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Quality indicators for global benchmarking of localised prostate cancer management

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1 **Title Page**

2

3 Quality indicators for global benchmarking of localised prostate cancer management

4

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42

43 **ABSTRACT**

44 **Purpose:** To develop a core set of clinical indicators that enables international benchmarking  
45 of localised prostate cancer management using data available in the TrueNTH Global  
46 Registry.

47  
48 **Materials and Methods:** An international expert panel completed an online survey and  
49 participated in a face-to-face meeting. Participants included urologists (n=3), radiation  
50 oncologists (n=3), psychologists (n=2), medical oncologist (n=1), nurse (n=1) and an  
51 epidemiologist (n=1) with prostate cancer expertise from seven countries. Current guidelines  
52 on prostate cancer treatment and potential quality indicators were identified from a literature  
53 review. These potential indicators were refined and developed through a modified Delphi  
54 process, during which each panellist independently and repeatedly rated each indicator based  
55 on its importance (satisfying the indicator demonstrates a provision of high-quality care) and  
56 feasibility (likelihood that data being used to construct the indicator could be collected at a  
57 population level). The main outcome measure was items with panel agreement (disagreement  
58 index < 1), median importance  $\geq 8.5$  and median feasibility  $\geq 9$ .

59  
60 **Results and Conclusions:** Thirty-three indicators received endorsement from the expert  
61 panel. These 33 prostate cancer quality indicators assess care relating to diagnosis (n=7),  
62 primary treatment (n=7), salvage treatment (n=1) and health outcomes (n=18).

63  
64 In summary, we have developed a set of quality indicators for measuring prostate cancer care  
65 from numerous international evidence-based clinical guidelines. These indicators will be pilot  
66 tested in the TrueNTH Global Registry. Reports comparing indicator performance will

67 subsequently be distributed to participating sites, with the purpose of improving the  
68 consistency and quality of prostate cancer management on a global basis.

69

ACCEPTED MANUSCRIPT

**70 BACKGROUND**

71

72 Evidence-based practice, which promotes the judicious conscientious use of scientific  
73 evidence to inform clinical management, is a pillar of modern medicine. Innumerable best  
74 practice guidelines discussing the management of localised prostate cancer (PCa) have been  
75 published, aiding practitioners to understand the most appropriate management for the large  
76 number of men diagnosed with this disease each year.

77

78 Despite the accessibility of these guidelines, practice commonly varies from that  
79 recommended. For example, the rate of patients in the United States with high-risk PCa  
80 receiving first-line radiotherapy with concomitant androgen deprivation therapy (ADT),  
81 which is a National Comprehensive Cancer Network (NCCN) and European Association of  
82 Urology (EAU) recommendation, ranged from 58% to 75% and was declining<sup>1</sup>. Significant  
83 discrepancies in PCa care among different geographical regions have also been evidenced<sup>2, 3</sup>.

84

85 Quality indicators (QIs) are explicitly defined, consensus-based, measurable items which  
86 enable comparison and act as a catalyst for improvement<sup>4</sup>. Indicators are currently being used  
87 to monitor PCa quality of care by the RAND Health Science Program in the United States<sup>5</sup>,  
88 the National Prostate Cancer Register of Sweden<sup>6</sup>, the prostate cancer centers certification  
89 program by the German Cancer Society<sup>7</sup> and the Prostate Cancer Outcomes Registry in  
90 Australia and New Zealand<sup>8</sup>. It remains a challenge to demonstrate that outcomes for men  
91 improve as a result of performance assessment against QIs, however promising examples  
92 exist. Dissemination of benchmarking provider performance to urologists in Victoria,  
93 Australia demonstrated improved adherence to three QIs over the 5-year study period<sup>9</sup>. In

94 Sweden, there was improvement in six out of nine QIs, including the number of men with  
95 very-low-risk disease undergoing AS, over a 3-year period<sup>6</sup>.

96

97 The existence of numerous PCa registries and the development of international consensus  
98 minimum datasets for localised PCa by the International Consortium for Health Outcome  
99 Measures (ICHOM)<sup>10</sup> provides an opportunity to harness existing infrastructure and  
100 investment to establish core QIs. The TrueNTH Global Registry<sup>11</sup> has modelled clinical and  
101 patient-reported data on the ICHOM standard set for localised PCa<sup>10</sup>. This will provide a  
102 platform where data can be used to evidence performance against QIs, which will provided to  
103 participating organisations and allow comparison amongst peers. The paper describes an  
104 effort to identify a consensus set of QIs to benchmark PCa management among international  
105 groups contributing to the registry.

106

## 107 **METHODS**

108 We used a modified Delphi process, which combines scientific evidence with the  
109 professional expert opinion<sup>12</sup>. Approval was gained from the Monash University Human  
110 Research Ethics Committee (2016-5551-5405).

111

### 112 **Panel composition and consent process**

113 The panel was composed using purposive sampling of fifteen international leaders of  
114 Movember-funded PCa research activities. These invited individuals have expertise in PCa  
115 and were from countries involved in the TrueNTH Global Registry. Informed consent was  
116 obtained at the project's commencement.

117

### 118 **Literature Review**

119 A range of international guidelines for the diagnosis and management of localised PCa,  
120 restricted to those published in English, were reviewed (Supplementary Table 1). We also  
121 evaluated grey literature on indicator initiatives in available PCa programs (Supplementary  
122 Table 1) to identify potential indicators not stated in the guidelines. These guidelines and  
123 recommendations were collated. Study Investigators (FS, JZ, LDS, JM and SE) derived  
124 indicators from these recommendations and determined if they could be objectively measured  
125 and developed within the limitations of the registry dataset.

