

We applied the well-established, systematic qualitative research methodology, grounded theory [21]. All study procedures were approved by the Cancer Institute NSW and the University of Sydney Human Research Ethics Committee [#15245]. GPs had an opportunity to discuss the study, and gave written consent, prior to participation.

Box 1. Han's (2011) taxonomy of uncertainty: a summary.

Sources of uncertainty:

1. *Probabilistic* uncertainty generated from the indeterminacy of a phenomenon's future outcome, such as the probability of benefit (or harm) from a test or treatment
2. *Ambiguity* signifies the lack of reliability, credibility, or adequacy of information about a phenomenon of interest, and includes imprecision (e.g. wide probability estimates of benefit /harm from treatment), conflicting opinions/evidence, and lack of information
3. *Complexity* is uncertainty arising from aspects of a phenomenon itself, which make it difficult to comprehend; e.g. numerous potential outcomes from a medical test or treatment or the existence of varied risk factors, symptoms, or signs of a given disease.

Issues of uncertainty:

1. *Scientific* uncertainty is disease-centred. Encompasses uncertainties about diagnosis, prognosis, causal explanations, treatment recommendations
2. *Practical* uncertainty is system-centred. Applies to the structures and processes of care (competence, quality, responsibilities)
3. *Personal* uncertainty is patient-centred. Psychosocial and existential issues (relationships, impact on life goals)

Locus of uncertainty:

Where the uncertainty resides: with the clinician or the patient

Participants and Setting

We recruited a sample of 69 GPs (40 Australian, 29 UK) for this study. In Australia we advertised via the newsletters and email lists of GP organisations (Medicare Locals) in Sydney, in mass and social media, and in medical journals. Rural GPs were accessed by phoning practice managers, through colleagues, and advertising with rural Medicare Locals [22].

We included GPs from the United Kingdom to also explore PSA testing reasoning and practice in a jurisdiction with comparatively lower rates of prostate cancer screening than Australia. We subsequently recruited 29 GPs throughout England (n = 24) and Scotland (n = 5). Our initial sample of GPs responded to an invitation distributed by academic colleagues through professional networks. We then broadened our sample by advertising via email to members of the Royal College of General Practitioners (RCGP), primary health care departments, university academic departments, and general practice and research mail lists. We also advertised via newsletter including the Society for Academic Primary Care (SAPC) and RCGP Scotland's eBulletin.

GPs were invited to contact KP if they were interested and willing to participate. Participating GPs were of varying ages, clinical experience, gender, and patient populations. All GPs who expressed interest in participating were included. GPs were compensated financially for their time.

Interviews / Data Collection

We generated data via in-depth interviews. The semi-structured interview schedule covered a broad range of topics, including GPs' recent clinical encounters involving PSA testing decisions; communicating information; screening pathways; and overdiagnosis. The schedule was modified between interviews, informed by the developing analysis. Uncertainty was not specifically included as a topic for discussion in the schedule; rather it was a recurring concept that was identified during data analysis. Interviews with Australian GPs took place between March 2013 and June 2014 and with UK GPs between September and December 2014. They were all conducted by KP, mostly by telephone and Skype, and ranged in duration from 18 to 70 minutes. All interviews were audio-recorded and transcribed verbatim.

Data Coding and Analysis

The analysis was led by KP, who coded the transcripts and wrote detailed memos which were regularly reviewed and discussed by the authors in analysis meetings. A subset of transcripts was read and coded by three authors independently; this coding was compared and discussed to inform the development of the central concepts in the study.

A longstanding point of contention in grounded theory methodology is the relation between the theory being produced, which is 'grounded' in the data collected, and existing relevant theory. While early expressions of grounded theory methodology [23] strongly emphasised the development of new theory *as opposed* to the testing of existing theory, contemporary mainstream grounded theorists strongly concur that qualitative empirical work must be conducted in the context of existing knowledge [24]. As uncertainty was identified as a core category in our data analysis, we turned to the literature to develop a better understanding of the concept, and identified Han's taxonomy of uncertainty in health care [14]. This taxonomy resonated with our interpretation of the data and suggested face validity for our early analysis of the sources and issues of uncertainty. We used Han's taxonomy to develop our analysis of GPs' experiences with uncertainty and categorised our data according to the 'sources' and 'issues' of uncertainty as described in the framework. In addition, we developed a new set of concepts related to how GPs respond to uncertainty in PSA testing, an issue that was not included in Han's typology.

Results

We identified considerable variation in GPs' interpretation, management, and experiences of uncertainty in terms of the source of the uncertainty they described, its impact on usual practice, and GPs perception of who should respond to uncertainty.

There seemed to be substantially more uncertainty experienced among Australian than UK GPs, perhaps partly explainable by the notable differences in conditions of practice for PSA testing between the two countries. The United Kingdom system is structured in several ways likely to decrease uncertainty. There is a clear policy directive against screening asymptomatic men for prostate cancer. There is an established norm of communicating with men who ask about PSA testing, and a structured approach to communication including a written information resource. In addition, referral pathways following particular test results are well-defined. In contrast, Australian policy is not clearly defined or directive, and at the time of this study there was no single authoritative document advising GPs how or what to communicate to men. The lack of policy clarity seems likely to contribute to the considerable variation in GP approaches to PSA testing [22].

Unsurprisingly, given these differences, Australian and UK GPs talked differently about prostate cancer screening. Asymptomatic men ask about prostate cancer screening frequently in Australian practice. Yet Australian GPs said they felt unsure about what is the "right" thing to do about PSA testing, expressed frustration about the lack of formal guidance to direct their practice, and many found talking with men about PSA testing a challenging experience because of underlying uncertainty. In contrast, the majority of GPs practicing in the UK were not routinely having discussions with asymptomatic men about PSA testing. They explained that screening men for prostate cancer is not a widely supported process, nor a common request from patients. When men did want a PSA test, GPs favoured providing them a standard government-produced information leaflet, to promote informed decisions. UK GPs considered conversations about PSA testing with asymptomatic men to be of low priority unless men asked, and overall did not express any notable uncertainty about whether to test men or not. As a result, there was comparatively less UK data about UK GP experiences of uncertainty. The results described below therefore predominantly describe the Australian data. We will return to the implications of this in the discussion.

Where Does GPs' Uncertainty Come from and What Is the Uncertainty About?

Table 1 outlines sources of GPs' uncertainty about PSA testing. We have included Han's definition of each source of uncertainty followed by a summary of how GPs described this type of uncertainty manifesting in their practice.

Table 2 captures the issues of uncertainty, again presented with Han's definition of the issues followed by specific examples in each cell from our data. Han's framework characterises 'personal uncertainty' as patient-centred. However because this study focused on the perspective of GPs, our data also includes personal uncertainty with a locus in GPs.

Our data indicate that GPs may experience a diverse range of uncertainties with respect to PSA testing. There were important differences however, between Australian and UK GPs' descriptions regarding what their uncertainty was about. Australian GPs' uncertainty was related to all three of the issues described above: scientific, practical, and personal. UK GP experiences of uncertainty were mostly about personal issues, because (a) GPs were clear about procedural expectations coming from government and medical bodies about PSA testing, and scientific uncertainty was dealt with via clear guidelines and norms; and (b) UK GPs expressed a sense that the medical profession was collectively managing the uncertainty so individual

GPs were facing less practical uncertainty because the UK system has processes in place to help them manage it. Thus the UK GPs' uncertainty was predominantly patient-centred; they were mostly concerned that when their patients sought or asked about PSA testing, they were then burdened with uncertainty due to the uncertain nature and quality of the available information. UK GPs did not feel uncertain themselves but worried that their *'patients have to make well-informed decisions and I suppose that's where it's such a minefield of uncertainty, it must be very difficult for people to say that they've made a well-informed decision'* (UKGP26).

Below we outline strategies GPs described using to handle uncertainty in the context of PSA testing of asymptomatic men. The information below draws primarily from the Australian data; where observations are based on UK data this is noted.

What Strategies Do GPs Use to Manage Uncertainty?

We identified three main approaches GPs used when faced with uncertainty around PSA testing, specifically about decision-making and responsibility:

Table 1. Sources of uncertainty (where is GP uncertainty coming from?).

Han's SOURCES of uncertainty	How does this taxonomy manifest in the context of PSA testing?
PROBABILISTIC UNCERTAINTY Generated from the indeterminacy of a phenomenon's future outcome, such as the probability of benefit (or harm) from a test or treatment	Several important potential outcomes may follow from PSA testing. Early diagnosis and treatment may decrease prostate cancer death for a small number of men. For the majority, any mortality benefit is outweighed by risk of harm: testing and treatment is associated with substantial harms, including impotence, incontinence, and anxiety. Although the probabilities of some of these outcomes can be estimated for populations, there is no way of knowing which individual patient will experience which outcomes.
AMBIGUITY Lack of reliability, credibility, or adequacy of information about a phenomenon of interest; includes imprecision (e.g. wide probability estimates of benefit /harm from treatment), conflicting opinions/evidence, and lack of information	The PSA test performs poorly as a screening tool. It is known that some screen-detected prostate cancers are more aggressive than others, but the PSA test cannot differentiate aggressive from non-aggressive cancers. This, together with uncertainties about treatment effects, uncertainty about how particular patients might react to different biomedical clinical outcomes (physically and psycho-socially), and how patients may respond differently to the risk of these outcomes, means it is unclear what test results might actually mean for each individual patient both at the point of testing and following an abnormal test result
COMPLEXITY Arising from aspects of a phenomenon itself, which make it difficult to comprehend; e.g. numerous potential outcomes from a medical test or treatment or the existence of varied risk factors, symptoms, or signs of a given disease. Confounding, interacting factors add complexity and complicate interpretations and outcomes. Personal judgment and clinical experience informs decisions.	The multiple-stage, multiple possibility sequence of testing and treatment outlined above add complexity to an evaluation of testing. Although the patient descriptors used in research studies and guidelines may seem simple (e.g. age 70+, asymptomatic) in general practice many individual patients are complex in ways not reflected in the evidence base. This includes the presence of comorbidities, and the difficulty in distinguishing symptomatic from asymptomatic men because of the multiplicity of causes of the symptoms commonly associated with prostate cancer. GPs consequently feel uncertain about how clinical descriptors should be applied.

doi:10.1371/journal.pone.0153299.t001

Table 2. Issues of uncertainty (what is the uncertainty ABOUT?).

Han's ISSUES of uncertainty (what is the uncertainty about?)	Probabilistic material as a Source of uncertainty (uncertainty arising from the probabilistic nature of information)	Ambiguity as a Source of uncertainty (uncertainty arising from the ambiguity of evidence or expert guidance):	Complexity as a Source of uncertainty (uncertainty arising from the interaction of multiple factors, some unknown):
SCIENTIFIC UNCERTAINTY *Disease-centred*. Uncertainties about diagnosis, prognosis, causal explanations, treatment recommendations	• GPs concerned about their inability to predict clinical outcomes (such as incontinence or impotence) following testing and treatment at the individual patient level. Probabilities can predict aggregate outcomes in a population, but cannot specify their exact distribution, or the probable severity of potential outcomes in any given individual.	• GPs concerned about conflicting estimates for particular outcomes for particular populations GPs uncertain about the conclusions that should be drawn from the evidence base for/ against screening for prostate cancer	• Interpretation of the benefits and risks of testing and treatment can change over time and depend on various assumptions (e.g. about patient values and current state). GPs concerned about evaluating benefits and risks and making treatment decisions relating to individual patients because of this complexity.
PRACTICAL UNCERTAINTY *System-centred*. Uncertainties about the structures and processes of care (competence, quality, responsibilities)	• GPs described probabilities as challenging to think about and apply in individual clinical encountersGPs unsure how urologists will work with patients referred with a high PSA result	• GPs uncertain about professional practice due to disagreement between guidelines GPs concerned about conflicting guidance from medical authority: professional organizations and colleagues vary in the recommendations they make about whether or not (and under what circumstances) to screen with PSAGPs unclear under what conditions they could be medically liableGPs concerned about inconsistent referral pathways and advice	GPs find communicating probabilistic information with specific patient types (e.g. health illiterate, anxious, determined to have the test) difficultGPs seeing a patient who usually consults a different GP found this a complex and 'awkward' situation in which to practice if their testing preferences were dissimilar to the GP they were replacing
PERSONAL UNCERTAINTY *GP/ patient-centred*. Uncertainties about psychosocial and existential issues (relationships, impact on life goals)	GPs concerned about their inability to predict the psychological and existential outcomes of testing and treatment that would be experienced by the patient	• GPs consider what is at stake for them as an individual clinician—legally, psychologically, professionally and socially—if they do or do not testGPs uncertain about what is the right thing to do in this context in order to be considered a 'good GP' and preserve relations with their patientsGPs concerned about whether it is ok to change PSA testing practice following personal and practice experiences	• GPs concerned about their ability to judge how 'good' any individual patient's consent/decision might be, and what the outcomes of poor/ inaccurate judgment may mean for them and their patientsGPs uncertain about individual patient tolerability of potential consequences of their decisionsGPs feel conflicted when their own personal preferences for testing/not testing conflict with advice they provide

doi:10.1371/journal.pone.0153299.t002

1. Sometimes GPs *took charge* of uncertainty, considered it a usual feature of their daily practice, and managed (at least some) uncertainties on their own
2. Sometimes GPs *engaged others* in managing uncertainty: they accepted some uncertainty as a challenge and used it as an opportunity to engage the medical profession, colleagues, and patients about how the uncertainty would be handled, to enable them to better support patients and find shared solutions
3. Sometimes GPs *sought to transfer* to other parties the responsibility for reducing or managing some uncertainties.

Some GPs tended to manage all types of uncertainty about PSA testing in a relatively consistent way, adopting one of the three approaches described above (i.e. some GPs usually took charge, usually accepted and engaged, or usually transferred, although this was never absolute). Other GPs were more variable in their approach, applying different management strategies in

different situations. Particular sources of uncertainty also tended to elicit particular types of responses. So GPs who tended to use different strategies to manage different types of uncertainties may call upon one or all of the techniques depending on the type of uncertainty, the particular situation, and the GPs individual interpretation of it and level of tolerance.

We describe the three categories of GPs approaches below.

1. GPs taking charge of uncertainty. When we describe GPs as "taking charge of uncertainty" we refer to circumstances when they recognised uncertainty, tolerated it, and accepted it as a lasting presence in their practice. They found ways through the uncertainty for themselves according to their *'own protocol'* (GP24) because *'the scientists and the doctors cannot tell you what's going to happen'* (GP17). GPs taking charge had settled into ways of dealing with some kinds of uncertainty and now just got on with it, acting confidently as lead decision-makers. It depended on the individual GP whether "taking charge" occasioned active recommendation of PSA testing or not.

Although these GPs might seek more medical information to inform further decisions following initial testing (e.g. actively PSA testing including repeat testing, ordering alternative tests), this was independent of external parties: they did not describe feeling any pressure to consult patients or recommendations before making decisions. Some GPs preferred to practice using a *'gut feeling sort of approach'* (GP21), because *'nobody really knows the right answers to any of these questions'* (GP18). For them, *'because the science is imperfect, then personality and medical judgement have. . .more of an important role'* (GP17). These GPs directed their PSA testing practice according to their clinical experience.

When GPs took charge of uncertainty about testing decisions, they did not routinely discuss uncertainty comprehensively with patients. Sometimes they believed a patient did not have the ability to cope with the complex information, and sometimes they assumed a position of making decisions on behalf of patients to protect them from navigating uncertain decisions, *'I think it's a lot easier for the patient to not be in that position [of making decisions grounded in uncertainty] at all'* (GP17). There were some GPs who disagreed with this as an appropriate approach; however the GPs using it as a strategy did so to protect their patients from the uncertainty in current knowledge.

When GPs took charge, they did not perceive or experience uncertainty as burdensome: they simply accepted that *'it's not clear and that's just the way it is'* (GP20), or '[the PSA test is] *not perfect but it's all we've got'* (GP26). One GP commented that all doctors should have the capacity to make decisions about the evidence around PSA testing, despite its uncertainty *'if you think it's too hot in the kitchen, get out. . .I have no sleepless nights worrying about missing one, I think that's just–just life'* (GP18). Ultimately, these GPs were comfortable acknowledging that GPs *'don't have to have the answers to everything in medicine'* (GP3).

Interestingly, how to handle *normal* PSA test results was a source of uncertainty for some UK GPs because all guidance following PSA testing is for symptomatic patients or abnormal test results. UK GPs really relied on having guidelines to direct their practice. These guidelines are, roughly: 1) don't test; 2) if someone happens to ask, give them this information; 3) if abnormal PSA result, refer to this hospital (clear procedure). As a result GPs said they were uncertain about how to proceed following normal PSAs. Should they, for example, tell the man that they could now stop worrying altogether, or that they should come back in x years? They wanted to avoid being in this position of uncertainty so their strategy was to, wherever possible, not test in the first place. In comparison, some Australian GPs described normal results as a source of relief and reassurance for them and their patients, because for them, the uncertainty of not knowing was greater than knowing a test result (abnormal of not). GPs told of how most patients in Australia receiving PSA testing expect to be tested annually, so GPs actively test them year-to-year in the hope of finding another normal result.

2. GPs engaging others in managing uncertainty. In some situations, GPs were committed to engaging others in managing uncertainty about PSA testing. They took uncertainty as a challenge, and engaged the medical profession, colleagues, and patients in their quest to make a good decision in the context of shared uncertainty. Engaging others occurred via relationships and communication. These GPs took it as their duty to grapple with the uncertainty and felt a sense of responsibility to share it with the profession (usually as a member of an organisation of GPs and specialists), and with patients: to inform them of uncertainty, ongoing debate and lack of consensus. They expected to be supported by GP and specialist colleagues to help manage their own emotional and informational needs (e.g. consulting colleagues and specialists for advice), and to in turn effectively support patients to make decisions.

Some GPs negotiating uncertainty felt more comfortable than others managing the uncertainty of the 'grey zone' of PSA test results. In this zone (>4ng/ml, <10ng/ml) the clinical implications of test results, and decisions about what to do, are most contested. GPs comfortable with managing the grey zone themselves via repeat testing or active surveillance (rather than external referral to a specialist) had *'no hesitation'* (GP31) to contact colleagues or specialists for advice and *'reassurance. . .of what to tell the patient'* (GP5) once uncertainty moved beyond the GPs' *'own level of comfort and expertise'* (GP31).

GPs who negotiated uncertainty were more inclined to talk about the uncertainty of PSA testing with their patients. They reported telling their patients that it is not possible to be sure about aspects of PSA testing, including probabilistic outcomes and individual prognosis, and therefore any advice offered had some degree of underlying uncertainty. GPs told patients they themselves don't know what to do about PSA testing of asymptomatic men and don't *'pretend to fully understand it'* (GP31), *'so I don't expect patients to have the capacity to–we say fully informed, but really we're not, so how can the patient be?'* (GP26). Yet these GPs were adamant that regardless of the limitations of the available knowledge base, *'the information needs to be on the table'* (GP31).

GPs who talked to patients about the uncertainties of PSA testing said they acknowledged the discord in professional opinion about what should be done with their patients. For many GPs this was a source of considerable frustration: *'every week and I'm like, for God's sake, can someone make a decision so I know what to do?'* (GP26). They often did not feel supported by the medical profession: *'It's up to individual GPs to sort it out himself–I mean it shouldn't happen this way, but we're not getting really helpful information from our so-called experts'* (GP28). The RACGP guidelines (as outlined in the introduction) were described as unhelpful, *'a blanket ethical statement'* (GP28) and GPs said they felt *'we're still in a mess with what we're actually advising men to do. . .we don't know what the hell we're doing'* (GP8). Some of these GPs reported clear ideas about how authorities should respond to support GPs and to support patients. This centred on consensus, talking the same language, and telling GPs exactly what information they should provide patients. Some GPs did, however, recognise the difficult position authorities are in when trying to produce policy in a complex situation; *'the opinions and the spectrum. . .it just reflects that it's unclear and that opinion is divided depending on who you talk to'* (GP20).

For many GPs an element of discomfort with uncertainty was ever-present. GPs felt guilty about possible negative psychosocial effects on their patients of understanding how messy and complex the situation is; '*the spiel that I give men about this leaves them with virtually no ability to make a good decision. . .I don't make things easier for people*' (GP8). GP attempts to share their knowledge of the uncertainties and experience of being uncertain about what to do with patients sometimes proved futile: for example if the patient wanted the GP to decide what to do on their behalf and preferred not to be engaged in/take on the lead role in decision making.

Of the three approaches, it was the GPs engaging others in the uncertainty of PSA testing who were most likely to experience that uncertainty as burdensome. They worked hard to

make an impossible situation as good as possible. But their work to mitigate the uncertainty was unrecognised and unrewarding; the more GPs tried to wrestle with the uncertainty, the more uncertain the situation appeared. Yet these GPs continued to take on some uncertainty as a challenge because doing something–engaging patients and the profession–felt appropriate and 'right' to them as GPs.

3. GPs transferring uncertainty. Finally, some GPs employed strategies of "transferring" responsibility for decision making in the face of uncertainty. They perceived uncertainty as problematic and uncomfortable and sought out other parties to reduce their experience of uncertainty. The external authorities could include: urologists, those researching the test, legal authority, or the health system. One GP described this process of transferring responsibility for decision-making as *'handballing it to somebody else'* (GP26).

In practice, GPs in this category were not likely to repeat PSA test results that returned in the grey zone, rather preferring to refer those patients immediately to specialists to make decisions about the next stage of management. In fact a subset of GPs were committed to immediate referral regardless of what the PSA test result was: '*even though it's [PSA] still well within the normal range for their age—I just think that's a specialist's [urology] decision, not mine'* (GP26). For GPs, having urology as a backup meant they could regard uncertain PSA results as *'not my problem, quite frankly'* (GP25).

Some GPs engaged in active PSA testing as a strategy for managing their uncertainty, particularly about potential legal ramifications of not testing; *'I would probably still send him for the test because I'd be worried somebody would sue me if I didn't'* (GP22). One GP said that when in a position of not knowing what to do *'I think medico-legal comes into that. . .you're more defensive in your acting'* (GP34). This subgroup of GPs looked to legal authority to protect them and justify their practice, and perceived medico-legal obligations influenced their practice particularly when they felt uncertain about what to do.

Some GPs left decision making entirely up to the individual patient to deal with; 'so I say well it's your decision and if you want to have it, you can. If you don't want to worry about it, that's ok with me too. So I let them decide basically' (GP21). A number of practices in Australia had implemented their own policy: a recall system whereby patients would be automatically notified when due for a PSA test with an accompanying pathology form. In these instances, GPs minimised repeated engagement with the uncertainties of PSA testing and personal responsibility for patient decision-making. By automating the process they effectively transferred responsibility for follow-up to a practice management system, and their patients would in turn choose how to respond to the automated invite.

Those GPs whose default-practice was to transfer responsibility had worked out a way of practicing which relieved them of the burden of advising and making practice decisions based on uncertain foundations (at least until their next consultation involving a PSA test). This risk-averse approach–transferring uncertainty to external authority as soon as possible–was perceived by GPs as a way to save patients from being burdened by GP uncertainty and meant the GP did not have to engage with what they considered an unresolvable situation.

How Do GPs Respond to Different Sources of Uncertainty?

Probabilistic uncertainty was identified as a major source of uncertainty by the GPs, yet they tended to speak of it as being more tolerable than uncertainties arising from ambiguity and complexity. Overall, GPs accepted responsibility for probabilistic uncertainty and shared their knowledge about it; it was not as common for GPs to attempt to transfer responsibility for this source of uncertainty. Many GPs described handling probabilistic uncertainty reasonably comfortably on their own. They saw it as central to the GP role and to clinical judgment, which

necessarily involves interpreting scientific evidence and probabilities. Individuals or organisations were not blamed or held directly responsible for probabilistic uncertainty. GPs described probabilistic uncertainty as challenging (e.g. indeterminate medical outcomes), but had mostly found a relatively settled way of dealing with it because they had few alternatives.

The two other types of uncertainty invoked different responses: uncertainty arising from ambiguity—for example, varied recommendations—and complexity—the vagueness of clinical descriptors, or the difficulty in judging patient understanding. Many GPs preferred to negotiate or transfer responsibility for these uncertainties. For example, a GP experiencing uncertainty in a testing decision might tell the patient about discordant recommendations to justify their uncertainty and immediately refer to specialists for further opinion. Some GPs appeared to hold that responsibility for ambiguity or complexity should be collective and others should be involved in negotiating decisions, or they preferred to transfer those decisions to specialists. Ambiguity and complexity commonly led to practical issues for GPs arising from this uncertainty–how to engage in 'good' practice and appropriate communication based on complex evidence and ambiguous guidance. Ambiguity and complexity were also a foundation for GPs' sense of personal burden, as some GPs expressed anxiety about their capacity to make 'good' decisions without good evidence, and ability to judge what level of information was suitable to support consent. Theoretically these sources of uncertainty could be modified or improved with system change (for example, consistent recommendations, established consent protocols) but GPs felt limited in their capacity to make changes at the clinical level.

Discussion

GPs described experiencing considerable and, at times, burdensome uncertainty in the context of PSA testing of asymptomatic men for prostate cancer. Locating and describing sources or types of uncertainty (Table 1) as per Han is important in this context because the various types of uncertainty produced different issues (Table 2), which GPs responded to and managed using distinct strategies (our 3 strategies outlined above).

Sources, Issues, and Management of Uncertainty

GPs in our study appeared to manage uncertainty arising from probabilistic information with reasonable confidence when compared to the other sources of uncertainty. One possible explanation for this finding is that GPs are familiar with probabilities and are trained to interpret and manage probabilistic information in the clinical setting. Numerous resources are available presenting probabilistic and statistical information in multiple formats (numerically, graphically) to assist GPs and to support the decision making capacity of their patients. While probabilistic uncertainty is particularly challenging in relation to PSA testing and cannot be readily resolved with leaflets or information sheets, we propose that such resources 'normalise' the probabilistic uncertainty inherent to this context. It is possible that GPs feel more comfortable taking charge or engaging with others about probabilistic uncertainty because they are better able to get a handle on the uncertainty they are dealing with because it is an ongoing and familiar type of uncertainty. Probabilistic information about outcomes is also the typical kind of information assumed to be shared in processes of shared decision-making.

It is clear from our results that uncertainty from ambiguity on the other hand was extremely frustrating for GPs; GPs were uncertain about guidance from medical authorities and were unclear of their clinical and legal obligations. These uncertainties are grounded in ambiguity, which, as the decision psychology literature has shown, people generally prefer to avoid (e.g. [25]. Ambiguity is more directly related to uncertainties about what to do in practice than probabilistic uncertainty, and perhaps leaves more scope for GPs to take a "wrong" course of

action. Aspects of ambiguity in this context are potentially modifiable, which could reduce some uncertainty for GPs. For example, clearer and more consistent expert guidance may assist. Yet even if more 'certainty' was implemented at the system-level via clear guidelines or consistent advice from authoritative sources, clinicians will inevitably still experience some personal uncertainty stemming from the complexity of this information, and because of diverse GP and patient value systems in the clinical context (e.g. questioning appropriateness of recommendations).

Complexity was also experienced as particularly uncomfortable for GPs; some GPs described feeling uncertain about their own clinical judgment. Complexity is essentially a source of uncertainty amenable to individual value judgment, interpretation, and assumptions. It is therefore difficult to offer training or advice to GPs about ideal management of complexity uncertainty in relation to PSA testing. While clearer expert opinion may lessen ambiguity, GPs are left to deal with complexity at the clinical level with the individual patient. Our data from UK GPs illustrates that even with system-level guidance and clear 'best practice' formulations, GPs continue to experience personal uncertainty because every patient and consultation involving PSA testing is different and involves difficult value judgments. Clinicians will invariably face ongoing uncertainty about the nature of medical evidence and individual and distributive health care [26].

The Burden of Uncertainty

Ordering PSA tests for screening purposes is paradoxical in relation to uncertainty. Testing is a response to uncertainty: an attempt to better predict a man's risk of developing prostate cancer. Yet while PSA testing aims to reduce uncertainty, the characteristics of the test when used as a screening tool mean that it tends to introduce more scientific, practical, and personal uncertainty than it eliminates. Faced with a PSA test result, the clinical significance of which is intrinsically uncertain, some GPs actively tried to lessen uncertainty by looking to guidelines on which to base decisions, or by sharing their knowledge with patients. However these strategies also tended to compound uncertainty, piling up knowledge about the uncertainties regarding outcomes, and GPs felt further burdened as a result. This is the great paradox of the PSA. If GPs chase certainty via more and more testing and investigation, this may create more uncertainty. Testing can undoubtedly create certainty for some GPs and patients at the individual level, but it comes at a cost of lots of uncertainty, including GPs' top line uncertainty about using the PSA test at all. This, as our research has demonstrated, is what inflicts considerable burden on GPs: because they have burdened patients with information which cannot provide any clear answer, because their efforts to locate certainty have gone unrewarded, and because of remaining uncertainty about what counts as good practice.

Uncertainty and the associated struggle is not just a burden to be borne by individual practitioners. There is an expectation that GPs will practice in line with professional standards and evidence-based medicine. If GPs are expected to act according to these standards, it would be reasonable to suppose that the health care system might owe GPs some reciprocal supports to make it possible for them to do so.

Ethical Considerations

There are judgments to be made about how best to involve men in PSA testing decisions. Our data touches on uncertainties about whether, when, and in what forms communicating about uncertainty is considered appropriate. Communicating uncertainty is not simply about probabilities; ambiguity and complexity are also key sources of GP uncertainty and subsequent burden. Any attempt to guide communication about uncertainty in PSA testing practice may be more effective if it addresses all three sources of uncertainty.

Ethical questions remain in relation to presenting uncertainty to patients who wish to avoid making medical decisions; coping with uncertainty is known to be a source of substantial stress and anxiety for many patients (e.g. [27]. Manson and O'Neill argue that a trusting and responsive relationship might be more valued by patients than detailed information exchange [28]. Perhaps in some situations, a "taking charge" approach, whereby GPs call on their professional experience and apply 'rules of thumb' to direct their practice might be appropriate, while in more complex situations, GPs may need to discuss and reach agreement with others regarding how decisions based on uncertainty will be allocated and resolved.

More work is needed to clarify under what circumstances uncertainty should be communicated to patients, and if so what aspect of the uncertainty construct should be addressed. Parascandola et al argue that respectful interaction with patients requires disclosure about uncertainty even when it is not offered to gain consent or in the service of patient decision making; as long as patients understand the general decision making context [29]. Ideally, doctors need to feel supported in their dealings with uncertainty. Research suggests that when doctors are comfortable with uncertainty and collaborate with patients in their medical care, patient trust and satisfaction are high [29].

Limitations

This analysis was inductive rather than commencing with research questions about uncertainty. Further research could test our findings and explore the impacts of uncertainty in more depth.

Conclusions

These important aspects of uncertainty require further and specific investigation, including the potential implications of clinician uncertainty for cost and quality of health care [30].

This study is a first step in mapping how clinicians practice under conditions of uncertainty. Our unique findings identified what doctors actually do in response to the different types of uncertainty encountered. These results have practical value: the GPs in our study responded to the various types of uncertainty and their associated issues differently. It seems likely that GPs and their patients will benefit from greater acknowledgment by the profession of specific sources of uncertainty and their unique implications, and in particular the often-neglected uncertainty arising from ambiguity or complexity. Achieving this would be an essential step in promoting GP engagement with uncertainty, and ultimately patient involvement in better informed decisions about PSA testing for prostate cancer.

Acknowledgments

We thank the General Practitioners for their participation in this research. The project was funded by NHMRC grant 1023197. Stacy Carter is supported by NHMRC Career Development Fellowship 1032963.

Author Contributions

Conceived and designed the experiments: KP SMC LR. Performed the experiments: KP. Analyzed the data: KP SMC VAE LR KM. Wrote the paper: KP SMC VAE LR KM.

References

1. Moyer VA (2012) Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement. Annals of Internal Medicine 157: 120–134. doi: 10.7326/0003-4819-157-2-201207170-00459 PMID: 22801674

2. RACGP (2012) Guidelines for preventive activities in general practice.
3. Politi MC, Han PK, Col NF (2007) Communicating the uncertainty of harms and benefits of medical interventions. Medical Decision Making 27: 681–695. PMID: 17873256
4. Quill TE, Suchman AL (1993) Uncertainty and control: learning to live with medicine's limitations. Humane Med 9: 109–120. PMID: 11656250
5. Hewson MG, Kindy PJ, Van Kirk J, Gennis VA, Day RP (1996) Strategies for managing uncertainty and complexity. Journal of General Internal Medicine 11: 481–485. PMID: 8872786
6. Han PK (2013) Conceptual, methodological, and ethical problems in communicating uncertainty in clinical evidence. Medical Care Research and Review 70: 14S–36S. doi: 10.1177/1077558712459361 PMID: 23132891
7. Chapple A, Ziebland S, Hewitson P, McPherson A (2008) Why men in the United Kingdom still want the prostate specific antigen test. Qualitative health research 18: 56–64. doi: 10.1177/1049732307309000 PMID: 18174535
8. Han PK, Hootsmans N, Neilson M, Roy B, Kungel T, Gutheil C, et al. (2013) The value of personalised risk information: a qualitative study of the perceptions of patients with prostate cancer. BMJ open 3: e003226. doi: 10.1136/bmjopen-2013-003226 PMID: 24038007
9. Hall KH (2002) Reviewing intuitive decision-making and uncertainty: the implications for medical education. Medical education 36: 216–224. PMID: 11879511
10. Ogden J, Fuks K, Gardner M, Johnson S, McLean M, Martin P, et al. (2002) Doctors expressions of uncertainty and patient confidence. Patient Education and Counseling 48: 171–176. PMID: 12401420
11. Katz J (1984) Why doctors don't disclose uncertainty. Hastings Center Report 14: 35–44.
12. Atkinson P (1984) Training for certainty. Social Science and Medicine 19: 949–956. PMID: 6515428
13. Gordon GH, Joos SK, Byrne J (2000) Physician expressions of uncertainty during patient encounters. Patient Education and Counseling 40: 59–65. PMID: 10705065
14. Han PK, Klein WM, Arora NK (2011) Varieties of Uncertainty in Health Care A Conceptual Taxonomy. Medical Decision Making 31: 828–838. doi: 10.1177/0272989X11393976 PMID: 22067431
15. Johnson BB, Slovic P (1995) Presenting uncertainty in health risk assessment: initial studies of its effects on risk perception and trust. Risk Analysis 15: 485–494. PMID: 7480948
16. Di Blasi Z, Harkness E, Ernst E, Georgiou A, Kleijnen J (2001) Influence of context effects on health outcomes: a systematic review. The Lancet 357: 757–762.
17. Frosch DL, Kaplan RM, Felitti VJ (2003) A randomized controlled trial comparing internet and video to facilitate patient education for men considering the prostate specific antigen test. Journal of General Internal Medicine 18: 781–787. PMID: 14521639
18. Volk RJ, Spann SJ, Cass AR, Hawley ST (2003) Patient education for informed decision making about prostate cancer screening: a randomized controlled trial with 1-year follow-up. The Annals of Family Medicine 1: 22–28. PMID: 15043176
19. Epstein RM, Hundert EM (2002) Defining and assessing professional competence. JAMA 287: 226–235. PMID: 11779266
20. Hoffman JR, Kanzaria HK (2014) Intolerance of error and culture of blame drive medical excess. BMJ 349: g5702. doi: 10.1136/bmj.g5702 PMID: 25315302
21. Charmaz K (2006) Constructing grounded theory: a practical guide through qualitative analysis. London: SAGE Publications.
22. Pickles K, Carter SM, Rychetnik L (2015) Doctors' approaches to PSA testing and overdiagnosis in primary healthcare: a qualitative study. BMJ open 5: e006367. doi: 10.1136/bmjopen-2014-006367 PMID: 25783420
23. Glaser B, Strauss A (1967) The discovery of grounded theory. 1967. Aldin, New York.
24. Bryant A, Charmaz K (2007) The Sage handbook of grounded theory: Sage.
25. Camerer C, Weber M (1992) Recent developments in modeling preferences: Uncertainty and ambiguity. Journal of risk and uncertainty 5: 325–370.
26. Griffiths F, Green E, Bendelow G (2006) Health professionals, their medical interventions and uncertainty: A study focusing on women at midlife. Social Science and Medicine 62: 1078–1090. PMID: 16233942
27. Germino BB, Mishel MH, Belyea M, Harris L, Ware A, Mohler J (1998) Uncertainty in prostate cancer. Ethnic and family patterns. Cancer Practice 6: 107–113. PMID: 9573910
28. Manson NC, O'Neill O (2007) Rethinking informed consent in bioethics: Cambridge University Press.

29. Parascandola M, Hawkins JS, Danis M (2002) Patient autonomy and the challenge of clinical uncertainty. Kennedy Institute of Ethics Journal 12: 245–264. PMID: 12472078

30. Rizzo JA (1993) Physician uncertainty and the art of persuasion. Social Science and Medicine 37: 1451–1459. PMID: 8303329

CHAPTER FIVE.

Doctors' perspectives on PSA testing illuminate established differences in prostate cancer screening rates between Australia and the United Kingdom:

A qualitative study

5. Overview of this chapter

The United Kingdom was identified as an interesting and relevant comparison case for this study. The prostate cancer screening policies of Australia and the UK draw on the same international research literature, and report similar rates of prostate cancer mortality, yet these jurisdictions have notably different rates of PSA screening in primary care.

The aim of the analysis presented in this chapter was to compare GPs' reasoning about prostate screening in two jurisdictions with different PSA policy environments to further understand the influence of different conditions of practice. We asked, how do GPs in Australia and GPs in the UK explain their PSA screening practices? What do any similarities or differences suggest about the influence of health systems on GPs' PSA screening practices? (Research Question 2.3). The GPs' accounts suggested that the organisation and structure of health care systems can contribute to explaining varied use of the PSA test as a screening tool in clinical practice.

5.1 Publication details

Pickles K, Carter SM, Rychetnik L, et al. Doctors' perspectives on PSA testing illuminate established differences in prostate cancer screening rates between Australia and the UK: a qualitative study. BMJ Open 2016;6:e011932.doi:10.1136/bmjopen-2016-011932

5.2 Authors' contributions

All authors conceived the study and were involved in designing the study and developing the methods. SC & LR obtained funding and are CIs on the NHMRC funded project grant. KP conducted the interviews, had full access to all data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis. KP drafted the manuscript. All authors contributed to the interpretation of the analysis and critically revised the manuscript.

5.3 Abstract

In this grounded theory study, GPs in Australia and the UK were interviewed about their use of the PSA test as a screening tool in primary care. The GPs' accounts revealed fundamental differences in whether and how prostate cancer screening occurred in their practice and in the broader context within which they operate. We found important drivers of more screening (Australia) and less screening (UK), including the history of prostate screening policy, organisational structures, and funding models. In Australia, screening processes and decisions were mostly at the discretion of individual clinicians, and varied considerably. In the UK, GP accounts reflected a consistent, organisationally embedded approach based on local evidence-based recommendations to discourage screening. We discuss these findings with reference to Gabbay and le May's mindlines theory, which considers the influence of local context on GP use of formal knowledge such as clinical guidelines.

5.4 Manuscript

The published version of the manuscript follows.

BMJ Open

Doctors' perspectives on PSA testing illuminate established differences in prostate cancer screening rates between Australia and the UK: a qualitative study

Kristen Pickles,[1] Stacy M Carter,[1] Lucie Rychetnik,[2] Vikki A Entwistle[3]

To cite: Pickles K, Carter SM, Rychetnik L, *et al*. Doctors' perspectives on PSA testing illuminate established differences in prostate cancer screening rates between Australia and the UK: a qualitative study. *BMJ Open* 2016;**6**:e011932. doi:10.1136/bmjopen-2016-011932

► Prepublication history for this paper is available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2016-011932).

Received 16 March 2016
Revised 4 November 2016
Accepted 9 November 2016

[1]Centre for Values, Ethics and the Law in Medicine, University of Sydney, Sydney, New South Wales, Australia
[2]School of Medicine, University of Notre Dame, Sydney, New South Wales, Australia
[3]Health Services Research Unit, University of Aberdeen, Foresterhill Aberdeen, UK

Correspondence to
Kristen Pickles;
kristen.pickles@sydney.edu.au

ABSTRACT

Objectives: To examine how general practitioners (GPs) in the UK and GPs in Australia explain their prostate-specific antigen (PSA) testing practices and to illuminate how these explanations are similar and how they are different.

Design: A grounded theory study.

Setting: Primary care practices in Australia and the UK.

Participants: 69 GPs in Australia (n=40) and the UK (n=29). We included GPs of varying ages, sex, clinical experience and patient populations. All GPs interested in participating in the study were included.

Results: GPs' accounts revealed fundamental differences in whether and how prostate cancer screening occurred in their practice and in the broader context within which they operate. The history of prostate screening policy, organisational structures and funding models appeared to drive more prostate screening in Australia and less in the UK. In Australia, screening processes and decisions were mostly at the discretion of individual clinicians, and varied considerably, whereas the accounts of UK GPs clearly reflected a consistent, organisationally embedded approach based on local evidence-based recommendations to discourage screening.

Conclusions: The GP accounts suggested that healthcare systems, including historical and current organisational and funding structures and rules, collectively contribute to how and why clinicians use the PSA test and play a significant role in creating the mindlines that GPs employ in their clinic. Australia's recently released consensus guidelines may support more streamlined and consistent care. However, if GP mindlines and thus routine practice in Australia are to shift, to ultimately reduce unnecessary or harmful prostate screening, it is likely that other important drivers at all levels of the screening process will need to be addressed.

Strengths and limitations of this study

- The published literature about prostate cancer screening in general practice is replete with quantitative studies: They have identified clinician and patient demographics associated with more or less screening, and have analysed rates of screening and frequency of discussions about prostate-specific antigen (PSA) testing. Our research is complementary to existing quantitative findings: We asked how PSA testing of asymptomatic men occurs in clinical practice, from the general practitioner (GP) perspective.
- This study applied grounded theory methodology to explore how clinicians describe their prostate screening practice, and relate these to points of variation in the respective healthcare systems. Grounded theory is a suitable approach for the investigation of complex multifaceted processes (like PSA screening) occurring in context.
- We interviewed a large number of highly informative participants (GPs) in Australia and the UK with diverse opinions and approaches.

BACKGROUND

Prostate-specific antigen (PSA) testing of asymptomatic men for prostate cancer risk is a contested issue internationally. In this paper, 'asymptomatic' will refer to those men attending clinical practice with no prior indications associated with prostatic disease. This is in contrast to the detection of prostate cancer in symptomatic men: men who have symptoms that could be related to locally advanced or metastatic prostate cancer such as frequency of urination, new onset bone pain and/or neurological symptoms involving the lower extremities.[1] PSA testing of asymptomatic men is not recommended as a population-screening programme in Australia or the UK, the two countries on which our analysis focuses.

