

Title: **Funding Of Prostate MRI Leads To Fewer Biopsies And Potential Savings To Health Systems In The Management Of Prostate Cancer**

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Funding Of Prostate MRI Leads To Fewer Biopsies And Potential Savings To Health Systems In The Management Of Prostate Cancer

Abstract

Objectives: To assess the impact of introduction of multi-parametric MRI of the prostate (mpMRIp) on the number of prostate biopsies performed in Australia.

Materials and Methods: Australian Medicare published statistics from 1st July 2007 to 30th June 2019 were obtained from publically available databases for PSA, prostate biopsy and mpMRIp. Analysis was divided into 3 time periods broadly based on availability of mpMRI to the Australian public: 2007-2012 (no mpMRIp), 2012-2018 (mpMRIp available, privately funded), and 2018-2019 (mpMRIp available with Medicare funding). Introduction of mpMRIp was hypothesised to reduce the number of prostate biopsies performed. Prostate specific antigen (PSA) testing numbers were used as a control. The economics model, proposed by the Medical Services Advisory Committee (MSAC), was analysed for cost savings.

Results: Accounting for variations in PSA testing, the introduction of mpMRIp from 2012 coincided with reduction in the number of prostate biopsies by an average of 354.7/month (95% CI 175,534.4; $p < 0.001$). Whilst the number of mpMRIp performed for the initial 12 months was underestimated by MSAC (38,470 vs. 20,149, +\$8.3M), we estimate the annual savings from reduced number biopsies and biopsy-associated complications to be \$13.2±9.6M

Conclusion: Availability of mpMRIp in Australia has correlated with a significant reduction in prostate biopsy rates, with an estimated annual saving of \$13.2±9.6M. Government funding of this diagnostic service has the potential to improve health equity and save on health expenditure.

Keywords: Prostate Cancer, MRI, health policy, prostate biopsy

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Introduction

Introduction of multiparametric magnetic resonance imaging of the prostate (mpMRIp) has transformed diagnosis of prostate cancer (PCa). Prior to this diagnostic aid detection had relied upon clinical examination and prostate specific antigen (PSA) screening (1-3). Confirmation of PCa via biopsy, historically involved non-targeted systematic sampling of the entire gland. This resulted in overdiagnosis and overtreatment of PCa (4, 5).

Multiple studies have demonstrated that mpMRIp performed prior to biopsy improves sensitivity of biopsy compared to non-targeted TRUS prostate biopsy, and conveys a high negative predictive value (PROMIS) (6). It improves detection of clinically significant prostate cancer with less insignificant cancer found (PRECISION) (7). A standardized reporting tool for mpMRIp, Prostate Imaging – Reporting and Data System (PI-RADS) version 1 and the current version 2 have been validated to increase the positive and negative predictive value of performing a biopsy (6-10). Multiple studies show good correlation of mpMRIp grading to final histopathology confirmed with radical prostatectomy specimens (10-12). Long term follow-up of patients with low-risk PCa indicates men on active surveillance can avoid protocol biopsies in favour of mpMRI and PSA surveillance with targeted biopsies where indicated (13).

Advances in both hardware and software, along with the wider accessibility to stronger 3 Tesla (3T) magnets and multiparametric sequences have allowed better quality mpMRIp and ability to forgo the patient unfriendly endorectal coil. In Australia, from 2012 mpMRIp was increasingly utilized by patients with financial means whilst patients without resources continued to undergo non-targeted prostate biopsy. After prolonged consultation, in December 2017 the Medical Services Advisory Committee (MSAC), a division of the Australian Government Department of Health, recommended government funding for mpMRIp (14). Two item numbers were approved ((#63541 and (#63543) to aid diagnosis of men suspected of prostate cancer and for men on active surveillance (AS) protocols, reimbursed at \$450 per service. There was no provision for usage in preoperative local staging, as this off-label use offers little advantage over conventional imaging, and is superseded by prostate specific membrane antigen (PSMA) positron emission tomography (PET) (12, 15). In their estimated budget, MSAC projected a total of 20,149 mpMRIp leading to 10,984 subsequent prostate biopsies (assuming biopsy rate of 0.52 for diagnosis and 0.59 for AS), in the first year of introduction. Costs were expected to be offset by \$8.1M, with anticipated fewer prostate biopsies and the complications arising from biopsy(14).

