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# The Collection of PROMs as Part of Real-World Federated Analytics: Lessons Learned from the REWINDER Project in Diabetes in Emilia-Romagna

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## OBJECTIVES

Patient-reported outcome measures (PROMs) have become an essential component of value-based and person-centred diabetes care. Nevertheless, their routine implementation remains uncommon because longitudinal PROMs collection, linkage with clinical information, and privacy protection pose substantial organisational and technical challenges. Federated analytics has been proposed as a strategy to overcome these barriers by enabling distributed analyses without transferring identifiable patient-level data. The REWINDER study ("Real-World data and patient-reported outcomes IN Diabetes") aimed at implementing a regional federated infrastructure integrating PROMs into routine diabetes care and exploring scalability beyond the pilot setting.

## METHODS

A federated infrastructure was implemented across three areas of Emilia-Romagna to combine clinical, administrative and PROMs data while preserving local data ownership. The design included the collection of target sample size of n=150 questionnaires in each area, using validated instruments of the ICHOM Diabetes Standard Set (PAID-5, PHQ-9 and WHO-5). Data were digitized locally using different means: Romagna and Reggio-Emilia used an existing application (Health Meeting and Smarty, respectively), while Parma performed data entry in an Excel sheet. PROMs were linked locally to other data sources included in the REWINDER database through unique patient identifiers and analysed using the NeuBIRO federated statistical platform. We evaluated data completeness, linkage quality, temporal consistency and operational feasibility prior to assessing patient outcomes.

## RESULTS

Baseline PROMs were available for n=521 individuals, mostly collected by Romagna (51.1%), followed by Reggio-Emilia 33.8%) and Parma (15.2%). However, the proportion of patients contributing complete longitudinal information decreased considerably after applying protocol requirements and successful linkage across data sources. The percentage of patients with a valid follow-up (between 4 and 10 months from baseline) was similar between Romagna (86.5%) and Parma (88.6%), but considerably lower in Reggio-Emilia (30.1%), reflecting organisational differences in data collection processes. Additional discrepancies emerged from asynchronous patient recruitment, incomplete availability of active patient lists and incomplete linkage of telephone follow-up interviews. Further results regarding the evaluation of linkage with demographical, clinical and population-based data available through the REWINDER cohort are currently in progress and will be available at the Conference.

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## CONCLUSIONS

The study demonstrates that federated collection and analysis of PROMs can be successfully embedded within routine diabetes care while maintaining data privacy. However, technical feasibility alone is insufficient to support sustainable large-scale implementation. Although federated analysis remained technically feasible despite these constraints, the experience demonstrated that organizational processes, rather than analytical methods, may represent the principal determinant of data quality and effective interoperability. Manual data collection procedures, heterogeneous local workflows and poorly synchronized follow-up substantially reduce the completeness and comparability of longitudinal patient-reported outcomes. A companion abstract presents the detailed results related to the statistical analysis of PROMs for the subset of people with Type 2 diabetes with valid follow-up.

Future federated infrastructures should prioritise native digital PROMs collection, automated linkage with clinical information systems, standardised operational protocols and integrated scheduling mechanisms. These organisational prerequisites are likely to have a greater impact on the quality and scalability of federated real-world evidence than further methodological refinements of distributed analytical models.

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