Hur använder vi vid UCR

guldgruvan för pragmatiska studier

- exempel från UCR

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

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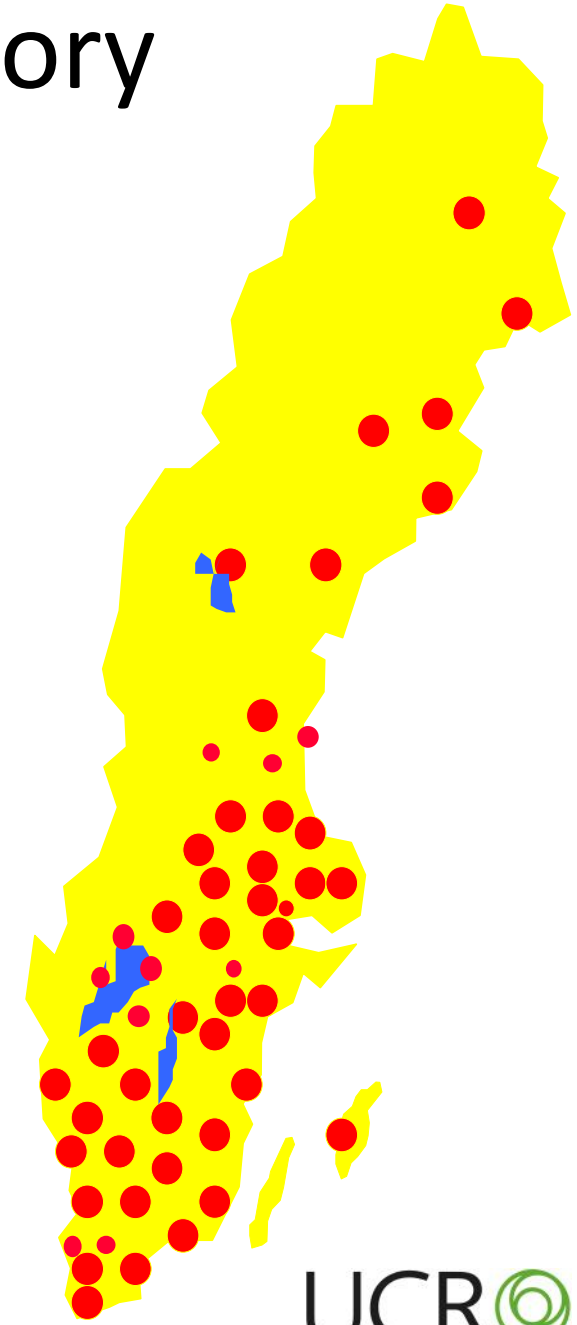
SWEDEHEART history

- 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



European Heart Journal (2005) 26, 308–313
doi:10.1093/eurheartj/ehi079

Special article

The Cardiology Audit and Registration Data Standards (CARDS), European data standards for clinical cardiology practice

M. Rachel Flynn[1], Conor Barrett[2], Francisco G. Cosío[3], Anselm K. Gitt[4], Lars Wallentin[5], Peter Kearney[6], Moira Lonergan[1], Emer Shelley[1], and Maarten L. Simoons[7]*

[1] *Department of Epidemiology and Public Health, Royal College of Surgeons in Ireland, Dublin 2, Ireland*
[2] *Cardiology Departments, Cork University Hospital, Cork and Mater Misericordiae University Hospital, Dublin, Ireland*
[3] *Cardiology Department, Hospital Universitario de Getafe, Madrid, Spain*
[4] *Cardiology Department, Ludwigshafen, Germany*
[5] *Uppsala Clinical Research Centre, University Hospital Uppsala, Sweden*
[6] *Cardiology Department, Cork University Hospital, Cork, Ireland*
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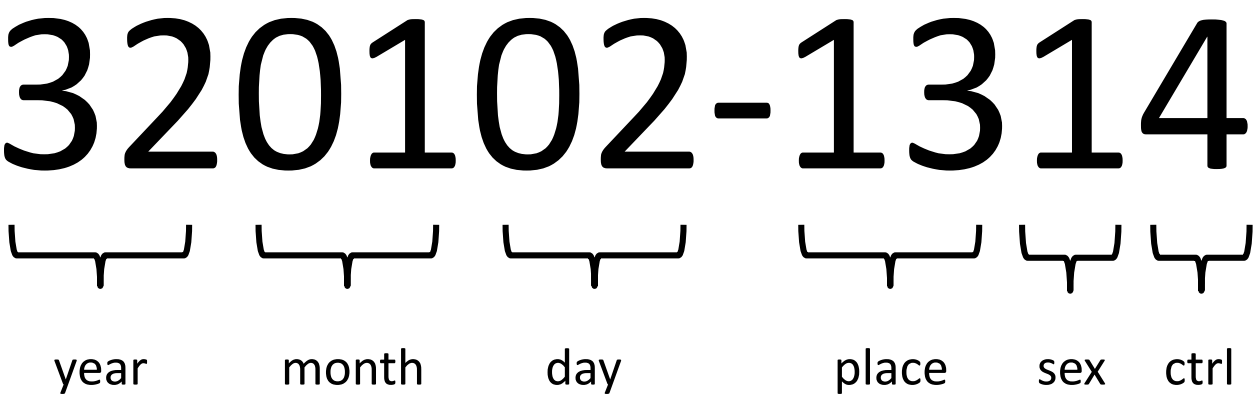
Received 2 November 2004; accepted 18 November 2004; online publish-ahead-of-print 17 December 2004

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 (pacemakers, implantable cardioverter defibrilla-

The Swedish personal identification number



A selection of mandatory Swedish national registries

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

Aims of SWEDEHEART

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.

