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Special article

The Cardiology Audit and Registration Data Standards (CARDS), European data standards for clinical cardiology practice

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Aims Systematic registration of data from clinical practice is important for clinical care, local, national and international registries, and audit. Data to be collected for these different purposes should be harmonized. Therefore, during Ireland's Presidency of the European Union (EU) (January to June 2004), the Department of Health and Children worked with the European Society of Cardiology, the Irish Cardiac Society, and the European Commission to develop data standards for clinical cardiology. The Cardiology Audit and Registration Data Standards (CARDS) Project aimed to agree standards for three modules of cardiovascular health information systems: acute coronary syndromes (ACS), percutaneous coronary interventions (PCI), and clinical electrophysiology (pacemakers, implantable cardioverter defibrillators, and ablation procedures).

Methods and results Data items from existing registries and surveys were reviewed to derive draft data standards (variables, coding, and definitions). Variables common to the three modules include demographics, risk factors, medication, and discharge and follow-up data. Modules about a procedure contain variables on the lesion, the device, and medication during the procedure. The ACS module includes presenting symptoms, reperfusion and acute treatments, and procedures in hospital and at follow-up.

Conclusions The data standards were discussed and adopted at a conference involving EU member states in Cork, Ireland, in May 2004. After a pilot study, the standards will be disseminated to stakeholders throughout Europe.

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Introduction

Information from registries is increasingly used to evaluate the process of care and patient outcomes.[1] Data collection on patients with acute coronary syndromes (ACS) and on those undergoing cardiac procedures is essential to improve the quality of patient care and the efficient use of resources in cardiology practice. Accordingly, clinical data related to patient care are collected in many European cardiology units. However, different local, national, and international organizations with interest in such data often request different data sets, albeit with much overlap. This results in unnecessary duplication of work, and reluctance to participate in national or international registries, such as the Euro Heart Survey programme. Furthermore, the absence of guidelines for data collection and clear definitions for data items are important causes of data errors in medical registries.[2] Also comparison of the results obtained in these databases is hampered, because the definitions of seemingly similar variables may differ.[3]

The European Society of Cardiology (ESC) and national societies of cardiology in Europe as well as the American College of Cardiology (ACC) and other professional societies have recognized the importance of developing and using data standards.[1–4] In 1998 a working group with expertise in epidemiology, biostatistics, and coronary interventions identified a minimum set of variables needed to risk-adjust outcomes of coronary interventions.[2] In 2001 the ACC identified key data elements and definitions for measuring the clinical management and outcome of patients with ACS.[3] A collaborative process among more than 50 cardiac surgeons developed an international data set for cardiac surgery. Such well-defined data sets allow the sharing of data and cross-analysis, thus greatly expanding the pool of patients and geographical area in which risk-stratified outcomes can be analysed and compared.[5]

Given the importance of agreeing a common European lexicon for describing the clinical management and outcomes of patients with a variety of cardiac conditions[1] the ESC worked in partnership with the Department of Health and Children in Ireland and the Irish Cardiac Society during the Irish Presidency of the European Union (January to June 2004) to develop data standards for priority modules of a cardiovascular health information system. This Project received support, including funding, from the European Commission.

The aim of the Cardiology Audit and Registration Data Standards (CARDS) Project was to develop expert consensus on data standards (variables, definitions, and coding) for priority modules of a cardiology health information system, to support data collection on:

(i) patients admitted to hospital with suspected acute coronary syndrome (ACS);
(ii) patients undergoing elective and non-elective percutaneous coronary intervention (PCI); and
(iii) patients in whom a pacemaker or implantable cardioverter defibrillator (ICD) is implanted, and who are undergoing an ablation procedure. These are collectively referred to as the clinical electrophysiology (EP) module.

Methods

A Co-ordinating Committee, three Expert Committees, and a Management Committee were established for the CARDS Project (appendix). The Co-ordination Committee, established in June 2003, agreed that the data standards would be compiled for the purposes of clinical audit, service planning, and epidemiology, and that approximately 100 data variables would be selected for each module.