Herein, we assess the impact of availability of mpMRIp on prostate biopsy in Australia, and evaluate the proposed MSAC budget 1 year after introduction of a government rebate for mpMRIp.

Methods:

The Australian Government Department of Human Services maintains a publically accessible online database of Medicare funded services (16). This database records services that take place, in either public and private health systems, where a government (medicare) rebate exists. It does not differentiate where the service is performed (i.e. public or private system). This database was accessed to assess the total numbers of mpMRIp item numbers (#63541 – clinical suspicion of PCa, based on family history, PSA elevation, and examination; and #63543 – AS) performed (appendix 1). To assess the effect of mpMRIp on the number of prostate biopsies (#37219), with potential confounder PSA testing (#66655), data was obtained for each respective service.

Data was divided into three time periods based on differing availability of mpMRIp:

- a) 2018-2019: mpMRIp – government rebate
- b) 2012-2018: MRI available - no government rebate
- c) 2007-2012: no MRI (very limited use, 1.5T magnets with endorectal coil was used minimally and infrequently due to patient discomfort and paucity of data on efficacy – for simplicity we have referred to this time period as ‘no MRI available’)

The Medicare Item Report database was accessed on 25th July 2019 (16) for data during the period 01/01/2007 – 31/06/2019. During our study period, in 2012 the United States Preventative Task Force issued a Grade D recommendation against PSA screening (17). As this statement significantly altered PSA screening practices (18) and subsequent downstream biopsy patterns, our analysis was adjusted to account for the impact of PSA testing. Modelling of the continuous monthly outcome (biopsies) used a general linear model with correlated errors; this used an autoregressive function of lag one, and the explanatory variables included time, monthly PSA rate and MRI time period. The analysis and modelling was done in Minitab 19 and GenStat (version 16).

Financial analysis

Financial analysis was calculated by adding the direct savings from a reduction in biopsies being performed to the projected savings from reduced readmissions for biopsy-related complications over a financial year (FY). This was calculated by multiplying the annual biopsy reduction rate by the cost of performing a prostate biopsy in a public hospital. Prostate biopsies in Australia are conducted in an operating theatre under sedation. There may be variation between hospitals when accounting for the costs of consumables, staffing, and theatre time. For purposes of modelling, we assigned a cost of \$2,400 to prostate biopsies, based on the value utilised by the MSAC - Public Summary Document (14). MSAC assumed re-hospitalisation rates of biopsy complications to be 0.4-5.5%. However, for broader inference we used global readmission rates from systematic reviews of 0-6.3%

(19). Due to rising sepsis rates caused by increasing antimicrobial resistance a decision was made to use both the lower (0.4%) and upper (6.3%) limit of readmission rates ($3.35 \pm 2.95\%$, 0.4-6.3%) (20). In a previous publication using Australian data, Roth et al reported average length of stay due to biopsy-related infection at 4 days with a total cost of \$7,362 per admission (21). This cost was adjusted for inflation to \$7,747 (Figure 2a). This figure does not include the less costly but more common complications of haematuria or urinary retention presentations (19).

A cost analysis was performed, generating a cost-benefit ratio (cost of MRI:savings). As this was a publically available database of de-identified data with a retrospective analysis applied it was not subject to ethics approval.

