Data validation guidelines: the start of the journey

Tine Philipsen
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The EACTS Adult Cardiac Database (ACD) and its benchmarking tool have been developed to assess cardiac surgery data and risk-adjusted outcomes on a European and international level, thereby improving the quality of cardiac surgery in Europe. The EACTS ACD data can be used for guideline development, quality improvement projects, research and collaboration between European centres, and for scientific and public reporting.

Data validation is an essential step in creating a useful database with assured consistency and completeness. However, current quality control of data varies greatly between units. As such, the EACTS ACD data validation team is working on data validation guidelines that can be implemented across all participating units.

Data validation survey
In 2017, the EACTS ACD data validation survey was sent out to all contributing centres of the Database. The goal was to assess current data validation practices, including metrics of data quality, consistency and completeness. Outcomes of the survey were presented at the EACTS Annual Meeting in October 2017 in Vienna.1

Several key outcomes were uncovered. Firstly, it was clear that the approach to data management in participating European cardiac surgery centres varied considerably, and was conducted by both medical and non-medical professionals.

In addition, the survey found that registration of data was mandatory in most participating centres (89.7%). All survey responders were convinced data registry should be mandatory, however. Registered data were mostly used for scientific and administrative purposes, but only 23% of data was actively used for quality control. What’s more, 24% of the units did not perform any data control before uploading to the EACTS ACD. Finally, while only 37% of units undertook external data control – mostly via the national societies of cardiothoracic surgery – approximately 70% of participants believed external data control would be helpful in further improving data quality.

Overall, the EACTS ACD survey demonstrated that data quality control ranges from the non-existent to the well-structured and highly organised. Therefore, there is a clear need for proper data validation guidelines implemented across all participating EACTS ACD units.

The data validation process
The EACTS ACD team aims to offer units assistance in proper data input practices, including guidance on how to follow a step-by-step process when entering data for validation (Flowchart). By following these steps, units that do not have the possibility to implement electronic or statistical data control protocols can rely on the EACTS ACD team to facilitate more accurate data.

The EACTS ACD data validation team is convinced that better data quality and benchmarking can lead to better outcomes in cardiac surgery in Europe. We are currently working on more elaborate data validation guidelines to advise all EACTS ACD participants on how to validate their data and improve data quality and productivity.

The journey continues...

Flowchart demonstrating the EACTS Adult Cardiac Database data validation process. A close collaboration between the data manager (single unit or national) and the EACTS ACD team is necessary. Completeness and correctness of the data are the unit’s responsibility, and all uploaded data should be adapted to EACTS ACD data definitions and demands. For mandatory data, completeness should be 100%. For every upload, a Data Quality Report (DQR) is produced, allowing the data manager to correct and reupload the data. After completion, a bespoke report including the results of the uploaded data will be generated for every participating unit.

References
Monitoring results with Adult Cardiac Database control charts

Hina Waheed and Simon Baldwin
on behalf of the Quality Improvement Programme (QUIP) Birmingham team

Since the initiation of the EACTS Adult Cardiac Database (ACD) in 2015, more than 100,000 cardiac surgical procedures from 54 different centres across Europe have been included. This rise in procedural numbers has led to the development of a control charts page in the benchmarking tool. These control charts enable participating centres to monitor their performance over time, and offer a baseline from which to assess whether process variations are consistent, or unpredictable.

QuORU dashboard – University Hospitals Birmingham (UHB)
Extensive research and testing of the ACD control charts was conducted at UHB by the Quality and Outcomes Research Unit (QuORU), in conjunction to developments made to QuORU’s own dashboard. The QuORU dashboard contains two control chart variants for two separate purposes.

The more commonly used control chart monitors monthly data values against the long-term average of a process. The purpose of the chart is to monitor long-term trends in a process, and sudden deviations (in a single month) from the trend.

The other chart variant (as in the ACD) measures average monthly performance against external standards, allowing processes to be benchmarked against other hospitals.

Contact Hina.Waheed@uhb.nhs.uk or Simon.Baldwin@uhb.nhs.uk for more information.

How to interpret ACD control charts

1. In control
When the rolling average is below the caution line, the process is in control, and no action is necessary.

2. Caution
When the rolling average is between the caution and action lines, the process may need adjustment. Each consecutive point between the caution and action lines is further evidence that the process may need adjustment.

3. Action
When the rolling average is above the action line, the process has moved out of control and requires adjustment.

Obituary: Costante Ricci

Professor Costante Ricci passed away on 3rd July 2018, aged 93. Professor Ricci was a founding member of EACTS, and played a significant role in shaping the Association in the early years.

He was a prominent academic thoracic surgeon in Italy, and many of his pupils are chiefs of division in universities and hospitals across Italy today.
Bespoke mapping for the Adult Cardiac Database

Hina Waheed and Simon Baldwin
on behalf of the Quality Improvement Programme (QUIP) Birmingham team

A key challenge for any centre participating in a national or international registry is the conversion of local hospital datasets to a registry format. For the large number of different registries currently active, this can be a big undertaking for clinicians and hospital informatics departments. One way in which many registries have addressed these issues is to collect real-time data via online tools. This way, ward clerks and clinical coders enter hospital data, and registries receive this data in the required format. However, this misses out on historical data, which is important for long-term monitoring of outcomes.

