Mapping PROMs to the OMOP-CDM: Insights and Lessons from the ICHOM Hand and Wrist Conditions Standard Set and the PROMOP H2O Project

Lisa Hoogendam[1,2,3], Laura Verbeij[4], Aniek Markus[5], Harm Slijper[3], Adnan Jouned[6], Florian Katsch[6,7], Marko Todorovic[6], Marta Ferri Peradalta[8], Romain Tching Chi Yen[9], Andreas Kremer[9], Sofia Bazakou[10], Tanja Stamm[11], Georg Duftschmid[6], Renske Los[5], Ruud Selles[1,2]

[1]Department of Plastic, Reconstructive, and Hand Surgery, Erasmus Medical Center, Rotterdam, The Netherlands;
[2]Department of Rehabilitation Medicine, Erasmus Medical Center, Rotterdam, The Netherlands;
[3]Xpert Clinics, Eindhoven, The Netherlands;
[4]Department of Quality and Patient Care, Erasmus Medical Center, Rotterdam, The Netherlands;
[5]Department of Medical Informatics, Erasmus Medical Center, Rotterdam, The Netherlands;
[6]Institute of Medical Information Management, Center for Medical Data Science, Medical University of Vienna, Vienna, Austria;
[7]Ludwig Boltzmann Institute for Digital Health and Prevention, Salzburg, Austria;
[8]Department of Medical Informatics, Vall d'Hebron Institute of Research, Vall d'Hebron University Hospital, Barcelona, Spain;
[9]Information Technology for Translational Medicine, Esch-sur-Alzette, Luxembourg;
[10]The Hyve, Utrecht, The Netherlands;
[11]Institute of Outcomes Research, Center for Medical Data Science, Medical University of Vienna and Ludwig Boltzmann Institute for Arthritis and Rehabilitation, Vienna, Austria

Background

In the context of Value Based Health Care, it is important that outcome measurement also includes the patient's perspective (1). Traditionally defined outcome measures depending solely on clinical information such as diagnoses codes or medication prescription often fail to capture this. Patient-Reported Outcome Measures (PROMs) are questionnaires that assess one or more outcome domains relevant to the patient, such as "pain", "functioning", and "activities of daily living". Typically, scores (e.g., 0-100) can be calculated for the assessed domains. Hence, PROMs are highly relevant to understand the real-world impact of conditions and medical treatments on patient well-being and can be used in shared decision-making (2).

The Observational Medical Outcomes Partnership Common Data Model (OMOP-CDM) is a widely adopted standard for harmonizing healthcare data (3). While the OMOP-CDM has been successfully used for research using clinical and medication data, PROMs are not (yet) commonly incorporated and present unique challenges. To enable the use of PROMs in large-scale evidence generation within the OMOP-CDM framework, we share insights from two mapping initiatives (XC and H2O) highlighting our experiences, lessons learned, and open questions in this work.

Methods

Mapping initiatives

As part of the EHDEN project, The Xpert Clinics ICHOM Hand and Wrist Set (will be referred to as "XC") was mapped to the OMOP-CDM. The International Consortium for Health Outcomes Measurement (ICHOM) defines global standard sets of outcome measures that matter most to patients (4). In 2021,

the ICHOM Hand and Wrist Conditions Standard Set was introduced (5) and implemented at Xpert Clinics, a specialized treatment center providing elective care for hand and wrist conditions in The Netherlands (6). This ICHOM Standard Set defines which outcomes should be measured for patients with hand or wrist conditions, which measurement instruments should be used, and at which timepoints in the treatment pathway the measurements should be taken. ICHOM defined measurement tracks, where the relevant outcome measures and follow-up period are based on affected anatomical region (i.e., finger, thumb, wrist, nerve) and severity of the condition. Notably, many outcome measures selected by ICHOM to evaluate treatment outcomes for hand and wrist conditions are PROMs.

The set further contained 3 medical surveys (e.g., pre-anesthesia screening), 3 Clinician-Reported Outcome Measures (CROMs), and 2 Patient-Reported Experience Measures (PREMs). In total, this resulted in 1033 questions and 5381 answers, of which 477 answers were unique. Usagi and Athena were used to identify relevant, standard concept_ids to represent questionnaires, questions, and answers.

As part of the Health Outcomes Observatory (H2O) project, the PROMOP initiative has been established to evaluate the feasibility of mapping a refined set of core outcomes to the OMOP-CDM. H2O collects standardized outcome data across different disease areas, emphasizing PROs. Independently established H2O observatories across Europe aim to gather, analyze, and share standardized outcomes for informed healthcare decisions and evidence generation through federated research (7). In H2O, a core outcome set was first defined, which consisted of 207 PROM questions, 147 PROM answers, and 108 clinical variables. Next, a mapping document to translate the H2O outcomes to OMOP concepts was created. Athena was used to identify relevant, standard concept_ids. This was done in peer-review style with all partners in the H2O consortium that have OMOP data. This document was used as ETL guide at all sites, and can later be used as a reference, for example, when building cohorts.

