Belgische Vereniging voor Cardio-thoracale Heelkunde (BVCTH)
Societe Belge de Chirurgie Cardio-thoracique (SBCCT)
Belgian Association for Cardio-Thoracic Surgery (BACTS)

Report of the database committee "Improving the quality of care through better data registration".

May 12th, 2011

BACTS Database Committee

Belgian Surgical Week, Oostende

Royal Belgian Society for Surgery (RBSS) npa
Koninklijk Belgisch Genootschap voor Heelkunde (KBGH) vzw
Société Royale Belge de Chirurgie (SRBC) asbl

in collaboration with
BAAS, BACTS, BAST, BELAPS, BGES, BSSO, BSVS, BTS, CC
and the sections of RBSS: BSAWS, BSBS, BSCRS, BSES, BSHBPS, BSUGIS, BeSOMS

TWELFTH BELGIAN SURGICAL WEEK
Ostend, Thermae Palace Hotel
11th-12th-13th-14th May 2011

GOOD CLINICAL PRACTICE AND RIGHT INDICATIONS IN SURGERY: A MATTER OF ETHICS OR ECONOMICS

Preliminary Programme

RBSS's Major Sponsors KCI Johnson&Johnson MEDICAL BV

BACTS

Database Roster

OFFICE	NAME	TERM OF OFFICE
Chair	Bernard A. Stockman	
Member	Liesbeth Bruckers	
Member	Erik de Worm	
Member	David Glineur	
Member	Herbert Gutermann	
Member	Marc A. Radermecker	
Member	Paul T. Sergeant	
Member	Constantin Stefanidis	
Member	Yves Victor Van Belleghem	
Member	Carine M. Vandeweyer	

Overview activity 2001-2009
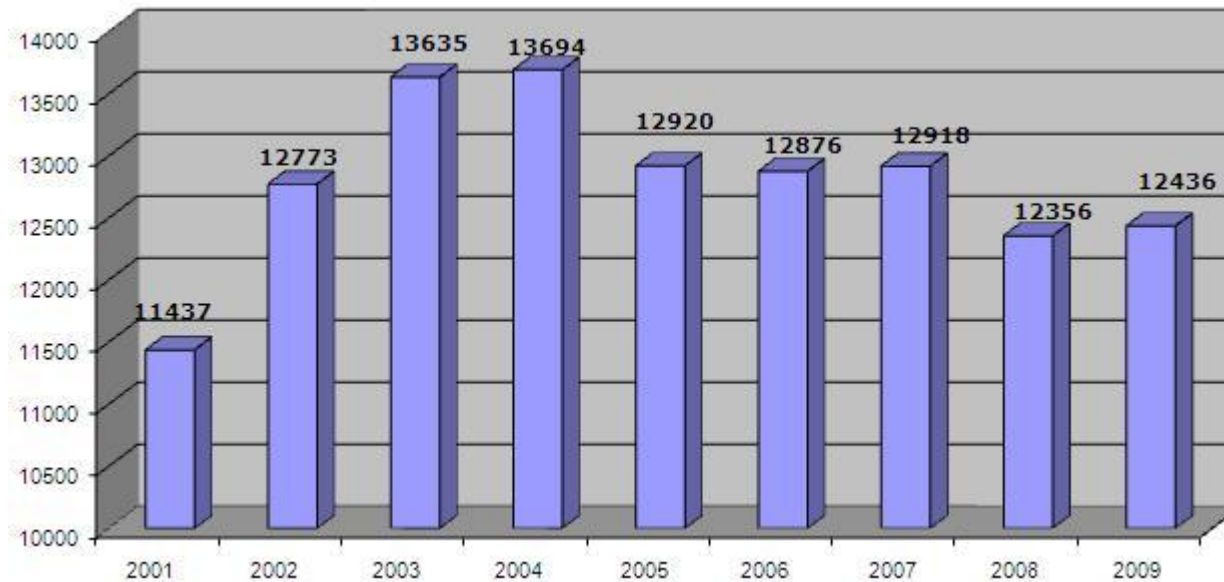
Number of cardiac operations
28 centres
2008: 1 centre missing

BACTS

Overview activity 2001-2009

Cardiac Operations - female
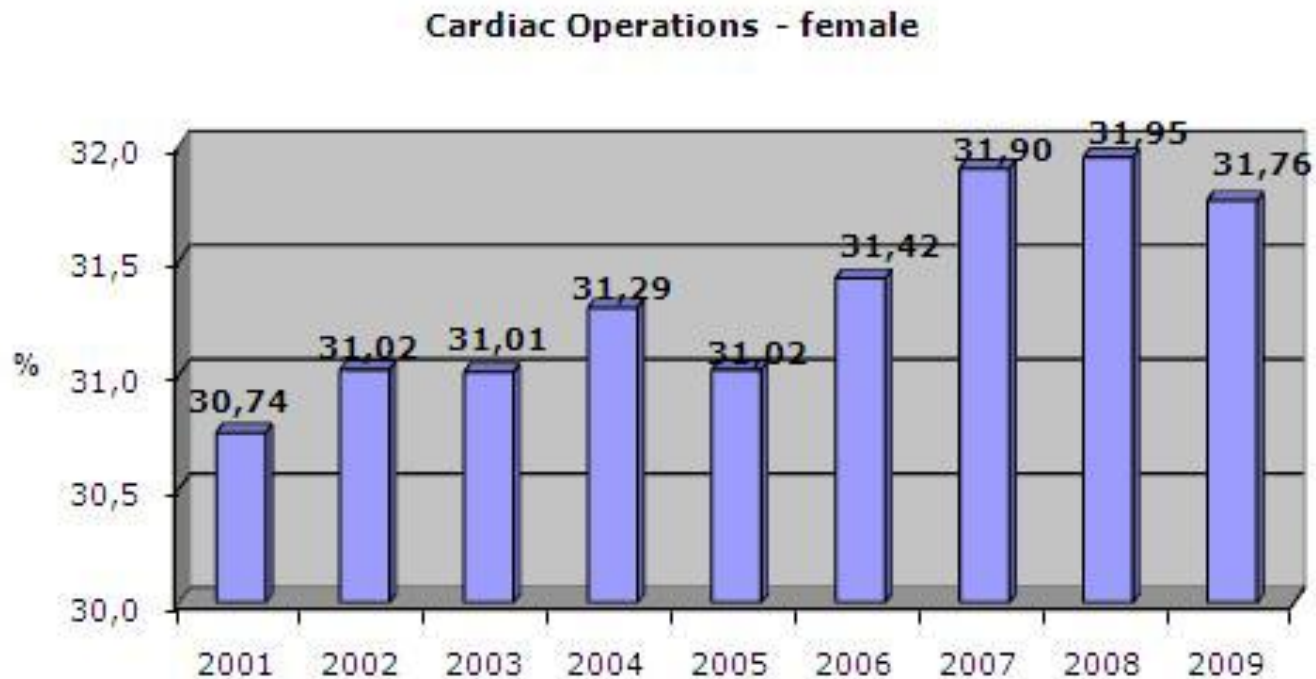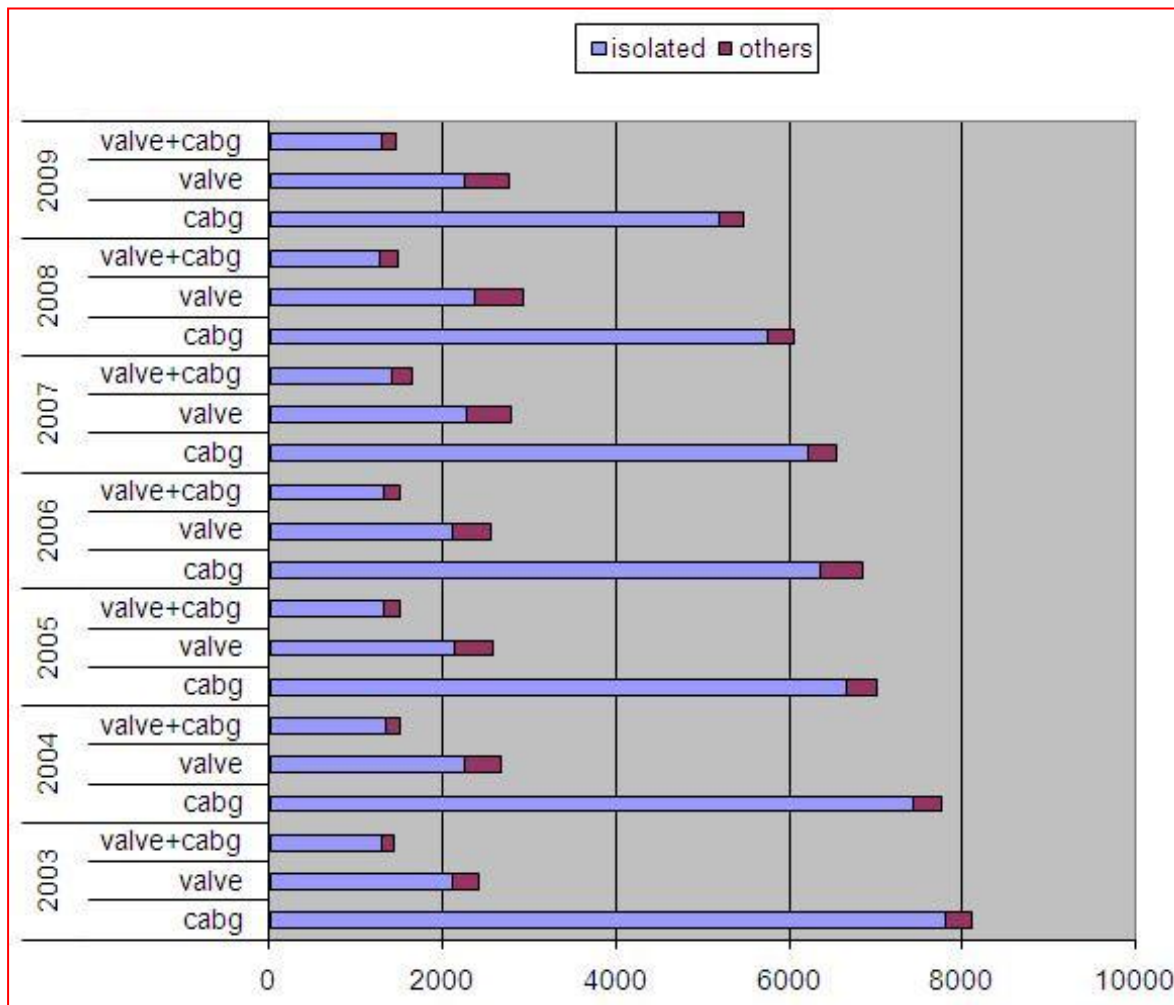
	2001	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**
isolated CABG	7012	7582	7795	7432	6665	6369	6209	5760	5196
CABG + other	257	309	301	312	330	358	341	304	276
valve only	1673	1914	2120	2244	2127	2118	2273	2388	2249
Valve + other	209	300	273	403	427	441	514	550	509
valve + CABG	859	1068	1299	1341	1322	1325	1417	1267	1285
valve + CABG + other	66	120	137	153	174	177	217	206	180
thoracic aorta	**304**	**368**	**439**	**468**	**445**	**593**	**542**	**544**	**544**