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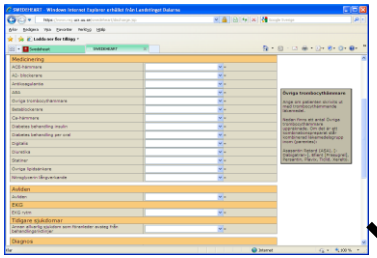
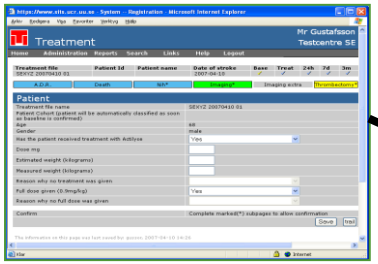
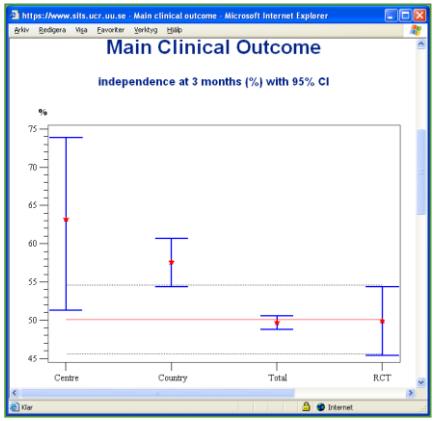
SWEDEHEART

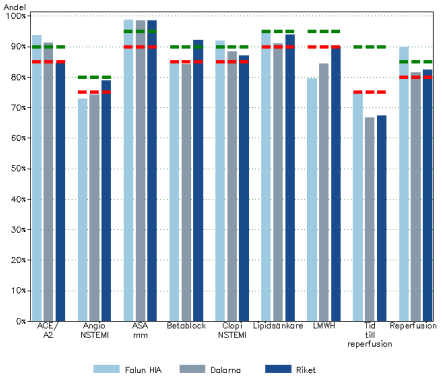
Caregiver



Patient







Electronic Patient-records

Other Health registries

Central server

Research db

UPPSALA UNIVERSITET
Karolinska Institutet
Linköpings universitet
LUNDS UNIVERSITET
GÖTEBORGS UNIVERSITET
UMEÅ UNIVERSITET

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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

JAMA. 2006;296:1749-1756

Context Whether the superior results of percutaneous coronary intervention (PCI) repc rdial in- farcl :tice has been questioned, especially whether it is superior to prehospital thrombolysis (PHT).

Objective To evaluate the outcome of different reperfusion strategies in consecu-

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

ORIGINAL ARTICLE

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*

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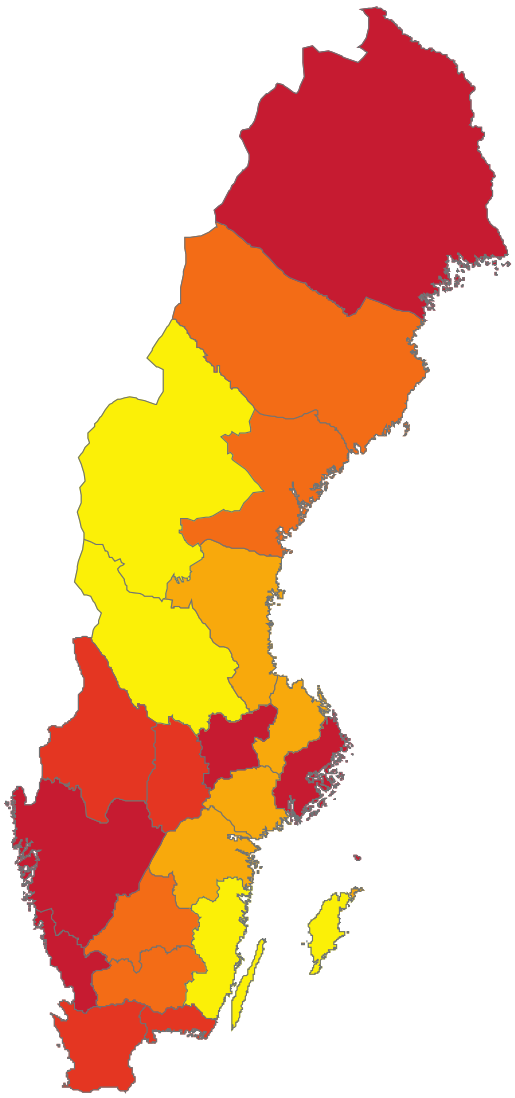
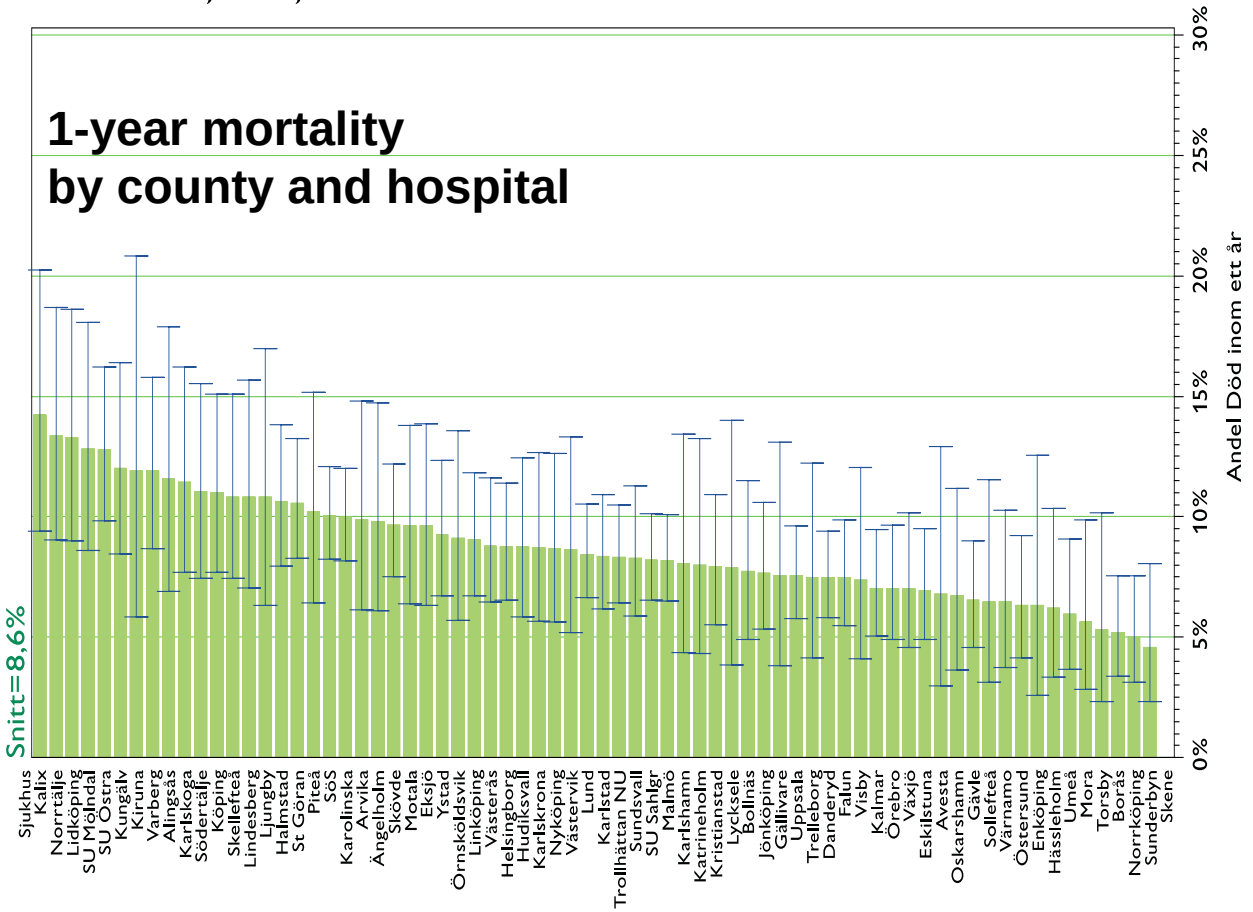
Treatment of acute MI in Sweden 2012

