Setting up the Prostate Cancer Outcomes Registry of New Zealand: reflecting and influencing clinical practice

Stephen Mark, Judith Clarke, Brett Shand, Jeremy Millar, Nathan Papa

ABSTRACT

AIM: To describe the establishment of a national prostate cancer clinical quality registry (PCOR-NZ) within the New Zealand healthcare system and discuss the challenges encountered and achievements obtained during its development. Additionally, to provide a descriptive snapshot of the patients enrolled thus far.

METHODS: A review of the processes underpinning the start-up and maintenance of the registry was undertaken. We also extracted data from PCOR-NZ in April 2021 to report on patients diagnosed between 2016 and 2019 that had at least 12 months of follow-up.

RESULTS: Following ethical approval in 2015, a steering committee made up of clinicians, public health specialists and patient representatives was constituted, and site recruitment commenced. Men aged ≥18 years with a diagnosis of incident prostate cancer from participating sites are eligible for enrolment in PCOR-NZ. The registry functions with an opt-out consent model and captures diagnosis, treatment and short-term outcomes, with a particular focus on quality-of-life measures. As of January 2021, 100% of public hospitals and 36% of private urology clinics in New Zealand are actively participating in the registry. 5,858 men, including 411 who identified as Māori (7.0%), were diagnosed between 2016 and 2019 and enrolled in the registry. Population coverage is currently estimated to be almost 70%. Opt-out is estimated to be 2.8%.

CONCLUSIONS: PCOR-NZ is providing quality diagnostic, treatment and outcome data for promoting enhancements in the care of men with prostate cancer. The registry resources are therefore valuable for informing and supporting quality improvement resourcing of this common cancer.

In New Zealand, prostate cancer is the most common cancer in men, with over 3,500 registrations and more than 600 deaths each year.[1] There is a wide range of treatment options for prostate cancer, including active surveillance, wait and watch, surgery, radiation therapy, hormonal therapy and chemotherapy. To ensure the best outcomes for patients, it is important to measure the burden of disease and the effect of treatment on the quality-of-life of patients. To achieve this goal, the Prostate Cancer Outcomes Registry of New Zealand (PCOR-NZ) was set-up as part of a binational registry with seven Australian jurisdictions (PCOR-ANZ).[2,3]

Population-based clinical outcome registries represent "real-world" clinical activity, which allows variance to be identified. Clinically significant variance may reflect acceptable local practice, or it may also be due to poor clinical performance. If poor performance is identified as the cause, changes in activity and ongoing registry measurement should result in improvement. The advantage of the PCOR-ANZ registry is that it provides a comparison across jurisdictions, which allows for quality improvements by collegial collaboration. Similar state-based registries have been operational in Australia for over a decade[2] and have identified and driven positive

change, such as increasing adoption of active surveillance for low-risk patients and decreasing positive surgical margin rates.[4]

This paper describes the processes and challenges faced during the set-up of this clinical quality registry within the New Zealand health care system. We also provide a descriptive analysis of enrolled patients and their associated patient reported outcome measures (PROMs) 12 months following treatment.

Methods

The PCOR-NZ was initiated to systematically collect demographic, diagnostic, treatment and outcome data to capture practice patterns and measure variation in the treatment and quality-of-life of newly diagnosed prostate cancer patients in New Zealand. The binational arrangement, with each participating state jurisdiction having its own registry and access to its own data, enabled cost and organisational efficiencies and the capacity to easily benchmark from both sides of the Tasman Sea. The objective was to better understand outcomes and learn how local changes might enable better treatment outcomes. Funding and ongoing support is provided by the Movember Foundation New Zealand (https://nz.movember.com/about/cause).

