



PIONEER's operational definitions: Harmonising clinical characteristics and phenotypes data of prostate cancer patients

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Background

- PIONEER is part of the Innovative Medicine Initiative's "Big Data for Better Outcomes" umbrella programme.
- PIONEER aims to transform the field of prostate cancer care with particular focus on improving prostate-cancer related outcomes, health system efficiency and the quality of health and social care across Europe by maximising the potential of Big Data.

Methods

- An online expert consensus meeting was conducted with healthcare professionals and data analysts (n=29).
- Thirty-six clinical concepts were captured to be converted into operational definitions ensuring that each building block of a clinical definition had an appropriate operational definition.

Conclusion

- The PIONEER operational definitions for the various outcomes and concepts defined in prostate cancer can be applied across big data.
- It will enable users of the PIONEER platform to harmonise datasets and hence efficiently define phenotypes and characteristics for various research questions across different data sets to maximize output.
- Multiple iterations between HCPs and data analysts might be needed to properly capture the more complex outcomes and concepts
- Further development of the common data model might be suggested during this exercise that will be forwarded to the OMOP community.

Results

- The 36 clinical concepts were divided based on generic terminology and the four predefined risk categories which resulted in 73 operational definitions.
- The experts aimed to define options of operational definitions, including the ideal option and a minimum requirement if needed.

Table 1 Example of two operational definitions

Term	Clinical Definition	Operational Definition
Need for curative treatment/ (Applicable to active surveillance specifically)	Patients discontinued from active surveillance and underwent treatment for various reasons including change in patient preference, increasing PSA, digital rectal examination suggestive of more advanced features, biopsy evidence of increased tumour volume or higher grade, doctor's decision, with or without new findings on MRI.	Option 1: Patient on AS (SNOMED 712837004) who continues on a different treatment and has information on rising PSA levels, DRE findings, or different treatment for their cancer. Option 2: Patient on Active surveillance (SNOMED 712837004) who continues with another treatment. If no SNOMED code available, Active Surveillance can also be defined as a prostate cancer patient with repeated biopsies (at least 1 after 1 year) and PSA measurements every 3 months; or no drop in PSA levels after diagnosis; or localised prostate cancer as per definition and no other treatments coded.

Next steps

- PIONEER will work together with the IMI EHDEN project to translate the operational definitions into OMOP-compatible definitions
- A study-a-thon is planned for early 2021 to demonstrate how to answer a clinically-relevant research questions using the PIONEER big data platform and the operational definitions

Introduction

- PIONEER developed core outcome sets for localised and metastatic prostate cancer and performed a systematic review of outcomes currently used for locally advanced and non-metastatic castration-resistant prostate cancer.
- To maximise the usage of various data sets within the PIONEER big data platform, we extended this work to develop operational definitions for the characteristics and phenotypes used in clinical outcome definitions.