BACTS

Overview activity 2001-2009
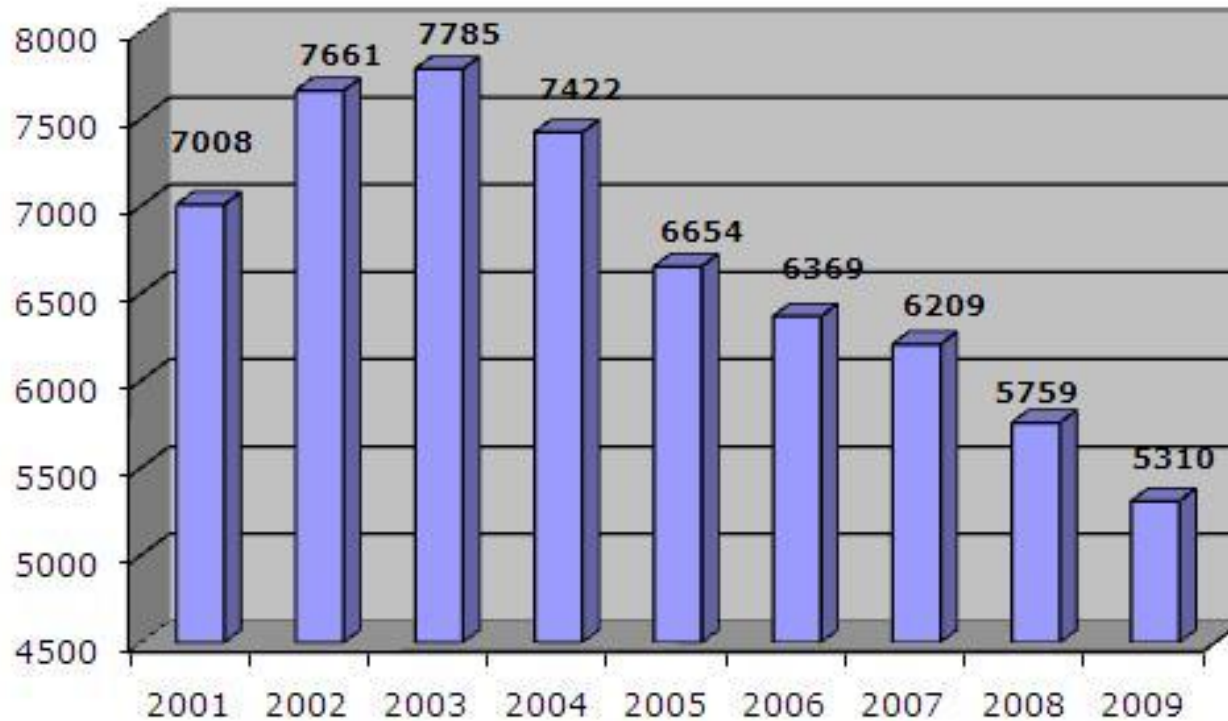
Isolated CABG

Overview activity 2001-2009
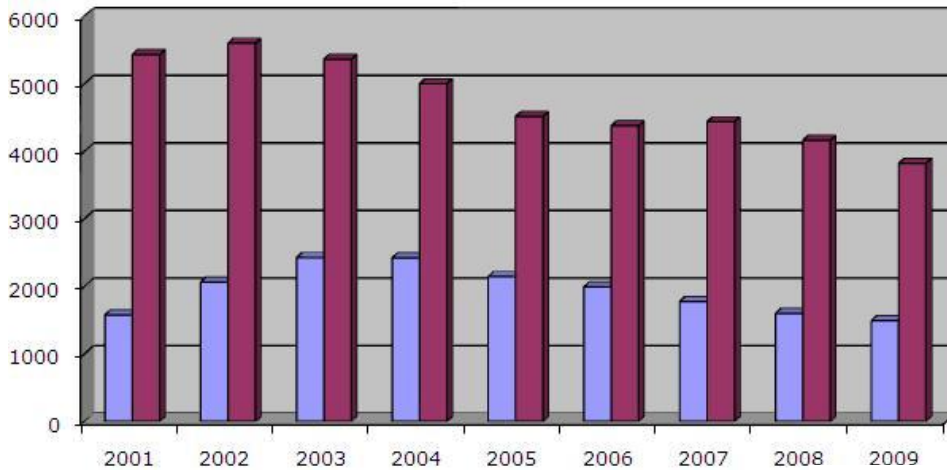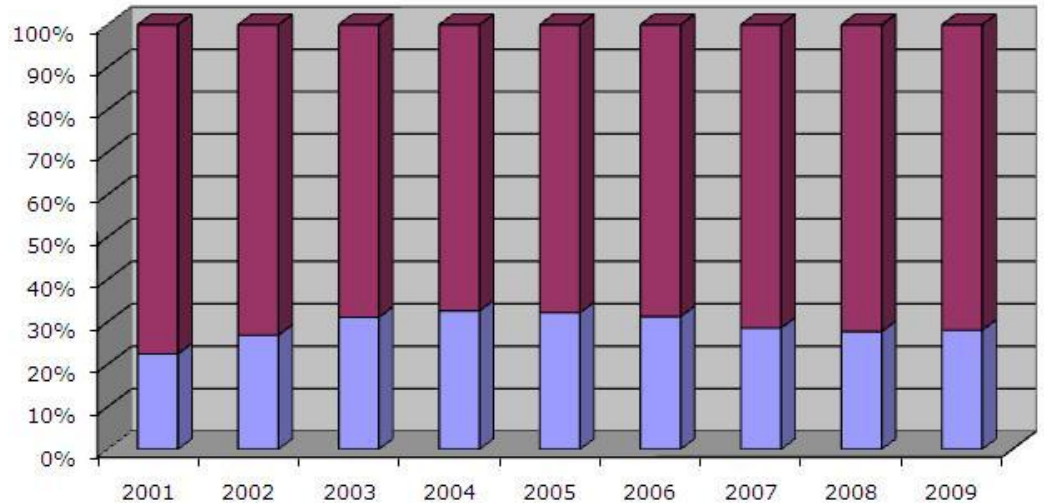
CABG: on-pump / opcab

