Hur använder vi vid UCR guldgruvan för pragmatiska studier

- exempel från UCR

Lars Wallentin, Professor Cardiology, Uppsala University and Uppsala Clinical Research Center
SWEDEHEART history

- Regional CCU registry 1989
- Swedish Heart Surgery registry 1992
- RIKS-HIA - National CCU registry 1995
- SCAAR – Coronary angiography and PCI 1998
- Internet platform - RIKS-HIA & SCAAR 2000 - 2002
- UCR National Registry Center 2002
- SEPHIA – secondary prevention, rehabilitation 2005
- Åland connected 2005
- Iceland connected 2008
- SWEDEHEART 2009
- Percutaneous valve interventions 2010
The Cardiology Audit and Registration Data Standards (CARDS), European data standards for clinical cardiology practice

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KEYWORDS
- Data standards;
- Clinical audit;
- Service planning;
- Acute coronary syndromes;
- Percutaneous coronary interventions;
- Pacemaker;
- ICD;
- Cardiac ablation

Aims Systematic registration of data from clinical practice is important for clinical care, local, national and international registries, and audit. Data to be collected for these different purposes should be harmonized. Therefore, during Ireland’s Presidency of the European Union (EU) (January to June 2004), the Department of Health and Children worked with the European Society of Cardiology, the Irish Cardiac Society, and the European Commission to develop data standards for clinical cardiology. The Cardiology Audit and Registration Data Standards (CARDS) Project aimed to agree standards for three modules of cardiovascular health information systems: acute coronary syndromes (ACS), percutaneous coronary interventions (PCI), and clinical electrophysiology (heart failure, implantable cardioverter-defibrillators...
The Swedish personal identification number

320102-1314

year  month  day  place  sex  ctrl
A selection of mandatory Swedish national registries

<table>
<thead>
<tr>
<th>Registry</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swedish Population Registry</td>
<td>Place of residency; country of own and parents’ birth; marital status</td>
</tr>
<tr>
<td>Swedish Censuses</td>
<td>Socioeconomic group; education; income; sick leave</td>
</tr>
<tr>
<td>Swedish National Insurance Agency</td>
<td>Sick leave, pensions</td>
</tr>
<tr>
<td>Swedish Education Registry</td>
<td>Highest education</td>
</tr>
<tr>
<td>Swedish 9th Grade Registry</td>
<td>Junior high school grades</td>
</tr>
<tr>
<td>Swedish Multi-Generation Registry</td>
<td>Number of children and siblings; identity of parents if born after 1932</td>
</tr>
<tr>
<td>Swedish Medical Birth Registry (since 1973)</td>
<td>Numbers of pregnancies and births; pregnancy outcomes</td>
</tr>
<tr>
<td>Swedish Prescription Registry (since 2005)</td>
<td>Pharmacy-expedited drug prescriptions</td>
</tr>
<tr>
<td>Swedish In-Patient Registry (since 1987)</td>
<td>All diagnoses of all hospitalisations; surgical and other procedures</td>
</tr>
<tr>
<td>Swedish Cancer Registry (since the 50’s)</td>
<td>All cancer diagnoses</td>
</tr>
<tr>
<td>Swedish Cause-of Death Registry</td>
<td>Causes of death, including contributing factors</td>
</tr>
<tr>
<td>Swedish Out-Patient Registries (since 2005)</td>
<td>Hospital-based -&gt; mandatory; primary care -&gt; voluntary</td>
</tr>
</tbody>
</table>
Aims of SWEDHEART

To support development and implementation of evidence-based therapy in coronary artery disease and catheter-based or surgical valve intervention:

– To monitor changes in quality and clinical practice over time

– To support continuous quality improvement

– To form the basis for research on coronary artery disease and valve interventions.
SWEDHEART

Caregiver

Patient

Electronic Patient-records

Other Health registries

Central server

Research db
Early revascularisation and 1-year survival in 14-day survivors of acute myocardial infarction: a prospective cohort study

Ulf Stenestrand, Lars Wallentin

Lancet 2002; 359: 1805–11

Long-term Outcome of Primary Percutaneous Coronary Intervention vs Prehospital and In-Hospital Thrombolysis for Patients With ST-Elevation Myocardial Infarction

Ulf Stenestrand, MD, PhD
Johan Lindbäck, MSc
Lars Wallentin, MD, PhD
for the RIKS-HIA Registry

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Anticoagulation Therapy in Atrial Fibrillation in Combination With Acute Myocardial Infarction Influences Long-Term Outcome: A Prospective Cohort Study From the Register of Information and Knowledge About Swedish Heart Intensive Care Admissions (RIKS-HIA)

Ulf Stenestrand, Johan Lindbäck, Lars Wallentin and for the RIKS-HIA Registry
Circulation 2005;112;3225-3231

The NEW ENGLAND JOURNAL of MEDICINE

Long-Term Outcomes with Drug-Eluting Stents versus Bare-Metal Stents in Sweden

Bo Lagerqvist, M.D., Ph.D., Stefan K. James, M.D., Ph.D.,
Ulf Stenestrand, M.D., Ph.D., Johan Lindbäck, M.Sc., Tage Nilsson, M.D., Ph.D.,
and Lars Wallentin, M.D., Ph.D., for the SCAAR Study Group
1-year mortality by county and hospital

Död inom ett år

<table>
<thead>
<tr>
<th>Mortality Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yellow</td>
</tr>
<tr>
<td>Orange</td>
</tr>
<tr>
<td>Orange Red</td>
</tr>
<tr>
<td>Red</td>
</tr>
<tr>
<td>Dark Red</td>
</tr>
</tbody>
</table>

- Yellow: 6.3–7.4%
- Orange: 7.4–7.8%
- Orange Red: 7.9–8.2%
- Red: 8.2–9.0%
- Dark Red: 9.2–11.2%

Map shows the distribution of mortality rates across different counties in Sweden.
Difference between expected and actual 1-year mortality including CI and adjusted for patient mix
Hospital therapy traditions influence long-term survival in patients with acute myocardial infarction

Ulf Stenestrand, MD, PhD, Johan Lindbäck, and Lars Wallentin, MD, PhD, for the Register of Information and Knowledge about Swedish Heart Intensive care Admissions (RIKS-HIA) Linköping and Uppsala, Sweden

A. Reperfusion treatment in STEMI

B. Heparin or LMWH in MI

C. Revascularization < 14d after MI

- Hospital with catheterization laboratory
- Hospital without catheterization laboratory

Activity index in 2000 vs. Activity index in 1999
Hospital therapy traditions influence long-term survival in patients with acute myocardial infarction

Ulf Stenebrand, MD, PhD, Johan Lindbäck, and Lars Wallentin, MD, PhD, for the Register of Information and Knowledge about Swedish Heart Intensive care Admissions (RIKS-HIA) Linköping and Uppsala, Sweden

Correlation of the hospitals’ activity index to (A) hospital size (Spearman r = 0.23, P = 0.059) and (B) 1-year mortality (Spearman r = -0.30, P = .014). Activity index was calculated as the mean rank of the 6 interventions: intravenous heparin or subcutaneous LMWH, intravenous β-blockers, intravenous nitroglycerin, echocardiography, revascularization within 14 days, and discharge prescription of statins. The line represents a kernel smoother.

Conclusions Even after adjustment for differences in patient characteristics, there are differences between the hospital treatment cultures for patients with AMI that persists over time. Concerning everywhere-available treatment options, the treatment activity is independent of the size of the center. A more active treatment tradition is associated with a lower short- and long-term mortality in AMI patients. (Am Heart J 2005;149:82-90.)
### Quality score for improvement of care

<table>
<thead>
<tr>
<th>RIKS-HIA Quality score</th>
<th>0.5 points</th>
<th>1 points</th>
</tr>
</thead>
</table>

**Reperfusion for STEMI/LBBB.**
- 80% (85%) for STEMI/LBBB within recommended time

**Coronary angiogram for target population with NSTEMI**
- 75% (80%) for NSTEMI

**LMW Heparin/ Heparin/ Fondaparinux for NSTEMI**
- 90% (95%)

**ASA, other platelet inhibitor or anticoag for MI**
- 90% (95%)

**P2Y12-blocker for NSTEMI**
- 85% (90%)

**Betablocker for MI.**
- 85% (90%)

**Lipid lowerer post MI**
- 90% (95%)

**ACEinh/ARB for target population post MI.**
- 85% (90%)
Acute myocardial infarction: a comparison of short-term survival in national outcome registries in Sweden and the UK

Sheng-Chia Chung, Rolf Gedeborg, Owen Nicholas, Stefan James, Anders Jeppsson, Charles Wolfe, Peter Heuschmann, Lars Wallentin, John Deanfield, Adam Timmis, Tomas Jernberg, Harry Hemingway
Controlled, prospective study

Strategy trials by cluster randomization

All hospitals connected to RIKS-HIA were invited to participate in the study.

The study was divided into 4 phases:

- Hospital participation in RIKS-HIA
- QUICC
- Control

<table>
<thead>
<tr>
<th>Group A</th>
<th>Group B</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Education & Implementation

Measurement I

Baseline measurement

01/07/01 - 30/06/02

Measurement II

01/05/03 - 30/04/04

Follow-up

01/07/01 - 30/06/02 01/05/03 - 30/04/04
Quality Improvement in acute Coronary Care Trials

Outcomes, Health Policy, and Managed Care

Improved adherence to Swedish national guidelines for acute myocardial infarction: The Quality Improvement in Coronary Care (QUICC) study

Rickard Carlhed, MD, MSc,a Mats Bojestig, MD, PhD, b Lars Wallentin, MD, PhD,a Gunilla Lindström, RN,a Anette Peterson, RN,b Christina Åberg, RN,a and Bertil Lindahl, MD, PhDa for the QUICC study group

Uppsala and Eksjö, Sweden

Improving guideline adherence through intensive quality improvement and the use of a National Quality Register in Sweden for acute myocardial infarction

Peterson, Anette RN; Carlhed, Rickard MD; Lindahl, Bertil MD, PhD; Lindstrom, Gunilla RN; Aberg, Christina RN; Andersson-Gare, Boel MD, PhD; Bojestig, Mats MD, PhD

Quality Management in Health Care. 2007; 16(1):25-37
Registry Randomized Clinical Trial - RRCT

- New concept for clinical research
- Integrates a randomized study with a clinical registry
- Complement to classical RCT

A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis

Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D., Anders Frost, M.D., Ph.D., Fredrik Borgström, Ph.D., Peter Fritzell, M.D., Ph.D., Patrik Öhagen, Karl Michaëlsson, M.D., Ph.D., and Bengt Sandén, M.D., Ph.D.

Table 4. Resource Use.*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Fusion Group</th>
<th>Decompression-Alone Group</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>During the procedure</td>
<td>(N = 113)</td>
<td>(N = 119)</td>
<td></td>
</tr>
<tr>
<td>Length of hospital stay (days)</td>
<td>7.4±8.4</td>
<td>4.1±6.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mean operation costs (U.S. $)†</td>
<td>12,200</td>
<td>5,400</td>
<td></td>
</tr>
</tbody>
</table>
SWEDEPAD
SWEdish Drug Elution trial in Peripheral Arterial Disease, N=2480

SWEDEVASC registry

Hypothesis
Drug eluting devices (DEB/DES) are superior to conventional endovascular therapy:
Lower amputation incidence for critical ischemia (SWEDEPAD 1)
Improved health related QoL with claudication (SWEDEPAD 2)

Funding: Heart-lung foundation. Swedish Research council (VR) and several stent manufacturers (Bard norden AB, Biosensors Europe, Boston Scientific, Cook Sweden AB, Eps Vascular AB, Meliora Medtech
Registry-based randomized clinical trials—a new clinical trial paradigm

Stefan James, Sunil V. Rao and Christopher B. Granger

Abstract | Randomized clinical trials provide the foundation of clinical evidence to guide physicians in their selection of treatment options. Importantly, randomization is the only reliable method to control for confounding factors when comparing treatment groups. However, randomized trials have limitations, including the increasingly prohibitive costs of conducting adequately powered studies. Local and national regulatory requirements, delays in approval, and unnecessary trial processes have led to increased costs and decreased efficiency. Another limitation is that clinical trials involve selected patients who are treated according to protocols that might not represent real-world practice. A possible solution is registry-based randomized clinical trials. By including a randomization module in a large inclusive clinical registry with unselected consecutive enrolment, the advantages of a prospective randomized trial can be combined with the strengths of a large-scale all-comers clinical registry. We believe that prospective registry-based randomized clinical trials are a powerful tool for conducting studies efficiently and cost-effectively.

James, S. et al. Nat. Rev. Cardiol. 12, 312–316 (2015); published online 17 March 2015; doi:10.1038/nrcardio.2015.33