Figure 1a: Model for estimated savings due to mpMRIp

Results:

The general linear model showed a reduction of an average 501.6 biopsies/month (95% CI 327.6,675.6; $p < 0.001$) after the introduction of mpMRIp from 2012 (analysis based on July 2007 to June 2019). To model for the effect of PSA testing on prostate biopsies, the general linear model (with correlated errors) showed for every 1,000 PSA tests there were an average of 10.7 prostate biopsies (C.I. 7.6-13.7, $p < 0.001$). Hence, the impact of mpMRIp, accounting for changes in PSA testing, still demonstrates a decline of prostate biopsies by an average of 354.7/month (95%CI 175,534.4; $p < 0.001$) (Table 1).

Comparing time periods 2007-2012 (no MRI available) to FY18/19 (government rebate), there was a decline of an average 414 biopsies/month (95%CI 120,708; $p = 0.007$). However, there was no statistically significant difference between time period 2012-2018 (no government rebate) and FY18/19 (government rebate) (Table 1).

In the year post introduction of government funding (July 2018-2019), there was a total 38,470 mpMRIp performed, grossly costing \$17.3M. The majority (82.5%) were for diagnosis (#63541, $n = 31750$) and only 17.5% were for active surveillance (#63543, $n = 6,720$). Over the timeframe analysed (2007-2019), both prostate biopsy and PSA testing steadily declined (Figure 1). There were 919,975 PSA tests and 24,647 prostate biopsies for FY07/08, down to 692,021 PSA tests and 19,923 biopsies for FY18/19. With respect to prostate biopsies this was an increase 1,165 compared to FY17/18 (18,758 biopsies).

MSAC estimates for active surveillance funding were close, with a saving of \$68,850. However, funding for mpMRIp used for diagnosis was grossly underestimated by 18,474 services, representing

an \$8.2M deficit. This was offset by estimated savings due to biopsies avoided and subsequent complications attributable to mpMRIp of \$13.2M (\pm \$9.6M) (Table 2, Figure 2b), which gave a cost-benefit ratio of 1.31.

Figure 2: shows that over time there has been a decline in the number of biopsies, but also in the number of PSAs. There appears to be a drop in the number of biopsies following the introduction of MRI.

Figure 1b: Estimated savings due to mpMRIp

Discussion:

The landscape of prostate cancer diagnosis and treatment has changed dramatically in Australia (22). Since the introduction of mpMRIp to Australia in 2012 our analysis shows there has been an average reduction of 504 biopsies/month ($p < 0.001$). To account for the coinciding USPTF grade D recommendation for PSA screening (17), which resulted in decreased PSA testing, analysis was performed to control for this. Our results suggest PSA screening accounts for 10.7 biopsies for every 1,000 tests ($p < 0.001$) and when controlling for reduced PSA testing there was still a significant reduction in biopsies we attribute to mpMRIp. Our analysis suggests a reduction of 414 biopsies/month (95%CI 120-708, $p = 0.007$), (or 4,968 \pm 3,528 biopsies annually) correlating to the availability of mpMRIp prostate. The study period encompasses PI-RADS v1. and v2, though both have been validated to have a high negative predictive value (82% for PCa, and 88% for csPCa [ISUP ≥ 2]), with PI-RADS v2 having equivalent specificity but improved sensitivity, enabling clinicians to use a “rule out” strategy for avoiding invasive prostate biopsies, which may explain this result (8, 10, 23, 24).

When specifically examining the 12 months since the introduction of the government rebate for mpMRI prostate, we found no statistically significant difference in biopsy rates. On raw numbers there have been more biopsies since the introduction (1,165 services) but it is too early and the data too scarce to make precise inferences. With widespread uptake of mpMRIp it can be inferred that more radiologists, including those with limited experience are reporting these studies. There is clear evidence that increased experience with PIRADS v2 reporting improves specificity (25), and inexperienced readers are more likely to report equivocal PIRADS 3 lesions, which would result in biopsy (26). This could potentially contribute to the increased biopsy rates for FY18/19. MSAC also noted that the availability of mpMRI could increase the attractiveness of using PSA for screening and therefore increase rates of PSA testing. MSAC suggested that it may be more difficult to deter clinicians from inappropriately using PSA testing for screening purposes if the follow-up test is non-invasive in nature (mpMRIp).