We reviewed the steps taken to commence PCOR-NZ, in particular the governance framework, recruitment and data collection procedures. We provide a description of the demographic, clinicopathologic and pre- and post-treatment quality-of-life outcomes for patients diagnosed and enrolled in the first four years of the registry (2016–2019). These are presented in aggregate and by treatment modality. To aid interpretation, each patient was assigned one treatment type according to a hierarchy, with surgery assigned first and radiation therapy (RT) second, including brachytherapy, androgen deprivation therapy (ADT) with or without chemotherapy and then non-interventional management (active surveillance or watchful waiting). If two treatments were recorded, the higher was assigned (e.g., RT with ADT was counted as "radiation therapy"). Non-interventional management strategies have been grouped together. Although non-interventional management approaches are quite different, they can be difficult to differentiate at a population level. Because watchful waiting is not curative treatment, patients in this group will either continue to be monitored or eventually receive palliative treatment, whereas patients receiving active surveillance may be treated subsequently by radiation or surgery with the intent to cure. The registry allows patients who started on active surveillance to be followed and divided into groups based on whether they continued to receive surveillance, had active treatment started or had their disease follow the natural history of ageing.

A major component of the PCOR-NZ has been the collection of PROMs prior to treatment (baseline) and then at 12 months after the treatment decision.[5] The collection of PROMS at 12 months is a standard within all international prostate cancer outcome datasets. PROMs for prostate disorders were measured using the 26-item Expanded Prostate Index Composite for Clinical Practice questionnaire (EPIC 26), a validated short form of EPIC-50 that follows long-term domain-specific changes in patients' views of symptoms, functional status and health-related quality-of-life.[6] The EPIC-26 questionnaire can be completed within 10–15 minutes, making it practical for use in research and quality assurance in both single- and multi-centre studies.[7] The questionnaire was sent to men by post or email. The responses in the questionnaire were transformed into a 0–100 score (100=best function) for the symptom domains of urinary incontinence, urinary irritation, bowel function, sexual function and hormonal (e.g., lack of energy, change in body weight, hot flashes etc). The domain scores were expressed graphically as violin plots for each treatment modality.

Results

National ethical approval to establish the PCOR-NZ was granted in 2015 by the National Health and Disability Ethics Committee (HDEC) following the submission of protocols and policies governing patient recruitment, data collection and usage. New sites were added to the HDEC approval as recruited. The registry (https://prostatecancerregistry.org/) is governed by a steering committee with an independent chairperson and made-up of radiation

oncology and urology clinicians, a Māori and a patient representative, a public health academic member, the PCOR-NZ manager and a PCOR-ANZ representative from Monash University, Australia.

A project to establish the registry was initiated in 2016. Sites were recruited at different time points depending on local approval processes and the ability to access and collect data. Notifications of new cases of prostate cancer are sent to PCOR-NZ from participating sites. Missed cases from these sites are captured through a quarterly linkage with the New Zealand Cancer Registry (NZCR, https://www.health.govt.nz/nz-health-statistics/national-collections-and-surveys/collections/new-zealand-cancer-registry-nzcr) (Figure 1). The Ministry of Health, despite indicating the value of such a registry, elected not to fund data collection, due in part to the registry being funded by the Movember Foundation and run by a charitable trust, the Centre for Health Outcome Measures New Zealand (CHOMNZ, www.chomnz.org.nz).

As a population-based registry, patient recruitment is via "opt-out consent," which is required to improve coverage and avoid selection bias. Upon receiving a notification of a new diagnosis from a participating site or the NZCR, data collectors, with approval to remotely access patient notes, check for evidence that the man has been notified of his diagnosis prior to uploading the case to PCOR-NZ and checking eligibility. Men can be deemed ineligible to participate as per agreed criteria, including being too unwell and non-English speaking, as well as at the discretion of the diagnosing clinician or data collector. Eligible men are sent a letter of invitation and an information sheet about the registry advising how to opt-out of the study. Men can opt-out at any time via email, mail or phone. If notification is received within three months of diagnosis, a "baseline" questionnaire on PROMS is also sent. If the questionnaire is not returned within three weeks, a follow-up call is made by registry staff, who provide another opportunity for men to ask questions or to opt-out of the study. Men may choose to opt-out of the registry completely or choose data collection only, whereby clinical data is collected but no questionnaires are sent. A similar process of contacting men, and another opportunity to opt-out, occurs when the 12-month PROMS questionnaire is sent.