Reflecting on mapping strategies

Both projects focused on re-using the existing vocabularies. Therefore, concepts outside of the observation domain were borrowed when they could be used to represent a variable in either of the projects. To represent the origin of the information, observation_type_concept_id was set to “patient filled survey” for PROMs and PREMs, and “healthcare professional filled survey” for CROMs. The two projects were performed independently, but after their completion, we presented our experiences to each other and discussed pros and cons of possible solutions to the specific challenges when mapping PROM data. Our key findings are summarized in this work.

Results

In Athena, we found exact matches for three PROMs: the EuroQol-5-Dimension 5-Level (EQ5D-5L), the Patient-Reported Outcomes Measurement Information System (PROMIS), and the European Organization for Research and Treatment of Cancer (EORTC), mostly from the OMOP Extension, LOINC, and SNOMED vocabularies.

Table 1 provides an overview of the challenges with mapping PROM identified from both projects, also describing why these challenges are relevant to PROM data, and possible solutions. Additionally, the considerations we had when choosing a solution and the chosen solution per project are described.

Table 1. Challenges with mapping and analyzing PROMs in the OMOP-CDM.

Challenge	**Why?**	**Potential solutions**	**Pros, cons & approach in Xpert Clinics ICHOM Hand and Wrist Set (XC) and/or H2O (if available)**
Capturing laterality and temporality in questions	For many PROM questions, exact matches are not available in established vocabularies. Somewhat similar variables may exist but are typically not specific enough and do not, for example, include laterality and/or temporality.	1. Creating custom concept_ids to exactly match the PROM questions 2. Using existing concept_ids and adding qualifier_ids to the mapping to make the match more specific.	Both in XC and H2O, for temporality (e.g., "in the last 7 days") and laterality (e.g., "left hand") we added qualifier_ids to re-use the existing vocabularies wherever possible.
Representing negative responses	In the OMOP-CDM, we typically only capture what is registered for that patient. However, for PROM data, negative responses (e.g., to questions like "Do you have hypertension?") are also available and relevant to include.	1. Use an appropriate concept for the questions in concept_id and "No" (Concept ID: 45878245) in value_as_concept_id. 2. For observations, qualifier_concept_id may be used to represent negation with concepts like "No history of" (Concept ID: 4032324). 3. Employ concepts that inherently express negation, e.g. "No history of malignant tumor of breast" (Concept ID:45763684).	Both in XC and H2O, the first solution was preferred, followed by the second solution whenever the first was not possible.
Encoding the scale (and direction) of the answer options	Many PROM answers are asked on a Likert scale. While the actual given answer is relevant, we also want to know which other answer options were available and what the direction (i.e., what was the "best" and "worst" score) was.	1. Translate Likert scale answers to "Grade x on a scale of 1 to 5" 2. Map the actual answers, e.g., "never", "sometimes", "always"	In XC, most PROMs were mapped to a "Grade X on a scale of 1 to 5" concept_id, to preserve the scale of the answer. However, it can be difficult to determine the direction of the scale (e.g., whether "always" is coded as "1" or "5"), when this is not explicitly described in the scoring manual of the PROM. H2O used exclusively actual answers with emphasis on

			reusing similar answer options. The translation to the answer scale should then be done during analysis.
Linking questions to questionnaires (and vice versa)	Typically, analyses of PROM data are performed per PROM (i.e., we will not mix data from two separate PROMs). Therefore, it is relevant to know from which PROM a question originates. Similarly, it is relevant to know which questions are asked within a PROM.	1. Precoordinated pairs (e.g., for the EQ5D-5L) 2. Linking questions to a questionnaire via observation_event_id 3. Considering sending out a questionnaire as an encounter and map this to the visit table. Link the questions to the visit	H2O used a H2O specific coding system linking disease, e.g. Lung Cancer, to questionnaires, e.g. EORTC, the specific questions, and answer sets. The reference file is used as basis for all following ETL implementations.
Linking questionnaires to clinical tracks or pathways?	To use PROMs in daily clinical care, they should be sent to the patient for completion at relevant timepoints, for example in the weeks before their clinic visit. In the ICHOM set, measurement tracks are defined, describing which questionnaires should be sent out to the patient at fixed timepoints during the care pathway.	1. Linking questionnaires to visits using the "visit_occurrence_id" 2. Not explicitly linking the questionnaires to moments in the care pathway, but deriving this from time since treatment	Within the H2O PROMOP project it was suggested to link questionnaire data to recent hospital visits and related measurements by using time based "visit_occurence_id" linking the different measurements to specific visits (either digital or at the hospital).
Tracking response rates and completeness (e.g. partial forms or skipped questions)	In the analysis of PROM data, it is important to know what the response rates were, and which data potentially needs to be imputed.	1. In token-based survey software (e.g., LimeSurvey), the status of the token can be added to the OMOP-CDM (e.g., "completed", "missed", "open - can be completed now"). All surveys are mapped when a token exists (i.e., the questionnaire was sent out). Only answered questions from (partially) completed PROMs are included in the dataset. The response rate can be calculated based on token_status. 2. All questions from all sent out questionnaires are mapped, regardless of their completion status. Questions where the answer is missing, indicate non-response.	XC has initially mapped all questions from send out questionnaires, but will include the token status in the next iteration and will then only include answered questions.