Participation in the Adult Cardiac Database (ACD) alleviates these challenges by a process we call ‘bespoke mapping’. Bespoke mapping involves minimal effort from clinicians or hospital informatics departments, and allows historical and near real-time* data collection to take place. Bespoke mapping works as follows:

1. The QUIP Birmingham team at University Hospitals Birmingham will contact the clinician or dedicated data manager representing your centre to request the fields (not the data itself) of your local hospital datasets. Fields that should not be submitted include:
   a. Patient name
   b. Patient address/post code/zip code
   c. Surgeon/technician name
   d. Surgeon/technician number
   We accept pseudonymous patient numbers (for more information on pseudonymisation, please contact the QUIP team)

2. An initial mapping report will be produced for your centre, detailing how we plan to convert your data to ACD format***. Dialogue to discuss this report will then take place with the clinician or dedicated data manager, until a final mapping report is agreed.

3. Using a provided user name and password, the clinician or dedicated data manager will upload the required data as it is collected in your local hospital databases (no conversion by the centre is required) via a secure FTP link (https://hed.iweb-storage.com/login). Sending data via other platforms (e.g. email) will be considered a serious data breach.

   For further information on how to securely upload your data, please go to http://www.eacts.org/quip/data-managers/ or contact EACTSFeedback@uhb.nhs.uk.

   *** Data mapping example:
   • Functioning transplant:
     o Option 1) No transplant
     o Option 2) Yes
   • Creatinine (umol l-1):
     o Option 1) <= 200
     o Option 2) > 200
   • Renal failure:
     o Option 1) None
     o Option 2) Acute
     o Option 3) Chronic
   • Dialysis:
     o Option 1) No
     o Option 2) Yes
   o Option 2) Chronic
   o Option 3) Acute
   o Option 1) No
   o Option 2) Yes

   Data managers should only send data to the ACD through the secure FTP link (https://hed.iweb-storage.com/login). Sending data via other platforms (e.g. email) will be considered a serious data breach.

   For further information on how to securely upload your data, please go to http://www.eacts.org/quip/data-managers/ or contact EACTSFeedback@uhb.nhs.uk.

4. A computer script is written by the QUIP Birmingham team to convert your data to ACD format, and the data is uploaded to the ACD. From here, it is viewable via the online benchmarking tool, or via standard/bespoke reports.

   The bespoke mapping process has successfully converted over 50 local hospital datasets to ACD format, and is all part of the free participation founded in the EACTS Quality Improvement Programme.

   * Subject to regularity of data uploads.
   ** Contact hina.waheed@uhb.nhs.uk or simon.baldwin@uhb.nhs.uk for more information.
Updating the Adult Cardiac Database

Giacomo Bortolussi on behalf of the Adult Cardiac Database

Last year, a renovated task force within EACTS was appointed to take charge of the Adult Cardiac Database (ACD). Collecting nearly 70,000 procedures from 41 European centres since 2010, the ACD was already an excellent entity. However, we felt that an update was necessary in order to reflect the evolution of knowledge and techniques over nearly a decade.

The task force immediately began working to revise the structure of the database, update the validation criteria and develop an online tool for analysis and output.

As the very essence of the database, data fields were our first focus. Beyond removing centres already collect these aforementioned variables. Moreover, recognizing that mortality alone is no longer a satisfactory measure of outcome, we added several new fields that described postoperative course. While mainly focusing on related complications, length of stay and follow-up were also included when available.

After choosing the data fields, we revised all their definitions and updated the data dictionary. Again, the core aim was to keep it as clear and simple as possible, both to avoid confusion and to help save time for those inputting the data.

As a word of reassurance, the task force is aware of the difficulties centres can face when called upon to adapt their own dataset to the ACD. For this reason, we decided to avoid producing changes too often, aiming at a limit of once every three years, with sufficient notice always given to participants.

But our mission is to improve the database and keep it up to date, thereby providing participants with useful tools they can apply in clinical practice. As such, we classified the revised variables in three categories, according to their importance:

1. Mandatory: limited information which all centres must provide to join and remain in the ACD
2. Essential: very important data, with required minimum completeness (but participants may omit some data at their discretion)
3. Optional: mostly new variables which we strongly encourage centres to provide, but without any formal restrictions

We will present the innovations more in detail at the 32nd EACTS Annual meeting in Milan, with the plan to implement the revised database from 2019.

The 13th European Mechanical Circulatory Support Summit

Evgenij V. Potapov
Co-Chairman EUMS; Department of Thoracic and Cardiovascular Surgery at the German Heart Centre, Berlin, Germany

The 13th European Mechanical Circulatory Support Summit (EUMS) will be held 1-3 November 2018 in Berlin, Germany. It is the largest European meeting in end-stage heart failure, offering a unique opportunity for cardiology and surgeons to meet and discuss the optimal treatment of patients suffering from end-stage heart failure, in an era where there are increasing numbers of patients, but fewer and fewer hearts available for transplantation.