A key performance indicator is to register 90% of men with a new diagnosis of prostate cancer in New Zealand. It is important that maximum participation of both doctors and patients is achieved so that sufficiently representative data are collected to inform the changes necessary to achieve population-level quality improvement. Public hospitals in New Zealand are currently managed by 20 district health boards (DHBs), and it has taken five years for the DHBs to be progressively recruited to PCOR-NZ. As of January 2021, 100% of public hospitals are actively participating in the registry. In the private health sector, although 53 of 57 (93%) of urologists working in private have signed agreements to participate, only 12 of 33 (36%) private clinics currently have systems in place that allow patients to be recruited to the registry and have data collected via remote access. The majority of private clinics participating are larger group private practices. Data entry is carried out manually as electronic data transfer is not currently available in New Zealand because of differences in information technology (IT) systems.

Data collection and collation and access to the registry are guided by strict protocols to ensure the security, privacy and confidentiality of participants and information collected. The data are stored on an ISO 27001-certified environment server at the PCOR-ANZ Monash University registry office in Australia and backed up daily in New Zealand on a hospital-level secure server. The accuracy and completeness of the data is checked by audits and reports and via triangulation with other New Zealand Ministry of Health datasets.

The PROMs, alongside other PCOR-NZ data, have been used to benchmark key quality outcome indicators against all institutions and clinicians participating in PCOR-ANZ. Because these indicators are qualitative measures that are often self-reported, they are likely to fluctuate naturally over time as different generations enter the register. Local and international benchmarking of patient outcomes from a similar region in Australia and New Zealand is therefore vital to obtain contemporary comparison and visibility of any outcome variance.

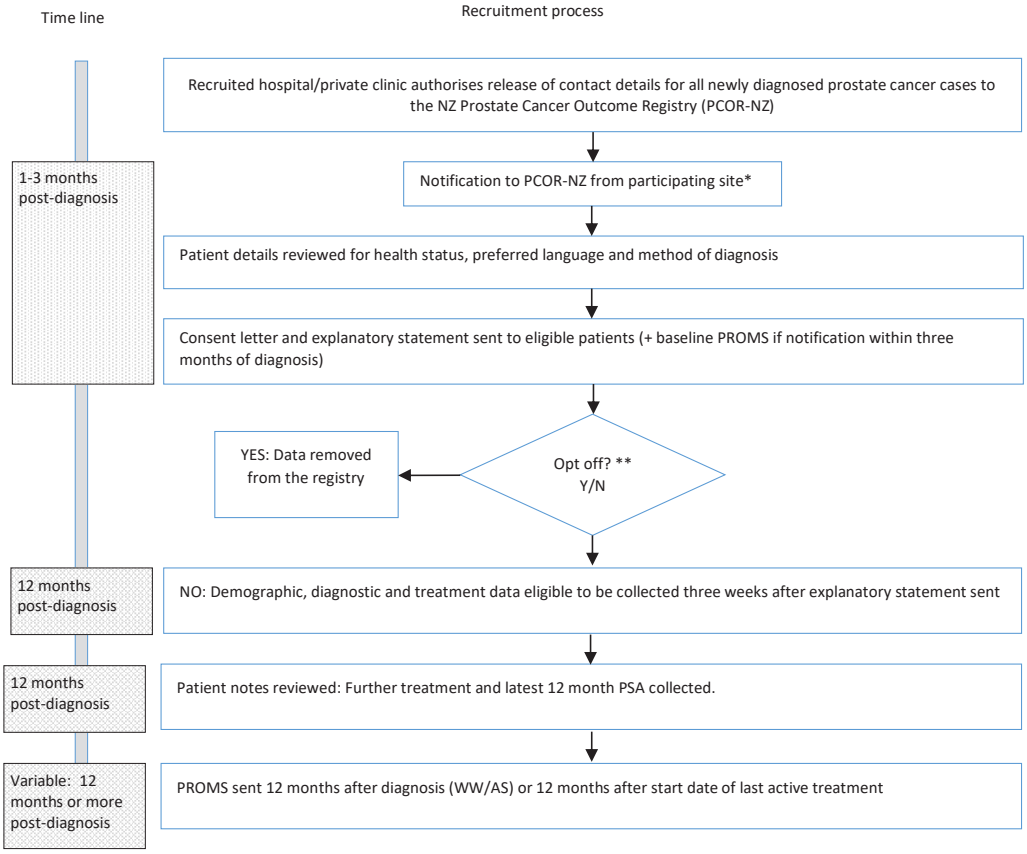
The outcome measures in PCOR-ANZ (e.g., EPIC-26) were selected by the Delphi system and deemed to be the most valuable validated outcome measures for both the patient and urologist to improve the quality of care. At this stage, baseline and 12-months PROMs are providing the most valid data in the PCOR-NZ, although follow-up is planned, possibly at five-years.

