Recruitment methods

Over a 2-year period, 350 European hospitals, which the EACTS consider to be potential participants, have been approached in a number of different ways: by email, phone and via personal meetings, either at conferences or hospital visits. The communication focuses on two things: the simplicity of the process by which hospitals can join the QUIP and on what the contents of the QUIP Charter mean. In many instances contact with the assistance of a local data manager or software professional was established. He, or she, then enabled the cardiothoracic surgery data overview to be sent over to QUORU for mapping.

National databases

During the recruitment process it became apparent that several countries either have a functioning national database, or were in an advanced state of development, working towards an improved national registry. Data transfer from national registries to the QUIP database would save each participating hospital the time and energy to contribute to both their national database, and to the QUIP. So the decision to organise data transfer from national registries directly to the QUIP database was an easy one. After concerns were raised over the quality and legality of such a construct, the QUIP Registration Form, was adapted so that the individual hospitals, but they cannot identify other centres.

France

Under auspices of the French Society of Thoracic and Cardiovascular Surgery, a national database called EPICARD was established in 2007. Presently, the next version, which is entirely web-based, is in a test phase. Read more on EPICARD elsewhere in this newsletter.

Belgium

For several years, the Belgian Association of Cardio-Thoracic Surgery (BACTS) has collected data from the 28 cardio-thoracic surgery departments in the BACTS Registry. In late 2015, it became clear that the local Ethics Committee had no objections to the transfer of anonymous data from the BACTS Registry to the QUIP database. To date, six Belgian hospitals have signed the QUIP Charter.

Czech Republic

In the Czech Republic, a national database is maintained by the Institute of Health Information and Statistics. The individual centres can recognise themselves when they consult the database, but they cannot identify other centres.

The Netherlands

Since 1993, the BHN registers intervention-related data on cardiac surgery and cardiac interventions for all 16 Dutch cardiac surgery centres. Read more on BHN elsewhere in this newsletter.

Spain

A total of 56 cardiothoracic surgery centres participate, on a voluntary basis, in the national SCCIS registry of the Spanish Society of Cardio-Thoracic and Vascular Surgery (SECTCV). The systematic collection of data and subsequent analysis allows for continuous quality improvement. Read more on the SCCIS elsewhere in this newsletter.

Sweden

Swevedhearth, the Swedish national database, is no longer owned by the individual hospitals, but by the Uppsala Clinical Research Center (UCR) and by the Swedish public health authorities. UCR is the country’s first-look source of expertise for the National Quality Registry and is a leader in quality control and evaluation of new treatment forms in the Swedish health and care services.
The EACTS Quality Improvement Programme

Rianne Kalkman
EACTS Administrative Director, Rotterdam, the Netherlands

Theo de By
QUIP Project Manager

EACTS’ Rianne Kalkman and Theo de By look back at 4 years of the EACTS Quality Improvement Programme (QUIP) with QUIP Director Domenico Pagano, Birmingham, UK

What is the purpose of the QUIP?

The aim of the QUIP project is the improvement of clinical outcomes for patients, and to promote the importance of integrating quality improvement initiatives into daily clinical practice. The benchmarking tool, developed as part of the project, is the main instrument to achieve this purpose.

How many hospitals are already participating?

At present, 54 hospitals have agreed with, and signed the QUIP Charter, in which the ground rules of the project are defined. While there are currently data from 21 centres in the tool, it is expected, based on agreements received so far, and given continued developing international relationships, that the number of hospitals and the data they provide will grow considerably in the months to come.

Are you collaborating with other societies?

Yes, since there are benchmarking projects, often under the auspices of national societies in different countries, the QUIP team is working together with representatives of those national societies. We experienced a positive interaction in which national software developers, anticipated a future connection with the QUIP. At the moment the connection between the QUIP and several national databases is in preparation, both in a technical and a contractual sense.

Is the QUIP for European centres exclusively?

No, in principle the QUIP is open to all members of the EACTS. The first group of hospitals to join the QUIP were those in Sweden, Denmark and Germany. However, the QUIP will be open to all centres in Europe.

How do you ensure the reliability of the data?

Firstly, the participating hospitals, by signing the QUIP Charter, commit themselves to provide accurate, complete and truthful data. Moreover, they ensure that participation in the QUIP complies with any applicable local laws and internal procedures. Since the accuracy of data depends on several factors, such as the reliability of the source, the robustness of software systems and of data communication, the QUIP team is preparing to implement an audit scheme. Such an audit scheme would consist of a combination of methods, including onsite visits, to verify the quality of the data.

What is, and what is not, included in the QUIP benchmarking tool?

