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Real-world data and patient-reported outcomes in diabetes in Emilia–Romagna (REWINDER): protocol of a federated cohort study for the regional evaluation of quality of care during and after COVID-19

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ABSTRACT

Introduction Real-world data and patient-reported outcomes in diabetes in Emilia–Romagna is a multi-centric observational cohort study aimed at improving diabetes care in the Emilia–Romagna region, by exploring trends and predictors of clinical and psychological parameters in a large population of people with diabetes, during and after the COVID-19 pandemic.

Methods and analysis The study has a mixed retrospective/prospective design. The retrospective component involves computerised data linkage of administrative and clinical data from the local health authorities of Romagna and Reggio Emilia, and the University Hospital of Parma, covering a population of approximately 100 000 prevalent cases with diabetes, followed throughout the years 2019–2024. The selection of data items collected in the reference time frame is based on the International Consortium for Health Outcomes Measurement (ICHOM) standard set for diabetes, including clinical, lifestyle, social and healthcare service measurements. The prospective component includes primary data collection of indicators of psychological well-being through the WHO-5 Well-Being Index, diabetes distress using the Problem Areas In Diabetes-Short Form and depression through the Patient Health Questionnaire-9, measured at 0–6 months in an overall sample of 455 people with type 2 diabetes. Statistical analysis will include descriptive analysis and multivariate logistic regression using a two-step federated approach.

Ethics and dissemination The study has obtained ethics approval from the Ethics Committee of Romagna and the Ethics Committee of Area Vasta Emilia Nord. The results of the study will be published in scientific journals to evaluate quality and outcomes of diabetes care across the region.

Trial registration number NCT06639100.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study leverages clinical data, administrative records and patient-reported outcome measures (PROMs) using a federated platform, providing a holistic approach in evaluating diabetes care.
⇒ The use of the International Consortium for Health Outcomes Measurement standard set for diabetes ensures consistent validated measurement of clinical and patient-reported outcomes.
⇒ Specialised software incorporates advanced privacy-preserving methodologies, including pseudonymisation and encryption, ensuring secure data handling in compliance with the General Data Protection Regulation.
⇒ Inclusion criteria for PROM data focus on a specific patient demographic (type 2 diabetes, aged 40–69 years, without severe complications), which may limit the generalisability of findings to other groups.
⇒ The study heavily relies on the accuracy and completeness of real-world data, which may induce variability or bias.

INTRODUCTION

In 2020, the Italian healthcare system was severely struck by the COVID-19 pandemic. Northern Italy accounted for over 70% of national cases, with the Emilia–Romagna region being heavily hit. In this context, people with chronic conditions faced limited access to outpatient care, further compounded by the lack of structured telemedicine and remote care systems, which were not yet widely implemented within the national healthcare framework. These limitations were further exacerbated by the fragmentation of health data and the absence of

a surveillance infrastructure capable of effectively leveraging direct communication between citizens and healthcare providers.[1] The significant reduction in access to healthcare services resulted in short- and long-term clinical consequences.

According to an international survey by the WHO,[2] 49% of participating countries reported partial or complete disruption of services for the management of diabetes and diabetes-related complications during the COVID-19 pandemic. This proportion exceeded that of cancer (42%) and of cardiac emergencies (31%).

In response to growing public concern, the Italian Ministry of Health acknowledged the need to integrate existing effective healthcare management models[3] with enhanced patient-centred approaches, fostered by remote consultation and strategies promoting patient self-management.[4 5]

The building block of this strategy was the implementation of health information systems that incorporate all patient-relevant data capable of identifying individuals with increased frailty.[6 7] In 2021, the "Romagna Local Health Authority" (AUSL Romagna) took part in a comprehensive review of existing diabetes data sources across Europe, serving as a model for the implementation and strengthening of diabetes information systems in the Emilia–Romagna region.[8]

In this context, the global standard set implemented by the International Consortium for Health Outcomes Measurement (ICHOM) provided a key reference for developing an effective information framework for person-centred diabetes care.[9] The included data set comprised diabetes control parameter (including glucose and intermediate outcomes), acute events (including cardiovascular events and amputations), chronic complications (eg, heart disease and peripheral artery disease), health services administrative information (hospitalisations and emergency department attendance), survival and three patient-reported outcome measures (PROMs) validated for use in the Italian language: the Problem Areas In Diabetes-Short form (PAID-5), the Patient Health Questionnaire-9 (PHQ-9) and the WHO Five Well-Being Index (WHO-5).[10–12] In addition, ICHOM also delivered a standardised outcome set for COVID-19.[13]

In Italy, a set of standardised national health databases is regulated by the law, covering the majority of the data items included in the ICHOM standard set.[14] However, clinical data items remain fragmented across distinct silos, for example, databases of outpatient diabetes clinics.[3] Notably, neither national nor local data sources currently provide access to PROMs, as these are not included in routine data collection.