Relevant European experts were identified and asked to participate in the Expert Committees, one for each module: ACS, PCI, and EP. Each committee included cardiologists, epidemiologists, statisticians, and healthcare planners, many with experience in large-scale clinical trials and registries. Each Expert Committee met on two occasions during the project (October 2003 and April 2004) to discuss and refine the evolving data standards. In between, most work was done by electronic data exchange.

Inventory of existing databases, registries, and surveys

A number of national and international cardiology registries are in operation in Europe and abroad, particularly for ACS and PCI. Between June and September 2003, relevant clinical guidelines and existing international data standards, databases, registries, and surveys were identified by members of the Expert Committees and literature searches.[6–19] Those responsible for these databases were contacted and asked to contribute to the CARDS Project by providing information, if necessary translated into English, on the data items which they collected.

In all, 39 stand-alone and multi-centre cardiology information systems in 17 countries were reviewed (*Tables 1*, *2*, and *3*). For example, the Euro Heart Survey programme includes surveys on coronary revascularization and on ACS.[20] The Shakespeare Registry is a multi-centre database that collects data on patients

Table 1 Databases used to develop the ACS matrix

Coronary Heart Attack Ireland Register (CHAIR)
Global Registry of Acute Coronary Events (GRACE)
Myocardial Infarction National Audit Project (MINAP)
Register of Information and Knowledge about Swedish Hospital Intensive Care Admissions (RIKS-HIA)
Spanish Register of Acute Myocardial Infarction (PRIAMHO II)
Spanish Register for patients over 75 with first MI (PPRIMM75)
Spanish Register for Non-ST-Elevation MI (DESCARTES)
Spanish Register on STEMI patients treated with primary angioplasty (TRIANA 1)
Spanish Register on STEMI/LBBB AMI patients not treated with primary angioplasty (TRIANA -2)
Euro Heart Survey on Acute Coronary Syndrome
Portugal's Acute Coronary Syndrome Register
Acute Coronary Syndrome Registry International (ACOS)
Italy's Acute Coronary Syndrome Register
Israel's Acute Coronary Syndrome Register
French Acute Coronary Syndrome Register (Cardioreport)
American College of Cardiology Clinical Data Standards Reference Guide

Table 2 Databases used to develop the PCI matrix

The European Coronary Intervention Register
Austria's National PTCA database
The Spanish Registry of Cardiac Catheter Interventions (SRCCI)
The Swedish Coronary Angiography Angioplasty Registry (SCAAR)
The American College of Cardiology Cath lab module v3.0
The British Cardiac Interventional Society's Coronary Angioplasty Register (BCIS)
The Mater Hospital Dublin PCI Register
Shakespeare Registry
Arbeitsgemeinschaft Leitender Kardiologischer Krankenhausarzte (German PCI Registry) (ALKK)
The Euro Heart Survey on Revascularization for Ischaemic Heart Disease 2001
The Polish PCI Register
The Italian Drug Eluting Stent Register (ELISIR)
The BHN-registration project (Denmark)
The Swiss Percutaneous Coronary Intervention Register

Table 3 Databases used to develop the clinical EP matrix

National Pacing Database—BPEG (UK and Ireland)
The European Pacemaker Register
The Swedish Pacemaker Register
The Danish Pacemaker Register
The Spanish Pacemaker Register
Implantable Cardioverter Defibrillators (ICD) database—(UK)
The European Registry for Implantable Defibrillators
The Danish ICD Register
The Swedish ICD Register
The Spanish ICD Register
Electrophysiology database—EPS (UK)
The Spanish Ablation Register

undergoing an elective, urgent, or emergency PCI in France, Germany, Israel, Portugal, and the United Kingdom. The Global Register for Acute Coronary Events (GRACE), another example of a multi-centre database, involves 95 centres in 14 countries in Europe, North and South America, Australia, and New Zealand.[21]

Some databases aim to collect data at a national level on all patients, such as the RIKS-HIA—Register of Information and Knowledge about Swedish Hospital Intensive Care Admissions (www.riks-hia.se). This database, devised in 1992, collects data on patients admitted to cardiac intensive care. Similarly the British Cardiac Interventional Society Coronary Angioplasty Register, collects data on patients undergoing PCI in 63 out of 64 hospitals in the United Kingdom (www.bcis.org.uk).