Prostate cancer incidence varies more than 25-fold worldwide. Incidence figures, which incorporate both life-saving diagnoses and

overdiagnosed cancers,[2] vary between Australia, where incidence is 115.22 cases per 100 000 population, and the UK, where incidence is 73.19 per 100 000. Despite this difference in reported incidence, the two countries have roughly equivalent prostate cancer mortality figures: 12.88 and 13.07 per 100 000, respectively.[3] There are many reasons for variation in incidence and mortality rates, which could be due to underlying differences in prostate cancer risk and population age structures, men presenting for testing, access and availability of treatment options, cancer coding and registration and diagnostic processes (such as availability of PSA testing and improved diagnosis).

An important factor influencing reported prostate cancer incidence in a population is PSA testing rates: higher testing rates produce higher incidence. Testing rates may be influenced by differences in professional and organisational policies, media, cultural beliefs and values. Annual PSA testing rates of asymptomatic men in general practice are difficult to ascertain. The data collected often do not distinguish men who have had a PSA for prostate cancer screening from those in whom established disease is being monitored.

Clinical practice in the UK and Australia is grounded in the same evidence base and international literature, yet the two jurisdictions have notably different rates of PSA testing. In the UK, a study in six English cities reported the annual practice-based PSA testing rate for 2007 (in men aged 45–89 years) to be 6.2%.[4] A more recent study analysed data from patient electronic records in primary care for men aged 45–84 years. It reported that for every 100 men enrolled with a general practitioner (GP) for one year, 5.03 (asymptomatic men) were tested in 2010, and the rate increased by 8% in 2011 to 5.45 per 100.[5] Note that the data this analysis was based on represent only 5% of the population in England and may not be representative of all practices.

Analysis of Medicare Australia's Medical Benefits Scheme records suggests that each year at least 20% of men aged 45–74 years have a PSA test, presumably for the purpose of early diagnosis of prostate cancer.[6] This number underestimates the actual number of PSA tests performed, by up to 40%.[7] The prevalence of PSA testing in men over 50 years in Australia was reported at 63% in 2003; that is, 63% of men >50 years had ever had a PSA test.[8] This proportion is likely to have risen since.[9]

This raises questions about how practice in the two jurisdictions, while drawing on the same evidence base, could be so markedly different. In table 1, we set out some important differences in the organisation and funding of primary healthcare between Australia and the UK, including subtle variance in the advice offered to GPs from expert authorities in relation to how actively physicians should offer testing. Any or all of these differences conceivably influence testing rates.

Here, we report on a comparative qualitative study of Australian and UK GPs' current approaches to, and reasoning about, PSA testing of asymptomatic men to address the following questions:

- How do GPs in the UK and GPs in Australia explain their PSA testing practices?
- How are these explanations similar and different?

Our analysis draws on Gabbay and le May's[14] concept of 'mindlines', which they developed to explain how GPs use research evidence in practice. They describe mindlines as 'collectively reinforced, internalised, tacit guidelines',[15] mainly grown and refined via training, experience and interaction with trusted sources, and mediated by features of primary care organisations, including their ethos and financial and structural elements. Their mindlines theory makes a valuable contribution to the evidence-based medicine (EBM) and knowledge translation literatures because the theory considers the influence of local context on GP adherence and use of formal knowledge like guidelines. We use our analysis of data collected from GPs practising in Australia and the UK to extend Gabbay and le May's theory of mindlines.

METHODS

Design

We applied the well-established, systematic qualitative research methodology of grounded theory.[15] Grounded theory is a method of conducting qualitative research that focuses on creating conceptual frameworks or theories through building inductive analysis from the data.[16] Grounded theorists are led by the experiences of the people in their inquiry and the substantive theories they develop closely reflect what those people experience and do. Specific methods of data collection and analysis are used to identify patterns in the research data. The twin foundations of grounded theory are the processes of constant comparison (a simultaneous and concurrent process of coding and analysis) and theoretical sampling (sampling with the aim of developing the properties of a developing idea or theory). These methods together guide the systematic development of emerging theory, and ensure findings remain firmly grounded in the collected data. All study authors have been formally trained in the methods described; SC has particular expertise in grounded theory methodology.

Participants and setting

We purposively recruited a sample of 69 GPs (Australia, n=40; the UK, n=29) for this study. In Australia, we advertised via the newsletters and email lists of GP organisations (Medicare Locals) in Sydney, and in mass and social media, and in medical journals. As analysis and sampling evolved, we invited additional rural and interstate GPs to answer specific analytical questions; for example, the influence of GP proximity to specialist services. Rural GPs were accessed by phoning practice managers, through colleagues, and advertising with rural Medicare Locals.[17] When we encountered GPs whose routine care was divergent from previously interviewed GP norms, we invited more GPs from that practice to

Table 1 A comparison of Australian and UK health systems and PSA testing context

	Australia	The UK
How is primary healthcare provided?	The Australian Medicare system is predominantly based around private practice and fee-for-service funding, that is, private practitioners in independent businesses are paid for each instance of service, mainly using public funds through the MBS, sometimes supplemented by patient copayments. Some GPs bulk bill, that is, GPs charge the Government (Medicare) directly for any medical service that their patient receives. In these practices, GPs receive the Medicare rebate (a fixed sum for each type of service) as payment, and patients pay nothing. There is considerable geographical variation in bulk billing practice depending on where the GP is based (less in more affluent areas and in rural, regional and remote areas,[10–12] where there is a greater shortage of doctors and healthcare services). There are standards but GPs are mostly free to set their own fees for consultations and procedures. Some charge substantially more than the value of the Medicare rebate. Australians can consult any GP they choose, including seeing multiple GPs in multiple practices.	The countries of the UK have centralised health systems—the NHS. General practices mostly operate as independent businesses managed by GPs delivering care under contract to the NHS and free to the patient at point of use. GPs receive some payment on a capitation basis (practices receive a fixed amount to manage a set of potential patients). There is virtually no fee for service element, but some of the money practices receive from the NHS is dependent on them supplying evidence that certain quality standards have been met (eg, that at least n% of people with a diagnosis of x have received intervention y). Almost all residents in the UK are registered to a GP practice near their usual home, and will consult GPs within that practice.
Are GPs advised to offer PSA testing?	RACGP advises its members not to raise the issue of PSA testing with patients, but if men ask, to fully inform them about the potential benefits, risks and uncertainties. USANZ advises for men at average risk of prostate cancer, who have been informed of the benefits and harms of testing and who decide to undergo regular testing for prostate cancer, offer PSA testing every 2 years from 50–69 years, and offer further investigation if total PSA is greater than 3.0 ng/mL.	Universal screening for prostate cancer is not recommended; however, PSA testing can be provided at patient request (UK National Screening Committee). EAU advises that informed men requesting an early diagnosis should be given a PSA test and undergo a DRE. A risk-adapted strategy might be considered based on the initial PSA level.
How should men be tested (if they choose to be tested)?	GPs advised to discuss the pros and cons of testing with eligible men. 2012 RACGP Red Book guidance advises GPs to perform PSA and DRE when a patient chooses screening, whereas Australian NHMRC guidelines do not recommend DRE for asymptomatic men in the primary care setting. USANZ suggests that GPs confident in performing DRE are still encouraged to do so.	GPs advised to discuss the pros and cons of testing with eligible men. DRE is not recommended as a screening test in asymptomatic men in the UK (NHS PCRMP). Men aged >50 years who request a PSA test can access the NHS PCRMP, an informed choice programme introduced by the Government in 2002 to ensure that men concerned about prostate cancer receive clear and balanced information. The PCRMP provides GPs with information to counsel any man who asks about PSA testing. It is an English initiative, but Wales, Scotland and Northern Ireland have adopted the same approach and use the same materials
Is the PSA test funded?	The Australian Government has subsidised PSA tests for men 50 years and over since 1989 through the MBS.[13]	PSA testing can be provided free on the NHS for men over 50 years on the condition they have made an 'informed choice' following a GP consultation.

DRE, digital rectal examination; EAU, European Association of Urology; GP, general practitioner; MBS, Medicare Benefits Schedule; NHMRC, National Health and Medical Research Council; NHS, National Health Service; NHS PCRMP, National Health Service Prostate Cancer Risk Management Programme; PSA, prostate-specific antigen (test); RACGP, Royal Australian College of General Practitioners; USANZ, Urological Society of Australia and New Zealand.

attempt to distinguish between personal and institutional influences on their practice.

We recruited 29 GPs throughout England (n=23), Scotland (n=5) and Wales (n=1) to explore PSA testing reasoning and practice in a jurisdiction with comparatively lower rates of prostate cancer screening than Australia. The initial sample of GPs responded to an invitation distributed by academic colleagues through professional networks. We then broadened the sample by advertising via email to members of the Royal College of General Practitioners (RCGP), primary healthcare departments, university academic departments and general practice and research mail lists. We also advertised via newsletter including the Society for Academic Primary Care and RCGP Scotland's eBulletin.

GPs were invited to contact KP if they were interested and willing to participate. An information sheet outlining the research project was emailed to all respondents. Participants were of varying ages, clinical experience, sex and patient populations: all GPs who expressed interest in participating were included. GPs were compensated for their time.

Interviews/data collection

We generated data via in-depth interviews. The semi-structured interview schedule covered a broad range of topics, including GPs' recent clinical encounters involving PSA testing decisions, communicating information about PSA testing to patients, screening pathways for PSA and overdiagnosis of prostate cancer. The schedule was modified between interviews based on the developing analysis to enrich the data available to answer our research questions. All GPs were asked to think back to their most recent consultation involving a discussion about PSA testing or to describe a typical consultation where the topic was raised. The aim of this approach was to open the discussion about, and provide context for, conversations about PSA testing and to use as a platform to guide prompts and to focus subsequent questions.

Interviews took place between March 2013 and June 2014 (Australian GPs) and between September and December 2014 (UK GPs). We continued to interview GPs until we judged we had reached theoretical saturation, that is, the point at which gathering more data ceases to yield any further insights about the emerging grounded theory. All interviews were conducted by KP, primarily by telephone or Skype, and ranged in duration from 18 to 70 min. All interviews were audio-recorded, and were transcribed verbatim.

Data coding and analysis

The analysis was led by KP, who coded the transcripts and wrote detailed memos which were reviewed and discussed by the authors in analysis meetings. A subset of transcripts was read and coded by three authors independently; this coding was compared and discussed to inform the development of the central concepts in the study. All concepts were derived directly from the data. Transcripts were not returned to participants for comment; all participants will receive a written summary of the research findings on study completion.

Role of the funding source

This study was funded by Australia's National Health and Medical Research Council (NHMRC) through a peer-reviewed competitive process. The funder had no role in the design, conduct or reporting of the study.

RESULTS

We identified notable differences in GPs' explanations of PSA testing in their individual practices, and within GPs' descriptions about the conditions of the respective health systems in Australia and the UK. One striking difference was that Australian GPs reported that they frequently spoke with asymptomatic men about being screened for prostate cancer, while UK GPs reported that they did this rarely. Another was that the process by which PSA testing occurred in each country appeared to be quite different. We explore below potential explanations for these differences.

How did UK and Australian GPs' descriptions of their practices differ?

Testing as an exception versus testing as routine

GPs' descriptions of a 'typical' consultation with a PSA-age man were very different in the two jurisdictions. Most GPs practising in the UK commented that PSA testing is quite uncommon and is certainly not considered routine practice. GPs said it would be 'rare' or 'unusual' for asymptomatic men to request PSA testing. UK GPs noted they may only receive a few PSA requests a year and some could not recall an example to refer to in the interview. The idea that a GP might introduce PSA testing as an issue for consideration for an otherwise healthy man was seen as strange; "*if they're coming in with other issues, then we wouldn't say, oh by the way, you don't want a PSA test, do you? That just wouldn't happen*" (GP1). UK GPs tended not to order the test unless specifically asked to do so, and some would "*work quite hard to talk [asymptomatic] people out of it*" (GP12).

In stark contrast, many Australian GPs talked about PSA testing as an everyday, usual part of consultations, and all reported that they commonly received requests for the test. Some said that on a typical day, they ordered several PSA tests for asymptomatic men. A significant proportion of the Australian GPs interviewed said that they might also raise PSA testing with a patient, unprompted. They reported that they would suggest testing because of a man's age, or raise it in the context of a health check. To quote one GP: "*people are used to sort of being screened…so we're tacking this onto the discussion basically*" (AGP21). Some GPs said their patients "*don't get a chance*" to initiate a discussion about PSA testing before the GP "*talks them into it there and then*" (AGP29).

How PSA testing occurred: immediate testing versus a cooling-off period with extra information

The main difference between UK and Australian GPs' descriptions of how PSA testing occurred was that for Australian men, a decision about testing, and the ordering of a PSA test, was likely to occur in the consultation in which it was first raised. In contrast UK GPs described a two-step process, with a 'cooling-off' period between discussion and testing (if testing occurred at all).

UK GPs consistently reported the use of written information leaflets (mostly from www.patient.co.uk). They would give these to men who asked about PSA testing to take away and read to help them decide whether they wanted to be tested. GPs said that verbal discussions within the consultations were relatively brief because of the comprehensiveness of this resource. GPs noted that having a built-in 'cooling-off period' effectively (1) demonstrates that PSA testing is not something to rush into, and (2) allows patients to absorb the information in the leaflet before making a decision. A number of GPs said that men decided not to have PSA testing after receiving the information, "*but whether that is because they've really understood the information or whether they've just picked up on the vibe, I couldn't really give you a good answer on that*" (GP15).

GPs in Australia did not commonly report providing written information to their patients; they predominantly described having a verbal discussion only. Some GPs described engaging men in quite a detailed explanation about PSA testing, while other GPs said their discussion was "*very, very brief*" (AGP14). One GP, for example, reported: '*I give them next to none [information]. I say 'Do you want to find out if you've got prostate cancer?*"' (AGP9). Sometimes there was no discussion prior to testing. Other GPs apparently tried—and said they would sometimes succeed—to counsel men out of having a PSA test, reporting, for example, that "*nine out of ten will choose not to have the test after appropriate explanation*" (AGP23). These examples illustrate the considerable diversity of practice in Australia compared with the relative consistency of practice in the UK.

What practice conditions did GPs report that might help explain differences in practice?

We explored GPs' descriptions of training, structures and availability of resources, which served as anchors for their use of PSA testing as a screening tool. We outlined the similarities and differences we observed in UK and Australian GPs' accounts of the conditions under which they practiced. Table 2 is a representation of the 'system': not just the health system but the broader social and funding structures, comprising several interacting components.

Figure 1 illustrates the direction in which the system factors presented in table 2 potentially influence prostate screening: towards more PSA testing or towards less PSA testing, and including those system factors with no reported impact on testing rates.

Here, we present three overarching themes we subsequently identified as underlying and likely contributing to the variation evident in the GP's accounts: (1) history of PSA testing policy, (2) healthcare structures and incentives and (3) GP's preferred source of knowledge.

The history of PSA testing policy in the two countries is an important distinguishing factor

A number of GPs in the UK reported the long-standing consistency of a central authoritative position discouraging prostate cancer screening. The policy could be summarised as 'don't raise it, and inform if asked'. From the mid-1990s all GPs in the UK were sent relatively easy-to-read summaries of the evidence together with written information to hand out to men who asked about the PSA test.[18] Dissemination of similar information has been used continuously since.

In contrast, in the Australian context, some GPs recalled the positive publicity that accompanied PSA testing when it was first introduced. Online documents indicate that, simultaneously, some Australian authorities actively encouraged and promoted PSA testing of asymptomatic men, while other official guidelines, released as early as 1995, recommended against prostate screening.[19 20] As shown in table 2, Australian GPs reported that the guideline environment is challenging to navigate, making it difficult for GPs to find consistent and centrally issued directive advice.

The early messaging to GPs seems to have had long-lasting implications. GPs in both countries commented on the tendency to continue practising in the manner in which they began. One UK GP explained, "*it's quite difficult to change your practice. I think if you're a GP who's never been doing the PSA test then it's easier for you to carry on not doing them*" (GP9). An Australian GP said,

> I guess we learn from our initial experiences and it's very hard to change your initial thoughts on a particular test. So my initial understanding was it's an amazing test, that it should be done, that it's very useful, that you're almost neglectful not to do it… the initial thing was PSA is useful and that has basically stuck in my head, that PSA testing is useful. (AGP1)

How healthcare structures and incentives drive practice

The clinicians' accounts clearly reflected the known differences in healthcare payment models between the two locations. In Australia, GPs are paid fee-for-service—a scheme dependent on the quantity of instances of patient care—thus more patients, procedures and appointments generate greater income for GPs. One GP commented on the implications of fee-for-service,

> If I went around having my 10 minute discussion with all my patients about why not to do PSA testing, I will make less money than [a GP] who does the 30 second—here Jack, that's a good idea, here, have the PSA test, we'll see you in a fortnight to check the result…one of the consequences of the current health system is that it feeds itself to making more diagnoses and being more busy, not less busy. (AGP23)

Table 2 Practice conditions reported by GPs that might explain differences in practice

	Situation in the UK	Situation in Australia	Differential effect on PSA testing
Prostate screening culture	Doctors screening healthy people, or healthy people demanding this, considered strange; *'it doesn't happen. People don't come in and say "they feel fine, they just want all their blood checks"…I don't think the NHS could really do that'* (GP21).	GPs report routinely offering (and encouraging) patients to have multiple tests, perhaps including PSA; healthy patients request health checks regularly. Some considered this 'normal' and/or 'responsible'.	'Screening culture' likely influences default screening practices; in Australia PSA has "*become a fairly entrenched part of the male [annual] health check up"* (AGP17).
GP training	UK GPs felt trained to avoid PSA testing, a 'really big topic' and 'classic case' in medical exams and training. "*The training that we received is … how you would have a discussion … when we're asked for [the test], and you almost felt like they were sort of trying to dissuade asymptomatic men from having it… that was definitely the sort of slant*" (GP16).	GPs in Australia did not comment much about their medical training and PSA testing; one GP who did said "*it's one of the areas where it's pretty much self-taught and you develop your own opinion*" (AGP4).	GPs in the UK are specifically trained how to advise asymptomatic men against screening, so seem likely to have more skills to do so, and to default to this practice.
Funding models	UK GPs spaced appointments to allow for appropriate care, because "*the expectation from the UK government as purchasers of the care would be that [men] be counselled around the limitations*" (GP15). They were acutely aware of "*a responsibility [for] spending the finite [NHS] resources*" (GP23). UK GPs and practices did not gain financially from test-ordering. Conversely: PSA testing "*just creates more work*" (GP6).	Some Australian GPs had systems to shorten consultations about PSA testing, for example, including PSA in routine bloodwork/'bucket testing', automatic recall so patients could be tested without seeing the GP. Some GPs blamed Australia's fee-for-service health system, which encouraged seeing (and testing) more patients:"*it feeds itself to making more diagnoses*" (AGP23).	The Australian fee-for-service funding model incentivises [over]servicing; the UK's NHS scarce resources model incentivises caution in creating burden on a limited system.
Guidelines	UK GPs saw NICE guideline (a clear policy directive) as authoritative, trustworthy, impartial advice against testing; the national guideline influenced practice. "*I think people are wary of practicing not in line with that and then they have potential then for criticism*" (GP3). The established norm is structured communication with men who ask about testing, using a written information resource.	GPs found Australia's competitive information environment about PSA testing hard to navigate: "*there's plenty of guidelines, but they're all different and there's nothing official…there's no hard and fast rule*" (AGP9). "*It's a very tricky area because…opinion is divided depending on who you talk to*" (AGP20). Many GPs did not use a guideline, citing patient demand, lack of time, unfamiliarity or a preference for their own judgement; some said RACGP guidance was an unclear 'cop-out'.	Having one authoritative guideline seems to encourage consistent practice. At the time of this study, such guidance did not exist in Australia, probably contributing to variation in PSA testing practice.[17]
Mass media and public profile	UK GPs reported that prostate cancer is sometimes in the news media but is "*certainly not something which is on the front page of newspapers everyday*" (GP8) and "*doesn't translate into a lot of men coming and asking*	Australian GPs said "*there has been a lot of media attention to PSA testing over the years*" (AGP15), a "*part of the big problem with the prostate cancer stuff*" (AGP23). Requests increased after media coverage;	Conflicting messages and promotion of PSA testing in Australia drives demand from patients; this is absent in the UK.

Continued

Table 2 Continued

	Situation in the UK	Situation in Australia	Differential effect on PSA testing
	for PSA tests" (GP1). Many said patients would only hear about PSA testing from their doctor.	'media-influenced' patients had preconceived ideas, assuming screening was widely endorsed if sanctioned on TV, "*so they see it as their right to have it*" (AGP15). "*Men know that it's available… so it's hard not to bring it up*" (AGP2).	
Practice protocols	All GPs within a single practice in the UK tended to test in a similar way: they "*practice as a group and with group support*" (GP20). This occurred via 'verbal agreement' rather than formal written protocols. Internal practice protocols sometimes permitted practice nurses to PSA-test asymptomatic men without GP involvement.	In the absence of Australian consensus guidelines, GPs developed their own testing protocol over years, "*I have built up my own idea of practice*" (AGP36). Practices need not have formal protocols as "*it is a judgement call at the moment*" (AGP39).	Presence or absence of protocols at practice level does not seem to explain differences between the two countries: both lacked protocols.
Method of screening	When UK GPs screened (rarely) they often did DRE before or instead of PSA. They thought DRE good or standard practice, and valued the information it provided: "*the two tests go together*" (GP14), "*it's a two-part process*" (GP23), "*doing a PSA alone is worse than doing nothing at all*" (GP7). UK urologists reportedly expect GPs to do DRE (although urologists will repeat it).	Australian GPs reported rarely doing DRE in asymptomatic men. Australian GPs were unsure they could detect abnormality via DRE.	In the UK, DRE was used prior to or instead of PSA, but was not recommended; conversely, until recently Australian guidelines recommended DRE with PSA but it was rarely done.
Referral systems for men with abnormal results	In the UK, referral pathways following particular test results are well defined: if PSA was abnormal, GPs would always refer to NHS urology to see the next available (possibly unnamed) consultant, entirely publicly funded. GPs' cancer referrals were audited and GPs made accountable for referrals.	After abnormal PSA test results, Australian GPs varied greatly in when, how and to whom they referred. In urban Australia, where there were more urologists, immediate referral after abnormal PSA was common; in rural Australia (fewer urologists) GPs managed abnormal PSA tests for months or years before referral. Australian urologists may be seen publicly or privately; private urology is a competitive marketplace.	Australia lacked a clear referral pathway for PSA testing, so decisions were made by individual GPs and patients, influenced by a business model of healthcare and a private health sector. In the UK, referral was streamlined and publicly funded.
Position taken by urology as a profession	UK GPs said urologists "*certainly do not push us to screen men who are otherwise well—if you asked any of them they'll probably say it's actively discouraged*" (GP1). (While not reported by these GPs, we know anecdotally and from the literature that some UK urologists have advocated PSA screening.) GPs described close communication and 'strong	Australian GPs said urologists "*encouraged PSAs to be done a lot more urgently*" (AGP37). Some GPs accepted this advice; others "*politely ignore [d] the advice from urologists in that respect. And from their organizations*" (AGP19), as "*they have made life very difficult because they're being very unfair on the evidence that's out there*" (AGP18). In rural areas, fly-in urologists ran monthly clinics, and influential seminars encouraging testing.	There was strong variation in GP perceptions and collaborations with urologists, within and between countries. Some Australian GPs were strongly sceptical of some urologists' position; UK GPs were less sceptical.

Continued

Table 2 Continued

	Situation in the UK	Situation in Australia	Differential effect on PSA testing
	links' with urology colleagues and "*total confidence in their department*" (GP14)	Some GPs thought these urologists had conflicted interests: "*they want a lot of work for themselves… unfortunately it has become an industry and they earn a living out of people's fear*" (AGP37).	
Perceived threat of not testing	UK GPs said medicolegal risk (which was not a common concern) hinged on quality of communication about PSA testing. They thought it highly unlikely a patient would complain about consent processes.	Many Australian GPs were concerned about medicolegal risk and felt obliged to at least discuss PSA testing with men. Active PSA testing could also maintain status and reputation as a 'good', thorough GP; "*I guess I do it because I want to practice good medicine…I want my patients to perceive that I practice good medicine…you do have to be seen to be proactive and do a quality job and quality job is screening*" (AGP1).	Australian GPs were much more concerned than UK GPs that PSA test-ordering had medicolegal implications, likely contributing to testing patterns.

DRE, digital rectal examination; AGP, Australian general practitioner; GP, general practitioner; NHS, National Health Service; PSA, prostate-specific antigen (test); RACGP, Royal Australian College of General Practitioners.

UK GPs reported that the focus of the UK capitation system is on quality of care rather than quantity of care. They described processes in place to support GPs to provide detailed evidence-based information to men who ask about prostate screening; "*What happens is you type it [PSA] in and because we have web-based patient data systems, they link…to the patient information stuff, so you tend to use what comes to hand very easily…and because it's online…it's as up to date as it can possibly be*" (GP28). Appointments about PSA testing in the UK are (or can be) a two-step process; a 'cooling-off period' is built into usual practice. A policy environment that encourages a two-step process serves to avoid overuse and to ensure decisions are well informed. The UK system looked to be built on an underlying assumption that men who know the facts about PSA testing are less likely to want it. UK GPs reported "*feeling quite supported over what we are doing*" (GP28) and seemed inclined to operate within the bounds of their health system, while Australian GPs often practiced according to individual standards.

In the UK, referral pathways following particular test results are well defined. GPs reported that the urology departments in their local hospitals had issued referral guidelines for GPs. These were often simplified versions of The National Institute for Health and Care Excellence (NICE) guidance and were seen as prescriptive: as one GP said, "*it's a very clear path, it's not a clinical decision*" (GP2). Most patients with abnormal PSA results in the UK are referred to a National Health Service (NHS) urology team and see the next available consultant initially on an unnamed basis. It is publicly funded (there are some private urologists, but they are a minority). These urologists therefore do not compete with one another for business to any great extent.

Urologists in Australia serve the public and private sectors: patients can be seen privately or as public outpatients, and private urology, in particular, is a competitive marketplace. The GPs who participated in this study often spoke of patients as consumers, who maintained substantial individual choice in healthcare decisions. Australian GPs reported selecting (with or without the patient) which individual, named urologist a patient will see. They described making this choice based on factors including the 'personalities' of the patient and urologist, and how 'interventionist' they perceived the urologist to be. The GPs varied greatly in when, how and to which specialist they referred abnormal PSA test results. Men could thus potentially receive very different care depending on their GPs approach to PSA testing and urology referral.

GPs appear to rely on different kinds of knowledge in determining their practice

Accountability, clear expectations set in central policy and support to apply best available evidence meant that UK GPs were equipped to practice in a relatively predictable and standardised way, including when directly asked about PSA testing by their patients. A number of GPs

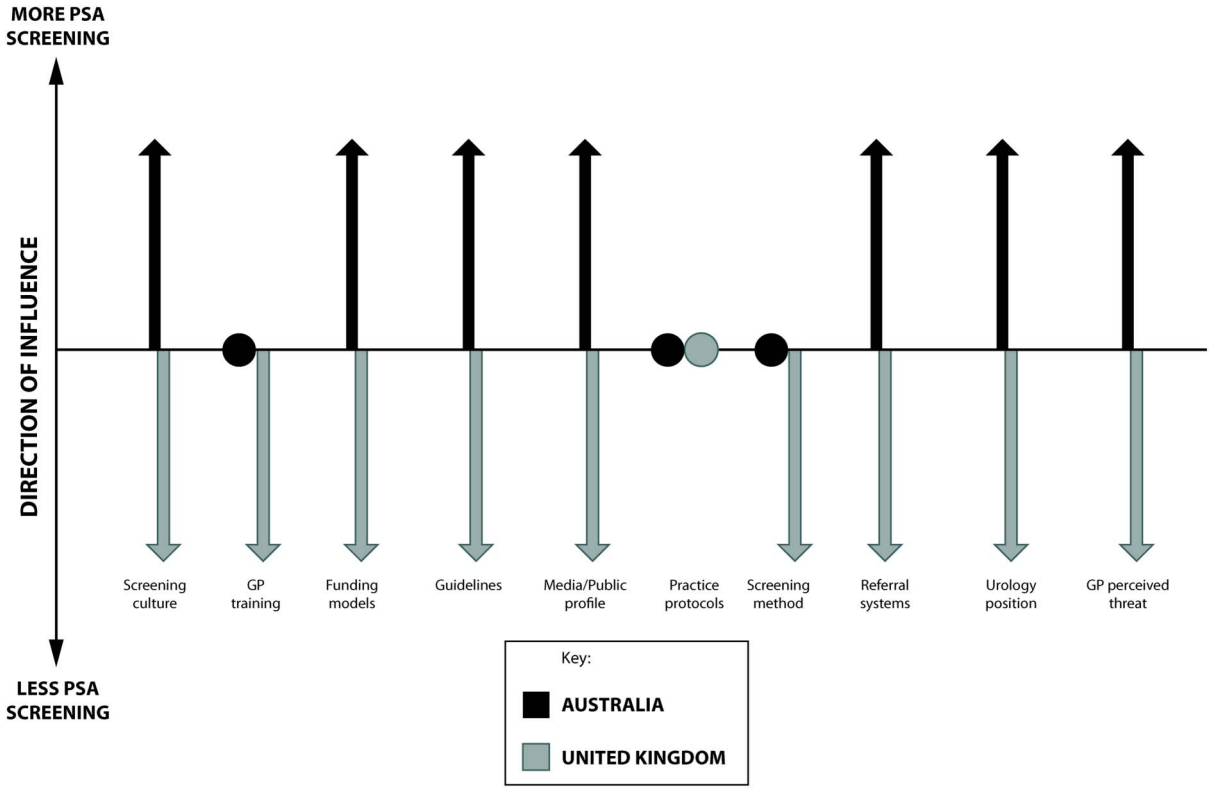


Figure 1 Direction in which system factors described in table 2 drive PSA testing in Australia (black) and the UK (grey). Upward arrows indicate drivers towards more PSA testing, downward arrows indicate drivers towards lower rates of PSA testing, circles indicate neutral factors with no reported impact. PSA, prostate-specific antigen.

from the UK commented throughout the interviews that they had never before reflected on why they approach consultations about PSA testing in the way that they described. They had never really had to grapple with what to do as in regular practice they could confidently follow the available authoritative, evidence-based guidance.

Many GPs in Australia also aimed to practice EBM by following a published guideline. However, there was a proportion who were more likely to practice according to a different idea of evidence: for whom the 'evidence' from their own experience or the experiences of colleagues was critically important in directing their approach to PSA testing. In the Australian context, ambiguity and contestability surround interpretations of the evidence,[21] and are accompanied by vague professional guidance. Some GPs described research-based directives as incompatible with their day-to-day practice and preferred to deal with what they described as routine cases using their own experience. We reflect on these issues further in the Discussion.

DISCUSSION

Australia and the UK draw on the same evidence base for prostate cancer screening. The PSA test is in principle available free to eligible men in both countries, and prostate cancer mortality is roughly equivalent. Yet, the rates of PSA testing for prostate cancer risk in the two countries are strikingly different. We identified fundamental differences in how PSA testing occurred and linked this to considerations of how testing was organised. Both countries have factors within their structural and organisational environments that seem to reinforce each other in influencing practice in a particular direction. This combination of multiple factors appears to explain the very different testing and incidence rates, serving mostly to drive more PSA testing in Australia and less PSA testing in the UK.

Australians have been shown empirically to have attitudes broadly in favour of cancer screening.[22] The Australian media has been shown empirically to deliver a generally pro-PSA-screening message.[23] These two combined seem likely to increase rather than limit patient demand for PSA testing, and thus to promote rather than retract a market for screening. A fee-for-service payment system allows Australian GPs significant scope to routinely offer PSA testing, and gives them a financial incentive to provide this service to fill the demands of the market. Mixed messages in the current Australian guidelines and some specialists publicly advocating for PSA testing do little to curtail use of the PSA test. In comparison, the medical training of GPs in the UK to avoid PSA testing, strong discouragement from the NHS, little patient demand, limited healthcare resources, and zero financial gains from screening for

GPs and public sector urologists were reflected in the GPs' explanations of low rates of testing in their respective practices.

What is being done in Australia to address divergent use of the PSA test?

The provision of and access to PSA testing in Australia is currently extremely heterogeneous, partly dependent on the reasoning and preferences of individual doctors. Newly released national evidence-based clinical guidelines aim to drive greater consistency in testing practices.[24] The consensus guidelines, which include an 'after the test' component, may prompt more evidence-based discussions and streamlined delivery of consistent information, and standardise referral pathways in Australia.

The authoritative consensus guidelines are a significant move in the right direction for 'smarter screening'[25] in Australia. An accompanying decision aid is being designed to provide an opportunity to make more informed decisions. Yet, the other drivers of screening remain in the Australian setting compared with the UK where PSA screening is discouraged at a system-wide level. The Australian guidance has focused attention primarily on prioritising individual choice. While the new NHMRC guidelines represent a first step in addressing inconsistencies in what GPs are advised to do, and will be a useful information resource to incorporate into evidence-based discussions; they may not suffice to address what is arguably the most important objective: to reduce unnecessary or harmful prostate screening. Although reducing PSA testing rates in Australia is not an explicitly agreed goal of the new NHMRC guidelines, the comparable death rates despite considerably less screening suggest it is likely that the lower rates of PSA testing under the UK system are preferable. In the following section, we suggest areas for consideration and evaluation (alongside the NHMRC guidelines), which may potentially decrease use of the PSA test for screening purposes in Australian primary care.

What can be done in Australia to improve screening practice?

By comparing Australia with the UK, we have identified features of the context in which screening options are offered that might not otherwise have been appreciated as significant in the Australian setting. Overall, Australian men have fewer practical barriers to undergoing a PSA test, alongside higher incentives for GPs to perform the test. We suggest that, if reducing the rate of PSA testing is a reasonable goal for Australian general practice, the following strategies (structural and organisational) may assist in achieving that goal.

Two-step consultations: Information provision that is separate from PSA testing availability via 'staggered' appointments, which incorporate a cooling-off period. Tambor *et al*[26] reported that when testing could be obtained conveniently as 'part of a battery of other tests' approach as used in the Australian context, uptake was considerably higher than when additional effort was required to have a test.

Incentivise informed shared decision-making (SDM), as the USA has introduced for lung cancer screening, for example.[27] UK GPs do not receive reimbursement specifically for engaging in SDM with patients; however, they are accountable for their screening activity and use of NHS resources. GPs in Australia may initially need financial encouragement to implement the NHMRC guidance (provide information rather than offering screening) if this is in contrast to their usual practice. Australia's fee-for-service GP payment system rewards activity in primary care, such as testing, rather than the giving of information to permit an informed choice about whether to test.

Fund PSA testing differently: In the USA, Medicare has considered imposing a penalty for physicians who perform 'non-recommended' prostate cancer screening with the PSA test as part of a federal effort towards value-based care.[28] Financial disincentives for GPs and men over time will potentially diminish harm caused by unnecessary screening (eg, of low-risk men or men with a limited life expectancy), as a financial barrier may result in more considered decisions on the part of men and their doctor. However, an ongoing and relevant counterargument is that doctors should not be rewarded for withholding a test that could help some men, nor restrict the options of men with limited financial means. Welch and others have suggested introducing a small cost to men for PSA testing.[29] Introducing a small cost for a PSA test with clearly communicated exceptions (eg, men with strong risk factors for prostate cancer) may be a reasonable option in Australia. There are plans in Australia to consider changes to the Medicare Benefits Schedule item number to align with the new PSA testing guidelines and only allow coverage for a PSA test every second year, rather than annually. However, the PSA test is currently in principle available free to men in Australia and the UK, suggesting cost may not be a key factor influencing more frequent testing in Australia. This would be a pertinent topic for further research.

Why might achieving a shift in GP practice be difficult?

Although the varied structural and organisational conditions in the respective healthcare systems of Australia and the UK seemed to explain much of the difference in GP accounts of their PSA testing practice—at the patient and consultation level—another layer to the decision-making environment was also evident. Gabbay and le May's theory of 'mindlines' is particularly relevant to our analysis. We hypothesise from our data that GPs from Australia and the UK are following different 'mindlines', shaped by their respective cultures, contexts and experiential knowledge.

We propose that UK GPs have internalised an organisationally embedded consistent mindline, based on the evidence-based recommendations from a trusted

authoritative voice. All GPs appeared to agree about what practice was appropriate, implementing a relatively similar version of evidence-based practice. There was less room to move in their individual interpretations of the evidence because the professional guidance was consistent and not contested—UK GPs were advised which evidence was appropriate, and provided with supporting materials to distribute to men. Funding arrangements also put explicit boundaries around what is considered acceptable practice. The mindline used by UK GPs seems to have developed during their training and was subsequently collectively shared and reinforced via reliable professional networks, including urologists. It was rarely challenged because of clear communication, a collective understanding of requirements and expectations, and limited exposure to men requesting prostate screening.

We suggest that, in contrast to the UK, GPs in Australia are accustomed to a noisy marketplace of conflicting advice, including from urologists. As a result, their mindlines appear to be more independently constructed based on individual experiences, and strongly influenced by contextual considerations. Like the UK GPs, the Australian GPs' mindlines were developed and reinforced via similar processes of experience, repetition and interactions, but these occurred within local circumstances and macro systems that looked very different to the UK situation. It is likely that Australian GPs' mindlines vary considerably from one GP to the next as they navigate and interpret the changeable conditions. Australian GPs described a broad spectrum of men regularly asking about PSA screening, each with very different expectations. So, while an individual Australian GP may have a relatively unified approach to PSA screening decisions and discussions, specific contexts and patient presentations could prompt temporary deviation from this mindline in favour of an alternative.

While producing guidelines (such as the NHMRC guideline) as a formal source of knowledge is essential, against a background of clinicians' diverse ingrained habits and history, guidelines are unlikely to be enough to alter established clinical practice in Australian GPs. Nonetheless, consistent guidelines provide a much needed foundation to build on. As Gabbay and le May conclude, practitioners have a collective responsibility to ensure their mindlines are based on research evidence wherever possible,[15] and the NHMRC guidelines provide a consensus regarding the appropriate evidence base. However, above all, our research has demonstrated the overwhelming influence of local contexts on clinical practice. GPs' established mindlines and rules of thumb appear to interact with the social and organisational context. If policy leaders want to promote practice consistent with the consensus guidelines, they are likely to need to work actively, alongside providing ongoing support for GPs, in directing how the NHMRC guidelines are received, implemented and used in practice. The process should prioritise establishing GPs' trust in the guidelines as a reliable source of information for supporting modified practice patterns among those whose practice is not aligned with the new recommendations. Our findings and Gabbay and le May's theory suggest that guideline dissemination might be best targeted through favoured sources of information, including influential GP and specialist colleagues—although conflicts of interest might make this challenging.

Future research might usefully explore the likelihood and feasibility of a cultural shift around PSA screening, examining men's and broader public enthusiasm to screen in Australia. Schwartz *et al*[30] found that the majority of American men they sampled would over-rule their physician's recommendations for less frequent or no screening. A closer look at urologists' 'mindlines' may also be relevant, as these appear to influence the mindlines of GPs.

Limitations

We interviewed a large number of highly informative participants (GPs) with diverse opinions and approaches; participation in the study was self-selecting. It is possible that physicians with particularly strong opinions about prostate cancer screening were more likely to volunteer.

CONCLUSION

Important drivers of prostate cancer screening are evident at a number of levels. PSA testing rates arise from more than individual GP attitudes towards screening: current and historical structures, systems and rules all play a significant role in creating the mindlines that GPs employ in their practice. It is likely that all of these influences will need to be addressed if these mindlines, and thus practice, are to change.

Twitter Follow Kristen Pickles @PicklesKristen, Vikki Entwistle @entwistlev, Stacy Carter @stacymcarter and Lucie Rychetnik @LucieRychetnik

Contributors All authors conceived the study and were involved in designing the study and developing the methods. SMC and LR obtained funding and are CIs on the NHMRC-funded project grant. KP conducted the interviews, had full access to all data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis. KP drafted the manuscript. All authors contributed to the interpretation of the analysis and critically revised the manuscript.

Funding The project was funded by NHMRC grant number 1023197. SC was supported by NHMRC Career Development Fellowship number 1032963 when this work was completed.

Disclaimer The funders had no role in the design or conduct of the study; in the collection, analysis, and interpretation of the data; or in the preparation or approval of the manuscript.

Competing interests All authors have completed the ICMJE uniform disclosure form at http://www.icmje.org/coi_disclosure.pdf and declare: SC was supported by NHMRC Career Development Fellowship number 1032963 when this work was completed; they have no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; they have no other relationships or activities that could appear to have influenced the submitted work.

Ethics approval All study procedures were approved by the Cancer Institute New South Wales and the University of Sydney Human Research Ethics Committee [#15245]. Each participant had an opportunity to discuss the study, and gave written consent prior to participation.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement No additional data are available.

Transparency KP affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted.