126

### 127 **Online survey**

128 In the first-round, panellists were asked to complete an online survey reviewing the refined  
129 list of proposed indicators. To maintain anonymity, each participant was given an  
130 identification number which was known only by two Investigators (FS and JZ). The  
131 indicators were presented chronologically, in line with the PCa management pathway (page 6,  
132 *Supplementary File 1*). Panellists received an accompanying document with each indicator's  
133 source, supporting strength of evidence and proposed construct (numerator and denominator)  
134 (page 22, *Supplementary File 1*). They were asked to rate each indicator's importance on a 9-  
135 point Likert scale (1= not important to 9= very important). Importance was defined as the  
136 extent to which satisfying the indicator demonstrated a provision of high-quality care and that,  
137 conversely, not meeting the indicator signalled poor-quality care. Panellists were asked to  
138 respond with 'unable to comment' if they could not give an informed professional opinion.  
139 They were encouraged to suggest modifications or propose new indicators.

140

141 To establish a consistent method of measuring indicators, panellists were asked to select a  
142 single risk stratification method which would be used to define low, intermediate and high-  
143 risk PCa.



144

145 **Expert panel meeting**

146 Using the first-round survey results, the median importance (MI) and disagreement index (DI)  
147 was calculated for all proposed indicators (*Table 1*). The MI ranged from 1-9. The DI is a  
148 continuous scale used to describe dispersion of ratings by panellists<sup>12</sup> (*Supplementary Table*  
149 *2*). A DI of 0 represents complete agreement among panellists while a  $DI \geq 1$  has been  
150 determined by RAND to indicate disagreement<sup>12</sup>. 'Unable to comment' responses were  
151 excluded from the calculations.

152

153 A traffic light system, with the colours green, amber and red, was used to differentiate  
154 between indicators with the greatest support and the greatest level of disagreement amongst  
155 panellists. Indicators with the greatest support, defined as a  $MI \geq 7$  and  $DI < 1$ , were categorised  
156 as *green*. All indicators with panel disagreement ( $DI \geq 1$ ) were *amber*. Indicators with panel  
157 agreement ( $DI < 1$ ) and the lowest level of support ( $MI < 7$ ) were classified as *red*. This system  
158 is summarised in *Table 1*.

159

160 *[Table 1 about here]*

161

162 In keeping with the RAND Delphi process<sup>12</sup>, an in-person meeting with an independent  
163 moderator (NW) was conducted to discuss survey results. All indicators from the first-round  
164 were addressed with a focus on those categorised as *amber* ( $MI > 7$ ,  $DI \geq 1$ ). Following  
165 discussion of each indicator, panellists independently re-rated importance and also feasibility  
166 using the same 9-point Likert scale from the first-round (1= not important and 9= very  
167 important; 1= not feasible and 9= definitely feasible). Feasibility was defined as the  
168 likelihood that the data being used to construct the indicator could be collected at a

169 population level and be considered both reliable (able to be consistently produced) and valid  
170 (measure what it ought to measure). This was completed using their identification numbers  
171 either online or on paper, depending on individual preference.

172

### 173 **Final review of indicators**

174 Following the panel meeting, indicators with  $MI \geq 7$ , median feasibility (MF)  $\geq 7$  and  $DI < 1$   
175 were presented to the panellists for review. With the final number of indicators restricted for  
176 practicality, they were asked to evaluate the cut-off point, in terms of MI and MF, for  
177 inclusion into the global registry.

178

## 179 **RESULTS**

180 11/15 (82%) of invited panellists accepted the invitation to participate in the study. *Table 2*  
181 provides a summary of their specialisation and country of practice.

182

183 *[Table 2 about here]*

184

185 The literature review revealed 352 potential indicators (76 diagnosis, 226 treatment and 50  
186 outcomes) (*Figure 1*). Using Donabedian's<sup>4</sup> framework for classifying quality of care, this  
187 comprised of 18 structure, 294 process and 40 outcome measures. Of these, 229 were  
188 removed because they were not able to be constructed from the global registry dataset. The  
189 remaining 123 indicators were rated in the online survey. Results demonstrated that there was  
190 agreement ( $DI < 1$ ) among panellists that 70/123 indicators were very important ( $MI \geq 7$ ) and  
191 that 4/123 (3%) were not important ( $MI < 7$ ). There was disagreement among panel members  
192 ( $DI \geq 1$ ) for the remaining 49/123 (40%).

193

194 *[Figure 1 about here]*

195

196 The expert panel meeting was undertaken over 10 hours with nine panellists. Two panellists  
197 who voted were unable to participate. The panel reached consensus that the NCCN risk  
198 prediction model<sup>13</sup> would be used to stratify patients. Following discussion of the 123  
199 indicators, 53 indicators were maintained without modification, 36 indicators maintained with  
200 modifications, 34 indicators removed and 6 indicators added. The number of indicators with  
201 disagreement reduced from 49 to 17. The panel retained all proposed structural indicators  
202 (100%), 35/78 proposed process measures (45%) and 18/43 proposed outcome indicators  
203 (42%).

204

205 For final review, 55 indicators with  $MI \geq 7$ ,  $MF \geq 7$  and  $DI < 1$  for both constructs were  
206 presented to the stakeholders (*Table 3*). Most indicators (28/55 (51%)) were treatment-  
207 related, 18/55 (33%) were outcome measures and 9/55 (16%) concerned diagnosis. The  
208 indicator, ‘men with high-risk localised PCa do not receive AS’ was removed as it was  
209 measured by ‘men with high-risk localised PCa receive active treatment within 12 months’.  
210 Three indicators (‘PSA level is taken post-surgery’, ‘PSA level is taken post-radiotherapy’,  
211 ‘PSA level is taken post-ablation therapy’) were merged into ‘PSA level is taken at 12  
212 months after the start of active treatment’. Of the remaining 52 indicators (*Supplementary*  
213 *Table 3*), the consensus was to prioritise those that received  $MI \geq 8.5$ ,  $MF \geq 9$  and  $DI < 1$  for both  
214 constructs. This resulted in a total of 33 QIs for the implementation set (7 diagnosis, 8  
215 treatment and 18 outcome); this list is presented in *Table 4*.

216

217 *[Table 3 about here]*

218

219 *[Table 4 about here]*

220

## 221 **DISCUSSION**

222 Of the 123 indicators presented to the panel, a set of 33 evidence- and consensus-based QIs  
223 were selected to initiate international PCa care benchmarking. This set of indicators addresses  
224 all major aspects of PCa management – diagnosis, intervention and patient-reported outcomes  
225 – and identifies areas of care which are potential targets for improving service.

226

227 Pre-treatment QIs which rated high in importance and feasibility included measurement of  
228 PSA level at diagnosis, documentation of clinical T-stage (cT) and use of imaging for staging.  
229 Previous cohort studies have demonstrated unnecessary and costly routine bone scans and  
230 computed tomography scans being performed for men with asymptomatic low-risk disease<sup>14</sup>.  
231 <sup>15</sup>. Conversely, there remains suboptimal use in high-risk men<sup>16</sup> despite recommendations<sup>13, 17</sup>.  
232 Feedback of QIs regarding the documentation of cT stage<sup>18</sup> and bone scans for low-risk  
233 disease<sup>19</sup> have been shown to improve compliance with guidelines.

234

235 There was discussion among the Delphi panel on the use of multi-parametric magnetic  
236 resonance imaging (mpMRI) for pre-treatment staging. Whilst the panel regarded digital  
237 rectal examination (DRE) as the mainstay of practice, there was recognition of evidence  
238 demonstrating the superiority of mpMRI in detecting extra-capsular extension, seminal  
239 vesicle invasion<sup>20</sup> and informing treatment planning<sup>20, 21</sup>. However, in the absence of clear  
240 guidelines on the optimal staging protocol, both DRE and MRI were considered appropriate  
241 for assigning a disease stage.

242

243 A treatment indicator which received the greatest support was curative treatment being  
244 instigated in high-risk patients within 12 months. Although multimodality therapy is often  
245 recommended for high-risk PCa<sup>13,22,23</sup>, the National Prostate Cancer Audit in UK reported  
246 that 39% of men with high-risk disease were undertreated with ADT monotherapy<sup>24</sup>.  
247 Likewise, the CaPSURE database demonstrated that 41% of high-risk patients received ADT  
248 monotherapy<sup>25</sup>. No age restrictions were placed on this indicator because elderly men with  
249 good quality-of-life may be suitable candidates for radical treatment<sup>17</sup>. Men who die within  
250 12 months of diagnosis will be excluded as they are likely unsuitable candidates for active  
251 intervention. On the contrary, the challenge faced by men with low-risk disease is  
252 overtreatment and the morbidity of treatment-related complications. Active surveillance (AS)  
253 has been increasingly adopted as a standard approach for these men<sup>6,9</sup>. There was unanimous  
254 consensus that the number of low-risk men on AS should be reported and that appropriate AS  
255 monitoring with a repeat prostate biopsy or MRI scan within 13 months of the diagnostic  
256 biopsy should also be measured.

257

258 Measurement of PSA level post-treatment was strongly advocated as it is the primary tool for  
259 measuring efficacy of treatment, detecting early signs of recurrence and need for salvage  
260 therapy<sup>17,26</sup>. Other post-treatment risk assessment measures included 30-day mortality post-  
261 radical prostatectomy (RP), positive margins rates post-RP and biochemical recurrence post-  
262 RP and radiotherapy. Biochemical recurrence<sup>27</sup> was defined by our working group as  
263  $PSA \geq 0.2$  ng/mL post-RP and  $\geq 2.0$  ng/mL rise above nadir post-radiotherapy. The panel did  
264 not endorse biochemical recurrence post-ablation therapy as an indicator due to the current  
265 lack of an agreed definition<sup>17,28</sup>. Instead, the rate of men who received radical or systemic  
266 treatment 18 months post-ablation therapy was nominated as a surrogate measure.

267

268 Routine collection of patient-reported outcomes (PROMs) has been shown to improve  
269 quality-of-life<sup>29</sup>, survival and lessen future hospitalisations<sup>30</sup>. In addition to EPIC-26,  
270 ICHOM recommended including one question from EORTC QLQ-PR25#50 and two  
271 questions from the Use of Sexual Medication/Devices to improve the interpretability of the  
272 sexual function domain from the EPIC-26<sup>10</sup>. During the panel meeting, the measurement of  
273 pre- and post-treatment urinary, bowel, and sexual domains scores (QI 28-33, Table 4) were  
274 initially dropped in favour of indicators which assessed whether the survey instruments were  
275 administered at baseline and 12 months post-treatment (QI 22-27, Table 4). However, they  
276 were reinstated during the final review when it was recognised that merely collecting the  
277 EPIC-26 survey was inadequate and that it was important to understand the attributes of  
278 health services where patient reported good quality-of-life scores.

279

280 This study had a number of noteworthy limitations. A substantial proportion of  
281 recommendations were precluded because they could not be objectively measured or  
282 captured by the global registry dataset. This most heavily impacted structural indicators, such  
283 as the frequency of multidisciplinary meetings (MDM), representation of every discipline at  
284 MDM, availability of specialist services including psychological counselling and uro-  
285 oncology nurses. The use of the word 'offer'<sup>17,22</sup> in patient-centred recommendations was  
286 also difficult to translate into measurable indicators. The inherent nature of the Delphi  
287 process means there is non-random selection of a small non-representative sample of  
288 panellists. The ratings are heavily influenced by personal experience and the availability of  
289 resources at different institutions. It is acknowledged that with a different composition of  
290 panellists, the final set of indicators could have been significantly altered. It is also  
291 recognised that there is a current lack of evidence demonstrating that these QIs will reduce  
292 PCa-specific survival.

