Database of Fondazione ReS

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Data source **Human** **Administrative healthcare records (e.g., claims)**

Administrative details

Administrative details

Data source ID

1000000155

Data source acronym

ReS database

Data holder

Fondazione ReS (Ricerca e Salute), CINECA partner

Data source type

Administrative healthcare records (e.g., claims)

Main financial support

Funding by own institution

Care setting

Hospital inpatient care

Hospital outpatient care

Other

Secondary care – specialist level (ambulatory)

Data source qualification

If the data source has successfully undergone a formal qualification process (e.g., from the EMA, ISO or other certifications), this should be described.

Yes

Description of the qualification

The ReS database is stored in the CINECA's Data Center. For the hosting service, CINECA makes use of applicative operating system in Cloud Computing – SaaS (Software as a Service) mode. The infrastructure management of the service is made through the IT Service Operation Management required by the reference framework ITIL V.3. Each time Local/Regional Health Authorities convey their administrative healthcare data to the ReS database, quality, completeness and accuracy data checks are made. Examples of main checks are: time consistency, comprehensive compilation of variables, a series of quality indicators (i.e., controls of overall figures of pharmaceuticals, hospitalizations, outpatient specialist care, specific drug groups and events).

Data source website

fondazioneres.it

Contact details

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Data source regions and languages

Data source countries

Italy

Data source languages

Italian

Data source establishment

Data source established

01/01/2018

Data source time span

First collection: 01/01/2018

The date when data started to be collected or extracted.

Publications

Data source publications

Identification of cases and estimate of direct costs of unresectable and advanced cutaneous squamous cell carcinoma: real-world data from a large Italian database

Real-world Prescription Pattern, Discontinuation and Costs of Ibrutinib-Naïve Patients with Chronic Lymphocytic Leukemia: An Italian Healthcare Administrative Database Analysis

Antiplatelet Therapy during the First Year after Acute Coronary Syndrome in a Contemporary Italian Community of over 5 Million Subjects

Open triple therapy for chronic obstructive pulmonary disease: Patterns of prescription, exacerbations and healthcare costs from a large Italian claims database

Acute lower respiratory infections: real-world evidence of antibiotic prescription pattern and costs from a large administrative Italian database

Prevalence, clinical impact and costs of hyperkalaemia: Special focus on heart failure

Prevalence, prescriptions, outcomes and costs of type 2 diabetes patients with or without prior coronary artery disease or stroke: a longitudinal 5-year claims-data analysis of over 7 million inhabitants

Coronary Artery Disease in Patients Older than 35 and Eligible for Cardiovascular Secondary Prevention: An Italian Retrospective Observational Analysis of Healthcare Administrative Databases

How many and who are patients with heart failure eligible to SGLT2 inhibitors? Responses from the combination of administrative healthcare and primary care databases

A methodology to assess the population size and estimate the needed resources for new licensed medications by combining clinical and administrative databases: The example of glycated haemoglobin in type 2 diabetes

Real-world data on new users of atypical antipsychotics: characterisation, prescription patterns, healthcare costs and early cardio-metabolic occurrences from a large Italian database

Insights into real-world treatment of cluster headache through a large Italian database: prevalence, prescription patterns, and costs

Prescription Pattern of Monoamine Oxidase B Inhibitors Combined with Levodopa: A Retrospective Observational Analysis of Italian Healthcare Administrative Databases

Primary Sjögren's syndrome in Italy: Real-world evidence of a rare disease through administrative healthcare data

Studies

List of studies that have been conducted using the data source

Identification of cases and estimate of direct costs of unresectable and advanced cutaneous squamous cell carcinoma: real-world data from a large Italian database

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Prescription Pattern of Monoamine Oxidase B Inhibitors Combined with Levodopa: A Retrospective Observational Analysis of Italian Healthcare Administrative Databases

Chronic Kidney Disease Eligible for SGLT2 Inhibitors Through the Integration of Italian Administrative and Primary Care Data

Italian healthcare resource consumptions and direct costs of adults with atopic dermatitis before and after dupilumab treatment

Italian healthcare resource consumption for patients on hemodialysis treated for chronic kidney disease-associated pruritus (CKD-aP)

A retrospective observational analysis of the realworld care pathway of people with hereditary transthyretin amyloidosis with polyneuropathy in Italy

Cardiovascular events after exacerbations of chronic obstructive pulmonary disease: Results from the EXAcerbations of COPD and their OutcomeS in CardioVascular diseases study in Italy

Clinical characteristics, use and switch of drugs for obstructive airway diseases among patients with COPD experiencing an exacerbation: a retrospective analysis of Italian administrative healthcare data

Real World Evidence in Oncology: an Italian examples-based expert opinion on advancing clinical and regulatory decision-making

Data elements collected

The data source contains the following information

Disease information

Does the data source collect information with a focus on a specific disease? This might be a patient registry or other similar initiatives.