BACTS

2008 report

www.bacts.org

**BACTS
Cardiac Surgical
Database Report**

FINAL REPORT 2008

**Compiled by
BACTS DATABASE COMMITTEE**

Version 11.02.2011

BACTS

The purpose of the Database Committee is

- To create, maintain and analyse a registry of the cardio-thoracic surgical activity in Belgium.

- To create therapeutic or epidemiological studies involving the cardio-thoracic therapy, with the intention to improve the quality of care

- The database will never serve to rank centres or surgeons, will never participate in malpractice investigation or conformity checking with legal requirements of centres and surgeons.

BACTS

Confidentiality

- All members of the committee, including the data manager and the data analyst are under the medical secret. The database is protected by secret entry-codes. In addition the names of the centres and the RIZIV/INAMI numbers are recoded into secret codes. The password and codes are kept in a sealed envelope with the chairman of the database committee. No database committee chairman or member has access to the actual identification of the centre or the surgeon. The Law on the Medical Secret: data cannot and should not be transferred to any third party, e.g. council of BACTS, Health authorities, industry. There are two exceptions: (1) there is a database-specific law ordering the transfer of these data; (2) all parties or centres give their written permission for each specific output
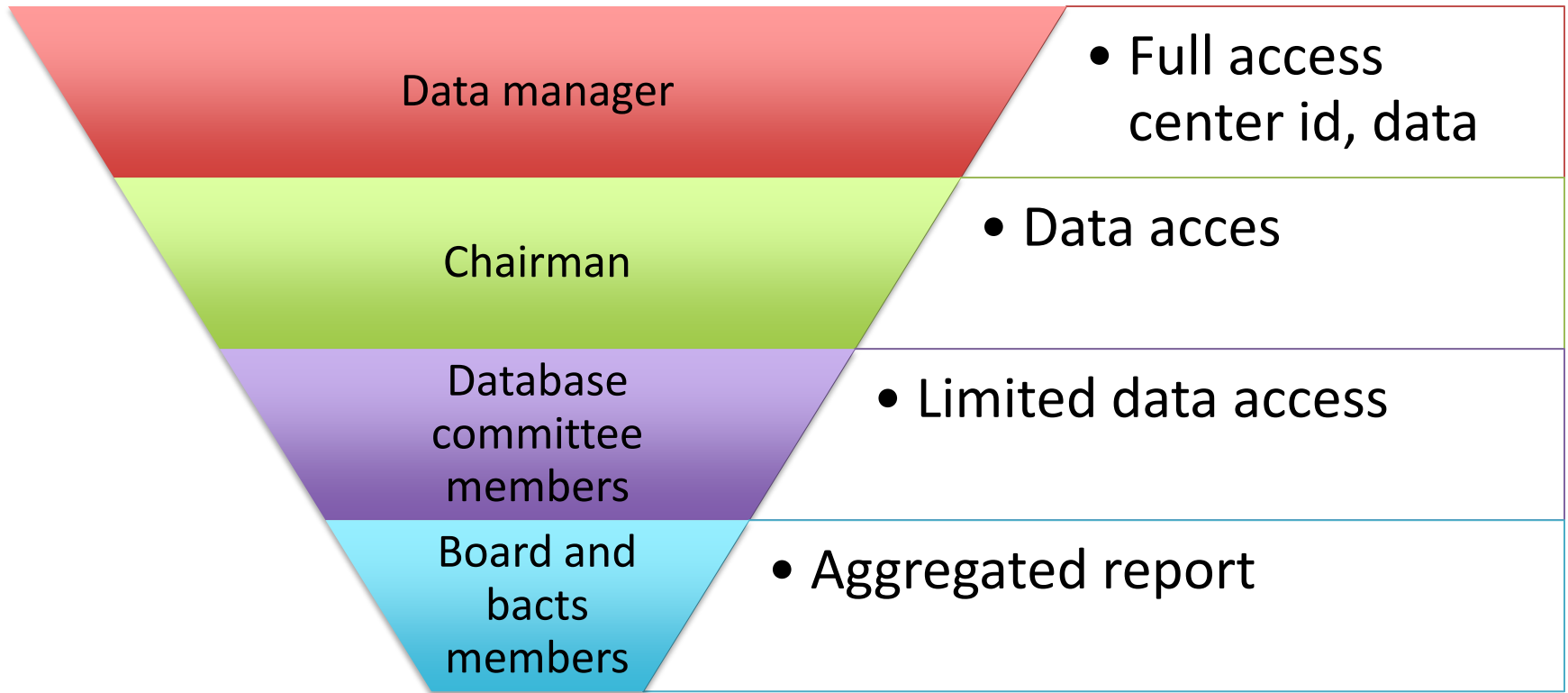
BACTS

Confidentiality

- No centre- or surgeon-specific information can be given to any third part outside the database committee without the written permission of the chairmNo centre-, nor surgeon- identified informationan of the centre or the individual surgeon. can be looked into by the members of the database committee.

BACTS

The access to the data

- The access to the data has three levels. The first two levels concern the Database Committee members.
    - The first level is unrestricted. This access is given to the chairman of the database committee, the data-analyst and the data manager.
    - The second level is restricted to a "need to know level", defined by the committee and this access is given to all the members of the committee.
    - The third level is restricted to the centre's own data. This access is given to the Chairman of the center. This access is unrestricted in time but limited to the data of the center.