293

294 The major strengths of this project included the heterogeneity of the panel, with 11 experts  
295 from seven different countries bringing important local perspectives to the discussion. The  
296 panel was facilitated by an independent experienced moderator to mitigate the probability of  
297 conversation being dominated by a few vocal participants. Indicators were constructed based  
298 on a pre-existing dataset, providing the opportunity for reports to be developed immediately.  
299 This project is novel in that it allows international benchmarking of PCa care and outcomes  
300 based on a common global dataset, which can act as a stimulus for improving PCa quality of  
301 care at each of the contributing sites.

302

303 Further effort to develop QIs which achieved MI and MF of 7 and 8 and investigate other  
304 potential indicators which cannot be currently measured by items in the global registry  
305 dataset will follow the initial rollout. Implemented indicators may demonstrate a ‘ceiling  
306 effect’ where it is difficult to further improve practice. Emerging technology may also change  
307 PCa management and evolve best practice guidelines. Accordingly, this set of indicators will  
308 be regularly re-evaluated to ensure their continued relevance and accuracy.

309

## 310 **CONCLUSIONS**

311 This study defined a set of 33 indicators conceived on the basis of existing international  
312 evidence-based clinical guidelines and endorsed by an international multidisciplinary expert  
313 panel. The indicators encompass the diagnosis, treatment and outcome aspects of PCa  
314 management. This set will be used to benchmark performance internationally in order to  
315 improve consistency and quality of care for men with PCa on a global basis.

316

317 **CONFLICT OF INTEREST DISCLOSURES**

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319

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399

Table 1: The criteria for indicator classification

		Median Importance								
		1	2	3	4	5	6	7	8	9
Disagreement Index	$<1$									
	$\geq 1$									

- There is panel agreement that the quality indicator is of low importance
- There is disagreement among the panel about the importance of the indicator
- There is panel agreement that the quality indicator is of high importance

Table 2: Background of the specialists involved in the Delphi panel

	<b>Urology</b>	<b>Radiation Oncology</b>	<b>Medical Oncology</b>	<b>Nursing</b>	<b>Public Health</b>	<b>Psychology</b>	<b>TOTAL</b>
<b>Australia</b>	-	1	-	-	1	-	<b>2</b>
<b>Germany</b>	1	-	-	-	-	-	<b>1</b>
<b>Ireland</b>	-	1	-	-	-	-	<b>1</b>
<b>New Zealand</b>	1	-	-	-	-	-	<b>1</b>
<b>Spain</b>	-	1	-	-	-	-	<b>1</b>
<b>UK</b>	1	-	-	1	-	1	<b>3</b>
<b>US</b>	-	-	1	-	-	1	<b>2</b>
<b>TOTAL</b>	<b>3</b>	<b>3</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>2</b>	<b>11</b>

Table 3: Distribution of indicators in the summary document for final approval

		FEASIBILITY				
		7	7.5	8	8.5	9
IMPORTANCE	7	2 Diagnosis	2 Primary Tx - Other	1 Primary Tx - RT		
	8	2 Primary Tx - 1 RP - 1 Other		3 Primary Tx - 1 AS - 2 RP	1 Primary Tx - RT	5 Primary Tx - 2 RP - 3 RT 1 Salvage Tx
	9	1 Primary Tx - RT	1 Primary Tx - AS		2 Primary Tx - AS	7 Diagnosis 8 Primary Tx - 1 AS - 2 RP - 3 RT - 2 Other 1 Salvage Tx 18 <sup>†</sup> Outcomes

<sup>†</sup>6 indicators added (QI 28-33, Table 4)

Tx = Treatment; RP = Radical Prostatectomy; RT = External Beam Radiotherapy (EBRT)/ Brachytherapy; AS = Active Surveillance; WW = Watchful Waiting; QI = Quality Indicator

Table 4: Implementation set of indicators selected

Indicator		Numerator	Denominator	Exclusion Criteria	Reporting Time Point	Sources
DIAGNOSIS						
1	Initial investigations of a male with localised PCa include measurement of PSA level	Number of men with PSA level taken at diagnosis  Note: PSA at diagnosis is PSA level taken within 180 days prior to or up to date of diagnosis.	Number of men with PCa	Men diagnosed via TURP or TURBT or biopsy taken using technique other than TRUS or transperineal or technique not stated.	Post diagnosis and pre-treatment <sup>†</sup>	- Alberta Health Services 2015 <sup>1</sup> - NCCN 2017 <sup>2</sup> - VIC OCP 2015 <sup>3</sup>
2	T category/stage (DRE or MRI) is documented prior to treatment for localised PCa	Number of men with PCa who had T category/stage documented	Number of men with PCa		Post diagnosis and pre-treatment <sup>†</sup>	- VIC OCP 2015 <sup>3</sup>
3	In men with high risk localised PCa, nodal staging using CT, MRI or PET is performed	Number of men with high risk PCa who underwent CT scan, MRI scan or PET scan	Number of men with high risk PCa		Post diagnosis and pre-treatment <sup>†</sup>	- EAU 2016 <sup>4</sup> - ESMO 2015 <sup>5</sup> - NCCP 2015 <sup>6</sup> - NZ PCT 2013 <sup>7</sup>
4	In men with high risk localised PCa, perform metastatic screening using a CT/MRI and a bone scan	Number of men with high risk PCa who underwent a CT/MRI and a bone scan	Number of men with high risk PCa		Post diagnosis and pre-treatment <sup>†</sup>	- Alberta Health Services 2015 <sup>1</sup> - EAU 2016 <sup>4</sup>
5	In men with intermediate risk localised PCa, a bone scan is not conducted	Number of men with intermediate risk PCa who did not have a bone scan	Number of men with intermediate risk PCa	Men with 4+3 disease	Post diagnosis and pre-treatment <sup>†</sup>	- NCCS 2013 <sup>8</sup>
6	In men with low risk localised PCa, a bone scan is not conducted	Number of men with low risk PCa who did not have a bone scan	Number of men with low risk PCa		Post diagnosis and pre-treatment <sup>†</sup>	- EAU 2016 <sup>4</sup> - NICE 2014 <sup>9</sup>