REFERENCES

1. Carter HB, Albertsen PC, Barry MJ, *et al*. Early detection of prostate cancer: AUA Guideline. *J Urol* 2013;190:419–26.
2. Mistry M, Parkin DM, Ahmad AS, *et al*. Cancer incidence in the United Kingdom: projections to the year 2030. *Br J Cancer* 2011;105:1795–803.
3. *Globocan 2012: estimated cancer incidence, mortality, and prevalence worldwide in 2012: International Agency for Research on Cancer*. World Health Organisation, 2012. http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx
4. Williams N, Hughes LJ, Turner EL, *et al*. Prostate-specific antigen testing rates remain low in UK general practice: a cross-sectional study in six English cities. *BJU Int* 2011;108:1402–8.
5. Moss S, Melia J, Sutton J, *et al*. Prostate-specific antigen testing rates and referral patterns from general practice data in England. *Int J Clin Pract* 2016;70:312–18.
6. Medicare Benefits Schedule Book Category 6: Australian Government Department of Health; 2014. Department of Human Services, Commonwealth of Australia. http://wiki.cancer.org.au/australia/Guidelines:PSA_Testing/Introduction#cite_note-Citation:Australian_Government_Department_of_Health_2014-16
7. Trevena JA, Rogers KD, Jorm LR, *et al*. Quantifying under-reporting of pathology tests in Medical Benefits Schedule claims data. *Aust Health Rev* 2013;37:649–53.
8. Holden CA, McLachlan RI, Pitts M, *et al*. Men in Australia Telephone Survey (MATeS): a national survey of the reproductive health and concerns of middle-aged and older Australian men. *Lancet* 2005;366:218–24.
9. Baade PD, Youlden DR, Coory MD, *et al*. Urban-rural differences in prostate cancer outcomes in Australia: what has changed. *Med J Aust* 2011;194:293–6.
10. Young AF, Dobson AJ. The decline in bulk-billing and increase in out-of-pocket costs for general practice consultations in rural areas of Australia, 1995–2001. *Med J of Aust* 2003;178:122–6.
11. De Abreu Lourenco R, Kenny P, *et al*. Factors affecting general practitioner charges and Medicare bulk-billing: results of a survey of Australians. *Med J Aust* 2015;202:87–90.
12. Jones G, Savage E, Hall J. Pricing of general practice in Australia: some recent proposals to reform Medicare. *J Health Serv Res Policy* 2004;9(Suppl 2):63–8.
13. Weber MF, Cunich M, Smith DP, *et al*. Sociodemographic and health-related predictors of self-reported mammogram, faecal occult blood test and prostate specific antigen test use in a large Australian study. *BMC Public Health* 2013;13:429.
14. Gabbay J, le May A. *Practice-based evidence for healthcare: clinical mindlines*. Abingdon, Oxon: Routledge, 2011.
15. Gabbay J, le May A. Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. *BMJ* 2004;329:1013.
16. Bryant A, Charmaz K. *The Sage handbook of grounded theory*. Sage, 2007.
17. Pickles K, Carter SM, Rychetnik L. Doctors' approaches to PSA testing and overdiagnosis in primary healthcare: a qualitative study. *BMJ Open* 2015;5:e006367.
18. Entwistle VA, Watt IS, Davis H, *et al*. Developing information materials to present the findings of technology assessments to consumers: the experience of the NHS Centre for Reviews and Dissemination. *Int J Technol Assess Health Care* 1998;14:47–70.
19. Prostate cancer screening: summary of the review prepared by the Australian Health Technology Advisory Committee. Canberra: Department of Health and Community Services; 1996.
20. Australian Cancer Society. Prostate cancer screening: guidelines for health professionals. *Cancer Forum* 1995;19:47–50.
21. Pickles K, Carter SM, Rychetnik L, *et al*. General practitioners' experiences of, and responses to, uncertainty in prostate cancer screening: insights from a qualitative study. *PLoS ONE* 2016;11:e0153299.
22. Livingston P, Wakefield M, Elwood JM. Community attitudes towards the early detection of cancer in Victoria, Australia. *Aust N Z J Public Health* 2007;31:26–9.
23. MacKenzie R, Chapman S, Barratt A, *et al*. "The news is [not] all good": misrepresentations and inaccuracies in Australian news media reports on prostate cancer screening. *Med J Aust* 2007;187:507–10.
24. Clinical practice guidelines PSA testing and early management of test-detected prostate cancer. Sydney: Cancer Council Australia 2016. Prostate Cancer Foundation of Australia and Cancer Council Australia PSA Testing Guidelines Expert Advisory Panel. Clinical practice guidelines PSA Testing and Early Management of Test-Detected Prostate Cancer. Sydney: Cancer Council Australia. http://wiki.cancer.org.au/australiawiki/index.php?oldid=122816 (accessed 24 Nov 2016).
25. Gulati R, Gore JL, Etzioni R. Comparative effectiveness of alternative prostate-specific antigen-based prostate cancer screening strategies. *Ann Intern Med* 2013;158:145–53.
26. Tambor ES, Bernhardt BA, Chase GA, *et al*. Offering cystic fibrosis carrier screening to an HMO population: factors associated with utilization. *Am J Hum Genet* 1994;55:626–37.
27. *Decision memo for screening for lung cancer with low dose computed tomography (LDCT)*. Centers for Medicare & Medicaid Services. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274
28. Beck M. Doctors could be penalized for ordering prostate tests: *The Wall Street Journal*, 2015. http://www.wsj.com/article_email/doctors-could-be-penalized-for-ordering-prostate-tests-1447993920-lMyQjAxMTE1MzI3MDkyNDA1Wj
29. Welch HA, Peter C. Why doctors shouldn't be punished for giving prostate tests: *The New York Times*; 7 January 2016. http://www.nytimes.com/2016/01/07/opinion/why-doctors-shouldnt-be-punished-for-giving-prostate-tests.html?_r=2
30. Schwartz LM, Woloshin S, Fowler FJ Jr, *et al*. Enthusiasm for cancer screening in the United States. *JAMA* 2004;291:71–8.

CHAPTER SIX.

Primary goals, information-giving and men's understanding:

A qualitative study of Australian and UK doctors' varied communication about PSA screening

6. Overview of this chapter

Communicating with men about the complexities of PSA screening is a challenging task for clinicians. Current international clinical guidance unanimously supports the concept of patient-informed decision making.

In light of our prior findings on practice variation between the Australian and UK contexts, we set out in this study to better understand GP communication practices in particular. In this paper we report on an empirical analysis of how GPs in the two locations describe their communication with men about prostate cancer screening (Research Question 1.2), reasons given for communicating with men as they do (Research Question 2.4), and the consequences of varied communication approaches (Research Question 3). It became apparent throughout the data collection process that GPs communicated with men about prostate screening in vastly different ways, and in some cases, not at all.

6.1 Publication details

Pickles, K, Carter SM, Rychetnik L, McCaffery K, Entwistle VA (2017). Primary goals, information-giving and men's understanding: A qualitative study of Australian and UK doctors' varied communication about PSA screening. *BMJ Open, in press.*

6.2 Authors' contributions

All authors conceived the study and were involved in designing the study and developing the methods. SC & LR obtained funding and are CIs on the NHMRC funded project grant. KP conducted the interviews, had full access to all data in the study, and takes responsibility for the integrity of the data and the accuracy of the data analysis. KP drafted the manuscript. All authors contributed to the interpretation of the analysis and critically revised the manuscript.

6.3 Abstract

In this grounded theory study we interviewed 69 general practitioners consulting in primary care practices in Australia and the United Kingdom. We present an analysis of how GPs explain their approach to communication with men about prostate cancer screening. GP approaches varied according to their goals for communication and specific practice situations. The reported consistency of PSA communication practices in the UK contrasted strongly with the significant variation reported in the Australian context. This analysis distinguished GPs' primary communication goals as a central component of consultations about PSA screening, which influenced their information provision and the depth of patient understanding GPs sought to develop. Situational and relational factors were particularly important in the communication process for Australian GPs. We consider the significance of context and its influence on communication practice.

6.4 Manuscript

The version of the manuscript that is in press at BMJ Open follows.

Primary goals, information-giving and men's understanding: A qualitative study of Australian and UK doctors' varied communication about PSA screening

Abstract

Objectives:

1. To characterise variation in general practitioners' (GPs') accounts of communicating with men about prostate cancer screening using the PSA test;
2. To characterise GPs' reasons for communicating as they do; and
3. To explain why and under what conditions GP communication approaches vary.

Study design and setting: A grounded theory study. We interviewed 69 GPs consulting in primary care practices in Australia (n=40) and the United Kingdom (n=29).

Results: GPs' explained their communication practices in relation to their primary goals. In Australia, three different communication goals were reported: to encourage asymptomatic men to either have a PSA test, or not test, or alternatively, to support men to make their own decision. As well as having different primary goals, GPs aimed to provide different information (from comprehensive to strongly filtered) and to support men to develop different kinds of understanding, from epidemiological to 'gist' understanding. Taking into account these three dimensions (goals, information, understanding), and building on Entwistle et al.'s (2008) Consider an Offer framework, we derived four overarching approaches to communication: *Be screened, Do not be screened, Analyse and choose,* and *As you wish.* We also describe ways in which situational and relational factors influenced GPs' preferred communication approach.

Conclusion: GPs' reported approach to communicating about prostate cancer screening varies according to three dimensions—their primary goal, information provision preference, and understanding sought—and in response to specific practice situations. If GP communication about PSA screening is to become more standardised in Australia, it is likely that each of these dimensions will require attention in policy and practice support interventions.

Introduction

Worldwide, many men undergo regular prostate-specific antigen (PSA) screening for prostate cancer risk in primary care. We will use *PSA screening* to refer to PSA testing in ostensibly healthy men who are not considered to be at high risk of prostate cancer for their age; this contrasts with PSA testing in men who have a diagnosis of prostate cancer or are experiencing acute symptoms that may suggest prostate disease. Although the value of the PSA test as a screening tool is scientifically contentious, the public perception of prostate screening is reportedly positive, including an inflated sense of the benefits and underestimation of the harms (1). Access to a PSA test is often via General Practitioners (GPs). The large number of men screened in some countries, and the extent of public misperception and scientific contention, make the communication between men and their GPs about prostate cancer screening especially important.

Communicating about screening is difficult. In-depth discussions about cancer screening can be complex, and may involve multiple statistical concepts, such as test sensitivity and specificity, and absolute and relative risk reduction figures from trial-based evidence. Chan et al. identified over 20 specific informational items that experts and patients identified for inclusion in an 'ideal' discussion about prostate screening (2). The authors synthesised the items into a core set of key facts that clinicians should provide about PSA screening to their patients (Figure 1, developed by KP), however we note that even some of these items are contentious or inconsistent with the various national guidelines that we will discuss in the next section.

Figure 1. Proposed content for informed consent for PSA screening (Chan et al., 1998, figure developed by KP)

Basic minimum

1. False positive PSA test results can occur.
2. False negative PSA test results and false negative biopsies of the prostate can occur.
3. Nobody knows whether regular PSA screening will reduce the number of deaths from prostate cancer.

Conversation

1. The PSA test is a blood test for prostate cancer.
2. Done together, the digital rectal examination and the PSA test can screen for prostate cancer.
3. The PSA screening test can detect prostate cancer sooner than the digital rectal examination alone.
4. An elevated PSA test result may lead to other tests to see whether prostate cancer is present.
5. The risk of getting prostate cancer is higher in a man who is older, has a family history of prostate cancer, or is African American.
6. Prostate cancer may grow slowly and not cause any symptoms. That is why prostate cancer may not kill older men. They may outlive this cancer and die from something else.
7. A man over age 70 is less likely to die from prostate cancer even though he is at higher risk to have it.

Brochure

1. The PSA screening test is controversial.
2. There are advantages and disadvantages to taking the PSA test. One disadvantage is that a man could end up worrying about what an elevated PSA test result means.
3. Done together, the PSA and DRE are most appropriate for men who have more than 10 years left to live.
4. A man with early prostate cancer can choose watchful waiting, radical prostatectomy, or radiation therapy.
5. There are side effects from prostate cancer treatment such as impotence, incontinence, narrowing of the urethra (strictures), trouble urinating, and rectal scarring.
6. Nobody knows whether treating prostate cancer early is helpful or whether one treatment is better than another.

Proposed communication standards for PSA screening discussions are reportedly challenging to implement in clinical practice e.g. (3-5). PSA tests are often ordered in the absence of any discussion; in the US, men report being unaware of being screened (6), not being asked for their screening preferences, and undergoing PSA testing without first discussing it with their doctor (7). Clinicians report offering screening without prior counselling (8). A survey of US physicians reported 20% acknowledged ordering PSA without telling patients (9). This can be for various reasons (10). Volk et al. surveyed US physicians and found that those physicians who reported ordering PSA tests without discussion were more likely to believe that patients wanted to be screened and that education is not needed. This was in contrast to those physicians who engaged patients in pre-screening discussion because they believed patients should know about the lack of evidence supporting screening (11). Physician beliefs about the limitations of the scientific evidence for PSA screening, the questionable utility of the PSA test, and ethical concerns regarding patient autonomy have also been identified as influencing the likelihood of discussions in US studies (10, 12). Physician beliefs can shape the content

of discussions; in a UK study, the strong personal views of clinicians against the value of PSA screening were reportedly clearly portrayed in their presentation of information about prostate cancer screening (13).

In addition to this work on physician knowledge, values and attitudes, some researchers have studied patient and practice factors that may facilitate or preclude discussions about prostate cancer screening. For example, in one study US physicians were less likely to discuss screening if a patient had already made a decision about screening, or was perceived to have limited ability to understand the information (10). Other studies have reported on factors affecting the quality of discussions, including a lack of time and the complexity of the topic (9).

Clinicians have cited clinical guidelines and scientific evidence about prostate cancer screening as factors guiding their practice e.g. (13). However this professional guidance varies widely, which may partly explain the observed variation in practice. Table 1 outlines the recommendations of key professional organisations in relation to communicating about prostate cancer screening, illustrating the main points of difference. “Informing” men about the benefits and harms of PSA screening is universally recommended; and use of decision support tools is recommended by half of the professional organisations. Only four of the ten guidelines advise whether GPs should raise the topic of PSA screening with men who do not ask about it in routine consultations. Medico-legal issues are referred to in only one, Australian, guideline. In practice, clinical guidelines may not always help GPs to decide how and what to communicate about PSA screening (14).

Table 1. The recommendations of professional organisations in terms of communicating about prostate screening

Items included in recommendation and guidance	Professional Organisation									
	PCFA/CCA[1]	**NHMRC[2]**	**RACGP[3]**	**USANZ[4]**	**NICE[5]**	**NHS/PHE[6]**	**USPSTF[7]**	**ACS[8]**	**NCI[9]**	**AUA[10]**
Is GP advised about whether to raise the topic with men if men do not raise it first?			✓		✓	✓	✓			
Is a decision aid recommended?	✓	✓	✓		✓					✓
Is a decision aid provided?						✓				✓
Is IDM[a] recommended?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Is SDM[b] recommended?			✓		✓		✓			✓
Is guideline accompanied by a clinician information sheet?[c]	✓	✓				✓	✓			
Is guideline accompanied by a patient information sheet?[d]		✓	✓		✓	✓				
Does guideline recommend clinician to share their own PSA screening decision?							✓			
Consider medico-legal responsibilities?			✓							

[1] PCFA/CCA: Prostate Cancer Foundation of Australia/Cancer Council Australia
[2] NHMRC: National Health and Medical Research Council
[3] RACGP: Royal Australian College of General Practitioners
[4] USANZ: Urological Society of Australia and New Zealand
[5] NICE: The National Institute for Health and Care Excellence
[6] NHS/PHE: National Health Service/Public Health England
[7] USPSTF: United States Preventive Services Task Force
[8] ACS: American Cancer Society
[9] NCI: National Cancer Institute of the National Institutes of Health
[10] AUA: American Urological Association

a. Informed Decision Making (IDM): The patient is presented with all the information pertinent to making a decision and then assumes final authority for the decision (30).
b. Shared Decision Making (SDM): The patient is provided with all the relevant information and works with the health care provider to reach a decision that reflects the health preference of the patient (30).
c. A clinician information sheet is a fact sheet summarizing the evidence of benefits, limitations, and associated risks of prostate screening to help clinicians to accurately inform men.
d. A patient information sheet is a fact sheet outlining the benefits, limitations, and associated risks of having a PSA test for prostate cancer risk.

Entwistle et al. characterised the two main ways that health care organisations communicate with the public about screening – *Be screened* and *Analyse and choose* – and proposed an alternative approach to communicating about screening, which they termed *Consider an offer* (15). The *Consider an offer* approach suggests health care providers should support people to assess an offer for screening, with a recognition that people may reasonably decline such offers. *Consider an offer* guides clinicians and patients to consider the source of screening recommendations and professional guidance. We return to the *Consider an offer* approach in the Discussion.

This study draws on a larger body of work investigating clinician's approaches to, and reasoning about, PSA screening in Australian and UK general practice. Despite similar levels of prostate cancer mortality, both PSA screening and prostate cancer incidence are lower in the UK than in Australia (16-19). Previous analyses from this study have illuminated systemic variation between the two jurisdictions, including in payment models, the history of PSA screening policy, screening culture, and referral patterns (14). The authors have also published earlier findings from the empirical work about how clinicians manage the potential for overdiagnosis (20) and their responses to uncertainty in relation to prostate screening (21). Table 2 summarises our previous findings regarding differences in PSA screening in the two jurisdictions. Note that prostate cancer screening is not recommended in either location.

Table 2. The organisation and occurrence of PSA screening in Australia and the United Kingdom
[Summary of findings, details reported in Pickles et al 2016]

	Australia	United Kingdom
For men asking about prostate screening	• PSA screening is available. GPs are advised to offer evidence-based decisional support to men considering whether or not to have a PSA test, including the opportunity to discuss the benefits and harms of PSA screening before making the decision.	• PSA screening is available, but with conditions. The National Health Service Prostate Cancer Risk Management Programme (PCRMP) has recommended that screening for prostate cancer be available for asymptomatic men, on the understanding that they have been provided with full and balanced information about the advantages and limitations of the PSA test.
Screening frequency	• GPs reported frequently providing PSA screening within routine consultations. • GPs reported often initiating discussion of PSA screening; GPs reported commonly receiving requests for PSA screening.	• GPs reported that PSA screening was rare in practice. • UK GPs reported not promoting PSA screening; they also reported that men rarely asked for PSA screening.
Guidance for GPs	• GPs are free to practice according to individual standards. • Australian guidance was mixed (see Table 1). The NHMRC has recently issued guidance to Australian GPs to drive greater consistency in practice.	• Government-issued standards for PSA screening and communication processes in clinical settings are in place. • Guidance has been distributed to all GPs in England and Wales to assist in the provision of information to men. • GPs can choose to follow issued guidance but seem inclined to operate within the bounds of their health system.
Preferred form of information provision	• GPs reported generally informing men via a verbal discussion of PSA screening.	• GPs reported relying on a standardized printed information leaflet. This was central to the consultation, sometimes alongside a brief verbal discussion.
Appointment structure	• PSA screening tests were usually discussed and ordered in a single appointment.	• Information-giving occurred in a separate appointment to PSA screening itself.

In the light of our prior findings on variation between the Australian and UK contexts, we set out to better understand GP communication practices in particular. The larger program of study examined the role of values, ethics, context, and evidence in cancer screening policy and practice. In this paper we present an analysis of how GPs in Australia and the United Kingdom explain their approach to communication with men about prostate cancer screening. We asked the following research questions, in respect of both settings:

1. How do GPs describe their communication with men about prostate cancer screening?
2. What are the reasons given by GPs for communicating with men as they do?
3. Why and under what conditions do GPs communication approaches vary?

Methods

Ethics approval

Study procedures were approved by the Cancer Institute New South Wales and the University of Sydney Human Research Ethics Committee [#15245]. GPs had an opportunity to discuss the study with KP prior to participation; all GPs provided informed written consent to participate and were compensated for their time. Participation was voluntary, participants could withdraw at any time, and confidentiality was protected. All responses were anonymised before analysis and potentially identifying information removed.

Design

We applied the well-established, systematic qualitative research methodology of grounded theory (22). Grounded theory is a method of conducting qualitative research that focuses on creating conceptual frameworks or theories through building inductive analysis from the data. All study authors have been formally trained in qualitative research methods; SC has particular expertise in grounded theory methodology.

Participants and Setting

We identified clinicians working in primary care practices as being in the best position to provide insight on our research questions, and most likely to face the question of PSA screening as part of their everyday practice. We purposively recruited a sample of GPs first in the Australian health care setting, and later in the United Kingdom (England, Scotland, and Wales), as our study evolved. Sampling for the broader study was initially driven by existing quantitative evidence on characteristics of GPs, patients, and practice contexts associated with higher or lower PSA screening rates. We aimed to recruit a set of GPs likely to have diverse practices. See Pickles et al. (14) for a detailed description of the recruitment process.

In Australia we advertised in newsletters and email lists of GP organisations, in mass and social media, medical journals, we phoned practice managers and via email and flyers distributed by rural GP

organisations. In the UK, academic colleagues distributed an invitation through their professional networks, we advertised to members of the Royal College of General Practitioners (RCGP), primary health care departments, university academic departments, and general practice and research via mail lists, and in organisational newsletters including the Society for Academic Primary Care (SAPC) and RCGP Scotland's eBulletin. GPs were invited to contact KP if they were interested and willing to participate. An information sheet outlining the research project was emailed to all respondents. All GPs who expressed interest in participating were included.

Overall, 69 GPs participated in this study, 40 GPs in Australia and 29 GPs in the UK. 44/69 of the GPs were male. The GPs ranged in clinical experience, working from 1-40 years in general practice, and were located in both metropolitan (n=32/69) and regional/rural (n=37/69) clinics, with varied patient populations.

Data collection

The field work for the prostate cancer element of this study was conducted by KP, a public health researcher, as part of a PhD degree. KP had no immediate personal or professional experience with prostate cancer or PSA screening.

We generated data via in-depth semi-structured interviews. An interview guide was prepared to provide general direction and an overview of potential question routes. The interview guide covered a broad range of topics, including GPs' recent clinical encounters involving PSA screening decisions, communicating information about the PSA test to patients; screening pathways; and overdiagnosis of prostate cancer. Example questions asked about communication included:

- Describe a recent consultation with an asymptomatic man involving the PSA test…Can you take me right back to the beginning and tell me as much as you can about the consultation. Who initiated the conversation about the PSA test?
- Should men be informed about overdiagnosis, false positives before having a PSA test?
- How well do you think men understand PSA screening?

The schedule was reviewed and modified between interviews based on the developing analysis to enrich the data available to answer our research questions. All GPs were asked to think back to their most recent consultation involving a discussion about PSA screening or to describe a typical consultation where the topic was raised.

Interviews took place between March 2013 and June 2014 (Australian GPs) and between September and December 2014 (UK GPs). We continued to interview GPs until we judged we had reached theoretical saturation; that is, the point at which gathering more data ceases to yield any further insights about the emerging grounded theory. All interviews were conducted by KP, primarily by telephone or Skype, and ranged in duration from 18 to 70 minutes. With GP permission, the interviews were audio-recorded and transcribed verbatim by a professional transcribing service to produce data for analysis. Transcripts were not returned to participants for comment; all participants will receive a written summary of the research findings on study completion.

Data coding and analysis

The analysis was led by KP, who coded the transcripts. A subset of transcripts was read and coded by three authors independently to ensure interpretive rigor. We coded to capture the range of variation in the GP-reported discussions about PSA screening and for conditions that could explain that variation. Codes were kept as similar to the data as possible to preserve context and to ensure that all concepts derived directly from the data. Codes were compared and discussed to inform the development of the central concepts in the study. KP wrote detailed memos during data collection and analysis which were reviewed and discussed by the authors in analysis meetings.

Results

We observed considerable diversity in the ways that GPs' described their communication about prostate cancer screening. Although the majority of variation occurred among Australian GPs, we also report on data from the UK because this helps illuminate the contrasting complexity of the Australian data, including the role of local context.

We first explain how Australian GPs varied in their descriptions of their communication. In the second section, we consider important ways in which UK and Australian GPs were similar and different.

Australian GPs' accounts of communicating with men about prostate cancer screening

Australian GPs' accounts varied greatly in how they introduced conversations about PSA screening with men, how screening discussions were framed, and their perceived informational obligations.

Screening men with little or no prior communication

A minority of interviewees reported ordering PSA tests for asymptomatic men with little or no prior communication with the patient. GPs were categorised as non-communicative if they reported (1) ordering PSA tests without explaining that to their patient, (2) ordering PSA tests at patient request with no further discussion, or (3) explaining PSA screening only after a positive PSA test result. We encountered occasional practices from which asymptomatic men were mailed pathology forms for a PSA test via practice recall systems, bypassing a GP consultation and opportunity for discussion.

Several possible justifications were provided by non-communicative GPs:

- Some GPs reasoned that because the information about PSA screening was 'confusing' 'complicated' and potentially contradictory, it should not be provided.
- Some GPs said their role was to ensure that men could be screened if they wanted, *'I see doctors purely as enablers, of what people want…If you don't want to read about it [the test], then fine; I'll just order one for you'* (AGP17).
- Some GPs considered it *'up to each patient to be informed appropriately'* (AGP14); if a man requested a PSA they would order a test assuming that man felt sufficiently informed from other sources.
- Some GPs considered it unnecessary to provide information unless the man received a cancer diagnosis, *'I don't think they need all that information at the level of PSA testing. I think, that once you've got your cancer diagnosis, you can talk about what you want to do with that then'* (AGP26).
- Some GPs did not appear to have a complete understanding of the epidemiological data, for

example, *'someone was saying that a certain number of people had to have radiation and surgery and have impotence and incontinence, for one person's life to be saved. I mean – I don't know how you get those figures'* (AGP2).

These were, however, minority views. We focus in what follows on the majority of GPs who *did* communicate with men in some way about PSA screening.

Communicating with men, with variation on three key dimensions

We identified three dimensions central to GP discussions with men about PSA screening:

1. The GP's primary communication goal. Some GPs had the goal of convincing the patient to screen, some had the goal of convincing the patient not to screen, and some had the goal of supporting decisions or facilitating patient choice;
2. The type of information the GP provided; and
3. The type of patient understanding the GP sought to achieve.

It appeared that Dimension 1 was dominant; GPs communicated in accordance with their preferred goal or outcome of the communication. In most cases, the GP's positioning on dimensions 2 and 3 was grounded in whether the GP felt strongly that patients should be screened or not, and the degree to which they directed men towards that preference. Below we explain these three dimensions, and GPs' reasoning about them.

<u>Dimension 1. GP's primary communication goal</u>

Some GPs aimed to convince men either to agree to be screened, or to agree not to be screened. These GPs had strong beliefs regarding whether or not PSA screening should occur routinely, and wanted patients to follow their advice, their '*guide…down the path'* towards what they *'thought was best'* (AGP29). GPs acknowledged '*bias will creep into that'* (AGP29); *'you can't help yourself but…what you believe in is the way you push the consultation'* (AGP18). However this approach was justified by beliefs that, '*…you can only do what you think is best for the patient'* (AGP29) and *'a lot of people do want to be told what to do…doctors are their reference point'* (AGP31). GPs recognised that men sometimes chose not to take the

advised pathway, for example, '*there are times when it wouldn't matter what you said to a patient they're still determined to have the test'* (AGP18).

An alternative communication goal was to support men to make decisions about screening consistent with their own values and preferences. GPs with this goal aimed to facilitate an informed decision making process and were determined to provide information to all men *'to make up their own mind'* (AGP16), because *'with the PSA test, I can't so easily say to myself, well, it's in your best interests so I don't need to inform you properly'* (UKGP9). GPs with this goal reasoned that a man *'should be empowered to know everything'* (UKGP28); *'should have the right and want to be able to make that decision for themselves about whether they have the test or not'* (AGP5).

Dimension 2. GPs' reported information provision

Because GPs had different goals in communicating, they provided different information, in both quality and quantity.

Some GPs claimed to provide men with 'complete' and 'unbiased' information, because they considered it their 'ethical obligation' as a health professional to do so; the patient, in this view, had a 'right' to be fully informed, so GPs should *'[put] all the information on the table'* (AGP31); *'I'm very keen that people are well-informed about really what it means if they are to undertake a PSA rather than just simply agreeing to what their idea might be'* (UKGP23). This sometimes extended to teaching patients how to locate and interpret information for themselves. Informing patients was described by some GPs as serving a self-protective legal purpose, *'I've informed the patient, the patient made his own decision, so he's got to then accept the consequences'* (AGP19).

In contrast to GPs who sought to provide comprehensive information, other GPs filtered information to '*actually tell them [patients] what counts the most'* (AGP4). Here GPs aimed to explain their own best judgment about the evidence, framing the evidence according to the GP's opinion regarding the value of PSA screening. This often took the shape of a personal recommendation either to have a PSA test or not. One GP, for example, said *'[patients] don't have that knowledge so you sort of, give an explanation why it needs to be done'* (AGP35); another, in contrast, thought *'my discussing it has probably been*

biased towards not getting it done' (AGP16). Some GPs considered such advising to be best practice, because information provision alone was not enough to help men decide what to do. For example, one GP who favoured PSA screening reasoned, '*If they really don't know what to do then [after receiving information], any doctor would be a fool not to say look, get it investigated because, the most stupid thing anyone could do is say oh don't bother about it…that's just a total recipe for disaster'* (AGP31).

Dimension 3. GPs' reported ambitions for men's understanding

All GPs aimed to support the development of patient understanding. However there were two different conceptions of what constituted appropriate understanding of the information presented and available options:

1) Sometimes GPs aimed to assist men to develop detailed *population-level understanding* of the evidence. They wanted men to understand all aspects of the information provided and described checking understanding, identifying gaps in patient knowledge, and clarifying misunderstandings, because *'I don't think their pre-existing understanding of the test is very good at all in most cases*' (UKGP21). Some of these GPs reported feeling personally and professionally responsible for presenting the 'right amount' and 'right level' of information for individual patients, *'[achieving understanding is] really the doctor's job, and our skill in trying to explain all that complicated evidence, as best as we can'* (AGP19). Some GPs commented they hoped men understood the detail of the evidence, otherwise it indicated they as a GP had done a *'bad job of explaining it'* (AGP6), however they also explained *'it's a very difficult thing to formally confirm that they understand the implications of having the test done without kind of interrogating them'* (UKGP1).

2) Alternatively, GPs might aim for men to develop overall *'gist' understanding*. GPs committed to 'gist' understanding were satisfied if their patient had a less complete grasp on the intricacies of the evidence base, as long as they had an overall understanding of what the GP perceived to be core issues; *'I feel like as long as they can understand that basic concept [in this instance, that PSA is not a perfect test] …then I feel like it's okay to still do the testing, even if they don't understand all the detail…I feel like that's a reasonable level of understanding, I don't feel like people need to have an absolutely thorough*

kind of understanding' (AGP5). Those GPs who thought 'gist' understanding was acceptable thought it was reasonable for men to trust their doctor to advise them appropriately.

Relationship between the dimensions

When taking account of the three dimensions along which GPs varied, we identified four overarching approaches to communication: (1 & 2) *Be Screened* and *Do not be screened* (GPs who guided men towards screening or not screening); (3) *Analyse and choose* (GPs who aimed to ensure men made their own independent, informed decision, based on a detailed epidemiological understanding); (4) *As you wish* (GPs who simply facilitated the man's stated preference to be screened or not screened). Two of these terms (*Be Screened* and *Analyse and choose*) align with Entwistle et al.'s characterization of communication approaches (15), as outlined in the introduction. Each GP we interviewed had a general preference to employ one of these four approaches in their everyday communication about PSA screening. In Table 3 we present an integrated illustration of the characteristics of each approach, ordered according to the 3 key dimensions evident in the GP accounts.

Table 3. Four GP approaches to communication about PSA screening in clinical interactions

BE SCREENED interactions	**DO NOT BE SCREENED interactions**
GP's primary goal: • GP strongly believed that the man should be screened • GP goal is to convince the man to screen **Information provided by GP:** • GP's personal judgment about the value of PSA screening • GP either tailored information provided to men to encourage men to be screened, or did not provide information (provided only encouragement to be tested) **Type of understanding that GP considered adequate:** • Gist understanding of information provided	**GP's primary goal:** • GP strongly believed that the man should not be screened • GP goal is to convince the man not to screen **Information provided by GP:** • GP's personal judgment about the harms /downsides of PSA screening • GP either tailored information provided to men to discourage screening, or did not provide information (provided only encouragement to avoid testing) **Type of understanding that GP considered adequate:** • Gist understanding of information provided
ANALYSE & CHOOSE interactions	**AS YOU WISH interactions**
GP's primary goal: • GP may personally support testing or not testing • Despite their personal beliefs about testing, GP's goal is to help the man to make his own informed decision **Information provided by GP:** • GP aimed to provide a comprehensive and impartial summary of best available evidence **Type of understanding that GP considered adequate:** • GP goal was to ensure men developed detailed understanding of their options, to make own informed decision	**GP's primary goal:** • GP may or may not have a strong position on the value of PSA screening • GPs' goal is simply to follow the man's expressed preference **Information provided by GP:** GP provided little information **Type of understanding that GP considered adequate:** • Ensuring men understood was not a priority for the GP. In some cases, GP perceived men to have already made a screening choice based on personal preference or gist understanding

Be Screened or *Do not be screened* interactions*.* If GPs had a strong preference that men should either be screened or avoid screening, they communicated in a directive way, oriented to encouraging the man either to screen or avoid screening respectively. This included offering personal judgment about the value – or harms – of PSA screening or framing the information they provided towards or away from screening. Some GPs gave a recommendation without offering men any further information. In *Be screened* and *Do not be screened* interactions, GPs considered it sufficient that men developed gist understanding of the information provided, because they thought it was reasonable for men to trust their doctor to advise them appropriately. These GPs strongly believed either that men should be screened routinely, or that they should not be screened at all, and they wanted patients to follow their advice.

Analyse and choose interactions*.* If GPs aimed to support men to make their own decisions, consistent with the man's personal preferences (i.e. a patient-directed decision), then they were not directive in their communication. In these interactions, GPs aimed to provide a comprehensive and impartial summary of the best available evidence; their goal was to ensure that men developed a detailed epidemiological understanding of their options in order to make an informed decision. They saw this as a neutral, educative role. For some, this approach was protective against potential medico-legal threats. GPs using this approach may personally favour either screening or not screening, but their primary commitment was to support the man's decision, regardless of their own professional beliefs about screening.

As you wish interactions*.* Sometimes GPs acted on patient wishes to be screened or not screened without questioning. In these interactions GPs did not attempt to direct men in any particular direction, and often provided little information, ensuring that the man understood PSA screening was not a priority. In some cases, GPs perceived men to have already made a screening choice based on personal preference or gist understanding. These consultations typically involved men with an already-established screening preference, mostly for screening; the GP simply acted in line with the man's instructions.

How GPs negotiate communicating within specific contexts

Many Australian GPs reported discussing PSA screening with men often, so had a prepared basic 'spiel'; as one reported, '*the PSA is such a common question that you get asked and you just have to have some idea in your head what you're going to say when they come in'* (AGP18). This spiel could be tailored to specific contexts as necessary. The interviews indicated that the GPs tended to have a preferred approach for most PSA interactions (to guide patient toward screening or not screening, to support men to make their own decision, or to act in accordance with the man's expressed preference), or that they had maintained a particular communication style over time. However we identified eleven situational and relational factors (see Table 4) that GPs described as temporarily shifting their usual or preferred communication goals and processes. These factors predominantly arose from specific circumstances of individual consultations. GPs described modifying their provision of information and/or advice, depending on the eleven factors described in Table 4.

Table 4. The effect of situational and relational factors on GPs' approaches to communication in PSA screening interactions, as described by GPs

Situations that encouraged particular approaches to communication about PSA screening, as described by GPs	Examples of how GPs reported modifying their communication
SITUATIONAL FACTORS…pertaining to patient and/or GP	
Patient was from an older or younger age group (particularly under 50 years or over 75 years), or had comorbidities	• Some GPs paid closer attention to which direction they 'coaxed' patients in these age groups; for example, some would particularly emphasise false positives and the potentially harmful diagnostic pathway to younger men under 50 years (*i.e. GP more likely to use Do not be screened approach*). • Some GPs who usually communicated in *Be Screened* mode provided comparatively less detailed information for older patients, particularly those with declining memory or those they perceived as being cognitively unable to 'handle the information', and *'pick[ing] the details of the intricacies…and a lot briefer [conversation]'* (AGP17) • Some GPs described defaulting to providing stronger recommendations with elderly men.
Patient had a family history of prostate cancer	• Conversations with men with family history of prostate cancer were described as being slightly different; some GPs said their interactions with these men would be more 'considered' and 'gentle' despite the majority of the men knowing their decision before coming to the doctor. • Some GPs who generally communicated in a way to achieve screening (*Be screened*) or not screening (*Do not be screened*) changed their approach more towards *Analyse and choose* and *As you wish* in situations where a family history was implicated – for both those determined to be tested and those not wishing to be tested.
Patient requested to receive a PSA test or was perceived to be determined to have a test	• These patients were perceived to have positive preconceptions about PSA screening which pre-empt any GP discussion. • Some GPs who would usually communicate with a particular goal in mind (*Be screened* or *Do not be* screened) said any conversation counter to the man's beliefs was not a productive conversation because their intentions could not be changed; *'they see it as their right to have it [a PSA test]'* (AGP15); *'he was so definite he wanted it'* (AGP6). GPs tended to take the *As you wish* approach in these situations, even if this was not their preference. • *'I think that what changes in that situation is their determination to have the testing done, most of these men have made a decision before I've said anything, that they're going to be tested, no matter what I say'* (AGP8).
Patient was interested in finding out more about screening	• Some GPs reasoned that a man's interest in PSA screening would drive the discussion, *'it tends to be very patient specific and tailored advice…and depends on what I think that they expect and hope to hear and are likely to do'* (AGP16). • GPs who usually took an *As you wish* approach, so did not communicate, would in some situations be required to shift to one of the other three approaches (*Be screened, Do not be screened, Analyse and choose*) because the man requested information. • Some GPs said the discussion would become 'more complicated' the more interested the patient was.
SITUATIONAL FACTORS…pertaining to service characteristics	
Rural location with limited access to urology services	• Some GPs were influenced by their access to a Urologist. Although they might prefer to recommend that men *Be Screened* or *Do not be screened*, they described instead shifting their approach towards *Analyse and choose* when based in a rural location; I *'just might try to explain the test, do a bit more pre-test counselling with the patient when I was in the country, just because I knew that I'd then be managing the result rather than just sending them onto a Urologist, like it's easy to do in Sydney'* (AGP5). GPs described how in rural locations it is common for GPs to have to manage abnormal PSAs for a longer period before they can access urologists for a second opinion. Some GPs were uncomfortable with this situation and consequently aimed to involve men more in the decision from the beginning. • Some GPs would talk to patients after PSA screening if it was abnormal but not before; i.e. they would take either a *Be Screened* or *As you wish* approach before testing, and provide counselling if needed after testing. These GPs perceived some men as resistant to seeing a GP at all, so thought it important to be seen to do a test because it was 'something' proactive for them while they were there, rather than simply talking.

Time available for the consultation (GP short of time)	• Some GPs who preferred an *Analyse and choose* approach engaged in less detailed discussion with patients about PSA screening when they were short of time. They described selecting out the information to include in discussions with men when they were time poor, more in line with the *Be Screened* or *Do not be screened* approaches. • Some GPs said it is often simply impractical to provide full information and support patients to develop detailed population-level understanding at each appointment so on occasions they *'just haven't had time to give a full spiel so I order it and I will have the discussion later with them, if it's positive'* (AGP13).
RELATIONAL FACTORS…pertaining to patient and/or GP	
GP made a judgement that the patient 'starting point' in terms of grasping the information was low and it would be difficult for them to understand PSA screening	• Some GPs who usually favoured *Analyse and choose*, reverted to a *Be Screened* or *Do not be screened* approach when communicating was difficult, *'If I had a patient who is extremely unintelligent and I tried to explain it and I didn't seem to be getting through to him, and I felt it was in his best interests, I might go ahead and do the test [or not do the test] anyway'* (AGP29) • Some GPs tailored the content accordingly; '*it really depends on the population you're dealing with … what you perceive they are capable of understanding'* (AGP31); *'You've got to target it at the level of the patient basically'* (AGP4). • *'If a man thinks PSA is just a blood test, then I mentally go oh dear, we need to go through this in more detail'* (AGP4).
Patient was perceived to be anxious, and so not receptive to information	• Sometimes GPs provided minimal information to manage anticipated patient anxiety; *'if you put too much information out there…most of it doesn't go in…there's too much information…'it's not possible for people to take that stuff in, they don't even want to'* (AGP7). • In such cases, GPs who would usually communicate in *Analyse and let choose* mode, acted in what they saw as their patient's 'best interests' (toward *Be screened* or *Do not be screened*), which could involve no communication, or being selective with the information they shared.
GP made a judgement that the patient was 'very switched on' and had 'done their homework'	• GPs were often more inclined to take the option of *As you wish* in situations involving well-informed men, regardless of the GP's usual practice. • Alternatively, GPs might take an *Analyse and choose* approach and tailor content accordingly; '*it really depends on the population you're dealing with … what you perceive they are capable of understanding'* (AGP31); *'You've got to target it at the level of the patient basically'* (AGP4).
GP aware of patient history of screening (GP has screened patient in the past or has discussed screening with patient previously, GP knows patient's screening preferences, or GP knows patient has been screened previously)	• Some GPs who would prefer the *Analyse and choose* approach said they *'may not give a full spiel'* (AGP13) to men who have been screened before and *'often do it [discuss] a little more quickly, because it is clear that they remember it from the year before. And if they are men who made the decision last year to have the test done, then they are often going to make the same decision this year…so it's a quicker conversation, but it's not a non-conversation. And it depends on the patient and how well I know them'* (AGP30). In these situations, GPs tended to shift to an interaction more like one of the other three approaches. • Some GPs were more likely to initiate screening with men who had had PSA screening with them in the past or had had many PSA tests, because *'generally a lot of my patients by now have had the spiel so many times that they often will, come in and say "It's time for my yearly prostate test'* (AGP29).
RELATIONAL FACTORS…pertaining to service characteristics	

Patient was the usual patient of another GP, and patient asked for a PSA test	• Sometimes GPs who preferred an *Analyse and choose* approach were consulted by patients who were routinely tested by another GP. In this situation, the GP would assume that the man had heard the talk before. They responded to this situation in several ways:
	  ○ Some GPs shifted to either the *Be screened* or *As you wish* approach and ordered PSA tests without discussing it with the man, reasoning that the discussion could be revisited if the PSA was abnormal.
	  ○ Some GPs maintained *Analyse and let choose* mode and actively engaged patients in a discussion, because they did not know what men had heard from previous GPs. This was sometimes with a view to changing the patient's mind: e.g. *'I am trying to create permission and faith for me to open the discussion up again, rather than just keep redoing the test'* (AGP30).
	• Some GPs found this position incredibly challenging if they preferred not to test (i.e. *Do not be screened*); *'because you have to undo the patient's expectations…you've got to decide whether you just go with the flow…or you sit down and ascertain what their appetite for negotiating is. Some of them are just locked into it and it's too late'* (AGP23).

GPs also shifted between the four communication approaches more readily when they were presented with complex cases; producing more fluid, responsive, and sometimes *'quite inconsistent'* (AGP16) conversations. Many GPs did have a primary goal when communicating (to encourage or discourage screening, or to support the man to make his own decisions) but these could change in different situations. Also, some men did not take the advised pathway – either toward screening or not screening, or some men preferred the GP to direct the decision, not wanting to engage with information or to make their own decision.

Comparison of communication approaches in Australia and the UK

UK GPs generally did not communicate about PSA screening unless men asked about it, so they often neither communicated about it as a screening test, nor ordered it. When men asked for a PSA test, information provision was central to consultations in the UK context, and most UK GPs commonly practiced according to the *Analyse and choose* or *Do not be screened* approaches. Few UK GPs described adjusting their conversations about PSA screening with patients.