The relevance of PROMs for personalised care, clinical decision-making and improved health outcomes[15 16] is supported by findings highlighting the impact of such indicators on outcomes in type 2 diabetes (T2D).[17–20]

A large population-based cohort study using health administrative data demonstrated that depression is associated with a 1.6-fold increased risk of long-term complications, an over twofold increased risk of acute complications and an almost threefold increase in mortality among people with T2D.[18] Depression in people with T2D also negatively impacts on self-care behaviours and adherence to medical appointments.[17] Notably, during the COVID-19 pandemic, people with T2D and depression experienced a higher frequency of emergency department admissions for diabetes-related complications.[19]

In addition to clinical depression, diabetes distress represents another relevant issue in person-centred care, as it affects the emotional burden associated with managing a complex chronic condition. Diabetes distress is a common condition strongly associated with suboptimal glycaemic control, reduced adherence to medications and lower quality of life (QoL).[21] Addressing diabetes distress is critical, as it directly impacts patients' ability to effectively manage their care.

The importance of evaluating psychosocial aspects in the management of diabetes has also been underscored by the American Diabetes Association, which emphasises the need for a comprehensive approach addressing both physical and mental health challenges.[22] In this context, the use of PROMs is essential for the systematic assessment of these psychosocial factors, enabling healthcare providers to tailor interventions prioritising the well-being of high-risk patients and enhancing overall quality of care.[23 24]

The project 'Real-world data and patient-reported outcomes in diabetes: a standard set for person-centred care in Emilia–Romagna during and after COVID-19' (REWINDER) is an observational study conceived during the COVID-19 pandemic, to support the development of resilient real-world data systems capable of monitoring continuity of care and patient outcomes during major disruptions to healthcare delivery.

The study aims to promote person-centred care by systematically leveraging individual health records to drive continuous improvements in quality of care and health outcomes at the population level.

The primary aim of the REWINDER study was to assess the evolution of glycated haemoglobin levels (HbA1c) during and after COVID-19 in a prevalent cohort of people with diabetes from three large healthcare authorities, using pre-pandemic levels as a baseline, while adjusting for all potential clinical and service-related confounders.

The secondary aims of the study are (a) to estimate the association between changes in HbA1c and three PROMs mentioned above in a sample of people with T2D and (b) to enable the repeated application of the approach through the development of a sustainable federated network, which could act as a new service model, making direct use of the available databases.

The following sections present the details of the study design and information framework specifically implemented for the conduct of the study.

METHODS AND ANALYSIS

The project includes a multi-centre cohort study intertwined with the design and implementation of a scalable federated network, to facilitate data sharing and analysis across participating clinical centres. The project officially started on 27 April 2022 and is expected to close on 26 April 2025.

Participating centres

The project involves three large healthcare organisations of Emilia Romagna, a densely populated region of 4 459 453 inhabitants in northern Italy. Altogether, the reference total population of the REWINDER study adds up to 2 104 342 residents in the region (47.2%), distributed as follows across the three participating centres: AUSL Romagna, a local healthcare authority covering a total population of 1 121 905; 'Local Health Authority of Reggio Emilia' (AUSL Reggio Emilia), with a population of 529 932; and 'Parma University Hospital' (AOU Parma), in charge of a population of 452 505. All population data refer to residents of each respective local health authority estimated by the National Institute of Statistics on 1 January 2019.

To fulfil the objectives of the study, each healthcare organisation will be responsible for all aspects related to data management, including extraction, merge and analysis of the local REWINDER database, using its own data governance infrastructure.

All personal clinical information, including PROMs, will be duly managed by operating units, including four outpatient diabetes clinics of AUSL Romagna, located in Ravenna, Faenza, Lugo and Rimini, with an average of 28 000 patients visited every year; two outpatient diabetes clinics at AUSL Reggio Emilia, with an average of 40 000 patients visited per year; one diabetes clinic at AOU Parma, with an average of 2500 patients visited per year.