7	In men with low risk localised PCa, a CT is not conducted	Number of men with low risk PCa who did not have a CT scan	Number of men with low risk PCa		Post diagnosis and pre-treatment <sup>†</sup>	- Alberta Health Services 2015 <sup>1</sup> - EAU 2016 <sup>4</sup> - NICE 2014 <sup>9</sup>
<b>PRIMARY TREATMENT</b>						
8	For pN0 men undergoing RP, adjuvant ADT is not given	Number of men who had RP with pN0 and did not receive adjuvant ADT  Note: Adjuvant ADT is defined as ADT within 6 months of RP	Number of men who had RP with pN0		Post primary RP <sup>†</sup>	- EAU 2016 <sup>4</sup>
9	Men with localised PCa who are undergoing radical EBRT receive a minimum dose of 74Gy in 1.8 – 2.0 Gy standard fractionation or the equivalent hypo-fractionated dose, 60Gy in 3.0 Gy fractions	Number of men undergoing EBRT with curative intent who receive dose $\geq 74$ Gy in 1.8 – 2.0 Gy fractional doses OR $\geq 60$ Gy in 3.0 Gy fractions	Number of men undergoing EBRT		Post primary EBRT <sup>†</sup>	- EAU 2016 <sup>4</sup> - NICE 2016 <sup>9</sup>
10	Men with low risk localised PCa receive AS	Number of men with low risk prostate cancer and on AS	Number of men with low risk PCa		Post diagnosis <sup>†</sup>	- BAUS 2013 <sup>10</sup> - Cancer Care Ontario 2014 <sup>11</sup> - NZ PCT 2013 <sup>7</sup>
11	For men on AS, MRI or repeat biopsy is performed within 13 months of the diagnostic biopsy	Number of men on AS who had MRI or repeat biopsy within 13 months of the diagnostic biopsy  Note: MRI can occur prior to diagnostic biopsy	Number of men on AS	Men who died within 13 months of the diagnostic biopsy	13 months post diagnosis	- NCCP 2015 <sup>6</sup> - NICE 2016 <sup>9</sup>

12	Men with high risk localised PCa receive active treatment within 12 months	Number of men with high risk PCa who have had RP or EBRT or HDR or LDR or whole-gland or focal-gland ablation therapy within 12 months of diagnosis	Number of men with high risk PCa	Men who died within 12 months of active treatment	12 months post diagnosis	- KCE 2014 <sup>12</sup> - NICE 2014 <sup>9</sup> - NZ PCT 2013 <sup>7</sup>
13	Men with high risk localised PCa do not receive LDR brachytherapy alone	Number of men with high risk PCa who receive LDR and primary EBRT	Number of men with high risk PCa who received LDR		Post primary LDR <sup>†</sup>	- NICE 2016 <sup>9</sup>
14	PSA level is taken within 12 months of active treatment	Number of men who had PSA taken within 12 months of active treatment	Number of men on active treatment  Note: active treatment includes RP, EBRT, brachytherapy, whole-gland or focal gland ablation therapy	Men who died within 12 months of diagnosis	12 months post active treatment	- NICE 2016 <sup>9</sup>
<b>SALVAGE TREATMENT</b>						
15	Men who have salvage RT post RP receive a salvage RT dose $\geq 66$ Gy at 1.8 - 2.0 standard fractionation or the equivalent hypo-fractionated dose, $\geq 48$ Gy in 3.0 Gy fractions	Number of men who had salvage EBRT initiated post-RP with a total receive dose $\geq 66$ Gy in 1.8 – 2.0 fractional doses or $\geq 48$ Gy in 3.0 Gy fraction	Number of men who received salvage EBRT post RP		Post salvage RT <sup>†</sup>	- NCCN 2017 <sup>2</sup>

CLINICAL OUTCOMES						
16	Death within 30 days of RP	Number of men who died within 30 days of the RP	Number of men who had RP		30 days post RP	- PCOR-ANZ <sup>‡</sup> 13
17	Men with low risk PCa who had a positive margin post-RP	Number of men with low risk PCa and had a positive margin post-RP	Number of men with low risk PCa and had a RP		Post primary RP <sup>‡</sup>	- PCOR-ANZ <sup>‡</sup> 13
18	Men with pT2 disease who had a positive margin post-RP	Number of men with pT2 disease and had a positive margin post-RP	Number of men with pT2 disease and had a RP		Post primary RP <sup>‡</sup>	- German Cancer Society <sup>‡</sup> 14 - IPCOR <sup>‡</sup> 15 - NPCR <sup>‡</sup> 16  - PCOR-ANZ <sup>‡</sup> 13
19	Men with pT3 disease who had a positive margin post-RP	Number of men with pT3 disease and had a positive margin post-RP	Number of men with pT3 disease and had a RP		Post primary RP <sup>‡</sup>	- IPCOR <sup>‡</sup> 15 - PCOR-ANZ <sup>‡</sup> 13
20	Biochemical recurrence at 1 year post RP	Number of men who had RP and a PSA level 12 month post RP $\geq 0.2$ ng/mL	Number of men who had RP		1 year post primary RP	- AUA 2013 <sup>17</sup> - EAU 2016 <sup>4</sup>
21	Radical or systemic treatment at 18 months post focal-gland or whole-gland ablation therapy	Number of men who had focal-gland or whole-gland ablation therapy and radical treatment or systemic treatment initiated within 18 months post focal-gland or whole-gland ablation therapy  Note: Radical treatment includes RP, EBRT or brachytherapy. Systemic	Number of men who had focal-gland or whole-gland ablation therapy	Men who died within 18 months of focal-gland or whole-gland ablation therapy	18 months post primary ablation therapy	- EAU 2016 <sup>4</sup> - Babaian et al. <sup>‡</sup> 18 - Donnelly et al. <sup>‡</sup> 19