The reported consistency of PSA communication practices in the UK contrasted strongly with the significant variation reported in the Australian context (Tables 3 and 4). The contextual factors considered in Table 4 were uncommon in UK GPs' accounts, due to fewer men requesting and fewer GPs suggesting prostate screening. UK GPs mostly reported giving the same standard information leaflet to all men who expressed interest in PSA screening, regardless of their personal circumstances. Many GPs practicing in Australia tended to filter information, and commonly practiced according to the *Be Screened* approach, but no UK GPs reported using this approach.

We identified different versions of the *Do not be screened* approach adopted by Australian and UK GPs. For the Australian GPs, this approach took the form of a personal recommendation against screening, directed by the GP and according to their personal – negative – perspective of PSA screening. For UK GPs, the *Do not be screened* approach also involved the GP recommending that the man should not be screened. However UK GPs explained this as enactment of a collective standard of care recommended

and issued by the UK National Health Service irrespective of their own personal preferences for or against screening.

Discussion

This analysis suggests that GPs' primary communication goals are a central component of consultations about prostate screening. Four distinct communication approaches – *Be Screened*, *Do not be screened*, *Analyse and choose*, and *As you wish* – were identifiable from the GP accounts of their preferred practice.

The terms *Be Screened* and *Analyse and Choose* align with Entwistle et al.'s Consider an Offer framework. We identified two additional ways of communicating unique to our empirical data, which we labeled *Do Not Be Screened*, and *As you wish.* The need for inclusion of a *Do not be Screened* element is likely a product of the Australian context where the PSA test is available and widely promoted for screening purposes in the media, despite the majority of relevant public health and health professional groups recommending against routine screening of asymptomatic men. This meant Australian GPs were regularly consulted by men expecting to be screened, and some reported feeling obligated to actively direct men away from wanting a PSA test for that purpose.

The *As you wish* category is also likely to be, in part, a reflection of the somewhat market-driven Australian health care system. *As you wish* interactions occurred when GPs' believed men had already made up their minds about their preferred choice, and could not be swayed by information presented by the GP. This led GPs to implement the man's choice and order the test, despite the lack of an evidence base to support that decision. There was no evidence of *As you wish* interactions in the UK data. As we previously reported (14), in the UK there is strong guidance to GPs to practice in a particular way. GPs are expected to steward limited NHS resources, and the PSA test is not publicly promoted to the same extent, limiting consumer expectations for screening. All of these are conceivable explanations for why *As you wish* interactions were less commonly reported in UK interviews.

The main issues raised by this analysis

The four variants raise important questions about patient-centered care, consumer demand, and the role of the health professional. It is well established in the literature that both patients and clinicians are rarely entirely rational, and may not necessarily know what is in the patient's best interest, particularly when faced with scientific uncertainty e.g. (23, 24). Humans tend, for example, to become sensitised to worst-case scenarios and disregard objective risk probabilities; this makes us vulnerable to pursuing, recommending, or accepting potentially harmful treatments (25). If this is so, an *As you wish* approach could mean patients are more exposed to increased harms, and that leaving patients to make decisions about their health care needs without professional guidance is potentially maleficent, or at least negligent. This problem is further complicated by the wide availability of possibly misleading information, provided by sources that have an interest in inflating perceptions of cancer risk. Some authors highlight that increased patient involvement in decision-making has potential for negative social consequences such as increasing patient demand for unproven services (26). Cribb and Entwistle reasonably argue that in some circumstances it may be ethically legitimate for health professionals to question and even influence the preferences of patients for these reasons (27).

Most current recommendations encourage GPs to discuss the benefits and harms of prostate cancer screening with patients. However, there may be considerable variation in what patients want and expect from GPs prior to making a decision about PSA screening. Degeling et al. ran three community juries on the topic of how GPs should communicate about PSA screening. Juries heard extensive expert evidence about PSA screening, consent and general practice. Two juries of general citizens (i.e. mixed gender and age) concluded that GPs should ensure men have enough knowledge to make their own decision. One jury of only men of PSA screening age concluded that men should be able to trust their GP (or a specialist) to provide just enough information at just the right time, expressed concern about the potential for information overload, and thought the degree of patient involvement depended on the patient (28). This suggests that citizens who are (atypically) well informed about the benefits and harms of prostate cancer screening may take different views and have different expectations on how GPs should communicate about PSA screening. If this is the case, it may be appropriate for GPs to have

at least a range of communication strategies available, to suit the needs of different patients. Men eligible for, or already receiving, PSA screening, may well prefer for GPs to direct the decision (*Be screened* or *Do not be screened* approaches) to avoid uncertainty. However men's preferences are arguably an insufficient guide; other considerations, including clinical practice guidelines, medical law and clinical ethics requirements, are relevant to determining what GPs should do.

A large component of this analysis is about awareness of and sensitivity to context and the importance of interpersonal relations and their influence on communication practice (see Table 4). Some of the GPs' communication decisions, based on situational or individual factors, were easily justified, because the situation presented was either clinically relevant (e.g. family history, older age), or professionally justified (e.g. low literate patient, patient request). While most guidelines advising on PSA screening suggest informed or shared decision making, they do not consider what may be a 'best' approach to situations involving the many local factors that GPs face in day to day practice, including relational factors, implicated in screening decisions (and the complexities of general practice). We identified a subtle web of relational issues that influenced GPs to move between communication options and particular types of decision pathways. These included managing colleague associations (what are GPs to do about patients who have come from a pro-screening GP to a GP who does not support PSA screening?), managing business, including patient lists (patient request, time pressures), and maintaining patient trust. These issues made the decision making process particularly complicated, and in addition to vague guidance on such matters, perhaps account for why many GPs appeared to have multiple, dynamic approaches. Accounting for relational variables as identified in this study can facilitate nuanced assessment of the different types of support clinicians might offer people who may struggle with particular decisions (29), and allows scope for professional expertise: the 'art' of medicine.

Implications for policy and practice

There are variable approaches to communication about PSA screening, some of which may be considered better than others. Guidance about communication - not just about the PSA test itself, but

also about how best to facilitate the decision – may be useful; we suggest there is a need for further higher level professional discussions about what the primary goals of GPs should be when communicating about PSA screening. Coming to an explicit agreement on what that purpose should be may assist in improving communication and providing clearer guidance for GPs working in the Australian context. For instance, one endpoint (that could be evaluated) may be that men can demonstrate they have a sense of their values in relation to the available options, to show evidence of rational, thoughtful, and informed decision making.

Limitations

As this is a qualitative study, we cannot infer the prevalence of the reported approaches to communication; the results of this study could be extended into quantitative survey research with whole populations of GPs to test prevalence. It is also possible that those GPs who did not participate were in some way different to those who did (that is, that these data are subject to selection bias), however the diversity in our respondents suggests that it is very unlikely that our sample was biased towards a particular view of PSA screening or corresponding communication style.

Conclusion

This empirical study produced evidence documenting varied approaches to communication. In the Australian setting, some flexibility in communication seems justified. Further, because of (a) the large number of men implicated, (b) the known harms of the screening process, and (c) that PSA is not a routine screening program, we argue that PSA screening is a particularly pressing case to necessitate dedicated effort to facilitate conversations that include but go beyond potential harms and benefits with men. This would include encouraging and enabling men who ask for screening to look carefully at why PSA screening is not recommended (to increase awareness of why a *Do not be screened* approach is justified). Assisting GPs to facilitate these conversations with patients should offer the advantage of supporting men's autonomy and reducing harm.

Chapter References

1. Hoffmann T, Del Mar C. Patients' Expectations of the Benefits and Harms of Treatments, Screening, and Tests: A Systematic Review. JAMA Intern Med. 2015;175(2):274-86.
2. Chan E, Sulmasy D. What should men know about prostate-specific antigen screening before giving informed consent? Am J Med. 1998;105(4):266-74.
3. Elwyn G, Scholl I, Tietbohl C, al e. "Many miles to go...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. BMC Medicine Informed Decision Making. 2013;13(Suppl 2:S14).
4. Han PKJ. Randomised controlled trial: Delivering a decision support intervention about PSA screening to patients outside of clinical encounters is ineffective in promoting informed decision-making. Evid Based Med. 2015;20(4):139.
5. Watson DB, Thomson RG, Murtagh MJ. Professional centred shared decision making: Patient decision aids in practice in primary care. BMC Health Serv Res. 2008;8(5).
6. Chan EC, Vernon SW, Ahn C, Greisinger A. Do Men Know That They Have Had a Prostate-Specific Antigen Test? Accuracy of Self-Reports of Testing at 2 Sites. American Journal of Public Health. 2004;94(8):1336-8.
7. Hoffman RM, Couper MP, Zikmund-Fisher BJ, Levin CA, McNaughton-Collins M, Helitzer DL, et al. Prostate cancer screening decisions: results from the National Survey of Medical Decisions (DECISIONS study). Archives of Internal Medicine. 2009;169(17):1611-8.
8. Han PK, Coates RJ, Uhler RJ, Breen N. Decision making in prostate-specific antigen screening. American Journal of Preventive Medicine. 2006;30(5):394-404.
9. Dunn AS, Shridharani KV, Lou W, Bernstein J, Horowitz CR. Physician-patient discussions of controversial cancer screening tests. American Journal of Preventive Medicine. 2001;20(2):130-4.
10. Guerra CE, Jacobs SE, Holmes JH, Shea JA. Are Physicians Discussing Prostate Cancer Screening with Their Patients and Why or Why Not? A Pilot Study. JGIM. 2007;22:901-7.
11. Volk RJ, Linder SK, Kallen MA, Galliher JM, Spano MS, Mullen PD, et al. Primary care physicians' use of an informed decision-making process for prostate cancer screening. The Annals of Family Medicine. 2013;11(1):67-74.
12. Linder SK, Hawley ST, Cooper CP, Scholl LE, Jibaja-Weiss M, Volk RJ. Primary care physicians' reported use of pre-screening discussions for prostate cancer screening: a cross-sectional survey. BMC Family Practice. 2009;10.
13. Cooper CP, Merritt TL, Ross LE, John LV, Jorgensen CM. To screen or not to screen, when clinical guidelines disagree: primary care physicians' use of the PSA test. Preventive Medicine. 2004;38:182-91.
14. Pickles K, Carter SM, Rychetnik L, Entwistle VA. Doctors' perspectives on PSA testing illuminate established differences in prostate cancer screening rates between Australia and the UK: a qualitative study. BMJ open. 2016;6(12):e011932.
15. Entwistle VA, Carter SM, Trevena L, Flitcroft K, Irwig L, McCaffery K, et al. Communicating about screening. British Medical Journal. 2008;337(7673):3.
16. Globocan 2012: Estimated Cancer Incidence, Mortality, and Prevalence Worldwide in 2012: International Agency for Research on Cancer, World Health Organisation; 2012 [Available from: http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx.
17. Moss S, Melia J, Sutton J, Mathews C, Kirby M. Prostate-specific antigen testing rates and referral patterns from general practice data in England. International journal of clinical practice. 2016;70(4):312-8.
18. Holden CA, McLachlan RI, Pitts M, Cumming R, Wittert G, Agius PA, et al. Men in Australia Telephone Survey (MATeS): a national survey of the reproductive health and concerns of middle-aged and older Australian men. The Lancet. 2005;366(9481):218-24.
19. Medicare Benefits Schedule Book Category 6: Australian Government Department of Health; 2014.
20. Pickles K, Carter SM, Rychetnik L. Doctors' approaches to PSA testing and overdiagnosis in primary healthcare: a qualitative study. BMJ open. 2015;5(3):e006367.

21. Pickles K, Carter SM, Rychetnik L, McCaffery K, Entwistle VA. General Practitioners' Experiences of, and Responses to, Uncertainty in Prostate Cancer Screening: Insights from a Qualitative Study. PloS one. 2016;11(4):e0153299.
22. Charmaz K. Constructing grounded theory: Sage; 2014.
23. Schwartz LM, Woloshin S, Fowler FJ, Welch HG. Enthusiasm for cancer screening in the United States. JAMA-J Am Med Assoc. 2004;291(1):71-8.
24. Tymstra T. 'At least we tried everything': About binary thinking, anticipated decision regret, and the imperative character of medical technology. Journal of Psychosomatic Obstetrics & Gynecology. 2007;28(3):131-.
25. Aronowitz RA. The converged experience of risk and disease. Milbank Quarterly. 2009;87(2):417-42.
26. Briss P, Rimer B, Reilley B, Coates RC, Lee NC, Mullen P, et al. Promoting informed decisions about cancer screening in communities and healthcare systems. American Journal of Preventive Medicine. 2004;26(1):67-80.
27. Cribb A, Entwistle VA. Shared decision making: trade-offs between narrower and broader conceptions. Health Expectations. 2011;14(2):210-9.
28. Degeling C, Rychetnik L, Pickles K, Thomas R, Doust JA, Gardiner RA, et al. " What should happen before asymptomatic men decide whether or not to have a PSA test?" A report on three community juries. The Medical journal of Australia. 2015;203(8):335-.
29. Entwistle VA, Carter SM, Cribb A, McCaffery K. Supporting patient autonomy: the importance of clinician-patient relationships. J Gen Intern Med. 2010;25(7):741-5.
30. Volk RJ, Spann SJ. Decision-aids for prostate cancer screening. Journal of Family Practice. 2000;49(5):425-.

CHAPTER SEVEN.

Discussion & Conclusions

7. Overview of this chapter

In this final Chapter I synthesise my analysis of how prostate cancer screening works in clinical practice in Australia and the United Kingdom, from the GPs' perspective. I present a practical model illustrating the core components of the screening process including its outcomes, derived from clinicians' accounts. Informed by this model, I draw some conclusions and make recommendations in the final section of this chapter.

Prostate cancer screening is a complex clinical decision regularly encountered by a large number of men and GPs in Australia. It is controversial due to the finely balanced benefits and harms, including harms incurred by overdiagnosis and overtreatment, and attracts substantial media coverage and attention. Recommendations on PSA screening are highly contested and politically charged (particularly in Australia), the right course of action remains unresolved, and conflicted interests are increasingly recognised.

These factors collectively raise important ethical questions and have direct implications in clinical care. Yet, as highlighted in the literature review presented in Chapter 1, little was known about GPs' views and experiences in relation to PSA screening of asymptomatic men. I wanted to know how GPs are thinking about PSA screening. Are they concerned? What are they prioritising?

In chapters 3-6 of this thesis I documented extensive variation in GPs' accounts of prostate cancer screening. This is the first study to systematically map GPs' reasoning and understanding of prostate cancer screening using the PSA test. These findings offer guidance for future policy and practice, grounded in the experiences of clinicians at the frontline of PSA screening.

To summarise my main findings:

- Australian GPs use one of four heuristics to decide what to do about PSA screening, based on different reasoning about over- and under- diagnosis (Chapter 3). There were GPs who (1) prioritised avoiding underdiagnosis; (2) weighed underdiagnosis and overdiagnosis case by case; (3) prioritised avoiding overdiagnosis; and (4) did not engage with overdiagnosis at all;
- GPs experience significant and diverse uncertainty about PSA screening and manage and respond to different types of uncertainties encountered with three different strategies (Chapter 4): they take charge of uncertainty; engage others in managing uncertainty; and/or transfer responsibility to other parties;
- From the GPs' perspective, the difference in screening practices in Australia and the UK is mostly explained by the history of prostate screening policy; organisational structures; and funding models (Chapter 5); and, lastly,
- GPs communicate with men about PSA screening using one of four approaches, which depend on the GPs' primary goals for the interaction in combination with specific practice situations (Chapter 6): these approaches can be summarized as (1) Be screened; (2) Do not be screened; (3) Analyse and choose; and (4) As you wish.

In Table 12 I provide a summary of key concepts I used in the earlier chapters of this thesis. I refer to these throughout this discussion.

Table 12: Key concepts used in this thesis and the meaning of the concept in context

What is the concept	How was the concept used	Chapter in which the concept was/will be described
Asymptomatic	Those men attending clinical practice with no prior indications associated with prostatic disease	#5: Comparison
Symptomatic	Men who have symptoms that could be related to locally advanced or metastatic prostate cancer	#5: Comparison
Values	The relatively sedimented evaluative attitudes of GPs: what they evaluated as important or unimportant in a relatively stable way	#7: Discussion
Underdiagnosis	Failing to diagnose in a situation where diagnosis would have been beneficial for the patient (e.g. through early detection of a cancer that would otherwise have caused death)	#3: Overdiagnosis
Overdiagnosis	A diagnosis that meets the pathological criteria for prostate cancer but does not benefit the patient because the cancer would not have become symptomatic in the patient's lifetime and/or would not have caused the patient's death	#3: Overdiagnosis
Personal burden	GPs' experiences of negative cognitive and emotional consequences as a result of being responsible for what feels like an impossible choice: including feelings of worry, guilt, self-blame, regret, insecurity, and anxiety	#3: Overdiagnosis
Heuristics	Intuitive cognitive shortcuts that people often use to form judgments and make decisions	#3: Overdiagnosis
Routine practice	A GP's usual practice in regards to screening, communication, and response to patient requests	#3: Overdiagnosis
Practice outcome	GPs' experiences of the consequences of their PSA screening decisions	#3: Overdiagnosis
Probabilistic uncertainty	Uncertainty generated from the indeterminacy of a phenomenon's future outcome, such as the probability of benefit (or harm) from a test or treatment (1)	#4: Uncertainty
Ambiguity uncertainty	The lack of reliability, credibility, or adequacy of information about a phenomenon of interest: includes imprecision, conflicting opinions/evidence, and lack of information (1)	#4: Uncertainty
Complexity uncertainty	Uncertainty arising from complex aspects of a phenomenon itself, which make it difficult to comprehend, such as numerous potential outcomes, and/or multi-morbidity (1)	#4: Uncertainty
Scientific uncertainty	Disease-centred. Uncertainties about diagnosis, prognosis, causal explanations, treatment recommendations (1)	#4: Uncertainty
Practical uncertainty	System-centred. Uncertainties about the structures and processes of care (competence, quality, responsibilities) (1)	#4: Uncertainty
Personal uncertainty	GP/patient-centred. Uncertainties about psychosocial and existential issues (1)	#4: Uncertainty
GPs "taking charge" (of uncertainty)	Describes circumstances when GPs recognised uncertainty, tolerated it, and accepted it as a lasting presence in their practice	#4: Uncertainty
GPs "engaging others" (managing uncertainty)	Describes circumstances when GPs took uncertainty as a challenge and engaged others (medical profession, colleagues, patients) to make decisions in a context of shared uncertainty	#4: Uncertainty
GPs "transfer responsibility" (for uncertainty)	Describes circumstances when GPs perceived uncertainty as problematic and sought out other parties to reduce their experience of uncertainty (e.g. urologists, health system, legal authority)	#4: Uncertainty
Mindline	Collective, internalised, tacit guidelines (2), mainly grown and collectively reinforced via training, experience, and interaction with trusted sources, and mediated by features of primary care organisations	#5: Comparison

Consider an offer	An approach to communicating about screening that suggests health care providers should support people to assess an offer for screening, with a recognition that people may reasonably decline such offers (3)	#6: Communication
Be Screened communication approach	GP guided man towards screening	#6: Communication
Do not be screened communication approach	GP guided man towards not screening	#6: Communication
Analyse and choose communication approach	GP aimed to ensure man made own independent, informed decision	#6: Communication
As you wish communication approach	GP facilitated man's stated preference to be tested or not tested	#6: Communication
Interpersonal trust	Trust placed in an individual or personal relationships (4)	#7: Discussion
Institutional trust	Trust placed in a system or institution (4)	#7: Discussion
Distal knowledge	Knowledge created and derived from outside of the care environment (for example, research evidence, clinical guidelines) (5)	#7: Discussion
Proximal knowledge	Knowledge created and derived from within a specific care environment, and dependent on contextual issues within that environment (5)	#7: Discussion

Earlier in this thesis, my goal was to understand and report on the range of positions taken by the GPs in this study, including the influence of those positions on screening practice. In this chapter, I synthesise and interpret these findings. The observed range of practice variation points to the necessity of understanding these issues beyond face value. In parts, I take a critical position, particularly on those beliefs and practices reported by GPs that are strongly in contradiction to agreed standards or the body of evidence, and thus arguably associated with doing more harm than good.

A model of PSA screening practices from the perspective of GPs

Throughout this chapter I will present and discuss a conceptual model of GPs' perspectives on their reasoning and use of the PSA test as a screening tool, and some of the key factors that influence their prostate screening practice. The model in its entirety is presented in Figure 9. Sections 7.1 to 7.3 inclusive systematically explain the components of the model: I provide an overview here.

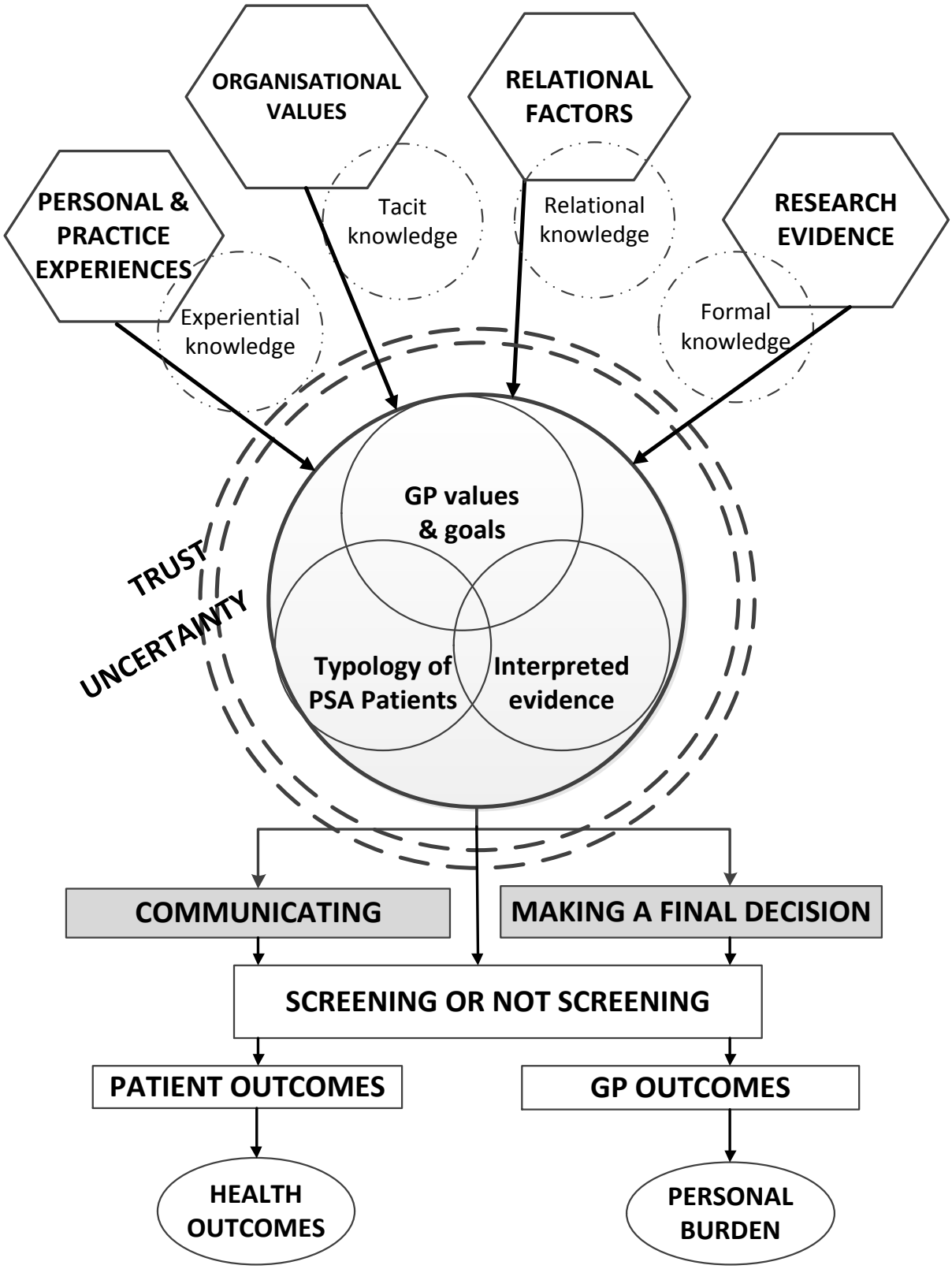
The three intersecting circles in the centre of Figure 9 represent three background conditions which appeared to be central to GP descriptions of their screening approach: GPs (1) develop or receive an interpretation of the research evidence; (2) hold relatively stable values and goals about PSA screening; and (3) form an intuitive typology of "PSA patients".

GPs described four relevant factors external to the clinic that influenced and shaped these background conditions, which I will refer to as *Sources of knowledge*: (1) personal and practice experiences, (2) organisational values, (3) relational factors, and (4) research evidence. GPs evaluated the four sources of knowledge via two filters – trust and uncertainty – which further determined to what extent they were integrated into the GP's screening approach.

Two key elements of screening interactions – communicating and making a final decision – mediate the final outcome. Here, GPs either engaged or did not engage patients and/or the profession in the process. There were relevant consequences for both the GP and the patient.

Sections 7.1 to 7.3 present a different component of the model; each of these sections also addresses one of my three central research questions. In Section 7.4 I provide reasons for why the PSA screening environment in Australia may be the way that it is. In Section 7.5 I suggest ways in which GPs might be better supported to respond to current practice demands, including challenges that might present.

Figure 8: An integrative model of how PSA screening works in primary care



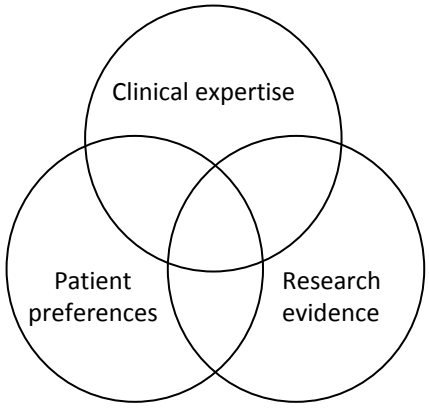
7.1 Research Question 1: How do GPs approach PSA screening?

In answering my first research question, I arrived at a model that was both similar and different to commonly-used models of evidence-based medicine (EBM). This model is at the core of Figure 9 and will be explained and referred to throughout this section.

EBM (ostensibly) provides a central framework for the contemporary practice of clinical medicine (Chapter 1). When EBM was first established, evidence-based clinical decision making was represented in Sackett's now well-known three-circle model (6). The three intersecting circles in the model (Figure 10) represented the types of knowledge that should be integrated when making clinical decisions: clinical expertise, research evidence, and patient preferences.

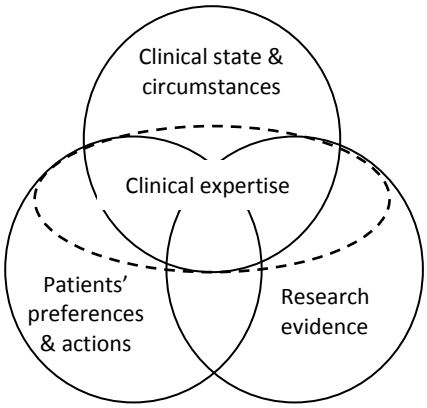
A fundamental assumption in establishing EBM was that superior patient care would be provided by clinicians whose practice was concordant with the best available evidence (7). It was hoped that disseminating high-quality evidence to practicing physicians would help reconcile different views on the practice of medicine, and in turn, result in less variation in practice (8).

Figure 9: Sackett's early model (1996) of the key elements for evidence-based clinical decisions (7)



Over time, EBM arguably emphasised more strongly that clinical expertise was a central factor in clinical interactions, and a necessary complement to research evidence (6). This was reflected in an updated model (Figure 11) (9). Thus the new model acknowledged that an 'evidence-based' decision will vary according to both patient preferences and the individual clinical circumstances.

Figure 10: Haynes' updated model (2002) for evidence-based clinical decisions (7)

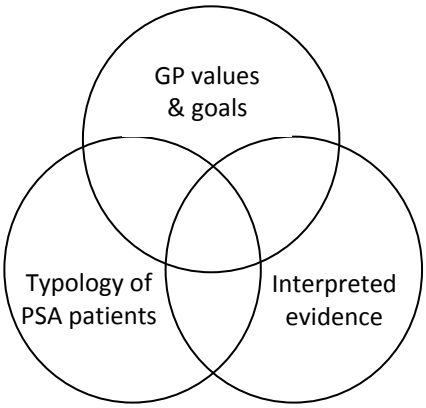


Both of these idealised models of EBM aim to promote a transparent, rational decision-making process (10). EBM encourages clinicians to aim to prioritise information from rigorous clinical trials in their work, to recognise agreed standards of evidence, and to increase uniformity and efficiency by limiting idiosyncrasies in medical care (11). However, consistent with many authors (e.g. (12, 13), my analysis suggests that the EBM model is an ideal: in the clinic GPs face human and evidentiary complexities that make doing 'pure' EBM very difficult.

Comparing my model to the traditional EBM model

Resonances between my model (Figure 9) and traditional EBM models are immediately evident, most obviously the three intersecting circles at the centre, which represent three central background conditions that GPs described bringing into any PSA screening situation. GPs (1) develop or receive an interpretation of the evidence; (2) hold relatively stable values and goals about PSA screening; and (3) form an intuitive typology of "PSA patients" (Figure 12).

Figure 11. Three background conditions central to GP descriptions of their screening approach



Sackett's model was intended to be prescriptive: it represented what, according to the authors, should occur in clinical practice: about how decisions *should* be made (7). My model represents not how GPs *should* be practicing, rather, how 69 GPs in Australia and the UK explained that they *are* practicing and how decisions are made. I will describe each of the three background conditions in turn.

GPs develop or receive an interpretation of the evidence about PSA screening

Research evidence has always been central to models of EBM (Figures 10 and 11). To some extent, these models were intended to centralise and institutionalise the synthesis of evidence, such that all clinicians should be accessing the same evidence base, potentially via clinical practice guidelines or evidence summaries. However, as previously described, the evidence base for PSA screening is contested, and clinical guidelines are discordant (Chapter 1).

GPs' *interpretations* of the research evidence (whether individually developed or received via guidelines) were central to whether and how evidence was applied in clinical practice. Chapters 3-6 suggest that GPs were more or less receptive to evidence-based recommendations and practice depending on their perceptions of the evidence.

- Different GPs perceived the evidence very differently. Some claimed the evidence showed that PSA screening was on-balance harmful, some that it was on-balance beneficial, some that the evidence was not guiding and decisions needed to be made case by case, and some seemed not to perceive the evidence to be important to their decision making (Chapter 3);

- GPs experienced varying degrees of uncertainty about the PSA screening evidence base. For example, some GPs accepted the nature of current evidence and managed decision making on their own, some engaged others to help them to make sense of the evidence, and some transferred responsibility for interpreting the evidence to others (Chapter 4);
- Different GPs had more or less guidance in interpreting the evidence base, and support to apply the best available evidence in practice. UK GPs received a clear evidence-based recommendation from government against PSA screening and directed care accordingly (and with resources to do so). Some Australian GPs felt uncertain and even despondent about the evidence base because of the ambiguous and contested versions of 'evidence-based' expert advice in their context. They practiced in ways consistent with their individual perceptions of the evidence, and with significant scope to do so within the Australian healthcare system (Chapter 5);
- Different GPs communicated with men about the evidence differently. Some had strong personal judgments about the evidence and framed conversations accordingly; some communicated epidemiological perspectives on the evidence; some did not feel it necessary, or appropriate, to share comprehensive details of the evidence base with patients (Chapter 6).

GP perceptions of the evidence thus directly impact on the care and advice that men receive, and on GPs personally. I return to these issues in Section 7.4.

GPs hold relatively stable values and goals about PSA screening

In Table 12 I described 'values' in line with Andrew Sayer's viewpoint (14), as the relatively sedimented evaluative attitudes of GPs: what they evaluated as important or unimportant in the context of PSA screening in a relatively stable way. I have denoted values in this way throughout this chapter and I discuss them in relation to the literature in Section 7.4. Here in Table 13 I present a range of values held by GPs in this study and the types of goals that GPs pursued towards achieving those values. I categorised the values into 2 main types. Type 1 were values that GPs deemed as important to a good clinical process or important outcomes in a patient. Type 2 were values that GPs deemed as important in their role as a GP.

There was wide variation in the interpretation of common core values (Table 13). For example: two GPs, each arguing that they should "minimise harm to patients" may avoid screening to avoid overdiagnosis, or promote screening to avoid underdiagnosis (Chapter 3). Similarly, many GPs valued "facilitating informed decisions", but GPs had very different views of what information should be provided or what patients should understand (Chapter 6).

Table 13: Values held by GPs and the types of goals that GPs pursued towards achieving those values

	Values held by GPs	**Range of goals that GPs pursued, motivated by that value** (the same value could inform very different goals, depending on how it was interpreted)	**Chapter in which the value or goal was described**
What did GPs value as an outcome in a patient?	'Preventing death' of patients	• To identify cancer risk early (to diagnose cancer early) • To advocate screening; to talk men into having a PSA test • To minimise potential legal ramifications	#3: Overdiagnosis #4: Uncertainty #6: Communication
	Minimising harm to patients	• To prioritise avoiding screening to minimise risk of harming (via overdiagnosis) • To prioritise screening to minimise risk of harming (via underdiagnosis)	#3: Overdiagnosis
	Supporting patient autonomy	• To support men to make their own decisions • To provide the PSA test if a man wants it	#6: Communication
	Facilitating informed decisions	• To provide men with comprehensive information • To provide the right amount and right level of information • To provide the GP's interpretation of the information • To seek 'epidemiological', in-depth patient understanding of the evidence	#6: Communication
	Facilitating shared decisions	• To encourage patient engagement • To understand patient reasons for wanting screening • To understand patient preferences for screening or not screening • To educate patients about how to do their own research about PSA screening • To share personal screening practice with patients	#3: Overdiagnosis #4: Uncertainty #6: Communication
	Fostering patient trust in GP	• To not confuse men with complicated information • To provide the GP's interpretation of the information • To seek 'gist' patient understanding (leave intricacies of evidence to GP) • To follow established and consistent organisational protocol	#3: Overdiagnosis #4: Uncertainty #6: Communication
	Wanting to have information about their male patients' prostate cancer risk	• To screen men, to better predict risk • To attain reassurance (of GP and patient) by screening	#3: Overdiagnosis #4: Uncertainty #6: Communication
	Keeping male patients healthy	• To ensure men stayed engaged with the health system • To comprehensively screen for overall health – smoking, weight, mental health, prostate cancer	#3: Overdiagnosis

What did GPs value in their role as a GP?	Being responsive to patient preferences	• To provide the PSA test if a man wants it • To make screening decisions in interaction and case-by-case	#3: Overdiagnosis #6: Communication
	Applying the 'art of medicine' to decide 'right' approach	• To advise patients according to situation and/or individual circumstances • To act in patient's best interests	#3: Overdiagnosis #4: Uncertainty #6: Communication
	Following 'best practice'	• To practice according to clinical guidelines and recommendations	#3: Overdiagnosis #6: Communication
	Providing confident screening decisions or opinions	• To make decisions about the evidence, with or without uncertainty (some GPs thought all GPs should have the capacity to do this) • To not burden patients with uncertainty	#4: Uncertainty #6: Communication
	Managing uncertainty	• To manage uncertainty by screening • To manage uncertainty by not screening in the first place (UK GPs)	#4: Uncertainty #5 Comparison
	Preserving professional legitimacy and reputation	• To avoid being judged as inadequate or ineffective • To build and maintain rapport with patients • To maintain patient lists • To avoid potential legal ramifications	#3: Overdiagnosis #4: Uncertainty #5 Comparison
	Practicing in line with personally and/or professionally-established norms	• To practice in the way one always has, or in the way one's institution has always encouraged	#5 Comparison #6 Communication
	Protecting health care resources	• To minimise screening of asymptomatic men (UK) • To not prioritise conversations about PSA screening with asymptomatic men unless they ask	#4: Uncertainty #5: Comparison

GP values, and how GPs assigned value, served as powerful anchors for their practice, and were in this way action-guiding (15). Value positions also provide perspective on GPs' sub-optimal practice, or practice contrary to that suggested by the epidemiological evidence. For example, some GPs justified talking men into PSA screening because the GP strongly valued 'preventing death', and believed that more screening would prevent more deaths.

GPs form an intuitive typology of "PSA patients"

The EBM model suggests that patients' preferences should be considered first whenever it is possible to do so (7). Some GPs' core values (Table 13) were about being responsive to patients; they considered the circumstances of each patient and shifted their screening rules accordingly (Chapter 3 & 6). However I refer to a GP's *intuitive typology of "PSA patients"* in this section. This is because it was relatively uncommon for GPs to describe individual cases of men telling them about their specific preferences or concerns.

Rather, GPs' descriptions of patient preferences appeared to be understandings based on a general sense of what patients collectively want and need. GPs referenced patient 'types' and what they tended to prefer, gathered from broader populations of patient preferences. In practice, they engaged and communicated with patients according to those generalised assumptions. The centrality of heuristics in human reasoning has been well recognised since the 1970s so it is not surprising that GPs would rely to some extent on heuristics for clinical decision making. However an approach that relies on broadly perceived 'patient types' is out of keeping with models of patient centred care and shared decision making that emphasise engagement with the particular patient and their individual values. If a GP assumes that a patient, and their values, will conform to a particular 'type', and so do not ask patients about their personal values, they may a) be incorrect; and b) miss an opportunity to discuss, and possibly influence, a patient's knowledge and values about screening. I return to "PSA patient" types in Section 7.3.

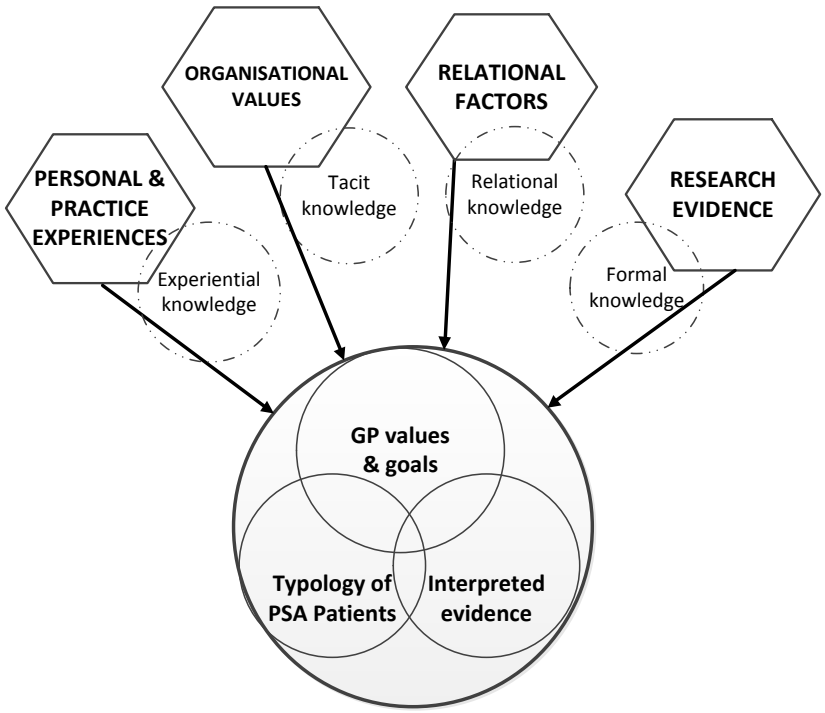
To re-cap, I have explained the relevance of GPs' interpretations of the evidence, variation in values and goals, and patient typologies to the PSA screening process. The following section focuses on four

sources of knowledge which further shaped GPs' interpretations, values, and practice. Note that these sources had influence independently of GPs seeing patients in the clinic.

7.2 Research Question 2: What factors influence GP approaches to PSA screening?

I synthesised the findings of my empirical work (Chapters 3-6) to discuss in this final chapter. When doing so, I noticed that GPs were talking about different types of 'evidence', which they called on (explicitly and implicitly) to help them to decide what to do about PSA screening. I consolidated my observations from Chapters 3-6 and produced four categories, which I labelled 'sources of knowledge'. I describe them here.

Figure 12: Four sources of knowledge (personal and practice experiences; organisational values; relational factors; research evidence) and the type of knowledge that each source provided (experiential, tacit, relational, formal)



Four sources of knowledge influence GP decisions and approach to PSA screening

The first type of knowledge that GPs drew on was *experiential* knowledge. The source of this knowledge was the GP's unique set of personal and practice experiences, particularly those related to PSA screening and prostate cancer. The second type of knowledge was *tacit* knowledge – a knowing *how* knowledge – provided by the GPs' organisational contexts (e.g. professional expectations, conditions of practice, and professional responsibility) and reinforced by organisational values. The third type of knowledge I have labeled *relational*. Unlike the two types of knowledge already presented – knowledge from clinical experience, and knowledge of organisational values – relational knowledge is knowledge from and about interpersonal interactions: about social and professional relationships, expectations, and status. The final type of knowledge that GPs accessed was *formal* knowledge. The source of this knowledge was the research evidence, translated into practice guidelines and recommendations from professional bodies.

Table 14: Sources of knowledge that shaped GP evaluations, the type of knowledge provided by that source, and how the type of knowledge was synthesised

Source of knowledge	**Type of knowledge provided**	**How was the knowledge synthesised?** (by GP or for GP)
Personal and practice experiences	Experiential knowledge	Heuristics (synthesised *by* GP)
Organisational values	Tacit knowledge	Mindlines (synthesised *by* GP)
Relational factors	Relational knowledge	Heuristics and/or mindlines (synthesised *by* GP)
Research evidence	Formal knowledge	Guidelines (synthesised *for* GP)

Sometimes the knowledge provided by each source was explicitly consolidated in practice *by* the GP themselves; in the form of heuristics, or rules of thumb – for example, when a GP established a preferred practice orientation, based on a particular experience/s. Sometimes the knowledge was implicitly/tacitly consolidated *by* the GP themselves; in the form of mindlines – for example, when a GP internalised a way of practicing consistent with the norms of their organisation. And sometimes knowledge was synthesised *for* the GPs by external authorities, in the form of guidelines summarising the research evidence (Table 14).

Now I will explain how the four sources of knowledge interacted with the three central background conditions (interpretations of the evidence, GP values and goals, and typology of "PSA patients") described in Section 7.1.