2012

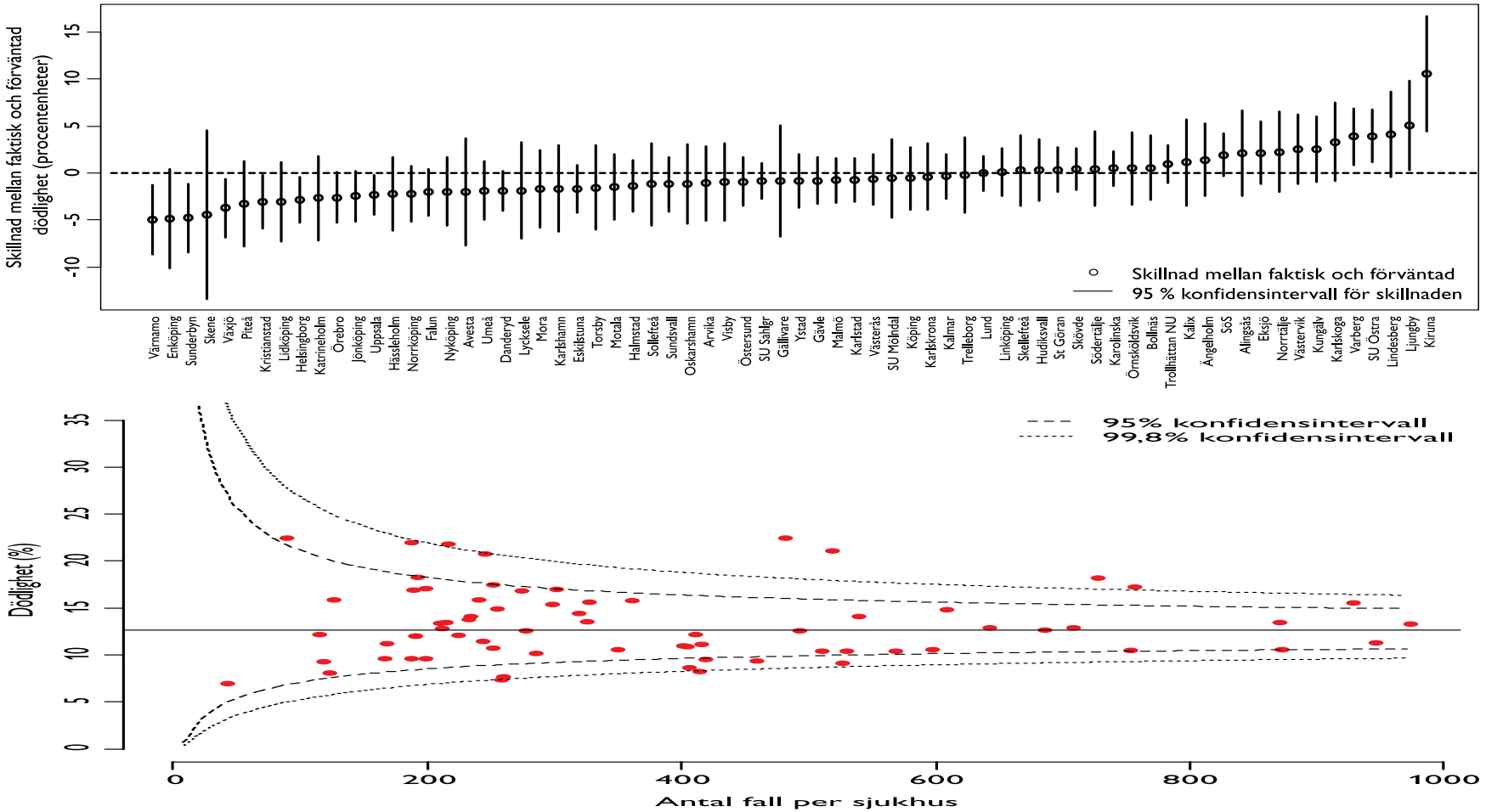


Död inom ett år

- 6,3–7,4%
- 7,4–7,8%
- 7,9–8,2%
- 8,2–9,0%
- 9,2–11,2%

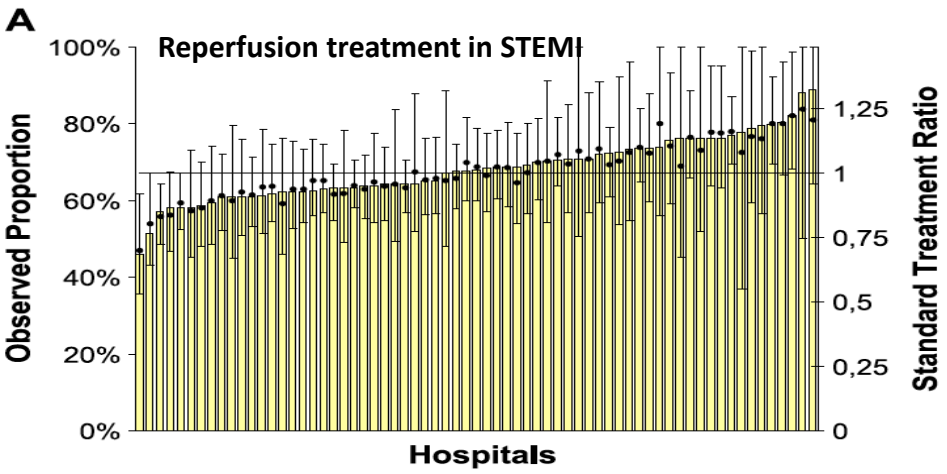


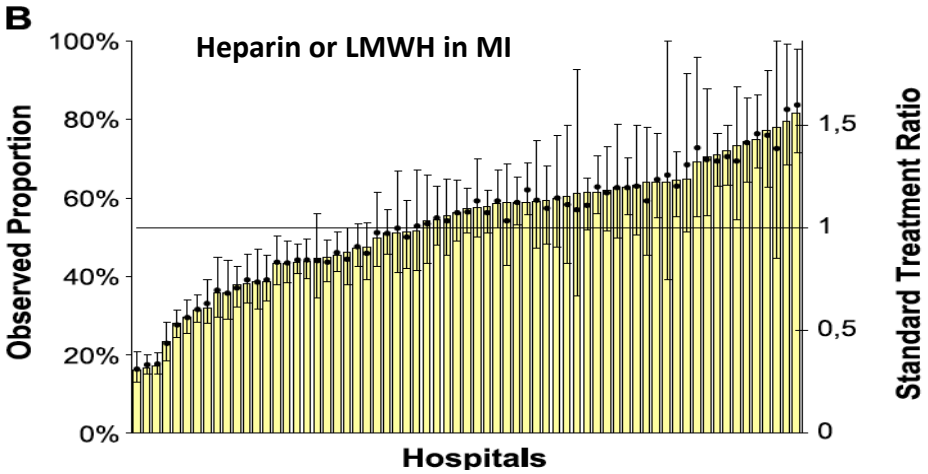
Difference between expected and actual 