

PIONEER's update and integration of a localised PCa core outcome set

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About PIONEER



- An IMI2 funded pan-European public private partnership consisting of 32 stakeholders from across 9 countries.
- PIONEER's goal is to ensure the optimal care for all European men diagnosed with prostate cancer (PCa) by unlocking the potential of big data and big data analytics.
- Work package 2 aims to define core outcome sets (COS) for localised PCa in the context of the patient's treatment pathway.

Introduction



Harmonising assessment of men with PCa is key for both clinical research and practice.

By collaborating with the original development groups, we aimed at updating the systematic reviews:

- A COS for localised PCa effectiveness trials (Maclennan, et al, 2017).
- A standard set of outcomes for clinical audit developed by the International Consortium for Health Outcomes Measurement (ICHOM) have been published.

Methods

The methodology of the project is split into three phases:



We performed a systematic review of systematic reviews of any interventions for men with localised PCa (T1a-T2c N0 M0) published between 1st January 2013 and 23rd of October 2018.



We compared the identified outcomes with the outcomes in the two existing outcome sets.



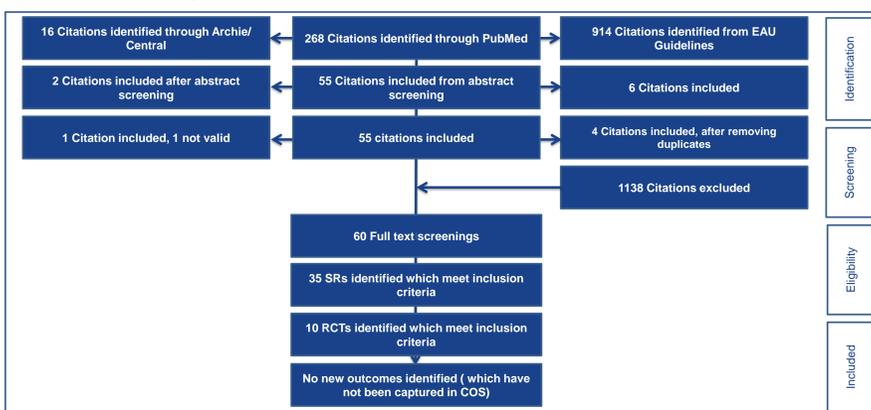
The Williamson and Clarke taxonomy (2018) was used to integrate the outcome sets.



Results and Discussion

- 1,198 references were identified and 10 RCTs included.
- After comparing the identified outcomes with the two existing COS, we integrated the both following the Williamson and Clarke taxonomy (see Table 2).

Table 1: PRISMA flowchart



Results and Discussion

Table 2: Integrated COS

Williamson/Clarke (revised) category scale	COMPACTERS COS	ICHOM COS
1. Mortality/survival	Death from any cause	Overall survival
	Death from prostate cancer	Cause specific survival
	Local disease recurrence	Metastasis-free survival
	Distant disease recurrence/metastases	Biochemical recurrence-free survival
	Disease progression	
	Need for salvage therapy	
	Treatment failure in ablative therapy	
	Need for curative treatment in active surveillance	
	Faecal incontinence	
Physiological/clinical		
8. Gastrointestinal outcomes	Bowel function	Bowel function
AND		
Resource use		
38: Adverse events/effects		
Physiological/clinical	Stress incontinence	Urinary incontinence
19: Renal and urinary outcomes	Urinary function	Urinary irritation/obstruction
AND		
Resource use	Bothersome or symptomatic urethral or anastomotic stricture	
38: Adverse events/effects		
Physiological/clinical	Sexual function	Sexual function
20: Reproductive system and breast outcomes		
AND		
Resource use		
38: Adverse events/effects		
Functioning	Overall quality of life	
30: Global quality of life		
Physiological/clinical	Positive surgical margin	
16: Outcomes relating to neoplasms: benign, Malignant and unspecified		
Physiological/clinical	Perioperative deaths	Major surgical complications
9: General outcomes		Major radiation complications
AND		
Resource use		
38: Adverse events/effects		
Physiological/clinical	Thromboembolic disease	
2: Blood and lymphatic system outcomes		
AND		
Resource use		
38: Adverse events/effects		
Physiological/clinical	Side effects of hormonal therapy	Hormonal symptom scores
5: Endocrine outcomes		
AND		
Resource use		
38: Adverse events/effects		

Conclusions

Following work, we aim to develop a PIONEER outcome set with the support of a multidisciplinary expert group to incorporate all stakeholder to ensure optimal care for prostate cancer patients.