Conclusion

Mapping PROM data to the OMOP-CDM presents unique challenges, particularly around representing negative and scaled responses, linking questions to questionnaires and care pathways, and missing data. By combining approaches from two completed, independent mapping initiatives (ICHOM Hand and Wrist Conditions Standard Set and the PROMOP H2O Project), we identified potential solutions and open questions. To support meaningful use of PROM data in large-scale real-world analyses, it would be beneficial to develop a preferred strategy in the OHDSI community for linking questions to questionnaires and to the care pathway to facilitate data analysis. Moreover, we recommend assessing response rates in studies using PROM data, to assess the reliability and generalizability of

the conclusions drawn from this data. Finally, the number of PROMs in the available vocabularies is limited. While this could sometimes be overcome by using concept_ids from similar PROMs or by adding qualifier_ids, extending the vocabularies with more PROMs would highly facilitate the use of PROMs in large-scale evidence generation using the OMOP-CDM.

References

1. Porter M. E. (2010). What is value in health care?. The New England journal of medicine, 363(26), 2477–2481. https://doi.org/10.1056/NEJMp1011024

2. Lagendijk, M., Mittendorf, E., King, T. A., Gibbons, C., Pusic, A., & Dominici, L. S. (2020). Incorporating Patient-Reported Outcome Measures into Breast Surgical Oncology: Advancing Toward Value-Based Care. *The oncologist*, *25*(5), 384–390. https://doi.org/10.1634/theoncologist.2019-0355

3. Voss, E. A., Makadia, R., Matcho, A., Ma, Q., Knoll, C., Schuemie, M., DeFalco, F. J., Londhe, A., Zhu, V., & Ryan, P. B. (2015). Feasibility and utility of applications of the common data model to multiple, disparate observational health databases. *Journal of the American Medical Informatics Association : JAMIA*, *22*(3), 553–564. https://doi.org/10.1093/jamia/ocu023

4. Bell, D., Kelley, T., & Hicks, N. (2015). How true outcomes-based commissioning can really 'liberate' healthcare services. *Future hospital journal*, *2*(2), 147–149. https://doi.org/10.7861/futurehosp.2-2-147

5. Wouters, R. M., Jobi-Odeneye, A. O., de la Torre, A., Joseph, A., ICHOM Hand and Wrist Working Group, & Hovius, S. E. R. (2021). A Standard Set for Outcome Measurement in Patients With Hand and Wrist Conditions: Consensus by the International Consortium for Health Outcomes Measurement Hand and Wrist Working Group. *The Journal of hand surgery*, *46*(10), 841–855.e7. https://doi.org/10.1016/j.jhsa.2021.06.004

6. Selles, R. W., Wouters, R. M., Poelstra, R., van der Oest, M. J. W., Porsius, J. T., Hovius, S. E. R., Moojen, T. M., van Kooij, Y., Pennehouat, P. Y., van Huis, R., Vermeulen, G. M., Feitz, R., Slijper, H. P., & Hand-Wrist Study Group (2020). Routine Health Outcome Measurement: Development, Design, and Implementation of the Hand and Wrist Cohort. *Plastic and reconstructive surgery*, *146*(2), 343–354. https://doi.org/10.1097/PRS.0000000000007008

7. Stamm, T., Bott, N., Thwaites, R., Mosor, E., Andrews, M. R., Borgdorff, J., Cossio-Gil, Y., de Portu, S., Ferrante, M., Fischer, F., Hameed, F., Hazelzet, J., Hopkins, D., Kalra, D., Metcalfe, T., Molero, E., Newson, R., Patalano, F., Prasser, F., Rose, M., Sachs, M. L., Soderberg, J., Strammiello, V., van de Poll, L., & Styliadou, M. (2021). Building a Value-Based Care Infrastructure in Europe: The Health Outcomes Observatory. *New England Journal of Medicine Catalyst,* 2-3. DOI: 10.1056/CAT.21.0146