1-year mortality including CI and adjusted for patient mix

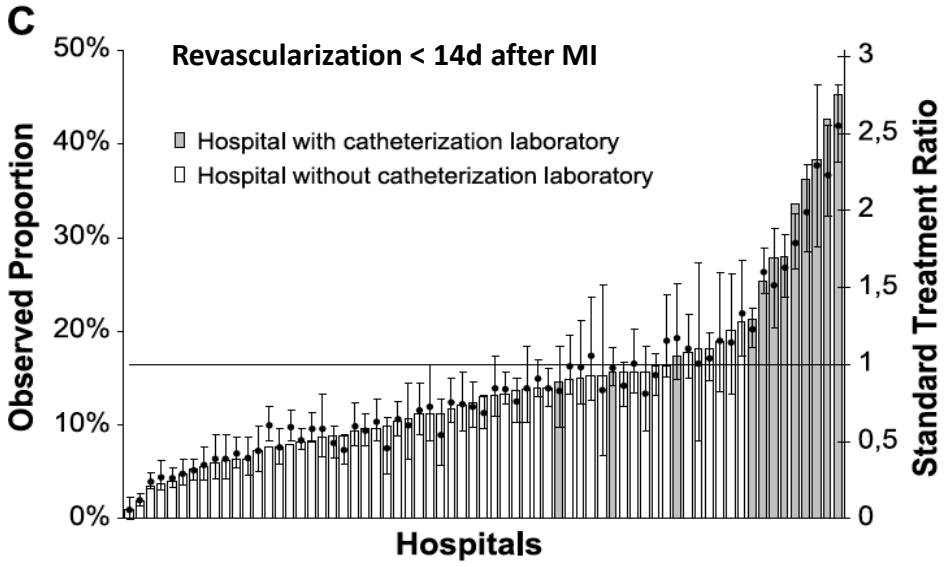


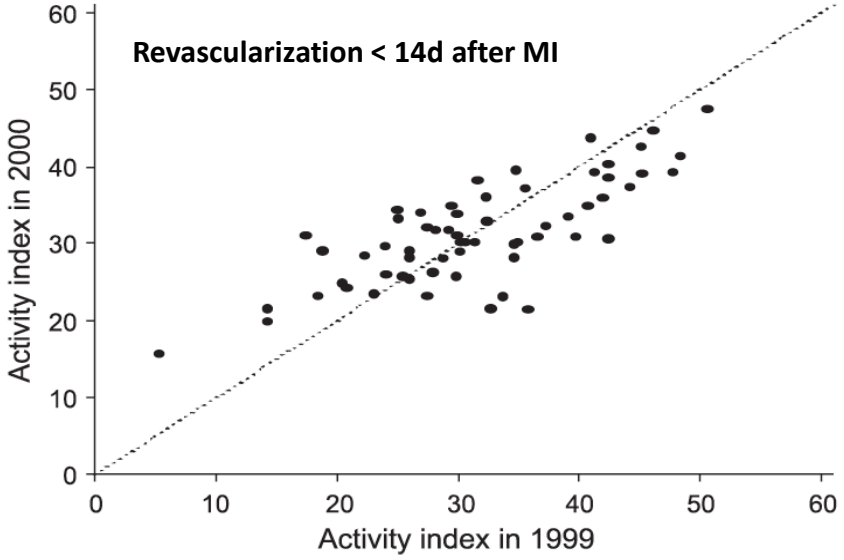
Hospital therapy traditions influence long-term survival in patients with acute myocardial infarction