The QUIP benchmarking tool makes use of anonymised data of surgical interventions. No individual patient data, or data that could identify the surgeon(s) involved, are transmitted to the database. The data obtained from individual hospitals represent baseline data and outcomes of interventions from a given year. When making use of the benchmarking tool, a surgeon can recognise the data and outcomes from his own hospital, while those of all other hospitals are presented anonymously.

How do you see the future of the QUIP?

Since the data provided by participants should minimally correspond with 75% of the data on which EuroSCORE II is based, the benchmarking tool is getting stronger with the increased number of cases that are uploaded into the tool. Envisioning that the number of interventions in the database grows to 100,000 or more, the QUIP will be able to offer clinical decision-making possibilities by enabling surgeons, who consider the modus of treatment for an individual patient, to search for similar cases and their outcomes in the QUIP database. Detailed risk stratification of specific patients will enable doctors to advise patients with more confidence about the risks involved in various procedures for patients sharing their characteristics and history. Thus, the QUIP database will serve as a clinical decision guide. Another possibility for the participants is to obtain data and specific reports to be used for scientific research purposes.

Theo de By
Managing Director
EUROMACS, EACTS, UK

1. State of affairs

At present, a total of 48 hospitals from 15 countries across Europe, provide regular updates to the EUROMACS Registry on approximately 3000 patients who have received mechanical circulatory support (MCS). Together, these contributors have so far submitted more than 11,000 specified follow-up events.

These accumulated data can be used as a benchmarking tool by individual hospitals to enable them to measure their outcome results and compare them with other hospitals in their region and across Europe. Moreover, researchers can correlate the data to gain science-based insights and to define factors that may influence patient care and outcomes. The registry also involves other stakeholders, such as the industry that manufactures the devices, to use the data to initiate new innovations and measure the results of these.

Recently, data from the collective registry of the Spanish Society of Thoracic-Cardiovascular Surgery (SECTCV) was added to the EUROMACS Registry. A similar possibility for collective contribution is anticipated with the French Society of Thoracic and Cardiovascular Surgery (SFCTCV). The results can then be copied into slides or text documents.

2. Quality control policy

To make sure that outcomes of analyses are reliable, a three-tier quality control policy is applied. The quality control policy consists of:

• Statistical analysis of the data submitted by the participating centres. EUROMACS provides regular overviews of missing or inconsistent data to the centres every 6 months. If data are faulty, or missing, the centres are invited to correct the non-compliance.

• Self-auditing by enabling centres to review their own data. After login, the EUROMACS website gives the possibility to export data for independent review.

• Onsite audits are a third instrument to guarantee that data collection and registration in the database reflects the reality in the participating centres.

3. Development of online benchmarking tools

Through a variety of useful online tools, EUROMACS offers participating hospitals the chance to obtain comparative data and statistics. These statistics consist of comparisons between data of the individual participating centre and the data of the entire registry.

By applying these benchmarking tools, the EUROMACS database continues to provide multi-functional analytic possibilities for cardiothoracic surgeons, cardiologists and other professionals who are engaged with providing care to patients with MCS. Registration of clinical data gives insight into the quality and quantitative aspects of the therapy over time. While some hospitals use EUROMACS to keep track of their own implantations and follow-up, others have the objective to compare their outcomes with those of all participating centres. Likewise, national societies, such as the Spanish SECTCV or the French SFCTCV, may use EUROMACS as a national tool to compare the performance of all MCS programmes in the country, either individually or collectively.

The link with EUROMACS, and in turn, with the EACTS, enables all participants to use the software and data so that they can benchmark themselves. The tools offered make it possible to identify strengths and weaknesses of the outcomes per hospital, or from a group of hospitals (if all those in that group agree), and to focus on improvements where necessary. It is expected that, over time, the available data will contribute to beneficial results for patients with MCS.

For more information please visit our website www.eacts.org/quip
The BHN registry and participation in QUIP
An update from the Netherlands

Theo de By
QUIP Project Manager, EACTS, London, UK
Evert K. Jansen
Free University Hospital, Amsterdam, the Netherlands

The adult cardiac database
The accumulation of data in the adult cardiac database, known as the BHN registry, has provided us with a good understanding of the timeliness, nature, quantity and quality of surgeries taking place in Dutch cardiothoracic surgery centres, as well as more detailed information on the patient population concerned and the types of surgical intervention required.

Operationalisation concepts:
- **Timeliness:** waiting time for elective interventions
- **Type:** type of interventions and techniques concerning the non-elective interventions
- **Quantity:** number of (non-)elective interventions and techniques
- **Quality:** (for preoperative risk-adjusted) mortality data concerning non-elective interventions
- **Patient population:** general medical and patient characteristics related to (non-)elective interventions

Financing of the registry
The BHN registry is financed through contributions from the participating hospitals. The health insurance institutions provide restitution of the costs associated with registration, to the participating hospitals.

