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

First published: 15/07/2024

Last updated: 15/07/2024

Study Finalised

Administrative details

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 institutions and networks

Institutions

Health Search, Italian College of General Practicioners

Italy

First published: 02/03/2010

Last updated: 20/08/2024

Institution | **Educational Institution** | **Other**

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

First published: 05/07/2017

Last updated: 01/10/2025

Institution | **Not-for-profit** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Database of Fondazione ReS

Health Search/IQVIA Health Longitudinal Patient Database

Data sources (types)

Administrative healthcare records (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