**Abstract**

Men treated for prostate cancer with curative intent face a recurrence rate of up to 53% at 10 years. $^{68}$Ga-PSMA imaging is a new technique that can more accurately stage cancer recurrences and facilitate personalised treatment. We evaluated the cost-effectiveness of $^{68}$Ga-PSMA PET/MRI for staging men with prostate cancer biochemical recurrence. A cost-effectiveness analysis using a decision-analytic model with Markov chains was constructed. $^{68}$Ga-PSMA PET/MRI was compared with usual care in staging of men with suspected prostate cancer recurrence. Men with biochemical recurrence from a study in Brisbane, Australia ($n = 30$) provided key estimates for the model. The primary outcomes were health system costs and years of life (survival) over 10 years. Deterministic and probabilistic sensitivity analyses were undertaken to address uncertainty in model estimates. On average, a strategy of $^{68}$Ga-PSMA was expected to cost AU$56,961 (US$39,426) and produce 7.48 life years compared with AU$64,499 (US$44,667) and 7.41 life years in usual care. Therefore, $^{68}$Ga-PSMA was potentially cost saving (− AU$7,592 95% UI − $24,846, $7,825) (− US$5,258) and slightly more effective 0.07 life years (95% UI − 0.01, 0.16). The likelihood that $^{68}$Ga-PSMA strategy was cost-effective at acceptable thresholds was 87%. The findings were sensitive to the lesion detection rate of the $^{68}$Ga-PSMA strategy (52–75%) and the cost of follow up in usual care (AU$1,947 to $2,635). In this exploratory economic evaluation, using $^{68}$Ga-PSMA PET/MRI to detect prostate cancer recurrence appears to be cost-effective relative to usual care.

**Keywords** Cost-effectiveness analysis · $^{68}$Ga-PSMA · Prostate cancer · Magnetic resonance imaging · Positron emission tomography · Biochemical recurrence

**Introduction**

Prostate cancer is diagnosed in 1.1 million men worldwide, affecting 15% of male cancers with the majority (759,000 or 70%) diagnosed in developed nations [1]. Although survival is generally high at 10 years, men treated with curative intent for localized prostate cancer have a 27–53% chance of recurrence within 10 years [2]. The first indicator of a cancer recurrence is a rising prostate-specific antigen (PSA) test, termed biochemical recurrence (BCR). At this time, it is important to diagnose if and where the cancer has spread. This has major ramifications with regards to potential therapeutic options. Historically, the
conventional imaging modalities undertaken were contrast enhanced computer-aided tomography (CT) of the chest and abdomen or pelvis technetium-99m diphosphonate scintigraphy (bone scan) often linked to a single-photon emission computerized tomography (SPECT) scan [3]. The results of these investigations determine the subsequent management of prostate cancer varying from surveillance, to palliative measures such as androgen deprivation therapy (ADT), or potentially curative salvage therapies (e.g., radical prostatectomy and radiotherapy).

68-Gallium-labelled Prostate Specific Membrane Antigen Positron Emission Topography (68Ga-PSMA PET) is a new imaging technology that involves a radiopharmaceutical (68Ga) being injected into the body which then attaches to prostate cancer cells via the PSMA ligand and can be imaged by PET/CT or PET/MRI combinations. The value of this technique lies in the ability to accurately stage cancer recurrences and facilitate more personalized treatments [4]. For example, radiotherapy may be expanded and concentrated to targeted locations or forgone altogether.

68Ga PSMA PET/CT is still at the investigational stages with several diagnostic accuracy studies and early stage trials underway including the ‘ProPSMA’ trial in Australia [5]. A recent prospective single-arm clinical trial of 635 men, assessed 68Ga-PSMA-11 PET/CT and showed a detection rate of 75% and a positive predictive value of 84% with histopathologic validation [6]. A meta-analysis revealed detection rates of: 33% in patients with PSA less than 0.2 ng/mL, 45% for PSA between 0.2 and 0.49 ng/mL, 59% for PSA between 0.5 and 1.0 ng/mL, 75% for PSA between 1 and 2 ng/mL, and 95% for PSA > 2.0 ng/mL. Although studies are still needed to definitively verify the accuracy of 68Ga-PSMA PET/CT, this new approach appears superior to conventional imaging for detecting sites of prostate cancer in different clinical settings, is sensitive for detecting regional and distant metastatic disease, and is highly specific [7]. Several studies are underway to identify the change in management following 68Ga-PSMA PET/CT, and longer-term patient consequences are still unclear [4]. 68 Ga-PSMA PET/CT has been the primary imaging technology used to date. Next generation PET/MRI hybrid scanners have recently also become available in select centres throughout the world. This imaging combines a PET scanner together with a high resolution 3T multi-parametric MRI. When used in combination with the 68Ga-PSMA ligand, this new modality has even less data than 68Ga-PSMA PET/CT available in the prostate cancer literature.