MSAC underestimated the demand for diagnostic mpMRIp by 18,474 services. The initial surge in mpMRIp numbers might be akin to the harvest effect of the 1990s when PCa rates peaked after introduction of PSA testing (27). There would have been a large pool of men who could not afford to self-fund their mpMRIp waiting. Similarly, with the government rebate imminent, men who may have self-funded their mpMRIp may have deferred having the test. Thus, the demand for mpMRIp should stabilize in the following years. A second reason could be “item number leakage”. MSAC expressed concern with unintended off-label use, such as operative planning and staging, usage in men with suspected PCa with a negative biopsy, and use in men with suspected recurrence post treatment with curative intent. It is not possible to obtain this level of clinical information from the Medicare data. Eligibility criteria, whilst having verifiable PSA levels, also allow for “abnormal digital rectal examination” which is a subjective assessment and known to have poor specificity (28). Large centrally collated databases are only as valid as the data supplied, and beyond an MBS orchestrated item number audit, there is no way to confirm authenticity of billing.

Medicare budgeted \$9.1M for mpMRIp, spent \$17.3M, with a consequent deficit of \$8.2M. However, we estimate savings related to decreased hospital admissions from prostate biopsy to be \$13.2±9.6M. Given that mpMRIp in Australia is relatively low cost this represents a significant saving. Furthermore, there may further savings as this analysis doesn't account for the wider economic burden of time away from the workplace. Prior to introduction of the government rebate, men were self-funding the mpMRI with the government benefitting with fewer biopsies performed and subsequently fewer biopsy related readmissions. Unavailability of the self-funded mpMRIp numbers does not impact conclusions drawn from this study, as it is a time series analysis. Thus the introduction of a rebate, with government now shouldering the cost of mpMRIp, represents a significant public health policy. Furthermore, the rebate also assists Medicare achieve one of its priorities in providing equitable universal health care by giving vulnerable and disadvantaged populations access to mpMRIp.

Estimates for funding AS imaging were accurate, which is to be expected, given it is a more defined population with less unknowns than screening for diagnosis. Men on AS are allocated a repeat mpMRIp at 12 months and every three years beyond that point. There has not been a provision for frequency of repeat mpMRIp for diagnosis and MBS is open to excessive billing in this regard. This may be due to a paucity of quality data on optimal re-scanning timeframes. However, there is now growing evidence to support rescanning of equivocal PIRADS lesions one year after the first negative biopsy (29).

There is another item number for PSA testing in men who have a diagnosed prostate disease, 66656. This was excluded from analysis as it includes not only men on AS, but men who have had a prostatectomy, management with radiation therapy, or ADT. Men on AS protocols are thought to

make up a small proportion of total biopsies, of which it was not possible to quantify in this paper, however, overseas data suggests 20% of total biopsies may be due to AS (30). Our study is limited by the constraints of a population database. Analysis of the effect on radical treatment, or “over treatment”, was initially attempted but Medicare does not differentiate radiotherapy coding between different organs. With such a large treatment group unavailable, we felt any analysis purely examining radical prostatectomy would be inadequate. The ability of mpMRIp to aid cancer detection, both with improved detection of clinically significant cancer and decreased detection of insignificant cancers, was not assessable using this dataset.

Our analysis of the financial impact is based on overall figures and estimates the readmission rate post prostate biopsy based on historical figures. However, this data is recent and from previous Australian data so we believe it remains relevant. Our modelling calculated a cost-benefit ratio of 1.31, which suggests for every \$1 spent by government on an mpMRIp, a return of investment of 76c was achieved. In its predictive modelling, MSAC performed economic evaluation using a cost-utility analysis with a 25-year time horizon, to estimate an incremental cost-effectiveness ratio, expressed in quality adjusted life years (QALY). As mpMRIp has only been available (and trackable) for one year, a times series analysis was utilized, dividing the total time analysed into 3 discrete periods, based on the status of mpMRIp. Thus, other techniques such as cost effectiveness or cost consequence were not performed, but we envisage these will become possible to perform with longer follow-up of mpMRIp data. Further cost effectiveness analysis using QALY or using incremental cost-effectiveness ratios, may be possible with longer follow-up of this data, which could help inform MRI costings. Cost consequence can be inferred when prostate cancer diagnoses are known and the number mpMRIp/year stabilises.