Table 15: The four sources of knowledge were integrated and used by GPs, with variable influence, when considering PSA screening

	INTERPRETED (GP or other) EVIDENCE	GP VALUES & GOALS	GP TYPOLOGY OF "PSA PATIENTS"
PERSONAL & PRACTICE EXPERIENCES	• Experiences provided tangible, experiential evidence of 'appropriate' care • Warranted particular ways of practicing • Not necessarily evidence-based or in accordance with guidelines	• Values constructed, de-constructed, confirmed, and disconfirmed by experiences • Particular experiences shaped practice goals • Personal screening behaviour influential (based on personal values)	• Experiences provided information about general patient preferences • GPs formed perceptions about specific patient types: "PSA patients"
ORGANISATIONAL VALUES	• Organisations guided what counted as relevant evidence • Organisations created environments encouraging (or discouraging) the utilization of evidence • Policy agendas of organisations influenced evidence use in clinical care	• Organisational contexts shaped/enabled particular GP roles, values, and corresponding goals for practice • Varied by origin and context *UK GPs:* • Shared values and goals professionally-derived, collective, and relatively aligned with other GPs and organisation • Organisational values – and goals – internalised by GPs (mindlines) as personal *Australian GPs:* • Most influenced by individual values and goals, derived from experiences and independent of organisation • Organisational values ambiguous and expected GP role (and corresponding goals for practice) unclear	• Institutional norms and infrastructure shaped what Australian and UK GPs prioritised as an outcome for a patient • Provided context for GP formation of mindlines about what patients want and need
RELATIONAL FACTORS	• Judged relevance of evidence in interaction with patients • Discounted or re-shaped evidence to fit relational expectations	• Values constructed in context of relationships and social interactions • Personal and professional values sometimes conflicted • Some relational factors influenced practice discordant to GP values and goals	• Preferences and characteristics of "PSA patient" derived in interaction • Established starting point for patient engagement (information and understanding)
RESEARCH-BASED EVIDENCE	• Uncommon for GPs to engage directly with research evidence to inform screening practice	• GPs could practice different versions of EBM depending on their values and goals • Some GPs framed evidence to fit with valued outcomes	• Guidelines are largely context-free until integrated and applied by GPs in clinical contexts • Research-based evidence cannot provide specific guidance for individual patients without interpretation

The first column of Table 15 illustrates how the four sources of knowledge were integrated and used by GPs, with variable influence, when considering PSA screening. GPs had very different interpretations of the evidence arising from experiences, organisations, relationships, and research respectively. They rarely discussed relying on research, or syntheses of research, as a source of knowledge: they were far more likely to rely on evidence available from the other sources to guide their practice.

Australian GPs commonly relied upon experiential knowledge as the most direct form of 'evidence' for decision-making. A one-off experience, like a man 'saved' by PSA screening or a man dying of prostate cancer when not screened (Chapter 3), trumped all other sources of evidence. GPs perceived experiential evidence as 'real'; experiences were easily recalled and intuitively meaningful, in contrast to the epidemiological research evidence. However this approach to clinical reasoning makes GPs prone to certain biases, as will be discussed in Section 7.4.

GPs acquired tacit knowledge from their respective organisations, which indirectly shaped their appraisals of the evidence. In Chapter 5 I drew on data from my comparative work to argue that organisational arrangements that provide or limit opportunity for evidence-based screening pathways, partly direct how and which guidelines are received and implemented, and facilitate 'appropriate' evidence utilisation in practice via resources and support. I return to the influence of practice conditions in Australia and the UK throughout this chapter.

In some contexts, relational factors prompted GPs to discount or re-shape the evidence to 'fit' with situational demands. In Chapter 6 I described how particular patient types, for example, strongly influenced whether GPs utilised evidence in screening decisions, and if they did use evidence, how that was done. Relational factors and consumer demand are closely associated and had important implications for GP outcomes and informing future practice (see Section 7.3).

As shown in the second column of Table 15, GPs prioritised particular values depending on experiential knowledge. The GP's professional context shaped the degree to which those values translated into goals for practice. UK GPs described practice goals in line with organisational values

that they shared with others in the profession, and internalised as their own. Most GPs in Australia, on the other hand, constructed individual practice goals in line with their personal values, and independent of their organisation. Experiential and relational types of 'evidence' thus factored particularly highly in the Australian context. Because the GPs had significant scope to practice in accordance with personal values, 'good' screening practice was sometimes in direct contrast to that supported by research-based evidence (formal knowledge) against screening (Chapter 3).

As shown in the last column of Table 15, the four sources of knowledge interacted with how GPs constructed typologies of "PSA patients": most implicitly developed a set of patient 'types'. GPs customised their approach to each patient, or developed a relatively uniform approach to apply to all patients depending on the guidance received from their organisation and how appropriate the GP thought it was to follow this guidance. For example, UK GPs accessed an information resource that facilitated and encouraged a standardised approach to all patients, while what Australian GPs came to know about "PSA patients" (experientially and/or interpersonally) often trumped formal guidance.

Some GPs' constructions of a "PSA patient" were very basic and automatic: "male, 50 years or older". Other GPs' "PSA patients" were very detailed and considered and demonstrated finely-tuned ways that GPs distinguish men; for example, "male, 50 years or older, no family history, requests PSA test after friend diagnosed with prostate cancer, anxious, low health literacy, may not be interested (or able to understand) detailed discussion…". Similar constructions of patients translated into markedly different outcomes, depending on GPs' values, organisational values, and context. An asymptomatic "male, 50 years or older" type in the UK context had significantly different implications in practice than a "male, 50 years or older" in the Australian context: Australian GPs commonly raised PSA screening (and/or screened) opportunistically with this type of patient, unprompted, while UK GPs consistently did not discuss the PSA test with any patient.

Next I describe two 'knowledge filters' (trust and uncertainty) through which GPs evaluated the incoming knowledge. Table 16 illustrates how components of the filters relate to the sources of knowledge.

Table 16: Sources of knowledge that shaped GP evaluations, the type of knowledge provided by that source, how the type of knowledge was synthesised, and the knowledge filters which shaped how that knowledge was received and utilised in practice

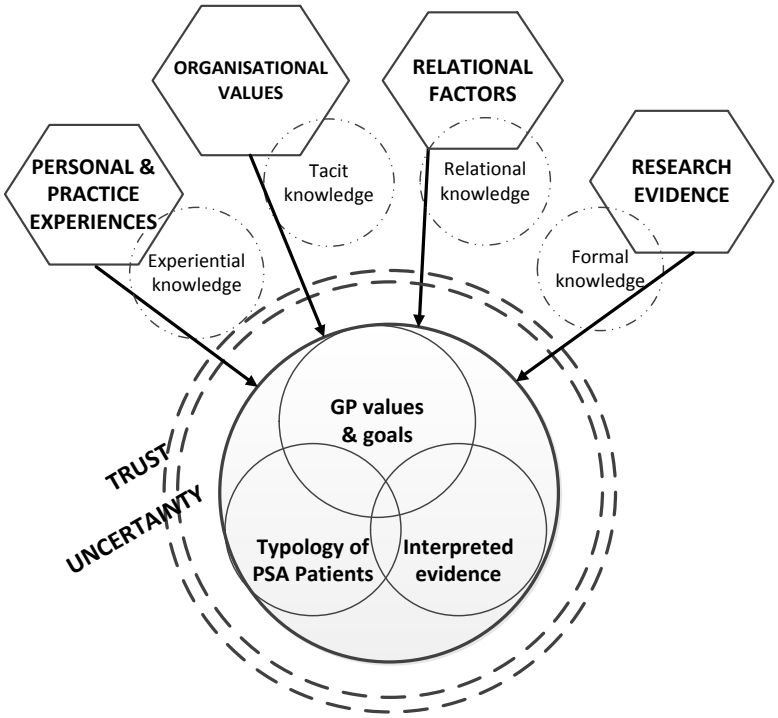
Source of knowledge	**Type of knowledge provided**	**How was the knowledge synthesised?** (by GP or for GP)	**Filter: Type of trust**	**Filter: Type of uncertainty**
Personal and practice experiences	Experiential knowledge	Heuristics (synthesised *by* GP)	Interpersonal	Personal
Organisational values	Tacit knowledge	Mindlines (synthesised *by* GP)	Institutional	Practical
Relational factors	Relational knowledge	Heuristics and/or Mindlines (synthesised *by* GP)	Interpersonal	Practical Personal
Research evidence	Formal knowledge	Guidelines (synthesised *for* GP)	Institutional	Scientific

Knowledge filters

GPs consciously or unconsciously judged the usefulness of each source of knowledge: asking, does the knowledge provided by this source align with or challenge my values? Does this knowledge help me to apply or understand the evidence, or provide more evidence? Knowledge was more likely to be integrated into screening considerations over other types if the source of knowledge was trusted, increased certainty about making a particular decision, or supported practicing in a particular, preferred, way.

Trust and uncertainty are represented as circular in the model (Figure 14) to indicate that deciding whether to trust and responding to uncertainty were ongoing processes, and responsive to changing conditions.

Figure 13: GPs evaluated the four sources of knowledge through two knowledge filters: trust and uncertainty



Filter one: How much do I trust this knowledge?

GPs more or less explicitly evaluated whether sources of knowledge were to be trusted to inform a good decision, or to help provide the best possible care. Here I consider trust – the 'mutual confidence that no party to an exchange will exploit the other's vulnerability' (16) – in terms of its function as a medium of interaction between social systems and individuals, after Niklas Luhmann (17). Trust is commonly conceptualised as being of two types: *institutional* (trust placed in the system or institution) and *interpersonal* (trust placed in the individual or personal relationships) (4). Both institutional and interpersonal types were relevant to the PSA screening process as I describe it in my model.

Longstanding trust in the NHS institution translated to minimal onus on individual GPs in the UK to interpret the evidence, the authenticity of practice recommendations, or to consider underlying interests. When GPs trusted their professional body (i.e. institutional trust) they had confidence in practicing to that guidance – derived from formal research-based knowledge – and in line with organisational values. In contrast, low trust in institutional guidance in the Australian context was common (Chapter 4); GPs found it challenging to locate the best advising authority in which to place

trust due to inconsistent advice, perceived conflicted interests, and 'experts' lack of relevant first-hand experience of the issues. Confusion and uncertainty undermined their overall trust in the system and formal knowledge. In response, many Australian GPs trusted the knowledge provided by individual experiences and relationships (i.e. interpersonal trust) to direct their care.

Filter two: How certain or uncertain is this knowledge?

GPs more or less explicitly evaluated the usefulness, or burden, of incoming information (they asked, *how much uncertainty is this source of knowledge likely to introduce or resolve*?), particularly whether it was perceived to provide more certainty or uncertainty.

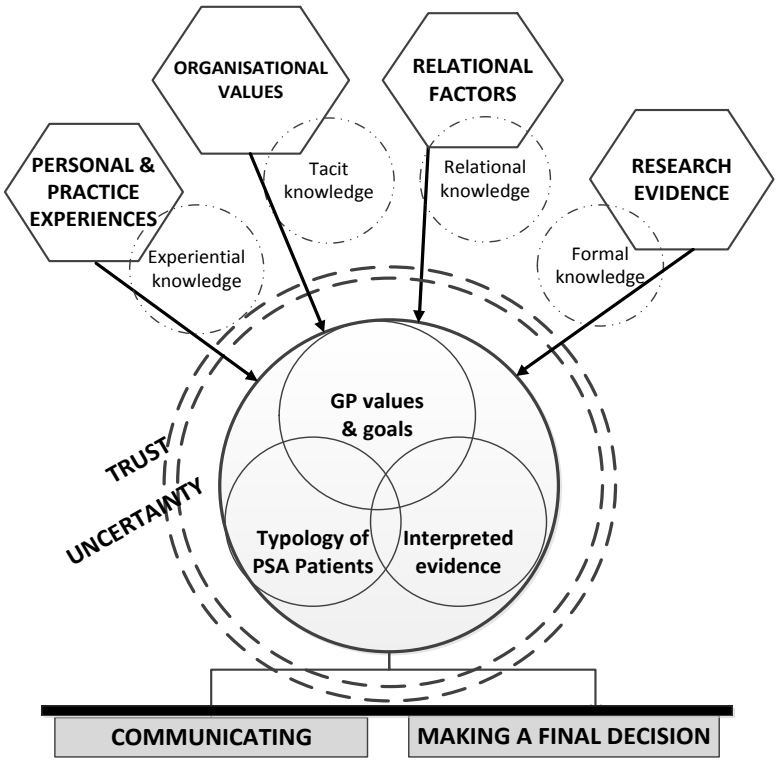
Filtering knowledge according to the degree to which it was uncertain was more necessary for Australian GPs, and less so for UK GPs. This is because in the UK, the healthcare structures and systems were far more strongly guiding than in Australia (Chapter 5). Paul Han conceptualises this kind of uncertainty as ambiguity uncertainty (system-centred)(1). This meant that UK GPs could take the direction from the NHS as a proxy for relative certainty: because GPs in this study perceived the NHS as trustworthy and its guidance as relatively certain, they could assume that the evidence was certain enough. In contrast, because the working environment of Australian GPs has historically contained so much ambiguity uncertainty, with different authorities constantly contradicting one another, they were more likely to perceive the evidence as uncertain, and to feel responsible for confronting this alone.

In the clinical encounter

So far I have focused on the central resources available when GPs were faced with the possibility of PSA screening in general practice. GPs drew on interpretations of the evidence, on values and goals, and their typologies of patient preferences. They could use any of four types of knowledge (experiential, tacit, relational, and formal), from four different sources, and varied their use of these depending on their view of how uncertain that knowledge was, and degree to which the GP trusted institutions and individuals to guide them.

Once the GP had, intuitively or explicitly, mobilised this set of resources available to them, there were several actions they may or may not take once faced with a patient. The solid horizontal line in Figure 15 represents the point at which a GP and patient came together in the clinic. Actions available to GPs included communicating with the patient about PSA screening, making a final decision about PSA screening, and finally doing or not doing a PSA test. I will now explain these three actions.

Figure 14: Most GPs engaged patients in communicating and making a final decision



Communicating and Making a final decision about PSA screening

At this stage, GPs engaged others in communicating and decision making or used their individual judgment to arrive at a decision. Consultations typically involved some degree of communicating and decision making. What that involved exactly, and by whom, depended on how the GP evaluated and was influenced by preceding factors, like relational information (Chapter 6) or uncertainty (Chapter 4). When a patient requested a PSA test, for example, a GP could take several pathways: the GP might (a) have a careful, impartial discussion about the evidence, (b) tell the patient why they should or should not be screened, from a personal or professional viewpoint, (c) issue an information leaflet with more or less talking around it, or (d) do as the patient wishes with no further discussion. Here,

GPs could change a patients mind about wanting a PSA test – some did – but this was mostly limited to those GPs who were highly engaged with the issues, had high trust in their institution to support them to do so, and/or had a patient interested in making an informed choice (Chapters 3, 5, 6).

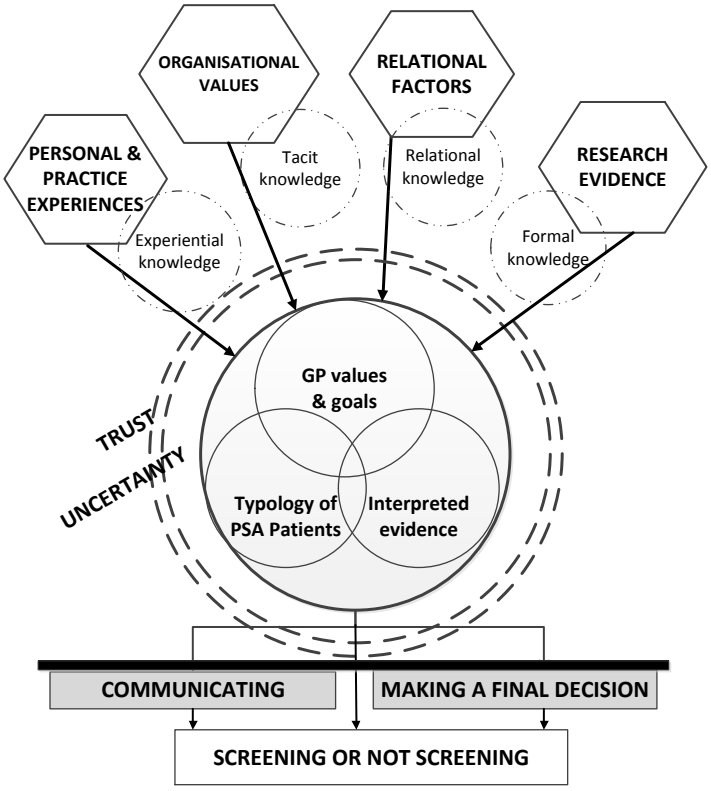
Clinical guidelines were not necessarily useful in aiding communicating or making a final decision. GPs found it challenging to have conversations with men about overdiagnosis for example (Chapter 3), and felt conflicted about involving patients in making decisions based on uncertainty (Chapter 4). At times, GPs determined that not all patients wanted to be active participants in the process (Chapters 3, 6). I have accordingly shaded Communicating and Making a final decision grey in the model because they are actions that sometimes happened and sometimes did not before a man was screened or not screened. The screening context determined their relevance (Chapters 5, 6): some institutional arrangements create more or less opportunities for discussion and involvement, from mailed pathology forms without a consultation in the Australian context (no opportunity) to staggered two-step appointments in the UK (ample opportunity) (Chapter 5).

7.3 Research Question 3: What are the consequences of this process?

Screening or not screening (Do GPs screen, or do they not?)

The point of this analysis is to help explain how and why a GP does or does not order a PSA screening test. While the outcomes might seem simple (yes/no, do they or don't they test) as the model shows there are many factors that can influence whether or not the test occurs, and even the degree to which the GP considers whether or not to test, or alternatively simply tests, or not, out of habit.

Figure 15: Screening outcome: Do GPs order a PSA test or do they not?



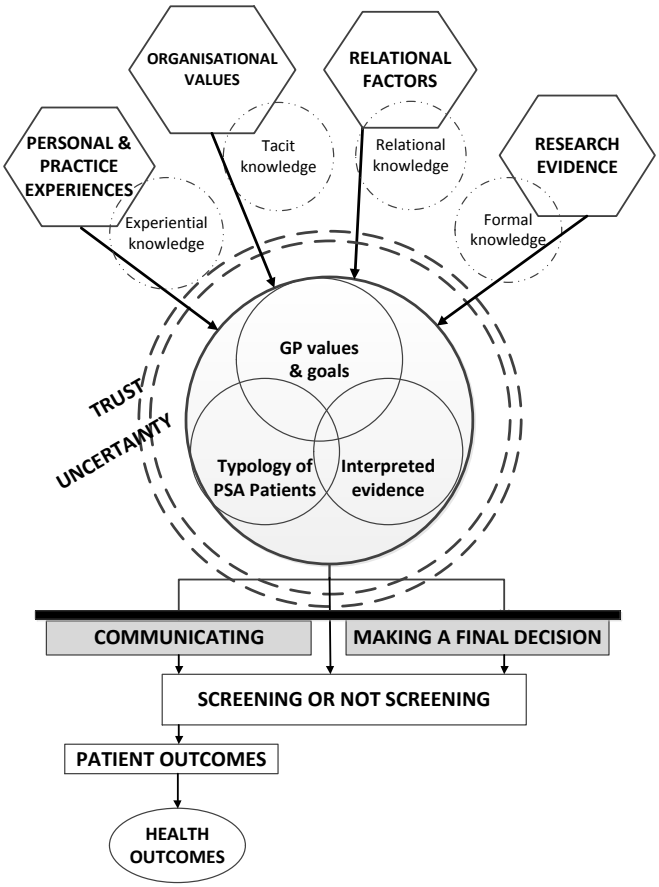
There were GPs who carefully weighed up the consequences of screening versus the consequences of not screening, and were deeply engaged in the process. They located this decision in the broader context of additional testing and treatment and associated harms (Chapter 3), and decided on the 'best' trade-off of risks and harms for the patient and/or the GP personally, in interaction. Having intimate knowledge of the fundamental issues did not make screening or not screening any easier (Chapter 3, 4). It is conceivable that some GPs will value early detection while others might want to avoid screening and treatment harms (Chapters 3, 4, 6).

A number of GPs were not necessarily thinking about ordering a PSA test in an evidence-based or patient-centred way. They were highly concerned about missing cancers and aimed to uniformly screen all men (Chapter 3), they felt anxious about legal ramifications, maintaining business, or preserving relationships with urologist colleagues (Chapters 3, 6), or screened in the pursuit of some certainty in this inherently uncertain situation (Chapter 4).

A relatively common scenario in the Australian context was where a GP's screening behaviour was habitual, a routine, or the PSA test was constructed as "just another test". GPs who did not engage with issues of overdiagnosis or underdiagnosis, or who ordered a PSA test in a battery of routine blood tests (Chapter 3, 4) illustrate the routine approach described. This process may represent (a) an active coping strategy to simplify the complexity, (b) an automatic process that may or may not involve internal reflection on the part of the GP, or (c) GP ignorance. These actions had direct implications for patients (Chapter 6) including patient satisfaction with the process, understanding of the issues, and health outcomes. I discuss patient outcomes in the following section.

Patient outcomes

Figure 16: GPs valued and prioritised different outcomes for patients



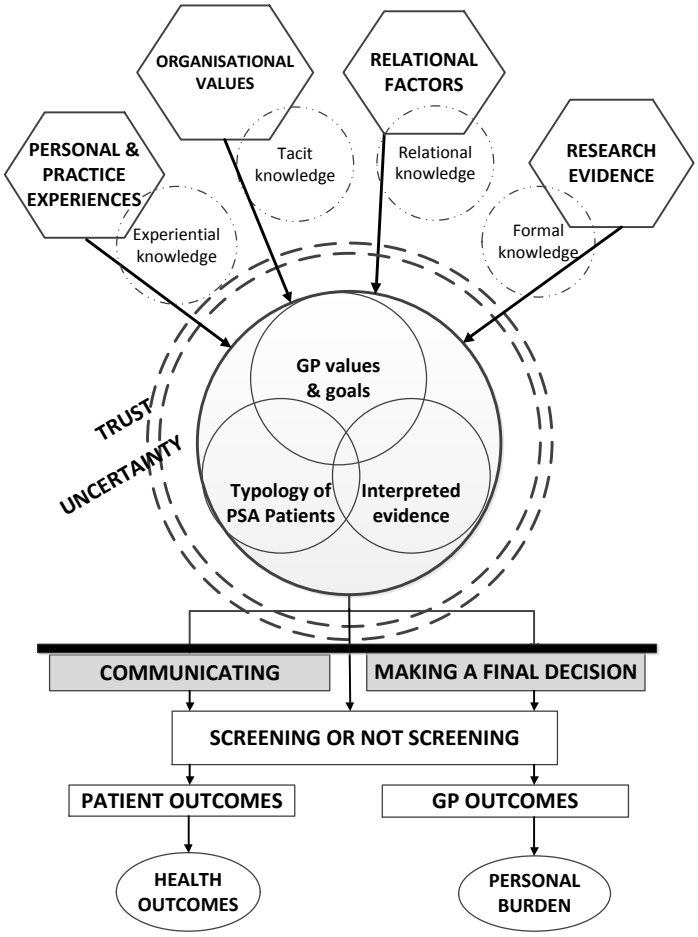
Whether, on balance, a man is likely to benefit or be harmed by PSA screening, remains a debated issue. Thus a GP, policymaker, or epidemiologist's conceptualisation of a 'good' patient outcome may differ to that valued by a patient. One patient's 'ideal' outcome might entail accessing a PSA test with little resistance; another's might be receiving reassurance (personally, or for a concerned partner or family member) about why screening is not warranted (Chapter 6). However GPs commonly reverted to intuitive "PSA patient" types to help them to decide whether to involve patients in the process and if they did, how that should be done (Section 7.1). Processes of care thus could transpire according to GPs' heuristics of patient values, rather than actual patient values. The *Be Screened (or Do not be screened)* and *As you wish* approaches described in Chapter 6 are good examples of the spectrum of patient involvement. In *As you wish* interactions GPs were led by the patient and their stated preferences, without questioning those wishes, while GPs strongly directed care in *Be screened* and *Do not be screened* interactions.

Some GPs did describe practicing to patient-centred values: valuing patient autonomy, facilitating informed or shared decisions, and fostering patient trust (Table 13), but the same espoused values could translate into very different practice from one GP to another. Because patients in Australia do not have the kind of continuity of care that is more typical in the UK, any given man could potentially see a range of possible GPs with a range of values. I have shown throughout this thesis that GPs are likely to vary widely in their PSA screening practices: some GPs' routines reduced, and some increased, the probability of negative patient outcomes such as false positives, overdiagnosis, worry and anxiety, or limiting opportunity for patient consent.

GP outcomes – personal burden

The emotional and cognitive personal burden borne by some clinicians identified in this study was significant, particularly for GPs practicing in Australia (which I explain below), and is likely a neglected issue in mainstream coverage of the topic. Personal burden will be the focus of this section and Table 17 below.

Figure 17: Personal burden was a significant and taxing outcome for some GPs in this study



I am using the term 'personal burden' to group GPs' reports of having to cope with feelings of worry, guilt, self-blame, regret, insecurity, and anxiety. The underlying source of the burden experienced appeared to be about confronting tension created between what the GP was able to do or wanted to do (e.g. order a PSA test, not order a PSA test, do an 'effective' job, avoid over or under diagnosis), and what the GP ought to do according to advice from professional organisations (Table 17). A good example of the experience of personal burden is the GPs who were torn between balancing overdiagnosis and underdiagnosis, reported in Chapter 3.

Personal burden was not a universal experience: not all GPs reported burden and there was diversity in the experience of it in those who did report it. This experience was unique to GPs practicing in Australia when compared to GPs practicing in the UK (Chapter 4). There are conditions in the contexts of GPs practicing in Australia that produced or shaped an emotional response, and conditions in the practices of GPs practicing in the UK that buffered GPs from potential burden (Chapter 5). The UK

comparison is an important reference because it demonstrates that it is possible to have a system response to PSA screening that does not burden GPs or have implications for their emotional wellbeing. I return to this argument in Section 7.5.

GPs who engaged with the most troublesome and contentious issues ultimately suffered the most burden. GPs who did not engage with the issues in any depth were mostly relieved of burden. This is the great paradox of PSA screening: the harder a GP tries to locate answers or certainty (turning to the evidence, professional guidance, or via more screening and investigation), the more uncertainty they will find or introduce and the more burden they are likely to experience (Chapter 4).

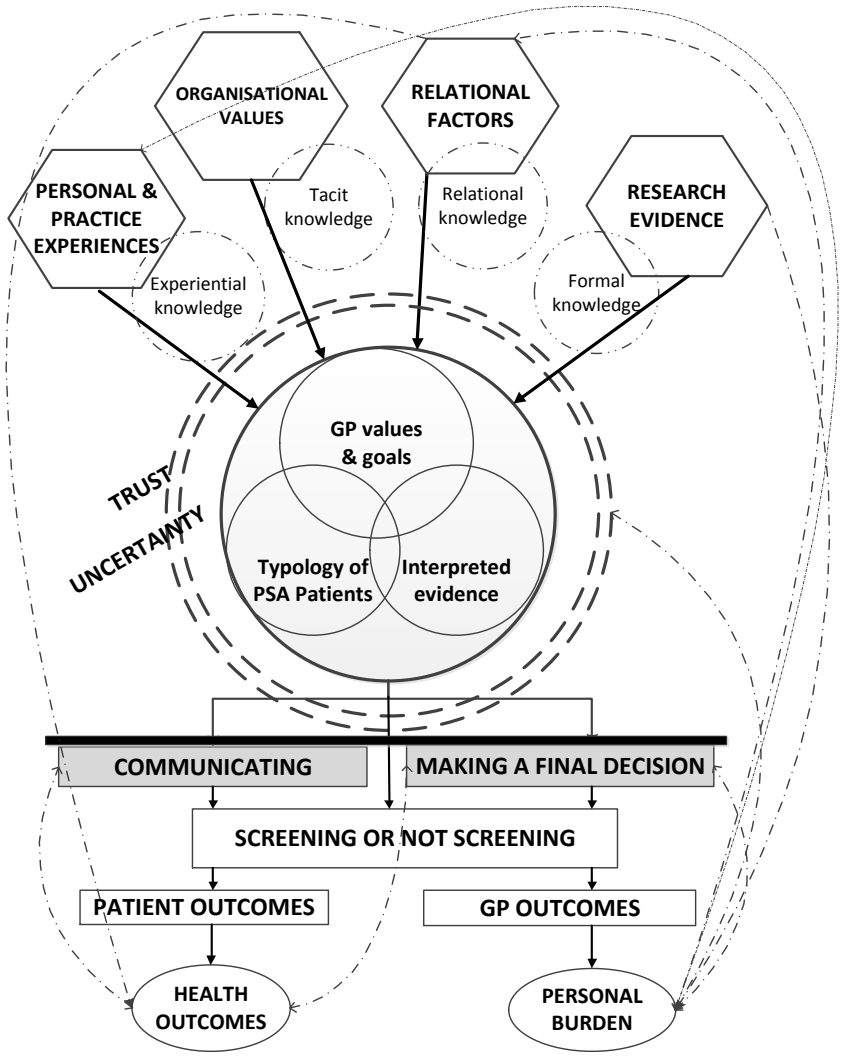
Table 17: GP experiences of personal burden

Source of personal burden	Characteristics of GPs who experienced this type of burden the MOST	Characteristics of GPs who experienced this type of burden the LEAST	Chapter in which personal burden was described
• No clear ideal, evidence-based course of action	• GP wanting to practice consistent with recognised 'evidence-based' standards • GPs concerned about overdiagnosis, who prioritised less screening • GPs who tried to understand or resolve uncertainty • GPs who tried to engage others in managing the issues	• GPs concerned about underdiagnosis, who prioritised screening • GPs who believed that screening saves lives • GPs not engaged with the issues • GPs who shared or transferred responsibility to others	#3: Overdiagnosis #4: Uncertainty #6: Communication
• Discordant and ambiguous advice from the medical profession and professional organisations	• Australian GPs who sought 'best practice' guidance • GPs who engaged with the issues	• GPs practicing within the UK health system • GPs who followed their own screening protocol • GPs not engaged with the issues • GPs who did what patients wanted	#3: Overdiagnosis #4: Uncertainty #5: Comparison
• Concern about burdening patients (with uncertainty, complexity, negative outcomes)	• GPs who tried to engage men in discussion about the issues • GPs who sought informed decision making and consent	• GPs who made decisions on behalf of patients • GPs supporting the attitude that GPs don't have to have the answers to everything • GPs who felt supported in their chosen screening approach	#4: Uncertainty #6: Communication
• Consumer demand	• GPs practicing within the Australian health care system • GPs who did not support screening • GPs who ordered PSA tests when they did not want to	• GPs practicing within the UK health care system • GPs who did what the patient wanted	#5: Comparison #6: Communication

Outcomes and experiences informed GPs' future practice

Sayer acknowledges that sedimented values are not completely stable, and can be recursively re-shaped by particular practices, persons, relationships, or institutions – which might affect our future valuations and influence how we act (14). The outcomes and experience of GPs' practice became important sources of knowledge for GPs' future practice, implicitly and explicitly. These 'feedback loops' provided knowledge *for* practice and knowledge *from* practice (represented in Figure 19 as broken lines bordering the model). GPs developed new rules and acted in particular ways in response to outcomes observed and experienced in the clinic (Chapters 3, 6).

Figure 18: Broken lines illustrate ways in which outcomes and experiences informed GPs' future practice



GPs confirmed, validated, or modified their screening behaviour based on the 'new' evidence gained in practice from a decision or approach that 'worked'. For example, GP experiences of personal burden, or having a patient 'saved' from PSA screening. GPs directed subsequent practice towards avoiding or achieving that experience or outcome.

Outcomes and experiences are not necessarily a source of reliable information, primarily because PSA screening provides false certainty. Normal PSA results, and biopsy-confirmed prostate cancer following screening (even if indolent), provide 'evidence' supporting the benefits of PSA screening. Both examples can erroneously reassure GPs, and patients, that screening is worthwhile, create consumer demand, and prime GPs to screen more if they find more prostate cancers. One GP did not screen and had a man die of prostate cancer; subsequently that GP screened all men; then a patient suffered a perioperative stroke following treatment. The GP was left in a position of feeling she/he had personally contributed to both outcomes. This case demonstrates that reasoning for all patients based on single cases is flawed. It seems likely that GPs' chance case experiences can skew their perceptions of the evidence generally depending on what cases they confront. I return to GP reasoning and cognitive biases in the following section.

Some 'feedback loops' indirectly encourage dubious screening practice; for example, financial incentives, healthcare system incentives (including to fill demand), and perceived threat of malpractice. Other system features block important feedback and create the opportunity for less than ideal practice, such as practice recall systems.

7.4 How can we explain current prostate cancer screening practice?

Each empirical chapter of this thesis offered a focused explanation of current PSA screening practice, from the perspective of GPs, drawn from the developing analysis: GP reasoning about under- and over-diagnosis, experiences of uncertainty, structural and organisational differences between screening contexts, and GP goals for the screening interaction. This section draws on and extends those discussions, informed by my empirical findings in combination with existing literature about knowledge, values, trust, uncertainty, and clinician wellbeing. I focus on four explanations: (1) GPs

implicitly or explicitly prioritise knowledge derived from their local environment (proximal knowledge); (2) GP reasoning, like all human reasoning, may be prone to cognitive bias; (3) there are complex layers to the screening process, each infused with values; and (4) GPs feel personally responsible for adverse consequences.

GPs implicitly or explicitly prioritise proximal knowledge

The four sources of knowledge that I described throughout this Chapter represented important points of reference for screening decisions; the knowledge provided by each source is not necessarily formal or "evidence"-based. Clarke and Wilcockson (2002) distinguish between two kinds of knowledge: *distal* knowledge created and derived from outside of the care environment (for example, research evidence, clinical guidelines) and *proximal* knowledge, derived from within a specific care environment, and dependent on contextual issues within that environment (5). When making decisions about PSA screening, GPs in this study prioritised and applied proximal knowledge – acquired from personal and practice experiences and organisational and relational contexts – over distal knowledge. Each source of knowledge was synthesised either *by* the GP (proximal) or *for* the GP (distal) to make sense in clinical practice.

Distal knowledge indicates professional standards of care, and is generally expected to drive evidence-based practice (18, 19). However you will recall in Chapter 5 that I proposed that GPs construct 'mindlines' from their specific care environments, after Gabbay and le May (2). Mindlines fit a view that knowledge is created and re-created in different contexts by a process of reduction and prioritisation of potentially relevant knowledge of different kinds (20). All GPs accessed diverse forms of proximal knowledge meaningful to their local context – not all conscious and explicit – and practiced in a way that made sense to their practice.

UK GPs primarily drew on tacit, proximal knowledge from their organisation. Because medical practice is fixed in externally legitimised knowledge and practices under the UK's NHS system (21), their mindlines and practices were strongly influenced by distal knowledge embedded in their organisation. For Australian GPs, proximal knowledge from experiences and relationships seemed intuitively

trustworthy, provided relative certainty when compared to distal sources, and enabled GPs to practice in a way consistent with their personal values. Clarke and Wilcockson argue that there is instability in decision making based on rapidly fluctuating proximal knowledge compared to the relative stability of distal knowledge (5). However, as I have explained, proximal and distal knowledge were not entirely separate entities. Some forms of proximal knowledge incorporated elements of distal knowledge and were thereby relatively stable and consistent sources. Individually interpreted proximal sources were more prone to personal biases, which I will now explain.

GPs' reasoning may be more or less subject to cognitive biases

Relatively judicious clinical reasoning is preferred over intuitive judgment in EBM (8) but was not common practice for GPs in this study. Rather, GPs synthesised knowledge from proximal sources via heuristics and mindlines and these played an integral role in helping GPs to navigate the complexities of PSA screening decisions and actions.

As noted, some knowledge may be more affected by cognitive biases and arbitrary reasoning than others. Heuristics are shortcuts in reasoning: intuitive cognitive processes that ignore parts of information to make decisions more quickly (22), and often develop beyond one's awareness (23). In this study heuristics were constructed by individual clinicians from specific interactions and related to their own clinical activity. For example, "this patient is the same type of patient as Mr Jones". Heuristic reasoning has been dismissed as undermining clinical thinking and heuristics as unreliable shortcuts (24, 25). Anchoring to single experiences, for example, can leave GPs susceptible to chance events and the influence of feedback loops. If a GP received evidence from a single experience that "screening saves lives", then they could overestimate the benefits of PSA screening, and maintain that initial impression once formed (26). Other authors suggest that heuristics are often at least as accurate as complex statistics in pointing to the right decision (27), and advantageous for professional practice (28). Making clinical decisions on the basis of heuristics and mindlines reflects the realities of clinical practice, rather than undermining the scientific foundation of medicine (29) or good clinical practice (30). They offer important insight into clinician values, reasoning, and judgments. Heuristics have

limitations, particularly when not adaptive to reflective thought, but are a useful function of clinical expertise, especially under uncertain conditions.

Values, mostly implicit, are embedded in every stage of the PSA screening process

There is often an assumption that research evidence – the epitome of EBM – is value-free. In reality, it is laden with judgments. Politicians, lobbying groups, the pharmaceutical industry, and researchers and universities themselves, influence the defining of research priorities, what counts as evidence, and how knowledge is distributed (20). GPs and patients bring their own values to the clinic. So although evidence is very important in making choices about PSA screening, it is evidence in the context of values, which are equally important.

There are researchers who argue that unacknowledged values are forms of psychological heuristics (31) that act as short cuts and provide immediate answers to problems we choose not to explore in detail (23). Some proponents of EBM argue that values can and should be controlled for as removable sources of bias for this reason (32). Sayer, on whom I have relied for my conception of values, takes a middle position, arguing that values are neither arbitrary, nor beyond the scope of reason. Rather, Sayer describes values as relatively stable ('sedimented') valuations: we evaluate practices, persons, relationships, or institutions based on sedimented values and usually act, at least in part, consistently with those values (14). On this view, values have normative force: they represent judgments about the things that matter – in this case, to GPs – and give decisions and actions meaning, significance, and moral worth (23, 33). They are both normative and potentially reasonable.

In this study, values helped explain why GPs had different priorities and why they made different kinds of judgments: they practiced in a way consistent with their values. There are writers who argue that the values of clinicians inevitably become prescriptive guides to what kinds of doctors they should be and how they should act (34, 35). Australian GPs had diverse ideas about what constituted a good GP and the corresponding 'right' course of action (both generally and particularly in respect of PSA screening), and were strongly guided by their personal (often conflicting) value systems. UK GPs were more strongly guided by values embedded in collective commitment to their profession, which left less

room for an independent effect of their personal values. The UK-based GPs I spoke to appeared to practice the way they did not mostly because they were prohibited from practicing otherwise, but because they had internalised a set of commitments and trusted the institution in which they were practicing to support that expected standard of care. Australian GPs had low institutional trust, for reasons outlined previously, high uncertainty about professional expectations, and expressed a strong sense of personal responsibility (and anticipated burden) for their actions. Because of discordant opinion, GPs in Australia could reasonably claim a professional commitment to different authoritative bodies to justify different practices, as there was authoritative advice available to support or reject many different courses of action with regard to PSA screening.

GPs' sense of personal responsibility for adverse consequences creates burden

The complexity of the screening process has been obscured by research and debate focused on the flaws in PSA screening evidence and policy, with little consideration for the GPs involved. The prostate screening literature tends to neglect the fact that many GPs who are not adequately supported experience considerable emotional and cognitive burden as a result of having to manage the PSA test. Literature from other healthcare contexts, such as emergency departments, similarly suggests that the wellbeing of those working in the 'helping professions' can be seriously compromised if they are not supported to perform their role (36). Yet compassionate and empathetic appreciation of the social, ethical, and emotional challenges faced by doctors in their routine daily work is often lacking (37). This study highlights the existence of a number of factors – ambiguous advice, uncertain expectations, and patient demand – that contributed to emotional and cognitive burden for GPs. To fully understand the practice of PSA screening in Australia requires understanding and taking seriously that burden. Health outcomes for patients are always a priority, but the wellbeing of practitioners is also important for a number of reasons including the sustainability of the healthcare system, the safety and quality of patient care (38), and simply what they are owed as fellow human beings. If the health system is to take doctors' wellbeing seriously, then those with agency in the health system will need to intervene, and to do so in ways that will not only improve outcomes for patients but also support GPs.

7.5 How might GPs be best supported to respond to current practice demands?

Throughout the empirical chapters I described a range of GP perspectives on these issues and drew on that information to make suggestions for policy and practice. Each chapter called for a considered response to current prostate screening practice as a priority, informed by GP insight about the challenges presenting in the clinic: GPs feel personally burdened making screening decisions under conditions of considerable uncertainty (Chapter 3 & 4); GP values and goals for practice determine men's (unequal) access to information and consent to PSA screening (Chapter 3, 4 & 6); and healthcare system factors, including social and funding structures, incentivise particular ways of practicing, which are not necessarily consistent with evidence-based or ethical practice standards (Chapter 5).

There are several ways in which explanations of the PSA process produced in this study can aid both GPs and those who wish to influence their practice. My findings suggest that to be effective, strategies must: (1) take account of the unique conditions of clinical interactions, including the different motivations (values and goals) of GPs and the consequences of importance to them (Section 7.1); (2) recognise the range of 'evidence' sources informing practice (Section 7.2); (3) consider the significant influence of trust, uncertainty, and patient engagement (Section 7.2); (4) account for the way in which case experiences can shape future practice (Section 7.3); and (5) acknowledge the substantial challenges faced by GPs, including the experience of personal burden (Section 7.3). In this final section I propose strategies at the level of the healthcare system, GPs' local practice environments, and targeting individual GPs, to offer important guidance for future policy and practice.

At the healthcare system level

In Australia currently, GPs receive extensive pressure to screen (Chapters 1, 3-6). There is an established screening culture, mostly in favour of PSA screening. Screening enthusiasm is perpetuated by mainstream media, creating significant patient demand. My UK comparative work illuminated – by contrast – features of the Australian healthcare system that encourage more rather than less screening (Chapter 5). Payment systems and a corresponding market for screening provide incentives to screen

in combination with less stringent conditions for providing the PSA test. GPs can refer borderline uncertain 'grey' PSA results to urology with no consequence, and urologists profit from this process. Australia has perhaps inadvertently established a system over the years that makes it much easier for GPs to order PSA tests than not, and with ample opportunities to do so.

There are no or few feedback loops that are negative or discouraging for clinicians who routinely screen patients in Australia (39). GPs receive credit for 'curing' disease that would never have harmed, positive feedback from patients for 'saving their life', and alarming feedback from patients with missed diagnoses (40). There is little reward for GPs avoiding overdiagnosis (Chapter 3). Patients can feel they have missed out, have not had enough care, or feel frightened about not knowing, and GPs are left with uncertainty and anticipated decisional regret (Chapter 4). GPs receive no feedback from patients whose cancer was overdiagnosed.