To this end, a prospective single-centre, single arm study was approved for recruitment from hospitals across Queensland and Northern New South Wales, Australia comparing 68Ga-PSMA PET/MRI to usual care imaging in the clinical setting of BCR (HREC/15/QPAH/355, ACTRN1261600186459) at the Princess Alexandra Hospital (PAH).

While there has been rapid clinical uptake of 68Ga-PSMA/PET CT or MRI techniques, it is also important to assess new technologies for their value for money. There has been no economic evaluation of this new technology. Until formal level I evidence is available for definitive evaluation of the intervention, we undertook an exploratory cost-effectiveness analysis to determine the expected outcomes of 68Ga-PSMA PET/MRI for staging prostate cancer in men with BCR. Imaging results from the prospective trial were used for the basis of the following health economic analysis. This type of analysis assessed health service resource use and health outcomes from 68Ga-PSMA PET/MRI staging and subsequent downstream consequences.

**Methods**

**Model structure**

A decision-analytic model with Markov chains was constructed with a duration of 10 years and annual cycles. It included four health states: local; nodal; distant disease and death (Online Appendix 1). Men could occupy only one health state in any one cycle but according to transition probabilities, could stay or move between the health states. They accrued health costs assigned to various treatments or follow-up investigations and accrued life years applicable to their disease severity and treatment course. Methods for this economic evaluation were governed by standardised guidelines in economic evaluations [8] and modelling studies [9].

**Description of strategies**

Two strategies were investigated; 68Ga-PSMA PET/MRI and ‘Usual care’. Specific details of the 68Ga-PSMA PET/MRI imaging acquisition and protocol are provided in Online Appendix 2. ‘Usual care’ involved investigations which typically involved a bone scan and MRI. Men positively diagnosed by 68Ga-PSMA PET/MRI with locally recurrent cancer were treated with 79.2 GY of radiation, while men diagnosed with ‘Usual care’ received 70.2 GY of radiation. Patients mistakenly diagnosed as lesion positive (false positives) were treated for their cancer according to the staging result. Patients mistakenly diagnosed as negative (false negatives) were under-treated as per the staging result.

**Clinical inputs**

Data for the model were derived from the clinical patterns of care for 30 patients with BCR after primary curative treatment (surgery (n = 23) or radiotherapy (n = 7)). They were
recruited to a pilot study (the PSMA PET/MRI Biochemical Recurrence Trial) located at a large metropolitan hospital in Brisbane, Australia and first identified from the hospital’s urology multi-disciplinary team meeting or referred from clinic for consideration in the trial. Patients were eligible if they were male with pathologically diagnosed prostate cancer and had biochemical recurrence defined as PSA > 0.2 ng/mL on at least two occasions after receiving radical prostatectomy or PSA 2.0 ng/mL above nadir two years post radiotherapy. They had a history of primary treatment for prostate cancer no sooner than three months post-surgery and two years post radiotherapy, no known problems with peripheral intravenous or central line access and provided informed signed consent. Men were excluded if they: were under 18 years old; were administered a radioisotope within five physical half-lives prior to study enrolment; were unable to lie flat during or unable to tolerate PET/MRI; had a prior history of any other malignancy within last two years or; had a contraindication to PET scan or 68Ga-PSMA ligand.

The PSMA PET/MRI Biochemical Recurrence Trial was the primary source of data on treatment probabilities (e.g., treatment radiation dose, ADT, etc. (Table 1)), diagnostic accuracy (sensitivity and specificity) and change in management parameters. Only treatment pathways post-prostatectomy were modelled due to data limitations. Other model inputs were sourced from the literature and include the most up-to-date estimates [10–20] (Table 1).