In our model, the unit cost for a prostate biopsy was \$2,400, based on the initial MSAC guideline (14). In Australia, prostate biopsies are performed in the operating theatre, with anaesthetic support for intravenous sedation. In countries where prostate biopsy is performed in the outpatient setting under local anaesthetic, the unit cost will be considerably lower and hence our cost analysis results would need to be remodelled.

MSAC approved funding for mpMRIp expressly for two purposes: to minimise excessive biopsies and reduce expenditure relating to this; and decrease rates of clinically insignificant prostate cancer. Our analysis shows the introduction of mpMRIp has been associated with a corresponding reduction in prostate biopsy rates and can save the health system money. PSMA-PET has shown improved specificity and sensitivity detecting metastatic disease and biochemical recurrence than conventional imaging, and may supersede mpMRIp in initial diagnosis (15, 31). There are already locally conducted trials assessing PSMA-PET ability to either replace or complement mpMRIp, which may represent the future (32). The cost of MRI in Australia remains low compared to biopsy, which is

often performed in an outpatient setting overseas. However, this study has international implications for countries looking to improve access and affordability to appropriate screening and diagnostic models for at risk men (33).

Conflict of interest: The authors have no conflicts of interest to disclose.

Appendix 1

63541 MRI prostate (clinical suspicion of cancer): July 2018 – June 2019

- *“a) a digital rectal examination (DRE) which is suspicious for prostate cancer; or*
- *b) in a person aged less than 70 years, at least two prostate specific antigen (PSA) tests performed within an interval of 1- 3 months are greater than 3.0 ng/ml, and the free/total PSA ratio is less than 25% or the repeat PSA exceeds 5.5 ng/ml; or*
- *c) in a person aged less than 70 years, whose risk of developing prostate cancer based on family history is at least double the average risk , at least two PSA tests performed within an interval of 1- 3 months are greater than 2.0 ng/ml, and the free/total PSA ratio is less than 25%; or*
- *d) in a person aged 70 years or older, at least two PSA tests performed within an interval of 1- 3 months are greater than 5.5ng/ml and the free/total PSA ratio is less than 25%.”(34)*

63543 MRI prostate (active surveillance): July 2018 – June 2019

- *“a) the patient is under active surveillance following a confirmed diagnosis of prostate cancer by biopsy histopathology; and*
- b) the patient is not planning or undergoing treatment for prostate cancer.”(34)*

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Table 1: Model of monthly biopsies, accounting for reduction in PSA testing, using MRI as an explanatory variable

MRI Time Period Comparisons (Early period minus later period)	Mean Difference		
	(biopsies/mo)	95% CI	P-value
2007-12 (no MRI) minus 2012-18 (self-funded)	354.7	175, 534.4	<0.001
2007-12 (no MRI) minus FY18/19 (Medicare)	414	120, 708	0.007
2012-18 (self-fund) minus FY18/19 (Medicare)	60	-212.4, 332.4	0.669

*a positive difference indicates a decrease over time

Cost Analysis

Table 2: MSAC Predicted Numbers vs Actual Numbers Funded for 12 months (June 2018-July 2019)– budgetary impact

Item	MSAC predicted		Actual (n)	Cost	Difference	Deficit
	(n)	Cost				
63541 (dx)	13,276	\$5,974,200	31,750	\$14,287,500	18,474	\$8,313,300
63543 (AS)	6,873	\$3,092,850	6,720	\$3,024,000	-153	-\$68,850

Total Savings = decreased biopsies [x_1] + decreased readmissions from complications [x_2]