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Data access

Role	Access
Data manager	• Full access center id, data
Chairman	• Data acces
Database committee members	• Limited data access
Board and bacts members	• Aggregated report

BACTS

Memory of understanding

Confidentiality
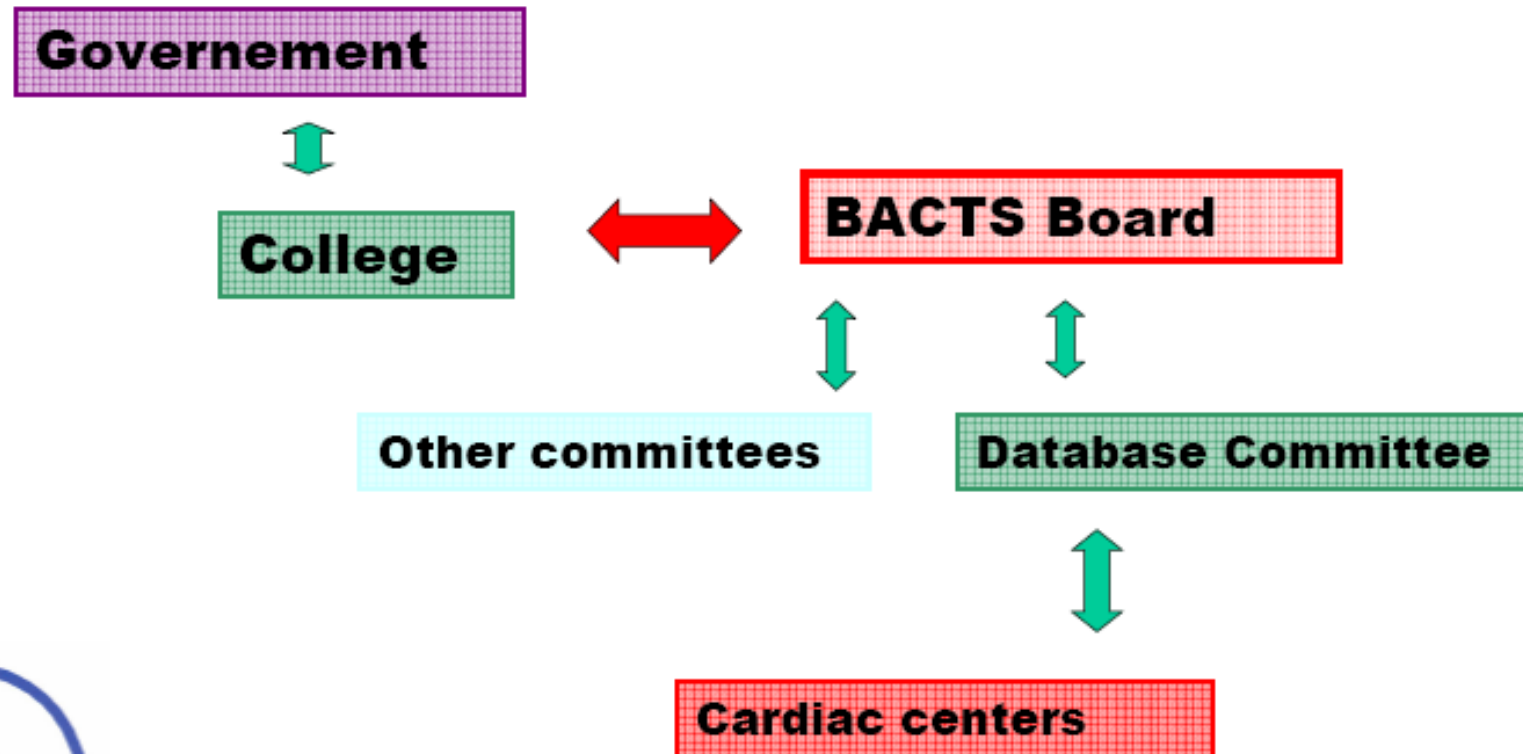
Patient anonymity is guaranteed

Center/surgeon anonymity is guaranteed

In practice: BACTS - College - DBC

Governement

College ⟷ BACTS Board

Other committees

Database Committee

Cardiac centers

BACTS

Quality control

Measuring risk → **Prediction of outcome** → **Risk adjusted analysis**
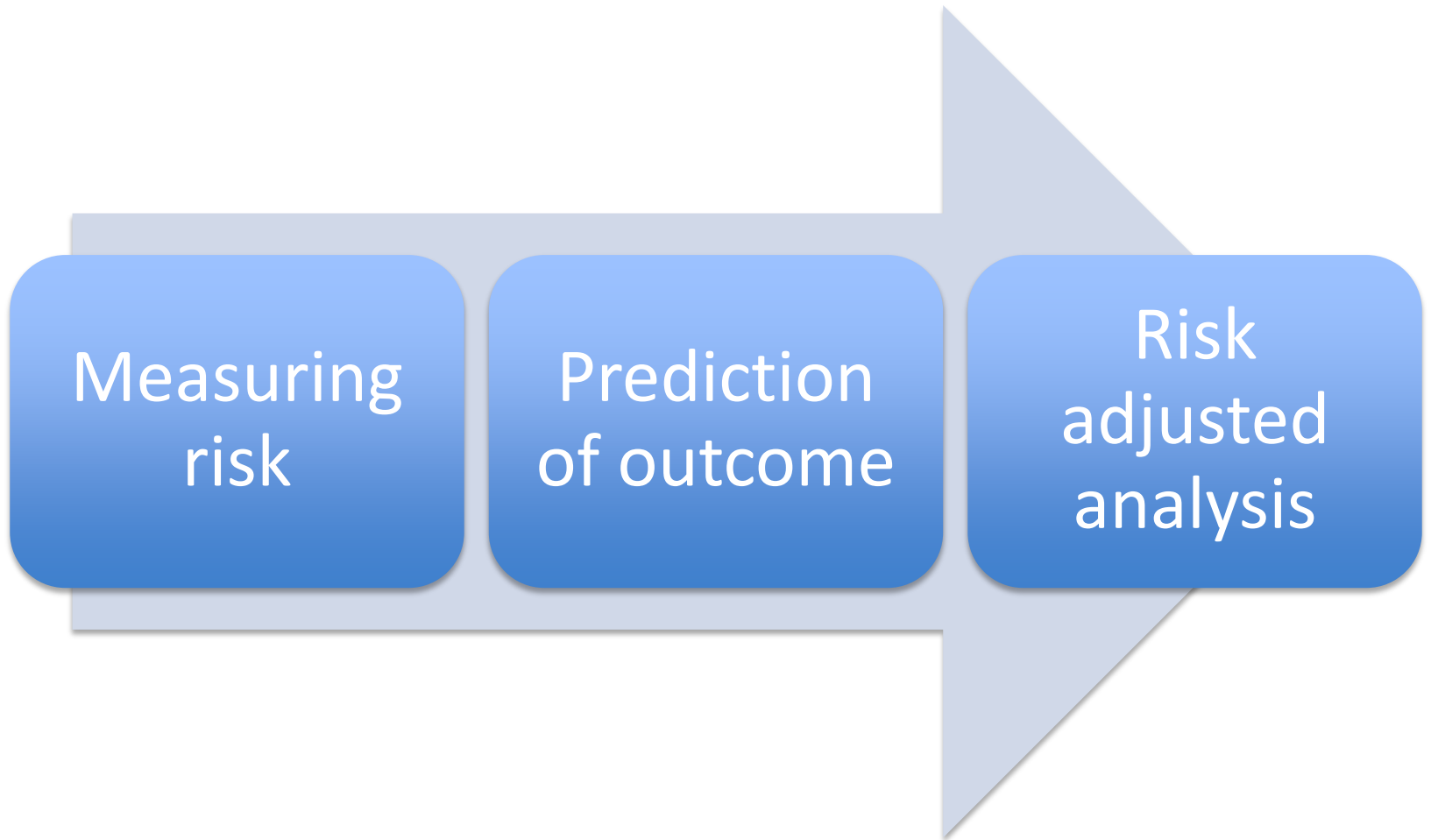
Risk-adjustment algorithm

- Risk factors

- Weighting of factors

- Validation of risk model
  - EuroSCORE
  - STS-score

EACTS

Adult Cardiac Surgery Database
Version 1.0

- Hospitalization

- Cardiac History

- Previous Interventions

- Pre-operative risk factors

- Pre-operative hemodynamics and catheterization

- Pre-operative status and support

- Operation – procedural factors

- Perfusion and myocardial protection

- Post-operative complications

- Discharge details

The European Association for Cardio-Thoracic Surgery
Fourth Adult Cardiac Surgical Database Report 2010

The EACTS database form

BACTS

EACTS

Adult Cardiac Surgery Database Version 1.0

- 86 fields

- Postoperative complications
  - Re-operation
  - New post-operative stroke
  - New post-operative dialysis
  - Multi-system failure

- Discharge details
  - Date of discharge/death
  - Destination on discharge
  - Patient status at discharge
  - Primary cause of death

