PROSTATE CANCER OUTCOMES | REGISTRY AUSTRALIA AND NEW ZEALAND

PCOR-ANZ CLINICAL QUALITY INDICATORS

The following indicators have been endorsed for reporting by participating organisations:

Indicator	Participant Category	Rationale	Calculation	Consideration
STRUCTURE				
Number of Participants treated at institution per year (by treatment).	All	Participants treated in high volume hospitals have shorter hospital stay, fewer complications, lower readmission rates, and higher mortality than Participants treated in low volume hospitals [34].	**Numerator:** RP= Yes, RT=Yes, BT= Yes, AS= Yes, WW=Yes **Denominator:** All Participants **Risk adjustment:** Yes [35]	Overall volume may not detect low volume in each treatment group.
PROCESS				
Positive margin rate post RP.	Stratified by stage pT2 [35]	The presence of a positive margin increases the risk of biochemical recurrence, local recurrence and the need for salvage treatment [36]	**Numerator:** PSM ≥ 1mm **Denominator:** All Participants having RP **Risk adjustment:** Yes [35]	Indicator does not consider the location of the margin e.g. apex, base.
PSA level recorded at diagnosis.	All	Without a PSA it is difficult to accurately identify appropriate treatment and to calculate risk of disease progression.	**Numerator:** PSA level is not null **Denominator:** All Participants **Risk adjustment:** No	Low risk: PSA ≤10 Medium risk: 10 < PSA ≤ 20 High risk: PSA >20
Documentation of clinical T stage in the medical record.	All	The clinical stage provides the best initial estimate of the extent of disease. The clinical stage is based on the results of the physical examination (including DRE), biochemical tests, prostate biopsy, endoscopy and any imaging tests [37]	**Numerator:** cT stage documented and recorded. **Denominator:** All Participants where DRE not refused/recorded as not taken. **Risk adjustment:** No	Low risk: stage ≤T2a Medium risk: stage = T2b. High risk: stage = T2c or T3 [38].

Active surveillance/watchful waiting for men with low risk disease.	Low risk [35]	Men with low-risk localised prostate cancer, for whom RP and RT is suitable, should be offered active surveillance as an option [39].	**Numerator:** Percent of Participants with no active treatment **Denominator:** All Participants with low risk disease (PSA <10; Gleason =6; cT≤2a) **Risk adjustment:** No	
Evidence that Participants in high-risk disease group received active treatment.	High risk [35] and age <80	Men with high-risk localised prostate cancer should not be offered active surveillance [39].	**Numerator:** % Participants receiving active treatment. **Denominator:** All Participants with high-risk disease (PSA>20 OR Gleason score ≥ 8 OR clinical stage ≥ T2c). **Risk adjustment:** Age <80 years	Active treatment ≠ hormone treatment Valid reasons exist why men with high-risk disease do not receive active treatment, including advanced age, multiple comorbidities and Participant choice.
Time from biopsy-confirmed diagnosis to first treatment	High risk [35]	Significant increases in the proportion of adverse pathological outcomes were found beyond 75 days overall, 150 days for Participants with Gleason ≤6, and PSA 0-10, 60 days for Participants with Gleason 7 and PSA >20, and 30 days for Participants with Gleason 8-10 and PSA 11-20 [40].	**Numerator:** Date of commencement of neo-adjuvant ADT, RT, RP minus date of diagnosis >90 days for men with high risk disease. **Denominator:** All Participants with high-risk disease (PSA>20 OR Gleason score ≥ 8 OR clinical stage ≥ T2c). **Risk adjustment:** No	Hormone treatment = active treatment High risk Participants only.