No

Rare diseases

Are rare diseases captured? In the European Union a rare disease is one that affects no more than 5 people in 10,000.

Yes

Pregnancy and/or neonates

Does the data source collect information on pregnant women and/or neonatal subpopulation (under 28 days of age)?

Yes

Hospital admission and/or discharge

Yes

ICU admission

Is information on intensive care unit admission available?

Yes

Cause of death

Captured

Cause of death vocabulary

ICD-9-CM

Prescriptions of medicines

Not Captured

Dispensing of medicines

Captured

Dispensing vocabulary

ATC

Advanced therapy medicinal products (ATMP)

Is information on advanced therapy medicinal products included? A medicinal product for human use that is either a gene therapy medicinal product, a somatic cell therapy product or a tissue engineered products as defined in Regulation (EC) No 1394/2007 [Reg (EC) No 1394/2007 Art 1(1)].

No

Contraception

Is information on the use of any type of contraception (oral, injectable, devices etc.) available?

No

Indication for use

Does the data source capture information on the therapeutic indication for the use of medicinal products?

Not Captured

Medical devices

Is information on medicinal devices (e.g., pens, syringes, inhalers) available?

No

Administration of vaccines

No

Procedures

Does the data source capture information on procedures (e.g., diagnostic tests, therapeutic, surgical interventions)?

Captured

Procedures vocabulary

Other

Procedures vocabulary, other

Italian local outpatient specialist care nomenclature

Healthcare provider

Is information on the person providing healthcare (e.g., physician, pharmacist, specialist) available? The healthcare provider refers to individual health professionals or a health facility organisation licensed to provide health care diagnosis and treatment services including medication, surgery and medical devices.

No

Clinical measurements

Is information on clinical measurements (e.g., BMI, blood pressure, height) available?

No

Genetic data

Are data related to genotyping, genome sequencing available?

Not Captured

Biomarker data

Does the data source capture biomarker information? The term “biomarker” refers to a broad subcategory of medical signs (objective indications of medical state observed from outside the patient), which can be measured accurately and reproducibly. For example, haematological assays, infectious disease markers or metabolomic biomarkers.

Not Captured

Patient-reported outcomes

Is information on patient-reported outcomes (e.g., quality of life) available?

No

Patient-generated data

Is patient-generated information (e.g., from wearable devices) available?

No

Units of healthcare utilisation

Are units of healthcare utilisation (e.g., number of visits to GP per year, number of hospital days) available or can they be derived? Units of healthcare utilisation refer to the quantification of the use of services for the purpose of preventing or curing health problems.

Yes

Unique identifier for persons

Are patients uniquely identified in the data source?

No

Diagnostic codes

Captured

Diagnosis / medical event vocabulary

ICD-9-CM

Medicinal product information

Captured

Medicinal product information collected

Active ingredient(s)

Brand name

Dose

Medicinal product vocabulary

ATC

Other

If 'other,' what vocabulary is used?

Italian marketing code

Quality of life measurements

Not Captured

Lifestyle factors

Not Captured

Sociodemographic information

Not Captured

Quantitative descriptors

Population Qualitative Data

Population age groups

Paediatric Population (< 18 years)

Neonate

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Estimated percentage of the population covered by the data source in the catchment area

9% of the Italian population

Description of the population covered by the data source in the catchment area whose data are not collected (e.g., people who are registered only for private care)

The population covered by the ReS database is composed only by people of whom data are collected in the administrative databases. Namely, each time a patient receives a healthcare service reimbursed by the Italian National Healthcare Service (SSN), the patient is registered in the related administrative database that is forwarded to ReS by the local/regional Health Authority with whom ReS has signed the specific agreement. Patients are not registered when they pay for the healthcare service (i.e., drugs, hospitalizations, inpatient/outpatient specialist care) which is only provided as out-of-pocket. Namely, this happens when the service is not reimbursed by the SSN (e.g., off label drug, OTC drug, services performed in private facilities or not affiliated with the SSN...) or when the patient does not want to be cared by the SSN.

Population

Population size

5312291

Population by age group

Age group	Population size
Paediatric Population (< 18 years)	729480
Adult and elderly population (≥18 years)	4582811

Median observation time

Median time (years) between first and last available records for unique individuals captured in the data source

6.00

Data flows and management

Access and validation

Biospecimen access

Are biospecimens available in the data source (e.g., tissue samples)?