The data allow trends in the diagnosis and management of prostate cancer across Australia and New Zealand to be compared and disparities in treatment and clinical outcomes to be identified. Examples of these indicators are shown in Table 1. The information is sent directly to clinical directors of hospital urology units and to participating clinicians as confidential six-monthly, risk-adjusted quality indicator reports. Participating sites and clinicians may apply for their own site-specific data, and external researchers may apply for de-identified data to be released from PCOR-NZ following a successful application to the steering committee. In addition, PCOR-NZ contributes to the TrueNTH Global Registry, an international project that centralises and compares clinical data on prostate cancer from 13 countries.

Registry profile

Five thousand eight hundred and fifty-eight men diagnosed with prostate cancer between 2016 and 2019 were consented and entered into PCOR-NZ. Four hundred and eleven (7.0%) identified as Māori, which was the most common ethnicity after European. Year-to-year accrual into the registry has been growing strongly, from 260 in 2016 to 2,887 in 2019 (Figure 2). The percentage of eligible men choosing to opt-out in the

Figure 1: Timeline of recruitment and data collection in PCOR-NZ.



* Quarterly extracts from NZCR provide secondary source of notifications (notifications are received 6–12 months post-diagnosis so these men are not eligible for baseline PROMS).

** Men can choose to opt-out or change to data collection only at any stage.

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registry is 2.8%. Compared to New Zealand Ministry of Health cancer registrations,[7] the current population coverage is estimated at almost 70%. The median age was 67 years, and the most common National Comprehensive Cancer Network (NCCN) risk category was intermediate (38%) (Table 2). Surgery was the most commonly recorded primary treatment overall (36%) and for intermediate risk cancer (56%). For low-risk disease, observational management was most common (71%), followed by surgery (21%). For high/very high risk, the most common treatment was radiation therapy (37%). Health-related quality-of-life after prostate cancer treatment varied according to treatment type (Figure 3). Symptoms of urinary incontinence were observed to be worse after surgery (median score 86, interquartile range (IQR): 61–100) versus RT (median score 100, IQR: 79–100). Symptoms of poor sexual function were notably less severe in patients managed by active surveillance or watchful waiting (median score 61, IQR: 27–88) than was observed with all other treatment types (median score<20).

Discussion

A goal of PCOR-NZ is to record and collate high-quality population-level data on the diagnosis and treatment of prostate cancer in New Zealand. This objective is being achieved, with recruitment increasing and data collection ongoing. The registry has the goal of data accuracy and nation-wide collection of prostate cancer. This is fulfilled by local case notification plus quarterly alignment with the NZCR and subsequent review with the patients enrolled in the New Zealand Radiation Oncology Registry. An independent audit, typically carried out from time-to-time in most cancer registries, may also be a useful additional assessment of accuracy. The registry has provided meaningful clinical information with standardised PCOR-ANZ reports sent every six months to hospital departments and individual clinicians. These reports provide comparisons of clinical practice and highlight variances in patient care and outcomes. The longer-term aim of the registry is to share de-identified data with agencies that develop policy and fund healthcare. This

Table 1: Quality indicators provided in reports issued by the PCOR-ANZ.

