

# Realization of the clinical practice guidelines for diabetes in Finland – A case study of the usability of electronic patient information systems and national registers to support evidence based decision making in health care (ER12-9451)

**First published:** 14/06/2013

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS4117

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### Study ID

26958

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### DARWIN EU® study

No

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### Study countries

## Study description

This is a retrospective database linkage study using patient information system data from selected primary and specialty health care organisations with linkage to nationwide registers. The overall objective of the study is to evaluate whether the electronic patient information systems and national registers can be used to support evidence based decision making in health care. The specific scientific objectives are to evaluate how the key elements of the Current Care guideline for diabetes (by the Finnish Medical Society Duodecim) are realized in practice and to investigate which factors explain successful implementation of treatment recommendations.

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## Study status

Finalised

## Research institutions and networks

### Institutions

**EPID Research Oy**

**First published:** 01/02/2024

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**Institution**

### Contact details

### **Study institution contact**

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Study contact

[pasi.korhonen@epidresearch.com](mailto:pasi.korhonen@epidresearch.com)

### **Primary lead investigator**

Pasi Korhonen

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 27/12/2012

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### **Study start date**

Planned: 03/03/2014

Actual: 26/02/2014

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### **Data analysis start date**

Planned: 31/05/2016

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### **Date of final study report**

Planned: 30/09/2016

Actual: 09/08/2017

## Sources of funding

- Other

## More details on funding

Association: Pharma Industry Finland

## Study protocol

[Study protocol\\_ER12\\_9451\\_2013-04-30 Clean.pdf](#) (978.75 KB)

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Methodological, to study treatment guideline implementation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To evaluate whether the electronic patient information systems and national registers can be used to support evidence based decision making in health care. To evaluate how the key elements of the Current Care guideline for diabetes are realized in practice and to investigate which factors explain successful implementa of treatment recommendations.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(A10A) INSULINS AND ANALOGUES

INSULINS AND ANALOGUES

(A10B) BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

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### **Medical condition to be studied**

Type 2 diabetes mellitus

## **Population studied**

### **Short description of the study population**

All patients who have a diagnosis for diabetes (ICD-10 code E10\*, E11\*, E13\* or E14\*, or ICPC-2 code T89 or T90), a written prescription for diabetic medication (ATC code A10A\* or A10B\*), HbA1c value  $\geq$  6.5%, glucose tolerance test  $\geq$  11 mmol/L or nutrition counselling related to diabetes in the electronic patient information systems within the selected study sites, or patients who have purchased prescriptions for diabetic medication (ATC code A10A\* or A10B\*) or who have special reimbursement for diabetes (refund code 103) in the Social Insurance Institution (SII) registers during 2009-2012.

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### **Age groups**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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)
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### **Special population of interest**

Other

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## **Special population of interest, other**

Type 2 diabetes mellitus patients

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### **Estimated number of subjects**

89000

## **Study design details**

### **Outcomes**

- Diabetes medications and related measurements- Frequency of follow-up measurements - HbA1c and S-LDL- Follow-up measurements every 12 to 15 months - Follow-up measurements every 1-3 years- Treatment decisions (other than diabetes treatment) based on follow-up measurements, - Mortality- Health care resource use: visits, contacts and hospital/PHC inpatient admissions.- Amputations of the lower extremities- Absence from work- Severe hypoglycemic events

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### **Data analysis plan**

The baseline characteristics will be presented as number of cases and percentages separately for each study site and for all sites combined.

Appropriate statistical tests will be applied to statistically quantify any between site differences. Baseline characteristics include: • Age • Gender • Smoking • BMI • Dietary habits • Physical exercise • Concomitant disease • Concomitant medication • Laboratory measurements  
Realization of current care guidelines will be evaluated for each site separately and for all sites combined.

Appropriate statistical tests will be applied to statistically quantify between site differences. A (multi) logistic regression model will be used to model the study end-points with respect to the baseline covariates and study sites. When possible a binomial endpoint will be used (i.e. never vs. ever start of metformin or under 1 month vs. over 1 month to start of metformin).

## **Documents**

## Study results

[9451\\_LTRY\\_Diabetes\\_report\\_V1\\_2017-08-09\\_with appendices.pdf](#) (2.66 MB)

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## Study, other information

[Annex5\\_Declaration of Interest\\_Tirkkonen\\_signed.pdf](#) (1.62 MB)

## Study publications

[Niskanen L., Hahl J., Haukka J., Leppä E., Miettinen T., Mushnikov V., Sipilä ...](#)

[Sulamaa A., Prami T., Sipilä R., Linna M., Hahl J., Miettinen T., Leppä E., Hau...](#)

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# 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.

## Conflicts of interest of investigators

[Annex5\\_DoIForm\\_Pasi Korhonen\\_signed.pdf](#) (1.57 MB)

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## Composition of steering group and observers

[Annex5\\_Declaration\\_of\\_interest\\_FabianHoti\\_signed.pdf](#) (1.57 MB)

[EUPAS4117-4133.pdf](#) (50.34 KB)

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## Signed code of conduct

[Annex 3\\_Declaration on compliance\\_signed.pdf](#) (576.83 KB)

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## **Signed code of conduct checklist**

[Annex2\\_Checklist of the code of conduct\\_signed\\_blackandwhite.pdf](#) (204.19 KB)

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## **Signed checklist for study protocols**

[ER12-9451\\_ENCePPChecklistforStudyProtocols\\_Signed.pdf](#) (304.48 KB)

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# Data sources

## **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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## **Data sources (types), other**

Prescription event monitoring, Nationwide registers: Register for reimbursed medications Health insurance Sickness allowance register Hospital care register (discharge register) Hospital benchmarking database Causes of death registry

# Use of a Common Data Model (CDM)

## **CDM mapping**

No

# Data quality specifications

## **Check conformance**

Unknown

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## **Check completeness**

Unknown

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## **Check stability**

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown