Identification and quality assessment of core outcome sets in prostate cancer and their 'mapping' into real world data sources

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Background: The Core Outcome Measures in Effectiveness Trials (COMET) Initiative aims to systematically identify studies developing core outcomes set (COS) to be reported in all clinical trials of specific conditions; however, studies recommending COS for other settings (e.g. routine care, registries) are also included in the COMET database.
Objectives: The aim of this study was to identify, summarize, and critically appraise the existing COS development studies using prostate cancer as a case study. Moreover, the degree of overlap between different types of COS (e.g. COS for clinical research, COS for practice) and existing real world data (RWD) sources was assessed.
Methodology: As part of the Big Data 4 Better Outcomes DO-IT European project, we conducted a targeted review of the COMET database to identify all COS studies developed for prostate cancer. Several characteristics including setting, methods for consensus, type of participants, outcomes included in COS and corresponding measurement instruments, timing and sources were extracted from the studies; outcomes were also classified according to a predefined 38-item taxonomy. The methodology adopted by the included studies was assessed based on the recent Core Outcome Set-STAndards for Development (COS-STAD) recommendations. A 'mapping' exercise was conducted between the outcomes recommended in COS studies and the variables routinely collected in administrative databases, disease registries and electronic medical records.
Results: In total, 11 COS development studies published between 1995 and 2017 were retrieved; of these, 8 were classified as 'COS for clinical trials and clinical research', 2 as 'COS for practice' and 1 as 'COS patient reported outcomes'. The outcomes recommended were mainly categorized into 'mortality and survival' (17%), 'outcomes related to neoplasm' (18%), and 'renal and urinary outcomes' (13%), without any relevant differences among COS study types. Within the COS-STAD framework, almost all the studies fulfilled the criteria belonging to the 'scope specification' domain, while several methodological weaknesses emerged in relation to the 'stakeholders involved' and 'consensus process' domains. The 'mapping' exercise showed a limited overlap between outcomes recommended in COS studies and those recorded in RWD sources, even when 'COS for practice' studies are used. However, some outcomes can be measured by uniquely identifying incident cases and tracking the care provided over time through the linkage of various databases.