Treatment probabilities were grouped into local, nodal and distant. Local treatments used radiation therapy or surveillance, nodal stage cancers were managed with prostate fossa plus pelvic node radiation or extended radiation plus ADT and distant disease treatment was life-long ADT. As the downstream effects of 68Ga-PSMA investigation are unknown, several assumptions were made. Patients who were false positive for recurrent cancer incurred the costs of nodal and distant prostate cancer but were expected to survive according to having local disease. Patients who were false negative for recurrent cancer received localized treatment with a survival expectation of nodal or distant cancer. All rates were converted into annual probabilities. Patients were followed up every six months with either 68Ga-PSMA or usual care.

Healthcare costs

The study took an Australian health system perspective and included costs for public hospital care and federally reimbursed services and pharmaceuticals. The Australian Medicare costing schedules were used to inform the costs of relevant services and therapies (e.g., doctors consultations, biopsies, radiotherapy, hormone therapies etc.). A recent health technology assessment report provided micro-costing information to inform the costs of radiotherapy [19]. The cost of 68Ga-PSMA PET/MRI was quoted based on the cost of the tracer and imaging by the Princess Alexandra Hospital Medical Imaging Department. Costs for palliation associated with the cancer death were also included [20], this included end-of-life chemotherapy. All costs are presented in 2018 Australian dollars (AUD) and United States dollars (US$) (0.69 AUD = 1 US$, OECD Purchasing Power Parities).

Analyses

The main outcomes were healthcare costs and life years across the two strategies. The Markov model aggregated the probabilities, costs and survival estimates assigned to the different health states across 10 years. Probabilistic sensitivity analysis was used to calculate the mean costs and effects of each strategy with 50 000 iterations. Uncertainty intervals (UI) (95% and 90%) were calculated by ranking the outcomes and excluding the top and bottom 2.5%, 5%, respectively. Parameter values were selected at random from assigned probability distributions for the main parameters (Online Appendix 2). Gamma distributions were used for cost estimates and beta distributions were used the probabilities. Incremental cost-effectiveness ratios were calculated which is the difference in strategy costs divided by the difference in strategy life-years. Future costs and life years were discounted at 3% per year to adjust to present values. To address significant uncertainty with the modelled parameters, sensitivity analyses were undertaken. Each parameter was varied through a range of plausible values, 95% confidence limits (when available) or 15% either side of the mean. A threshold of AU$50 000 (US$34 626) per life year gained was used to benchmark whether the 68Ga-PSMA was cost effective versus usual care.

Results

Over 10 years, a strategy of using 68Ga-PSMA to detect prostate cancer recurrence was expected to cost on average, AU$56 961 (US$39 426) compared with AU$64 499 (US$44 667) in usual care (Table 2). The 68Ga-PSMA strategy would produce 7.48 life years compared with 7.41 life years for usual care. Therefore, 68Ga-PSMA was potentially cost saving (~$7 592 95% UI − $24 846, $7 825) (~US$5 258) and produced more life years 0.07 (95% UI − 0.01, 0.16) (Table 2). This result indicates that on average, 68Ga-PSMA is superior to usual care, although there was large variation in the incremental cost-effectiveness ratio (Table 2) with small changes to model inputs.

The most important driver of the model was the percentage of patients where 68Ga-PSMA detected prostate cancer lesions. When the lesion detection rate was low at 52% (from 61% in the base case), costs were $53 659 (US$37
Table 1  Key model inputs, sensitivity values and sources