Diagnosis
PSA level documented at diagnosis.
Clinical T category documented in the medical record.
Treatment
PSA level documented post-radical prostatectomy.
High/very high risk or metastatic disease with no treatment.
The proportion of low-risk prostate cancer cases managed with interventional treatment.
Low-risk disease in men who have a radical prostatectomy.
Active treatment in men with low-risk disease.
Clinical outcomes
Mortality.
Prevalence of positive surgical margins post-radical prostatectomy • Intermediate risk (a) at all institutes and (b) public institutes • High/very high risk (a) at all institutes and (b) public institutes • pT2 (a) at all institutes and (b) public institutes.
Patient reported outcome measures at 12-month follow-up post-prostatectomy
Urinary bother and incontinence.
Bowel bother and function.
Sexual bother and function.

information will assist in supporting Te Aho o Te Kahu – Cancer Control Agency (https://teaho.govt.nz/) with their key principles of being equity-led, knowledge driven and outcomes focused.

The registry encountered significant challenges during its development. Although ethical approval for the registry was granted by the HDEC, and endorsements were received from a variety of national health, Māori and IT organisations, a replicable pathway to recruit across the 20 DHBs was never established. Requirements for approval at each DHB to participate in the registry and to collect data were complex and varied from simple CEO approval via HDEC locality authorisation to lengthy consultation and documentation requirements, each with different forms and processes. Approvals to recruit, gain IT access and set-up notification systems across the 20 DHBs has taken five years to complete nationally. DHBs require annual updates and advice on HDEC amendments and changes to documentation, which results in duplication of work. A simpler standard system of process sign-off and reporting of updates would be valuable if further national data collections are to be undertaken.

The process of establishing the registry at private urology clinics was less cumbersome with each clinician signing an agreement to participate and a clinical director providing approval via HDEC locality authorisation. The challenge for private clinics in New Zealand has been accessing patient notes and collecting data. Using local resourcing within private clinics for this work proved unsuccessful due to the time commitment required and the complex nature of the data being collected. Instead, CHOMNZ have moved to a system whereby a CHOMNZ-approved data collector either visits the clinic rooms to collect data (two sites) or is provided with remote access to the clinic's electronic patient management systems (seven sites). A challenge remains for those private clinics that are either paper based or have electronic systems that cannot be remotely accessed by CHOMNZ, or that have security

Figure 2: Number of men enrolled in PCOR-NZ between 2016 and 2019.

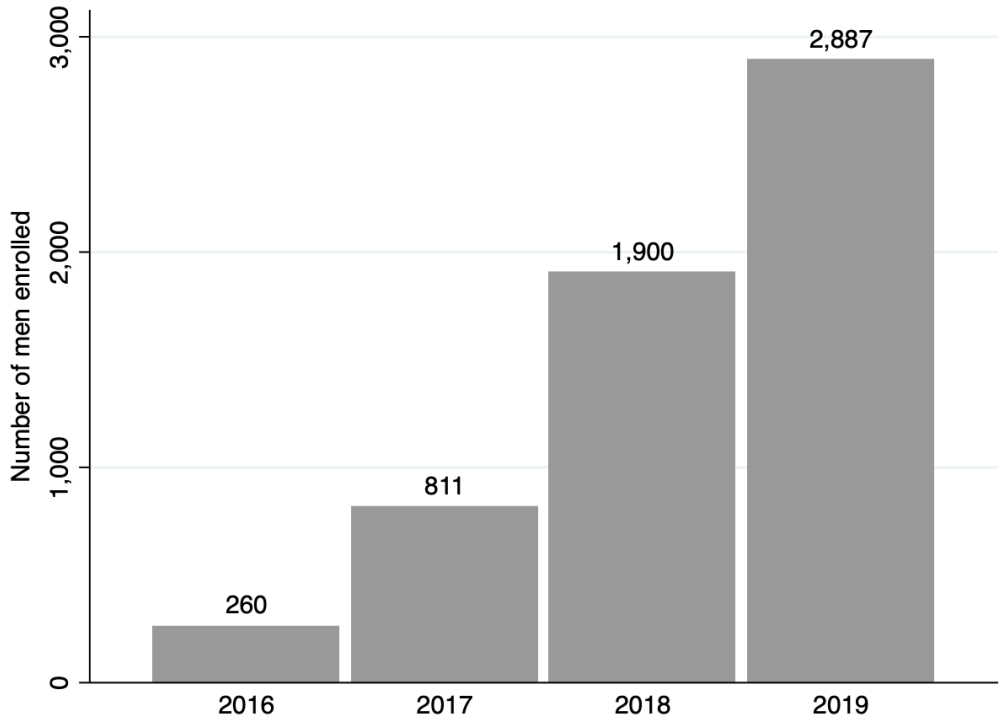

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Table 2: Characteristics of registry participants diagnosed between 2016 and 2019 by primary treatment received. Median (IQR) or n (column %). n=128 with other or unknown treatment.

