Example from clinical research

Soffia Gudbjörnsdottir
Swedish National Diabetes Register (NDR)
The Swedish National Diabetes Register

- To improve diabetes care
- Started 1996
- Internet-based quality registry
- Interactive statistical reports
- Immediate access real-time results and comparative national statistics
- Local quality control
- Benchmarking-public results
- Ideally, all diabetic patients should be registered once every year
- >90% of all patients with diabetes
Number of patients registered in NDR

Nationella Diabetesregistret, Registercentrum VGR, Göteborg
<table>
<thead>
<tr>
<th>Clinical characteristics</th>
<th>Treatments</th>
<th>Complications</th>
<th>Processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of registration</td>
<td>Microalbuminuria</td>
<td>Diabetic nephropathy</td>
<td>S-Creatinine</td>
</tr>
<tr>
<td>Caregiver code</td>
<td>Diabetic nephropathy</td>
<td>Ischemic heart disease</td>
<td>Stroke</td>
</tr>
<tr>
<td>Social security number</td>
<td>Creatinine</td>
<td>Amputation</td>
<td>Impairment</td>
</tr>
<tr>
<td>Year of diabetes onset</td>
<td>Stroke</td>
<td>Fundoscopy/retinal photo</td>
<td>Examination</td>
</tr>
<tr>
<td>Type of diabetes</td>
<td>Ischemic heart disease</td>
<td>HbA1c</td>
<td>Amputation</td>
</tr>
<tr>
<td>Diabetes treatment</td>
<td>Cardiovascular disease</td>
<td>Visual impairment</td>
<td>Smoking</td>
</tr>
<tr>
<td>HbA1c</td>
<td>Diabetes</td>
<td>Artificial limb</td>
<td>Physical activity</td>
</tr>
<tr>
<td>Height &amp; weight</td>
<td>Cardiac</td>
<td>Ischemic heart disease</td>
<td>Physical activity</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Hypertension</td>
<td>Amputation</td>
<td>Physical activity</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>Hypertension</td>
<td>Complications</td>
<td>Physical activity</td>
</tr>
<tr>
<td>Blood lipids</td>
<td>Hypertension</td>
<td>Ischemic heart disease</td>
<td>Physical activity</td>
</tr>
<tr>
<td>Lipid-lowering treatment</td>
<td>Lipid-lowering</td>
<td>Hypertension</td>
<td>Physical activity</td>
</tr>
<tr>
<td>Aspirin treatment</td>
<td>Lipid-lowering</td>
<td>Hypertension</td>
<td>Physical activity</td>
</tr>
</tbody>
</table>

SWEDISH NATIONAL DIABETES REGISTER
An integrated risk model for clinicians

The NDR risk model for 5-year risk of CVD

- 58-year old man with DM2
- Diabetes duration 5 years
- HbA1c 8.0%
- BMI 32 kg/m²
- Systolic BP 150 mmHg
- Total cholesterol 4.3 mmol/l
- HDL cholesterol 1.0 mmol/l
- Non-smoker
- Macroalbuminuria
- No atrial fibrillation
- No previous CVD

ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD
Real-time statistics publicly available
Real-time statistics publicly available

### Indicators

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Time period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andel Blodtryck &lt; 130/80</td>
<td>2013 - Helår</td>
</tr>
</tbody>
</table>

### Patient group

- Diabetes type: Typ 2 diabetes (incl. MODY)
- Gender: Alla

### Clinic or PC

- Clinic type: Medicinsklinisk
- Age group: Alla

Show results
LDL <2,5 mmol/l in patients with lipid lowering drugs

Andel LDL <2,5, lipidsänkande läkemedel

Primary care

Nationella Diabetesregistret, Registercentrum VGR, Göteborg
Personal Identity Number

Prescribed Drug Register

Medical Birth Register

National Patient Register

Causes of Death Register

Other Quality Register

Education Register (Statistics Sweden)

Cancer Register

SWEDISH NATIONAL DIABETES REGISTER
Type-1 diabetes – common in young adults

CONCLUSIONS:
The incidence of type 1 diabetes in patients aged 34 and younger was two to three times higher than previously reported. The registries can be used to reliably assess incidence rates in this age group.
41-45 years