Diabetes clinics will continuously collect personal, anthropometric and clinical data using a common standardised electronic format and data management software ('Smart Digital Clinic', developed and maintained by the company Meteda).

Finally, local healthcare organisations will merge administrative and clinical data in accordance with the agreed-upon secure procedures. The aggregated results produced by local organisations will be finally analysed by the coordinating centre.

Cohort study design

The multi-centric cohort study adopts a mixed retrospective/prospective design. Computerised data linkage of administrative and clinical datasets will be used in the retrospective component, to construct a study cohort of approximately 100 000 individuals with diabetes at 1 January 2019 (*time zero*) from participating centres.

All records available for these subjects from regional data sources will be used to monitor their conditions and services up to 6 years, until 31 December 2024. The prospective component will include the primary data collection of the above-mentioned PROMs not routinely available (WHO-5, PAID-5 and PHQ-9).[25–27]

Study population

The definition of the prevalent cohort at time zero (baseline) is based on a validated algorithm applied by the regional government to identify all people with diabetes in the Emilia–Romagna region.[28]

The algorithm works as follows:

- Definition of time zero (1 January 2019 for the present study), reference year (year 2019) and a 3 year 'recruitment phase', starting 2 years before time zero and including the whole reference year (1 January 2017 to 31 December 2019):
  1. Selection of the cohort, inclusion of all individuals alive and resident in the region, meeting at least one of the following three conditions:

  a. At least one hospital admission during the recruitment, with a primary or secondary diagnosis of diabetes mellitus (ICD-9-CM 250.xx) OR pre-existing diabetes in pregnancy (ICD-9-CM 648.0x), excluding admissions classified under MDC 14 (pregnancy, childbirth and puerperium) (source: national hospital discharge database—SDO).

  b. At least two dispensations of medications during the recruitment phase, with the following ATC codes: A10A, insulins and analogues, and A10B, hypoglycaemic agents, excluding insulins (source: national database of pharmaceutical prescriptions: AFT, FED).

  c. Registration for an exemption from payments of dedicated healthcare services with code 013 (diabetes) at any date in the reference year (source: regional registers of exemptions).

Data items

All data items collected for this study, except for PROMs, have been part of routine data collection for over two decades. In the Italian decentralised healthcare system, local health authorities must meet all criteria and regulations set by the national and regional governments, but they are free to implement primary, secondary and tertiary services according to their managerial style and population needs. During the pandemic, different territories experienced varying levels of emergencies. However, data collections remained solid and fairly standardised in the Emilia–Romagna region, including clinical databases maintained as part of standard practice in diabetes.[3]

The selection of data items included from the above databases has been based on the ICHOM standard set for diabetes, covering glycaemic control, acute events, chronic complications, diagnoses and procedures recorded during hospitalisation, lifestyle and social factors, healthcare service and PROMs.[9]

The following domains have been identified for data linkage and integration (see figure 1):

- administrative databases, namely, hospital discharge records, prescriptions, specialist visits, exemptions