The European Association for Cardio-Thoracic Surgery
Adult Cardiac Surgical Database
Version 1.0; page 8

Unique patient Identifier

Date-of-surgery   dd / mm / yyyy

Post-operative complications

Re-operation
- ○ No re-operation required
- ☐ Re-operation for graft problems
- ☐ Re-operation for valve problems
- ☐ Re-operation for bleeding / tamponade
- ☐ Sternal resuturing for any reason
- ☐ Re-operation for other cardiac problems

New post-operative stroke
- ○ None
- ○ Transient   ○ Permanent

New post-operative dialysis   ○ No   ○ Yes
Multi-system failure   ○ No   ○ Yes

Discharge details

Destination on discharge
- ○ Not applicable - patient deceased
- ○ Home
- ○ Convalescence / Nursing home
- ○ Another unit within the same hospital
- ○ Another hospital

Patient status at discharge   ○ Alive   ○ Deceased

Primary cause of death
- ○ Not applicable
- ○ Cardiac   ○ Infection
- ○ Neurological   ○ Pulmonary
- ○ Renal   ○ Valvular
- ○ Vascular   ○ Other

Designed by
Dendrite Clinical Systems

This form is laid out so that questions requiring a single response are identified by round radio buttons next to the options, whereas questions where more than one response may be selected are identified by square tick-boxes next to the options.

BACTS

BACTS 2012 Registry

- Based on EACTS version 1.0
  - No update announced
  - limitations

- Euroscore 2010 modifications not incorporated yet

- Software: datafile in Filemaker Pro

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Belgische Vereniging voor Cardio-thoracale Heelkunde (BVCTH)
Societe Belge de Chirurgie Cardio-thoracique (SBCCT)
Belgian Association for Cardio-Thoracic Surgery (BACTS)

Home

The new BACTS-2012 Registry is a copy of the EACTS's Adult Cardiac Surgery Database (Version 1.0). No update of the EACTS-dataset has been announced for the near future.

There are some minor modifications of the original EACTS-dataset.

The BACTS 2012-Dataset will be a significant improvement compared to the BACTS-CPT registration.

However, we realize that this dataset has limitations and cannot fulfill the data-needs for every cardiac surgeon.

We provide a FileMaker Pro application for the BACTS 2012 Registry. With this application the Excel-file for data-submission can be generated.

The FileMaker Pro application has some extra fields, that are not included in the BACTS 2012 Registry Dataset but that have been added for convenience.

Centres are free to use the FileMaker Pro application. Also other software can be used to generate the Excel-file.

The EuroSCORE 2010 changes or not incorporated yet.
The BACTS 2012 registry is designed for adult cardiac surgery. All congenital cardiac surgery should be reported in the EACTS Congenital Database: www.eactscongenitaldb.org

Here you will find the beta-versions of the dataset, data-specifications and the FP-application. You also will find an example of a Data Collection Form (DCF). Please contact the data-manager for the login and password of the FP-application. You can download a trial-version of Filemaker Pro at http://www.filemaker.com/be/ to evaluate this software. This beta-version is for evaluation only, it will be impossible to export/import the data from this version into the final version.

- Data Collection Form (DCF) [word / pdf]
- Data Specifications
- FilemakerPro-application (beta-version)
- Registry Concept
- Improving the quality of care through better data-registrations

The new BACTS 2012 Registry will go live the 1st of January 2012.

The BACTS Database Committee

BACTS

BACTS 2012 Registry concept

proces of data merging and analysing
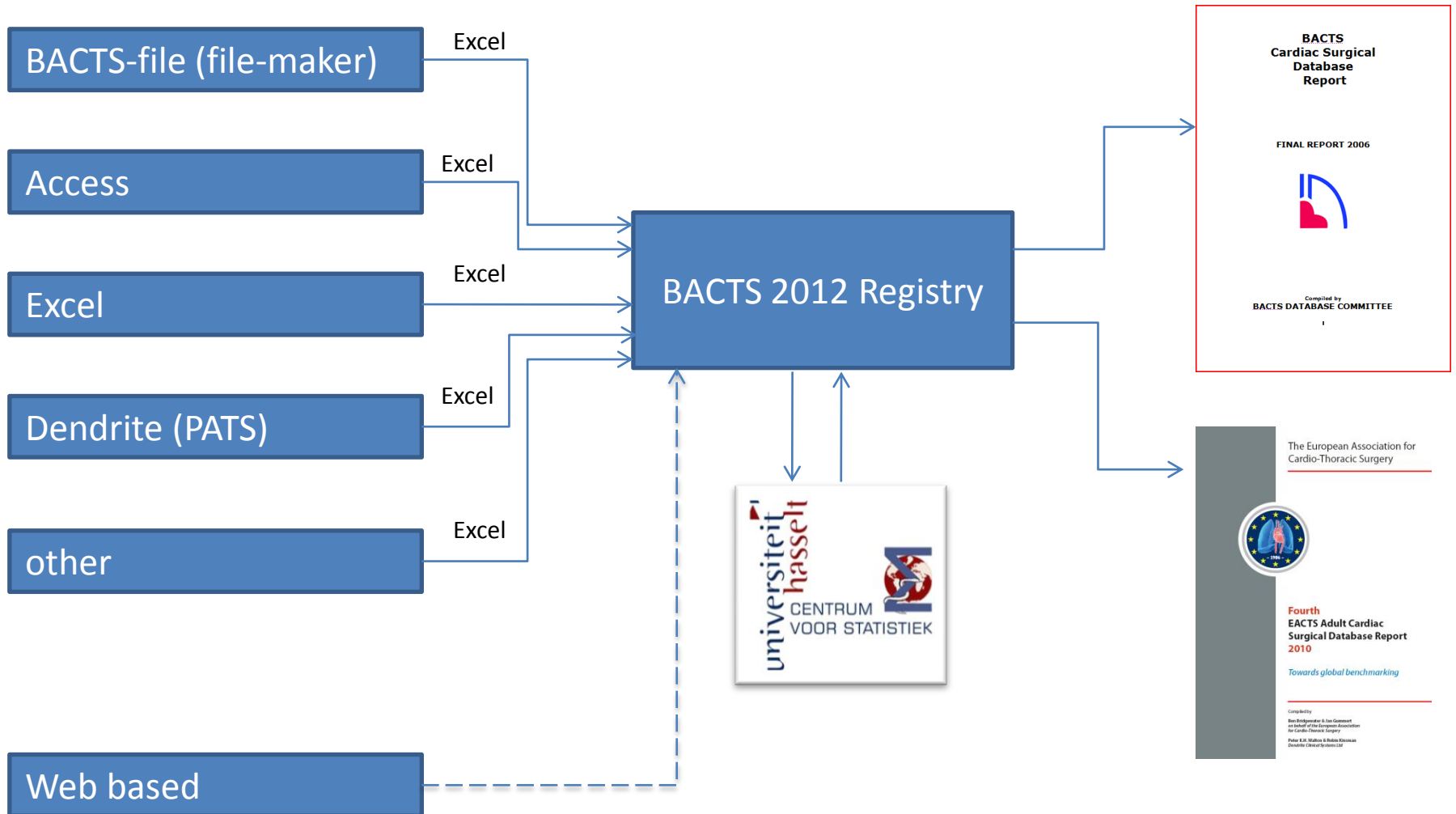
BACTS 2012 Registry software

- Filemaker Pro 11
  - Empty database
  - Export function to Excel
  - Expandable with TAVI, Afib, …
- Stand alone version
- Hospital network
  - Filemaker server and Filemaker Pro licenses
- External IT company support

Belgian Association for CardioThoracic Surgery

BACTS Cardiac Database

List of patients

Generating Excel-file

Patient:

Surname	Brad		Gender	● M ○ F
Name	Pitt		Date of birth:	
ID number	22041965M123			22/04/1965

Date of admission	21/02/2011
Date of operation	22/02/2011
Date of discharge/death	24/02/2011

Surgeon 1
1/09434/79/140

Surgeon 2
1/06255/57/140

Tabs: BACTS-data | TAVI-data | AFib-data | Personal data

Sub-tabs: Preoperative data | Operative data | Postoperative data

Inner tabs: Cardiac History | Previous Intervention | Risk Factors for CAD | Comorbidity | Haemodynam. and Catheterisation | Preop Status and Support | EuroSCORE

Angina Status	CSS 0
Dyspnoea	NYHA 3
Most recent myocardial infarction	No MI
Number of previous myocardial infarctions	unknown
Congestive heart failure	Yes

(A low EF alone, without clinical evidence of heart failure does not qualify as heart failure)

Myocardial infarction

- Two of the following four criteria are necessary:
  1. Prolonged (>20min) typical chest pain not relieved by rest and/or nitrates
  2. Enzyme level elevation: either - CK-MB > 5% of total CPK
     - CK greater than twice normal
     - LDH subtype 1 > LDH subtype 2
     - Troponin > 0,2 μg/ml
  3. Any wall motion abnormalities as documented by LV Gram, Echo and/or EF < 45%
  4. Serial ECG (at least 2) showing changes from baseline or serially in ST-T and/or Q waves that are 0,03 s. in width and/or ≥ 1/3 of the total QRS complex in 2 or more contigious leads.

Belgian Association for CardioThoracic Surgery

BACTS Cardiac Database

Patient:

Surname	Brad
Name	Pitt
ID number	22041965M123

Gender: ◉ M ○ F

Date of birth: 22/04/1965

Date of admission	21/02/2011
Date of operation	22/02/2011
Date of discharge/death	24/02/2011

Surgeon 1: 1/09434/79/140

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Tabs: BACTS-data | TAVI-data | AFib-data | Personal data

Sub-tabs: Preoperative data | Operative data | Postoperative data

Sections: Cardiac History | Previous Intervention | Risk Factors for CAD | Comorbidity | Haemodynam. and Catheterisation | Preop Status and Support | EuroSCORE

Age: **46** years

Gender: **M**

Logistic EuroSCORE: 19,59 %

- COPD ☐ — Longterm use of bronchodilators/steroids
- Peripheral vascular disease ☐ — Claudication, stenotic carotid artery >50%, surgery of abdominal aorta or peripheral arteries
- Neurologic dysfunction ☒ — Disabled in walking or daily life functioning
- Previous heart surgery ☐

- Serum creat. > 2,2 mg/dl ☐
- Active endocarditis ☐ — Patient still under antibiotic treatment for endocarditis at time of surgery
- Critical condition ☐ — Ventricular tachycardia/fibrillation, reanimation, ventilation, inotropic support, IABP, acute renal failure
- Unstable angina ☐ — Requiring IV nitrates
- Recent myocard. infarction ☐ — < 90 days
- Pulmonary hypertension ☒ — syst. PAP > 60 mmHg

- LVEF 30-50% ☐
- LVEF <30% ☐
- Emergency (< 24h after admission) ☐
- Other than isolated CABG ☒
- Surgery of the thoracic aorta ☒
- Postinfarction VSD ☐

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Belgian Association for CardioThoracic Surgery

BACTS Cardiac Database

Patient:

Surname	Brad
Name	Pitt
ID number	22041965M123

Gender ⦿ M ○ F

Date of birth: 22/04/1965

Date of admission	21/02/2011
Date of operation	22/02/2011
Date of discharge/death	24/02/2011

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1/09434/79/140

Surgeon 2
1/06255/57/140

Tabs: BACTS-data | TAVI-data | AFib-data | Personal data

Sub-tabs: Preoperative data | Operative data | **Postoperative data**

Inner tabs: Complications | Discharge details | Follow-up

Reoperation	Re-operation for bleeding/tamponade
New postop stroke	None
New postop dialysis	No
Multi system failure	No

Logged in by: BACTS

BACTS

Belgian Association for CardioThoracic Surgery

BACTS Cardiac Database

Patient:

Surname	Brad	
Name	Pitt	
ID number	22041965M123	

Gender: ● M ○ F

Date of birth: 22/04/1965

Date of admission	21/02/2011
Date of operation	22/02/2011
Date of discharge/death	24/02/2011

Surgeon 1
1/09434/79/140

Surgeon 2
1/06255/57/140

Tabs: BACTS-data | TAVI-data | AFib-data | Personal data

Subtabs: Preoperative data | Operative data | Postoperative data

Sub-subtabs: Complications | Discharge details | Follow-up

Date of discharge/death	24/02/2011
Patient status at discharge	Alive
Destination at discharge	Home
Primary cause of death	

Belgian Association for CardioThoracic Surgery

BACTS Cardiac Database

Patient:

Surname	Brad	Gender	●M ○F
Name	Pitt	Date of birth:	
ID number	22041965M123		22/04/1965

Date of admission	21/02/2011
Date of operation	22/02/2011
Date of discharge/death	24/02/2011

Surgeon 1
1/09434/79/140

Surgeon 2
1/06255/57/140

BACTS-data | TAVI-data | AFib-data | Personal data

Preoperative data | **Operative data** | **Postoperative data**

Complications | Discharge details | **Follow-up**

Status at follow-up
- **Alive**
- Deceased

Date of last follow-up [ ] (preferentially > 30 days postop.)

BACTS 2012 Registry Timeframe

- 15th BACTS Congress: announcement
- February 24: Extensive presentation
  - Final Version: Data fields, definitions, format
  - Beta version of FP11-file
- Spring 2011: Start implementation of registry in all centers
- Mid 2011: final version FP-11 file
- January 1, 2012: BACTS 2012 Registry goes live
- CPT registration stops

BACTS 2012 Registry

- Risk-adjusted outcomes analysis

- Improvement of quality of care

The European Association for
Cardio-Thoracic Surgery

Fourth
EACTS Adult Cardiac
Surgical Database Report
2010

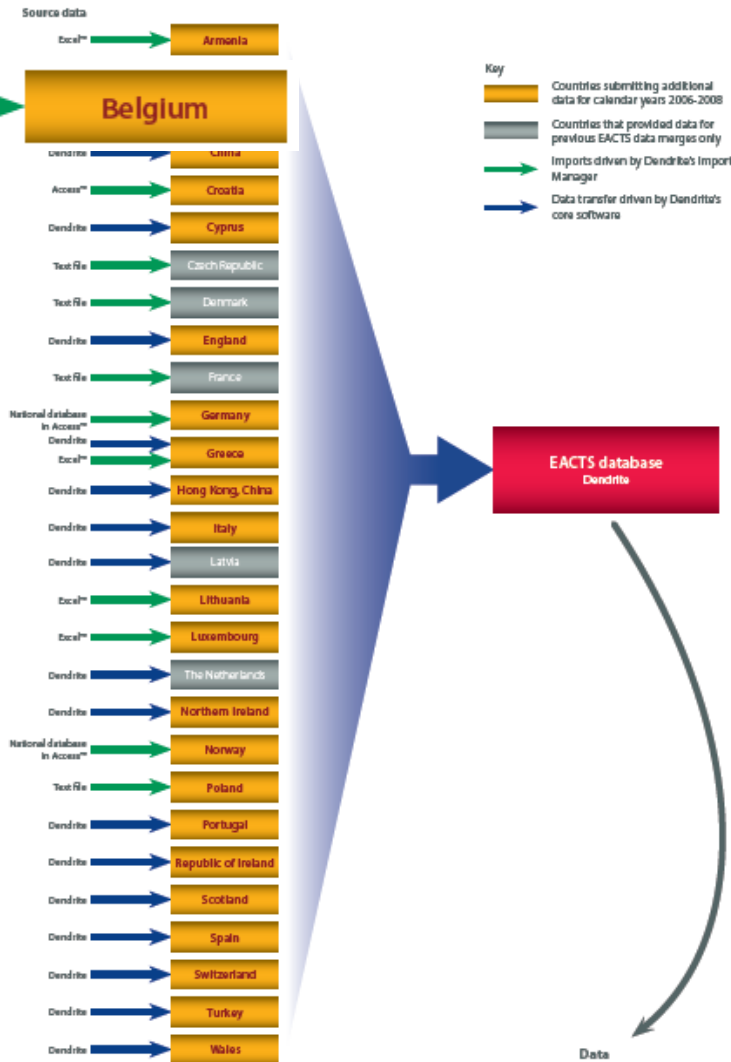*Towards global benchmarking*

Compiled by

Ben Bridgewater & Jan Gummert
on behalf of the European Association
for Cardio-Thoracic Surgery