The Society of Thoracic Surgeons (STS), was the first medical or surgical society to develop and use a database for quality assurance purposes. STS published in the Journal of the American College of Cardiology, which showed significant regional variability in surgical results. These data were obtained from administrative reports; however, the reliability of administrative outcome data has been questioned in the past, and its suboptimal quality was suggested by the New York State DoH in the late 1980s.

The CAC studied pertinent literature to identify patient risk factors related to short-term adverse outcomes for CABG surgery. These risk factors were included in a database together with patient demographics, type of interventions and techniques, care, admission and discharge dates, procedures performed, and patient disposition at discharge, to create a registry. The new registry was used for the first time to assess hospital performance in the seminal 1990 paper published in the Journal of the American Medical Association (J Am Coll Cardiol 1990;15:303-10):

The Society of Thoracic Surgeons (STS), was the first medical or surgical specialty society to recognise that a national database of procedures would not only be a powerful tool for quality improvement and professional advancement, but would also provide abundant clinical material for outcomes research. In addition, an accurate understanding of outcomes would permit more realistic estimations of individual risk for patients. A national database for adult cardiac surgery procedures was voluntarily initiated by the STS in 1989, and first data were accepted in 1990.

The Spanish Society for Thoracic-Cardiovascular Surgery (SECTCV) started collecting surgical activity data submitted on a voluntary basis in 1986, and has continued to do so ever since. In 2013, 56 hospitals submitted data on surgical activity and overall mortality. In 2012, the Spanish Society of Cardiology (SEC) published the results of a ‘Quality Registry in Cardiology’ (RECALCAR), which showed significant regional variability in surgical results. These data were obtained from administrative reports; however, the reliability of administrative outcome data has been questioned in the past, and its suboptimal quality was suggested by the New York State DoH in the late 1980s.

In 2013, the SEC and the SECTCV, produced a joint document on ‘Quality Indicators for Hospital Heart Disease Units’ (INCARDIO). In this report, the outcome measures were defined for cardiac surgery as well as for the different cardiac subprocedures (interventional cardiology, electrophysiology etc.), with the intention to identify those performance measures that would have an impact on outcomes. In order to fulﬁll the requirements of the INCARDIO document, it was considered necessary to create hospital databases, into which data required for quality assurance purposes would be collated and could then be used for benchmarking at a national level. In this context, the SECTCV took the initiative to create a ‘patient speciﬁc’ national registry for cardiac surgery. As previously discussed, 56 hospitals were already submitting a specific dataset to the Spanish National Registry (as well as to the EACTS QUIP registry) obtained from patient-specific datasets. Different options were explored, and eventually the SECTCV decided to make use of the EACTS Quality Improvement Programme (QUIP) to develop the Spanish patient-speciﬁc registry for cardiac surgery. The EACTS QUIP meets all the requirements established in the INCARDIO document for outcomes measurement in cardiac surgery, and therefore it made sense to join the EACTS QUIP as a national society. The accepted proposal was to establish a Spanish QUIP Registry, located at the Hospital Universitario A Coruña, Spain, with a dedicated team of surgeons and a data manager to oversee the process. All contributing hospitals would send the QUIP dataset to the Spanish QUIP Registry, and from there, individual hospital data would be forwarded to the EACTS QUIP in Birmingham, UK. In this way, the SECTCV would hold a robust and quality assured patient-speciﬁc national registry, and the contributing units could make use of the EACTS QUIP resources for benchmarking purposes and research.

In January 2016, all Spanish cardiac surgical units were invited to a meeting organised by the SECTCV in Madrid, Spain, in which the plan for a Spanish QUIP Registry was explained. All hospitals with cardiac surgical practices where invited to join the registry and the response was encouraging with the majority expressing the intention to submit data. Initially diﬃcult arose from the fact that only a proportion of hospitals were using a common database system. For these hospitals, a macro with the QUIP dataset (previously translated into Spanish) was sent to each hospital. The remaining hospitals were provided with a spreadsheet containing the QUIP dataset. At present, the submission process is in place and 10 hospitals have so far started to submit data. It is still early days, but it is expected that the number of hospitals submitting data will increase in the future.

