

The manifold presentations of PROMS and questionnaires: patient-reported outcomes in OMOP use cases

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Background and rationale

PROMS and QoL questionnaires are essential in HTA (Health Technology Assessment), drug approval and drug safety analyses, as well as for clinical guideline development. There is a high demand for high-quality longitudinal data sets that have information about effects and impact of a treatment on the patients' daily life. Observational data sets with patient-reported outcomes and QoL questionnaire data could fill at least part of this need. Currently, however, OMOP-CDM and OHDSI tools do not really support PROMS data and/or standardized analytics with this type of data.

Clinical centers, registries, and research organizations across Europe do work with PROMS and QoL questionnaires in health care practice. Many of them are in the process of converting their data onto OMOP-CDM with support of IMI2 EHDEN. In the EHDEN PROMS Special Interest Group (SIG), we set out to develop conventions and potential best practice recommendations for capturing PROMS and questionnaire data in OMOP-CDM.

Methods

- We adopted a use-case driven approach, working with data partners in the EHDEN network
- Inventory of common and recurring issues as well as often-used solutions to address these issues
- Potential best practice recommendations were formulated for selected PROMS / questionnaires, focusing on the quick wins.
- The proposed recommendations were tested in a few focused case studies, with a few to determine value added and usability of the approach.

Results

Initial findings and lessons learned are reported, as well as on-going and further work of the EHDEN PROMS Special Interest Group. Apart from proposing conventions for standardized structural and semantic mapping of PROMS and questionnaire data, we discuss an approach to improve the representation of provenance of data in OMOP. Also, we indicate how one could capture the context of use and the 'quality of implementation' of a questionnaire in OMOP-CDM. Using this mechanism to represent available PROMS data from data partners in the EHDEN network, we illustrate how this approach will improve the quality and reusability of patient-reported data in combination with clinical data.

Discussion

This exercise is a rudimentary first step, looking for possibly relevant factors and attributes that may impact the meaning of PROMS and questionnaire data in an OMOP-CDM.

We explicitly did not aim for a full harmonization, but rather wanted to develop use case specific conventions and partial solutions. The idea is to build upon these early results by seeking wider collaboration in the OHDSI and EHDEN communities in subsequent iterations.

We expect that the reported approach and proposed conventions in this exercise may open up future opportunities for standardized analytics with PROMS data, including improved support of federated analysis of (vertically partitioned) longitudinal clinical data that need to be combined with PROMS data in other data sets.