EE198

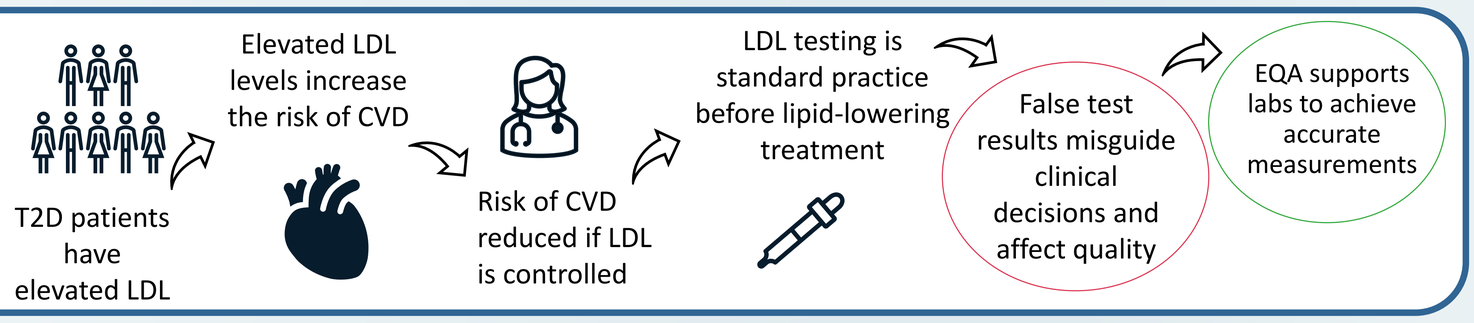
# Integrating Health Economic Analysis into External Quality Assessment of Laboratory Tests

## - Evaluating Costs and Consequences of Bias in Lipid Tests in the Prevention of Cardiovascular Disease in Swedish Diabetes Patients

**G. Keel, M. Karlsson, S. Tähti, L. Galkus, F. Örneholm, P. Lindgren**

## BACKGROUND

Lipid screening is routine in type 2 diabetes (T2D) care for preventing cardiovascular disease. External quality assessment (EQA) of testing has demonstrated that bias is inherent to equipment and methods used in LDL testing.

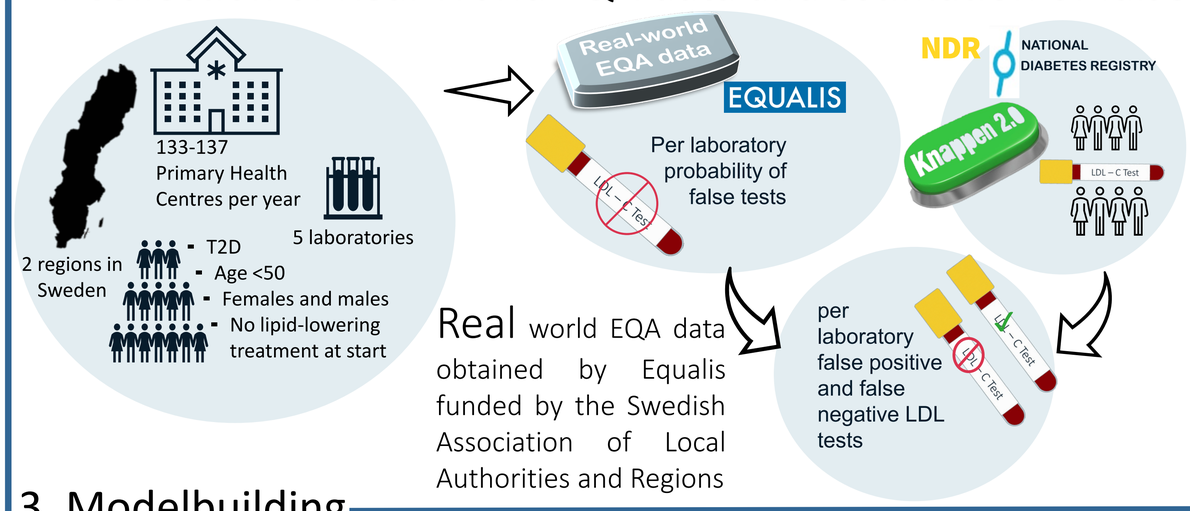



## AIM

To demonstrate that health economic methods can be incorporated into EQA practices through estimating the costs and consequences of bias in LDL testing methods among T2D patients in two geographic regions in Sweden.

## METHOD

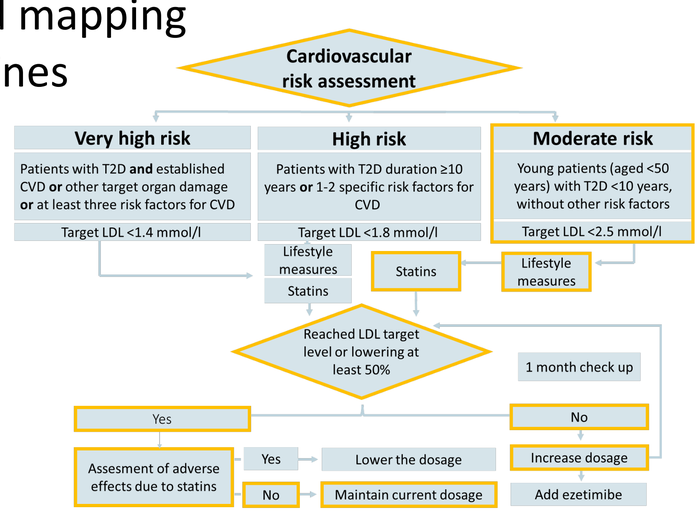
### 1. Collection of Real World EQA data and estimation of false test counts




Data on patients above & below the LDL threshold per laboratory were obtained from the NDR. EQA data provided bias rates applied to these counts to quantify false tests per laboratory.