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





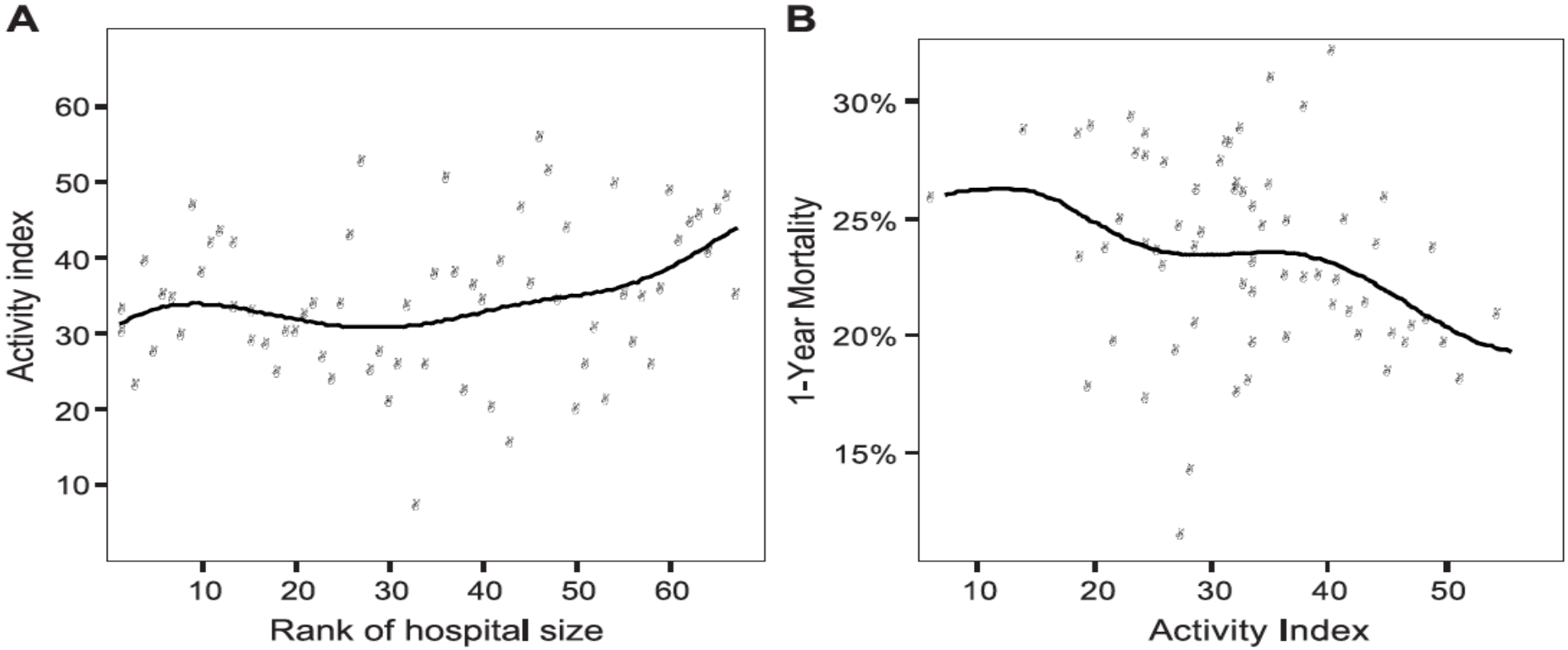




Hospital therapy traditions influence long-term survival in patients with acute myocardial infarction

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

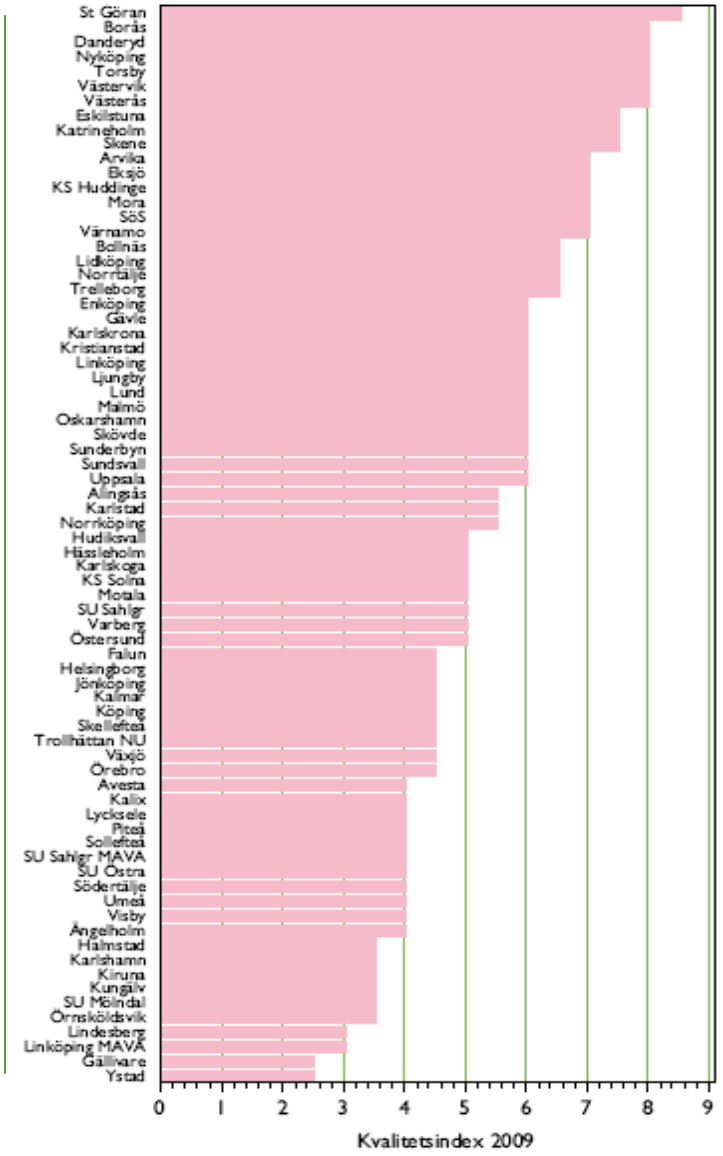
Correlation of the hospitals' activity index to **(A)** hospital size (Spearman $r = 0.23$, $P = 0.059$) and **(B)** 1-year mortality (Spearman $r = -0.30$, $P = .014$). Activity index was calculated as the mean rank of the 6 interventions: intravenous heparin or subcutaneous LMWH, intravenous β-blockers,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



