Bottom-up building approach and cooperation with government - the SwedeHeart registry

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My disclosure

- I do not have any disclosure on current topic.
- I do not have any conflict of interest on current topic.

K-RCCVC to benchmark the SwedeHeart

The Swedish National Quality Registries

ROK and Sweden

- **General information in ROK and Sweden.**

ROK		Sweden
100,201 Km^2	Geographic area	444,964 Km^2
51,515,399 (‘15)	Population	9,753,627 (‘15)
505.1/Km^2	Population density	20/Km^2
$ 1,377,873.11 Million	GDP	$492,618.07 Million (‘15)
$ 27,221.5	GDP/capita	$50,272.9 (‘15)
7.4% (‘14)	Healthcare expenditure/GDP	11.9% (‘14)

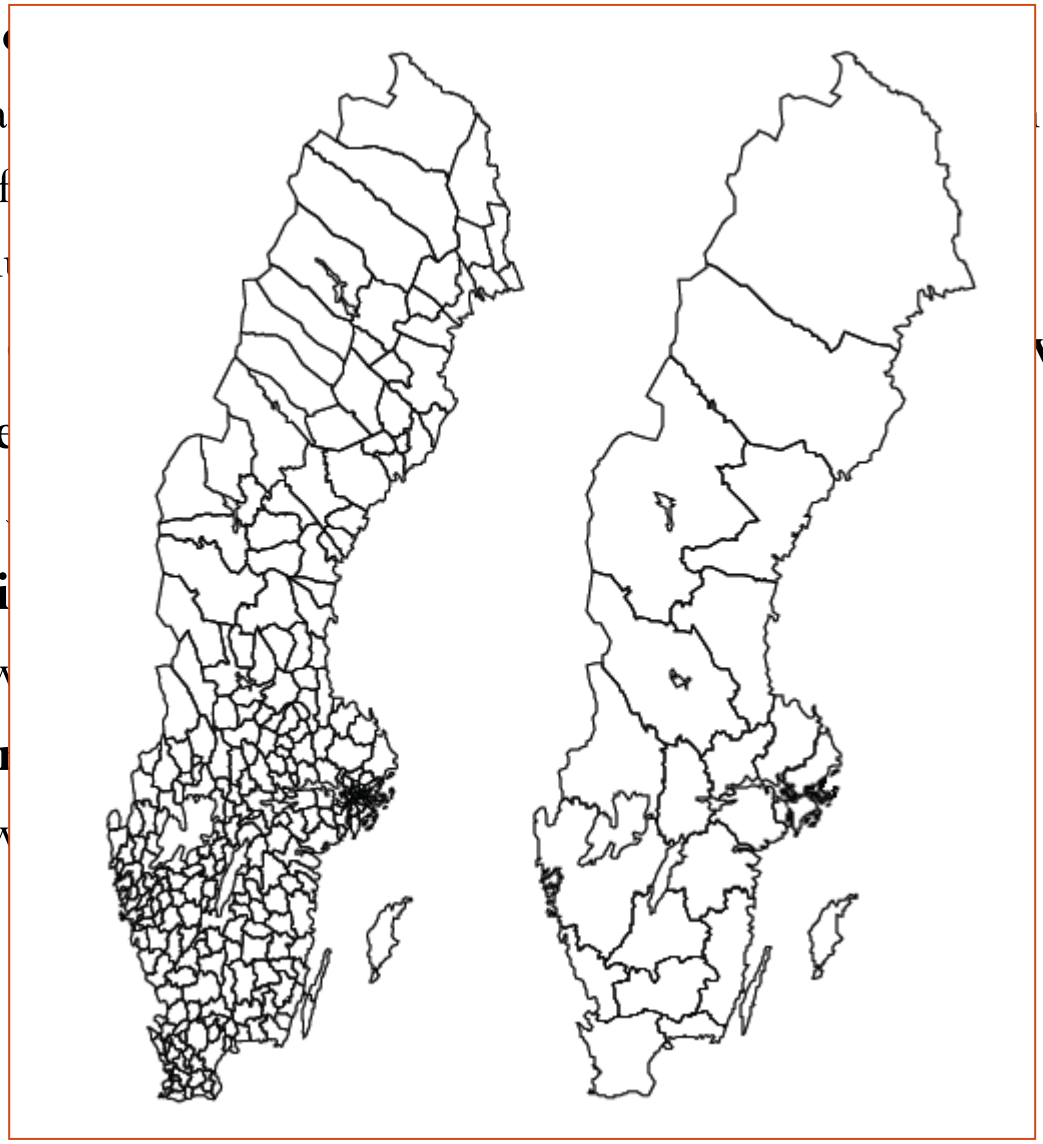
http://data.worldbank.org/indicator/NY.GDP.PCAP.CD

Swedish Health Care

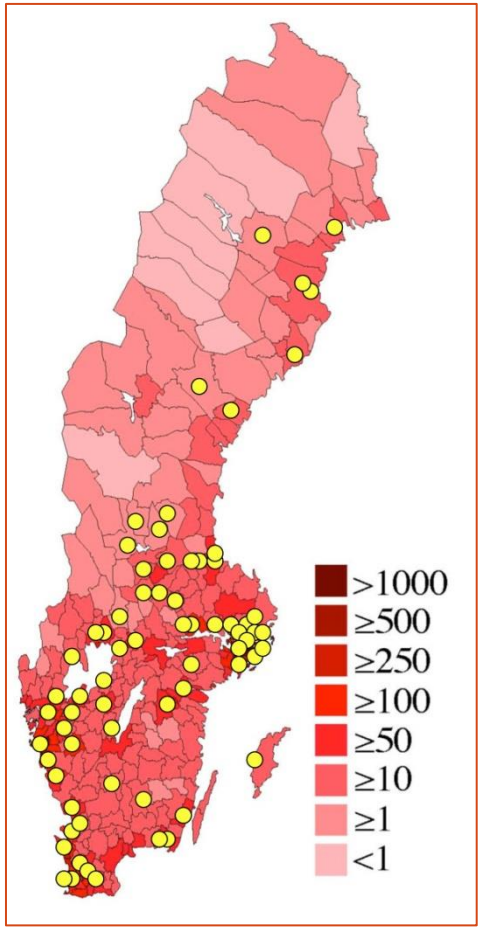
- **Decentralizati**
  - Municipalities a
  - Strong local self
  - State-county-mu
- **Right to taxes**
- **Financing of se**
  - 70%: Taxes > 1
- **290 municipali**
  - Population betw
- **21 county cou**
  - Population betw

