Overarching Use Case of the German Medical Informatics Initiative MII “POLAR_MI – POLypharmacy, Drug interActions, Risks”

First published: 27/11/2020

Last updated: 14/03/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47999

EU PAS number

EUPAS36582

Study ID

47999

DARWIN EU® study

No

Study countries

☐ Germany

Study description

POLAR uses methods and processes of the German Medical Informatics Initiative (MII) to contribute to the detection of medication related health risks, particularly of polypharmacy in elderly patients with multimorbidity. This is often associated with an increased risk for medication errors and drug-drug or drug-disease interactions, which either reduce or intensify the desired effect of individual active substances or lead to undesired adverse drug effects (ADE). In the light of the aging population, potentially inappropriate medications (PIM), which should be avoided in patients due to an unfavorable risk/benefit-ratio, represent a risk factor. Thus, POLAR focusses on the detection and prevention of medication-related problems in an interdisciplinary approach that creates a health IT infrastructure capable of supporting IT-based medication therapy safety across all four MII health-IT consortia. POLAR therefore involves experts from medical informatics, biometry, epidemiology, pharmacy, pharmacology and health care research from 21 institutions. In POLAR we will: 1. develop and use methods to collect retrospectively available patient related data on prescribed drugs from the hospital information systems of 13 university hospitals via their MII-infrastructures (data integration centres). 2. provide and deploy a set of algorithms, which are able to classify a selected range of medications as "high risk prescriptions”. 3. provide scoring systems to identify patients at high-risk for relevant drug-related problems. 4. identify and quantify the occurrence of major medication-related problems including PIM and contraindicated medications, frequent ADE and ADE-associated out-comes (e.g. new diagnoses, healthcare utilization, readmission, mortality). Special subprojects focus on (a) record linkage regarding 1-year mortality, and medication use and ADE in outpatient care, respectively, and (b) a text corpus for natural language processing with regard to ADE

Study status

Ongoing

Research institutions and networks

Institutions

Institute of Medical informatics, Statistics and Epidemiology (IMISE)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University Medical Centre Hamburg-Eppendorf

Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Heidelberg University Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University Medical Center Freiburg

Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

University Hospital Erlangen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Leipzig (University, University hospital) Jena (University, University hospital), Aachen (RWTH University, University hospital) University Hospital Hamburg-Eppendorf, Bonn (Rheinische Friedrich Wilhelms University, University hospital) University Hospital Halle, University Hospital Tübingen University Hospital LMU München, University Hospital Kiel University Hospital Heidelberg, University Hospital Gießen University Hospital Freiburg, F. Alexander University

Erlangen-Nürnberg University Hospital Erlangen, University Medicine Mannheim Witten/Herdecke University

Networks

German Medical Informatics Initiative (MII)

Contact details

Study institution contact

Markus Löffler

Study contact

markus.loeffler@imise.uni-leipzig.de

Primary lead investigator

Markus Löffler

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2020

Actual: 01/02/2020

Study start date
Planned: 01/02/2020

Actual: 01/02/2020

Data analysis start date
Planned: 01/01/2021

Date of interim report, if expected
Planned: 30/04/2021

Date of final study report
Planned: 28/02/2023

Sources of funding

- Other

More details on funding

Federal Ministry of Education and Research

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

https://www.medizininformatik-initiative.de/en/POLAR

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Analysis of adverse events leading to hospitalisation or occurring during the hospital stay. Establishing interoperable standards for analyzing routine clinical data in 13 university hospitals.

Main study objective:

It is the primary objective of this project to develop, implement and evaluate IT-based tools for the assessment of medication safety that can be shared and used across different university hospitals.

Study Design

Non-interventional study design

Cohort

Case-control

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Renal impaired

Estimated number of subjects

767000

Study design details

Outcomes

We will identify and quantify the occurrence of major drug-related problems including potentially inappropriate medications (PIMs) and contraindicated medications, frequent adverse drug events (ADE) and ADE-associated outcomes (e.g. new diagnoses, readmission to hospital, mortality). For example, we will analyse - associations of PIMs and adverse drug events (ADEs) - prevalences of contraindicated drug use with focus on high risk populations - potentially inadequate prescribing in renal insufficiency - ADE-related hospital admissions and readmissions due to suspected ADEs In addition, we will develop risk models for predicting ADEs. See study protocol for more detail

Data analysis plan

Descriptive analysis: absolute and relative frequencies, incidence, prevalence. Association studies (drug exposure - adverse (drug) event): Raw and adjusted regression models, Odd's ratios, relative risks depending on study design. For selected AE's (e.g. falls) validation studies will be conducted (ROC-analysis).

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Retrospective Analysis of Electronic Health Records used in university hospitals

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No