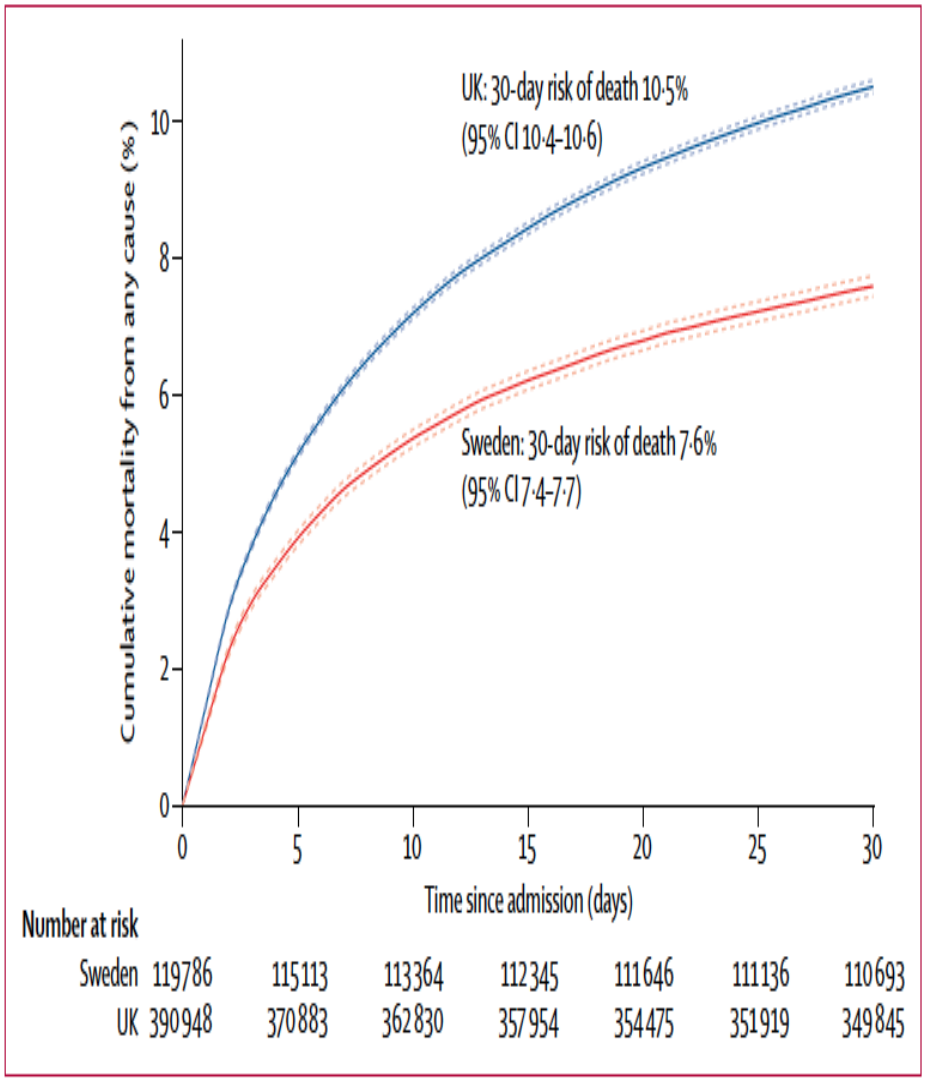
Conclusions Even after adjustment for differences in patient characteristics, there are differences between the hospital treatment cultures for patients with AMI that persists over time. Concerning everywhere-available treatment options, the treatment activity is independent of the size of the center. 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.)