Inbuilt feedback mechanisms in the Australian healthcare system, such as these, require immediate attention: they conflict with goals of reducing unnecessary or harmful prostate screening, have considerable ethical and public health implications, and substantial cost to the healthcare system. Although individual GPs undoubtedly have a role to play in reducing the prevalence of PSA screening, it is (1) difficult for individual GPs to find solutions alone because of the dominant social, financial, and political factors contributing to the current situation, and (2) arguably beyond the professional responsibility of individual GPs because these complicated circumstances – creating demand, expectation, and uncertainty – are not typically addressed in EBM directives (41).

Debate over the appropriate healthcare system response to PSA screening has been controversial for decades (Chapter 1). My UK comparison case provides good evidence that system-level changes could effectively influence a different and arguably 'better' way of practicing. I suggest 'better' because UK GPs rarely experienced the uncertainty or personal burden described by Australian GPs, in combination with documented comparable death rates despite considerably less screening. In Chapter 5 I suggested that systems-level features such as the two-step screening process described in the UK may help to avoid overuse, ensure adequate information provision, and ultimately maximise opportunities for GPs to create evidence-based mindlines. Financial incentives, penalties, funding

arrangements, tort reform and clarification, and established consent protocols may put additional explicit boundaries around what is considered acceptable practice. For instance, GPs in Australia can currently order PSA tests routinely, without discussion, or in a battery of other blood tests, with or without patient knowledge. Structural intervention, with insight from this study, may gradually influence a shift in GPs' default screening positions (e.g. 'tick box' screening) by strongly discouraging or preventing particular approaches while providing pathways encouraging more evidence-based care.

It is necessary that strategies are sensitive to context if policymakers want them to be applicable and utilised. Some interventions will be effective in some contexts but not in others. Adopting practice from the UK model will be futile if those strategies cannot work in the Australian context because of the challenges I have presented, the different healthcare systems, and established clinical practice (fewer men in the UK request a PSA test and fewer GPs suggest a PSA test). PSA screening is accepted as routine care in Australia; many will not see any problem with the status quo, and some have a vested interest in maintaining this. The UK has taken a consistent, blanket approach that is rarely complicated by individual patient request or contested professional guidance; thus it works in that context. In 2012, the RACGP advised its members not to raise the issue of PSA screening unless requested by a man. This is likely an ineffective approach to addressing routine screening (and many GPs reported it to be so) because too many men and GPs know about the PSA test and are actively using it in practice. If men know the test is available - GPs said it is hard not to bring it up.

The two health systems are historically significantly different, but it seems reasonable, given that the evidence is international and the cultures of the two countries similar, that there should be similar expectations of GPs in terms of practical and ethical obligations, and that they can in turn expect to be supported by the system (with resources) to practice within that framework, regardless of their starting position. The challenge is to intervene in the system to provide them with the supports and structures that will facilitate this. Australian policymakers, medical organisations, and individual GPs could be implementing small, targeted changes in numerous places to collectively impact on screening attitudes and default screening positions, with a particular focus on the feedback mechanisms built

into the Australian healthcare system. Future generations of men and GPs should be able to have the opportunity to decide what is best, without being influenced by the current culturally- and market-driven screening enthusiasm. Some efforts to intervene have begun in the Australian context, such as the impending release of a patient decision aid and a push to publicly fund PSA tests with screening intent every two years, rather than annually, to align with the recently revised prostate screening recommendations. An informed understanding, and consideration for the broad and local circumstances contributing to screening patterns is imperative to influencing sustainable and effective changes; I propose possible solutions at the local level in the following section.

In the practice environment

Addressing the specific care environments in which decisions take place and where heuristics and mindlines are formed can alter the organisational routines in which GPs' personal routines are embedded (2). Many of the issues identified and questions raised in this study are not resolvable with scientific clarity or explanations, and guidelines (formal, distal knowledge) in isolation seem incapable of offering a simple solution to the 'swampy lowlands' (42) – the confusing, 'messy' human concerns - of this clinical problem. Guidelines commonly attach no value to many things that matter to GPs, in particular, those things that may be undermining GPs' perceptions of the usefulness of the scientific evidence. These include avoiding underdiagnosis, preserving professional legitimacy (Chapter 3), or responding to everyday clinical realities such as patient demand (23). Mindlines have also been largely ignored by those responsible for the development of guidelines (20). I have shown that GPs perceive there to be a proliferation of mutually contradictory formal guidelines in this area, which consequently has undermined trust in formal guidelines in general on PSA screening; I have also shown the relevance of mindlines to GPs' practice in this area. These two findings suggest that what may be more pressing than the development of yet another prescriptive guideline may be the additional provision of clear guid*ance*, taking account of the significant diversity in GP approaches and the considerable ambiguity uncertainty they described. I have argued throughout this thesis that it is not unreasonable for GPs to expect that expert bodies will provide clear guidance wherever possible, with explicit

acknowledgement of the challenges faced by GPs when balancing these issues. Professional guid*ance* would focus on process, in combination with explicit endpoints outlined in guidelines.

I suggest a collective effort from medical authorities to deliver guidance – involving open and transparent professional discussions – to clarify expectations, obligations, and to support GPs to make it possible to provide the best possible care, to practice to expected professional standards, and in specific local environments. This guidance may entail a suite of best approaches – to match the multiple, dynamic approaches of GPs (Chapters 3-6). For instance, flowchart guidance for GPs unclear about the screening process as a whole (especially relevant to those GPs treating the PSA as just another blood test); or professional training with GP educators to guide GPs not confident with application of knowledge or with resisting deeply (historically) ingrained attitudes and practice that are not aligned with current recommendations. The Journal of the American Medical Association (JAMA), for example, followed publication of new cholesterol guidelines with a pragmatic article on how to apply the guideline in clinical practice and when to consider ignoring it (43). Detailed 'how to' resources built into online systems accessible in the clinic, including less conventional issues (e.g. 'how to' – ethically and legally – discourage men who ask for a PSA test), might be useful starting points to support GPs, and create opportunities for reflective critical dialogue amongst clinicians and the profession. Integrated process evaluation (to identify inconsistencies in implementation) and outcome evaluation (to monitor effectiveness in practice, including unanticipated consequences) of the suggested interventions would be essential. For instance, educational visits for GP training purposes may be well received and increase GP knowledge, but effect little change in their screening behaviour.

Even with clear and consensual professional guidance, there is always likely to be some range of variation in practice. However some types of variation will be reasonable, while others will arguably be unacceptable. Conditions that would justify variation include GP and patient values, specific practice conditions, and the unpredictable realities of general practice. Reasons for variation that could reasonably be rejected include practice motivated by profit or protecting reputation; or indiscriminate, defensive, or automatic screening due to clinician disengagement with the central issues. This is because screening is not inconsequential: there is potential to cause considerable and

irreversible harm to men (e.g. overdiagnosis and overtreatment) and to the healthcare system (e.g. financially, resources, trust in the profession). I suggest ways in which policymakers and the profession can intervene on individual GPs or groups of GPs – perhaps practicing in this way – in the following final section.

At the individual GP level

Behavioural researchers propose strategies like facilitated workshops, role-play with clinician educators, and self-monitoring activities in clinical decision making to stimulate behaviour change in health practitioners (44). However my model of PSA screening practices, from the perspective of GPs, suggests (1) it is not reasonable to just intervene on GPs and expect them to change, without also changing the many elements of the system that permit or even press GPs into screening; and (2) it will be important to consider not just end points (behaviours) but also the many parts of the process that lead to the behaviours: sources and types of knowledge (proximal and distal, formal and informal, explicit and tacit), trust and uncertainty, and the set of resources – interpretations of the evidence, GP-held values and goals, typologies of patients – that a clinician brings into the consultation.

Although in this section about implications I focus on PSA screening because this was the focus of my research, it seems important to note that, as generalists, GPs are faced with a wide array of patients and clinical presentations each day, and need somehow to remain across the practice recommendations for each of these presentations. Thus any of the recommendations below need to be considered in light of the many demands on any individual GP's expertise and time.

Nevertheless, given that PSA screening is prevalent in Australia, is generally thought to generate considerable harm, and could be otherwise (as demonstrated by the UK case), it seems reasonable that PSA screening should be one of the priorities for practice improvements in Australia. Prostate cancer screening is one issue in a collection of current challenges to primary care. It has been recognised as one of several key areas requiring attention under the international 'Choosing Wisely' programs, which are centered on reducing overuse and overprescribing, iatrogenic harms, and wasted resources. PSA screening is a good case study to draw from to question problematic practices that have become

ingrained in the health care system and in clinicians' routine care, for challenging the way we think about healthcare, and designing for a more sustainable health care system delivering more effective, necessary care. Recent policy shifts would suggest that PSA screening is an ongoing public health priority in the Australian context.

Sources and types of knowledge

Key skills for processes conducive to evidence-based knowledge translation include first knowing who to trust for useful and reliable advice; and being able to question that advice (i.e. critical appraisal skills) (30). Tonnelli argues that institutions need to facilitate training of doctors in critical appraisal of all sources of evidence, equivalent to the training they receive for appraising scientific evidence (45). Individual clinicians also need to have capacity (with institutional support) to question professional advice. Current medical education reportedly rarely teaches students how to manage and/or resolve potential conflicts of interest, for instance, despite their being ubiquitous in the profession (46). Researchers have designed social models to train clinicians to recognise social and cultural forces shaping evidence, decisions, and policies when making clinical decisions (e.g. (47)); and the Consider an Offer framework described in Chapter 6 entails critically evaluating professional guidance (3).

Continuous and critical evaluation of one's own and others' medical practice is important to ethical and evidence-based practice. A great deal of unreflective practice, and acceptance, was evident in both Australia and the UK: GPs reached decisions before being able to explain their reasoning for doing so, and/or ceased to register any conflicting evidence. Paying specific attention to intentional and meaningfully engaged practice is warranted, with a focus on developing more nuanced clinical expertise and ethical judgment (48).

Clinicians will continue to use shortcuts in reasoning like heuristics to manage the cognitive load of medical decision-making; some are essential to clinicians' understanding and practice of the 'art' of medicine. But as noted, they can be biased by availability and memorability. Further research into intuitive and heuristic reasoning and how evidence might be incorporated into such reasoning is necessary; Gigerenzer et al argue that if the profession can formalise and understand heuristics then

their use can be effectively taught, leading to less practice variation and more efficient medical care (22). Greenhalgh et al proposes that deeper study of mindlines, to determine how best to produce expert clinicians and expert patients, is key to preventing further harm (49).

Trust and uncertainty

In Australia currently, there are many voices of authority advising GPs on 'best practice', creating confusion and uncertainty about expected standards of care and longstanding distrust in the overall system because of ongoing disagreement (Chapter 4 & 5). In addition, GPs perceive there to be much at stake for them individually in relation to prostate screening and scope to take a 'wrong' course of action. GPs feel uncertain, distrust the evidence and authorities, and experience burden when grappling with the difficult value and normative judgments under these conditions. Building institutional trust is of high priority in taking seriously issues of trust, uncertainty, and the cognitive and emotional burden experienced by GPs, as well as cultivating evidence-based approaches. Institutional trust includes trust in groups of people like doctors, and in systems of knowledge, like science (50).

In building institutional trust, the aim is to establish trust founded on professional roles, rules, and norms. This could include, for example, the introduction of formal conversations amongst clinicians in a clinic with the aim of agreeing on collective norms and targets and accepting mutual responsibility for achieving them (30). The goal of such endeavors is not only to build institutional trust, but to in turn bring individual GP values in line with those of their organisation (or to provide support for GPs to practice in a way that is somewhat discordant with their personal values if this serves other, arguably more important, values such as reducing harm or maintaining trust). Other goals include to reduce dissonance, uncertainty, and burden at the individual level, and to reduce reliance on unreliable sources of knowledge at risk of cognitive bias and jeopardising patient care, such as one-off experiences.

Institutional trust underpinned UK practice. The challenge for Australian doctors is to locate where to place trust with good judgment, and to avoid the groupthink that might arguably come with trusting. It

should be noted that I am not advocating blind obedience, which leads people to stop thinking when confronted with an apparent source of authority, whether human (e.g. a charismatic urologist who advises GPs to start screening all men at 40 years) or technological (e.g. a PSA test result) (51), making people less rather than more critical (50). I am instead proposing that institutions seek to provide a consistent trustworthy platform from which GPs can confidently take direction in combination with applying individual clinical reasoning and expertise.

Central set of resources

In this last section I return to the three background conditions (interpretations of the evidence, GP values and goals, and patient typologies), which were central to GPs' descriptions of their screening approach, and propose how individual GPs might be supported to more effectively utilise these resources in clinical practice.

Interpretations of the evidence. Although it is reasonable to expect GPs to have varying statistical literacy; it is their professional responsibility to be familiar enough with the best current research evidence about PSA screening (not necessarily a detailed epidemiological account) to have an informative evidence-based conversation with patients. Clinicians also have a recognised collective responsibility to ensure their mindlines are concordant with research evidence where possible (2). Some GPs interviewed were already attentive to epidemiological evidence: such GPs might be trained or encouraged to share evidence and uncertainty with patients using decision aids (52), to practice to a consistent standard. Greenhalgh et al note that few clinicians are aware that decision aids, like infographics and options grids, exist (49), so active support is likely to be necessary if they are to be used more often. There is, however, an issue regarding equal access to good quality care for men regarding PSA screening. While GPs may be differently motivated to act in accordance with the evidence and to explain the evidence to their patients, it seems difficult to justify men receiving advice, clinical care, and opportunity for consent more or less arbitrarily, as a result of the GP they happen to see. Thus, over time, and given the high public profile and demand for PSA screening, it does seem important to aim to bring all GPs up to an equivalent standard in their interpretations and communication of the evidence. Main et al (53) describe 'core information sets' which might be useful

to ensure consistent information is provided. Core information sets are constructed by clinicians, for example, and include baseline information which they consider pertinent to a specific clinical problem or process (encompassing values, beliefs, goals) but which is not typically discussed or included in guidelines and decision aids, with their focus on outcomes.

GP-held values and goals. Acknowledging GP values and exploring them seriously and in a formal way should be of high importance in this context: they helped to explain practice variation and the GP experience. Ascertaining and integrating values is an important part of several movements in health care, including EBM (15). Values-based practice (VBP) is a relatively new skills-based approach to working with complex and conflicting values in health care; its proponents emphasise that it can support both evidence-based and ethical practice (15). There are examples of policy and service developments in values-based practice in the UK including a national framework for values-based practice supporting a number of initiatives, particularly in mental health (15). A key starting point in VBP is providing clinicians with opportunities to become more aware of their own values and how they influence their practice (54). Learnable clinical skills – such as communication skills – are also at the heart of VBP, and are essential to arriving at shared understandings of different values and of what matters for effective decision making (15). Given the centrality of values in determining practice variation in this context, any attempt to intervene is likely to benefit from incorporating the principles of VBP.

GP typologies of PSA patients. Identifying and acknowledging patient values is similarly as important and relevant to VBP, but as noted many times throughout this thesis, were not commonly elicited or prioritised in screening decisions. Like GPs, patients will attach different value to different processes and outcomes. A focus on ways to make the values of all parties involved explicit, for reflection, collective deliberation, and ongoing critical appraisal (55), may thus help to locate shared solutions to the complexities of PSA screening.

To summarise:

Target	How might GPs be best supported to respond to current practice demands?
System	• Financial incentives, penalties, funding arrangements, tort reform/clarification • Consider supporting a two-step screening process
Practice environment	• A collective effort from medical authorities to deliver guidance, for example: o Flowchart guidance for GPs unclear about the screening process as a whole o Professional training with GP educators to guide GPs not confident with application of knowledge or with resisting deeply (historically) ingrained attitudes and practice that are not aligned with current recommendation o Detailed 'how to' resources built into online systems, including less conventional issues (e.g. 'how to' – ethically and legally – discourage men who ask for a PSA test)
Individual GP	• Training doctors in critical appraisal of all sources of evidence and to support individual clinicians to have capacity to question professional advice • Teach medical students how to manage and/or resolve potential conflicts of interest (social models have been designed to assist) • Continuous and critical evaluation of one's own and others' medical practice to facilitate intentional and meaningfully engaged practice • Build institutional trust • Aim to bring all GPs up to an equivalent standard in their interpretations and communication of the evidence • Acknowledge GP values and explore them seriously and in a formal way • Values-based practice as a way forward, currently utilised in mental health in the UK

Evidence-based medicine will rightly remain at the core of clinical practice, guidelines, and policies, and healthcare systems, and is ideally the central component of public debate and clinical discussions about PSA screening. However EBM mechanisms alone seem unlikely to be able to influence the future of PSA screening in Australia. Rather than focusing solely on translating research evidence into practice, which to date has been the apparent focus of the NHMRC in this area, it is equally if not more important to think about how GPs can be supported to balance multiple, potentially conflicting, types of knowledge (including that from the research evidence), and to put structures and processes in place to support the informational and emotional needs of GPs. This study has demonstrated the multiple forms of knowledge and resources that are developed over time and mobilised in a PSA screening decision. Given this complexity, it seems important to address the range of influences on PSA screening at the same time, rather than expecting another synthesis of the evidence to do the work. A multi-pronged approach seems more likely to increase effective support for GPs and in turn, to influence reasoned care, curtail inappropriate use of resources, prevent patient morbidity from unnecessary intervention, and reduce GP burden. With recent policy shifts, it is an opportune time to commit seriously to addressing these wide-ranging issues.

In the following section I outline strengths and limitations of this study; in the final section I conclude this chapter, and the thesis.

7.6 Strengths and limitations

Limitations of this study:

It is possible that those GPs who did not participate were in some way different to those who did (that is, that these data are subject to selection bias). However I heard a very wide and conflicting range of views, expressing very different perspectives on PSA screening, and have been able to report significant differences in the range of practice. This diversity suggests that it is, at least, unlikely that I inadvertently sampled a cohort with uniform and unusual reasoning and screening practices.

As in any qualitative study, I am not able to infer prevalence of reported practices, beliefs, attitudes or values. The results of this study could be extended into quantitative survey research with whole populations of GPs to test prevalence. As with any interview-based study, I relied on GPs' own accounts of their reasons, values and practices. These accounts came from Australia and the UK during 2013 and 2014: policy and practice changes over time may change the perspectives of GPs, and my findings may not be transferable to all contexts.

Public and patient perspectives were not included in this study; additional qualitative research might explore their perspectives on interacting with clinicians about PSA screening, to further inform policy and practice.

Strengths of this study:

An empirical synthesis across all PSA screening practice is the unique contribution of this study: it provides a nuanced analysis of how and why GPs test the way they do. I identified what matters to GPs and issues that encourage, prevent, and justify practicing in particular ways. These findings highlight the central place of values, interpretations of the evidence, and the number of divergent value judgments that can be made based on the same evidence-based 'facts'.

I have showed diversity in what GPs considered to be good practice or a good decision or outcome, and the unique influence of informal sources of knowledge, trust and uncertainty, context, and "feedback loops" that are implicated in the process.

Data were derived from a large mixed sample of GPs practicing in two countries; with the inclusion of various practice types and locations. Data may therefore apply to similar settings with similar health care systems. The process model that was generated from this data might have value as a workable model for any primary care encounter, not limited to PSA screening. Future work could investigate whether, for example, the model has relevance when applied to similarly contentious public health issues, such as breast cancer screening: Do the three background conditions apply? Are the four sources of knowledge relevant and if so, how are they balanced? It might also be of interest to examine whether issues of trust and uncertainty are integrated into the decision-making processes of clinicians practicing in different contexts with diverse health care systems, such as the United States. Do clinicians in the US also experience burden? Lastly, quantitative work, integrating elements of the model, could usefully ascertain the prevalence of the concepts evident in my analysis, in larger populations of GPs.

7.7 Conclusions

This research provides an in-depth comparative analysis of important drivers of prostate cancer screening reported from the perspective of GPs in two locations with diverse screening rates. For Australian GPs on the frontline, decision-making about PSA screening is extremely difficult and complex, and often personally burdensome. GP perspectives on PSA screening of asymptomatic men have not been considered in any great detail. The considerably diverse interpretations of 'best' practice illuminated in this study – based on GP values, trust, uncertainty, and context – is important, because GPs are the key reference point for advising on prostate screening. The questionable utility of the PSA test, the recognised harms of the screening process, and the lucrative business of PSA screening are central to considerations. Many GPs in this study felt uncertain, burdened, and/or unsupported, with little professional guidance, in knowing how to respond to these specific demands,

and limited in their capacity to make changes at the clinical level. I began this research project in 2012, the same year that the USPSTF recommendation discouraging PSA-based screening was released. Recently (April 2017), the Task Force proposed an updated recommendation in light of developments in the evidence (see Chapter 1). Policy continues to evolve, and attract substantial debate, in this field, and GPs are unlikely to feel less uncertain now than they did when my PhD research began. Given that past attempts to intervene in PSA screening practice in Australia seem to have had limited effect, a new approach that better reflects the complexity of this issue seems warranted. The model I have developed is one attempt to elucidate how PSA screening can and should be managed in primary care; it is my hope that it will make a contribution to finding more effective solutions.

Chapter References

1. Han PK, Klein WM, Arora NK. Varieties of Uncertainty in Health Care A Conceptual Taxonomy. Med Decis Making. 2011;31(6):828-38.
2. Gabbay J, le May A. Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. British Medical Journal. 2004;329(7473):1013.
3. Entwistle VA, Carter SM, Trevena L, Flitcroft K, Irwig L, McCaffery K, et al. Communicating about screening. British Medical Journal. 2008;337(7673):3.
4. Luhmann N. Familiarity, confidence, trust. Trust: Making and breaking cooperative relations. 1988:94-107.
5. Clarke CL, Wilcockson J. Seeing need and developing care: exploring knowledge for and from practice. International journal of nursing studies. 2002;39(4):397-406.
6. Sackett DL, Rosenberg WM, Gray JM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. British Medical Journal. 1996;312(7023):71-2.
7. Haynes RB, Devereaux PJ, Guyatt GH. Clinical expertise in the era of evidence-based medicine and patient choice. Evidence Based Medicine. 2002;7(2):36-8.
8. Djulbegovic B, Guyatt GH, Ashcroft RE. Epistemologic inquiries in evidence-based medicine. Cancer control: journal of the Moffitt Cancer Center. 2009;16(2):158-68.
9. Sackett DL, Richardson WS, Rosenberg W, Haynes RB. Evidence-based medicine: how to practice and teach. EBM Second Edition Churchill Livingstone: Edinburgh. 2000.
10. Satterfield JM, Spring B, Brownson RC, Mullen EJ, Newhouse RP, Walker BB, et al. Toward a transdisciplinary model of evidence-based practice. Milbank Quarterly. 2009;87(2):368-90.
11. Timmermans S, Mauck A. The promises and pitfalls of evidence-based medicine. Health Affairs. 2005;24(1):18-28.
12. Lambert H. Accounting for EBM: notions of evidence in medicine. Social science & medicine. 2006;62(11):2633-45.
13. Kerridge I. Ethics and EBM: acknowledging bias, accepting difference and embracing politics. Journal of evaluation in clinical practice. 2010;16(2):365-73.
14. Sayer A. Why things matter to people: Social science, values and ethical life: Cambridge University Press; 2011.
15. Fulford K. Values-based practice: a new partner to evidence-based practice and a first for psychiatry? Mens sana monographs. 2008;6(1):10.
16. Sabel CF. Studied trust: Building new forms of cooperation in a volatile economy. Human relations. 1993;46(9):1133-70.
17. Luhmann N. Trust and power. 1979. John Willey & Sons. 1979.
18. Guyatt G, Rennie D, Meade MO, Cook DJ. Users' guides to the medical literature: a manual for evidence-based clinical practice: AMA press Chicago, IL; 2002.
19. Carlsen B, Glenton C, Pope C. Thou shalt versus thou shalt not: a meta-synthesis of GPs' attitudes to clinical practice guidelines. Br J Gen Pract. 2007;57(545):971-8.
20. Wieringa S, Greenhalgh T. 10 years of mindlines: a systematic review and commentary. Implementation Science. 2015;10(1):45.
21. Nettleton S, Burrows R, Watt I. Regulating medical bodies? The consequences of the 'modernisation'of the NHS and the disembodiment of clinical knowledge. Sociology of health & illness. 2008;30(3):333-48.
22. Gigerenzer G, Gaissmaier W. Heuristic decision making. Annual review of psychology. 2011;62:451-82.
23. Kelly MP, Heath I, Howick J, Greenhalgh T. The importance of values in evidence-based medicine. BMC medical ethics. 2015;16(1):69.
24. Klein JG. Five pitfalls in decisions about diagnosis and prescribing. British Medical Journal. 2005;330(7494):781-3.
25. Elstein AS. Heuristics and biases: selected errors in clinical reasoning. Academic Medicine. 1999;74(7):791-4.

26. Bar-Hillel M. On the subjective probability of compound events. Organizational behavior and human performance. 1973;9(3):396-406.
27. Gigerenzer G, Todd PM. Simple heuristics that make us smart: Oxford University Press, USA; 1999.
28. Gigerenzer G. Gut feelings: The intelligence of the unconscious: Penguin; 2007.
29. Gabbay J, le May, Andree. Practice-based evidence for healthcare: Clinical mindlines. Abingdon, Oxon: Routledge; 2011.
30. Gabbay J, le May A. Mindlines: making sense of evidence in practice. British Journal of General Practice; 2016.
31. Kahneman D. Thinking, fast and slow: Macmillan; 2011.
32. Catwell L, Sheikh A. Evaluating eHealth interventions: the need for continuous systemic evaluation. PLoS Med. 2009;6(8):e1000126.
33. Greenhalgh T, Russell J. Why do evaluations of eHealth programs fail? An alternative set of guiding principles. PLoS Med. 2010;7(11):e1000360.
34. Toon PD. Towards a philosophy of general practice: a study of the virtuous practitioner. Occasional paper (Royal College of General Practitioners). 1999(78):iii.
35. Schei E. Doctoring as leadership: the power to heal. Perspectives in Biology and Medicine. 2006;49(3):393-406.
36. Potter C. To what extent do nurses and physicians working within the emergency department experience burnout: A review of the literature. Australasian Emergency Nursing Journal. 2006;9(2):57-64.
37. Nettleton S, Burrows R, Watt I. How do you feel doctor? An analysis of emotional aspects of routine professional medical work. Social Theory & Health. 2008;6(1):18-36.
38. Boorman S. The Final Report of the independent NHS Health and Well-being review,(2009). Department of Health. NHS health and well-being review–the government response. 2009.
39. Ransohoff DF, McNaughton-Collins M, Fowler FJ. Why is prostate cancer screening so common when the evidence is so uncertain? A system without negative feedback. Am J Med. 2002;113:663-7.
40. Elmore JG. Solving the Problem of Overdiagnosis. Mass Medical Soc; 2016.
41. Daly J. Evidence-based medicine and the search for a science of clinical care: Univ of California Press; 2005.
42. Schön DA. The reflective turn. Case studies in and on educational practice. 1991.
43. Montori VM, Brito JP, Ting HH. Patient-centered and practical application of new high cholesterol guidelines to prevent cardiovascular disease. J Am Med Assoc. 2014;311(5):465-6.
44. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. Quality and safety in health care. 2005;14(1):26-33.
45. Tonelli MR. Integrating evidence into clinical practice: an alternative to evidence-based approaches. Journal of evaluation in clinical practice. 2006;12(3):248-56.
46. Pauker SG, Wong JB. How (Should) Physicians Think?: A Journey From Behavioral Economics to the Bedside. J Am Med Assoc. 2010;304(11):1233-5.
47. Berkwits M. From practice to research: the case for criticism in an age of evidence. Social science & medicine. 1998;47(10):1539-45.
48. Glasziou P, Moynihan R, Richards T, Godlee F. Too much medicine; too little care. British Medical Journal Publishing Group; 2013.
49. Greenhalgh T, Howick J, Maskrey N. Evidence based medicine: a movement in crisis? British Medical Journal. 2014;348:g3725.
50. Ward PR, Coffey C, Javanparast S, Wilson C, Meyer SB. Institutional (mis) trust in colorectal cancer screening: a qualitative study with Greek, Iranian, Anglo-Australian and Indigenous groups. Health Expectations. 2015;18(6):2915-27.
51. Cialdini RB, Goldstein NJ. Social influence: Compliance and conformity. Annu Rev Psychol. 2004;55:591-621.
52. Spiegelhalter D, Pearson M, Short I. Visualizing uncertainty about the future. Science. 2011;333(6048):1393-400.
53. Main BG, McNair, Angus G. K, Huxtable, Richard , Donovan, Jenny L, Thomas, Steven J, Kinnersley, Paul, Blazeby, Jane M. Core information sets for informed consent to surgical

interventions: baseline information of importance to patients and clinicians. BMC Medical Ethics. 2017;18(29).
54. Petrova M, Dale J, Fulford BK. Values-based practice in primary care: easing the tensions between individual values, ethical principles and best evidence. Br J Gen Pract. 2006;56(530):703-9.
55. May C, Montori VM, Mair FS. We need minimally disruptive medicine. British Medical Journal (Online). 2009;339.

Appendices

Appendix I.

Carter SM, Williams J, Parker L, Pickles K, Jacklyn G, Barratt A. Screening for Cervical, Prostate and Breast Cancer: Interpreting the Evidence. *American Journal of Preventive Medicine,* 2015 49(2): 274-85

Appendix II.

Degeling C, Rychetnik L, Pickles K, Doust J, Gardiner R, Glasziou P, Newson A, Thomas R, Carter S. "What should happen before asymptomatic men decide whether or not to have a PSA test?" A report on three community juries. *Medical J Aust,* 2015; 203(8):335

Appendix III.

McCaffery, K, Jansen, J, Scherer, L, Thornton, H, Hersch, J, Carter, S, Barratt, A, Moynihan, R, Waller, J, Sheridan, S, Brodersen, J, Pickles, K, Edwards, A. Walking the tightrope: communicating overdiagnosis in modern healthcare. *BMJ,* 352:1348, 2016

Screening for Cervical, Prostate, and Breast Cancer

Interpreting the Evidence

Stacy M. Carter, PhD, Jane Williams, MDevStud, Lisa Parker, MA, Kristen Pickles, MPH, Gemma Jacklyn, MPH(Hons), Lucie Rychetnik, PhD, Alexandra Barratt, PhD

Cancer screening is an important component of prevention and early detection in public health and clinical medicine. The evidence for cancer screening, however, is often contentious. A description and explanation of disagreements over the evidence for cervical, breast, and prostate screening may assist physicians, policymakers, and citizens faced with screening decisions and suggest directions for future screening research. There are particular issues to be aware of in the evidence base for each form of screening, which are summarized in this paper. Five tensions explain existing conflicts over the evidence: (1) data from differing contexts may not be comparable; (2) screening technologies affect evidence quality, and thus evidence must evolve with changing technologies; (3) the quality of evidence of benefit varies, and the implications are contested; (4) evidence about harm is relatively new, there are gaps in that evidence, and there is disagreement over what it means; and (5) evidence about outcomes is often poorly communicated. The following principles will assist people to evaluate and use the evidence: (1) attend closely to transferability; (2) consider the influence of technologies on the evidence base; (3) query the design of meta-analyses; (4) ensure harms are defined and measured; and (5) improve risk communication practices. More fundamentally, there is a need to question the purpose of cancer screening and the values that inform that purpose, recognizing that different stakeholders may value different things. If implemented, these strategies will improve the production and interpretation of the methodologically challenging and always-growing evidence for and against cancer screening.

(Am J Prev Med 2015;49(2):274–285)

Introduction

Cancer screening is well established in high-income countries, but its evidence base is constantly evolving and often contentious. This leaves physicians and policymakers in a difficult position, forced to act in the context of methodological complexity and substantive disagreement.[1,2] Three cases of screening for cancer or cancer risk are considered: cervical, prostate, and breast screening. The unique characteristics of the disease, test, and program in each case are outlined in Table 1. Tables 2–4 catalogue sources of controversy in each case; these are discussed in more depth below. The concluding section presents five common themes that may help explain the ongoing controversies.

The aim is not to synthesize the evidence but to provide the "backroom" story of the evidence on cancer screening and better illuminate why experts so often disagree.

Cervical Screening

Cervical screening is one of the best-supported and least controversial forms of cancer screening. Nonetheless, there are potentially contentious features of the cervical screening evidence base. These are as follows: (1) dependence on observational data; (2) understanding, communicating, and managing the balance of benefit and harm; and (3) the uncertain future impact of new technologies.

The first challenge in the cervical screening evidence base is the status of the existing evidence. Screening was

From the Centre for Values, Ethics and the Law in Medicine, University of Sydney (Carter, Williams, Parker, Pickles); Sydney School of Public Health (Jacklyn, Barratt), University of Sydney; and the School of Medicine (Rychetnik), University of Notre Dame, Sydney, Australia

Address correspondence to: Stacy M. Carter, PhD, Centre for Values, Ethics and the Law in Medicine (VELiM), Level 1, Medical Foundation Building (K25), 92-94 Parramatta Road, University of Sydney, Camperdown, New South Wales 2006, Australia. E-mail: stacy.carter@sydney.edu.au.

0749-3797/$36.00
http://dx.doi.org/10.1016/j.amepre.2015.01.009

Table 1. Disease, Test, and Program Characteristics in Each Case

	Cervical cancer	Prostate cancer	Breast cancer
Tests used	Pap smear using conventional and/or liquid based cytology ± computer-assisted reading; HPV DNA testing increasing ± cytology; visual inspection with acetic acid/liquid iodine (VIA/VILI) in LMICs	PSA test; new testing methods, including use of biomarkers, are being developed; DRE also used	Mammogram; fixed or mobile mammogram unit; recently widely upgraded to digital technology
When test was invented	Pap test developed late 1930s	First commercial PSA test released in 1986	X-ray used for breast disease 1910s; first screening RCT 1963–1975
When test was first used for screening	Used to screen asymptomatic women from the 1940s	USFDA approved PSA test for prostate cancer screening in 1994	Ad hoc screening from mid-20th century[3]; population screening programs 1980s onwards (based on publication of results from early RCTs)
What test is designed to detect	Abnormal cells on the cervix (cytology, VIA/VILI) or presence of oncogenic HPV strains (HPV test)	Raised serum PSA levels	Variations in soft tissue radiolucency; originally diagnostic
Relationship between test and target disease	HPV-caused lesions are potential precursors for cervical cancer	Poor; test not developed to screen for cancer; elevated PSA may not indicate cancer risk	Cancers have characteristic (often subtle) soft tissue appearances on x-ray
What results of screening are reported	Lesions: nature and severity (grade) of changes; reporting standards differ; HPV reported by type	PSA levels, expressed as nanograms of PSA per milliliter (ng/mL) of blood	Apparent presence of masses and lesions suspicious for invasive and/or in situ cancer
Contention over test itself	Cytology is prone to human error; terminology and reporting standards vary; sensitivity and specificity estimates vary widely[4]	There is no meaningful "normal range" for the PSA test in screening	There is variation in what degree of suspicion constitutes a positive screen
Variations between jurisdictions that may change the evidence base regarding benefit and/or harm	IARC recommends 3-yearly cytology screening from 25 years; evidence base pools data from widely varied programs:[5] start-age ranges from 18–30 years, interval 1–5 years; reporting standards, terminology and treatment vary	Differences in target age, recommended finishing ages, screening intervals, definition of "abnormal," biopsy thresholds	Differences in target age, screening intervals, thresholds for recall and biopsy; service studies may differ in participant population age (and therefore underlying cancer risk), follow-up, out-of-study screening
Developments in the test	Tests that detect oncogenic-type HPV may supersede cytology as primary screening test	New test rules in development; variations proposed (free:total PSA ratio, PSA density, velocity, doubling time, prostate health index) for clinical significance; no evidence these improve health outcomes[2]	Increasing use of tomosynthesis (integrated 2/3D mammography) and MRI, which may contribute to both benefit and harm

DRE, digital rectal examination; HPV, human papillomavirus; IARC, International Agency for Research on Cancer; LMICs, low- and middle-income countries; MRI, magnetic resonance imaging; PSA, prostate-specific antigen; USFDA, U.S. Food and Drug Administration; VIA, visual inspection of the cervix using acetic acid to highlight precancerous lesions; VILI, visual inspection of the cervix using Lugol's iodine to highlight precancerous lesions.

established in parts of Europe and North America between the late 1940s and early 1960s, and data from those programs, rather than from controlled trials, provide the evidence base for cervical screening effectiveness. Observational studies compared screened and unscreened populations and showed reduced cervical cancer incidence and mortality in the former.[5,30,31] This evidence base clearly shows that cervical screening reduces morbidity and mortality: what is less clear is who to screen, when, and how to optimize benefit and minimize harm.

The cervical screening evidence base is susceptible to the well-known biases of any observational study.[1] It is not clear how these biases should be taken into account. In addition, the observational data about cervical screening cross jurisdictions in which there are substantially different programs

Table 2. Main Issues in Cervical Cancer Screening

Issue	Explanation
Incidence and mortality of cervical cancer is low in high-income countries	The incidence of cervical cancer is much lower than, e.g., breast or prostate cancer, so number needed to screen over many years to avoid one death is high.[6]
Cervical screening reduces morbidity and mortality from cervical cancer	Early Nordic observational studies suggest a mortality benefit from screening using the Pap test. Organized programs confer greater benefit than opportunistic screening.[5]
There is no RCT evidence from high-income countries	Because Pap test screening for cervical cancer was introduced so early, it was not possible or ethical to conduct an RCT of its effectiveness.
RCTs are being conducted in LMICs	These will be a useful evidence base for LMICs.
It is easy to overstate the benefits of cervical cancer screening because the underlying mortality rate is low	Because incidence is low, number needed to screen is high and absolute risk reduction low. Statements of benefit may obscure the relatively small absolute number of people affected. E.g., mortality is often said to have halved in the decade following commencement of organized screening in Australia: this is accurate, but the absolute change was from only 4/100,000 to 2/100,000 women.
Most cervical lesions regress	It has been recognized since the 1970s that most cervical lesions will not progress to cervical cancer.
It is not clear what proportion of lesions regress, or which lesions will regress	It may never become clear which lesions will regress or what proportion of them will regress. CIN3 progression to cancer has been estimated at 12%,[7] 20%,[6] and 30%[8] in different studies.
Overtreatment is difficult to measure and to manage	The majority of treatment is overtreatment, but as it is not possible to identify which lesions will regress, this may not be resolvable with the technology currently available. There are vastly more abnormal results than there are invasive cancers, especially in women aged <25 years; e.g., in Australia in 2010 the incidence of invasive cancer in women aged <25 years was 1.5/100,000, but 40,000 of the 250,000 screens in women aged <25 years returned an abnormal result.[9] Perinatal morbidity in treated women is the main iatrogenic harm of concern.[10]
The evidence base is affected by differences in program design between countries	Evidence about cervical screening comes mostly from monitoring data from screening programs. However, different countries run their programs differently. They use different tests, screening ages, and screening intervals. They classify and report on their programs using different terminology and standards. Then the data from these very different contexts are combined. This has implications for the evidence base.
Screening technology is changing	Because of HPV vaccination, a move away from cytology seems likely; an alternative future might be mass HPV screening with cytological examination of those with positive HPV tests. It is unclear what the incremental benefits and costs of these new technologies over existing screening programs will be. This is a rapidly evolving part of the evidence base in cervical screening.

CIN3, Cervical intra-epithelial neoplasia; HPV, human papilloma virus; LMICs, low- and middle-income countries.

and reporting standards. This means that these observational data from different settings may not be as easily comparable as is often assumed (Table 1). To minimize bias, meta-analysis of RCT evidence is the preferred method for estimating benefit and harm in screening. RCT evidence of different screening technologies, and combinations of technologies, is emerging. This may add more certainty to the cervical screening evidence base, although some of the findings from RCTs in low- and middle-income countries (LMICs) may not be transferable to other settings.[32–35]

The second challenge in this evidence base concerns understanding, communicating, and managing the balance of benefit and harm; this problem has several dimensions. It is easy to inadvertently overstate the

Table 3. Main Issues in Prostate Cancer Screening

Issue	Explanation
Most prostate cancer is not life threatening	Although prostate cancer can be life threatening, the vast majority of cases are indolent.
Early trials of PSA screening were of poor quality	Early trials—which reported very positive findings—had serious methodological problems, including low participation in screening, failure to randomize, and failure to analyze by intention to screen.
Large RCTs are currently underway	The ERSPC trial[11] and the USA PLCO[12] trial have made interim reports but are ongoing. These are the only large, methodologically sound trials of PSA screening conducted to date.
There is controversy over the design of the current large RCTs	ERSPC included different countries using different screening tests and procedures. Those screened in the trial were more likely to be treated in a University hospital. The Swedish subset of ERSPC compared volunteer screenees (probably a healthier group) to whole-population controls (particularly significant because Sweden was one of only two, out of seven, subgroups to report statistically significant reductions in prostate cancer mortality after 11 years). These patterns are likely to bias results in favor of screening. In PLCO, >50% of controls were screened during the trial, and 44% of participants had previously been screened. Methodologists disagree on whether these biases are fatal to the results of the trials.
PSA screening may decrease prostate cancer death	Some trials suggest reductions in incidence of prostate cancer death. Observational studies in highly screened populations suggest lower prostate cancer mortality.
PSA screening is unlikely to decrease all-cause mortality	Only ERSPC has reported a mortality benefit, which was very small in absolute terms. 1,055 men would have to be screened to prevent one death from prostate cancer over 11 years.[13]
The PSA test is not prostate cancer-specific	PSA test has poor sensitivity and specificity for detecting prostate cancer. A PSA >4.0 ng/mL produces a 6.2% false positive rate but detects only 20.5% of cancer cases.[14] PSA test cannot distinguish increased cancer risk from other common conditions, e.g., benign prostatic hyperplasia, prostatitis. Certain medications (e.g., finasteride), ejaculation, and prostate manipulation can also increase PSA levels.
PSA test manufacturers and PSA thresholds vary between studies, laboratories, and clinicians	Studies and laboratories employ more than one kind of PSA test and different abnormal thresholds. The evidence base is thus hard to interpret because of lack of comparability. Conventional threshold for further investigation is 4 ng/mL, but men with PSA levels 4–10 ng/mL may not have prostate cancer,[15] and men with results <4 ng/mL can show histological evidence of prostate cancer.[16,17] Lowering the threshold below 4 ng/mL would increase overdiagnosis and overtreatment of clinically unimportant disease.[18,19] A meaningful threshold for screening may not exist because of the test's poor sensitivity and specificity; i.e., the PSA test has little utility as a screening tool for prostate cancer. There is currently no alternative test available.
PSA screening can increase the likelihood of receiving treatment	In the U.S., e.g., up to 90% of men with prostate cancer diagnosed as a result of PSA testing receive treatment.[20]
Prostate cancer treatment can produce considerable negative consequences	Treatment can result in erectile dysfunction or impotence, anxiety, urinary incontinence, bowel dysfunction, or death.