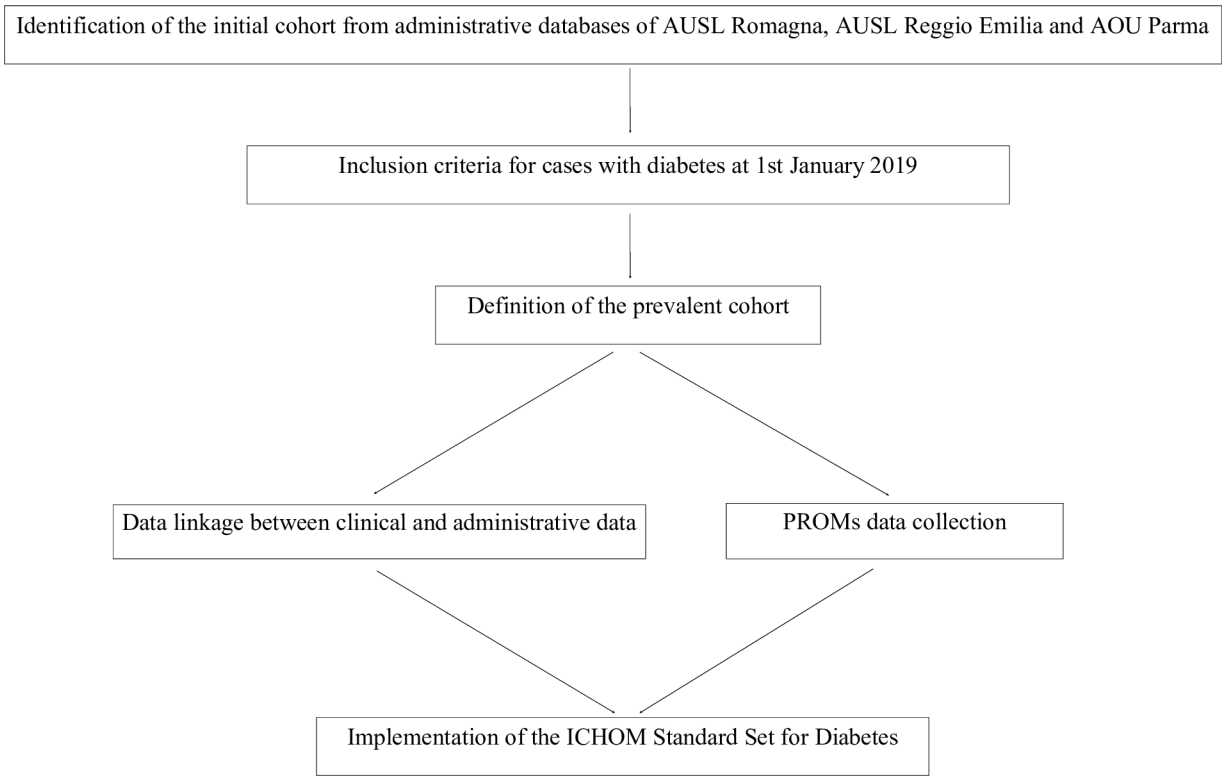

Figure 1 Flow chart for the prevalent cohort of people with diabetes. ICHOM, International Consortium for Health Outcomes Measurement; PROMs, patient-reported outcome measures.

and mortality records for all people with diabetes captured by the validated algorithm;

- clinical records, such as clinical data routinely collected using the system '*Smart Digital Clinic*' adopted by the diabetology units, including all people with diabetes captured by the validated algorithm, who visited at least once in any specialist unit of participating local health authorities during the recruitment timeframe.
- PROMs**:** collected ad hoc, using questionnaires administered during clinical visits at two separate time points (baseline and 6 months follow-up).

All clinical and administrative records for individuals selected in the cohort will be extracted and linked across using a unique identifier, allowing a 6year follow-up between 1 January 2019 and 31 December 2024. PROMs will be collected during the last year of observation on a subset of eligible participants (see below for details).

Outcomes

The study involves both clinical and patient-reported outcomes. The primary outcome is the intermediate glucose control marker HbA1c; secondary outcomes include several clinical parameters reported in table 1.

With regard to PROMs, we focused on three validated instruments acknowledged for their capacity to independently assess patients' QoL and functional status.[29] These measures serve as a valuable complement to clinical indicators, such as HbA1c, and underscore the importance of their routine incorporation into diabetes registries for ongoing longitudinal assessment.

The questionnaires include the PAID-5,[30 31] to assess diabetes-related distress, that is, the emotional burden related to diabetes and its management[26 32]; the PHQ-9 to screen patients for potential major depression in primary care[10 27 33]; and the WHO-5 developed by the WHO to evaluate psychological well-being as an essential aspect of overall QoL.[12 25]

All definitions presented above were compliant with the global ICHOM standard set for diabetes.[9]

Case-mix variables

A range of case-mix variables will be used to adjust the results obtained in prediction models (see table 2). In addition, we will request access to COVID-19 status recorded in administrative databases of participating centres, with basic information on diagnosis (date of positive/negative status) and hospitalisation (length of stay and mode of discharge).

Prospective data collection of PROMs

The measurement of PROMs has never been part of standard diabetes care practice in Emilia–Romagna. REWINDER introduces their use for the first time, adopting a set of validated instruments, applied at baseline and after 6 months on a subset of people included in the study cohort.