		treatment refers to ADT.				
PATIENT-REPORTED OUTCOMES						
22	EPIC-26 is completed at baseline	Number of men completed EPIC-26 within 90 days before or after diagnosis	Number of men with PCa		Post diagnosis and pre-treatment <sup>†</sup>	- Wei et al. <sup>‡20</sup> - NPCR <sup>‡ 16</sup> - PCOR-ANZ <sup>‡ 13</sup>
23	EORTC QLQ-PR25 is completed at baseline	Number of men completed EORTC QLQ-PR25 within 90 days before or after diagnosis	Number of men with PCa		Post diagnosis and pre-treatment <sup>†</sup>	- Van Andel et al. <sup>‡21</sup>
24	Utilisation of Sexual Medication/Devices is completed at baseline	Number of men completed Utilisation of Sexual Medication/Devices questionnaire within 90 days before or after diagnosis	Number of men with PCa		Post diagnosis and pre-treatment <sup>†</sup>	- Miller et al. <sup>‡ 22</sup>
25	EPIC-26 is completed 12 months post diagnosis for men on AS and 12 months post active treatment for men receiving active treatment	Number of men completed EPIC 26 within 9-15 months of diagnosis (AS)/ or 9-15 months of active treatment	Number of men with PCa	Men who died within 15 months of diagnosis (AS)/ within 15 months of active treatment	15 months post diagnosis (AS) / 15 months post active treatment	- Wei et al. <sup>‡ 20</sup> - IPCOR <sup>‡ 15</sup> - PCOR-ANZ <sup>‡ 13</sup>
26	EORTC QLQ-PR25 is completed 12 months post diagnosis for men on AS and 12 months post active treatment for men receiving active treatment	Number of men completed EORTC QLQ-PR25 within 9-15 months of diagnosis (AS)/ or 9-15 months of active treatment	Number of men with PCa	Men who died within 15 months of diagnosis (AS)/ within 15 months of active treatment	15 months post diagnosis (AS) / 15 months post active treatment	- Van Andel et al. <sup>‡ 21</sup>
27	Utilisation of Sexual Medication/Devices is completed	Number of men completed Utilisation of	Number of men with PCa	Men who died within 15 months of	15 months post diagnosis (AS)	- Miller et al. <sup>‡ 22</sup>

	12 months post diagnosis for men on AS and 12 months post active treatment for men receiving active treatment	Sexual Medication/Devices within 9-15 months of diagnosis (AS)/ or 9-15 months of active treatment		diagnosis (AS)/ within 15 months of active treatment	/ 15 months post active treatment	
28	Sexual bother at 12 month adjusted by treatment group and PROMs at baseline	Change in the mean score of sexual bother between the baseline and 12 months by type of treatment	Number of men with PCa	Men who did not complete EPIC-26 at baseline or at 12 months	15 months post diagnosis (AS) / 15 months post active treatment	- PCOR-ANZ <sup>†</sup> 13 - RAND <sup>†</sup> 23
29	Urinary bother at 12 month adjusted by treatment group and PROMs at baseline	Change in the mean score of urinary bother between baseline and 12 months by type of treatment	Number of men with PCa	Men who did not complete EPIC-26 at either baseline or at 12 months	15 months post diagnosis (AS) / 15 months post active treatment	- PCOR-ANZ <sup>†</sup> 13 - RAND <sup>†</sup> 23
30	Bowel bother at 12 month adjusted by treatment group and PROMs at baseline	Change in the mean score of bowel bother between baseline and 12 months by type of treatment	Number of men with PCa	Men who did not complete EPIC-26 at either baseline or at 12 months	15 months post diagnosis (AS) / 15 months post active treatment	- PCOR-ANZ <sup>†</sup> 13 - RAND <sup>†</sup> 23
31	Sexual function at 12 month adjusted by treatment group and PROMs at baseline	Change in the mean score of sexual domain score between baseline and 12 months by type of treatment	Number of men with PCa	Men who did not complete EPIC-26 at either baseline or at 12 months	15 months post diagnosis (AS) / 15 months post active treatment	- NPCR <sup>†</sup> 16 - PCOR-ANZ <sup>†</sup> 13 - RAND <sup>†</sup> 23
32	Urinary function at 12 month adjusted by treatment group and PROMs at baseline	Change in the mean score of urinary incontinence domain score between baseline and 12 months by type of treatment	Number of men with PCa	Men who did not complete EPIC-26 at either baseline or at 12 months	15 months post diagnosis (AS) / 15 months post active treatment	- NPCR <sup>†</sup> 16 - PCOR-ANZ <sup>†</sup> 13 - RAND <sup>†</sup> 23

		Change in the mean score of urinary obstructive domain score between baseline and 12 months by type of treatment				
33	Bowel function at 12 month adjusted by treatment group and PROMs at baseline	Change in the mean of bowel domain score between baseline and 12 months by type of treatment	Number of men with PCa	Men who did not complete EPIC-26 at either baseline or at 12 months	15 months post diagnosis (AS) / 15 months post active treatment	- NPCR <sup>†</sup> 16 - PCOR-ANZ <sup>†</sup> 13 - RAND <sup>†</sup> 23
<p>† Quality Indicator (QI) report will be disseminated to participating sites every six months.</p> <p>**All risk is based on the NCCN risk classification and is assessed based on the highest primary Gleason score (if more than one biopsies were undertaken), the latest clinical T and the latest PSA prior to systemic or radical treatment. In the absence of a clinical T, men can be assumed to be low risk if Gleason score <math>\leq 6</math> (Grade group = 1) and PSA &lt; 10.</p> <p>† Due to the lack of clinical guidelines, a range of grey literatures on indicator initiatives by prostate cancer programs were used as the basis of quality indicators</p>						