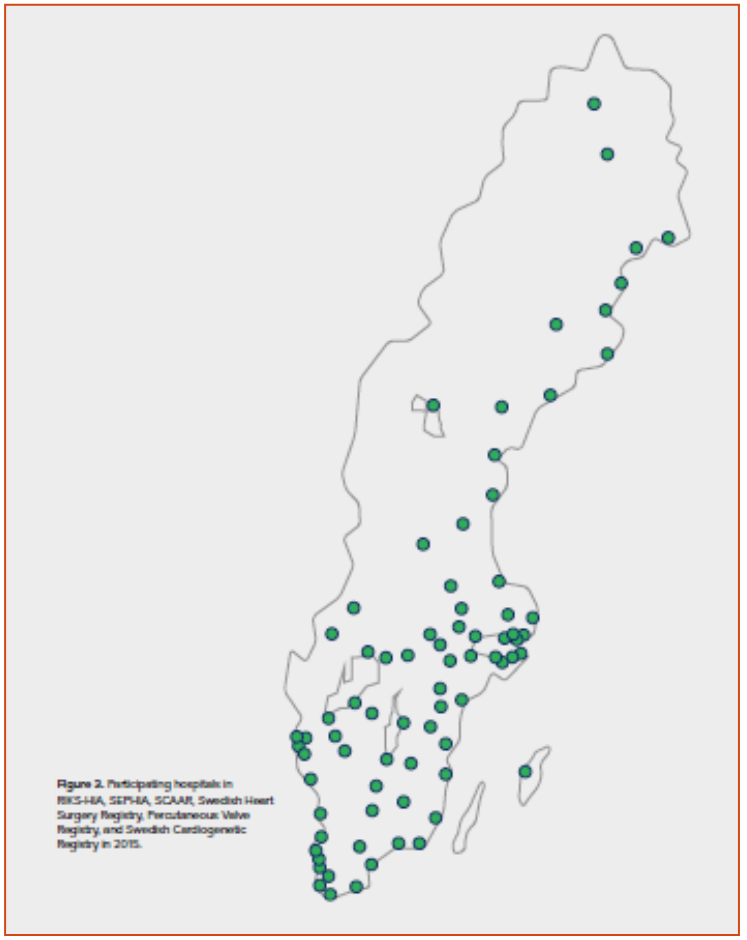
of public services

vices

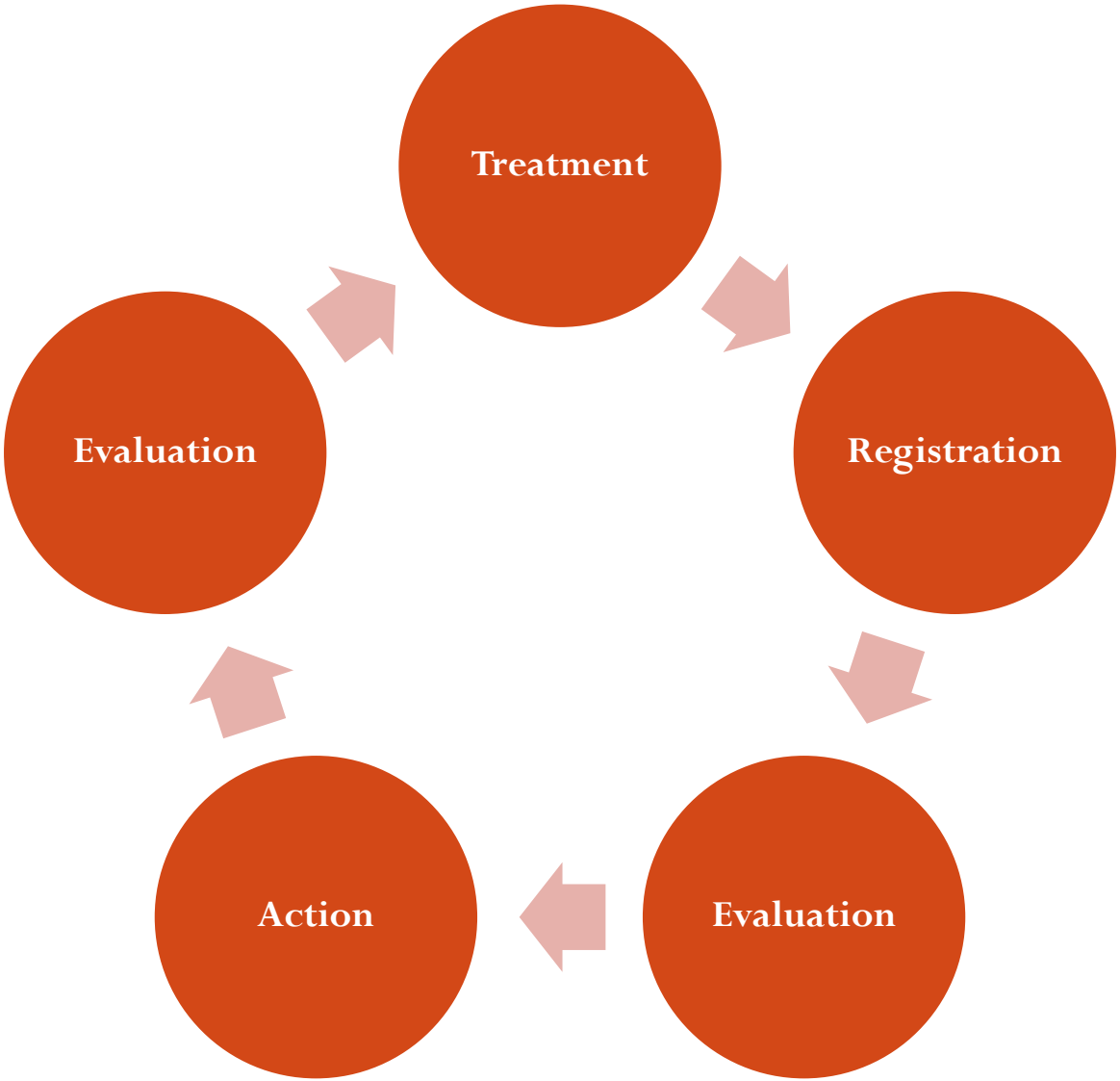


Swedish Health Care





Nationwide registry

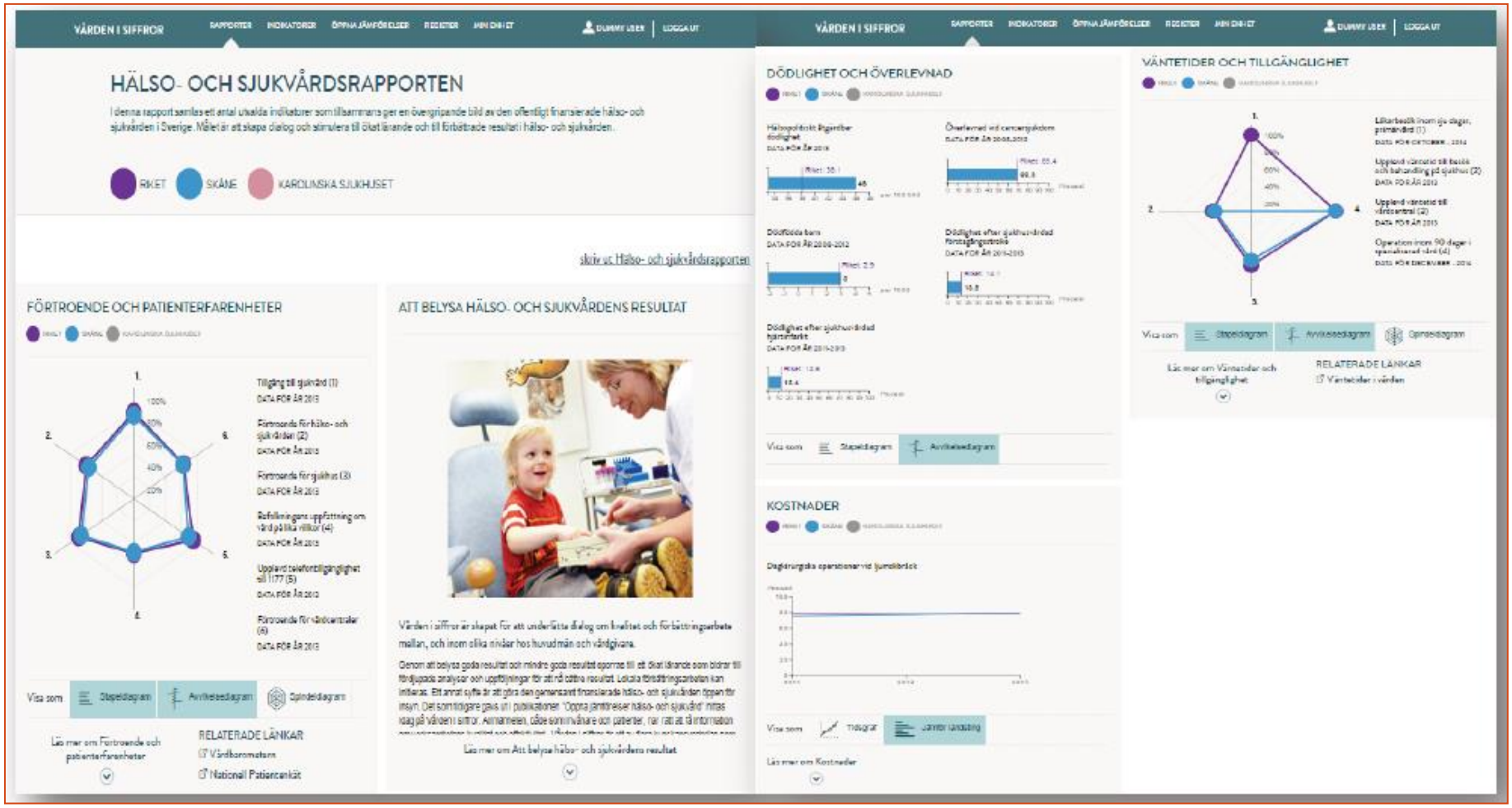


Nationwide registries in Sweden

- **Nationwide registries in Sweden**
  - 96 certified registries, total 108 registries
    - 35 Million Euros (43.365 Billion KRW) for 96 certified registries
  - From SwedeHeart, cancer to Hip joint replacement, Cataract registry
- **Conditions**
  - Consent
    - Usually verbal consent is enough
    - written consent for specific medical research
  - Related acts
    - Swedish patients data act
    - National board regulations SOSFS 2008;14
    - The personal data act, legislation on Biobanking
    - New EU data protection law
  - Direct liking to related national registries
    - Often performed
    - National quality registries and health registries such as;
      - Birth, death, twin, drug registries

Nationwide registries in Sweden

- **Tools for online reports**



Nationwide registries in Sweden

- **Office of national quality registries**
  - Funding and follow up
  - IT-service tools and projects
    - Basically in-house and open source program
    - Link to OCS/EMR, practically merged
  - Development projects for registries
    - Quality, patients involvement
  - Education
    - Web, conferences, meetings
  - Industry collaboration support
  - International collaboration support

Nationwide registries in Sweden

- **Swedish philosophy; why and for what ?**
  - Why
    - Safety and follow-up
    - Patient outcome
    - Clinical research
    - Health economics
    - Risk factors, prevalence, incidence
    - Method development
  - What
    - Development of guidelines
    - International and local comparisons in healthcare-benchmarking
    - Industry follow-up of new drugs/devices
    - Epidemiological studies
    - Feasibility studies
    - Real world studies
      - Medical effect and cost
    - Answering questions from health authorities

Nationwide registries in Sweden

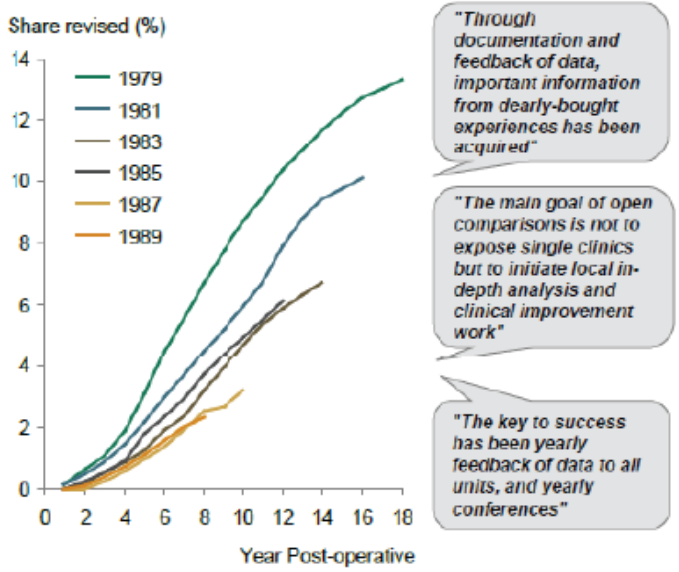
- **The best possible care for the patient**
  - The new drug/devices – hip athroplasty registry

Sweden's hip arthroplasty registry has defined international best practice

Feedback essential for continuous quality improvement

Decrease seen in cumulative revision frequency for mechanical loosening after operation with cemented implant

- 3% revision for patients operated in 1987, 9% revision for patients operated in 1979

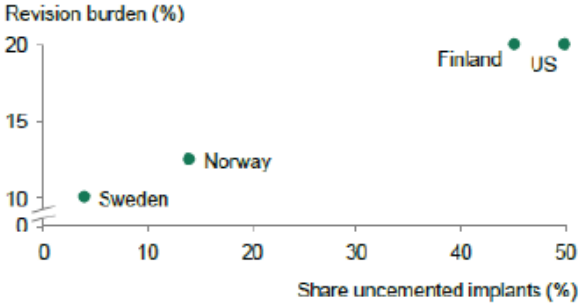


"Through documentation and feedback of data, important information from dearly-bought experiences has been acquired"

"The main goal of open comparisons is not to expose single clinics but to initiate local in-depth analysis and clinical improvement work"

"The key to success has been yearly feedback of data to all units, and yearly conferences"

Sweden with lowest revision burden after total hip arthroplasty



Sweden has a high share of cemented implants and low revision frequency compared to other countries

- In Sweden more than 90% of THAs done with cemented fixation
- Revision frequency for cemented fixation 7%, uncemented fixation 12%

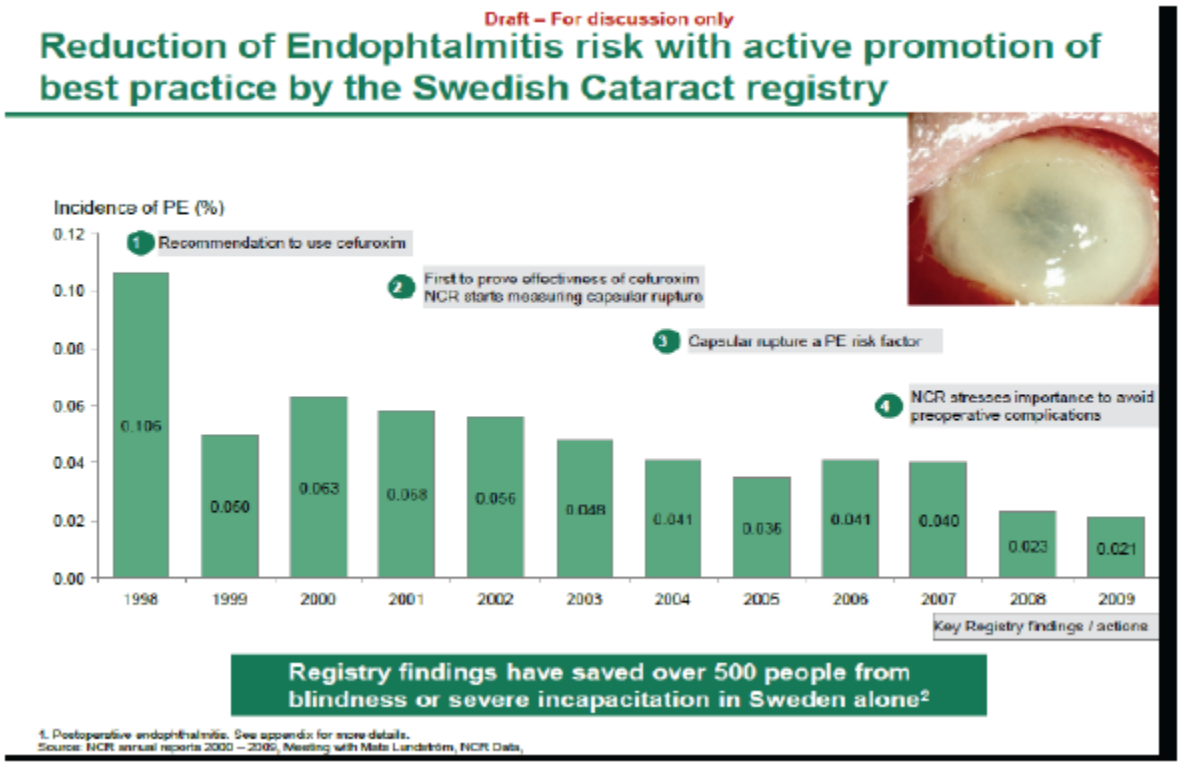
Low revision frequency for cemented THAs due to use of well-documented types of implant

- 5 brands cover 80% of THA operations

Source: Herberts P, Malchau H. Långårig registrering har ökat kvaliteten på höftplastiker. Läkartidningen. 1999;96:2469-76.

Nationwide registries in Sweden

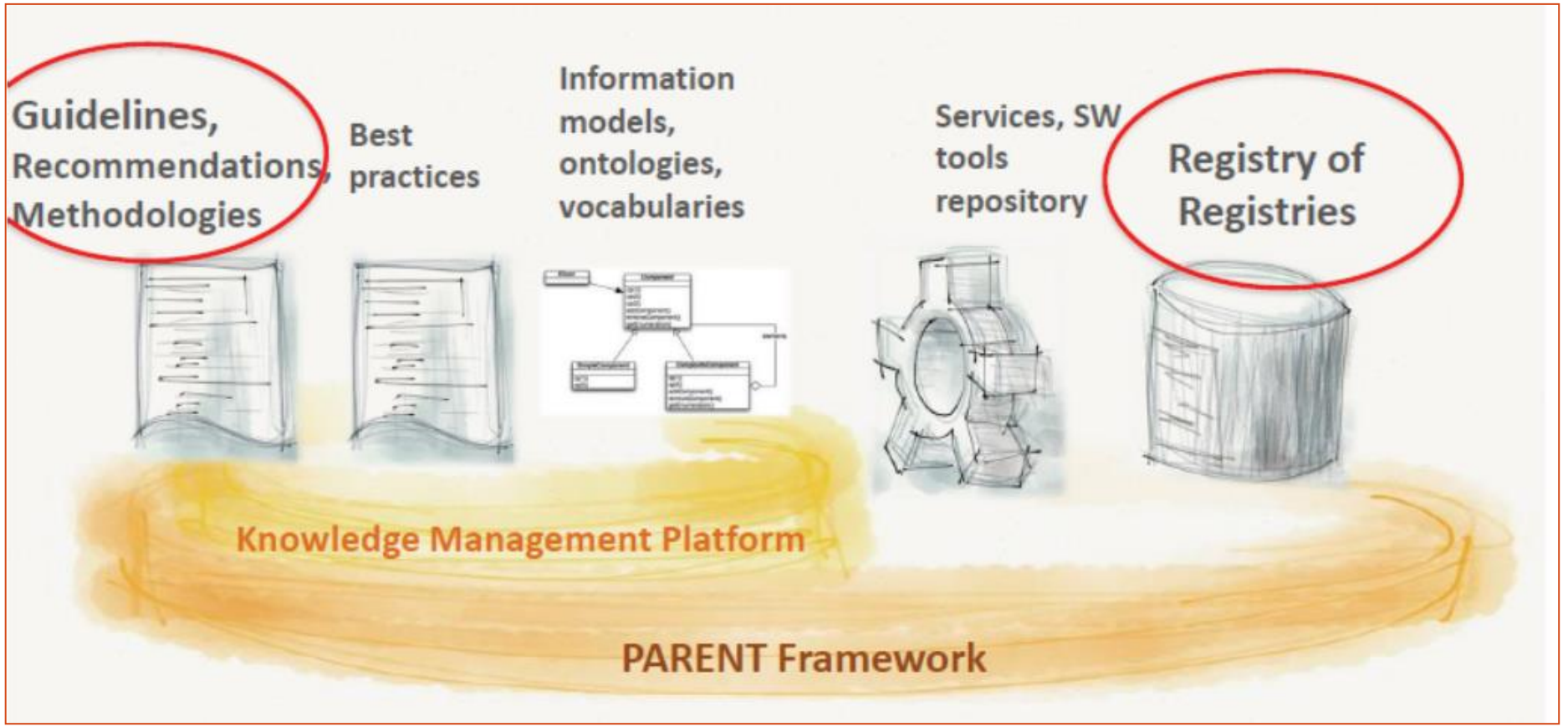
- **The best possible care for the patient**
  - Improvement of working procedures – cataract registry



EUREQUO
European Registry of Quality Outcomes for Cataract & Refractive Surgery

Nationwide registries in Sweden

- **PARENT framework: the tools**

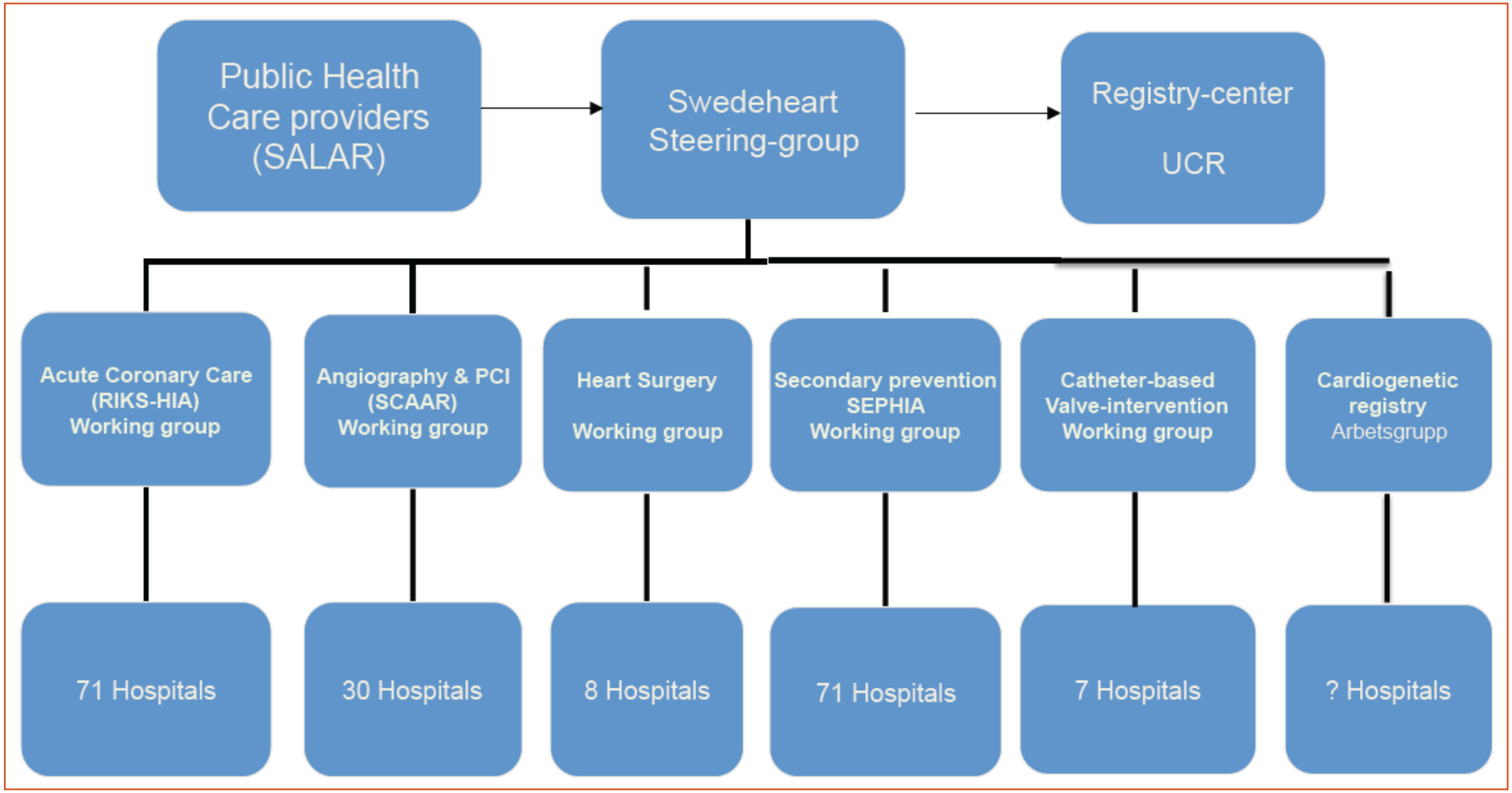


The SwedeHeart Registries

SwedeHeart – History

- **From the early 1980s – Lars Wallentin in Uppsala Univ.**
  - Voluntary action for registration of some cardiologists in Uppsala
    - "Getting our ACS patients who treated in our CCU well after discharge?"
  - Bottom-up procedure
    - Started with papers, then used one Mac.
    - Small grants → company sponsored
  - Government needed data for CV disease.
    - Number one killer in Sweden
    - RIKS-HIA data: well matched in Sweden Statistics.
    - Government started funding for the SwedeHeart
  - Government helps but, not governs makers of registries.
    - Uppsala operates whole procedures of the SwedeHeart
    - Swedish government funding – Swedish Heart Association – UCRO
  - Cath lab hospital – community hospital – patient experience response

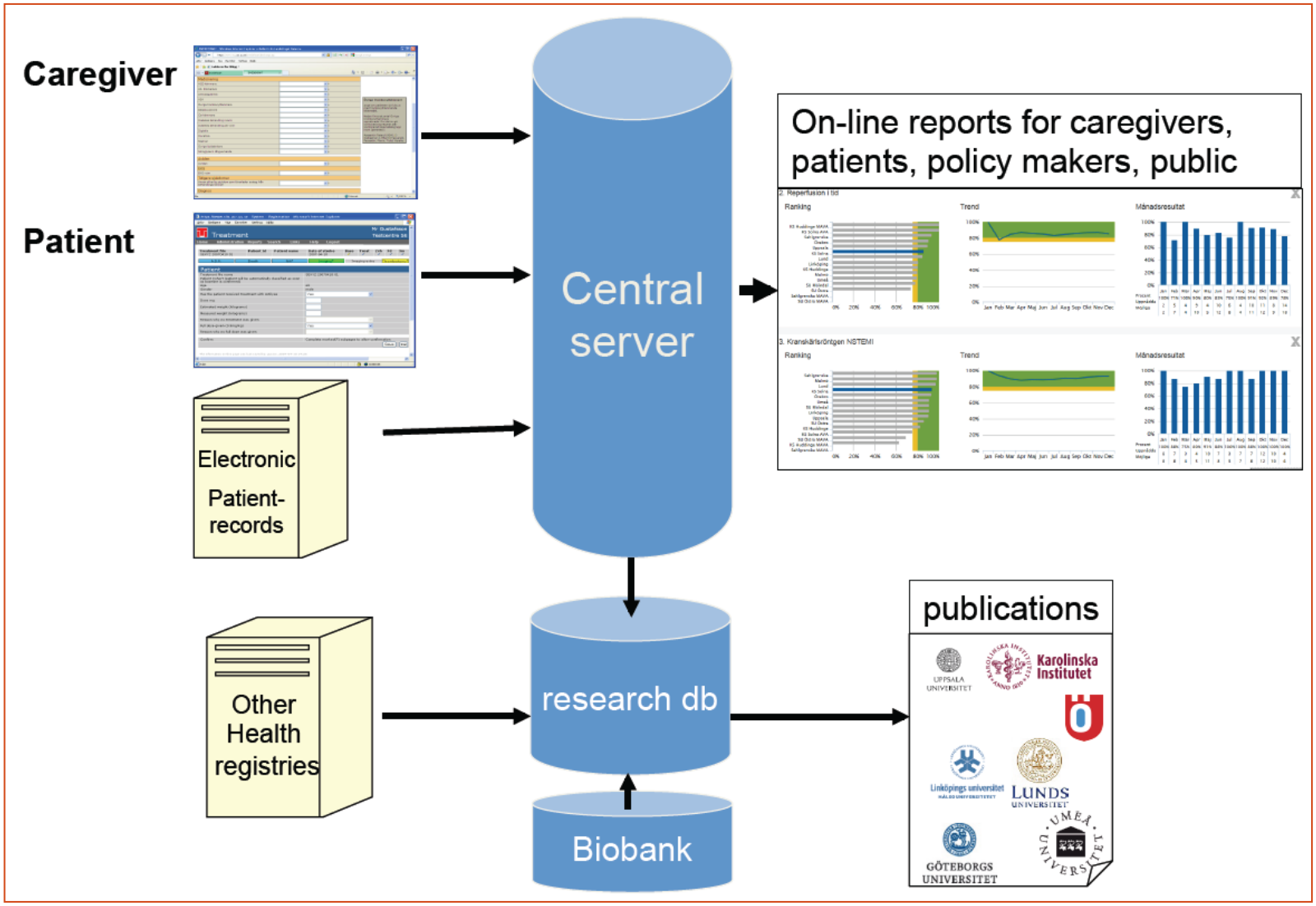
SwedeHeart – organizations



SwedeHeart – organizations

- **Number of cases yearly: 80,000**
  - RIKS-HIA
    - 20,000 AMI
    - 10,000 UA
    - 25,000 other causes to symptoms
  - SCAAR
    - 40,000 CAG or PCI
  - Heart surgery registry
    - 7,000 heart surgery
  - SEPHIA
    - 7,000 secondary prevention
  - TAVI
    - 500 catheter based valve intervention
- **> 500 variables**
  - Baseline data, process- and outcome measures
  - Monitoring
    - 95~95% agreement between patients records and registry

SwedeHeart – organizations



Recording variables

- **Patients with symptoms suggestive of ACS (RIKS-HIA)**
  - Patient demographics
  - Admission logistics
  - Risk factors
  - Past medical history
  - Medical treatment before admission
  - Electrocardiographic changes, biochemical markers
  - Other clinical features and investigations
  - Medical treatment in hospital, interventions
  - Hospital outcome
  - Discharge diagnosis
  - Discharge medications

Recording variables

- **Patients with symptoms suggestive of ACS (RIKS-HIA)**
  - Recorded by discharge and after 6-10 weeks
  - PROM (patient reported outcome measures): with mailing
    - The Somatic Health Complaints Questionnaire (SHCQ)
    - Minimal Insomnia Symptom Scale (MISS)
    - Physical activity according to Grimby scale
    - Cardiac Self Efficacy Scale (CSES)
  - PREM (Patient Reported Experiences Measures): with mailing
    - Patients' views on their care

The SwedeHeart is merged with;

- **Registries at the National Board of Health and Welfare**
  - The national registry of cause of death
  - The national patient register (all ICD codes, all admission since 1987)
  - The Swedish prescribing drug register (all dispensed drugs since 2005)
- **Statistics Sweden (SCB)**
  - Marital status, country of birth, income, educational level
- **The Swedish Social Insurance Agency**
  - Sick leave
- **Other National Quality Registries**
  - About 100 at present

The SwedeHeart starts with …

- The Swedish personal identification number …

The Swedish personal identification number

The SwedeHeart starts with …

- **CARDS (the Cardiology Audit and Registration Data Standards)**

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

EUROPEAN SOCIETY OF CARDIOLOGY®

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]*

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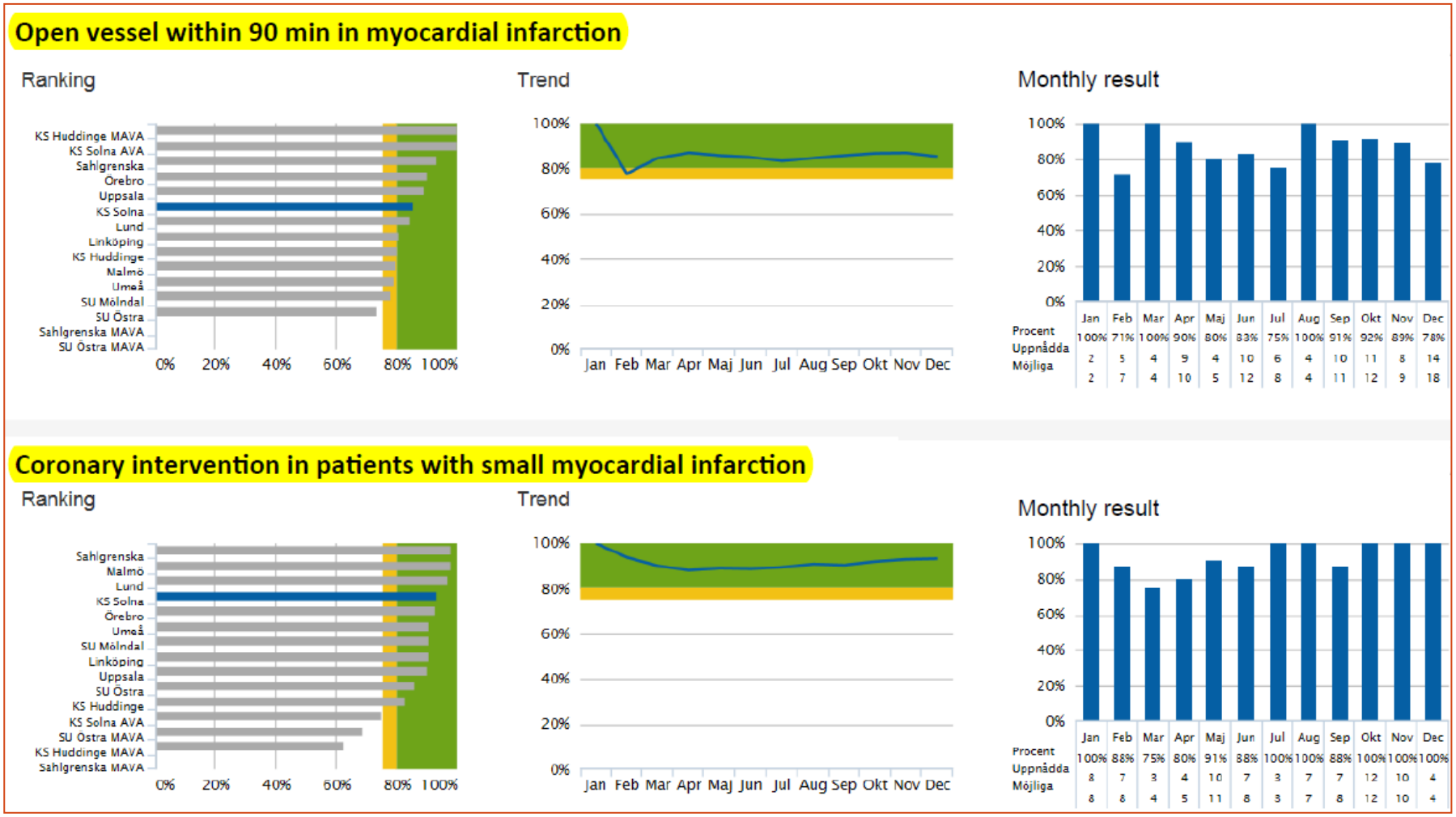
[2] *Cardiology Departments, Cork University Hospital, Cork and Mater Misericordiae University Hospital, Dublin, Ireland*
[3] *Cardiology Department, Hospital Universitario de Getafe, Madrid, Spain*
[4] *Cardiology Department, Ludwigshafen, Germany*
[5] *Uppsala Clinical Research Centre, University Hospital Uppsala, Sweden*
[6] *Cardiology Department, Cork University Hospital, Cork, Ireland*
[7] *Chief Department of Cardiology, Thoraxcenter, Erasmus University Medical Center, PO Box 2040, 3000 CA, Rotterdam, The Netherlands*

Received 2 November 2004; accepted 18 November 2004; online publish-ahead-of-print 17 December 2004

