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Information from cardiovascular and arthroplasty registries

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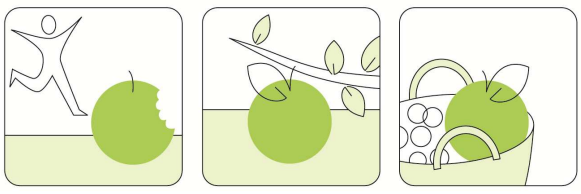

MAIN BENEFICIARY

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ASSOCIATED BENEFICIARIES

EFORT/EAR Verein zur Unterstützung der Tätigkeit von nationalen Endoprothesenregistern, *Austria*

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BQS Bundesgeschäftsstelle Qualitätssicherung gGmbH, *Germany*

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CARDIOVASCULAR PILOT

Information from Cardiovascular (CV) registries

In CV registries the following information are collected:

1	Patient code (anonymous)
2	Hospital Code
3	Country
4	Age
5	Gender
6	Smoking
7	Hypertension
8	Dyslipaemia
9	Peripheral artery disease
10	Diabetes
11	Family History of CHD
12	Other CVD
13	Previous angina
14	Congestive heart failure
15	Previous revascularization
16	Previous CABG
17	Previous renal failure
18	Previous stroke
19	Time symptom-1st monitorization
20	Time symptom-revascularization
21	Ventricular fibrillation < 24h
22	Ventricular tachycardia < 24h
23	Atrio-ventricular blockade < 24h
24	Atrial fibrillation of flutter < 24h
25	Severe mitral valve dysfunction
26	Admission Killip class
27	Glycaemia mg/dl
28	Total cholesterol mg/dl
29	LDL cholesterol mg/dl
30	HDL cholesterol mg/dl
31	Triglycerides mg/dl
32	Hemoglobin mg/dl
33	Ventricular fibrillation >24h
34	Ventricular tachycardia >24h
35	Atrio-ventricular blockade >24h
36	Atrial fibrillation of flutter >24h
37	Killip class maximal > 24 h
38	Oral Beta Blockers. Discharge
39	Statins. Discharge
40	ACE Inhibitors. Discharge
41	Coronary angiography
42	Thrombolysis

43 Revascularization with primary angioplasty
45 Cardiac death 0-30 days
46 ReMI 0-30 days
47 Angina post infarction 0-30 days
48 Cardiac death 30 days-6 months
49 Readmission for ReMI 30 days-6 months
50 Angina / revascularization 30 days-6 months

Statistical analyses performed

For each procedure (CABG, coronary angiography and coronary angioplasty) and selected outcome three types of multivariate models adjusting for sex, age, severity of myocardial infarction and comorbidity is fit: first including hospital as a fixed effect and comparing each hospital rate with the average rate and second adding to the former the variable “hospital” as a random effect but extending the model with characteristics at the hospital level (i.e. number of beds, catheter laboratory existence, etc.) as fixed effects. Eventually models further extended with country characteristics also as fixed effects are considered.

The former models allow benchmarking hospitals regardless of their characteristics. The second approach allows to benchmark hospitals taking into account their characteristics. The third approach permits also to take into account the country characteristics if they are found to be relevant to outcome. Potential confounders at Individual and Hospital level (and eventually at country level) can be determined with a multilevel general multiple linear regression model.

Several models can be fit with increasing complexity in the number of variables, in such a way that all the country administrative discharge data can be used regardless of their completeness for benchmarking hospitals (and eventually countries).

Analysis can be done fitting a logistic model in a Bayes methodology. For random effect (i.e. hospital) residuals can be obtained where a positive value means an excess risk, and, conversely with a negative value. The 95% credibility interval is calculated for each estimate.

ORTHOPAEDIC PILOT

Information from Arthroplasty registries (shortened questionnaire)

In the current Arthroplasty registries the following variables are collected:

Basic Data
Country, Name of the Register, Address, e-mail address, website, Contact person
Legal Status
Society, Project of Public health Institutions, Foundation, Research Project

Staff
Head, Supervisory Board, Medical staff, Statistician, Administrative Staff, IT-Staff, Other relevant staff or boards

History of the Register
First outcome related Register in the country started
Initiative started for present Register: (year, which)
Decision to set up the register (year, who):
Start of the Pilot project
Start of the National Data collection
Receive > 75% compliance
Receive > 90% compliance
Validation process started (year):
Strategy for Validation used
Sources of information used for validation
Validation published (year, title)
First publication of the Register in a peer reviewed journal (year, title, journal)
First annual Report (specify year, title, on line availability if any)
Start feedback mechanisms to partners (year)
Initial funding
Later funding
Start present funding