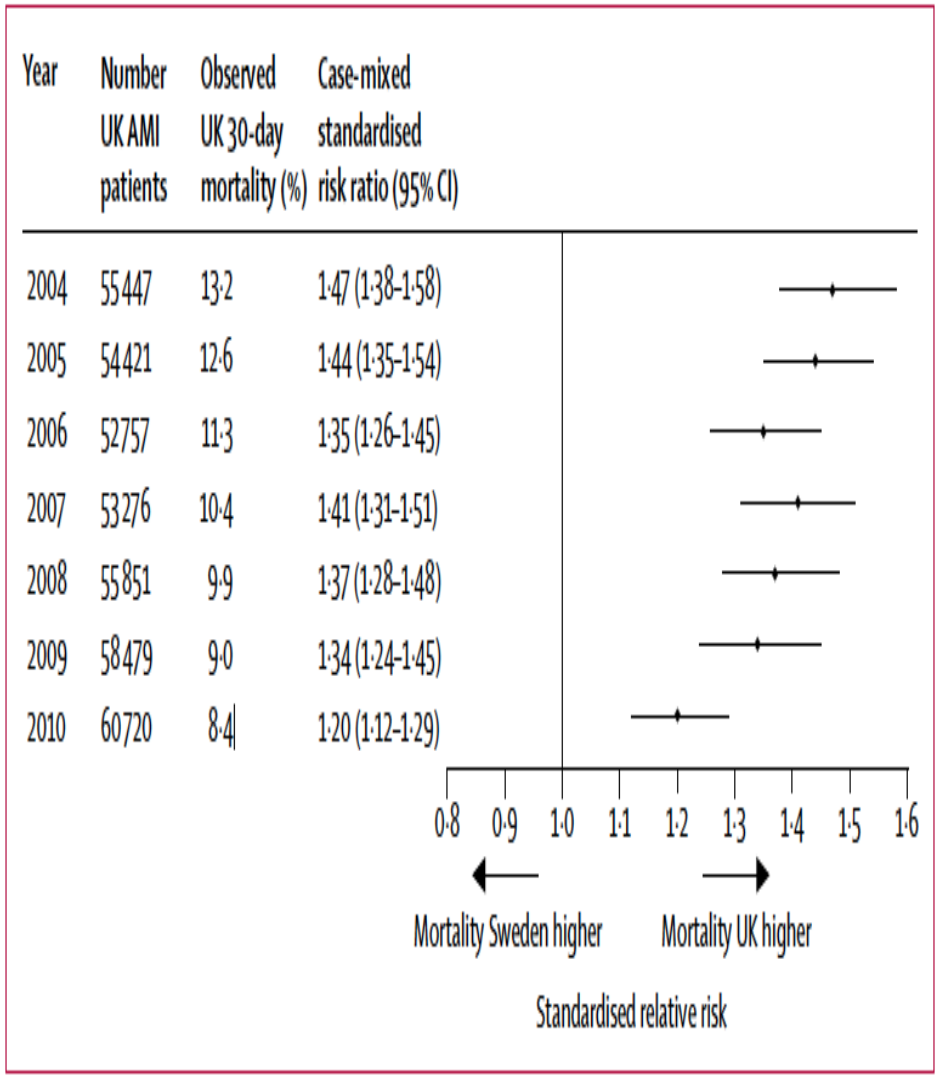
Quality score for improvement of care

RIKS-HIA Quality score	0,5 points	1 points
Reperfusion for STEMI/LBBB.	80%	85%
Reperfusion for STEMI/LBBB within recommended time	75%	90%
Coronnary angiogram for target population with NSTEMI	75%	80%
LMW Heparin/ Heparin/ Fondaparinux for NSTEMI	90%	95%
ASA, other platelet inibitor 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%



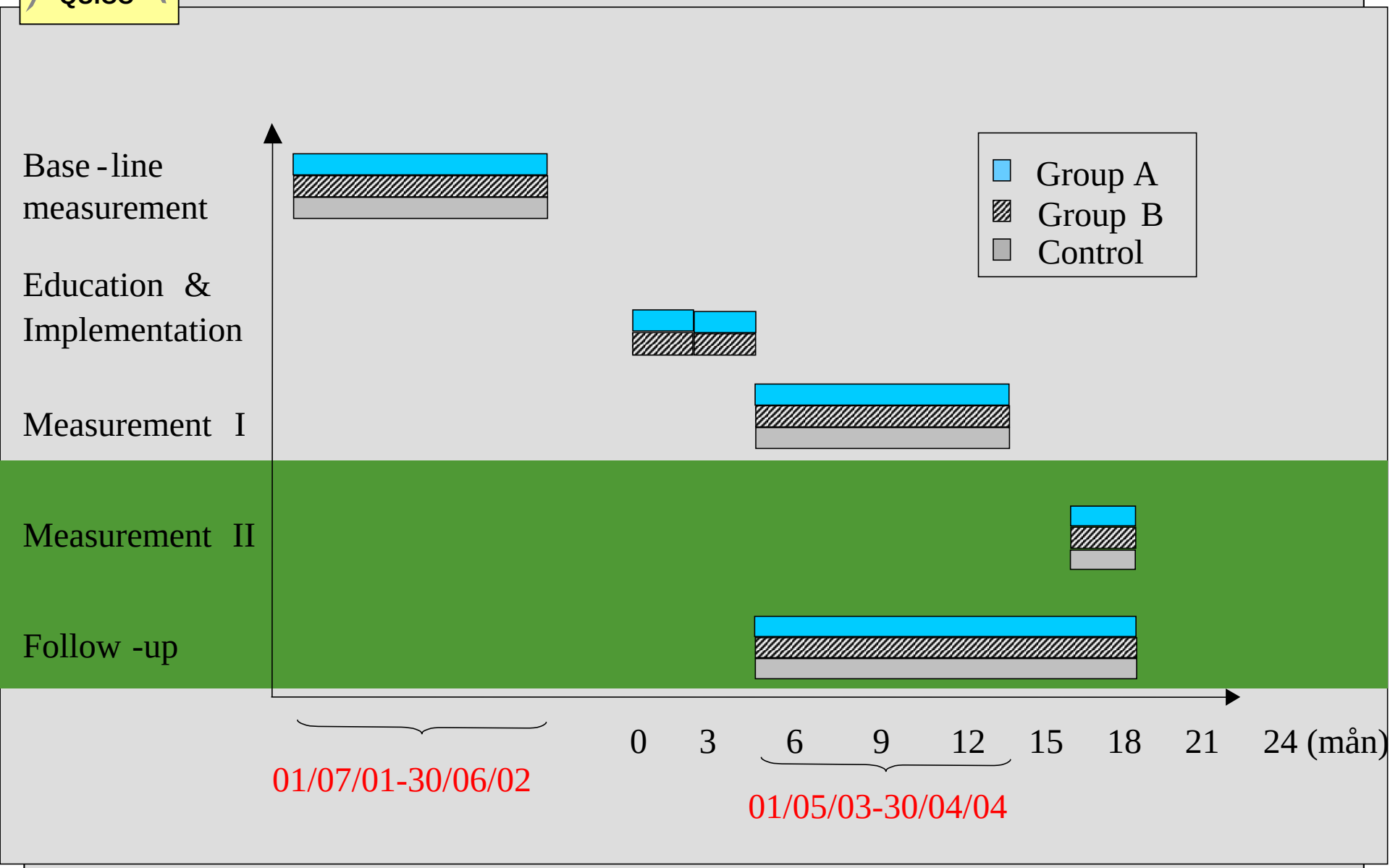
Acute myocardial infarction: a comparison of short-term survival in national outcome registries in Sweden and the UK





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

Strategy trials by cluster randomizationon



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, PhD[a] for the QUICC study group
Uppsala and Eksjö, Sweden

(Am Heart J 2006;152:1175-81.)

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

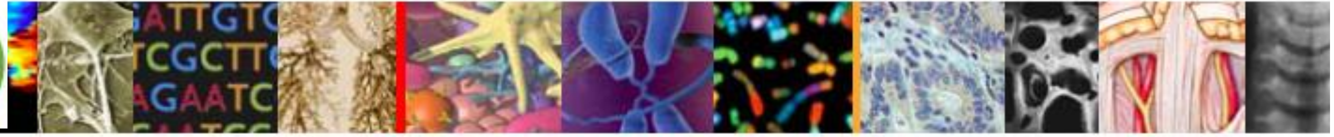
Improved Clinical Outcome After Acute Myocardial Infarction in Hospitals Participating in a Swedish Quality Improvement Initiative

Rickard Carlhed, Mats Bojestig, Anette Peterson, Christina Åberg, Hans Garmo and Bertil Lindahl

Circ Cardiovasc Qual Outcomes 2009;2;458-464; originally published online September 1, 2009;

Cluster-randomized trial to evaluate the effects of a quality improvement program on management of non–ST-elevation acute coronary syndromes: The European Quality Improvement Programme for Acute Coronary Syndromes (EQUIP-ACS)