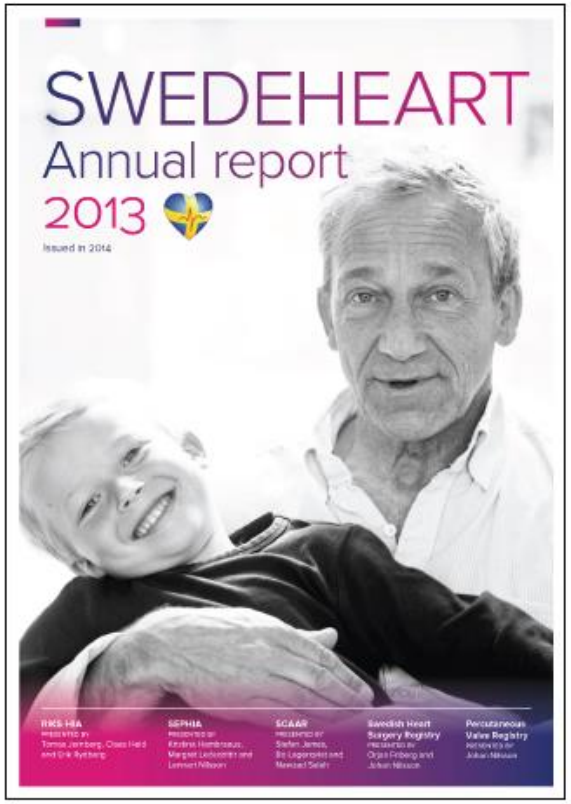
The SwedeHeart; Quality at a glance

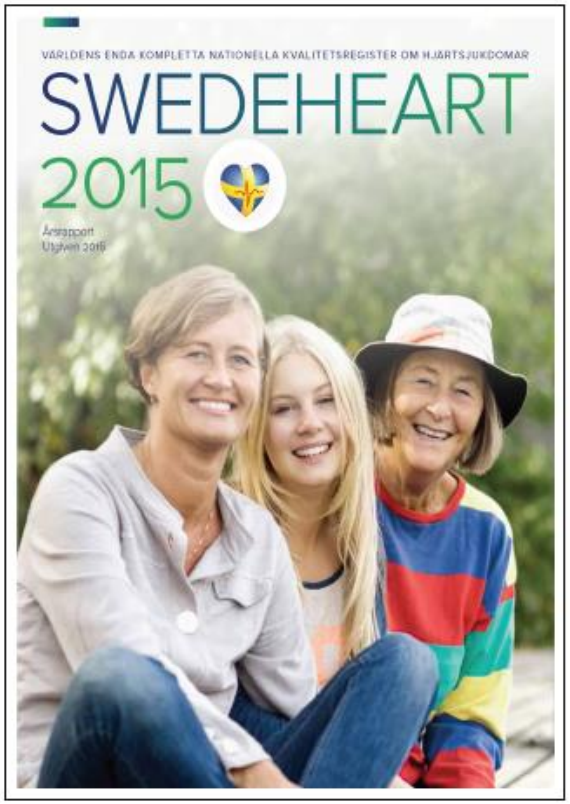
- On-line reports for each institution, not for each clinician



The SwedeHeart; Annual reports

- **Open for public, media and health policy makers**

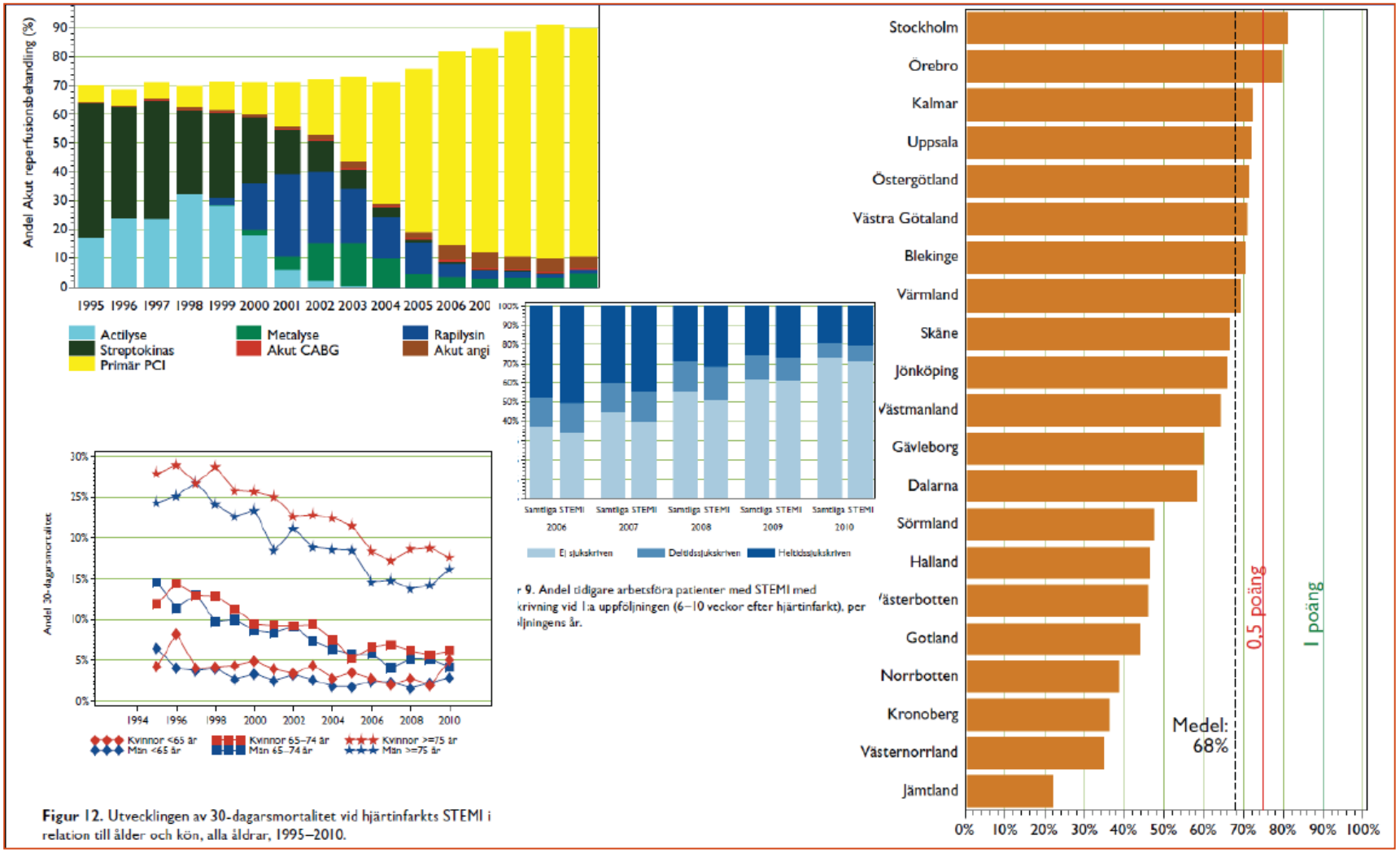




http://www.ucr.uu.se/swedeheart

The SwedeHeart; Annual reports

- **From demographics to clinical outcomes**



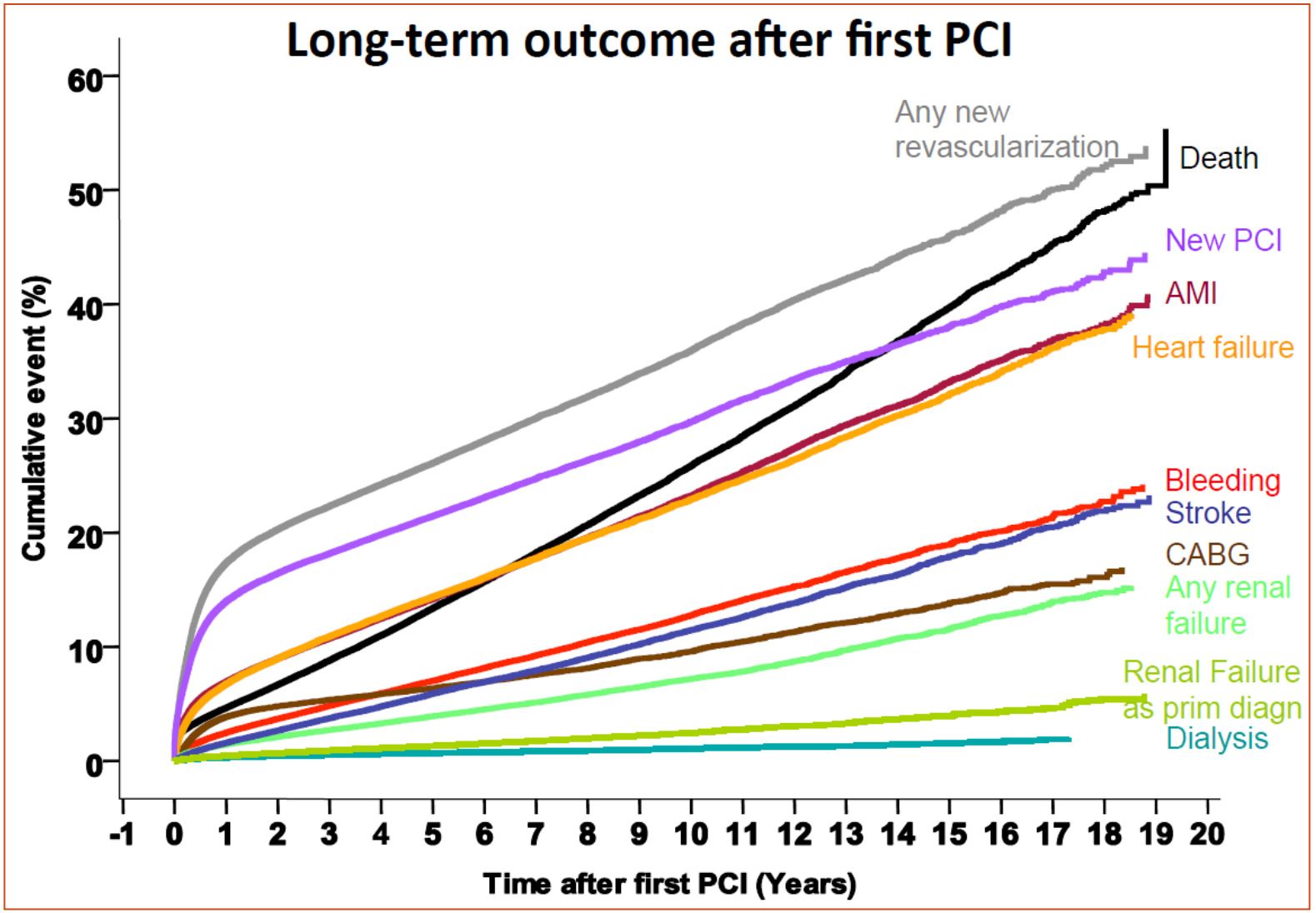
Figur 12. Utvecklingen av 30-dagarsmortalitet vid hjärtinfarkts STEMI i relation till ålder och kön, alla åldrar, 1995–2010.

r 9. Andel tidigare arbetsföra patienter med STEMI med krivning vid 1:a uppföljningen (6–10 veckor efter hjärtinfarkt), per iljningens år.

http://www.ucr.uu.se/swedeheart

The SwedeHeart; Annual reports

- Pride with long-term clinical data in Sweden



Annual report of the SwedeHeart

- **The RIKS-HIA Quality Index**

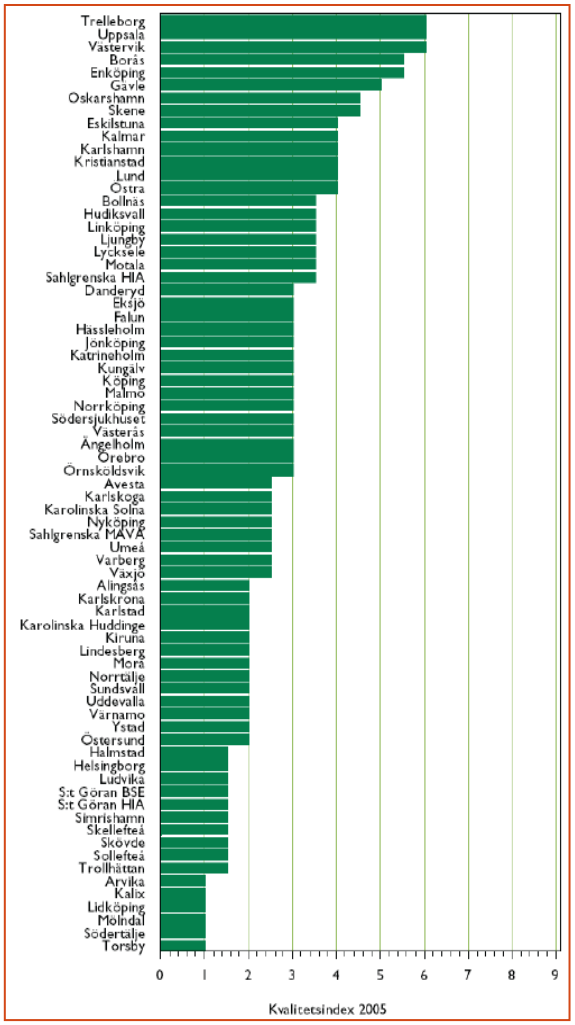
Quality indicator	0.5 points %	1 point %
Reperfusion in STEMI	80	85
Reperfusion in STEMI within recommended time (PCI within 90 min and thrombolysis within 30 min)	75	90
Coronary angiography in NSTEMI	75	80
P2Y12 blockers in NSTEMI	85	90
ACEI/ARB in target group for MI	85	90
Proportion of patients (< 80 years) with MI as principal diagnosis included in RIKS-HIA	90	95
Proportion of patients with MI (< 75 years) in RIKS-HIA undergoing follow-up in SEPHIA	70	90
Proportion of smokers who have stopped smoking after 12–14 months	60	70
Proportion of patients who have participated in a physical exercise programme after 12–14 months	50	60
Proportion of patients with LDL-cholesterol < 1.8 mmol/L or 50 % reduction after 12–14 months	40	60
Proportion of patients with systolic blood pressure < 140 mmHg after 12–14 months	70	75