The 6 month follow-up has been pragmatically chosen to allow a mid-term perspective over the natural variability of the personal experience, within the limited time frame of the project. The feasibility of the approach is confirmed

Table 1 Outcomes included in the real-world data and patient-reported outcomes in diabetes in Emilia–Romagna study

Category	Outcome	Coding*	Data source	Timing
Glycaemic control	HbA1c	mmol/mol	Clinical records	Last value
	Time-in-range	Percentage of time in the range of 70–180 mg/dL	Clinical records	Last value
Intermediate outcomes	BMI	kg/m^2	Clinical records	Last value
	Lipid profile	mg/dL	Clinical records	Last value
	Blood pressure	mm Hg	Clinical records	Last value
Acute events	Diabetic ketoacidosis, hyperosmolar hyperglycaemic syndrome	250.1, 276.2, 250.2	Clinical/Adm. records	Annually
	Hypoglycaemia	251.0, 251.1, 251.2	Clinical/Adm. records	Annually
	Acute cardiovascular events	410, 430, 431, 432.x, 434.x,	Clinical/Adm. records	Annually
	Lower limb amputation	84.1x	Clinical/Adm. records	Annually
Chronic complications	Autonomic neuropathy	337.1	Clinical/Adm. records	Annually
	Peripheral neuropathy	357.2	Clinical/Adm. records	Annually
	Charcot's foot	713.5	Clinical/Adm. records	Annually
	Lower limb ulcers	707.1 (0–9)	Clinical/Adm. records	Annually
	Peripheral artery disease	440.2x, 440.3x, 443.91, 250.7x	Clinical/Adm. records	Annually
	Ischaemic heart disease	414xx, 411.xx	Administrative records	Annually
	Chronic heart failure	402.01, 402.11, 402.91, 404.01, 404.11, 404.91, 428.xx	Administrative records	Annually
	Chronic kidney disease/dialysis	585, 585.81, V45.1, V56.1, V56.2, V56.3	Administrative records	Annually
	Cerebrovascular disease	433.xx, 435.xx, 437.0, 437.1	Administrative records	Annually
	Vision	250.5, 362.0x	Administrative records	Annually
	Periodontal health	523.9	Administrative records	Annually
Health services outcomes	Hospitalisation	Date of admission and discharge	Administrative records	Annually
	Emergency room attendance	of emergency room attendance	Administrative records	Annually
Survival	Vital status	Yes/No	Administrative records	Continuous
Patient-reported outcomes	Depression	PHQ-9	PROMs	0–6 months
	Diabetes distress	PAID-5	PROMs	0–6 months
	Psychological well-being	WHO-5	PROMs	0–6 months

*ICD-9-CM, Version 2007.
BMI, body mass index; HbA1c, glycated haemoglobin; PAID-5, Problem Areas in Diabetes Scale 5; PHQ-9, Patient Health Questionnaire-9; PROMs, patient-reported outcome measures.

by a recent systematic review, including different types of studies using 6 month follow-up to observe natural changes over time.[34]

Inclusion and exclusion criteria

Inclusion criteria for PROMs are T2D diagnosis >1 year, age between 40 and 69 years and willingness to provide informed consent to participate in the study.

Exclusion criteria are severe comorbidities, cognitive impairment, major psychiatric disorders or pregnancy.

Sample size justification

For the primary aim of the study, there was no formal calculation of sample size, as we planned to include all subjects with diabetes from three densely populated areas of Emilia–Romagna region, in charge of their healthcare services.

The number of subjects targeted for the measurement of PROMs was determined by formal sample size calculations. Briefly, we identified an acceptable level of concordance between the clinical and psychological evaluations,

Table 2 Case-mix variables included in the real-world data and patient-reported outcomes in diabetes in Emilia–Romagna study

Category	Variable	Data source	Timing
Demographic factors	Sex Year of birth Ethnicity	Clinical records	Baseline
	Educational level	Administrative records	Baseline
Diagnosis profile	Year of diagnosis Comorbidities COVID-19 status (positive/negative diagnosis and hospitalisation)	Clinical/administrative records	Baseline Annually Annually
Lifestyle and social factors	Smoking Alcohol consumption Physical activity Social support	Clinical records	Baseline Annually Annually Annually
Treatment factors	Diabetes treatment Blood pressure lowering therapy Statins/lipid-lowering therapy	Clinical records	Annually Annually Annually

for an early prediction of increased risk of diabetes complications.

To calculate the desired sample size, we hypothesised an interrater agreement measured by Cohen's Kappa=0.5 between pre and post changes of +0.3% HbA1c for the clinical evaluation (indicating a meaningful lack of control) and −5 points decrease of PHQ-9 for the psychological assessment (indicative of depression).