ERSPC, European Randomized Study of Screening for Prostate Cancer; PLCO, Prostate Lung Colorectal and Ovarian Cancer trial; PSA, prostate-specific antigen.

mortality benefit of cervical screening, particularly in high-income countries. This is because mortality from cervical cancer in high-income countries is considerably lower than for cancers such as breast and prostate. This was true even prior to widespread Pap testing. For example, the age-standardized mortality rate from cervical cancer in the United Kingdom was approximately 8/100,000 in 1971, compared to 37.5/100,000 for breast cancer and 20/100,000 for prostate cancer.[36] Thus, even substantial proportional (or relative risk) reductions in

Table 4. Main Issues in Breast Cancer Screening

Issue	Explanation
Mortality benefit exists	Most studies show mortality benefit from organized mammographic screening—especially for women aged 50–70 years—of approximately 20%.[21–24]
The extent of mortality benefit is contentious	Estimates of benefit vary considerably. Different study types are used, including RCTs, observational studies, and modelling. Meta-analysis of RCTs is widely regarded as the best way to identify population benefits, but different meta-analyses include or exclude different RCTs because of differing judgments about study quality.[21–24]
Mortality benefit is less than originally thought	Recent meta-analyses of RCTs suggest that benefit is lower than suggested by the earliest studies. This can be partly attributed to problems in quality with some of the RCTs. It has been hypothesized that treatment improvements in recent decades may leave less room for screening to have an effect and make older trial data less relevant.[21–24]
The harm from false positive screening tests varies between programs and populations	The rate of false positives varies as a result of factors such as the following: ● Test factors, e.g., equipment quality; skill of the clinicians reading the mammograms ● Differing policies and standards regarding acceptable levels of false positives and false negatives ● Frequency of screening in the program (increased frequency tends to increase the absolute number of false positives) ● Individual participant factors (e.g., greater breast density in some women, including pre-menopausal women and women taking hormone replacement therapy [HRT]) that can make mammogram interpretation more challenging (and false positives more common) ● Population factors: the frequency of false positives in part depends on the positive predictive value of the test, which depends on the prevalence of disease in the screened population. This depends on population risk profile (e.g., younger women have lower incidence).[25]
The extent of overdiagnosis is contentious	Estimates of overdiagnosis vary as a result of factors including the population studied; research questions asked (e.g., total cancer or invasive cancer only); methods used (e.g., comparing incidence in intervention and control arms of RCTs, comparing observational annual incidence data, comparing observational cumulative incidence data, using simulated population models); correction for possible biases such as lead time; and fundamental assumptions when estimating overdiagnosis in models.[1,10,26,27]
Biological consequences of in situ disease is unclear	Before the onset of screening, in situ disease was mostly diagnosed in conjunction with an invasive cancer. It was not anticipated to be a common isolated finding on screening. It is unclear what the right response to increased diagnosis of in situ disease should be. Knowledge of the natural history of in situ breast diseases is improving but still incomplete. Diagnosis and management are controversial, especially for less aggressive diseases (e.g., low-grade DCIS), where risk of death is only slightly increased but surgery to negate the risk may be extensive.[21–24]
There are small radiation harms of screening	Harm from radiation during mammography is generally agreed to be real and may be greater in women screened more often (e.g., those identified as carrying potentially harmful mutations in the *BRCA1* or *BRCA2* genes).[28,29] However, in screening of the general population, these risks are extremely small and likely to be further reduced by the implementation of digital mammography.

BRCA1/BRCA2, BReast CAncer susceptibility gene 1 and 2; DCIS, ductal carcinoma in situ.

mortality attributed to screening may represent only small reductions in the absolute number of deaths prevented in well-resourced countries (Table 2). Cervical cancer, however, remains a significant burden and leading cause of cancer mortality in some low-income regions.[37]

In addition, the treatments triggered by screening may be unnecessary and harmful in some cases. Cervical screening reduces cancer incidence as well as mortality. This is because it detects cellular abnormalities on the cervix, or pre-cancerous lesions, caused by human papillomavirus (HPV) (Table 1). Cervical cancer is a

rare outcome of persistent infection over a long time. However, cellular abnormalities are common: there is an estimated lifetime incidence of 40% in women born since 1960.[6] Also, progression appears to be less linear than originally thought,[38] and most HPV infections regress spontaneously. This means that four of five women with dysplasia may be treated unnecessarily,[6] but at present it is not possible to identify which individual high-grade lesions will regress, and can be left untreated, or will progress, and require treatment (Table 2).

The evidence does suggest a solution, however: to focus on minimizing harm, particularly in women aged <25 years. The evidence shows that (1) HPV infection is most likely to spontaneously regress in this group; (2) paradoxically, these women also experience more abnormal cytology, treatment, and cervical incompetence and perinatal morbidity as a result of treatment; and (3) crucially, there is no mortality benefit in screening this age group. [10,39] As a result, many countries are delaying commencement of screening until age 25 years (Table 1), recommending screening thereafter only every 3–5 years, or both.[40,41] Although this change is supported by the evidence, in many jurisdictions women continue to be screened earlier and more often than these guidelines would support.[5,42,43]

Finally, it is important to anticipate the future impact of new technologies on the evidence base and on practice.[44,45] Research increasingly supports screening women aged ≥ 30 years using an oncogenic-type HPV test instead of or in addition to cytology.[32] The U.S. Preventive Services Taskforce (USPSTF), for example, now recommends that women aged 30–65 years can screen with a combination of cytology and HPV testing every 5 years if they wish, rather than with cytology alone every 3 years.[33] The U.S. Food and Drug Administration (FDA) has recently approved the use of HPV testing alone as a primary screening test,[46] which seems likely to result in further revision of recommendations. The recommendations are somewhat ahead of the evidence—with the exception of an Indian cluster RCT,[34] primary HPV testing has not yet shown mortality benefit. Similarly, comparative benefits and harms of different sequential combinations of HPV and cytology testing are not yet clear. However, RCTs of newer screening technologies (e.g., HPV tests, including self-testing and testing in vaccinated populations, and computer-assisted cytology reading) are underway. HPV vaccination will further reduce underlying risk in the population and thereby potentially reduce the relevance of the existing evidence on cervical screening.

Screening for Prostate Cancer

Unlike cervical screening, prostate-specific antigen (PSA) testing for prostate cancer risk is intensely contested[47]; this includes contention over the relationship between evidence and practice. Important issues include (1) inconsistency between the findings of different trials (and tension over the interpretation of observational findings); (2) variation in tests and thresholds for abnormality within and between studies; and (3) evidence suggesting that the PSA test performs poorly for screening purposes.

The first challenge is the quality and interpretation of research about the efficacy and effectiveness of PSA testing. Observational data from highly-screened communities are sometimes used to argue that testing reduces prostate cancer mortality.[16,48,49] However, as noted earlier, findings from observational studies may be misleading because of characteristic biases such as lead time, length time, and selection bias.[2,18] Early RCTs were of poor quality (Table 3).[2,18] Since then, two ongoing RCTs have reported results: the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the U.S. Prostate, Lung, Colorectal, and Ovarian Cancer (PLCO) Screening Trial. PLCO has shown no effect on prostate cancer–specific or all-cause mortality.[50] ERSPC reported reduced prostate cancer mortality in screened men but no change in all-cause mortality.[11] There is considerable controversy over trial design (Table 3). Although difficult to quantify, frequency of testing and follow-up and type of treatment provided after diagnosis are likely to affect outcomes reported from trials.[12,13,51]

Expert bodies increasingly advise against PSA screening. The USPSTF concluded that the mortality benefit is very small and outweighed by risk of harm.[52] The American College of Preventive Medicine has similarly concluded that populations should not be routinely screened with the PSA test, owing to insufficient evidence.[53] The Australian National Health and Medical Research Council evidence guideline on PSA testing in asymptomatic men has recently concluded that there is no effect of PSA testing on all-cause mortality and that no conclusions can be drawn about prostate cancer mortality.[54] These decisions are consistent with the evidence, which suggests that PSA testing may reduce the short-term risk of dying from prostate cancer by a very small amount, at the cost of a much greater risk of harm, including from false positive results, overdiagnosis, and overtreatment. The question this raises is: If a screened man will not die any later than an unscreened man, is it meaningful to prevent him from dying of prostate cancer in particular? And at what cost (harms to the man as well as expense to the man and the health system) should this goal be pursued? This question seems to divide experts, not least according to whether they care for men with the disease or have experienced it themselves.

The second problem in the PSA testing evidence is interpretability and comparability of PSA results. This is an issue for many screening tests (Table 1), but especially for the PSA test. Manufacturers and laboratories employ divergent PSA calibrations, producing different readings from the same sample.[55] Even when identical methods are used, thresholds set to separate "normal" from "high-risk" PSA levels often differ. Within and between studies, different standards are often combined, potentially invalidating conclusions.[16,56] Tests and thresholds used by different countries participating in large trials often vary (Table 3), and trial study groups have been unable to identify acceptable PSA cut offs for prostate cancer screening. This makes it difficult to compare study results and apply them to real-life settings.

The final problem with interpreting the evidence about PSA testing is addressing the potential for harm. The evidence suggests that sensitivity and specificity of the test are poor (Tables 1 and 3), which means cancers are missed (poor sensitivity) and false positives are common (poor specificity). The evidence suggests that PSA testing increases diagnosis of indolent disease, frequently cascades to diagnostic biopsies and follow-up treatments, and produces physical and psychological harms and costs: for every life saved by the PSA test, up to 48 men may be overtreated (Table 3).[57] Determining whether this is acceptable requires difficult debate over the nature of a good outcome, and what harm or expense that outcome might justify.

Screening for Breast Cancer

Like the evidence for PSA testing, the evidence for breast screening has been controversial. Important features of this evidence base include (1) uncertainty regarding the extent of breast cancer mortality reduction benefit; (2) uncertainty regarding the extent of harm; and (3) disagreement about managing in situ disease.

The first challenge for the evidence on breast screening is that despite a considerable body of research, the degree to which breast screening reduces breast cancer mortality remains unclear. The evidence base includes 11 RCTs (1971–2006), numerous observational studies, and mathematical models. It is probable that an invitational program of breast screening by mammography offers a population breast cancer mortality benefit, particularly for women aged 50–70 years. If poorer-quality RCTs are removed from meta-analyses, this benefit is reduced, but by how much is unclear (Table 4). Absolute and relative benefits are lower in women aged <50 years.[58] Also, treatment has greatly improved in recent decades, so including RCTs from the 1970s–1990s may overstate the benefit of screening (Table 4).[1,21–24,26] The degree to which widely observed declines in breast cancer mortality are attributable to improvements in treatment remains contested.[59] It is unclear how this can be resolved. Incremental changes in technology—from film mammography to digital mammography, tomosynthesis (integrated two-/three-dimensional [2/3D] mammography) and magnetic resonance imaging (MRI) to screen high-risk women—may also affect the balance of screening benefits and harms.[60,61]

The second concern is the extent of harm that is caused. Invitational mammography programs cause harm, including false positives and overdiagnosis. The absolute rate of false positives can vary according to the equipment used, skill and experience of film readers, test thresholds, and screening frequency (Table 4).[25] Although the rate of false positives per screen may be low, they accumulate; thus the chance of false positive recall or biopsy over a lifetime is much higher. Increasingly, evidence suggests that breast screening produces overdiagnosis of both invasive and in situ breast cancer. Although experts agree that mammography screening causes overdiagnosis, there is disagreement on its extent. A recent meta-analysis suggests that, in women invited to screening, there is an 11% lifetime risk of overdiagnosis as a proportion of cancers that are diagnosed, and a 19% risk during the active screening period.[21,24] Harms, especially overdiagnosis, may tend to outweigh benefits in women aged >70 years as they age.[62] However, the relevant evidence is highly contentious for methodological and other reasons explained in Table 4.[26,27]

The final challenge in this evidence base concerns ductal carcinoma in situ (DCIS), which represents approximately 17%–34% of screen-detected cases and 20%–25% of all newly diagnosed cases of breast cancer in the U.S.[63] Women are rarely diagnosed with DCIS because they experience symptoms: DCIS is diagnosed almost entirely as a result of screening. Overdiagnosis of DCIS is widely considered an important harm of mammographic screening. However, the evidence is not clear on either the natural history of DCIS or how aggressively DCIS should be treated. More research is needed to evaluate treatments for in situ disease.[21,26]

What Characteristics of the Screening Evidence Base Could Explain Expert Disagreement?

In high-income countries, cancer screening is a familiar feature of preventive medical care. Screening is expected—with good reason—to be informed by evidence. Across these

three cases, there are two less-often discussed tensions and three more explicit tensions that help to explain why interpreting the evidence is such a difficult task.

Tensions in the Evidence Base That Are Discussed Less Often

Two tensions in the evidence base are under-examined: the comparability of data between studies and contexts, and the impact of technological developments. These tensions are also difficult to resolve and potentially destabilizing.

Data from different contexts may not be comparable, particularly for observational data from monitoring studies. As shown, the evidence base contains data from different times, countries, and programs, and from populations with varying event rates (Table 1). Transferability of this evidence is difficult for several reasons. Because screening trials are particularly large and need long follow-up to show effects, they can be especially susceptible to the passage of time. When early trials were conducted, screening techniques were less developed, treatments less effective, cancer incidence lower, and cancer mortality often higher. Breast screening evidence, for example, includes decades-old trials; treatment has progressed substantially since they were conducted. Evidence from screening trials is also susceptible to local variation (e.g., in disease biology, event rates, and age distribution), not least because screening is applied to whole populations, not just people who are ill. As HPV vaccination is implemented differently around the world, for example, the underlying event rate for cervical cancer will change dramatically. The resource intensiveness of cancer screening trials also means that (1) few trials are done (leaving less evidence to interpret); (2) trials are often funded by industry (changing the research questions); and (3) trials are somewhat dependent on local screening and treatment practices (e.g., target age, screening intervals, testing techniques, follow-up time, available treatment). The variability and transferability of screening evidence is a challenge for methodologists, and even more so for clinicians and policymakers, as the characteristics on which the evidence depends are not always made clear in reporting.

The second under-examined tension is that screening technologies affect evidence quality; thus, evidence must evolve with changing technologies. Cancer screening relies on complex cascades of technology for collecting, imaging, analyzing, and interpreting possible changes in human bodies. Without the technology, there is no screening, but as technology evolves, it potentially makes existing evidence obsolete.[64]

The evidence on PSA is hampered by poor technology. The PSA test has limited sensitivity and specificity, studies and laboratories use multiple test types and different thresholds, there is no meaningful "normal range," and new test rules do not appear to change patient outcomes. Some propose using test results only within, rather than between, patients, but the poor test characteristics of PSA make even this problematic. It is understandable that clinicians want to retain some tool to measure prostate cancer risk.[65] However, given the test characteristics of the PSA, it may not be possible to generate a meaningful evidence base about its use in populations.

The cervical screening evidence base is shifting because of changing technology; tests that detect oncogenic-type HPV may become the primary form of screening in vaccinated populations. Mammography remained relatively constant in the 20th century, changing only incrementally from film to digital mammography. In the 21st century, we face substantial technological change, with moves to tomosynthesis (integrated 2/3D mammography) and MRI screening of high-risk women. Although tomosynthesis is receiving considerable attention in the lay press and peer-reviewed literature, attempts to estimate its effects have been based on opaque assumptions and limited evidence. It seems possible that both MRI and tomosynthesis will enhance both the benefits and harms of screening, but at present this is unknown.[60,61]

Acknowledged Tensions in the Evidence Base

Three other, more explicit, tensions are over the quality of evidence of benefit, the relatively new evidence regarding screening harm, and risk communication.

The quality of the evidence of benefit from screening varies, and the implications of this evidence are contested. When one expert says to another, "You are wrong about the evidence on screening," she is likely to mean this: "I disagree with the criteria that you have used to separate good-quality studies, which should be included, from poor-quality studies, which should be excluded. I therefore disagree with your conclusion."

The cancer screening evidence base contains observational studies, RCTs, and modeling of widely varying quality and with disparate results. Early studies of screening generally suggested greater benefit, and later studies less benefit, which may be because early trials were poorly designed (e.g., PSA) or because recent treatment improvements leave less room for screening to provide benefit (e.g., breast screening). Even new trials contain methodological flaws (e.g., PLCO, ERSPC), and methodologists often disagree about study design, particularly over whether screened and unscreened groups are comparable.

New RCTs are expensive and logistically challenging, and so are rare. Thus, new conclusions generally arise from re-analyses of existing research findings rather than from new trials. Researchers performing meta-analyses must decide on criteria for including and excluding studies. The recent Marmot review of the evidence on breast screening demonstrates that this is possible,[21] even in high-profile situations, but disagreement over criteria is likely to remain. And when new analyses produce new findings, those whose settled beliefs are challenged may perceive the chosen criteria as arbitrary or incorrect. This highlights the importance of transparency regarding how and why meta-analyses are conducted.

The second acknowledged tension is that evidence about harm is relatively new, and there are gaps in that evidence and disagreement about what it means. Initially, cancer screening researchers focused on measuring screening benefits; they have only recently turned to potential harm. For all three cases—cervical, prostate, and breast cancer (including DCIS)—there is limited evidence about which instances of disease or pre-disease are aggressive and require treatment, and which will be indolent or regress. Because of this, many people will be overtreated and may be harmed. Researchers are trying to address this gap by studying the mortality benefit of treatment for small, Grade 1, node-negative breast cancers, for example, or the genetic profile of aggressive versus indolent prostate cancers. This work may assist in the future. In the meantime, existing knowledge suggests opportunities to reduce harm. For example, there is currently no way to determine which cervical lesions will regress or progress. However, epidemiological data demonstrate that women aged 18–25 years are most likely to have unnecessary treatment, experience harm from treatment, and fail to benefit from treatment. This has led some jurisdictions to restrict cervical screening to women aged >25 years.

Even when evidence about screening harm emerges, experts often disagree about what it means and how to respond. This may be in part because public health and medical professionals have learned to think in a particular way, and have taught citizens to think similarly, of cancer and pre-cancer as progressive and life-threatening, and screening as one of few defenses against this threat. For the first several decades of screening research, harm was rarely measured. Although later research suggested that screening may harm, it may be difficult for this evidence to reach public attention given the powerful cultural meaning of cancer death.[66,67] New facts about screening harm are hotly contested, with regard both to their accuracy and their implications. And screening programs continue to be evaluated primarily against increasing participation targets, rather on the likely balance achieved between benefit and harm.

For example, it is generally accepted that prostate biopsies and prostate cancer treatments are likely to produce harm. This is taken as a fact, but that fact is interpreted very differently. Some argue that most screen-detected prostate cancers are indolent, so most diagnosis is overdiagnosis, and most harm done is unnecessary. They conclude that insurers or policymakers should constrain clinicians who test healthy men, thus preventing harm. Others take a different view, that without PSA testing, clinicians have no way of diagnosing tumors that would develop or metastasize. These experts tend to take the view that insurers or policymakers should leave testing open to clinicians and allow the possibility of harm to be dealt with via more judicious decisions about treatment. Their opponents might counter with studies showing that men diagnosed with prostate cancer generally proceed to treatment rather than "watching and waiting."[20] Although each party can present data of some kind to support their claims, it is worth remembering that data become evidence only through interpretation and that experts are susceptible to biases in this interpretive process.[68,69]

The final acknowledged tension is that evidence about outcomes is often poorly communicated, despite the evidence about communication. Researchers and programs tend to express outcomes using relative risks, which incorporate baseline risk and are easier to generalize across contexts. However, research shows that relative risks encourage lay people and clinicians to overemphasize benefits and minimize harms. This has been acknowledged as ethically problematic, potentially biasing or manipulating people's perceptions, misleading them, and undermining their autonomy.[70] If experts are obliged to communicate honestly with citizens—an obligation that seems supportable—this becomes an urgent issue to address for all forms of cancer screening.

Conclusions

The benefits and harms of screening are often finely balanced—more than anticipated when screening was established. There are both unique and shared characteristics of cervical, prostate, and breast screening that help to explain the challenge of balancing benefit and harm. These include the incomparability of data from different times, places, and programs; the instability of the very technology on which screening is based; disagreement on which studies are sufficiently well designed to be taken seriously; gaps in knowledge; and disagreement about

how to understand newly emerging evidence of harm. This suggests five principles for evaluating and using the evidence:

1. attend closely to transferability;
2. consider the influence of technologies on the evidence base;
3. query the design of meta-analyses;
4. ensure harms are defined and measured; and
5. improve risk communication practices.

However, even more fundamental are questions about the purpose of screening and who should make decisions about screening. Should insurers or policymakers leave screening options open for clinicians and patients to choose? Or should they be directive, promoting some forms of screening and limiting others to minimize harm? Should community engagement and deliberation guide screening policy and practice? And what should the purpose of screening be? There are many potential aims of cancer screening, including preventing cancer death, reducing all-cause mortality, minimizing anxiety, maximizing cost efficiency, and minimizing avoidable harm. These different aims reflect different values, which may differ between patients, clinicians, funders, and policymakers. Questions about the evidence base need resolution. This should be complemented with clear thinking about the aims of screening. Only when the aims of screening are clear will researchers be able to generate an evidence base sufficient to assist decision making, and clinicians be able to best support their patients to make good screening decisions.

This work is supported by the Australian National Health and Medical Research Council (NHMRC), under Project Grant number 1023197. SC is supported by NHMRC Career Development Fellowship number 1032963. LP is supported by NHMRC Postgraduate Scholarship number 1038517. JG is supported by NHMRC Postgraduate Scholarship number 1074626. JW is supported by an Australian Postgraduate Award. Our sincere thanks to four anonymous reviewers and the Editor for their critical and constructive engagement.

No financial disclosures were reported by the authors of this paper.

References

1. Bretthauer M, Kalager M. Principles, effectiveness and caveats in screening for cancer. *Br J Surg*. 2013;100(1):55–65. http://dx.doi.org/10.1002/bjs.8995.
2. Moyer VA. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2012;157(2):120–134. http://dx.doi.org/10.7326/0003-4819-157-2-201207170-00459.
3. Gershon-Cohen J, Berger S. Detection of breast cancer by periodic X-ray examinations: a five-year survey. *JAMA*. 1961;176(13):1114–1116. http://dx.doi.org/10.1001/jama.1961.63040260015013a.
4. Fahey MT, Irwig L, Macaskill P. Meta-analysis of Pap test accuracy. *Am J Epidemiol*. 1995;141(7):680–689.
5. International Agency for Research on Cancer. *Cervix Cancer Screening*. Lyon, France: IARC Press, 2005.
6. Raffle AE, Alden B, Quinn M, Babb PJ, Brett MT. Outcomes of screening to prevent cancer: analysis of cumulative incidence of cervical abnormality and modelling of cases and deaths prevented. *BMJ*. 2003;326(7395):901. http://dx.doi.org/10.1136/bmj.326.7395.901.
7. Ostor A. Natural history of cervical intraepithelial neoplasia: a critical review. *Int J Gynecol Pathol*. 1993;12(2):186. http://dx.doi.org/10.1097/00004347-199304000-00018.
8. McCredie MRE, Sharples KJ, Paul C, et al. Natural history of cervical neoplasia and risk of invasive cancer in women with cervical intraepithelial neoplasia 3: a retrospective cohort study. *Lancet Oncol*. 2008;9(5):425–434. http://dx.doi.org/10.1016/S1470-2045(08)70103-7.
9. Australian Institute of Health and Welfare. *Cervical screening in Australia 2010-2011*. 20132013.
10. Kyrgiou M, Arbyn M, Martin-Hirsch P, Paraskevaidis E. Increased risk of preterm birth after treatment for CIN. *BMJ*. 2012;345:e5847. http://dx.doi.org/10.1136/bmj.e5847.
11. Roobol MJ, Kerkhof M, Schroder FH, et al. Prostate cancer mortality reduction by prostate-specific antigen-based screening adjusted for nonattendance and contamination in the European Randomised Study of Screening for Prostate Cancer (ERSPC). *Eur Urol*. 2009;56(4):584–591. http://dx.doi.org/10.1016/j.eururo.2009.07.018.
12. Andriole GL, Crawford ED, Grubb 3rd, et al. Mortality results from a randomized prostate-cancer screening trial. *N Engl J Med*. 2009;360(13):1310–1319. http://dx.doi.org/10.1056/NEJMoa0810696.
13. Schröder FH, Hugosson J, Roobol MJ, et al. Prostate-cancer mortality at 11 years of follow-up. *N Engl J Med*. 2012;366(11):981–990. http://dx.doi.org/10.1056/NEJMoa1113135.
14. Saenger A. PSA standardization. Mayo Foundation for Medical Education and Research; 2013. http://www.mayomedicallaboratories.com/articles/hottopics/2009-10b-psa.html.
15. Harris R, Lohr KN. Screening for prostate cancer: an update of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2002;137(11):917–929. http://dx.doi.org/10.7326/0003-4819-137-11-200212030-00014.
16. Loeb S, Chan DW, Sokoll L, et al. Prostate specific antigen assay standardization bias could affect clinical decision making. *J Urol*. 2008;180(5):1959–1962. http://dx.doi.org/10.1016/j.juro.2008.07.036.
17. Thompson IM, Pauler DK, Goodman PJ, et al. Prevalence of prostate cancer among men with a prostate-specific antigen level < or =4.0 ng per milliliter. *N Engl J Med*. 2004;350(22):2239–2246. http://dx.doi.org/10.1056/NEJMoa031918.
18. Ilic D, Neuberger MM, Djulbegovic M, Dahm P. *Cochrane Database Syst Rev*. 2013:1 CD004720.
19. Welch HG, Schwartz LM, Woloshin S. Prostate-specific antigen levels in the United States: implications of various definitions for abnormal. *J Natl Cancer Inst*. 2005;97(15):1132–1137. http://dx.doi.org/10.1093/jnci/dji205.
20. Welch HG, Albertsen PC. Prostate cancer diagnosis and treatment after the introduction of prostate-specific antigen screening: 1986-2005. *J Natl Cancer Inst*. 2009;101:1325–1329. http://dx.doi.org/10.1093/jnci/djp278.
21. Independent UK Panel on Breast Cancer Screening. The benefits and harms of breast cancer screening: an independent review. *Lancet*.

2012;380(9855):1778–1786. http://dx.doi.org/10.1016/S0140-6736(12)61611-0.
22. Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, Humphrey L. Screening for breast cancer: an update for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2009;151(10):727–737. http://dx.doi.org/10.7326/0003-4819-151-10-200911170-00009.
23. International Agency for Research on Cancer. IARC Handbooks of Cancer Prevention Volume 7: *Breast Cancer Screening*. Lyon: IARC Press; 2002.
24. Gøtzsche P, Nielsen M. Screening for breast cancer with mammography. *Cochrane Database Syst Rev*. 2011(1): CD001877.
25. Elmore JG, Armstrong K, Lehman CD, Fletcher SW. Screening for breast cancer. *JAMA*. 2005;293(10):1245–1256. http://dx.doi.org/10.1001/jama.293.10.1245.
26. Autier P, Esserman L, Flowers C, Houssami N. Breast cancer screening: the questions answered. *Nat Rev Clin Oncol*. 2012;9(10):599–605. http://dx.doi.org/10.1038/nrclinonc.2012.126.
27. Biesheuvel C, Barratt A, Howard K, Houssami N, Irwig L. Effects of study methods and biases on estimates of invasive breast cancer overdetection with mammography screening: a systematic review. *Lancet Oncol*. 2007;8(12):1129–1138. http://dx.doi.org/10.1016/S1470-2045(07)70380-7.
28. Berrington de, Gonzalez A. Estimates of the potential risk of radiation-related cancer from screening in the UK. *J Med Screen*. 2011;18(4):163–164. http://dx.doi.org/10.1258/jms.2011.011073.
29. Moyer VA. Risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2014;160(4):271–281. http://dx.doi.org/10.7326/M13-2747.
30. Hakama M, Chamberlain J, Day N, Miller A, Prorok P. Evaluation of screening programs for gynecological cancer. *Br J Cancer*. 1985;52:669–673. http://dx.doi.org/10.1038/bjc.1985.241.
31. International Agency for Research on Cancer. Screening for squamous cervical cancer: duration of low risk after negative results of cervical cytology and its implication for screening policies. *BMJ*. 1986;293(6548):659–664.
32. Ronco G, Dillner J, Elfström KM, et al. Efficacy of HPV-based screening for prevention of invasive cervical cancer: follow-up of four European randomised controlled trials. *Lancet*. 2014;383(9916):524–532. http://dx.doi.org/10.1016/S0140-6736(13)62218-7.
33. Moyer VA. U.S. Preventive Services Task Force. Screening for cervical cancer: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2012;156(12):880–891. http://dx.doi.org/10.7326/0003-4819-156-12-201206190-00424.
34. Sankaranarayanan R, Nene BM, Shastri SS, et al. HPV screening for cervical cancer in rural India. *N Engl J Med*. 2009;360(14):1385–1394. http://dx.doi.org/10.1056/NEJMoa0808516.
35. Vesco KK, Whitlock EP, Eder M, et al. *Screening for Cervical Cancer: A Systematic Evidence Review for the U.S. Preventive Services Task Force*. Portland, OR: Oregon Evidence-based Practice Centre, 2011.
36. Cancer Research UK. Cancer mortality statistics. www.cancerresearchuk.org/cancer-info/cancerstats/mortality/.
37. Ferlay J, Shin HR, Bray F, Forman D, Mathers C, Parkin DM. Estimates of worldwide burden of cancer in 2008: GLOBOCAN 2008. *Int J Cancer*. 2010;127(12):2893–2917. http://dx.doi.org/10.1002/ijc.25516.
38. Schiffman M, Castle PE, Jeronimo J, Rodriguez AC, Wacholder S. Human papillomavirus and cervical cancer. *Lancet*. 2007;370(9590):890–907. http://dx.doi.org/10.1016/S0140-6736(07)61416-0.
39. Sasieni P, Castanon A, Cuzick J. Effectiveness of cervical screening with age: population based case-control study of prospectively recorded data. *BMJ*. 2009;339:b2968. http://dx.doi.org/10.1136/bmj.b2968.
40. Bastos J, Peleteiro B, Gouveia J, Coleman MP, Lunet N. The state of the art of cancer control in 30 European countries in 2008. *Int J Cancer*. 2010;126(11):2700–2715.
41. Vesco KK, Whitlock EP, Eder MP, Burda BU, Senger CA, Lutz KM. Risk factors and other epidemiologic considerations for cervical cancer screening: a narrative review for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2011;155(10):698–705. http://dx.doi.org/10.7326/0003-4819-155-10-201111150-00377.
42. Corbelli J, Borrero S, Bonnema R, et al. Differences among primary care physicians' adherence to 2009 ACOG guidelines for cervical cancer screening. *J Womens Health*. 2014;23(5):397–403. http://dx.doi.org/10.1089/jwh.2013.4475.
43. Henderson JT, Yu JM, Harper CC, Sawaya GF. U.S. clinicians' perspectives on less frequent routine gynecologic examinations. *Prev Med*. 2014;62:49–53. http://dx.doi.org/10.1016/j.ypmed.2014.02.004.
44. Meyerson BE, Crosby RA, Van Der Pol BJ, Zimet GD. Thinking differently about cervical cancer screening in high-risk populations. *Am J Prev Med*. 2012;43(2):221–224. http://dx.doi.org/10.1016/j.amepre.2012.04.021.
45. Perkins RB, Anderson BL, Sheinfeld Gorin S, Schulkin JA. Challenges in cervical cancer prevention: a survey of U.S. obstetrician-gynecologists. *Am J Prev Med*. 2013;45(2):175–181. http://dx.doi.org/10.1016/j.amepre.2013.03.019.
46. Food and Drug Administration (FDA). FDA approves first human papillomavirus test for primary cervical cancer. 2014. www.fda.gov/newsevents/newsroom/pressannouncements/ucm394773.htm.
47. American Academy of Family Physicians. AAFP, USPSTF issue final recommendation against routine PSA-based screening for prostate cancer. AAFP Breaking News 2012. www.aafp.org/news-now/health-of-the-public/20120522psascreenrec.html.
48. Wallner LP, Jacobsen SJ. Prostate-specific antigen and prostate cancer mortality: a systematic review. *Am J Prev Med*. 2013;45(3):318–326. http://dx.doi.org/10.1016/j.amepre.2013.04.015.
49. Jemal A, Ward E, Wu X, Martin HJ, McLaughlin CC, Thun MJ. Geographic patterns of prostate cancer mortality and variations in access to medical care in the United States. *Cancer Epidemiol Biomarkers Prev*. 2005;14(3):590–595. http://dx.doi.org/10.1158/1055-9965.EPI-04-0522.
50. Chapman S, Barratt A, Stockler M. *Let Sleeping Dogs Lie? What Men Should Know before Getting Tested for Prostate Cancer*. Sydney: Sydney University Press, 2010. ses.library.usyd.edu.au/bitstream/2123/6835/3/Let-sleeping-dogs-lie.pdf.
51. Chou R, Croswell JM, Dana T, et al. Screening for prostate cancer: a review of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2011;155(11):762–771. http://dx.doi.org/10.7326/0003-4819-155-11-201112060-00375.
52. U.S. Preventive Services Task Force. Screening for prostate cancer. U.S. Preventive Services Task Force; 2012. www.uspreventiveservicestaskforce.org/prostatecancerscreening/prostatefinalrs.htm.
53. Lim LS, Sherin K. Screening for prostate cancer in U.S. men: ACPM position statement on preventive practice. *Am J Prev Med*. 2008;34(2):164–170. http://dx.doi.org/10.1016/j.amepre.2007.10.003.
54. NHMRC. *Prostate-Specific Antigen (PSA) Testing in Asymptomatic Men*. Canberra: NHMRC; 2014. www.nhmrc.gov.au/guidelines/publications/men4.
55. Zhu X, Albertsen PC, Andriole GL, Roobol MJ, Schroder FH, Vickers AJ. Risk-based prostate cancer screening. *Eur Urol*. 2012;61:652–661. http://dx.doi.org/10.1016/j.eururo.2011.11.029.
56. Sokoll L, Chan D. Total, free, and complexed PSA: analysis and clinical utility. *J Clin Ligand Assay*. 1998;21:171–179.
57. Andriole G, Djavan B, Fleshner N, Schroder F. The case for prostate cancer screening with prostate-specific antigen. *Eur Urol Suppl*. 2006;5:737–745. http://dx.doi.org/10.1016/j.eursup.2006.06.013.
58. Moss SM, Cuckle H, Evans A, Johns L, Waller M, Bobrow L. Effect of mammographic screening from age 40 years on breast cancer mortality at 10 years' follow-up: a randomised controlled trial. *Lancet*. 2006;368(9552):2053–2060. http://dx.doi.org/10.1016/S0140-6736(06)69834-6.

59. Berry DA, Cronin KA, Plevritis SK, et al. Effect of screening and adjuvant therapy on mortality from breast cancer. *N Engl J Med*. 2005;353(17):1784–1792. http://dx.doi.org/10.1056/NEJMoa050518.
60. Lord S, Lei W, Craft P, et al. A systematic review of the effectiveness of magnetic resonance imaging (MRI) as an addition to mammography and ultrasound in screening young women at high risk of breast cancer. *Eur J Cancer*. 2007;43(13):1905–1917. http://dx.doi.org/10.1016/j.ejca.2007.06.007.
61. Ciatto S, Houssami N, Bernardi D, et al. Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study. *Lancet Oncol*. 2013;14(7):583–589. http://dx.doi.org/10.1016/S1470-2045(13)70134-7.
62. Royce TJ, Hendrix LH, Stokes WA, Allen IM, Chen RC. Cancer screening rates in individuals with different life expectancies. *JAMA Intern Med*. 2014;174(10):1558–1565. http://dx.doi.org/10.1001/jamainternmed.2014.3895.
63. Kerlikowske K. Epidemiology of ductal carcinoma in situ. *J Natl Cancer Inst Monogr*. 2010;2010(41):139–141. http://dx.doi.org/10.1093/jncimonographs/lgq027.
64. Irwig L, Houssami N, Armstrong B, Glasziou P. Evaluating new screening tests for breast cancer. *BMJ*. 2006;332(7543):678–679. http://dx.doi.org/10.1136/bmj.332.7543.678.
65. Han PKJ, Coates RJ, Uhler RJ, Breen N. Decision making in prostate-specific antigen screening National Health Interview Survey, 2000. *Am J Prev Med*. 2006;30(5):394–404. http://dx.doi.org/10.1016/j.amepre.2005.12.006.
66. Hoffman RM, Elmore JG, Fairfield KM, Gerstein BS, Levin CA, Pignone MP. Lack of shared decision making in cancer screening discussions. *Am J Prev Med*. 2014;47(3):251–259. http://dx.doi.org/10.1016/j.amepre.2014.04.011.
67. Rosenbaum L. Invisible risks, emotional choices—mammography and medical decision making. *N Engl J Med*. 2014;371(16):1549–1552. http://dx.doi.org/10.1056/NEJMms1409003.
68. Finkel AM. Perceiving others' perceptions of risk. *Ann N Y Acad Sci*. 2008;1128(1):121–137. http://dx.doi.org/10.1196/annals.1399.013.
69. Sjöberg L. The allegedly simple structure of experts' risk perception: an urban legend in risk research. *Sci Technol Human Values*. 2002;27(4):443–459. http://dx.doi.org/10.1177/016224302236176.
70. Shaw D, Elger B. Evidence-based persuasion: an ethical imperative. *JAMA*. 2013;309(16):1689–1690. http://dx.doi.org/10.1001/jama.2013.2179.

"What should happen before asymptomatic men decide whether or not to have a PSA test?" A report on three community juries

Abstract

Objectives: To elicit the views of well informed community members on the ethical obligations of general practitioners regarding prostate-specific antigen (PSA) testing, and what should be required before a man undergoes a PSA test.

Design and setting: Three community juries held at the University of Sydney over 6 months in 2014.

Participants: Forty participants from New South Wales, of diverse social and cultural backgrounds and with no experience of prostate cancer, recruited through public advertising: two juries of mixed gender and ages; one all-male jury of PSA screening age.

Results: In contrast to Royal Australian College of General Practitioners guidelines, the three juries concluded that GPs should initiate discussions about PSA testing with asymptomatic men over 50 years of age. The mixed juries voted for GPs offering detailed information about all potential consequent benefits and harms before PSA testing, and favoured a cooling-off period before undertaking the test. The all-male jury recommended a staggered approach to providing information. They recommended that written information be available to those who wanted it, but eight of the 12 jurors thought that doctors should discuss the benefits and harms of biopsy and treatment only after a man had received an elevated PSA test result.

Conclusions: Informed jury participants preferred that GPs actively supported individual men in making decisions about PSA testing, and that they allowed a cooling-off period before testing. However, men of screening age argued that uncertain and detailed information should be communicated only after receiving an elevated PSA test result.

Chris Degeling PhD, BVSc[1]

Lucie Rychetnik PhD, MPH[2]

Kristen Pickles MPH[1]

Rae Thomas PhD[3]

Jennifer A Doust BM BS, PhD, FRACGP[3]

Robert A Gardiner MD, FRCS, FRACS[4]

Paul Glasziou BM BS, PhD, FRACGP[3]

Ainsley J Newson PhD, LLB(Hons), BSc(Hons)[1]

Stacy M Carter PhD, MPH(Hons)[1]

1 Centre for Values, Ethics and the Law in Medicine, University of Sydney, Sydney, NSW.

2 University of Notre Dame, Sydney, NSW.

3 Centre for Research in Evidence-Based Practice, Bond University, Gold Coast, QLD.

4 The University of Queensland Centre for Clinical Research, Redland City, QLD.

chris.degeling@sydney.edu.au

doi: 10.5694/mja15.00164

Prostate-specific antigen (PSA) testing of asymptomatic men remains controversial.[1] Testing may improve prostate cancer survival rates,[2] but can also lead to harms, such as repeated investigations and the unwanted effects of treatments, including incontinence and impotence.[3-5] Evidence regarding benefits and harms alone has not resolved tensions over PSA testing.[6] Disagreement among experts and in guidelines has confused public communication in Australia and internationally.[7,8]

In December 2014, the Prostate Cancer Foundation of Australia (PCFA) and the Cancer Council Australia (CCA) released clinical consensus guidelines for general practitioners for public comment,[9] after the National Health and Medical Research Council (NHMRC) had published information on the topic for health practitioners.[10] These documents established criteria for identifying men more likely to benefit than to be harmed by PSA testing. However, it remains unclear if and when GPs should introduce the subject of PSA testing in consultations with individual men. The Royal Australian College of General Practitioners (RACGP) advises GPs not to broach the subject of PSA testing, but to provide full information regarding the benefits, risks and uncertainties of testing and treatment if patients specifically ask about it.[11]

In this article, we report the outcomes of three community juries convened in 2014 to consider the dilemmas associated with PSA testing. A community jury is a group of citizens brought together to receive detailed evidence about a specific problem and to then deliberate on this problem.[12] Our aim was not to capture the opinions of the broader community, but to ascertain what a well informed citizenry would accept as legitimate PSA testing policy and practice, and the reasons for their views. Community juries are an established, appropriate method for investigating such questions.[12] Community juries have been used in Australia and elsewhere to consider questions related to cancer screening.[13,14] Unlike surveys and focus groups, they involve extensive provision of information, constructive and structured dialogue between ordinary members of the public and experts, and adequate time for consideration of the problem. The process is similar to a legal proceeding, but the outputs are not legally binding; they instead provide evidence for policy making.

We consulted major stakeholders (consumer organisations, GPs, epidemiologists, urologists, the CCA) to design the questions that the juries would consider. All agreed that the key issues to be explored were:

- whether GPs should initiate discussions with asymptomatic men about the PSA test;
- when men should be given information about the potential benefits and harms of testing, biopsy and treatment.

Valid consent for interventions is integral to an ethical health care system, and providing adequate and timely information is fundamental to valid consent. While this has been noted in relation to PSA testing,[15,16] it is not yet clear what should happen before men decide for or against taking a PSA test. Noting the work currently being undertaken by the NHMRC, CCA and PCFA, we sought information on what selected groups of members of the public consider to be the obligations of GPs regarding informing men about PSA testing, and what else might be required

before a man could validly consent to a PSA test.

Methods

Community jury research is a deliberative method, with the following general characteristics:

- a group of citizens is convened for 1 to 3 days;
- they are asked to consider a specific problem;
- they hear evidence from (often opposed) experts, and ask the experts questions;
- they are given time for deliberation and to come to a documented conclusion.

There are two main approaches in community jury research: participants draft open recommendations as a group, or vote on options specified by the researchers.[17] We used both approaches in our investigation: Jury 1 tested an open approach, while Juries 2 and 3 were asked to vote on specific options (Box 1).