The meeting will discuss new drugs and interventional devices, as well as presenting future technologies, including “intelligent” pumps and creative solutions for unusual, real-life cases.

Participants will also learn: How to use guidelines to find the right treatment for the right patient at the right time; how to use temporary mechanical circulatory support (MCS) systems in emergency situations and in the ICU; new surgical techniques for ventricular assist device (VAD) implantation as well as unusual solutions for complex surgical problems in VAD patients.

As usual, ongoing topics such as the annual EUROMACS report, complications during long-term support or how to recognise and promote myocardial recovery in adults and children will be in discussed in detail by leading experts from around the world. What’s more, new fields such as shared care or the role of social media will be touched upon. All of this will be delivered via an interactive programme of lectures, live-in-a-box cases and keynote presentations that will sit alongside a special focus on current European and North American guidelines in practice.

The targeted audience for EUMS includes cardiologists, heart failure specialists, emergency and ICU specialists (ECLS), cardiac surgeons, perfusionists, heart failure nurses, VAD coordinators, medical industry (cardiac devices including ECLS development and production), paediatric cardiologists and congenital heart disease surgeons.

A central part of the meeting is dedicated to young physicians and scientists. Teams of young residents and scientists from USA and Europe, including teams from Bad Oeynhausen and Berlin will fight it out in the Quiz. Additionally, a team of leaving legends will show us their best performance.

The aim of the meeting is not to cover everything in the MCS field, but to provide a platform for sharing and developing new knowledge and ideas.

I look forward to welcoming you to Berlin.

The Programme:

Thursday 1 November
- Session 1 The heart failure patient – drugs, clips, device therapy – the right treatment for the right patient at the right time
- Session 2 Guidelines in practice – the transatlantic express
- Session 3 Temporary mechanical circulatory support
- Session 4 The frail patient
- Session 5 Weaning

Friday 2 November
- Session 1 The right ventricular challenge
- Session 2 The left ventricular challenge
- Session 3 The device challenge
- Session 4 How to reduce side effects of long-term left ventricular assist device therapy
- Session 5 Shared care

Saturday 3 November
- Session 1 Paediatric
- Session 2 Intelligent pumping and smart materials
- Session 3 Unusual cases and creative solutions
- Session 4 Update of current and prospective devices

### Thursday, 18 Oct

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<tr>
<th>Domain</th>
<th>Session Title</th>
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<tbody>
<tr>
<td>Cardiac</td>
<td>Techno-College: New Technology meets common practice – How to enhance your surgical portfolio TAVI Training Coronary Artery Disease, Experimental Myocardial infarction and Heart Regeneration A practical approach to aortic valve repair Prediction and avoidance of complications in transcatheter procedures</td>
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<tr>
<td>Congenital</td>
<td>Tetralogy of Fallot &amp; pulmonary atresion / VSD Heart failure &amp; Mechanical Circulation</td>
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<tr>
<td>Thoracic</td>
<td>Techno-College: Trachea/airway Innovations in thoracic surgery</td>
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<td>Vascular</td>
<td>Treatment of type B aortic dissection in the era of stent-grafting – Acute dissection Working from inside the aorta with surgical input</td>
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### Friday, 19 Oct

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<th>Domain</th>
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<tr>
<td>Cardiac</td>
<td>2018 ESC/EACTS Guidelines on myocardial revascularisation Late-breaking Clinical Trials Techno-College: Interventional Therapies How to become a hybrid surgeon VAD co-ordinators</td>
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<tr>
<td>Congenital</td>
<td>Nightmare cases &amp; unsolved clinical problems Long-term outcome after surgical repair in CHD</td>
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<tr>
<td>Thoracic</td>
<td>Oligometastatic disease Rare thoracic cancers (EUROCAN)</td>
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<tr>
<td>Vascular</td>
<td>“Gut feeling”: management for type A dissection while awaiting evidence, Endovascular fix of open failure</td>
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### Saturday, 20 Oct

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<tr>
<td>Cardiac</td>
<td>Rare and Uncommon Diseases Managing patients with multi-vessel disease in the modern era Evidence based decision making in TAVI Techno-College: The Lion’s Den and emerging technologies</td>
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<tr>
<td>Congenital</td>
<td>Single ventricle 1: Can we avoid univentricular palliation Surgery in adults presenting with heart disease</td>
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<tr>
<td>Thoracic</td>
<td>Surgery for Ground Glass Opacities – a waste of time? Techno-College: Anatomical segmentectomies</td>
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<tr>
<td>Vascular</td>
<td>Challenging the guidelines in thoracic aortic surgery Aortic Arch Repair – The Brain in Focus</td>
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<tr>
<td>General</td>
<td>Allied Health Programme</td>
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View the full programme at http://www.eacts.org/educational-events/eacts-annual-meeting/