

Title: PIONEER's update and integration of a localised prostate cancer core outcome set for effectiveness trials and a standard set for clinical practice

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Introduction & Objectives: Harmonising prostate cancer (PCa) outcomes is crucial in 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 and one for clinical audit developed by the International Consortium for Health Outcomes Measurement's (ICHOM). Although these two COS broadly overlap, their purpose and methodology differ. Both approaches were updated, integrated and standardised as part of the PIONEER project. PIONEER is a consortium using Big Data to answering key questions in PCa, funded through the IMI2 Joint Undertaking under grant agreement No. 777492.

Materials & Methods: To standardise terminology, two expert group meetings were conducted with clinicians, patients, academics and industry representatives. The aim was to develop a COS which incorporated both of the above-mentioned COS, in addition to a systematic review of RCTs published since 2013 was conducted. During the first face-to-face meeting, the group was presented with the standardised terms following the Williamson and Clarke taxonomy and was asked to discuss and vote on their preferred terminology using modified nominal group technique. Prior to the second meeting, the overview and results of the first meeting were circulated to remind participants of the discussion and to give them time to reflect and prepare for the second meeting during which the aim was to reach consensus on the updated terminology.

Results: 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; and (3) to be applicable for effectiveness trials, systematic reviews, guidelines, clinical practice and Big Data. Figure 1 describes the process and indicates the outcomes included in the COS and the terms which the expert group agreed should be used

Conclusions: 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. Interim work will focus on reaching consensus on the most appropriate definitions of clinician observed outcomes as well as the psychometric properties and feasibility of the outcomes identified.

Figure 1. Overview of PIONEER localised prostate cancer core outcome set development

