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

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000260

EU PAS number
EUPAS1000000260

Study ID
1000000260

DARWIN EU® study
No

Study countries
Italy

Study description
Purpose: To develop and validate a model to estimate glycated haemoglobin (HbA1c) values in patients with type 2 diabetes mellitus (T2DM) using a clinical data source, with the aim to apply this equation to administrative databases.

Methods: Using a primary care and administrative Italian databases, namely the Health

Search database (HSD) and the ReS (Ricerca e Salute) database, we selected all patients aged 18 years or older on 31 December 2018 being diagnosed with T2DM and without prior prescription of sodium-glucose cotransporter-2 (SGLT-2) inhibitors. We included patients prescribed with and adherent to metformin. HSD was used to develop and test (using 2019 data as well) the algorithm imputing HbA1c values ?7% according to a series of covariates. The algorithm was gathered by combining beta-coefficients being estimated by logistic regression models using complete case (excluding missing values) and imputed (after multiple imputation) dataset. The final algorithm was applied to ReS database using the same covariates.

Results: The tested algorithms were able to explain 17%–18% variation in assessing HbA1c values. Good discrimination (70%) and calibration were obtained as well. The best algorithm (three) cut-offs, namely those providing correct classifications ranging 66%–70% was therefore calculated and applied to ReS database. By doing so, from 52 999 (27.9, 95% CI: 27.7%–28.1%) to 74 250 (40.1%, 95% CI: 38.9%–39.3%) patients were estimated with HbA1c ?7%.

Conclusion: Through this methodology, healthcare authorities should be able to quantify the population eligible to a new licensed medication, such as SGLT-2 inhibitors, and to simulate scenarios to assess reimbursement criteria according to precise estimates.

Study status
Finalised

Research institution and networks

Institutions

Health Search, Italian College of General Practicioners
Italy
First published: 02/03/2010
Last updated 25/06/2014

Institution | Educational Institution | Other | ENCePP partner

Fondazione ReS (Ricerca e Salute), CINECA partner
Italy
First published: 05/07/2017
Last updated 12/04/2024

Institution

Not-for-profit ENCePP partner

Contact details

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Study timelines

Date when funding contract was signed
Actual:
12/03/2021

Study start date
Actual:
12/04/2021

Date of final study report
Actual:
12/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Astra Zeneca SpA

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study topic:
Disease /health condition

Study type:
Non-interventional study

Study design:
Retrospective longitudinal cohort study

Main study objective:
To develop and validate a model to estimate glycated haemoglobin (HbA1c) values in patients with type 2 diabetes mellitus (T2DM) using a clinical data source, with the aim to apply this equation to administrative databases.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medical condition to be studied
Diabetes mellitus
Type 2 diabetes mellitus

Population studied

Short description of the study population
All patients aged 18 years or older on 31 December 2018 being diagnosed with T2DM and without prior prescription of sodium-glucose cotransporter-2 (SGLT-2) inhibitors.

Age groups
Adult and elderly population (>18 years)
Adults (18 to < 65 years)
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Elderly (? 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Study design details

Setting
In-hospital and local outpatient settings in public and affiliated with SSN facilities as regards the database of Fondazione ReS. Primary care as regards the database of Health Search.

Summary results
The tested algorithms were able to explain 17%–18% variation in assessing HbA1c values. Good discrimination (70%) and calibration were obtained as well. The best algorithm (three) cut-offs, namely those providing correct classifications ranging 66%–70% was therefore calculated and applied to ReS database. By doing so, from 52 999 (27.9, 95% CI: 27.7%–28.1%) to 74 250 (40.1%, 95% CI: 38.9%–39.3%) patients were estimated with HbA1c ?7%.

Documents

Study publications
A methodology to assess the population size and estimate the needed resources f…

Data management

Data sources

Data source(s)
Database of Fondazione ReS

Data sources (types)
Administrative data (e.g. claims)
Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Yes

Check completeness
Yes

Check stability
Yes

Check logical consistency
Yes

Data characterisation

Data characterisation conducted
Yes