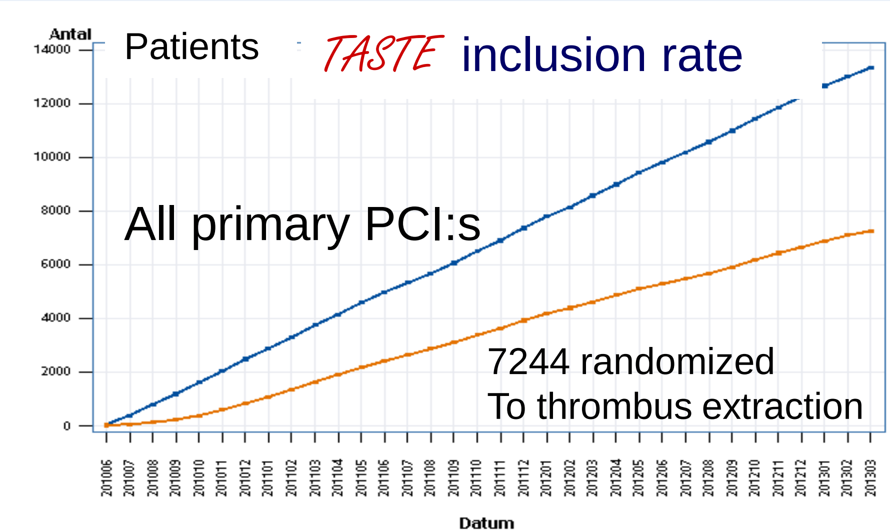
Marcus D. Flather, MBBS, FRCP,[a,b,k] Daphne Babalis, MSci,[a,b,k] Jean Booth, MSc,[a,k] Alfredo Bardaji, MD, PhD, FESC,[c,k] Jacques Machecourt, MD, FESC,[d,k] Grzegorz Opolski, MD, PhD, FESC,[e,k] Filippo Ottani, MD,[f,k] Héctor Bueno, MD, PhD,[g,k] Winston Banya, MSc,[a,b,k] Anthony R. Brady, MSc,[h,k] Mats Bojestig, MD, PhD,[i,k] and Bertil Lindahl, MD, PhD[j,k] *London, United Kingdom; Tarragona, and Madrid, Spain; Grenoble, France; Warsaw, Poland; Forli, Italy; and Jönköping, and Uppsala, Sweden*

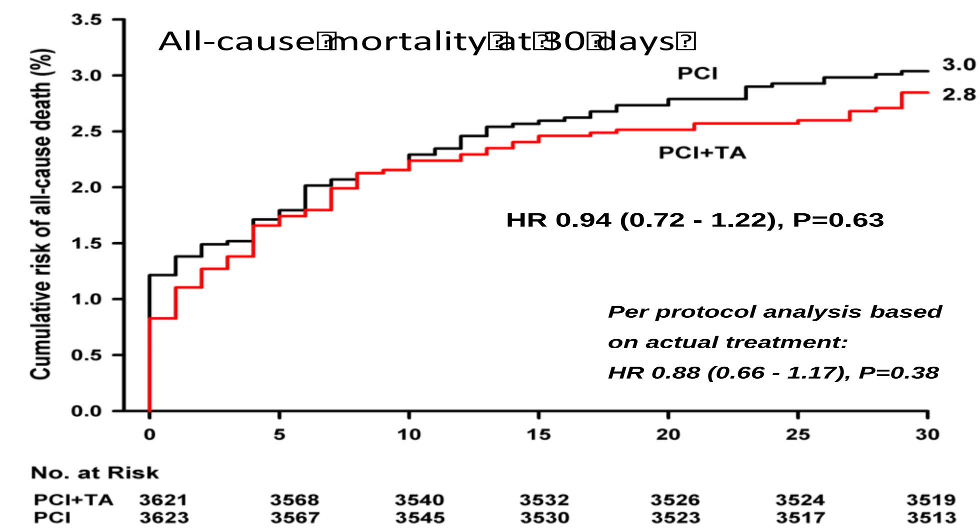


The NEW ENGLAND JOURNAL of MEDICINE

The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.





Registry Randomized Clinical Trial - RRCT

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

Fröbert O, Lagerqvist B, James S NEJM 2013, 2014

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2016 VOL. 374 NO. 15

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

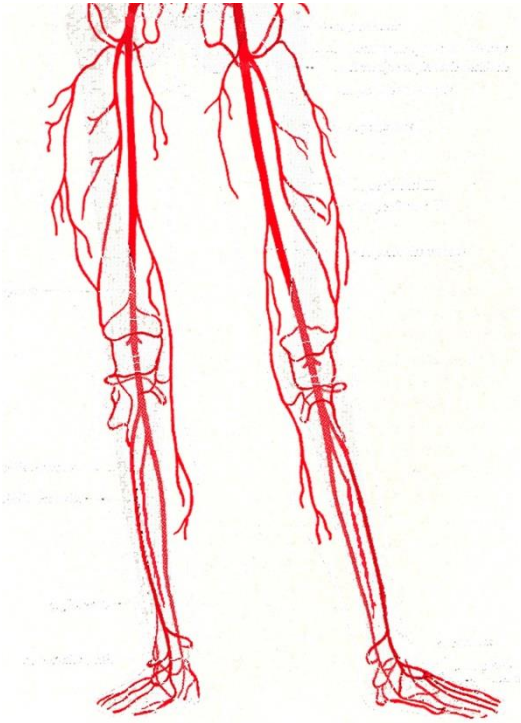
Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D., Anders Frost, M.D., Ph.D., Fredrik Borgström, Ph.D., Peter Fritzell, M.D., Ph.D., Patrik Öhagen, Karl Michaëlsson, M.D., Ph.D., and Bengt Sandén, M.D., Ph.D.

Table 4. Resource Use.*

Variable	Fusion Group	Decompression-Alone Group	P Value
During the procedure	**(N=113)**	**(N=119)**	
Length of hospital stay (days)	7.4±8.4	4.1±6.1	<0.001
Mean operation costs (U.S. $)†	12,200	5,400	

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

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PERSPECTIVES

OPINION

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/nrcadio.2015.33

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