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

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Background and aim

Harmonising prostate cancer (PCa) outcome reporting, definition and measurement is crucial for clinical practice and research.

- Two core outcome sets (COS) have previously been published for localised PCa:
  - one for effectiveness trials developed using the Core Outcome Measures in Effectiveness Trials (COMET) methodology.
  - one for clinical audit developed by the International Consortium for Health Outcomes Measurement's (ICHOM).
- Our aim was to seek consensus on which terms best reflect the underlying concepts indicated, suggest a standard term and thereby facilitate the congruency of terminology for research, audit and Big Data activities.

Methods and results

First we updated systematic reviews (2013-2019) to survey novel outcomes (no new outcomes were identified). Second, we held two one-hour consensus meetings with a multidisciplinary expert group in 2018. Finally we organised the outcomes within the Williamson/Clarke taxonomy.

- The expert group represented patients, clinicians, academia and pharma (Table 1).
- COMPACTERS and ICHOM terms were introduced but neither group's terms were given preference.
- The chair introduced each outcome and facilitated discussion.
- Voting was performed by a show of hands and verbal agreement.

Table 1: Participant list

Role/specialism	Participation 1st meeting	Participation 2nd meeting
Epidemiologist, UK (WP2, chair)	X	X
Researcher, UK (WP2, observer)	X	X
Patient advocate, BE	X	X
Patient advocate, UK	X	X
Epidemiologist, NL	X	X
Urologist, FI	X	X
Urologist, NL	X	X
Urologist, DE	X	
Prostate cancer researcher, SE	X	X
Oncologist, Industry, ES	X	X
Economist , Industry, NL	X	
Patient advocate, UK	X	
Researcher, UK (observer)	X	X

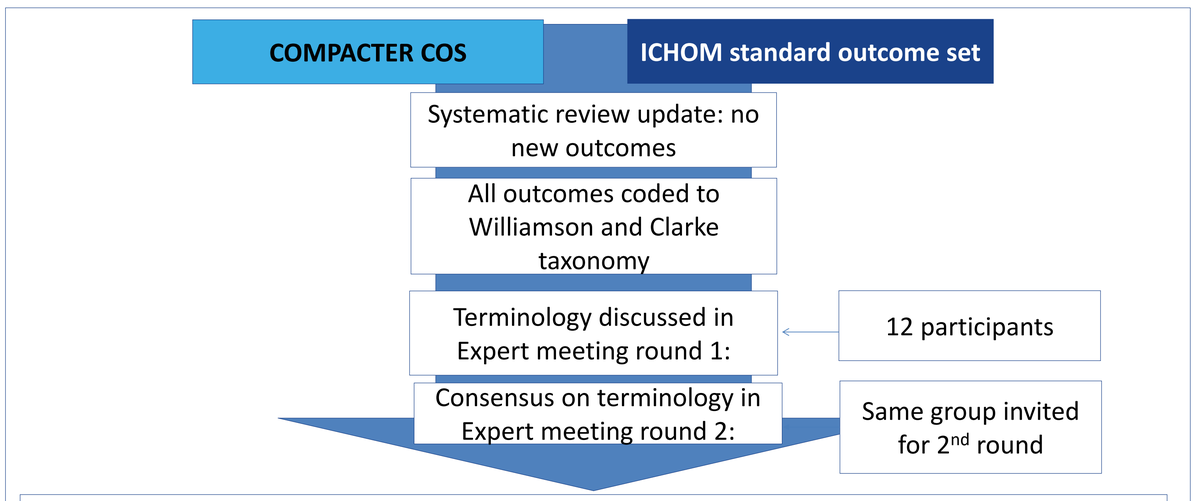
Existing COS terminology was integrated to reflect several points:

(1) to incorporate all stakeholder opinions;

(2) to reflect terminology used across Europe in practice and in research;

(3) to be applicable for effectiveness trials, systematic reviews, guidelines, clinical practice and Big Data.

Figure 1: Process and outcomes included in the COS



Conclusions

Next we will use further systematic review and consensus methods to a) seek agreement on the most appropriate definitions, measurements and timepoints of clinician reported outcomes and b) assess the psychometric properties of PROMS, then seek consensus on the most methodologically sound and feasible PROMS to be used in future research and audit. **Creating an updated, integrated and standardised COS enables PIONEER to recommend one single COS for localised PCa, which can be applied in different healthcare settings across Europe and promotes outcome reporting consistency in trials, audit, critical reviews of the evidence base, clinical practice guidelines, and Big Data projects.**

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