	All participants (n=5,858)	Surgery (n=2,101)	Radiation therapy (n=1346)	ADT +/- chemother-apy (n=651)	AS or WW (n=1,632)
Age at diagnosis, years	67 (62–72)	65 (60–69)	69 (64–74)	76 (69–81)	67 (62–71)
Ethnicity					
European	5,099 (87)	1,865 (89)	1,144 (85)	543 (83)	1,444 (88)
Māori	411 (7.0)	100 (4.8)	131 (9.7)	64 (9.8)	104 (6.4)
Pacific Islander	119 (2.0)	37 (1.8)	24 (1.8)	21 (3.2)	34 (2.1)
Other	186 (3.2)	77 (3.7)	39 (2.9)	17 (2.6)	45 (2.8)
Unknown	43 (0.7)	22 (1.0)	8 (0.6)	6 (0.9)	5 (0.3)
PSA at diagnosis, ng/ml *	7.3 (5.3–12.3)	6.4 (5.0–9.2)	9.4 (6.2–15.2)	31.9 (15.4–100)	6.0 (4.8–8.5)
Clinical T-stage					
cT1	2,956 (50)	1,153 (55)	566 (42)	88 (14)	1,110 (68)
cT2	1,356 (23)	528 (25)	446 (33)	165 (25)	190 (12)
cT3/4	496 (8.5)	61 (2.9)	192 (14)	224 (34)	11 (0.7)
cTX	1,050 (18)	359 (17)	142 (11)	174 (27)	321 (20)
ISUP Grade Group					
1	2,030 (35)	405 (19)	172 (13)	22 (3.4)	1,408 (86)
2	1,622 (28)	904 (43)	469 (35)	52 (8.0)	150 (9.2)
3	821 (14)	411 (20)	273 (20)	86 (13)	38 (2.3)
4	608 (10)	219 (10)	212 (16)	141 (22)	21 (1.3)
5	682 (12)	152 (7.2)	213 (16)	293 (45)	11 (0.7)
Not recorded	95 (1.6)	10 (0.5)	7 (0.5)	57 (8.8)	4 (0.2)
NCCN risk category					
Low	1,581 (27)	335 (16)	112 (8.3)	9 (1.4)	1,116 (68)
Intermediate	2,243 (38)	1,259 (60)	614 (46)	40 (6.1)	280 (17)
High/Very High	1,194 (20)	409 (19)	442 (33)	239 (37)	82 (5.0)
Regional (cN1)	178 (3.0)	28 (1.3)	90 (6.7)	53 (8.1)	0
Metastatic	385 (6.6)	12 (0.6)	54 (4.0)	308 (47)	2 (0.1)
Not recorded	277 (4.7)	58 (2.8)	34 (2.5)	2 (0.3)	152 (9.3)

* 350 no recorded PSA. ADT = androgen deprivation therapy. AS = active surveillance. ISUP = International Society of Urological Pathology. NCCN = National Comprehensive Cancer Network. PSA = prostate specific antigen. WW = watchful waiting.