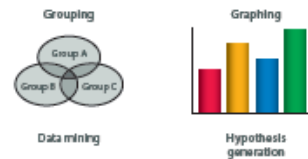**Peter K.H. Walton & Robin Kinsman**
Dendrite Clinical Systems Ltd

BACTS

The European Association for Cardio-Thoracic Surgery
Fourth Adult Cardiac Surgical Database Report 2010

Consumer Comprehension of Surgeon Performance Data for Coronary Bypass Procedures

Karen Donelan, ScD, Robert S. Rogers, BA, Andy Eisenhauer, MD,
Elizabeth Mort, MD, MPH, and Arvind K. Agnihotri, MD

Mongan Institute for Health Policy, Massachusetts General Hospital, Boston; Division of Cardiology, Brigham and Women's Hospital, Boston; Department of Surgery, Division of Cardiac Surgery, Massachusetts General Hospital Heart Center, Boston; Harvard Medical School, Boston; and Department of Quality and Safety, Massachusetts General Hospital, Boston, Massachusetts

Background. Public and private organizations have called for increased transparency in reporting of outcomes data for hospitals and surgeons, including risk-adjusted coronary artery bypass graft surgery (CABG) mortality data. Limited information is available about how the public actually interprets these data.

Methods. Four different graphical and tabular displays of CABG outcomes for surgeons, three of which were modeled on current state public r[...] 337 adults. Each display contained[...] thetical surgeons. For each form[...] asked to choose which surgeon th[...] least likely to choose based on t[...] they were asked questions about [...]

Results. Accurate identification [...] mance varied by display format, [...] one display and a low of 16% o[...] identified the surgeon with the [...] across all four displays. Responde[...] college education were significant[...]

tify the surgeon with the lowest risk-adjusted mortality, compared with respondents having no college education (21% to 72% vs. 9% to 59%; $p < 0.01$). In one display, the surgeon with the lowest risk-adjusted mortality was effectively penalized for taking on higher-risk patients; respondents tended to select the surgeon with the lowest-risk population but the highest risk-adjusted mortality. Overall, 82% of respondents said that access to these [...]

Conclusions. Comprehension by the public of risk-adjusted CABG outcomes is limited and varies by display format. Poorly constructed displays may have led to misinterpretation, with potential unintended adverse consequences such as risk aversion. Further work is needed to design displays that maximize accurate interpretation by the public and more clearly define the risk and benefit of public reporting of surgeon performance.

BACTS

30 day - Risk adjusted mortality for isolated CABG

Tabel 2   30 dages dødelighed efter isoleret CABG 2004-2005 justeret for Euroscore

Center	Antal indgreb i analysen	Dødelighed uden justering (%)	Dødelighed justeret (%)	95% sikkerheds-grænser
Rigshospitalet	1252	3.0	3.5	(2,6-4,4)
Gentofte	915	1.7	2.1	(1,0-3,2)
Odense	768	3.3	2.7	(1,8-3,7)
Skejby	835	2.3	1.9	(1,0-2,9)
Aalborg	556	2.7	2.6	(1,3-3,8)
Total	4326	2.6		

*P-værdi for afvigelse fra landsgennemsnittet. Samlet test for forskel mellem centre: P= 0,21
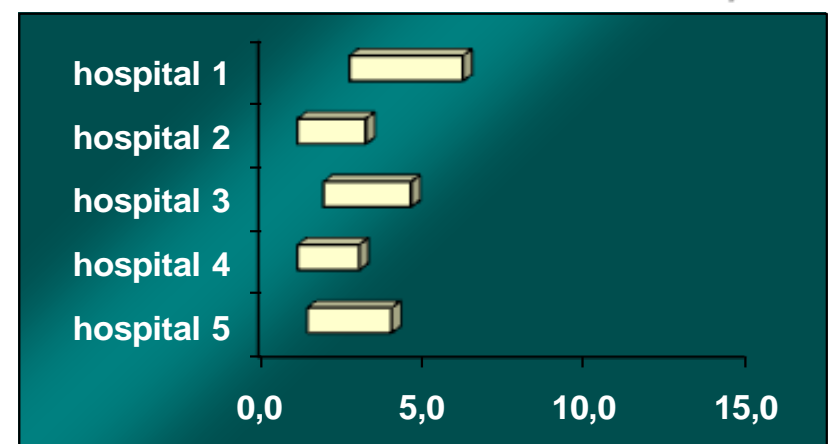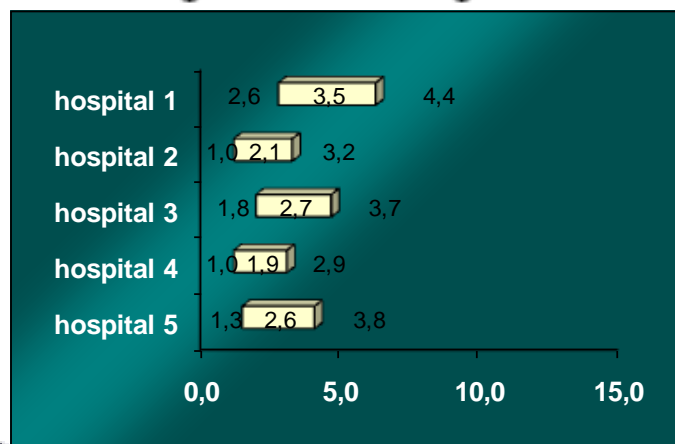
The Society for Cardiothoracic Surgery in Great Britain & Ireland
Sixth National Adult Cardiac Surgical Database Report

Table 4a. **All cardiac surgery.** Results of cardiac surgery displayed on the Healthcare Commission website; 3 years of data to the end of March 2007. Compared to the complex re-calibrated logistic *EuroSCORE* with 99% CIs

	Counts	Deaths	Actual mortality	Predicted mortality	Upper CI	Lower CI
Aberdeen Royal Infirmary	1,665	69	4.1%	4.3%	5.9%	2.9%
Bart's & the London	4,927	168	3.4%	4.1%	5.0%	3.3%
Blackpool Victoria Hospital	2,938	82	2.8%	3.2%	4.2%	0.4%
Bristol Royal Infirmary	4,328	119	2.7%	3.2%	4.1%	2.4%
Castle Hill Hospital, Hull	2,809	110	3.9%	3.2%	4.3%	2.3%
Derriford Hospital, Plymouth	2,705	87	3.2%	3.3%	4.3%	2.3%
Edinburgh Royal Infirmary	2,713	113	4.2%	3.7%	4.8%	2.6%
Freeman Hospital, Newcastle	3,029	112	3.7%	4.1%	5.2%	3.1%

Public reporting

- Unsolved methodological problems

- Unintended consequences

- Pitfalls

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Public reporting

- Pitfalls
  - Ranking of centers/surgeons
  - Gaming: patient selection
  - Up-scoring
  - Limitations of scoring-systems: no adequate correction for procedural/patient complexity
  - Focus on risk, not on quality of procedure

Does reporting of coronary artery bypass grafting from administrative databases accurately reflect actual clinical outcomes?

Michael J. Mack, MD, Morley Herbert, PhD, Syma Prince, RN, Todd M. Dewey, MD, Mitchell J. Magee, MD, and James R. Edgerton, MD

Objectives: Quality assessment of coronary artery bypass grafting has traditionally been performed with data from clinical databases. Administrative databases that rely primarily on information collected for billing purposes increasingly have been used as tools for public reporting of outcomes quality. The correlation of administrative data with clinical data for clinical quality assessment has not been confirmed.