No

Access to subject details

Can individual patients/practitioners/practices included in the data source be contacted?

No

Description of data collection

The administrative healthcare data collected in the ReS database are exactly those periodically forwarded to the Italian Ministry of Health for reimbursement purposes by Italian local and regional Health Authorities. The forwarding to the Italian Ministry of Health is mandatory. Each Italian local and regional Health Authority that has signed the specific agreement with Fondazione ReS, send these administrative healthcare data to ReS to be hosted by CINECA, which makes use of applicative operating system in Cloud Computing – SaaS (Software as a Service) mode through the infrastructure IT Service Operation Management required by the reference framework ITIL V.3.

Event triggering registration

Event triggering registration of a person in the data source

Other

Event triggering registration of a person in the data source, other

A person is collected in the data source if he/she has received whatever healthcare reimbursed by the Italian national health Service (SSN)

Event triggering de-registration of a person in the data source

Death

Loss to follow up

Other

Event triggering de-registration of a person in the data source, other

Change of residency to an area not covered by the ReS database, i.e., with whom ReS has not signed the specific agreement. Admission to a private residential healthcare facility

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Event triggering creation of a record in the data source

Every healthcare service reimbursed by the Italian National Health Service (SSN) (i.e., public facilities/affiliated with the SSN), among hospital discharge, drug dispensation by local/hospital pharmacy, access to the emergency department, performance of a prescribed specialist service within a local outpatient specialist ambulatory

Data source linkage

Linkage

Is the data source described created by the linkage of other data sources (prelinked data source) and/or can the data source be linked to other data source on an ad-hoc basis?

Yes

Linkage description, possible linkage

The choice of HbA1c as illustrative example is based on four main reasons: (i) T2DM is a clinical context which is currently debated for the recent approval of SGLT-1/2 inhibitors, whose indication required specific values of HbA1c to be prescribed; (ii) T2DM can be accurately identified both in clinical and administrative databases, since every clinical process (drug prescriptions, outpatient visits, clinical examinations, hospital admissions) related to this condition can be retrieved in these data sources; (iii) HbA1c values are expectedly well-registered in clinical data source (i.e., missing values [n around 30%]) for most of the T2DM patients, so allowing the use of multiple imputation (MI) methods; (iv) this patients category is featured by comorbidities which can be commonly defined in clinical and administrative databases to form the covariates vector for the model imputing HbA1c values. Although this algorithm was not developed for prognostic purpose, we were compliant with Transparent Reporting of Multivariable Prediction Model for Individual Prognosis and Diagnosis (TRIPOD) statements. To develop a model to estimate HbA1c values to identify the diabetes patients being eligible to SGLT-2 inhibitors (ATC: A10BK*; A10BD*), in both data sources, we excluded those already prescribed with these medications in the overall look-back period. Still in both databases, we included those prescribed (i.e., at least two prescriptions) with metformin in 2018 and adherent to this medication as per a variable medicine possession ratio (VMPR)≥80%. Namely,

VMPR was operationally defined as the cumulative number of days for each prescription (i.e., the number of Prescribed Daily Dosages) divided by the number of variable days of follow-up of each drug users. Finally, only for HSD, the date of highest values of HbA1c after metformin use, during 2018, was the study event date. Thus, according to the eligibility criteria for SGLT-2 inhibitors, HSD was used to develop and test the algorithm estimating HbA1c values ≥7%, which are not available in administrative data source. Given the presence of common covariates in HSD and ReS database, the combination of beta coefficients, composing the algorithm

obtained with HSD, was adopted to estimate the missing values of HbA1c in the ReS data source. The demographics and clinical determinants used to develop and apply (to ReS database) the imputation algorithm were operationally defined using ICD-9-CM and ATC codes in keeping with the same harmonization process previously described.

Data management specifications that apply for the data source

Data source refresh

Yearly

Informed consent for use of data for research

Not Required

Possibility of data validation

Can validity of the data in the data source be verified (e.g., access to original medical charts)?

No

Data source preservation

Are records preserved in the data source indefinitely?

No

Data source preservation length (years)

The records are preserved until the agreement with local/regional health authorities is renewed years

Approval for publication

Is an approval needed for publishing the results of a study using the data source?

No

Data source last refresh

08/09/2023

Common Data Model (CDM) mapping

CDM mapping

Has the data source been converted (ETL-ed) to a common data model?

No