http://www.ucr.uu.se/swedeheart/arsrapport-2015

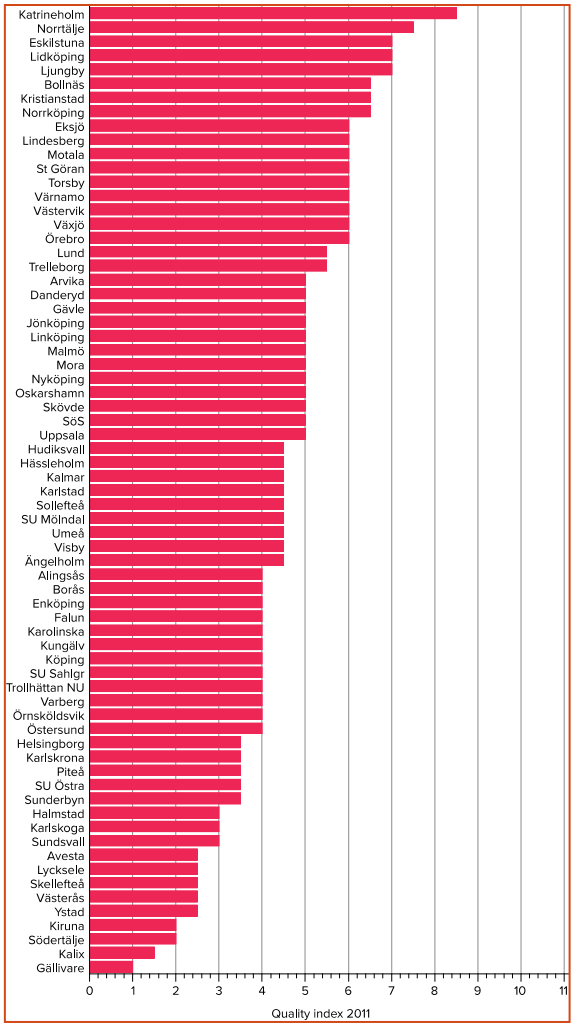
Annual report of the SwedeHeart

- **The RIKS-HIAs Quality Index**

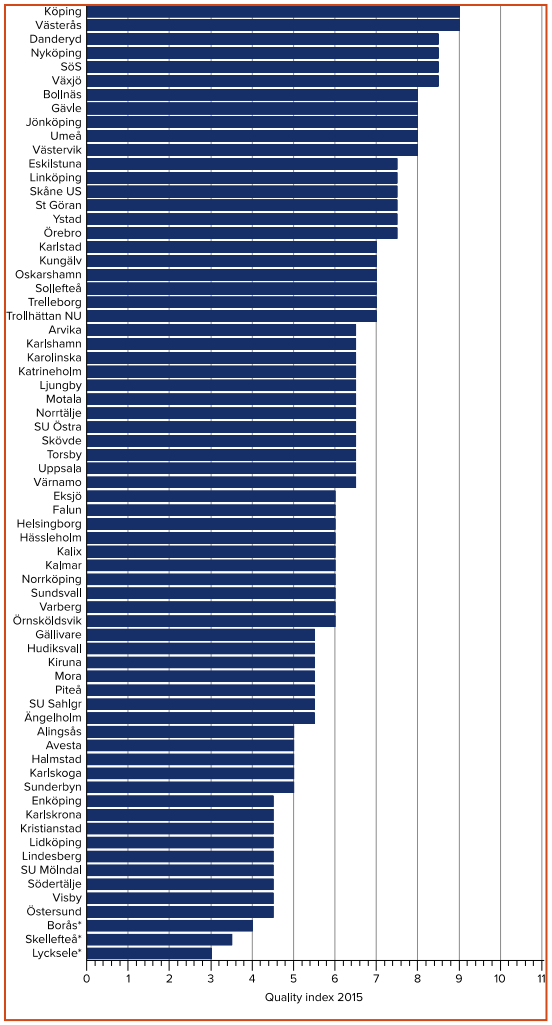
2005



2011



2015



http://www.ucr.uu.se/swedeheart/arsrapport-2015

Annual report of the SwedeHeart

- **The RIKS-HIA**

Trend in mean age with MI

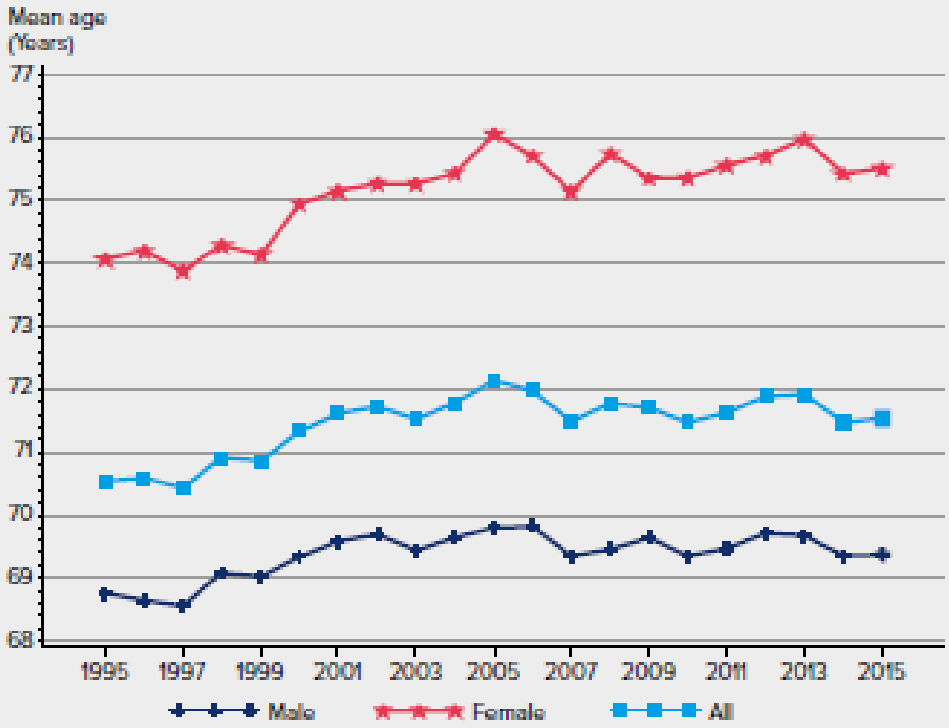


Figure 43. Trend in mean age of patients with MI, all ages, 1995–2015.

The mean age has remained stable around 71.5–72 years.

Trend in background factors in patients with MI

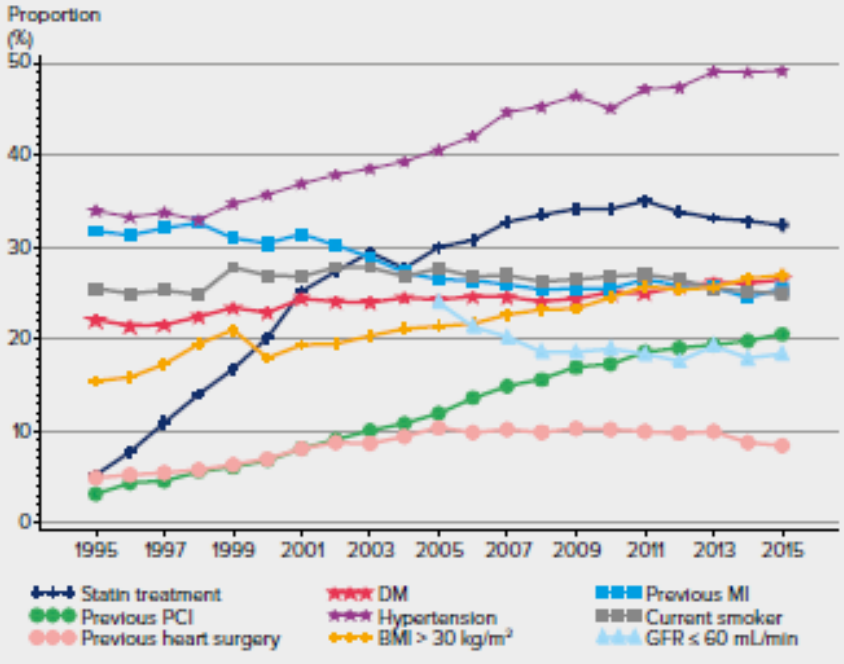


Figure 44. Trend in background factors in patients with MI < 80 years, 1995–2015.

The proportion of patients with hypertension, obesity, and previous PCI have continued to increase, whereas the proportion of smokers and patients with DM, chronic kidney disease, and statin-treatment have remained on the same level.

http://www.ucr.uu.se/swedeheart/arsrapport-2015

Annual report of the SwedeHeart

- **The RIKS-HIA**

ECG to primary PCI

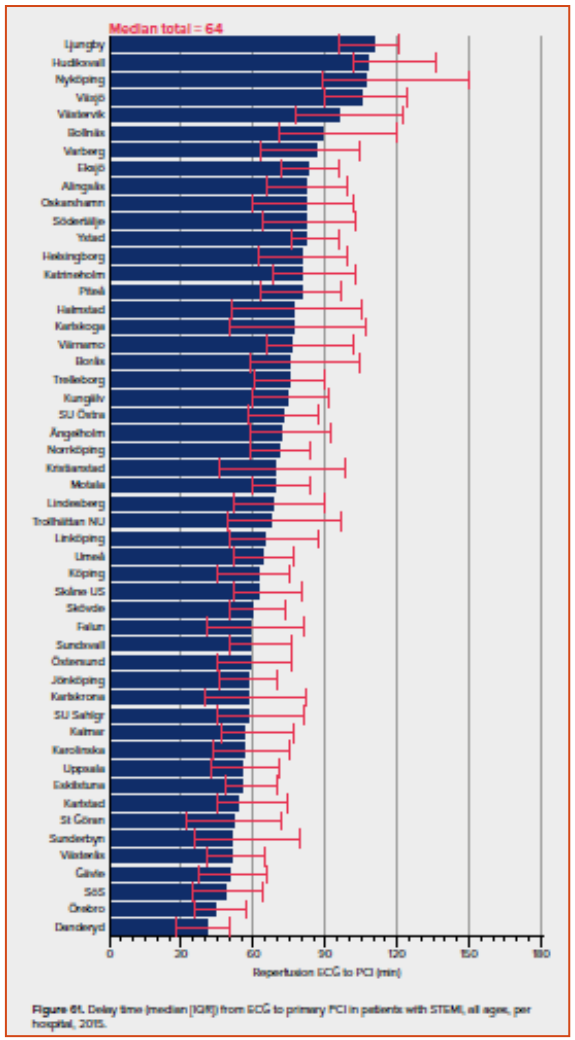
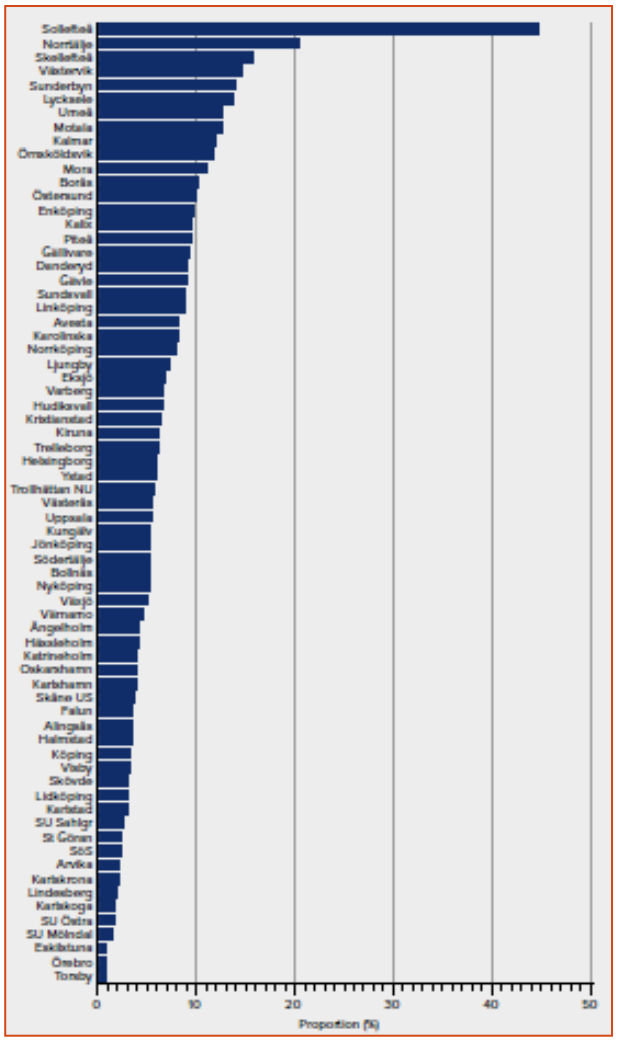


Figure 61. Delay time (median (IQR)) from ECG to primary PCI in patients with STEMI, all ages, per hospital, 2015.

Rate of IV beta blocker in AMI

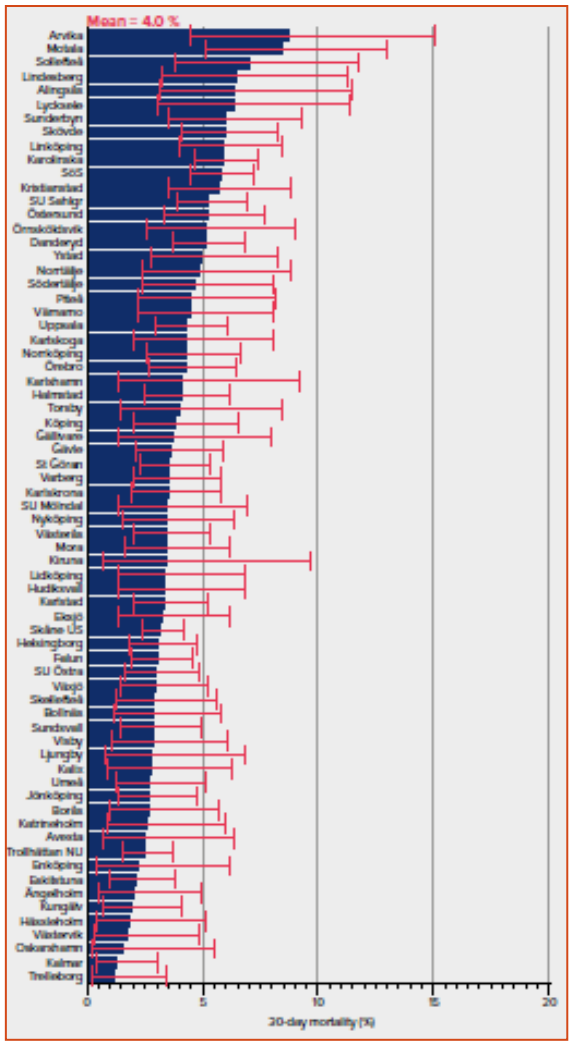


http://www.ucr.uu.se/swedeheart/arsrapport-2015

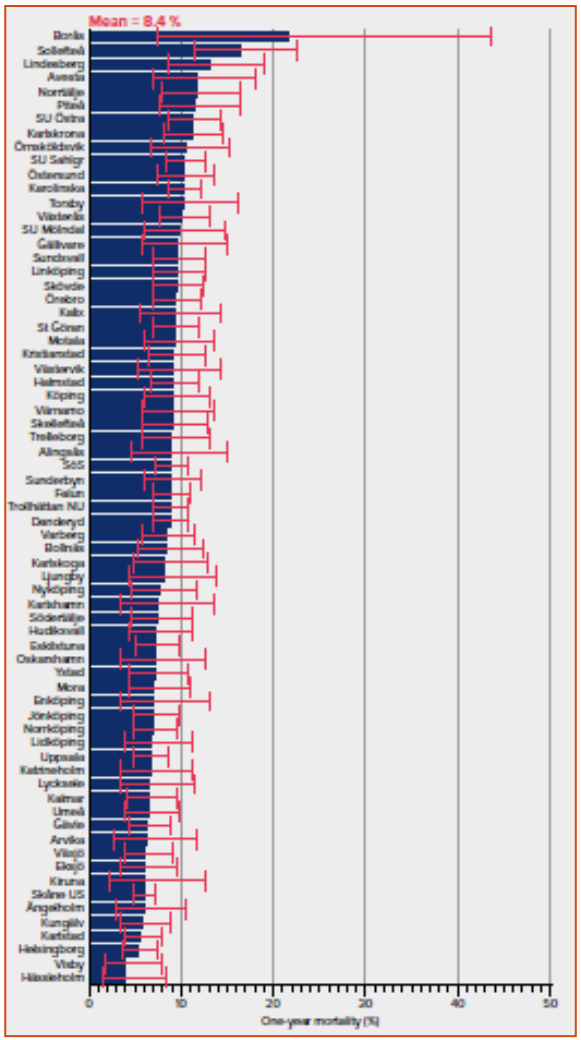
Annual report of the SwedeHeart

- **The RIKS-HIA**

30 day mortality per hospital



1 year mortality per hospital



http://www.ucr.uu.se/swedeheart/arsrapport-2015

Annual report of the SwedeHeart

- **The RIKS-HIA**

1Mo mortality per county

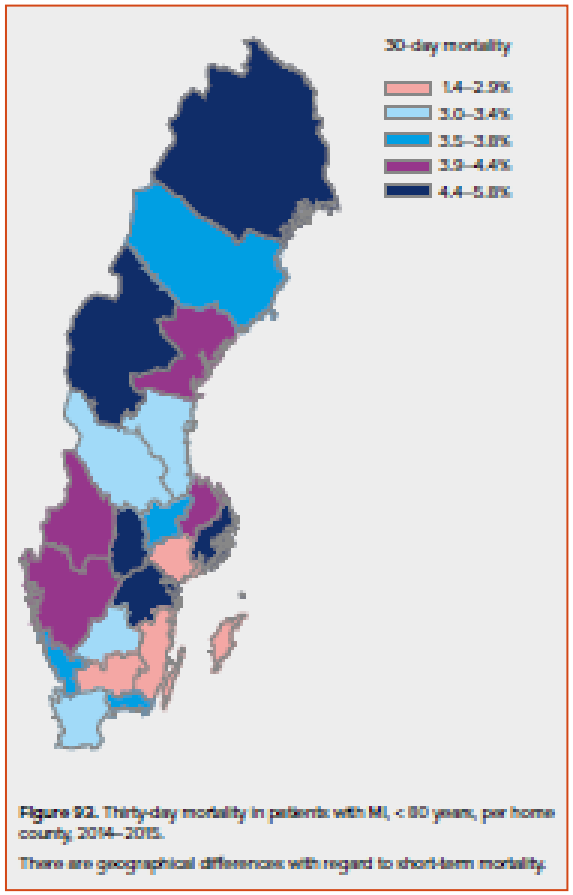


Figure 93. Thirty-day mortality in patients with MI, < 80 years, per home county, 2014–2015.