Based on the parameters required for sample size calculations,[35] we fixed an alternative hypothesis of Kappa=0.35 (approximately two-thirds), a proportion of individuals with the outcome equal to 25% (estimated from clinical databases of AUSL Romagna, AUSL Reggio Emilia), alpha=0.05 and power=90%, obtaining a minimal sample size equal to 455 patients overall, with complete 6-month follow-up.

All sample size calculations have been performed using the PowerBinary function of the kappaSize package[36] of the R language.[37]

Data collection procedures

Participating centres will receive the PROMs instruments from the coordinating centre.

Each diabetes clinic will organise the administration and data collection according to its internal procedures, which may differ across centres. Eligible patients will be asked to provide informed consent and to complete the questionnaire autonomously during routine clinical visits.

If needed, healthcare professionals will be available to support patients throughout the process until completion. All questionnaires will be securely stored in the clinic, including personal ID of the patient for recall after 6 months. Filled questionnaires will be sequentially digitised using local information systems, complying with internal rules of data governance to store personal information, for matters related to the provision of care (see below for pseudo-anonymisation). This step will be carried out at AUSL Romagna using an existing platform ('HealthMeeting') that can be used in the future directly by the patients, in view of a sustainable collection of PROMs.

Data analysis plans

Descriptive analyses will be carried out at local and central level, using frequencies and summary measures to report on the characteristics of the study population and check for the annexed data quality (eg, evaluating the impact of missing data).

Univariate and multivariate analyses will be used to explore the association between predictors and pre–post changes in HbA1c in the overall cohort and in the subgroups with PROMs. All results will be reported as ORs with 95% CIs. Hypothesis tests will use an alpha=0.05.

In multivariate analyses, primary outcomes will be dichotomised using relevant cut-offs for meaningful clinical interpretation, enabling the use of logistic regression for the estimation of multivariate ORs from federated aggregates. COVID-19 status (positive/negative diagnosis and hospitalisation) will be used on an individual basis, whenever available, as a predictive factor to explore its association with the outcome. Pre–post-pandemic trends in outcome levels will be analysed for specific subgroups of interest.

Indirect standardisation will be used to benchmark the performance of each centre vs the regional average, adopting a two-step federated approach (local use of regression coefficients previously estimated in the global model). The functionality of the federated network will be evaluated using a mix of qualitative and quantitative criteria.

The final analysis will be run using the NeuBIRO software (see below).[38]

NeuBIRO statistical software

NeuBIRO () is a federated, open-source statistical software designed to process clinical and administrative data securely and anonymously in the context of healthcare systems.[38] NeuBIRO is a multi-platform Java application developed in Groovy (http://groovy.codehaus.org/), using H2 as an embedded DBMS (http://www.h2database.com). All statistical routines used for federated analysis in NeuBIRO are written in R (community-based open source by the R project (https://www.r-project.org/)).[37]

The NeuBIRO software is operated autonomously by each participating centre, ensuring that each personal ID remains de-identified and protected under General Data Protection Regulation (GDPR)-compliant protocols. In this way, individual-level data are never shared across providers, and the final results are produced by the coordinating centre only using aggregate data.

A customised version of NeuBIRO has been installed on a central server for restricted use by participating centres, each accessing the system using Remote Desktop Protocol through their own set of assigned credentials. The specific adaptation developed for the REWINDER project allows performing longitudinal analysis of the study cohort, using linked tables in each database through a common SHA-256 encrypted personal identifier.

Briefly, the local data extracted at each participating centre are loaded, linked across and transformed into a manageable set of tables that can be processed by each local centre separately, producing descriptive statistics used for local reports, as well as aggregate tables defined as 'statistical objects', specifically designed to perform the overall analysis of the study cohort. The set of local tables is transferred to the central server, where the coordinating centre runs the REWINDER global analysis. At the central server, specialised statistical routines perform multivariate logistic regression for the overall study cohort. The coefficients obtained by the multivariate models may be reused as a by-product of the main analysis to standardise and benchmark the results obtained by each centre vs the global average.

ETHICS AND DISSEMINATION

Ethics has been carefully tackled from the different but strictly related points of primary data collection and information infrastructure.