Recruitment and selection

We recruited three community juries in 2014 — two of mixed gender and ages (Juries 1 and 2), and one of men of PSA screening age (Jury 3) — by placing advertisements and articles in the mass and social media in Sydney. Of 119 respondents, 42 were unavailable on the days scheduled for the juries; 37 with recent personal or close family member experience of prostate cancer treatment, biopsy or active PSA monitoring were also excluded. We sought socioeconomic and cultural diversity for our juries. Juries 1 and 2 were socioculturally diverse but of above-average educational attainment; the all-male Jury 3 was also socioculturally diverse, but its educational attainments broadly matched those of the general Australian population. Forty participants were thus recruited according to their eligibility, sociodemographic characteristics and availability (Box 2).

Each jury commenced with an evening orientation session (Day 0), during which the questions and the jury process were introduced and consent was obtained. Jury Day 1 focused on interrogating the evidence and understanding the ethical, legal and practical aspects of the problem. Testimony on the following themes was prerecorded by selected experts and shown to jurors in a video presentation:

- basic biology, diagnosis, treatment and prognosis of prostate cancer;
- qualitative empirical evidence on how Australian GPs manage PSA testing in their practices;
- ethical and legal aspects of patient consent (in general, and with regard to screening);
- potential harms of screening asymptomatic men for prostate cancer; and
- potential benefits of screening asymptomatic men for prostate cancer.

Each presentation lasted about an hour. Prerecording ensured that the evidence presented was standardised, although some experts slightly modified their presentations for Juries 2 and 3 according to the more specific options considered by these juries. The biographical sketches of the experts and the video presentations shown to Juries 2 and 3 are available online.[18]

Immediately after each video, the relevant expert was available for questions through a conference calling system. Facilitated by a researcher, these question-and-answer sessions allowed jurors to clarify or challenge the arguments presented. Facilitation focused on promoting constructive dialogue and fair interaction between jurors. Our observations of unstructured deliberations and the transcripts indicated that this inclusivity was maintained during non-facilitated periods.

For the first hour of Jury Day 2, jurors reflected on, discussed and debated the evidence, aided by a researcher acting as facilitator. Juries then deliberated for an hour without the researchers, and either reached a set of recommendations (Jury 1) or majority verdicts on the questions posed (Juries 2 and 3). The recommendations or verdicts, the underlying reasoning, and dissenting views were reported to the research team in a final, facilitated feedback session.

Data collection and analysis

The three deliberative groups (juries) were the units of analysis in this study. All jury deliberations (facilitated and non-facilitated) and expert question-and-answer sessions were

1 The questions addressed to the three juries, and the options available for their verdicts

Jury 1 deliberated and drafted recommendations on the open question:

Consent and PSA testing for prostate cancer: "What should happen before men decide whether or not to be tested?"

Juries 2 and 3 were asked to vote on two questions:

Part A. Select 1 or 2:

1. Should GPs introduce the topic of PSA testing during appointments with male patients who have no symptoms?

   OR

2. Should they wait until men ask about it?

Part B. Which of these options do you endorse? (Please give your reasons):

1. Men without symptoms should get all the information about the possible benefits and harms of testing, and biopsy and treatment, before they decide whether or not to have a PSA test.

   OR

2. Men should not get information about possible benefits and harms of biopsy and treatment before PSA testing. Instead, the doctor should wait until they know the test result. If the test result is raised, then the doctor should give information.

Jurors were asked to endorse either B1 or B2, and to give reasons for their decisions. The juries were repeatedly reminded that the questions were specifically about PSA testing for asymptomatic men. ◆

audio-recorded and transcribed. During the final session, the verdicts and reasons were recorded by a researcher on a flipchart. Each point was reviewed by the jury to ensure accuracy. Transcripts were subsequently reviewed to identify key reasons why jurors supported or rejected the presented options.

Ethics approval

Our study was approved by the Cancer Institute NSW Population and Health Services Research Ethics Committee (HREC/12/CIPHS/46).

Results

Jury 1

In response to the question, "What should happen before men decide whether or not to be tested?", Jury 1 recommended that:

- GPs should initiate discussions about PSA testing with 50–70-year-old asymptomatic men, and provide information about the limitations of the test and the potential benefits and harms of biopsy and treatment;
- these discussions should be encouraged but not mandatory;
- discussions should inform a man's decision making rather than be constrained by formal procedures (eg, signing a form);
- GPs should consider a cooling-off period, so that men need to wait 1 to 2 days after the discussion before being tested; and
- the community should be informed about expert uncertainty regarding the PSA test, to stimulate discussion between men and their GPs.

Problems discussed by Jury 1 without reaching a consensus were:

- the appropriate content for a patient information sheet;
- how to communicate to men that they can opt out of PSA testing; and
- whether to discourage PSA testing by charging a fee.

2 Characteristics of the jury participants

	Jury 1	Jury 2	Jury 3
Number	13	15	12
Age			
< 40 years	2	5	1
40–70 years	10	8	9
> 70 years	1	2	2
Range, years	28–70	19–75	37–74
Median, years	52	49	57
Gender			
Male	9	9	12
Female	4	6	0
Highest educational attainment			
High school	2	3	1
Trade or diploma	0	1	7
Bachelor degree	4	7	3
Postgraduate degree	7	4	1
Cultural background/ethnicity*			
Australian	11	11	7
Southern/eastern European	0	1	0
Southeast Asian	1	0	1
Northeast Asian	1	2	2
Southern/central Asian	0	1	1
Northwest European	0	0	1
Socioeconomic status of suburb†			
Low	1	1	2
Middle	1	4	4
High	11	10	6

* Based on the Australian Standard Classification of Cultural and Ethnic Groups (ASCCEG).[22]
† Based on Socio-Economic Indexes for Areas (SEIFA).[23] ◆

Juries 2 and 3, part A

Similar to Jury 1, the majority view of both Juries 2 and 3 was that GPs should introduce the topic of PSA testing to asymptomatic men aged 50–70 years (Box 3). Prostate cancer was seen as a legitimate health concern for older men, so that PSA testing was an appropriate topic for general health discussions. Jury 3 (all males) also argued that GPs were best placed to inform men about PSA testing, as GPs were a more reliable point of access to medical advice; relying on other information sources would be "leaving it to chance". All men, they said, should have equal access to the same information.

A minority in both Juries 2 and 3 voted that GPs should not raise the topic of PSA testing with asymptomatic men because other, more important health issues should receive priority, and because men might be more inclined to have a PSA test if GPs raised the topic. They were particularly concerned about the unreliability of the test and the risks of unnecessary treatment ensuing.

Juries 2 and 3, part B

Like Jury 1, the majority of Jury 2 (mixed gender) voted that detailed benefit–harm information about PSA testing and prostate biopsy and treatment should be provided in advance to support informed decision making. This was a minority position in the all-male Jury 3 (Box 3).

3 The outcomes of the deliberations of the three juries

Jury 1 recommendations

GPs should:

- initiate discussions with 50–70-year-old asymptomatic men about PSA testing;
- be prepared to provide men with information about all the potential harms and benefits;
- consider instituting a cooling-off period so that men need to wait before taking the test.

Juries 2 and 3 verdicts

Part A

1. Should GPs introduce the topic of PSA testing during appointments with male patients who have no symptoms?

   OR

2. Should they wait until men ask about it?

   Jury 2 (mixed gender, $n = 15$) voted 12–3 for option 1;

   Jury 3 (all men, $n = 12$) voted 10–2 for option 1.

Part B

1. Men without symptoms should get all the information about the possible benefits and harms of testing, *and* biopsy *and* treatment, before they decide whether or not to have a PSA test.

   OR

2. Men should *not* get information about possible benefits and harms of biopsy and treatment *before* PSA testing. Instead, the doctor should wait until they know the test result. *If* the test result is raised, *then* the doctor should give information.

Jury 2 (mixed gender, $n = 15$) voted 13–2 for option 1;

Jury 3 (all men, $n = 12$) voted 8–4 for option 2. ◆

The reasons given by members of Juries 2 and 3 for their views included:

- men have a right to know relevant information before making a decision; and
- after an elevated PSA test result, it might be difficult to refuse subsequent biopsy and treatment, and men may not obtain the information needed to decide about the next steps.

Similar to Jury 1, Juries 2 and 3 supported a cooling-off period so that men could reconsider their decision before testing.

The majority of Jury 2 (13 of 15) supported providing all information before PSA testing. However, 10 of the 13 objected that our wording (especially "should" and "all") was too prescriptive. They wanted GPs to be free to provide information tailored to an individual's level of interest and personal requirements.

Two-thirds of the all-male Jury 3 voted that information about the benefits and harms of biopsy and treatment should be provided only after an elevated PSA test result had been received. These jurors argued that the PSA test alone was not intrinsically harmful, and favoured staggering the delivery of information, with written information available to those who wanted it at any particular point. Jury 3 members, in particular, were concerned about "information overload". They felt that most men would not want to understand the harms and benefits of prostate biopsy and treatment until it was directly relevant to them. They trusted GPs to tell them what they needed to know in a timely manner, avoiding unnecessary anxiety. Notably, some participants argued that details about the risks of biopsies and treatment options should be provided to men by urologists because of their specialist expertise.

Discussion

After two days of deliberation, all three community juries recommended that GPs should discuss the PSA test with asymptomatic men over 50 years of age as part of routine care. Jurors felt GPs were best placed to consistently inform men about PSA testing, rather than relying on their being informed (or not) by other sources. All three juries wanted GPs, if prompted, to provide information about the limitations, benefits and risks of testing, biopsy and treatment, and to offer to provide more details if desired by the patient. The concept of a cooling-off period to allow men to think about whether or not they wanted a PSA test was also highly valued.

All Jury 3 members were men, and many were having, and appeared committed to, routine annual PSA tests. They also reached different conclusions to the other juries about when information should be provided. While Juries 1 and 2 focused on what would be good for men generally, members of Jury 3 often focused on their own personal experiences and preferences, including a shared inclination to rely on a doctor's assessment of the particular information that was required to inform a patient's decisions. This suggests that, although an informed public prefers GPs to take an active role in educating men about the PSA test, some men of screening age may not wish to be burdened with uncertain and detailed information about the consequences unless they have received an elevated PSA test result.

There are valid reasons why GPs might resist raising awareness of the PSA test. Simply mentioning it may encourage men to favour being tested; patients differ in their information needs;[19] and communicating the potential harms of PSA screening is difficult.[20,21] The new consensus recommendations and NHMRC-developed information resources promise to support GPs in the challenging task of discussing the topic. Models for communicating information about screening in a balanced and patient-centred way have also been described in the literature. The "consider an offer" model,[19] for example, suggests that GPs help men consider and evaluate recommendations or offers of screening, while explicitly acknowledging that the

offer might reasonably be refused. Rather than encouraging screening or expecting people to analyse detailed evidence, whether they felt ready to do so or not, such patient-centred approaches could help individuals decide how much information they wish to receive, and to reflect on their values and preferences regarding benefits and harms when deciding whether or not to be screened.

A limitation to this study is that community juries are comprised of small groups of engaged citizens whose views may not represent those of the general public. However, as all three juries came to similar conclusions, it is likely that our findings are replicable. Our unit of analysis was the deliberative group, but we note that the findings from the all-male jury differed from those of the mixed-gender juries, and that the men in the mixed juries endorsed the final recommendations of the juries in which they participated. This suggests that gender-related factors may influence jury processes.

The juries were clear: GPs should raise the topic of PSA testing and explain the benefits and harms, but tailor their information to the individual patient. Timing of information provision was less clear. PSA testing, the juries concluded, is a health issue that matters to men, and GPs are a reliable, trustworthy source of advice on health issues. These jury outcomes invite critical reflection by professional bodies about how GPs should actively support individual men making decisions about PSA testing.

Acknowledgements: Chris Degeling, Kristin Pickles, Lucie Rychetnik and Stacy Carter received funding from NHMRC project grant #1023197. Stacy Carter is also supported by an NHMRC Career Development Fellowship (#1032963) and Paul Glasziou by an NHMRC Australia Fellowship (#0527500). Rae Thomas, Jennifer Doust and Paul Glasziou received funding from Bond University and NHMRC program grant #633033.

Competing interests: No relevant disclosures. ■

1 Barry MJ. Screening for prostate cancer — the controversy that refuses to die. *N Engl J Med* 2009; 360: 1351-1354.

2 Schröder FH, Hugosson J, Roobol MJ, et al. Prostate-cancer mortality at 11 years of follow-up. *N Engl J Med* 2012; 366: 981-990.

3 Chou R, Croswell JM, Dana T, et al. Screening for prostate cancer: a review of the evidence for the US Preventive Services Task Force. *Ann Intern Med* 2011; 155: 762-771.

4 Ilic D, O'Connor D, Green S, Wilt TJ. Screening for prostate cancer: an updated Cochrane systematic review. *BJU Int* 2011; 107: 882-891.

5 Welch HG, Black WC. Overdiagnosis in cancer. *J Natl Cancer Inst* 2010; 102: 605-613.

6 Brett AS, Ablin RJ. Prostate-cancer screening — what the US Preventive Services Task Force left out. *N Engl J Med* 2011; 365: 1949-1951.

7 Moyer VA. Screening for prostate cancer: US Preventive Services Task Force recommendation statement. *Ann Intern Med* 2012; 157: 120-134.

8 Urological Society of Australia and New Zealand. PSA testing policy 2009. http://www.usanz.org.au/uploads/29168/ufiles/USANZ_2009_PSA_Testing_Policy_Final1.pdf (accessed Jul 2015).

9 Prostate Cancer Foundation of Australia and Cancer Council Australia; PSA Testing Guidelines Expert Advisory Panel. Draft clinical practice guidelines PSA testing and early management of test-detected prostate cancer. Sydney: Cancer Council Australia, 2014. http://wiki.cancer.org.au/australia/Guidelines:PSA_Testing/Guideline_development_process (accessed Jul 2015).

10 National Health and Medical Research Council. PSA testing for prostate cancer in asymptomatic men: information for health practitioners. 2014. http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/men4d_psa_testing_asymptomatic_men_140304.pdf (accessed Jul 2015).

11 Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 8th ed. Melbourne: RACGP, 2012. http://www.racgp.org.au/your-practice/guidelines/redbook/ (accessed Jul 2015).

12 Degeling C, Carter SM, Lychetnik L. Which public and why deliberate? — A scoping review of public deliberation in public health and health policy research. *Soc Sci Med* 2015; 131: 114-121.

13 Rychetnik L, Doust J, Thomas R, et al. Community Jury on PSA screening: what do well-informed men want the government to do about prostate cancer screening — a qualitative analysis. *BMJ Open* 2014; 4: e004682.

14 Paul C, Nicholls R, Priest P, McGee R. Making policy decisions about population screening for breast cancer: the role of citizens' deliberation. *Health Policy* 2008; 85: 314-320.

15 Wollin D, Loeb S. Patient perceptions and shared decisions about PSA screening. *Rev Urol* 2013; 15: 206-207.

16 Knight SJ. Decision making and prostate cancer screening. *Urol Clin North Am* 2014; 41: 257-266.

17 Lenaghan J, New B, Mitchell E. Setting priorities: is there a role for citizens' juries? *BMJ* 1996; 312: 1591.

18 Center for Values, Ethics and the Law in Medicine, University of Sydney. Project 5: Prostate screening from the perspective of citizens [website]. 2014. http://cancerscreeningethics.org/prostate-screening-projects/project-5-community-juries (accessed Jul 2015).

19 Entwistle VA, Carter SM, Trevena L, et al. Communicating about screening. *BMJ* 2008; 337: a1591-1593.

20 Howard K, Brenner AT, Lewis C, et al. A comparison of US and Australian men's values and preferences for PSA screening. *BMC Health Serv Res* 2013; 13: 388.

21 Gattellari M, Ward JE. Will men attribute fault to their GP for adverse effects arising from controversial screening tests? An Australian study using scenarios about PSA screening. *J Med Screen* 2004; 11: 165-169.

22 Australian Bureau of Statistics. Australian Standard Classification of Cultural and Ethnic Groups (ASCCEG), 2011. http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/1249.0Main+Features12011?OpenDocument (accessed Jul 2015).

23 Australian Bureau of Statistics. SEIFA 2011. http://www.abs.gov.au/ausstats/abs@.nsf/mf/2033.0.55.001 (accessed Jul 2015). ■

BMJ 2016;352:i348 doi: 10.1136/bmj.i348 (Published 5 February 2016)

ANALYSIS

Walking the tightrope: communicating overdiagnosis in modern healthcare

Communication that empowers the public, patients, clinicians, and policy makers to think differently about overdiagnosis will help support a more sustainable healthcare future for all, argue **Kirsten McCaffery and colleagues**

Kirsten J McCaffery *health psychologist* [1], Jesse Jansen *cognitive psychologist*[1], Laura D Scherer *social psychologist*[2], Hazel Thornton *independent citizen advocate*[3], Jolyn Hersch *health psychologist*[1], Stacy M Carter *public health ethicist*[4], Alexandra Barratt *epidemiologist*[1], Stacey Sheridan *primary care provider*[5], Ray Moynihan *research fellow*[6], Jo Waller *health psychologist* [7], John Brodersen *professor*[8 9], Kristen Pickles *PhD student*[4], Adrian Edwards *general practitioner*[10]

[1]School of Public Health, University of Sydney, New South Wales 2006, Australia; [2]Department of Psychological Sciences, University of Missouri, Columbia, USA; [3]Department of Health Sciences, University of Leicester, Leicester, UK ; [4]Centre for Values, Ethics and the Law in Medicine, University of Sydney; [5]Division of General Medicine and Clinical Epidemiology, School of Medicine, University of North Carolina, Chapel Hill, USA; [6]Bond University, Queensland, Australia; [7]Epidemiology and Public Health, University College London, UK; [8]Research Unit and Section of General Practice, Department of Public Health University of Copenhagen, Denmark; [9]Primary Health Care Research Unit, Zealand Region, Denmark; [10]Division of Population Medicine, School of Medicine, Cardiff University, UK

Overdiagnosis and overtreatment have serious implications for individuals, healthcare systems, and society,[1 2] and effective strategies are urgently needed to help the public, clinicians, and policy makers address this problem. Communication about overdiagnosis has been highlighted as essential for moving forward but presents several challenges, such as the potential to confuse the public, undermine trust, and adversely affect people who already have a diagnosis. Various communication based strategies offer real promise; we describe what is known and what we need to know to communicate effectively and safely about overdiagnosis and overtreatment.

What are the key messages to be communicated?

Understanding of overdiagnosis among the general public and health professionals is limited, so it is essential to communicate what it means for individuals, the health system, and society (box 1). By definition, overdiagnosis will not improve prognosis and will probably harm individuals (for example, by unnecessary intervention) or society (opportunity costs). For individuals, it is important to communicate the nature (physical or psychological), likelihood, and duration of the harms. For societies with free public healthcare, the financial strain and opportunity cost are usually at system level—resources wasted on unnecessary tests and treatments are unavailable for people in greater need. But in private healthcare systems, overdiagnosis can be a huge personal financial burden, even for those with insurance.

Communication is further complicated because it is usually impossible to know whether an individual has been overdiagnosed or benefited from the diagnosis—overdiagnosis can only be observed at the aggregate level. Recent efforts to communicate the concept and likelihood of overdiagnosis in breast screening have had some success, albeit with much room for improvement. When given a patient decision aid including an infographic and icon array (figure⇓), 29% of women understood both the concept and quantitative outcomes of breast screening (including deaths avoided, false positive results, and overdiagnosis); 59% of women understood the conceptual information alone.[3]

Communication based strategies to mitigate overdiagnosis

Several communication based strategies have been applied in the areas of overtesting and overtreatment and directed at individual, community, or policy levels (box 2).

Strategies for individuals

Shared decision making is a consultation process where a clinician and patient jointly make a health decision. It changes

Correspondence to: K J McCaffery kirsten.mccaffery@sydney.edu.au

Box 1: Overdiagnosis and its consequences[1 2]

Overdiagnosis occurs when a diagnosis is "correct" according to current professional standards but when the diagnosis or associated treatment has a low probability of benefiting the person diagnosed.[2] It is caused by a range of factors such as:

- Use of increasingly sensitive tests that identify abnormalities that are indolent, non-progressive, or regressive (overdetection)
- Expanded definitions of disease—for example, attention-deficit/hyperactivity disorder and dementia—and lowering of disease thresholds, such as osteoporosis (overdefinition)
- Creation of pseudodiseases (also called disease mongering), such as low testosterone and restless leg syndrome
- Clinicians' fear of missing a diagnosis or litigation
- Public enthusiasm for screening or testing and desire for reassurance
- Financial incentives

Potential consequences of overdiagnosis

- Psychological and behavioural effects of disease labelling
- Physical harms and side effects of unnecessary tests or treatment
- Quality of life affected by unnecessary treatment
- Hassles of unnecessary tests and treatments
- Increased financial costs to individuals
- Wasted resources and opportunity costs to the health system
- Overmedicalisation of society

the way decisions are framed by identifying that there is a decision to be made (not an obligatory test or default treatment), and explaining the range of options available and their benefits and harms. It also involves deciding with patients "what is most important to them" in terms of their values, preferences, and circumstances.[4] Importantly, the option of doing nothing or active surveillance can be discussed as a deliberate or positive action[5] to counter people's bias for tests and treatment, especially in cancer.[6] Consumer led interventions that teach patients to ask about benefits and harms of different options have shown some success.[7] Shared decision making is increasingly part of clinical training, often combined with evidence based healthcare,[8] and this should be enhanced to include understanding and communicating about overdiagnosis.

Patient decision aids support shared decision making. High quality evidence from 115 trials shows that they improve patients' knowledge and understanding of options and their risks and benefits, and increase consistency between patients' values and choices.[9] Decision aids have successfully informed women about overdiagnosis in breast screening,[3] reduced men's desire for prostate specific antigen (PSA) testing[10] or surgical management for prostate cancer, and reduced preferences for potentially unnecessary elective surgery.[9] A trial of a decision aid communicating overdiagnosis in breast screening (879 women approaching age 50) increased informed choice compared with controls and did not increase anxiety; worry about breast cancer decreased (box 2).[3] A pilot study of a breast screening decision aid for women over 75 years (n=45) including information on overdiagnosis had similar findings.[11 12] However, information on the harms of overdiagnosis and overtreatment is rarely presented.[13 14] Consumers consistently overestimate the benefits of screening, tests, and treatments and underestimate the harms,[13] and although shared decision making is widely espoused, it is not often implemented.[15]

Strategies for communities

Mass media and direct to consumer campaigns can influence large numbers of people simultaneously and promote sustained beneficial changes in behaviour.[16] For example, a mass media campaign about back pain, driven partly by concerns about unnecessary back imaging, changed both community and general practitioner beliefs about management, resulting in reduced imaging, work insurance claims, and healthcare usage.[17] Scaled down versions of the programme have been replicated in several countries.[16] Other important initiatives include the Choosing Wisely campaign, now operating in nine countries (www.choosingwisely.org), and the UK's "do not do" list.

Policy directed strategies

Deliberative democratic methods (such as community juries) support policy decisions by gathering informed public responses about disputed issues, such as what services are available or reimbursed by health funds. Because overdiagnosis is scientifically and politically contested, this topic is ideal for deliberative democratic methods. Deliberative methods must meet exacting standards and are time consuming.[18] Community juries have considered PSA testing in Australia[19 20] and mammographic screening in New Zealand, where participants changed their recommendation at least partly because of potential harms from overdiagnosis.[21] Disseminating findings from juries could enhance community health literacy, leading to better informed citizens and more transparent decision making.

Changing terminology: Behaviours can be influenced by medical terminology, and changing the names for medical conditions may help reduce the effect of overdiagnosis. In one study, describing ductal carcinoma in situ as "non-invasive cancer" resulted in 13-16% more women choosing surgical treatment (rather than medication or active surveillance) compared with calling it a "breast lesion" or "abnormal cells."[22] Similar findings were reported in Australia.[23 24] Independent experts convened by the US National Cancer Institute[25] and National Institute of Health have proposed dropping the word "cancer" entirely in this case, arguing for it to be reserved for lesions likely to progress if untreated.[25 26] Similar arguments exist for thyroid and prostate cancer,[27] but effects of disease labels extend beyond cancer. Parents were more likely to accept medication when "gastro-oesophageal reflux disease" (compared with no label) was used to describe excessive irritability in infants, even when told the drugs would not control the symptoms.[28]

Potential challenges to effective communication

Low levels of awareness: Awareness of overdiagnosis is low, particularly for cancer screening with few people understanding overdiagnosis of cancer is even possible.[29 30] In one study, 18% of Australian men and only 10% of women said they had been

Box 2: Examples of effective communication strategies for overdiagnosis or overtreatment

Community back pain campaign (three year campaign 1997-99)[17]

- Significant improvements in community (n=4730) beliefs about back pain over three years in Victoria (where campaign was run) versus New South Wales (no campaign)
- General practitioners'(n=2556) knowledge improved—for example, time when patients can to return to work, not prescribing complete bed rest. In a patient scenario, GPs in Victoria were 2.51 times less likely to order tests for acute low back pain and 0.40 times as likely to order lumbosacral radiographs. Over the duration of the campaign insurance claims for back pain reduced by 15%

Patient decision aids[9]

- Cochrane review of 115 randomised controlled trials reported that decision aids reduced number of people choosing major elective surgery in favour of more conservative options (relative risk 0.79) and reduced number of men choosing PSA testing (RR 0.87) in nine studies
- A randomised trial of a decision aid for women approaching 50 years (n=879), which explicitly explained the concept of overdiagnosis and presented quantitative information on its likelihood, found that it increased informed choice by 9% (intervention24% *v* control 15%), reduced intentions to screen by 13% (74% *v* 87%)[3]

Changing disease terminology

- Study of 394 women compared the commonly used cancer term for ductal carcinoma in situ (non-invasive cancer) with non-cancer terms (breast lesion, abnormal cells). Results showed 47% preferred surgery when cancer term was used compared with 34% and 31% respectively[22]

Citizen juries

- 27 men randomly allocated to PSA screening community jury (12 men) or control (15 men). The jury concluded that the Australian government should not invest in PSA testing and recommended an education programme for GPs with better quality and consistent information about PSA for doctors and patients. After the jury, men had significantly lower intentions to screen compared with controls[24]

told about overdiagnosis in screening for prostate and breast cancer respectively.[31] Similarly, a US survey reported only 9.5% of men and women (aged 50-69 years) said they had been informed about overdiagnosis when discussing cancer screening.[32] Further US and UK studies reported that only about half of respondents had heard of "cancers that grow so slowly that they are unlikely to cause [you] problems in [your] lifetime."[33 34] There are few publications reporting clinician awareness, but one recent survey among 126 university affiliated clinicians in the US found 28% listed overdiagnosis as a potential harm of PSA testing, and 56% listed unnecessary treatment.[35]

Cognitive biases and counterintuitive messages: Longstanding, prominent public health messages have emphasised the benefits and ignored the harms of early diagnosis for many diseases.[36 37] This makes the concept of overdiagnosis unfamiliar, counterintuitive, and difficult to understand. There is widespread faith in the importance of early detection,[38 39] and people may choose cancer screening because it is the apparent default decision, even if their informed preferences would be different.[40-42] Furthermore, when people are predisposed towards an intervention, they may perceive benefits to be high and risks low, even when explicitly told otherwise.[43] Suggesting a reduction in tests that are popular with the public can provoke emotionally charged, even hostile responses,[44] reflecting cognitive dissonance.[45]

Uncertainty and trust: Intolerance of uncertainty and anxiety about missing rare cases underpin much medical excess.[46] Communicating about overdiagnosis requires us to acknowledge the inherent uncertainty in the size and extent of the problem and its consequences. These issues are often hotly contested.[47] Communicating uncertainty adds complexity and may lead to confusion and avoidance of decision making[48] and can undermine trust in the healthcare provider.[49] However, distrust can also arise when patients discover that information about harms has been withheld. Clinicians often avoid discussing uncertainty with patients,[48] but studies of breast and prostate screening show that people want to be told about overdiagnosis.[19 29]

Vested interests and persuasive communication: Vested interests may influence how information is presented in the media and the scientific arena. Pharmaceutical and device manufacturers have direct interests in maximising product sales. Industry funded disease awareness campaigns often increase the numbers of people portrayed as patients.[50] Narrowing the boundaries that define disease or raising diagnostic thresholds is a threat to turnover, profit, and professional interests.[51] Similarly patient advocacy groups, often also industry funded, can have interests in portraying their condition as widespread, severe, and treatable to optimise media, professional, and policy attention and to attract resources.[52] Politicians too have seen mileage in supporting screening programmes without offering more nuanced assessments of their benefits and harms, including risks of overdiagnosis.[53]

Further research directions

We need studies about what the public, patients, and clinicians currently know, understand, and want to know about overdiagnosis and their attitudes, reactions, and choices when provided with such information. Then we can research effective communication—how to increase understanding among all parties and the effectiveness and acceptability of such strategies. Once effective interventions are identified, we need to understand how to implement them within healthcare systems that currently reward overdiagnosis. However, research must also consider potential harms of communicating overdiagnosis, and herein lies the tightrope. Possible harms include cognitively overburdening and confusing the public, adversely affecting patients already diagnosed and treated, and creating distrust in conventional medicine.[29] A careful evidence based approach is essential.

Achieving widespread understanding about overdiagnosis will take time, but we have some tools to move forward. Given that high health anxiety is largely a consequence of the health system itself, the health community must be patient with and sympathetic towards those who do not share this concern about overdiagnosis. Successful communication that empowers the public, patients, clinicians, and policy makers to think differently about overdiagnosis will help support more sustainable healthcare for all.

We thank Teppo Jarvinen, Angie Fagerlin, and Elizabeth Dawson for reading and providing thoughtful comment on this manuscript and all

Key messages

- Overdiagnosis provides no benefits to patients and is a challenge to the sustainability of modern healthcare systems
- Communication based strategies could help reduce overdiagnosis and its negative impact on individuals and health systems
- Mass media education, shared decision making, terminology changes for disease states, and deliberative methods (juries) all have potential as effective communication strategies

participants of the preventing overdiagnosis research workshop on communication, held in Oxford, September 2014. We thank Brooke Nickel for administrative support.

Contributors and sources: This article was produced following the 2014 preventing overdiagnosis conference research planning day. KJMcC and AE led writing of the manuscript. Each author contributed to sections of the paper and commented on drafts. KJMcC is guarantor. The authors have expertise in shared decision making, public communication about overdiagnosis, risk communication, and decision science.

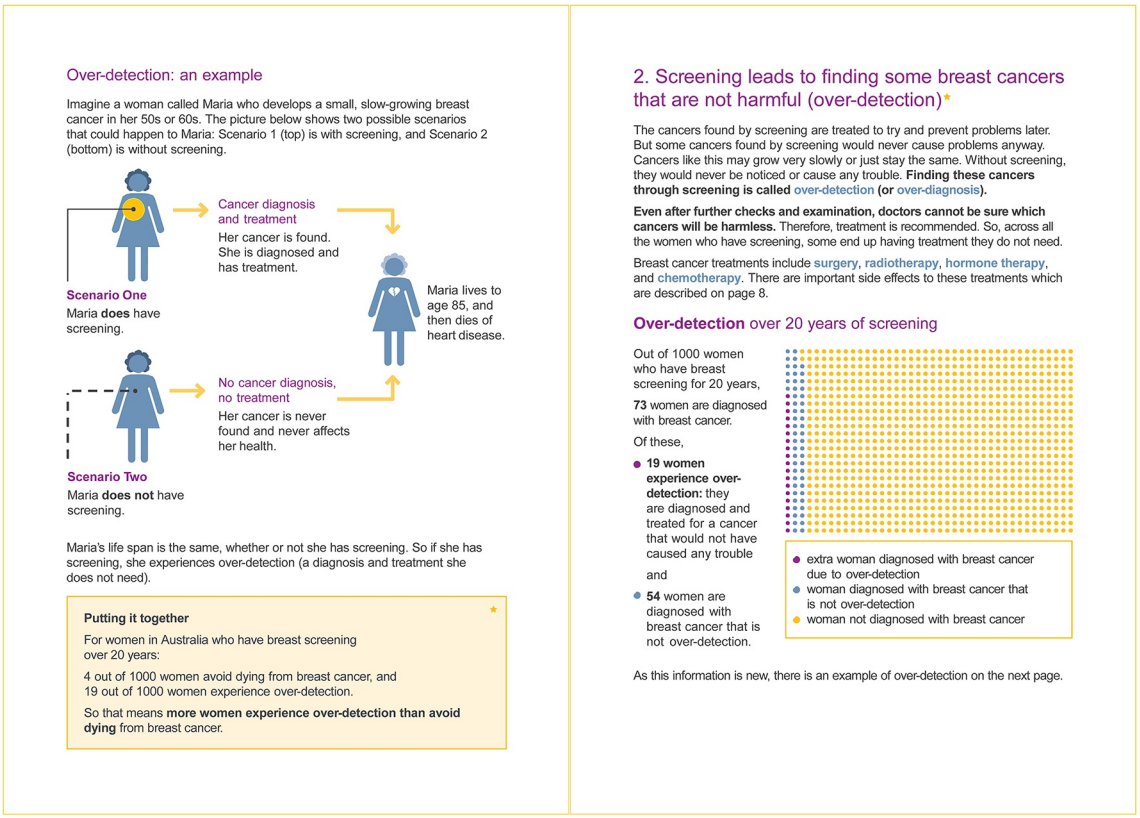
Competing interests: We have read and understood BMJ policy on declaration of interests and declare KJMcC is supported by a National Health and Medical Research Council (NHMRC) career development fellowship (1029241), JJ is supported by an NHMRC early career fellowship (1037028), and. JW is supported by a career development fellowship from Cancer Research UK (C7492/A17219).

Provenance and peer review: Commissioned; externally peer reviewed.

1 Heath I. Overdiagnosis: when good intentions meet vested interests. *BMJ* 2013;347:f6361.
2 Moynihan R, Doust J, Henry D. Preventing overdiagnosis: how to stop harming the healthy. *BMJ* 2012;344:e3502.
3 Hersch J, Barratt A, Jansen J, et al. Use of a decision aid including information on overdetection to support informed choice about breast cancer screening: a randomised controlled trial. *Lancet* 2015;385:1642-52.
4 Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361-7.
5 Gavaruzzi T, Lotto L, Rumiati R, et al. What makes a tumor diagnosis a call to action? On the preference for action versus inaction. *Med Decision Making* 2011;31:237-44.
6 Fagerlin A, Zikmund-Fisher BJ, Ubel PA. Cure me even if it kills me: preferences for invasive cancer treatment. *Med Decision Making* 2005;25:614-9.
7 Shepherd HL, Barratt A, Trevena LJ, et al. Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Educ Counsel* 2011;84:379-85.
8 Hoffmann TC, Bennett S, Tomsett C, et al. Brief training of student clinicians in shared decision making: a single-blind randomized controlled trial. *J Gen Intern Med* 2014;29:844-9.
9 Stacey D, Legare F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2014;1:CD001431.
10 Sheridan SL, Golin C, Bunton A, et al. Shared decision making for prostate cancer screening: the results of a combined analysis of two practice-based randomized controlled trials. *BMC Med Inform Decision Making* 2012;12:130.
11 Schonberg MA, Hamel MB, Davis RB, et al. Development and evaluation of a decision aid on mammography screening for women 75 years and older. *JAMA Intern Med* 2014;174:417-24.
12 Schonberg MA, Kistler CE, Nekhlyudov L, et al. Evaluation of a mammography screening decision aid for women aged 75 and older: protocol for a cluster-randomized controlled trial. *J Clin Trials* 2014;4:191.
13 Hoffmann TC, Del Mar C. Patients' expectations of the benefits and harms of treatments, screening, and tests: a systematic review. *JAMA Intern Med* 2015;175:274-86.
14 Heleno B, Thomsen MF, Rodrigues DS, et al. Quantification of harms in cancer screening trials: literature review. *BMJ* 2013;347:f5334.
15 Hoffmann TC, Legare F, Simmons MB, et al. Shared decision making: what do clinicians need to know and why should they bother? *Med J Aust* 2014;201:35-9.
16 Buchbinder R. Self-management education en masse: effectiveness of the back pain: don't take it lying down mass media campaign. *Med J Aust* 2008;189(10 Suppl):S29-32.
17 Buchbinder R, Gross DP, Werner EL, et al. Understanding the characteristics of effective mass media campaigns for back pain and methodological challenges in evaluating their effects. *Spine* 2008;33:74-80.
18 Blacksher E, Diebel A, Forest PG, et al. What is public deliberation? *Hastings Center Rep* 2012;42:14-7.
19 Rychetnik L, Doust J, Thomas R, et al. A Community Jury on PSA screening: what do well-informed men want the government to do about prostate cancer screening—a qualitative analysis. *BMJ Open* 2014;4:e004682.
20 Centre for Values Ethics and the Law in Medicine. Cancer screening ethics: project 5 prostate screening. 2015. http://cancerscreeningethics.org/prostate-screening-projects/project-5-prostate-screening-from-the-perspective-of-citizens-call-for-participants/.
21 Paul C, Nicholls R, Priest P, et al. Making policy decisions about population screening for breast cancer: the role of citizens' deliberation. *Health Policy* 2008;85:314-20.
22 Omer ZB, Hwang ES, Esserman LJ, et al. Impact of ductal carcinoma in situ terminology on patient treatment preferences. *JAMA Intern Med* 2013;173:1830-1.
23 McCaffery K, Nickel B, Moynihan R, et al. How different terminology for ductal carcinoma in situ impacts women's concern and treatment preferences: a randomised comparison within a national community survey. *BMJ Open* 2015;5:e008094.
24 Nickel B, Barratt A, Hersch J, et al. How different terminology for ductal carcinoma in situ (DCIS) impacts women's concern and management preferences: a qualitative study. *Breast* 2015;24:673-9.
25 Esserman LJ, Thompson IM Jr, Reid B. Overdiagnosis and overtreatment in cancer: an opportunity for improvement. *JAMA* 2013;310:797-8.
26 Allegra CJ, Aberle DR, Ganschow P, et al. NIH state-of-the-science conference statement: diagnosis and management of ductal carcinoma in situ (DCIS). *NIH Consensus and State-of-the-Science Statements* 2009;26:1-27.
27 Redberg RF. My thyroid story. *JAMA Intern Med* 2013;173:1769.
28 Scherer LD, Zikmund-Fisher BJ, Fagerlin A, et al. Influence of "GERD" label on parents' decision to medicate infants. *Pediatrics* 2013;131:839-45.
29 Hersch J, Jansen J, Barratt A, et al. Women's views on overdiagnosis in breast cancer screening: a qualitative study. *BMJ* 2013;346:f158.
30 Waller J, Douglas E, Whitaker KL, et al. Women's responses to information about overdiagnosis in the UK breast cancer screening programme: a qualitative study. *BMJ Open* 2013;3:e002703.
31 Moynihan R, Nickel B, Hersch J, et al. Public opinions about overdiagnosis: a national community survey. *PloS One* 2015;10:e0125165.
32 Wegwarth O, Gigerenzer G. Less is more: Overdiagnosis and overtreatment: evaluation of what physicians tell their patients about screening harms. *JAMA Intern Med* 2013;173:2086-7.
33 Schwartz LM, Woloshin S, Fowler FJ Jr, et al. Enthusiasm for cancer screening in the United States. *JAMA* 2004;291:71-8.
34 Waller J, Osborne K, Wardle J. Enthusiasm for cancer screening in Great Britain: a general population survey. *Br J Cancer* 2015;112:562-6.
35 Elstad EA, Sutkowi-Hemstreet A, Sheridan SL, et al. Clinicians' perceptions of the benefits and harms of prostate and colorectal cancer screening. *Med Decision Making* 2015;35:467-76.
36 Jorgensen KJ, Gotzsche PC. Presentation on websites of possible benefits and harms from screening for breast cancer: cross sectional study. *BMJ* 2004;328:148.
37 Wilson AJ, Robertson J, Ewald BD, et al. What the public learns about screening and diagnostic tests through the media. *Med J Aust* 2012;197:324-6.
38 Welch HG, Schwartz LM, Woloshin S. Overdiagnosed: making people sick in the pursuit of health. Beacon Press, 2011.
39 Arkes HR, Gaissmaier W. Psychological research and the prostate-cancer screening controversy. *Psychol Sci* 2012;23:547-53.
40 Samuelson W, Zeckhauser R. Status quo bias in decision making. *J Risk Uncertainty* 1988;1:7-59.
41 Kahneman DKJ, Thaler RH. Anomalies: the endowment effect, loss aversion, and status quo bias. *J Econ Perspect* 1991:193-206.
42 Halpern SD, Ubel PA, Asch DA. Harnessing the power of default options to improve health care. *N Engl J Med* 2007;357:1340-4.
43 Slovic P, Peters E. Risk perception and affect. *Curr Direct Psychol Sci* 2006;15:322-5.
44 Schleifer D, Rothman DJ. "The ultimate decision is yours": exploring patients' attitudes about the overuse of medical interventions. *PloS One* 2012;7:e52552.
45 Festinger L. *A theory of cognitive dissonance.* Vol 2. Stanford University Press, 1962.
46 Hoffman JR, Kanzaria HK. Intolerance of error and culture of blame drive medical excess. *BMJ* 2014;349:g5702.
47 Duffy SW, Agbaje O, Tabar L, et al. Overdiagnosis and overtreatment of breast cancer: estimates of overdiagnosis from two trials of mammographic screening for breast cancer. *Breast Cancer Res* 2005;7:258-65.
48 Han PK. Conceptual, methodological, and ethical problems in communicating uncertainty in clinical evidence. *Med Care Res Rev* 2013;70(1 suppl):14-36S.
49 Longman T, Turner RM, King M, et al. The effects of communicating uncertainty in quantitative health risk estimates. *Patient Educ Couns* 2012;89:252-9.
50 Moynihan R, Heath I, Henry D. Selling sickness: the pharmaceutical industry and disease mongering. *BMJ* 2002;324:886-91.
51 Moynihan RN, Cooke GP, Doust JA, et al. Expanding disease definitions in guidelines and expert panel ties to industry: a cross-sectional study of common conditions in the United States. *PLoS Med* 2013;10:e1001500.
52 Woloshin S, Schwartz LM. How a charity oversells mammography. *BMJ* 2012;345:e5132.
53 Hunt J. Innovation and efficiency. Speech to the King's Fund, 23 Nov 2014. Innovation and efficiency. www.gov.uk/government/speeches/innovation-and-efficiency.

Cite this as: *BMJ* 2016;352:i348

Figure



Infographic and icon array explaining overdiagnosis in breast screening in a patient decision aid developed by Hersch et al[3]