The SECTCV develop patient-specific registry
An update from Spain

J. Rafael Sadaba
Hospital de Navarra
Pamplona, Spain

The first attempts to measure, and thus improve, outcomes in cardiac surgery were led by David Axelrod, New York’s State Health Commissioner for 12 years, who became increasingly concerned about the frequently five-fold variation in hospital mortality rates for coronary artery bypass graft (CABG) surgery across the State. Unfortunately, the information available at the hospital level at that time was woefully inadequate to offer any explanation for this variation. The dilemma facing the Commissioner and the State’s Cardiac Advisory Committee (CAC) – a group charged by the New York State Department of Health (DoH) to oversee the quality and provision of cardiac care – was how to assess relative quality of care, while taking into account that some hospitals may have been treating much sicker patients than others.

The CAC studied pertinent literature to identify patient risk factors related to short-term adverse outcomes for CABG surgery. These risk factors were included in a database together with patient demographics, type of interventions and techniques, care, admission and discharge dates, procedures performed, and patient disposition at discharge, to create a registry. The new registry was used for the first time to assess hospital performance in the seminal 1990 paper published in the Journal of the American Medical Association (J Am Coll Cardiol 1990;15:303-10):

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EACTS QUIP participation
All of the participating hospitals accepted Quality Improvement Programme (QUIP) participation in principle. In the Spring of 2016, some legal hurdles, with respect to the relationship between the individual centres and the national registry to have to be overcome. Finally, an agreement taking into consideration all of the necessary regulations has been accepted by all parties, by which the individual centres authorises the BHN to transfer data from the Dutch registry to the QUIP database on a regular basis.
With increasing numbers of patients on mechanical circulatory support (MCS), the necessity to organise and upscale adequate care for patients with assist devices is growing. In 2015, a survey carried out across eight hospitals, learned that the largest centres had 80 patients or more on assist devices living at home. As the technology within these devices improves, patients live for extended periods with a device; survival times of >8 years have already been reported.

A key role in the organisation of patient care, specifically for those out-patients on mechanical support, is fulfilled by the Ventricular Assist Device (VAD) Coordinator function. This relatively new role in the area of end-stage heart failure, requires specialised knowledge on the management of recipients during periods of long-term follow-up. Issues including the technical functioning and (solving of) multifunctional possibilities of assist devices, as well as case reports and benchmarking.

**Objectives and methods**

Under the auspices of the French Society of Thoracic and Cardiovascular Surgery (Société Française de Chirurgie Thoracique et Cardio-Vasculaire [SFTCV]), a national database, given the name EPICARD, was established in 2007. EPICARD is the property of the cardiac surgery community and is overseen by a scientific committee who have responsibility for the data and for ensuring anonymity rules are respected. To date, 68 cardiac surgical teams are registered and combined data have been accumulated from over 250,000 surgical cases. The system can be used for benchmarking at a national level.

The aim is to register data on epidemiology and assessment practices, EPICARD enables participating surgeons to obtain data for study purposes, while taking into account the general risk factors associated with all forms of cardiac surgery. Thanks to the efforts of all the participants, data from EPICARD has been supplied to the French Ministry of Health, and can thus be considered an elementary source of information on cardiac surgery care activity in France. At present, submission of data to EPICARD is voluntary; however, from January 2018, the participation of all cardiac surgeons will be required in order for them to be members of the SFTCV.

**EPICARD: A database for France with multifunctional possibilities**

**Jean-Louis de Brux**
Le Centre Hospitalier Universitaire d’Angers, France

**Charles De Riberolles**
Hospital Gabriel Montpied, France

**Jean-Marc Frijou**
Le Centre Hospitalier Universitaire de Montpellier, France

**Objectives and methods**

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**The philosophy of quality and transparency**

The French National High Authority for Health (HAS) demands both quality and transparency. Despite this, individual physician accreditation remains a voluntary process, it is not mandatory. However, French legislation, aimed at increasing the efficiency with which hospitals function, looks at regional functionality to avoid superfluous spending, and thus forces cardiothoracic and vascular units to be transparent about their productivity and quality of care.

True to WG Williams, the SFTCV considers, ‘One of our responsibilities as doctors is to know the results of the treatments we offer our patients’. If surgeons want to avoid an ‘external’ view of our guardianship and control the image we project, we must be compelled by ‘participation and rigour’.

**Past upgrades and developments in 2016**

Since 2007, two major upgrades of EPICARD have been carried out:

- Version 1 evolved to integrate practical ‘news’, such as TAVI and cardio-circulatory and respiratory assistance, and to take into account the suggestions of some users.
- Version 2 added elements for the assessment of the EuroSCORE II in practice.

Version 3 is now underway, using software that is entirely web-based and therefore more user-friendly than previous versions; it is hoped that it will remove the last hurdles for those who still might see data collection as an administrative burden.