OUTCOMES				
5-, 10-year and 15-year overall survival	Stratified by stage [35] and age.	An individual's prognosis depends on the type and stage of cancer, as well as their age and general health at the time of diagnosis. In Australia, the 5- 10- and 15-year survival rate for men diagnosed with prostate cancer is 92%, 93% and 77% respectively.	**Numerator:** Death = Yes (death date not null) **Denominator:** Diagnosis date + 5, 10 and 15 years **Risk adjustment:** Stage and age	Survival analysis. Cox proportional hazard analysis with risk adjustment.
Clinical and/or biochemical disease-free survival after primary treatment by RT or RP	***Clinical recurrence:*** All Participants who have had RP or RT. Stratified by stage pT [35]. ***Biochemical recurrence:*** Participants who have had RP. Stratified by stage pT [35].	15–30% of Participants treated for prostate cancer, will experience a recurrence [41].	***Clinical recurrence*** **Numerator:** Imaging positive for prostate cancer metastases **Denominator:** All Participants who have had RP or RT. **Risk adjustment:** Yes ***Biochemical recurrence*** **Numerator:** Any PSA>0.2ng/mL 12 months post RP **Denominator:** Participants having RP	RT not included as 12 months post-RT many men will be receiving ADT which will mask the possibility of disease progression PCOR-ANZ collects PSA only at 12 months post treatment, so change from nadir not possible nor collection of 5,-10,- and 15-year recurrence.

Participant assessment of urinary, sexual, and bowel function	All	Urinary function is better post RT and BT than post RP [42]. Sexual function is better post BT than post RT or RP [42]. Bowel function is worse post RT and BT, than post RP [42]. Urinary domain score, classified as 0 to 49 severe, 50 to 69 moderate and 70 to 100 mild [43]. Sexual stratification 0-32 (severe), 33-44 (moderate), 45-59 (mild/moderate), 60-74 (mild), 75-100 (none) [43]. Bowel function has not been reported in terms of severity scores.	***Urinary function*** **Numerator:** Number of Participants with severe urinary symptoms (EPIC-26 summary score<50) 12 months after treatment **Denominator:** All Participants **Risk adjustment:** No ***Sexual function*** **Numerator:** Number of Participants with severe sexual dysfunction (EPIC- 26 summary score<33) 12 months post treatment **Denominator:** All Participants **Risk adjustment:** No ***Bowel function*** **Numerator:** Number of Participants with severe bowel dysfunction (EPIC-26 summary score<50) 12 months post RT **Denominator:** All RT Participants **Risk adjustment:** No	Bowel function score has not been reported so an arbitrary score of 50 was selected, to match the score for urinary function. This requires further development and validation. Literature focus on minimally-important differences, which require baseline and follow up scores to calculate. PCOR-ANZ does not collect baseline EPIC 26. Recovery of sexual and urinary function is time dependent with maximal urinary recovery requiring up to 18 months and maximum sexual recovery often taking even longer [44]. PCOR-ANZ collects data only to 12 months post active treatment.

Participant assessment of urinary, sexual, and bowel bother	All	Urinary and sexual bother is similar post RP, RT and BT [42]. Bowel bother is higher post RT and BT, than post RP [42].	***Urinary bother*** **Numerator:** number of Participants responding to the question "Overall, how big a problem has your urinary function been for you during the last 4 weeks?" with "Big problem" **Denominator:** All Participants **Risk adjustment:** No ***Sexual bother*** **Numerator:** Number of Participants responding to the question "Overall, how big a problem has your sexual function been for you during the last 4 weeks?" with "Big problem" **Denominator:** All Participants **Risk adjustment:** No ***Bowel bother*** **Numerator:** Number of Participants responding to the question "Overall, how big a problem has your bowel function been for you during the last 4 weeks?" with "Big problem" **Denominator:** Only RT Participants **Risk adjustment:** No (RT only)	No bowel bother for non-RT Participants. PCOR-ANZ does not collect baseline EPIC.

Rate of in-hospital death from surgical complications	RP only	The risk of postoperative mortality after RP is relatively low for otherwise healthy older men up to age 79 (30)	**Numerator:** Death = Yes (death date not null) and RP date +/- 30 day **Denominator:** All Participants having RP **Risk adjustment:** No	

Abbreviations:

- **ADT**: adjuvant deprivation therapy
- **AS**: active surveillance
- **BT**: brachytherapy
- **cT**: clinical stage T
- **DRE**: digital rectal examination
- **EPIC**: Extended Prostate Cancer Index Composite
- **NCCN**: National Comprehensive Cancer Network
- **PCOR-ANZ**: Prostate Cancer Outcomes Registry – Australia and New Zealand
- **PSA**: prostate-specific antigen
- **PSM**: positive surgical margins
- **pT2**: pathological stage T
- **RP**: radical prostatectomy
- **RT**: radiotherapy
- **WW**: watchful waiting