There are geographical differences with regard to short-term mortality.

1 year mortality per county

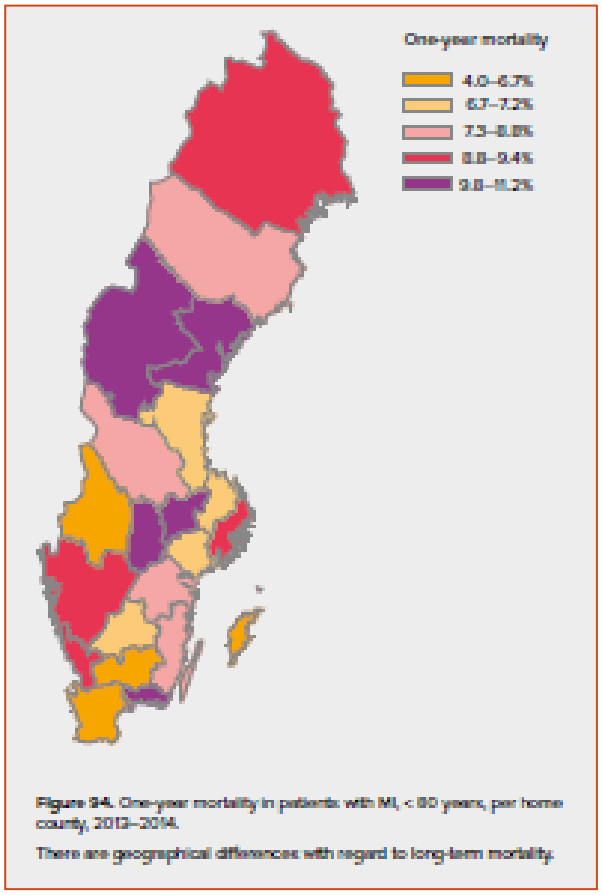


Figure 94. One-year mortality in patients with MI, < 80 years, per home county, 2013–2014.

There are geographical differences with regard to long-term mortality.

http://www.ucr.uu.se/swedeheart/arsrapport-2015

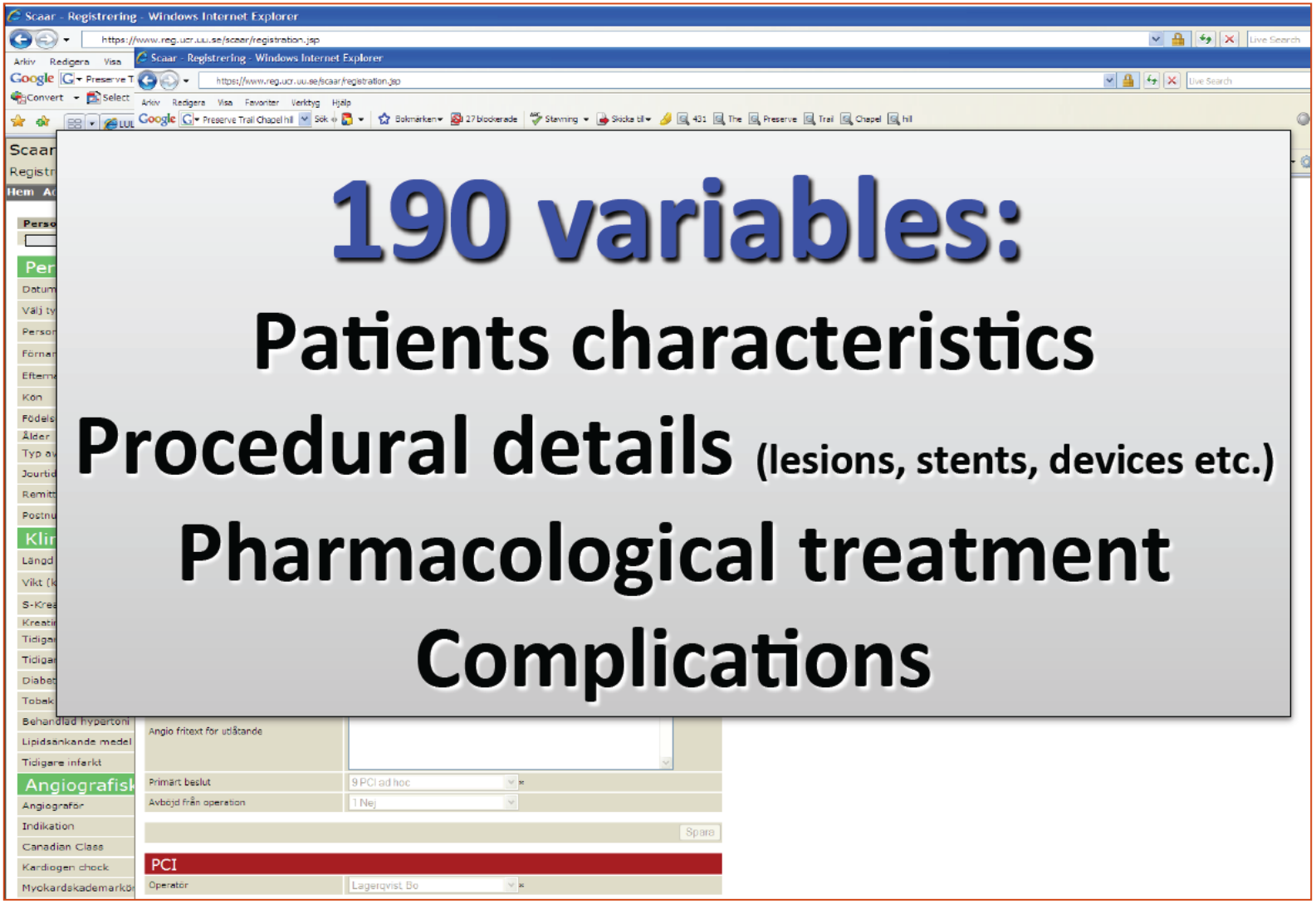
Admit the difference of outcome …

- **Clinical outcome differences are real and exist.**
  - Difference of geography (island), long-distance transfer, insufficient medical resources
    - e.g. Gotland
- **Media control**
  - Media likes to make provocative headlines.
    - e.g. Our state (or municipality is the worst area of AMI care in nation.)
- **Incentive-disincentive system**
  - Induce competition, but data will be fabricated.
  - We will lose the opportunities to improve our quality of care.
  - Goal is in improvement for our citizens, not in numbers or indices.
- **Find the reasons in poor quality institutions and areas**
  - Listen the voices of healthcare providers, analyze the data.
  - Make funds and administrative supports to improve those institutions and areas.