| Description                                                                 | Value | Sensitivity values | Source/rationale               |
|-----------------------------------------------------------------------------|-------|--------------------|--------------------------------|
| **Structural inputs**                                                      |       |                    |                                |
| Duration (years)                                                           | 10    | 5                  | Author assumption              |
| Discounting rate                                                           | 3%    | 0%, 5%             | Applied to costs & life years  |
| **Diagnosis probabilities**                                                |       |                    |                                |
| 68GA-PSMA detection rate                                                   | 61%   | 52%, 70%, 75% [6]  | Pilot data, Fendler (2019) [6] |
| 68GA-PSMA true positive                                                    | 68%   | 59%, 79%           | Pilot data, ± 15%              |
| 68GA-PSMA true negative                                                    | 99%   | 79%, 100%          | Afshar-Oromieh (2015) [10]     |
| Usual care detection rate                                                  | 22%   | 18%, 25%           | Pilot data, ± 15%              |
| Usual care true positive                                                   | 99%   | 85%, 100%          | Pilot data, ± 15%              |
| Usual care true negative                                                   | 50%   | 43%, 58%           | Pilot data, ± 15%              |
| **Treatment probabilities**                                                |       |                    |                                |
| Localized lesion                                                           |       |                    |                                |
| Radiotherapy 70 GY—usual care                                             | 100%  | –                  | Pilot data                     |
| Radiotherapy 79 GY—68GA-PSMA                                              | 80%   | 68%, 92%           | Pilot data, ± 15%              |
| Surveillance—68GA-PSMA                                                     | 20%   | 17%, 23%           | Pilot data, ± 15%              |
| Nodal lesion                                                               |       |                    |                                |
| Radiotherapy 70 GY (with ADT, without ADT)—usual care (no lesion detected) | 50%, 50% | 42.5%, 57.5%       | Pilot data, ± 15%              |
| Extended radiotherapy (with ADT, without ADT)—68GA-PSMA                   | 71%, 29%, 60%, 25%, 82%, 33% | Pilot data, ± 15% |                                |
| Extended radiotherapy (with ADT, without ADT)—usual care                   | 67%, 33%, 57%, 28%, 77%, 38% | Pilot data, ± 15% |                                |
| **Distant disease**                                                        |       |                    |                                |
| ADT for rest of life if distant disease detected                           | 100%  | –                  | Pilot data                     |
| **Annual recurrence probabilities**                                        |       |                    |                                |
| Local stage after radiotherapy 70 GY                                       | 0.8%  | 0.7%, 0.9%         | Michalski (2018) [11]          |
| Local stage after radiotherapy 79 GY                                       | 0.4%  | 0.3%, 0.4%         | Michalski (2018) [11]          |
| Nodal stage after extended radiotherapy with ADT                           | 8.3%  | 6.8%, 9.8%         | James (2016) [12]              |
| Nodal stage after extended radiotherapy without ADT                        | 6.3%  | 4.9%, 7.8%         | Pommier (2016) [13]            |
| Nodal stage after false negative radiotherapy 70 GY                        | 4.8%  | 3.9%, 5.8%         | Shipley (2017) [14]            |
| **Annual mortality probabilities**                                         |       |                    |                                |
| Local stage after surveillance                                             | 2.2%  | 1.8%, 2.6%         | Klotz (2015) [15]              |
| Local stage after radiotherapy 70 GY & 79 GY                               | 3.5%  | 2.9%, 4.1%         | Michalski (2018) [11]          |
| Nodal stage after extended Radiotherapy without ADT                        | 3.2%  | 2.5%, 4.5%         | Pommier (2016) [13]            |
| Nodal stage after radiotherapy + ADT                                        | 3.9%  | 3.3%, 4.5%         | James (2016) [12]              |
| Nodal stage after false negative radiotherapy 70 GY                        | 4.4%  | 3.6%, 5.3%         | Shipley (2017) [14]            |
| Distant stage after ADT                                                    | 3.7%  | 3.0%, 4.4%         | Shipley (2017) [14]            |
| Distant stage after delayed ADT                                            | 6.2%  | 5.7%, 6.7%         | Messing (2006) [16]            |
| **Unit costs (AUS)**                                                       |       |                    |                                |
| Ga68 PSMA imaging                                                          | 1000  | 900, 1100          | Expert opinion                 |
| Usual care—imaging                                                        | 1125  | 957, 1294          | MBS (1) [17]                   |
| Biopsy                                                                     | 843   | 716, 969           | MBS (2) [17]                   |
| Prostate/pelvis radiotherapy                                               | 20,828 | 17,704, 23,953     | MBS (4) [17, 19]               |
| ADT for 12 monthsb                                                         | 15,741 | 13,379, 18,102     | PBS (6), MBS(3) [17, 18]       |
| ADT and extended radiotherapy                                              | 38,668 | 32,867, 44,468     | PBS (6), MBS(3,4) [17–19]      |
| Radiotherapy to prossa 70 Gy                                               | 11,930 | 10,140, 13,719     | MBS (5) [17, 19]               |
| Radiotherapy to prossa 79 GY                                               | 13,095 | 11,131, 15,060     | MBS (5) [17, 19]               |
| Follow-up imaging under 68GA-PSMA strategy                                 | 1811  | 1540, 2083         | MBS (66,655,104) [17], Expert opinion |
Table 2

