Post-market clinical follow-up and registries – the example from SWEDHEART

ESC: Engaging with the new European regulatory landscape for medical devices – Challenges and opportunities

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Head of Department of Cardiology, Lund University, Sweden
Data bases for baseline characteristics and outcomes in Sweden

Since 1947

540219-9750

year month day place sex ctrl

Public mandatory registries

Outpatient diagnosis registry

Prescription registry

Population registry

Hospital admission registry ICD

EHRs Hospitals and primary care

Sweden statistics
Data bases for baseline characteristics and outcomes in Sweden

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Quality Registries

Outpatient diagnosis registry

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Sweden statistics
SWEDEHEART

- The Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies (SWEDEHEART) was launched 2009 after merging of the:
  - National registry of acute cardiac care (RIKS-HIA)
  - Swedish coronary angiography and angioplasty registry (SCAAR)
  - National registry of secondary prevention (SEPHIA)
  - Swedish heart surgery registry

- Registries evolved from the users to fulfill a need from the profession!
SWEDEHEART: Funding

- The registry is financed by the **Swedish government** and the Association of Local Authorities and Regions (the **counties public health care provider**)
- Also supported by the Swedish Heart & Lung Foundation.
- Participating hospitals are not reimbursed by the registry and costs of local data entry are borne by their internal budget.
SWEDEHEART

• SWEDEHEART includes patients with acute coronary syndrome (ACS), and patients undergoing coronary angiography/PCI or heart surgery.

• The registry enrolls 80,000 cases each year:
  - 30,000 with ACS
  - 40,000 undergoing coronary angiography/PCI
  - 7,000 undergoing heart surgery
  - 6,000 followed for secondary prevention (1 y).

• The platform is in direct contact with the Swedish National Population Registry for immediate access to personal data and deaths.

• The registry is continuous year after year. A patient that has a new MI or PCI is reported again.
Since 2006, the number of angiographies and PCIs have continued to increase, although at a lower rate than previously observed. Since 2002, therapeutic PCI procedures have been separated from PCI procedures with use of intracoronary physiology only (fractional flow reserve [FFR] and instantaneous wave-free ratio [iFR]). The number of CABG procedures following coronary angiography continues to display a declining trend.
SWEDEHEART

• ACS patient information is collected prospectively for **106 variables** and include patient demographics, admission logistics, risk factors, past medical history, medical treatment prior to admission, electrocardiographic changes, biochemical markers, other clinical features and investigations, medical treatment in hospital, interventions, hospital outcome, discharge diagnoses and discharge-medications.

• For patients undergoing coronary angiography/angioplasty on any clinical indication approximately **150 variables** are registered.

• For patients <80 years with ACS a follow-up visit is performed after 6-10 weeks and after 12-14 months. From these visits approximately **75 new variables** are added.
Recurrent registrations of a patient in SWEDHEART

Stable Angina → PCI

ACS → MI/Stent thrombosis

Secondary Prevention → 1 year

Heart Attack at home → Death

Time (years)

SCAAR

RIKS-HIA & SCAAR

SEPHIA

Cause of death registry

Death automatically transferred to SWEDHEART
Merging with other registries

• The use of personal identification number enables merging with the National Cause of Death Register and the National Patient Registry, which includes diagnoses at discharge for all hospital stays in Sweden.

• Every merge of registries is approved by the National Board of Health and Welfare, the Swedish Data Inspection Board and an ethical committee.

• After merging of the registries, researchers have access to hospital identity but not to patient identity.
Monitoring

- To ensure the correctness of the data monitors visit about 20 hospitals each year and compares data entered into the SWEDEHEART with the information in the patients’ records from 30–40 randomly chosen patients in each hospital.
- In 2007, there was a 96.1% agreement.
- In 2016, there was a 97% agreement.
- Regarding patients with ACS over 90% are covered by the registry.
- For angiography and PCI 100% are covered.
The main purpose of the registry is to support the improvement of care.

The long-term goals are to contribute to decreased mortality and morbidity and increase cost effectiveness.

The registry compares performance of participating hospitals and different treatment modalities and medical devices.

A national, regional and county based report is presented on a yearly basis.

http://www.ucr.uu.se/swedeheart/
Figure 72. Proportion of performed coronary angiography with stable coronary artery disease in which intracoronary pressure measurement (FFR or iFR) has been used, 2016.

Target point is set at 30%.

FFR/iFR have a great value for diagnosis and decision. The diagnostic tool has a high priority (Priority 3) in the Sweden National Heart Guidelines, 2015. FFR has recommendation and evidence level IA according to the ESC/EACTS guidelines, 2014.
Thirty-day mortality after PCI in STEMI patients, per hospital, 2007–2016 (mean value and 95 % CI).
Stents in SCAAR

• All stents placed in Sweden since before 2000
• **Brand, length, diameter, pressure, postdilatation, bifurcation, lesion severity (A-C), CTO.**
• Patient demographics, STEMI, NSTEMI, stable angina etc.
• **New PCI:** Question is asked if this is an acute stent thrombosis or not.
• Analysis **segment level:** Restenosis, Stent thrombosis.
• Analysis **patient level:** Death, MI and revascularisation.
• We can provide: **Safety, Performance, Benefit-to-Risk, State-of-the-art** (comparison with similar products).
Stent: Restenosis


Approximately 300,000 stents placed.
Stent: Restenosis

Restenosis in most used stents implanted >1000 times in Sweden, 2007 - January 23th 2018.

Cumulative rate of restenosis

Time (years)

Number at risk

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Stent: Stent thrombosis


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Stent: Stent thrombosis

Stent thrombosis in most used stents implanted >1000 times in Sweden, 2007 - January 23th 2018.

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Stent use over time
Examples of post-marketing stent evaluations in SCAAR

1. One of the most commonly used DES: Overall performance compared to other modern DES “state-of-the-art”, but also performance of subgroups: small diameter stents, bifurcations, diabetics etc. N > 10000.

2. Niche product, covered stent: n = 140

3. New introduction of extra long stent, n=700 the first year.
Figure 54. Proportion of bleedings at puncture site in PCI patients, per vascular closure device with more than 50 uses, 2016 (bars representing 95 % CI; number of bleedings above the bar).
Figure 33. Number of different types of drug eluting balloons (DEB) used, 2009–2016.
Other Swedish registers

- SWEDVASC (Vascular Surgery)
- SWENTRY (Percutaneous valves)
- Thoracic Surgery
- Orthopedic registers
- Diabetes
- Rheuma
- >100 registers

http://kvalitetsregister.se/index.html
Other countries

• The SWEDEHEART platform has been implemented or is under development in Norway, Iceland and England.

• Interest has been expressed from Denmark, Netherlands, France and Uganda(!).
Limitations

• Wires, balloons, guide catheters, aspiration catheters are not covered by the registry.
• We discuss adding an extra module to capture these devices
Conclusion

• The SWEDEHEART and other Swedish registries are excellent for post-marketing follow-up of medical devices.
• They are prospective, nationwide, with high coverage, continuous, long-term and detailed.