X_1 = [biopsies saved] x [cost of biopsy, \$2,400]

X_2 = [biopsies saved] x [readmission rate, 0.0335 ± 0.0295] x [cost of admission, \$7,477]

Figure 1a: Model for estimated savings due to mpMRIp

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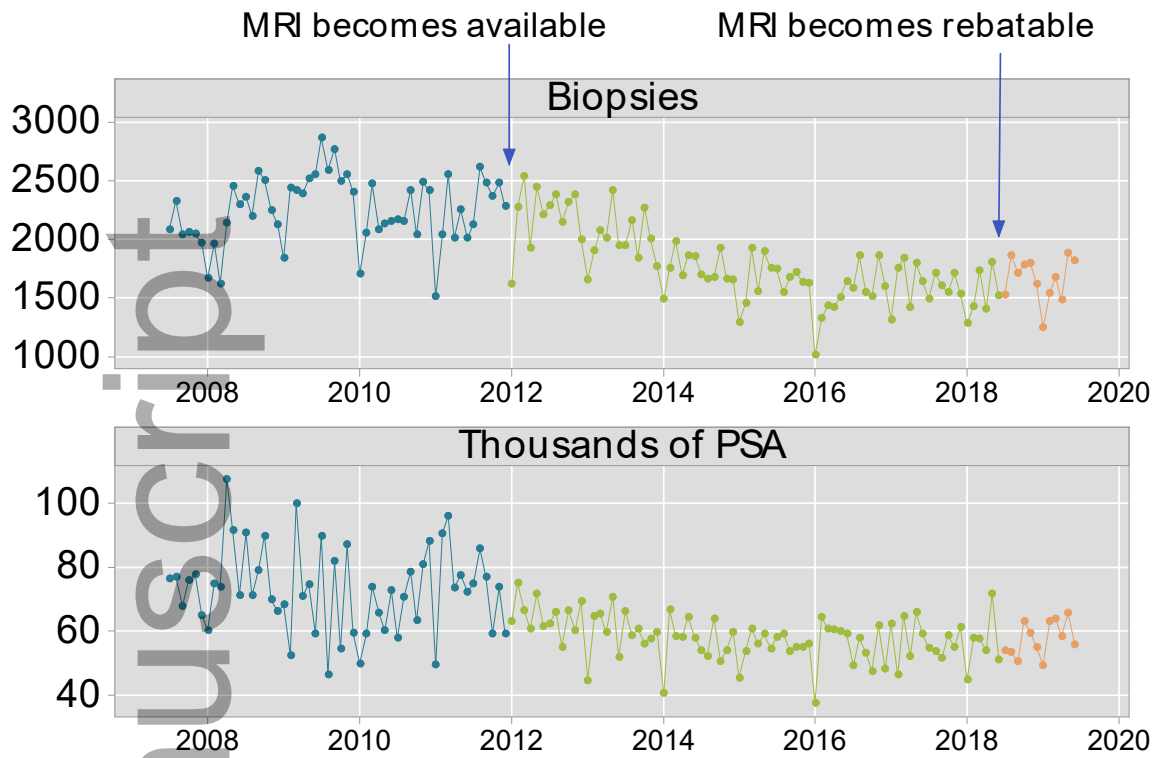


Figure 2: shows that over time there has been a decline in the number of biopsies, but also in the number of PSAs. There appears to be a drop in the number of biopsies following the introduction of MRI.

Total Savings = decreased biopsies [x₁] + decreased readmissions from complications [x₂]

[biopsies saved] = [414±294] x 12 months = 4,968 ± 3,528

X₁ = 4,968 ± 3,528 x [\$2,400] = \$11,923,200 ± \$8,467,200

X₂ = [4,968 ± 3,528] x [0.0335 ± 0.0295] x \$7,477 = \$1,244,382 ± \$1,095,799

Total Savings = X₁ + X₂ = **\$13,167,582 ± \$9,562,999**

Figure 1b: Estimated savings due to mpMRIp