56-60 years

The Lancet 2011; 378: 140–6

Glycaemic control and incidence of heart failure in 20 985 patients with type 1 diabetes: an observational study

Marcus Lind, Ioannis Bounias, Marita Olsson, Soffia Gudbjörnsdottir, Ann-Marie Svensson, Annika Rosenqren
The relationship between glycaemic control and heart failure in 83,021 patients with type 2 diabetes

Conclusion
- Heart failure should be considered a major diabetic complication in type 1 and 2 diabetes
- Glycaemic control is an independent risk factor of heart failure in type 1 and type 2 diabetes.
- Good glycaemic control could prevent heart failure
Glycemic Control and Excess Mortality in Type 1 Diabetes

Marcus Lind, M.D., Ph.D., Ann-Marie Svensson, Ph.D., Mikhail Kosiborod, M.D., Soffia Gudbjörnsdottir, M.D., Ph.D., Aldina Pivodic, M.Sc., Hans Wedel, Ph.D., Sofia Dahlqvist, Mark Clements, M.D., Ph.D., and Annika Rosengren, M.D., Ph.D.

The NEW ENGLAND JOURNAL of MEDICINE

Glycemic Control and Excess Mortality in Type 1 Diabetes

Marcus Lind, M.D., Ph.D., Ann-Marie Svensson, Ph.D., Mikhail Kosiborod, M.D., Soffia Gudbjörnsdottir, M.D., Ph.D., Aldina Pivodic, M.Sc., Hans Wedel, Ph.D., Sofia Dahlqvist, Mark Clements, M.D., Ph.D., and Annika Rosengren, M.D., Ph.D.

ABSTRACT

BACKGROUND

The excess risk of death from any cause and of death from cardiovascular causes is unknown among patients with type 1 diabetes and various levels of glycemic control.
Registry-based observational study to determine the excess risk of death according to the level of glycemic control in Swedish population of persons with type 1 diabetes.

For each patient, five controls were selected from the general population and matched according to age, sex and county.
Hazard ratio (relative risk) for death (total and CVD) for Persons with type-1 diabetes compared with controls - by sex and age

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Type 1 Diabetes</th>
<th>Reference</th>
<th>Hazard Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. of events (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Death from any cause</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–34 yr</td>
<td>160 (1.6)</td>
<td>283 (0.6)</td>
<td>2.84 (2.34–3.45)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>35–49 yr</td>
<td>428 (8.9)</td>
<td>524 (2.2)</td>
<td>4.26 (3.75–4.84)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>50–64 yr</td>
<td>631 (21.6)</td>
<td>1217 (8.4)</td>
<td>2.86 (2.60–3.15)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>367 (50.3)</td>
<td>1046 (29.2)</td>
<td>2.20 (1.96–2.48)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>18–34 yr</td>
<td>90 (1.1)</td>
<td>110 (0.3)</td>
<td>4.11 (3.11–5.43)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>35–49 yr</td>
<td>239 (6.2)</td>
<td>280 (1.4)</td>
<td>4.39 (3.70–5.22)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>50–64 yr</td>
<td>482 (19.6)</td>
<td>638 (5.2)</td>
<td>4.17 (3.70–4.69)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>304 (43.4)</td>
<td>737 (21.3)</td>
<td>2.62 (2.29–3.00)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Death from cardiovascular causes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>18–34 yr</td>
<td>18 (0.2)</td>
<td>26 (0.1)</td>
<td>3.49 (1.91–6.36)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>35–49 yr</td>
<td>144 (3.0)</td>
<td>140 (0.6)</td>
<td>5.36 (4.25–6.77)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>50–64 yr</td>
<td>238 (8.2)</td>
<td>414 (2.9)</td>
<td>3.17 (2.70–3.72)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>149 (20.4)</td>
<td>416 (11.6)</td>
<td>2.25 (1.87–2.72)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–34 yr</td>
<td>11 (0.1)</td>
<td>8 (0.0)</td>
<td>6.94 (2.79–17.25)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>35–49 yr</td>
<td>67 (1.7)</td>
<td>46 (0.2)</td>
<td>7.50 (5.16–10.92)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>50–64 yr</td>
<td>161 (6.5)</td>
<td>112 (0.9)</td>
<td>7.92 (6.22–10.08)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥65 yr</td>
<td>139 (19.8)</td>
<td>282 (8.1)</td>
<td>3.12 (2.55–3.83)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Conclusions