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Figure 1: The number of indicators involved in each stage of refinement and elimination

	Diagnosis	Primary Treatment				Salvage Treatment	Outcomes	TOTAL
		AS/WW	RP	RT	Other			
Literature Review	76	43	82	57	36	15	43	352
Feasibility Review	15	13	17	18	13	4	43	123
Online Survey	MI $\geq$ 7 DI<1	MI $\geq$ 7 DI<1	MI $\geq$ 7 DI<1	MI $\geq$ 7 DI<1	MI $\geq$ 7 DI<1	MI $\geq$ 7 DI<1	MI $\geq$ 7 DI<1	MI $\geq$ 7 DI<1
Panel Meeting	MI MF DI-1 MIS6 DI<1	MI MF DI-1 MIS6 DI<1	MI MF DI-1 MIS6 DI<1	MI MF DI-1 MIS6 DI<1	MI MF DI-1 MIS6 DI<1	MI MF DI-1 MIS6 DI<1	MI MF DI-1 MIS6 DI<1	MI MF DI-1 MIS6 DI<1
Final Review	9	5	7	9	5	2	18 <sup>†</sup>	55 <sup>†</sup>
Final Set	9	4 <sup>‡</sup>	6 <sup>‡</sup>	8 <sup>‡</sup>	5 <sup>‡</sup>	2	18	52 <sup>‡</sup>
Implementation Set (MI $\geq$ 8.5, MF $\geq$ 9, DI<1)	7	7				1	18	33

MI: Median importance

MF: Median feasibility

DI: Disagreement index

AS/WW: Active surveillance/ watchful waiting

RP: Radical prostatectomy

RT: Radiotherapy

\* 6 indicators added (QI 22-27, Table 4) during the panel meeting.

◇ 34 indicators were removed during the panel meeting.

‡ 3 indicators related to PSA level were merged into 'PSA level is taken at 12 month after the start of active treatment'.

† 6 indicators added (QI 28-33, Table 4)

**ABBREVIATIONS:**

ADT	Androgen deprivation therapy
AS	Active surveillance
cT	Clinical T-stage
DI	Disagreement index
DRE	Digital rectal examination
EAU	European Association of Urology
ICHOM	International Consortium for Health Outcome Measures
MF	Median feasibility
MI	Median importance
mpMRI	Multi-parametric magnetic resonance imaging
NCCN	National Comprehensive Cancer Network
NPCR	National Prostate Cancer Registry of Sweden
PSA	Prostate specific antigen
PCa	Prostate cancer
PCOR-ANZ	Prostate Cancer Outcomes Registry in Australia and New Zealand
PROMs	patient-reported outcomes
QI	Quality indicator
RP	Radical prostatectomy

*Supplementary Table 1: International guidelines and grey literature used*

<b>Guidelines or prostate cancer programs where indicators were derived</b>	<b>Number of guidelines</b>	<b>References</b>
Australasian	5	(1-5)
European	8	(6-13)
American and Canadian	5	(14-18)
Grey literature on indicator initiatives in available prostate cancer programs	6	(19-24)

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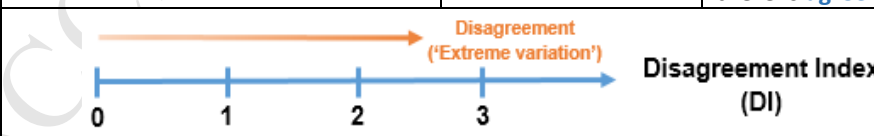
## Supplementary Table 2: How the statistics are calculated

## HOW THE STATISTICS ARE CALCULATED

Supplementary Table 2a: Example rating of how each panellist rated the proposed indicator

Panellist ID	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11
Rating given (from 1-9)	9	9	X	9	9	9	9	7	9	7	9

Supplementary Table 2b: How the statistics, which have been used to classify indicators, are calculated (1)

Measure	Definition	How to calculate	Results
<b>Median</b>	An observation at the 50 <sup>th</sup> percentile	50 <sup>th</sup> percentile	9
<b>Lower IPR</b>	An observation at the 10 <sup>th</sup> percentile	10 <sup>th</sup> percentile	7
<b>Upper IPR</b>	An observation at the 90 <sup>th</sup> percentile	90 <sup>th</sup> percentile	9
<b>IPR</b>	The interpercentile range. It is a measure of dispersion of a distribution.	Upper IPR – Lower IPR	2
<b>IPRCP</b>	The central point of IPR	(Lower IPR + Upper IPR)/2	8
<b>Asymmetry index</b>	The distance between the central point of the IPR and the central point of the 1-9 scale, i.e. 5	Absolute value (5- IPRCP)	3
<b>IPRAS</b>	The interpercentile range adjusted for symmetry. It is a measure of the degree of asymmetry across the 9-point scale.  Using the numbers supplied by the RAND document <sup>1</sup> : <b>IPRAS = 2.35 + (1.5 x Asymmetry Index)</b>	= IPRr + (CFA x Asymmetry Index)  IPRr is the interpercentile range required for disagreement when there is perfect symmetry.  CFA is the correction factor for asymmetry, which is a constant set at 1.5	<b>6.85</b>
<b>Disagreement Index (DI)</b>	It is a measure which shows if there was wide or limited dispersion of panellist ratings	IPR/IPRAS	0.29  <b>0.29 &lt; 1 Therefore, there is agreement</b>
	 <p>If the DI is <math>\geq 1</math>, then it indicates 'extreme variation' in ratings. The lower the DI, the lower the level of disagreement (i.e. the higher the level of agreement/ better consensus).</p>		
Note: 'Unable to comment' responses were excluded when calculating the statistics.			

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Supplementary Table 3: Final set of indicators (median importance of 7-9 and a median feasibility score of 7-9 and DI<1 for both constructs)

DIAGNOSIS		DIMENSION OF QUALITY OF CARE (1)
1	Initial investigations of a male with localised PCa include measurement of PSA level	Process
2	T category/stage (DRE or MRI) is documented prior to treatment for localised PCa	Process
3	In men with high risk localised PCa, nodal staging using CT, MRI or PET/CT is performed	Process
4	In men with high risk localised PCa, perform metastatic screening using a CT/MRI and a bone scan	Process
5	In men with intermediate risk localised PCa, a bone scan is not conducted	Process
6	In men with high risk localised PCa, a bone scan is conducted	Process
7	In men with cT3/cT4, a bone scan is performed	Process
8	In men with low risk PCa, a bone scan is not conducted	Process
9	In men with low risk localised PCa, a CT is not conducted	Process
PRIMARY TREATMENT		
10	Men with low risk localised PCa receive AS	Process
11	Men with low risk PCa with $\leq 2$ positive cores and minimal biopsy core involvement ( $< 50\%$ cancer per biopsy) receive AS	Process
12	For men on AS, MRI or repeat biopsy is performed within 13 months of the diagnostic biopsy	Process
13	In men on AS with a primary Gleason grade of 4 or 5 on repeat biopsy, active treatment is initiated	Process
14	Men with low risk localised Pca who received RP, nerve-sparing is performed	Process
15	Men with intermediate risk localised PCa who received RP, nerve-sparing is performed	Process
16	For pN0 men undergoing RP, adjuvant ADT is not given	Process
17	For pN0 men undergoing RP, even those with positive margin rate, adjuvant ADT is not given	Process
18	Men with pT3 disease, positive margin(s) and detectable PSA post-RP receive EBRT within 6 months of RP	Process
19	The recommended prescribed doses for adjuvant post-prostatectomy RT are 64–72 Gy in standard fractionation or the equivalent of hypofractionation	Process
20	Men with localised PCa who are undergoing radical EBRT receive a minimum dose of 74Gy in 1.8 – 2.0 Gy standard fractionation or the equivalent hypo-fractionated dose, 60Gy in 3.0 Gy fractions	Process
21	RT should treat the prostate planning target volume with 74-78Gy	Process
22	Men with low risk localised Pca undergoing EBRT do not receive	Process

	adjuvant ADT	
23	Men with low risk localised PCa who receive LDR brachytherapy receive it as monotherapy	Process
24	Men with high risk localised PCa and undergoing EBRT receive 2-3 years of adjuvant ADT	Process
25	Men with high risk localised Pca who received HDR brachytherapy and also receive EBRT within 30 days	Process
26	Men with high risk localised PCa do not receive LDR brachytherapy alone	Process
27	Men with high risk localised PCa treated with a combination of EBRT (40–50 Gy) and LDR brachytherapy receive > 1 year ADT	Process
28	Men treated with focal therapy have had assessment with MRI prior to focal therapy	Process
29	Number of men treated at the institution per year having RP	Structure
30	Number of men treated at the institution per year having EBRT or brachytherapy	Structure
31	Men with high risk localised PCa receive active treatment within 12 months	Process
32	PSA level is taken within 12 months of active treatment	Process
<b>SALVAGE TREATMENT</b>		
33	In men with undetectable PSA post RP who have biochemical recurrence, salvage RT is not started after PSA $\geq$ 2.0ng/mL	Process
34	Men who have salvage RT post RP receive a salvage RT dose $\geq$ 66 Gy at 1.8 - 2.0 standard fractionation or the equivalent hypo-fractionated dose, $\geq$ 48 Gy in 3.0 Gy fractions	Process
<b>OUTCOMES</b>		
35	EPIC-26 is completed at baseline	Outcome
36	EORTC QLQ-PR25 is completed at baseline	Outcome
37	Utilisation of Sexual Medication/Devices is completed at baseline	Outcome
38	EPIC-26 is completed 12 months post diagnosis for men on AS and 12 months post active treatment for men receiving active treatment	Outcome
39	EORTC QLQ-PR25 is completed 12 months post diagnosis for men on AS and 12 months post active treatment for men receiving active treatment	Outcome
40	Utilisation of Sexual Medication/Devices is completed 12 months post diagnosis for men on AS and 12 months post active treatment for men receiving active treatment	Outcome
41	Sexual bother at 12 month adjusted by treatment group and PROMs at baseline	Outcome
42	Urinary bother at 12 month adjusted by treatment group and PROMs at baseline	Outcome
43	Bowel bother at 12 month adjusted by treatment group and PROMs at baseline	Outcome
44	Sexual function at 12 month adjusted by treatment group and PROMs at baseline	Outcome
45	Urinary function at 12 month adjusted by treatment group and PROMs at baseline	Outcome
46	Bowel function at 12 month adjusted by treatment group and PROMs at baseline	Outcome

47	Death within 30 days of RP	Outcome
48	Men with low risk PCa who had a positive margin post-RP	Outcome
49	Men with pT2 disease who had a positive margin post-RP	Outcome
50	Men with pT3 disease who had a positive margin post-RP	Outcome
51	Biochemical recurrence at 1 year post RP	Outcome
52	Radical or systemic treatment at 18 months post focal-gland or whole-gland ablation therapy	Outcome

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