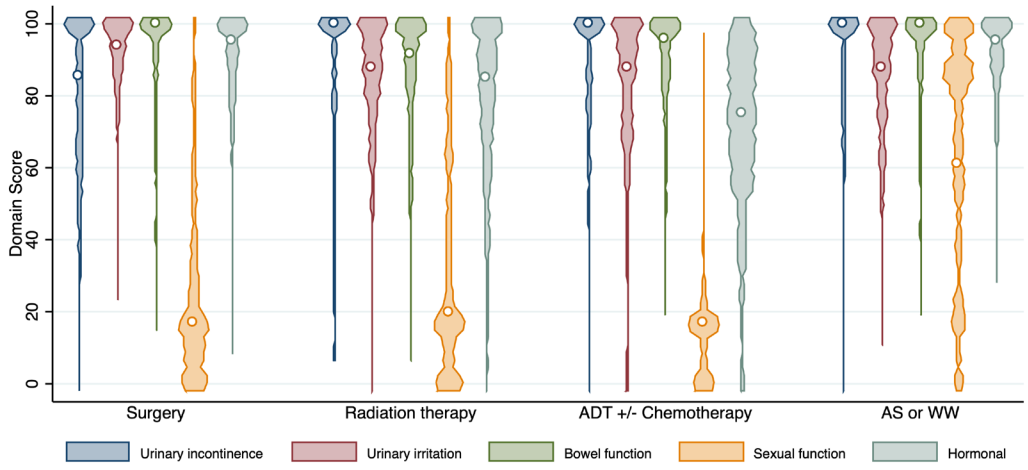
or privacy concerns in providing remote access. Consequently, the estimated 30% of men missing from PCOR-NZ were diagnosed or treated almost exclusively at these non-contributing private sites.

Another challenge for the registry has been the need for rapid case ascertainment to enable the collection of pre-treatment PROMs at baseline. There is therefore a reliance on participating sites to provide notifications on a regular and timely basis. A variety of sources are used across sites, with the accuracy and completeness of this information being reliant on the quality of the reporting systems in place. A second source of notifications is by a quarterly linkage to the NZCR. This has proved useful as a mechanism for capturing missed cases. The difficulty with notifications received through the NZCR is that diagnosis is reported by pathology laboratories rather than by diagnosing institute. Despite most laboratories processing local cases, it is not always possible to ascertain which hospital or private clinic is managing the patient, so these men cannot always be uploaded to PCOR-NZ. In addition, the lag between diagnosis date and coding means men in the NZCR extracts may have been diagnosed between 6 and 12 months earlier. As baseline PROMs can only be completed in the first three months post diagnosis, the late notification of men from the NZCR makes them ineligible to be sent a baseline PROMs questionnaire.

Overall, the responses in the analytic sample, grouped by treatment type, were consistent with those reported in international studies.[8–10] Observational management was associated with the best quality-of-life outcomes, as seen in other international studies.[11–12] Future work focused on PROMs will assess the variance of quality-of-life across age and ethnicities after adjustment for baseline clinicopathologic factors and pre-treatment function.

In conclusion, PCOR-NZ, a constituent of PCOR-ANZ and the TrueNTH Global Registry, is providing quality diagnostic, treatment and outcome data for promoting improvements in care in men with prostate cancer. It has achieved coverage from all districts of New Zealand, and in future years its findings will be readily generalisable to the entire population. The registry also distributes important clinical information on prostate cancer care to urologists, urology clinics and hospital departments and allows contemporary local and international benchmarking of outcomes to be examined. PCOR-NZ resources are therefore valuable for informing and supporting quality improvement resourcing of this common cancer.

Figure 3: Violin plots for each symptom domain score, by primary treatment, 12 months after treatment started.



Circle indicates median score.

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Competing interests:
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Author information:
Stephen Mark: Consulting Urologist, Department of Urology, Christchurch Hospital, Christchurch, New Zealand.
Judith Clarke: PCOR-NZ National Manager, Centre for Health Outcome Measures New Zealand (CHOMNZ), Christchurch, New Zealand.
Brett Shand: Clinical writer and analyst, Christchurch, New Zealand.
Jeremy Millar: Director Research, Alfred Health Radiation Oncology, Melbourne, Victoria, Australia.
Nathan Papa: Lead – Prostate Cancer Outcomes Registry Research Group, School of Public Health and Preventive Medicine, Monash University, Melbourne, Australia.

Corresponding author:
Mr Stephen Mark, Department of Urology, Christchurch Hospital, Private Bag 4710, Christchurch, New Zealand, +64 3 355 5219
stephen@urology.co.nz

URL:
www.nzma.org.nz/journal-articles/setting-up-the-prostate-cancer-outcomes-registry-of-new-zealand-reflecting-and-influencing-clinical-practice

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