Patients with type 1 diabetes and good metabolic control, \( HbA1c \leq 6.9\% \) (52 mmol/mol) – had a risk of death from any cause or from cardiovascular causes that was twice as high as the risk for matched controls.
Patients with type 1 diabetes have a loss of life expectancy at age 20 years of approximately 12 years, compared with the general population.

Livingstone et al, JAMA, 2015
What’s new in type 1 diabetes?

• It is more common than we thought
• HbA1c is strongly related to heart failure
• It is associated with increased mortality, and diminished life-expectancy
• There are modifiable risk factors...

HAVE WE IMPROVED PROGNOSIS IN TYPE 1 DIABETES?
The Swedish National Diabetes Register

• Excellent opportunities for long-term studies of a large (and increasing) patient population; epidemiology, health economics, cancer, cardiology, therapy, social sciences and so on

• > 70 original scientific papers – Good collaborations!
  • Annika Rosengren
  • Marcus Lind

• PROM (Patient Reported Outcome Measurements) - A new area to explore

• Risk factor control is improving
• Much less variation between units
• NDR is an important tool for improvement
• Real-time statistics, publicly available
• Focus on PROM
• Focus on early diagnosis
Clinical Use and Effectiveness of Lipid Lowering Therapies in Diabetes Mellitus—An Observational Study from the Swedish National Diabetes Register

Björn Eliasson¹*, Ann-Marie Svensson², Mervete Miftaraj², Junmei Miao Jonasson²,³, Katarina Eeg-Olofsson¹, Karolina Andersson Sundell⁴, Soffia Gudbjörnsdóttir¹,²

¹Department of Medicine, University of Gothenburg, Sahlgrenska University Hospital, Göteborg, Sweden, ²National Diabetes Register (NDR), Göteborg, Sweden, ³Department of Oncology, Institute of Clinical Sciences, University of Göteborg, Göteborg, Sweden, ⁴Nordic School of Public Health, Göteborg, Sweden
The triglycerides-to-HDL-cholesterol ratio and cardiovascular disease risk in obese patients with type 2 diabetes: An observational study from the Swedish National Diabetes Register (NDR)

Katarina Eeg-Olofsson a,*, Soffia Gudbjörnsdottir a, Björn Eliasson a, Björn Zethelius b, Jan Cederholm c on behalf of the NDR

aDepartment of Medicine, Sahlgrenska University Hospital, University of Gothenburg, Gothenburg, Sweden
bDepartment of Public Health and Caring Sciences/Geriatrics, Uppsala University, and Medical Products Agency, Uppsala, Sweden
cDepartment of Public Health and Caring Sciences/Family Medicine and Preventive Medicine, Uppsala University, Uppsala, Sweden
Fig. 1 – Hazard ratios (95% CI) for outcomes with categories of BMI and TG:HDL < 1.9 or ≥1.9, fully adjusted by model 2 (age, sex, smoking, and a history of CVD, diabetes duration, HbA1c, type of hypoglycaemic treatment, systolic BP, LDL cholesterol, cumulative albuminuria), in 54,061 patients with type 2 diabetes aged 30–74 years
Level of physical activity associated with risk of cardiovascular diseases and mortality in patients with type-2 diabetes: report from the Swedish National Diabetes Register

B Zethelius¹,², S Gudbjörnsdottir³, B Eliasson³, K Eeg-Olofsson³ and J Cederholm¹ (on behalf of the Swedish National Diabetes Register)

Main conclusions: Low physical activity -> 25% greater risk of coronary and cardiovascular events than high activity, and 70% greater risk of a fatal CV event.