The study protocol was submitted and obtained ethics approval from the Ethics Committee of Romagna, competent for AUSL Romagna, on 10 December 2021 (prot. N. 10124), and from the Ethics Committee of Area Vasta Emilia Nord, competent for AOU Parma and for AUSL-IRCCS di Reggio Emilia on 10 May 2022 (prot. N.19887) and on 07 September 2022 (prot. N. 0112029), respectively.

Written informed consent was obtained for all subjects completing PROMS.

Regarding the information infrastructure, the NeuBIRO software runs in a federated infrastructure that implements privacy protective measures by design.[39 40] In particular, only data using pseudonym identifiers are used by centres, while anonymous data are shared across the network for final global analysis. The impact on privacy of such federated infrastructure has been assessed in previous EU projects in diabetes, acknowledging its full compliance with the GDPR.[41–45]

The dissemination strategy involves different types of stakeholders.

A summary project report will be produced for regional authorities (in Italian) to facilitate the uptake of new knowledge and innovation at the regional level.

The results of the study will be included in a stream of scientific papers that will evaluate diabetes care across the region, including the qualitative assessment of the federated network.

Clinical outcomes included in the report have been earmarked for a project web page, to ensure participation and engagement of health professionals, patients and the general public.

DISCUSSION

The REWINDER project is expected to generate actionable insights to guide targeted interventions for high-risk groups among people with diabetes in the Emilia–Romagna region.[46] The successful application of federated analytics on real-world data already available within healthcare organisations provides a solid foundation for the development of a sustainable population-based diabetes registry in the region.

The consolidation of clinical networks that share data to improve care quality may also support the implementation of new models of integrated care,[47] potentially extending to other non-communicable diseases.

The use of PROMs, as recommended by ICHOM, offers valuable perspectives for identifying at-risk subgroups who could benefit from ongoing monitoring through extended primary data collection. Systematically integrating mental health assessment—particularly depression, anxiety and diabetes distress—into routine diabetes management may help identify vulnerable populations and tailor interventions more effectively.[48] This approach is aligned with the growing recognition of mental health as a key component of precision diabetes medicine, with equal attention to physical and psychological health outcomes.

This protocol has several strengths:

- A federated data model that enables secure, scalable and GDPR-compliant integration across healthcare centres.
- The inclusion of both administrative data and PROMs for a comprehensive assessment of diabetes care.
- Demonstrated operational resilience during system-wide disruptions such as the COVID-19 pandemic, ensuring continuity in data collection.

However, the study also presents relevant limitations:

- Potential misclassification or incomplete coding in administrative datasets.
- Restriction of the PROM sample to individuals aged 40–69 years, which may limit the generalisability of findings.
- The pre–post observational design, which precludes causal inference but remains valuable for generating hypotheses for future studies.

These aspects will be further examined during the analysis and interpretation phases.

Overall, the coordinated strategy adopted in REWINDER aims to support the continued enhancement of high-quality care, both within the specific context of diabetes and across its complications. The strengthened federated infrastructure for real-world data may serve as a replicable model, within and beyond Emilia–Romagna, for advancing the implementation of truly person-centred health systems.

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Contributors All authors provided a substantial contribution to the development and implementation of the method as well as the production of the manuscript. FC and PDB conceived and drafted the project proposal. FC coordinated the design and technical implementation of the study protocol, steering the development of the federated network. FC, MM, ADC, MPF, RCB, MMB and PDB liaised as members of the Scientific Board to ensure the correspondence between the project protocol and its implementation on field. RM drafted the present paper and supervised collection and management of patient-reported outcome measures (PROM) data. RA and AmB supported the data collection of PROMs throughout the project. AmB and SG coordinated the customisation and use of NeuBIRO. ArB and EI coordinated the definition and extraction of administrative data. CTDI ensured compliance of the protocol with all ethical requirements, acting as project manager. PDB chaired the project as principal investigator, leading the writing of the present report as senior author. All authors revised and completed the production of the manuscript, revising and agreeing on its present contents. The project has been coordinated by the Director of the Diabetology Unit at Ravenna, AUSL Romagna (PDB, PI), supported by a Project Manager (CTDI, PM). The project was steered by a Scientific Board, including the PI as Chair, a Vice-Chair (FC) and three distinguished academic members (MMB, MPF and RCB). Administration was led by the Research Evaluation Office of AUSL Romagna. The guarantor is PDB, the PI and the Director of the Diabetology Unit at Ravenna, AUSL Romagna.

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