The SCAAR

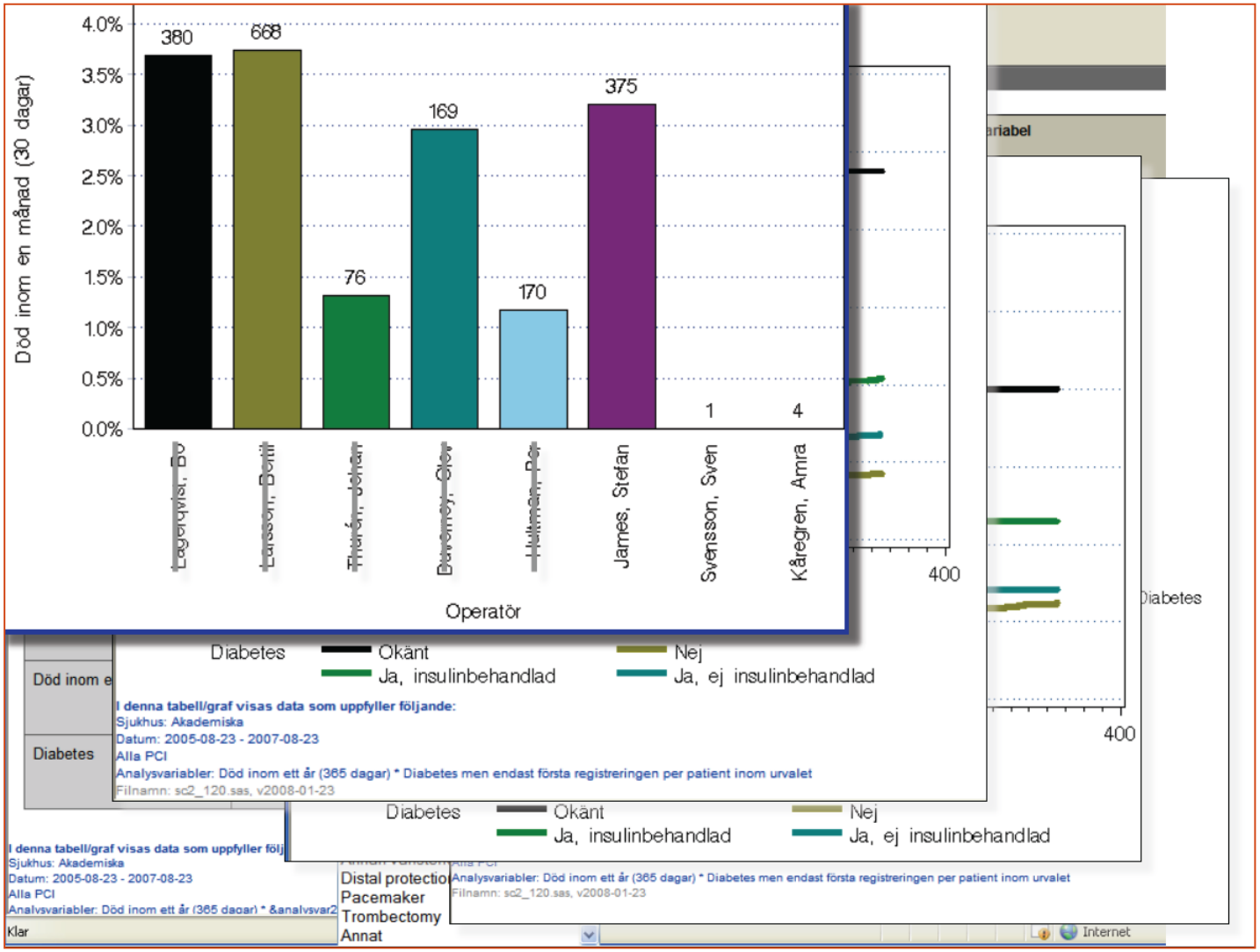
Data entry on-line by the operator

- 190 variables



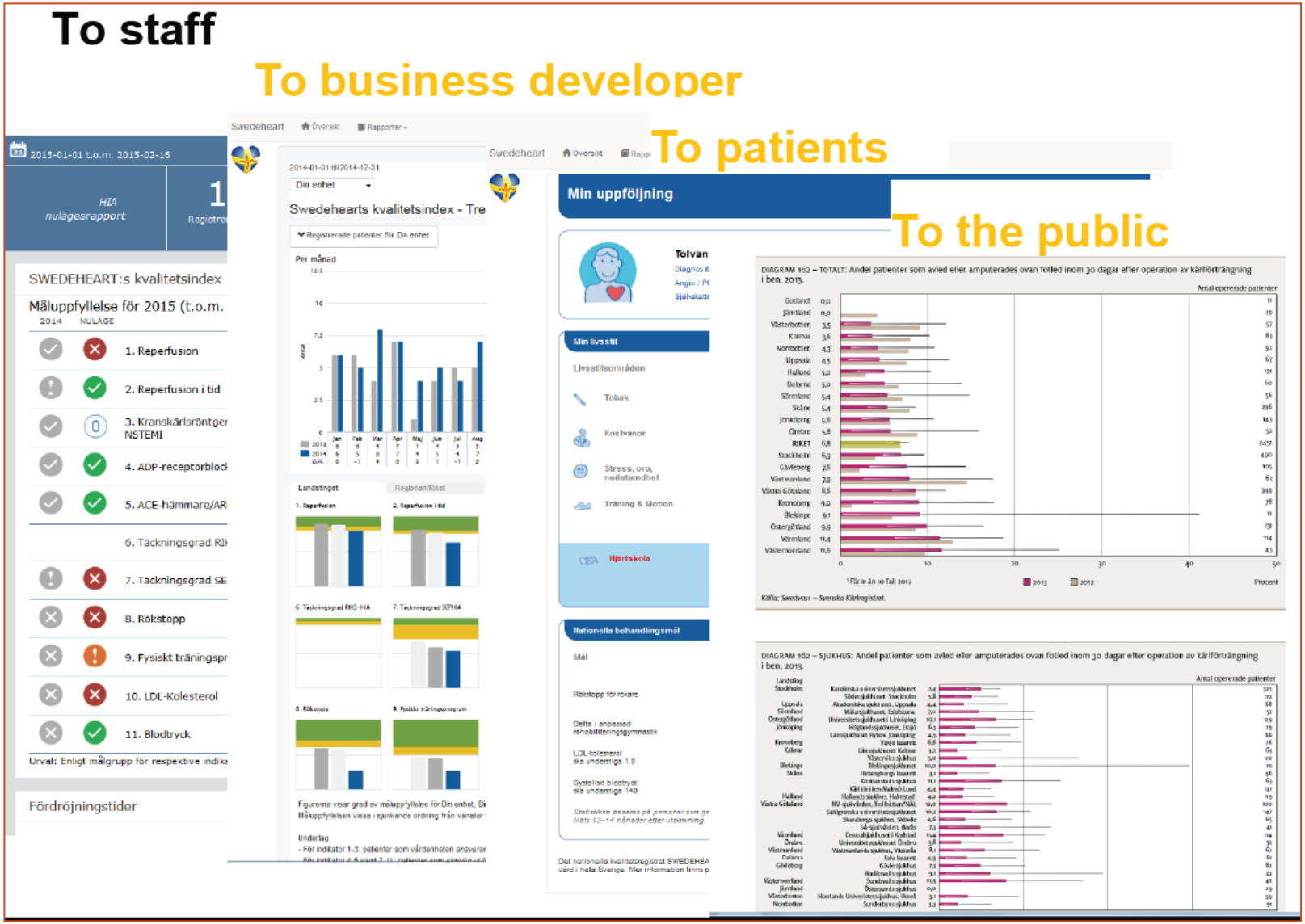
Real-time measurement for quality

- **On-line reports**



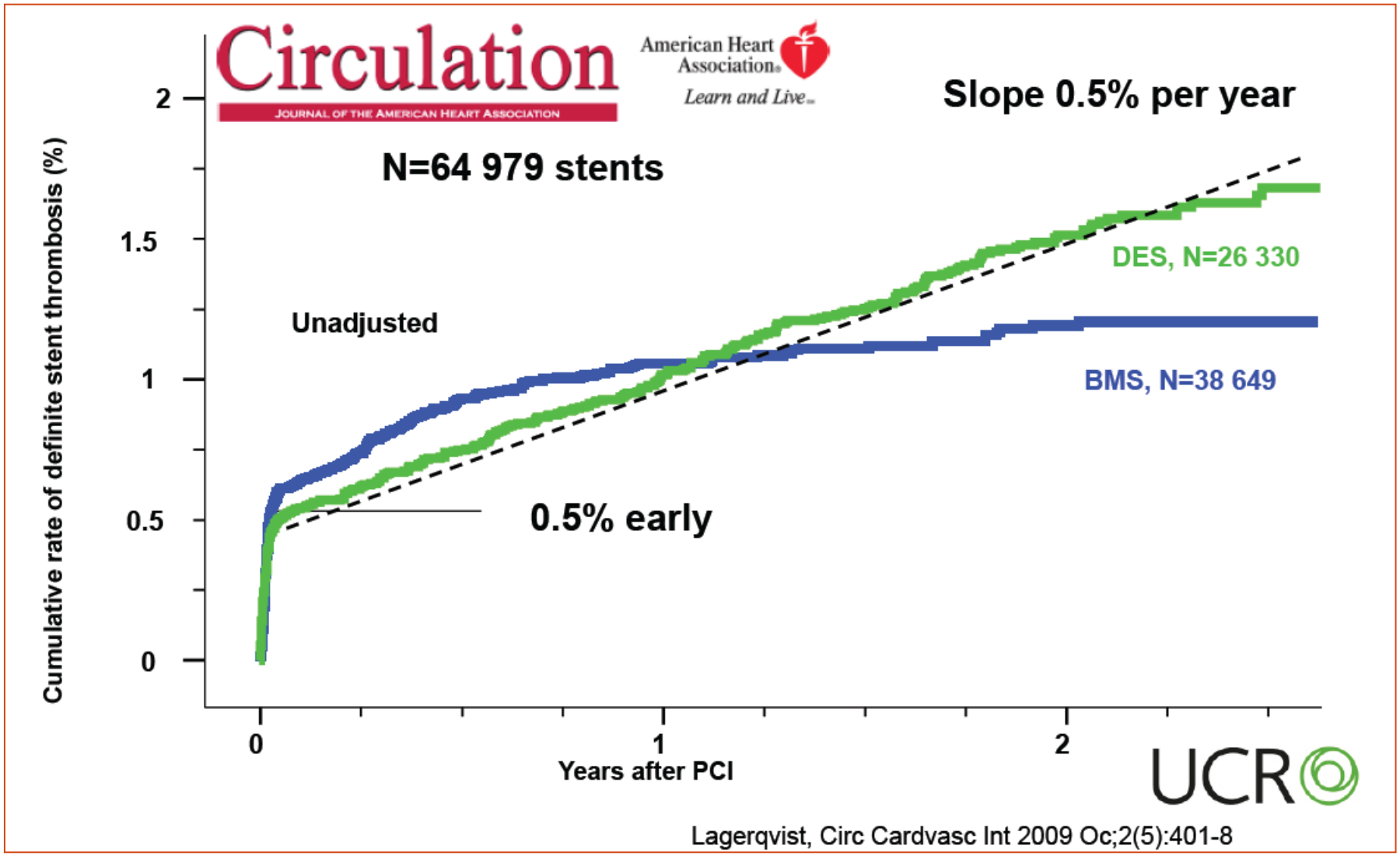
Feedback for multi-teams

- **Feedback**



Scientific achievement

- **DES ST never asleep ..**



Scientific achievement

- **DES will kill you ..**

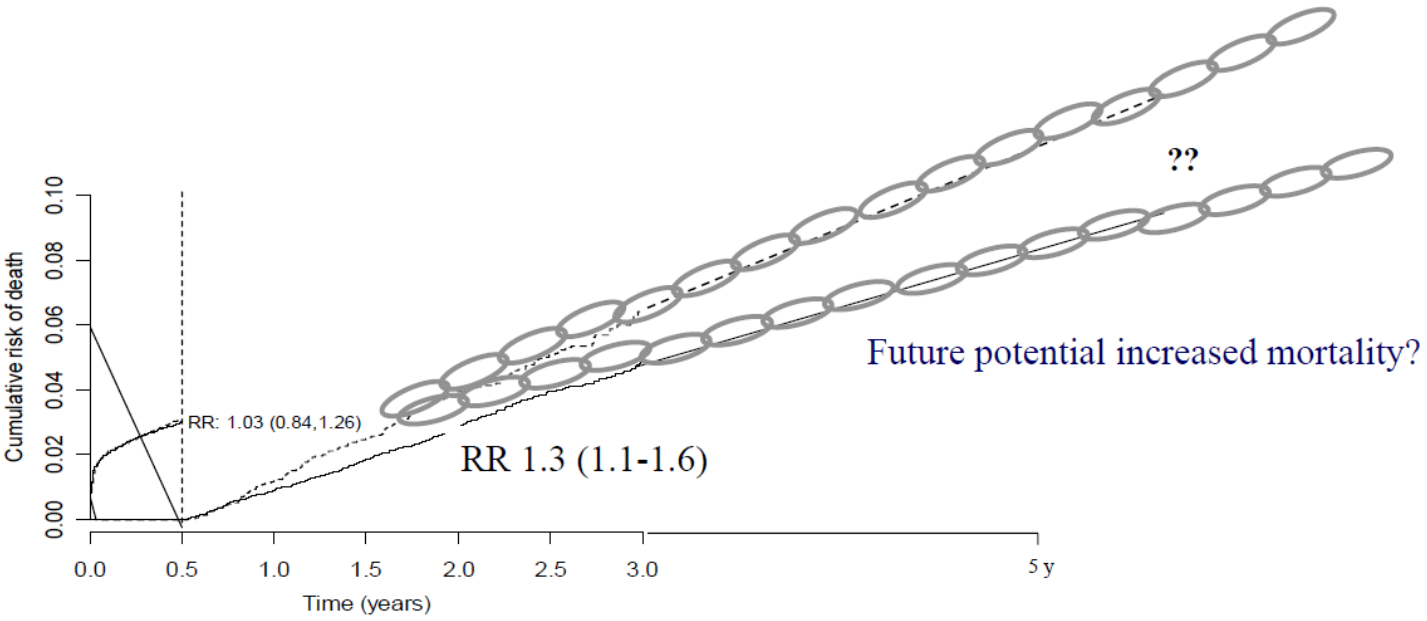
N Engl J Med 2007;356:1009-19.

ORIGINAL ARTICLE

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*

Patients enrolled 2003-2004 and followed
max 3 years
N=19 771



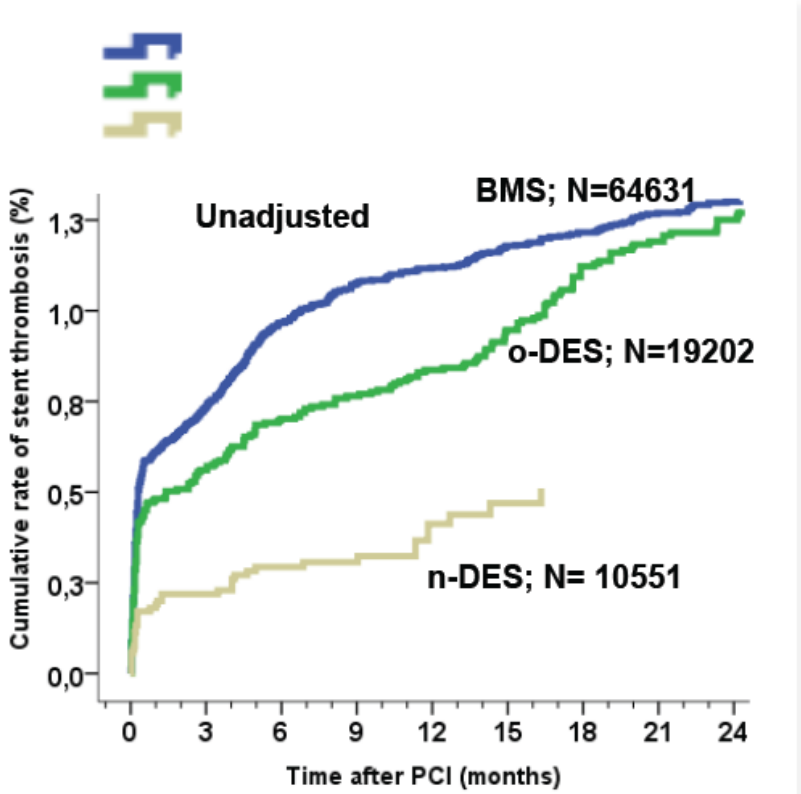
N Engl J Med 2007;356:1009-19.

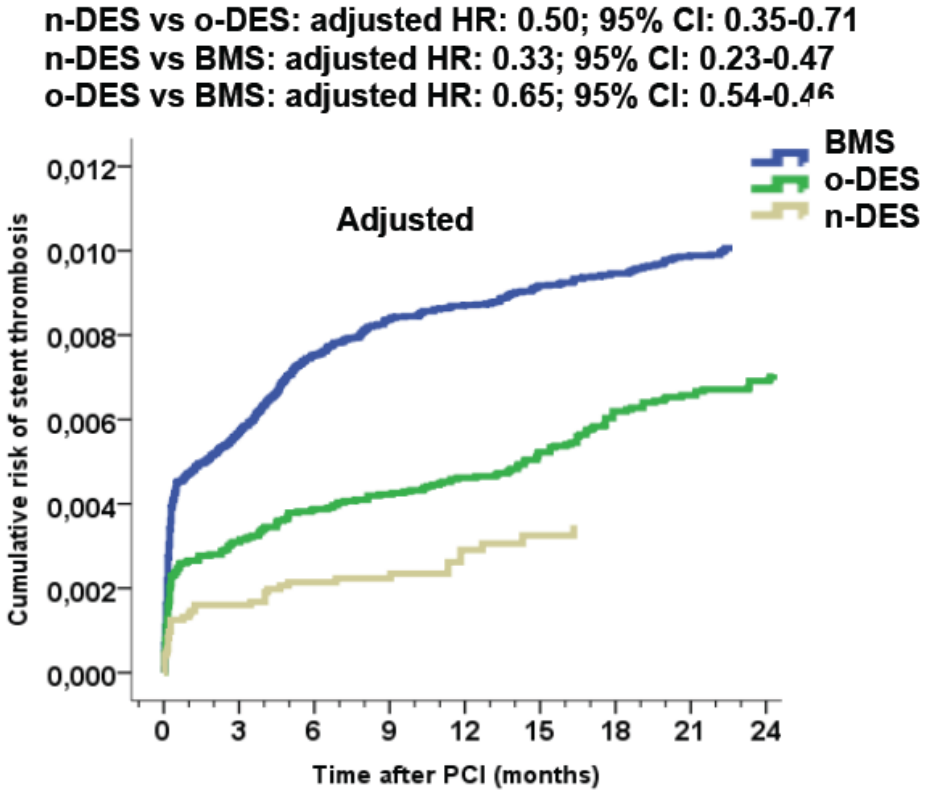
Scientific achievement

- The SCAAR Scare

Scientific achievement

- Newer generation DES … the new hope (ST @ 2 years)





Prospective registry-based RCT ; a new concept for clinical research

RCT .. Is not holy grail.

- **RCT …**

Strengths

- Correctly designed studies with adequate power are gold standard
- Extinguishes confounding

Weaknesses

- Highly selected populations due to exclusion criteria
- Often selected specialized study centers
- Often surrogate endpoints
- Long time to plan and complete
- Expensive
- Often sponsored by industry- only studies with economic interest will be performed

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New trials of the SwedeHeart

European Heart Journal (2009) **30**, 2165–2173
doi:10.1093/eurheartj/ehp299

CardioPulse

SWEDEHEART: Sweden's new online cardiac registry, the first of its kind

Covering all hospitals in Sweden, **SWEDEHEART** is unique because it allows long-term follow-up and immediate feedback, says Ulf Stenestrand, MD, PhD, Associate Professor of cardiology and Senior consultant interventional cardiologist, Department of Cardiology, University Hospital, Linköping, Sweden, and President of SWEDEHEART.