Inhouse / Outsource
Activities done by the core team in the Register itself, activities outsourced and to whom

- Data collection
- Databank basic
- Databank adjustment
- Statistical evaluations
- Printing
- Validation

Data collection
Basic philosophy

- Outcome research related
- Not outcome research related

Main goal of the Register
Initial data collection
Follow up/Reference data collection

Physical location of the databank
- Network
- Online-server
- Offline server
- Not connected workstation

Software and Hardware used
IT - Data security at the server (firewalls):
Data security backup
Access to data (persons, PIN-restricted)

Processing of information collected
- Paper forms
- Fax
- Informatic support (Floppy, CD)
- Online
- Others

Data collection in Hospitals
- Information collected redundant (= Paper forms filled by the surgeon even the information is already available in the inhouse IT system)
- Excerpt from an existing dataset (= automatic excerpt from information collected for other purposes in the hospital IT system)
- Mixed data collection (= automatic excerpt from information collected for the Register in the hospital IT system

Proposed time for data collection
- Hospitalisation
- Before surgery
- After surgery
- Discharge
- After discharge
- Clinical control/FUP examination
- Questionnaires to patients periodically sent

Data collection procedures at staring point (in general):
- By surgeon at the operating room
- Review of the medical history at discharge
- By nurses

Data collection procedures at Follow up (in general):
- By surgeon at the controls
- Retrospective Review of the medical history
- By nurses

Plausibility checks at documentation: Which, Where

Connection to other databanks/data sources
Discharge Register
Inhabitants Register /Deceased persons:
Economical data
Others

Legal status of the data collection
- Patient consent mandatory
- Permission by law
- Official project of a public institution under special conditions concerning data collection

Participation to the Register
- Mandatory
- Voluntary

Actions to support participation
Owner of the data

Validation
Number of departments performing Arthroplasty
Number of Departments in cooperation with the Register
% of Departments included
% of Market covered (Number of Cases)
% of cases/implants/patients collected at the Register database referring to the total number in the area in the previous year (Report)
% of clinicians reporting to the Register / total number of physicians performing Arthroplasty

Validation procedures of the Register
- Routine
- Publications

Implant tracking
Implant Databank
Connection to the Register Databank:

Information collected
- Implant name
- Article number
- Lot-Number
- Implant specifications

Size
Maintenance
Organisation and Management of the Implant databank

Access of Stakeholders to not published datasets

Public Health Institutions
- Ministry of Health
- Regional Public Health Institutions
- Public Health Insurances:
- Private Health Insurances
- Manufacturers
- Patients

Physicians
- Own Department
- For Revisions
- All data

Others

Extraordinary Reports on Demand

Implants
Since, Nr/year, Total:
- Hip
  - o Total
  - o Partial
- Knee
- Monocondylar
- Ankle
- Shoulder
- Elbow
- Toe
- Wrist
- Finger

Evaluations
Definition of Revision (Endpoint)
Indicators calculated
Statistical methods

Additional clinical forms

Documentation of Revisions (more than one reason)
- Multiple Choice (equal)
- Algorithm how to select the main reason
- Main reason defined by the surgeon/centre

How

Strategy of Analyses
Who is defining the Strategy of Analyses
Who is performing the analyses
Statistical methods

Review process and Reporting
Preparation of the first Report (persons, time frame, access to information)
Review processes before establishing the final Annual Report

Preparation of the department Report
- Review process by the core team
- Automatic generation

Data Publication
Annual report (in English, yes or no)
Scientific Publications (Literature list, www-address where available)
Extraordinary Reports on Demand

Impact and external Auditing
Impact of the Register for the Sponsors, Public Health, Physicians, Patients
Quality control activities / feedback
Regular meetings
External auditing

Parameters

Main parameter (main target)
Main indicator evaluated
Parameters included in the departments report
Structure of the departments report

Present data collection forms
How and who conceived

Modifications of the forms
Which additional parameters, When, Why
Additional benefit
Quitted Parameters: When, Why, Retrospective view

Present and Historical Forms

Budget
Global Budget
Covered by
Expenses
Personnel
Travel and accommodation
IT
Outsource service

Historical reports