### 2. Reviewing and mapping of clinical guidelines

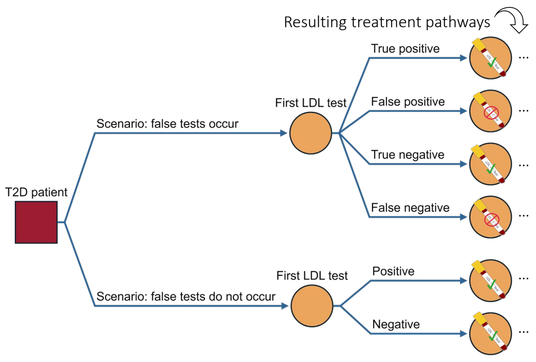
A Swedish primary care physician was consulted to clarify how guidelines were interpreted and applied in practice. The mapped guidelines were adjusted accordingly and used as the basis for cost estimation in the short-term model (see below).




### 3. Modelbuilding

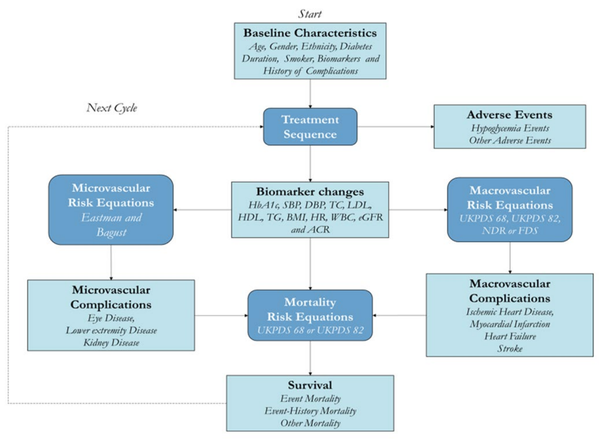
#### A) Short term model (3 years)

A Decision tree model was designed according to clinical guidelines. False positive & negative rates were used to estimate the short-term cost of correcting bias in LDL tests, as compared to labs making no change to methodology.




#### B) Long term model (40 years)

IHE-DCM- an internationally applied health economic Markov model developed by the Swedish Institute for Health Economics (IHE) for analysis within the T2D treatment space. The model is formally validated by the Assessment of the Validation Status of Health-Economic Decision Models and deemed acceptable for use in decision making by the Swedish Pharmaceutical Benefits. Outputs included costs, clinical outcomes and quality of life. The model predicted macrovascular events associated with CVD including myocardial infarction, ischemic heart disease, stroke, and heart failure.




## RESULTS

### A) Short term model (3 years)

| | w/o false tests | w/ false tests | Change |
|---|---|---|---|
| False positive patients | | 2 338 | -2 338 |
| False negative patients | | 3 611 | -3 611 |
| True positive patients | 4 097 | 2 948 | 1 149 |
| True negative patients | 65 155 | 60 355 | 4 800 |
| Total cost (million SEK) | 3656 | 355 | 11 |

- The total cost difference over 3 years was SEK 11 million
- Costs increase when false negatives are corrected as more patients are being treated

### B) Long term model (40 years), cumulative cost effects for full regional populations

| | Consequences of correcting false negatives | Consequences of correcting false positives | Net |
|---|---|---|---|
| **QALYs** | 29 | -13 | 16 |
| Total Cost (SEK) | -890 729 | 322 824 | -567 905 |
| Treatment costs | 2 230 168 | -1 097 128 | 1 133 040 |
| Microvascular costs | 269 591 | 121 441 | 148 150 |
| Macrovascular costs | 3 390 488 | 1 541 392 | -1 849 095 |

| CV events | Failure to treat false negatives | Treatment of False positives | Correction of false tests |
|---|---|---|---|
| **Ischemic Heart Disease** | +4.7 | -2.2 | -2.5 |
| **Myocardial Infarction** | +4.5 | -2.1 | -2.4 |
| **Stroke** | +0.9 | -0.4 | -0.5 |
| **Heart Failure** | +0.3 | -4.9 | -0.2 |

- Correcting false testing resulted in a savings of SEK 1.8 million and avoided 5.6 macrovascular events.
- Positive effects of statins occur for all patients, including those experiencing false positives. Thus, correcting false positive tests increases macrovascular event rates.

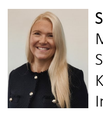
## CONCLUSIONS, LIMITATIONS AND FUTURE DIRECTIONS

- The health economic results of EQA could quantify the effects of bias on individual patients, and thus allow for increased patient safety through minimizing the risk of improper treatment.
- They also demonstrate the impact of decisions made within laboratory medicine for healthcare stakeholders such as decision makers, management, clinicians, and most importantly, patients.
- False-positive patients usually do not experience the positive impacts of the drug treatment. However, this does highlight a degree of incongruence between evidence and guidelines.
- Next, we will analyze LDL across Sweden and initiate a study on prostate-specific antigen (PSA) testing

## WHO WE ARE



George Keel, PhD
Research Manager
The Swedish Institute for Health Economics (IHE)


Sonja Tähti
Master's Student
Karolinska Institutet (KI)


Filip Örneholm
Data scientist, Equalis


Mathias Karlsson, MD, PhD
CEO, Equalis


Lukas Galkus
Master's Student
KI


Peter Lindgren
Managing Director, IHE
Professor, KI


An interdisciplinary team of researchers exploring 1) how health economic methods can be applied to quantify the impact of eliminating bias in health care laboratory testing through EQA, and 2) how to incorporate these findings into the modification of clinical guidelines.

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Contact: george.keel@ihe.se