| Description                                      | Usual care | GA68 PSMA | Mean difference (95% uncertainty interval) |
|--------------------------------------------------|------------|-----------|-------------------------------------------|
| Model duration—10 years (base case)              |            |           |                                           |
| Mean costs $AU                                   | $64,499    | $56,961   | − $7,592 (− $24,846, $7,825)              |
| Mean costs US$                                   | US$44,667  | US$39,426 | − US$5,258 (− US$17,206, US$5,419)        |
| Mean life years                                  | 7.41       | 7.48      | 0.069 (− 0.006, 0.163)                    |
| Incremental cost per life year saved             |            |           |                                           |
| − SAU110,511 (− US$76,531)                       |            |           |                                           |
| Uncertainty interval—95%                         |            |           |                                           |
| Uncertainty interval—90%                         |            |           |                                           |
| Model duration—5 years                           |            |           |                                           |
| Mean costs $AU                                   | $44,159    | $40,881   | − $3,278 (− $14,230, $6,568)              |
| Mean costs US$                                   | US$30,581  | US$28,311 | − US$2,270 (− US$9,855, US$4,549)         |
| Mean life years                                  | 4.32       | 4.34      | 0.018 (− 0.005, 0.046)                    |
| Incremental cost per life year saved             |            |           |                                           |
| − SAU344,136 (− US$238,322)                      |            |           |                                           |
| Uncertainty interval—95%                         |            |           |                                           |
| Uncertainty interval—90%                         |            |           |                                           |
| Discounting—5%                                   |            |           |                                           |
| Mean costs $AU                                   | $60,863    | $53,902   | − $6,961 (− $23,235, $7,403)              |
| Mean costs US$                                   | US$42,149  | US$37,328 | − US$4,821 (− US$16,091, US$5,127)        |
| Mean life years                                  | 6.88       | 6.94      | 0.062 (− 0.007, 0.145)                    |
| Incremental cost per life year saved             |            |           |                                           |
| − SAU269,496 (− US$186,632)                      |            |           |                                           |
| Uncertainty interval—95%                         |            |           |                                           |
| Uncertainty interval—90%                         |            |           |                                           |

GA68-PSMA, PET/MRI produced fewer costs and improved survival (Fig. 2). With our model estimates, the likelihood of 160 (US$43,111) and 7.48 life years. The findings were also sensitive to the cost of usual care and 68Ga-PSMA follow-up investigations, detection rate under usual care and the mortality rate of radiation treatment in both local and nodal disease. However, the 68Ga-PSMA strategy remained superior (i.e., cost-saving, higher life years) compared with usual care in all values tested in the one-way sensitivity values (see Fig. 1 for the ten most important model variables). When the model duration was reduced to 5 years, a strategy of 68Ga-PSMA remained cost saving ($3,278) and produced more life years (0.018). Increasing the discount rate to 5 (from 3% in the base case), which reflects a reduced value of present day dollars, resulted in the strategy of 68Ga-PSMA having fewer cost savings ($6,961) and fewer life years saved (0.062) than the base case analysis (Table 2).

In probabilistic sensitivity analyses, on the whole 68Ga-PSMA PET/MRI produced fewer costs and improved survival (Fig. 2). With our model estimates, the likelihood of...
a $^{68}$Ga-PSMA strategy being cost-effective was 87% at the threshold of AU$50,000 (US$34,626) per life year saved (Fig. 3). The majority of findings were cost-saving (Fig. 2).

**Discussion**

This study demonstrates that introducing $^{68}$Ga-PSMA PET/MRI to investigate biochemically recurrent prostate cancer could be cost-effective within the Australian health system. The findings are sensitive to both estimates of diagnostic accuracy, costs (of follow up care) and downstream patient mortality rates. The item cost of $^{68}$Ga-PSMA PET/MRI imaging was less than usual care imaging, although the treatment strategies for patients detected by $^{68}$Ga-PSMA PET/MRI was more expensive. These factors combined with the differing treatment specific survival rates resulted in a high range in cost per life years gained. Internationally, the costs of imaging and treatment strategies could fluctuate, although the theme of creating financial savings through prevention of non-beneficial therapies will be consistent. The limited gain in life years due to $^{68}$Ga-PSMA PET/MRI imaging should carry to patients outside Australia. Further research on more definitive and long-term findings would be beneficial in future economic evaluations.

Evidence is growing on the clinical use and acceptability of $^{68}$Ga-PSMA PET/CT in imaging algorithms in Australia and elsewhere in the world [6]. Currently there is no Federal Government reimbursement for $^{68}$Ga-PSMA PET/CT imaging in Australia. Evidence on the cost-effectiveness of this new technology will be required to support this decision. The evidence supporting the use of $^{68}$Ga-PSMA PET/MRI is even more scarce. Given the small numbers of such scanners around the world, it is important that those centres with access to this modality collect and publish data in order to inform the field as to the utility and potential cost effectiveness of this imaging modality. The utility of PSMA PET/MRI may in the future, also be expanded to staging

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**Fig. 1** Tornado plot of one-way sensitivity analyses $^{68}$GA-PSMA $^{68}$Gallium Prostate-specific membrane antigen, ADT Androgen deprivation therapy, ext. Extended, FP false positive, GY grays, TP True positive
in primary disease or initial prostate cancer diagnosis as a “one stop shop”.

Whilst the $^{68}$Ga-HBED-CC or PSMA-11 ligand used in this study has been the most studied ligand to date, further development of other PSMA ligands with alternative radio-isotopes such as $^{(18)}$FDCFPyL are ongoing. These and other similar tracers may have advantages over the original PSMA tracers due to their longer half-life and lack of urinary excretion which is particularly useful in the BCR setting by removing the “halo effect” around the bladder caused by urinary excretion of the tracer [21]. Comparison in the various clinical settings against standard of care imaging and indeed to other PSMA ligands is ongoing and requires further validation.

The local and international field are currently struggling to rationalise the use of this disruptive imaging technology in all stages of prostate cancer. Unfortunately, none of the clinical trials which currently inform practice utilise this imaging and all are based on standard imaging. This technology clearly leads to stage migration and there is also significant lead time bias introduced through the use of molecular imaging. Without appropriately designed and powered trials using these technologies with well-defined hard clinical endpoints, many patients may be inappropriately managed on the basis of unproven and experimental imaging results. It is well acknowledged that PSMA imaging does change management of patients, however the current world literature is unclear on the definition of “change in management” and if the change is for the better. The potential benefits from avoiding futile or inappropriate local therapies or directing more targeted therapy however as indicated in this analysis may be substantial in terms of financial cost and also morbidity, side effects, and survival (progression free, metastasis free and/or cancer specific) in the individual patient.

Limitations of this study include the reliance on a small single-arm study for treatment pathways and their probabilities, a lack of follow-up on long-term outcomes and different management strategies within usual care, which may not be widely generalizable. Despite this, as $^{68}$Ga-PSMA shows superior diagnostic performance to usual staging, it may not be ethical or feasible to undertake a large randomised control trial. Other natural or pseudo-experimental approaches, such as stepped-wedged or interrupted time series designs, may provide evidence to observe differences in diagnostic protocols with large samples. Therefore this economic model offers a practical solution to investigate the expected cost-effectiveness of this new technology. This study is strengthened by the high rate of histologic biopsy validation of the imaging findings, which are often technically difficult and highly invasive for men and for which the majority of the current literature is lacking.

### Conclusions

Advanced molecular imaging in prostate cancer has arrived in force and will be here to stay in one form or another. The rapid acceptance of this technology by clinicians highlights
the dire clinical need for more sensitive and specific imaging modalities to replace the inadequate usual care CT and Bone scan. However enthusiasm for new technologies must be tempered by sufficient quality data, through well designed and performed studies, to support their use and cost effectiveness. How these disruptive technologies improve patient outcomes is also yet to be determined and will require ongoing investigation. This current study however, does support from a health economic analysis perspective in the BCR setting in the Australian health system, the use of $^{68}$Ga-PSMA PET/MRI as a cost effective replacement for the usual CT and Bone Scan staging scans.

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