Comparative effectiveness studies

Comparative effectiveness

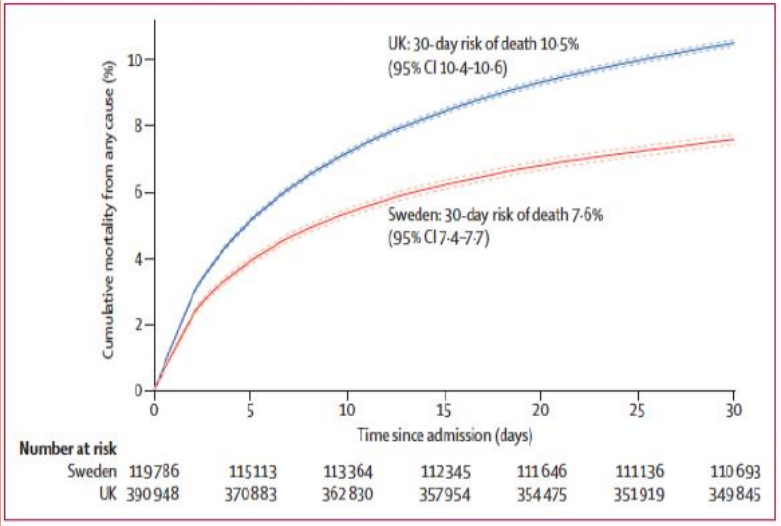
Hospitals' 30 day mortality rates for acute myocardial infarction and between hospital variation in mortality were greater in the UK than in Sweden

This was associated with, and may be partly accounted for by, the greater variation in practice as regards guideline recommended treatment for acute myocardial infarction in the UK hospitals

More consistent healthcare across all hospitals with better use of guideline recommended treatment may not only reduce practice variation but also deliver improved clinical outcomes for patients with acute myocardial infarction

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



the bmj | BMJ 2015;351:h3913 | doi: 10.1136/bmj.h3913

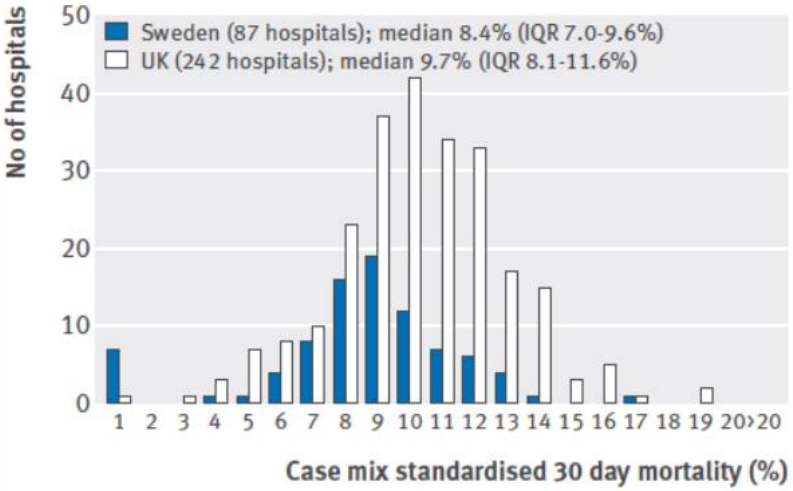


Fig 4 | Hospital variation in case mix standardised 30 day mortality (%) in Sweden and UK, 2004-10

Registry based RCT (R-RCT)

- **R-RCT …**

Strengths

- Correctly designed studies with adequate power are gold standard
- Extinguishes confounding
- Unselected patient populations –generalizable
- Large number of events – makes it possible to identify rare events
- Inexpensive

Challenges

- Data quality
- Variable definition

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R-RCT vs. classical RCT

- Combines the advantages of a clinical registry and randomized study
- Complement to classical RCT –No substitute
- No formal definition

•RRCT •Evaluation of therapeutic options available/used in routine clinical care	⟷	RCT Approval of new pharmaceutical agents and medical devices

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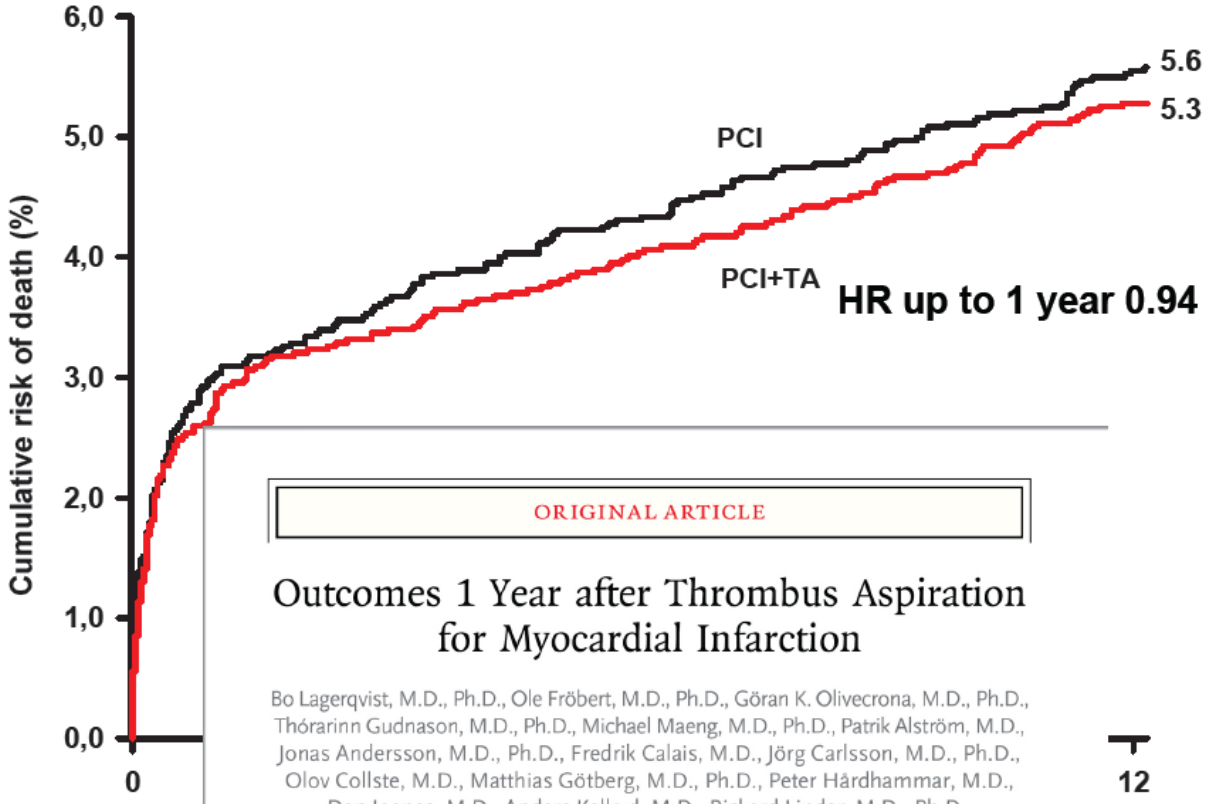
TASTE with R-RCT

TASTE

All-cause mortality up to 1 year

SWEDE HEART



ORIGINAL ARTICLE

Outcomes 1 Year after Thrombus Aspiration for Myocardial Infarction

Bo Lagerqvist, M.D., Ph.D., Ole Fröbert, M.D., Ph.D., Göran K. Olivecrona, M.D., Ph.D., Thórarinn Gudnason, M.D., Ph.D., Michael Maeng, M.D., Ph.D., Patrik Alström, M.D., Jonas Andersson, M.D., Ph.D., Fredrik Calais, M.D., Jörg Carlsson, M.D., Ph.D., Olov Collste, M.D., Matthias Götberg, M.D., Ph.D., Peter Hårdhammar, M.D., Dan Ioanes, M.D., Anders Kallryd, M.D., Rickard Linder, M.D., Ph.D., Anders Lundin, M.D., Jacob Odenstedt, M.D., Elmir Omerovic, M.D., Ph.D., Verner Puskar, M.D., Tim Tödt, M.D., Ph.D., Eva Zelleroth, M.D., Ollie Östlund, Ph.D., and Stefan K. James, M.D., Ph.D.

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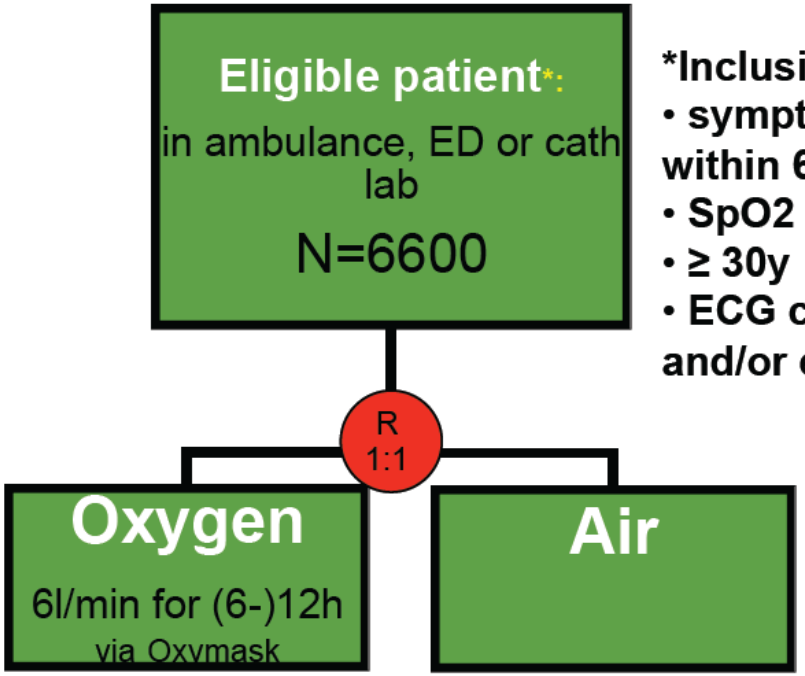
DETOX in AMI with R-RCT

DETO$_2$X – AMI



***Inclusion criteria:**
- **symptoms suggestive of AMI within 6h**
- **SpO2 ≥ 90%**
- **≥ 30y**
- **ECG changes indicating ischemia and/or elevated troponin levels**

Primary Endpoint: 1-year total mortality

Additional secondary endpoint and sub studies

Data analysis through **SWEDEHEART** registry and **national mortality registry**

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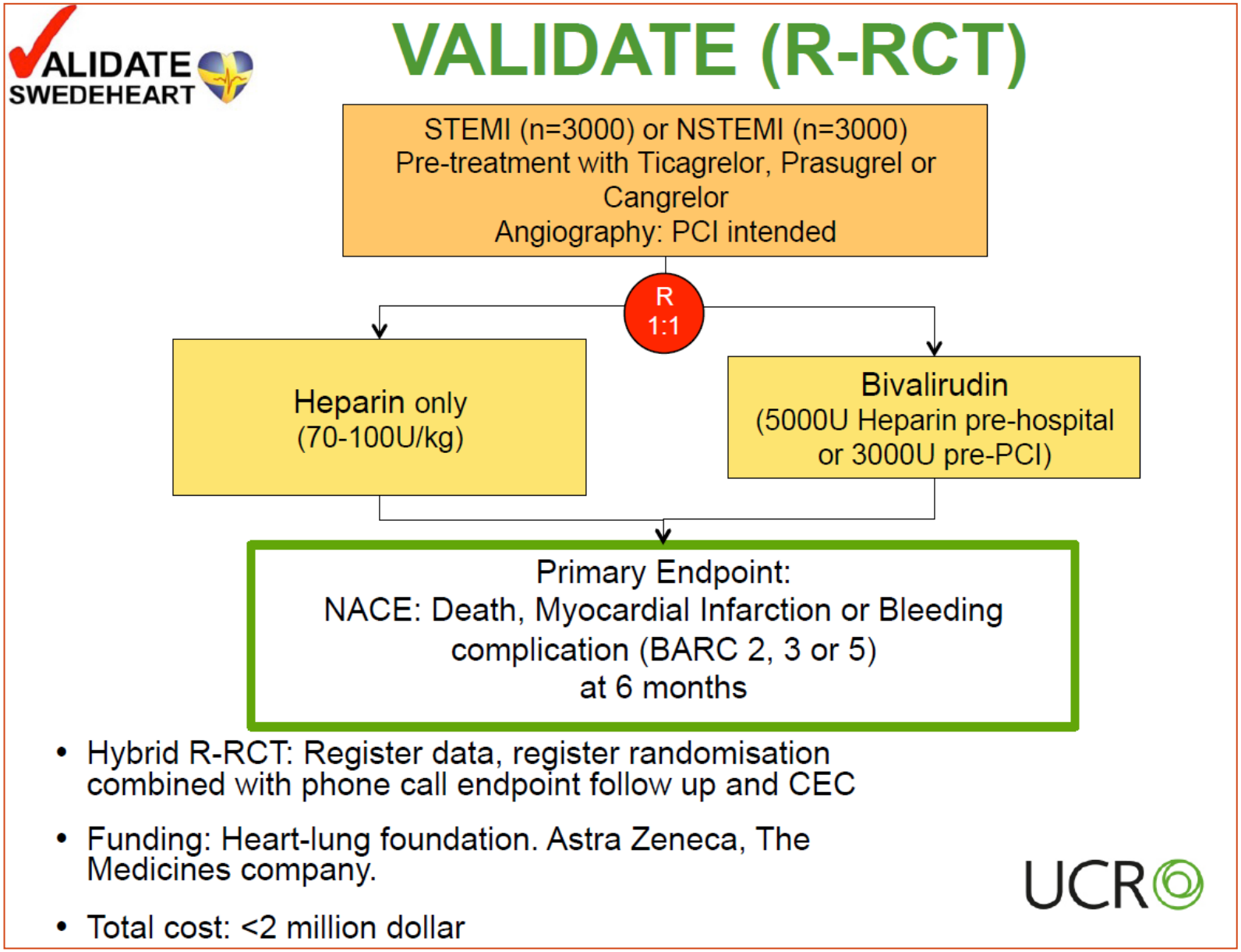
Funding: Swedish Research council (VR)

VALIDATE with R-RCT



VALIDATE with R-RCT

Randomisation Module

Primärt beslut	9 PCI ad hoc *
Avböjd från operation	
	Spara

Randomisation results

Validate

Studienummer	100001
Randomiseras till	Heparin
TIMI-flöde före	1 Partiell fyllnad *
Synlig tromb i kärlet?	2 Liten (största diameter < ½ kärldiameter KD) *
Avvek du från radomiserad behandling?	0 Nej *
Hade du någon trombotisk komplikation under proceduren?	2 Ja, ledare, guide el dylikt trombotiserade *
TIMI-flöde efter	3 Normalt *
Kommentar (studierelaterat, skrivs ej ut på utlåtandet)	
Totalmängd heparin givet under procedur:	8000 *
Mättes ACT?	1 Ja *
Vad var max ACT?	325 *
Hur lång tid innan PCI fick patienten ticagrelor/prasugrel?	3 3–6 timmar *

PCI

- Register identifies eligible patients
- Asks the operator if patient agrees to participate
- If yes, immediate randomisation result
- Performed in a few seconds

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Conclusion

- **Bottom-up is key points.**
  - Healthcare providers dedicate.
  - Central/Local governments make budgets.
  - Data will be opened for publics.

- **Direct linking with national data statistics.**
  - Starts with number of citizens.
  - Connects among registries.

- **Evaluation is essential, but Incentive/disincentive will ruin.**
  - Find weak points, then help them positively.