Conclusions: Substantial variability of reported outcomes is seen in administrative data sets compared with an audited clinical database in the end points of the number of procedures performed and mortality. This variability makes it challenging for the nonclinician unfamiliar with outcomes analysis to make an informed decision.

BACTS

Administrative databases

- Build for financial purposes
- Non-clinician extracts data from medical records
- Codes
  - DRG: allocation to highest paying DRG
  - ICD-9
  - MKG/RCM
  - MFG/RFM
  - RIZIV/INAMI
- Code order

BACTS

Administrative databases

- Limitations
  - Procedural groups
  - Date of surgery / discharge
  - Risk factors / Complications
  - Risk stratification
  - Outcomes
- Not accurate for
  - Auditing the quality of care
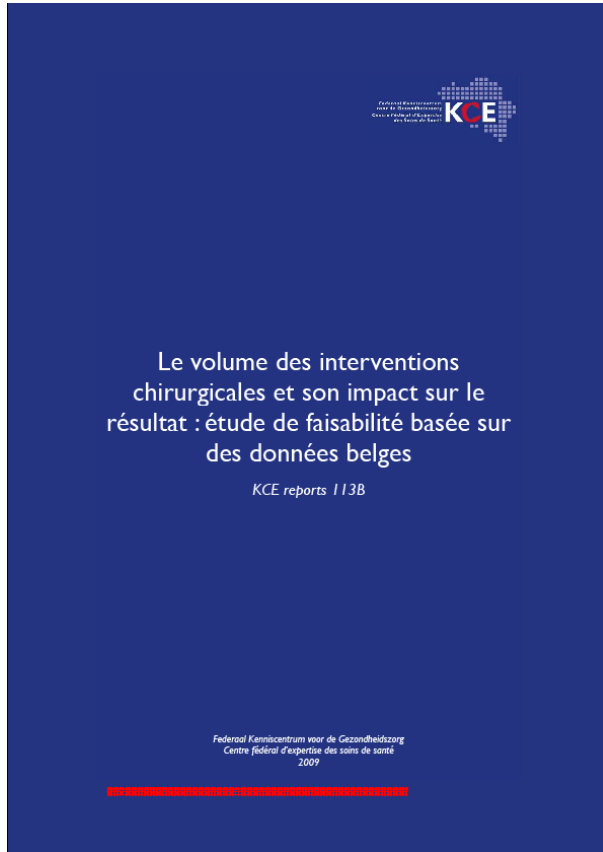 - Risk adjusted outcome analysis
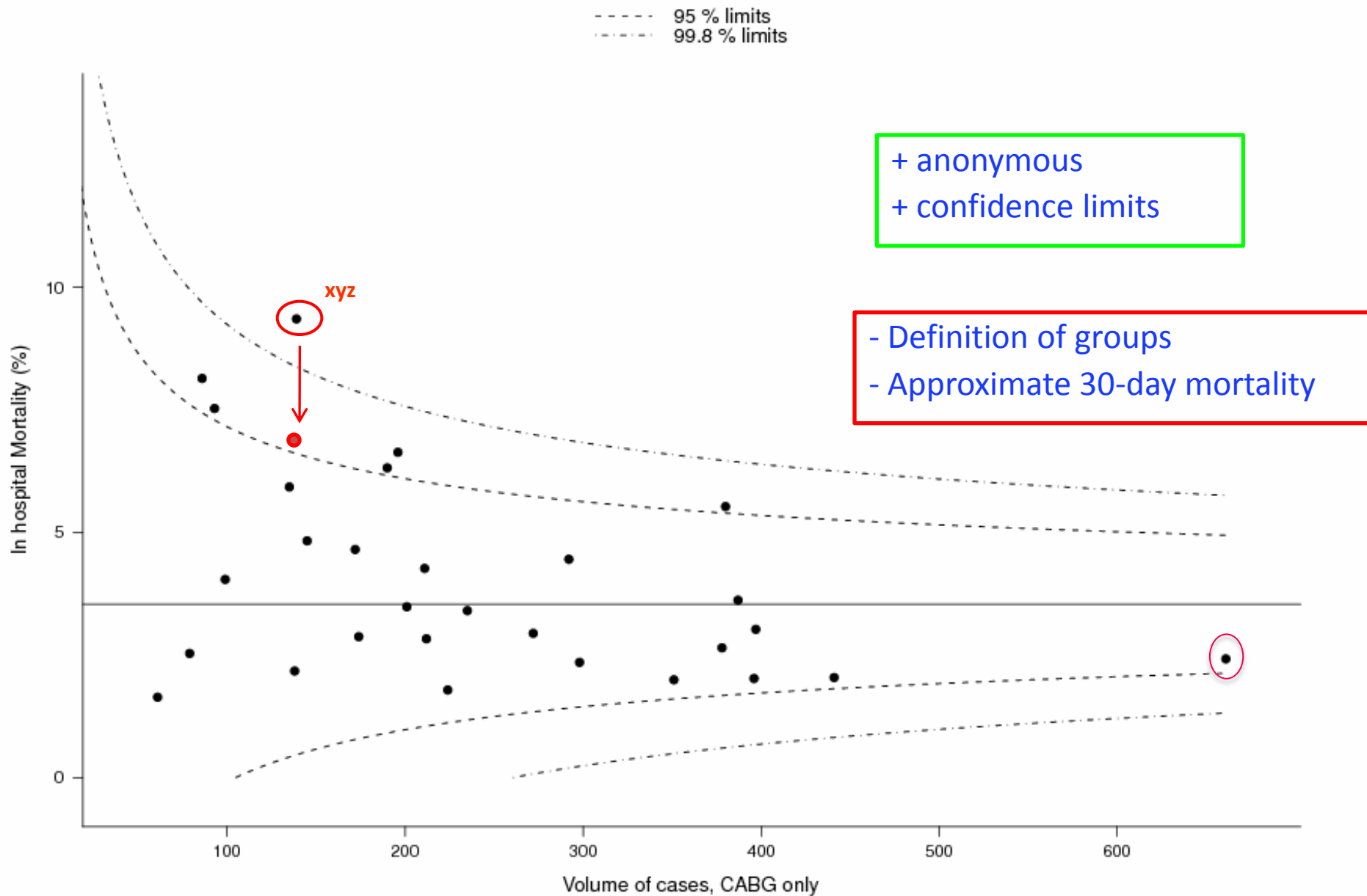
BACTS

KCE report

Figure 6.11: Funnel plot of the in-hospital mortality by center after isolated CABG

Quality control

- Complex process:
  - Correction variability of pathology
  - Correction variability of clinical condition,
  - Correction variability of procedural complexity
- Outlier identification
  - Secondary process is mandatory
  - Quality of the data
  - Identification of unusual variability in subset of patients.

Procedure of outlier confirmation

- Presumed outlier
  - Internal check of registry
  - Invitation of centre by database manager (Carine)
  - Two steps
    - Review of the quality of the data
    - review of cases with negative outcome: unusual variability/risk records are excluded in the analysis

- Confirmed outlier
  - Remedial processes: not the task of the database committee
  - Confidentiality by database committee

BACTS

Procedure of outlier confirmation

- Adaptation of MOU
  - Procedure has to be discribed
  - Invitation: voluntary participation in data check, centre ask involvement of the database committee
  - Presumed outlier – confirmed outlier

- Proposal of new MOU
  - To be discussed in the board
  - To be approved during the general assembly

Conclusion

- The ultimate goal of the database committee is quality improvement
- The BACTS 2012 registry could lead to a better quality of care
- The aggregated report will be available in the public domain
  - Available for everybody.
  - Only the aggregated report will be visible.
  - The data are anonymous
  - The database committee guarantees the confidentiality as described in the memory of understanding.

BACTS