The data standards drafting process

The contents of the databases, registries, and surveys, including the variables, coding options, and definitions from all of the identified sources, were reviewed by the Expert Committees. In October 2003, each Expert Committee met to select data variables to form the first draft of the data standards, taking into consideration the relevance of different variables for clinical audit, service planning, or epidemiological research.

Also, the Expert Committee members emphasized that variables and definitions included in the data standards should be readily and reliably accessible from patients' clinical records. Subsequently the drafts were circulated to other experts for evaluation (February 2004). These experts were identified by the Co-ordination Committee and included cardiologists, nurses, epidemiologists, statisticians, IT managers, database administrators, data collectors from existing registries, device manufacturers, and software vendors from all EU member states.

Variables common across the data standards, including demographics, risk factors, discharge, and follow-up data, were identified and discussed by the Co-ordination Committee. Where possible, variables included in more than one module used exactly the same variable name, coding, and definition. The aim was to achieve comparability and to prevent conflicting definitions between modules, and to enable data to be transferred from one module to another or downloaded to different modules from electronic patient records.

Each Expert Committee met again in March or April 2004 to review these comments and to agree the draft data standards.

The agreed draft data standards were circulated to the delegates for a Consensus Conference, which was held in Cork, Ireland, on 9–11 May 2004. The meeting was attended by representatives of Health Ministries from all EU member states, including service planners, advisors on cardiology services, and epidemiologists. Invited experts included representatives of device manufacturers and of other European professional associations.

Contents of data standards: information on all modules

The data standards for ACS, PCI, and EP have a consistent structure and the variables can be categorized under the following general headings: demographics, past history, risk factors, presenting symptoms, procedure/event, outcome, discharge details, and follow-up.

- Demographics: this section is identical across the three modules and contains variables such as date of birth, sex, and hospital identification number.
- Past history: past medical history, previous procedures, and medication prior to hospital admission. There are many variables common to more than one module in this section, particularly to the ACS and PCI data standards. The EP data standards place emphasis on underlying diseases, previous EP procedures, and prior medication of particular relevance to the procedure the patient is undergoing.
- Risk factors: height, weight, diabetes, hypertension (all collected in the EP module) hyperlipidaemia, and current smoking status.
- Presenting symptoms: this section differs between modules and includes variables on presenting symptoms, clinical presentation, initial diagnosis, and indication for intervention. In the ACS module this section focuses on the patient's presenting symptoms, and the ECG and biochemical markers underlying the clinical diagnosis.
- Procedure/event: the structure of this section is similar for the PCI module and the pacemaker and ICD components of the EP module that relate to the implantation of a device. They include date and time of

procedure, information on the type of device, the anatomical location of access and placement, and medication used during the procedure. The EP ablation data standards cover similar data items and variables on ablation targets and techniques. For the ACS module, this section covers the acute event and therefore includes data on immediate reperfusion treatment, i.e. thrombolysis and/or PCI.
- Outcome: the structure of this section is similar across the three modules and places emphasis on both immediate and long-term complications after the procedure/event. It also collects data on other relevant procedures and interventions during the patient's hospital stay.
- Discharge details: survival status at time of discharge, date of discharge and medication at discharge. The PCI module collects additional data on discharge destination and the ACS module contains variables on the ECG and on discharge diagnosis.
- Follow-up: the number of variables and hence the amount of detail for this section varies from module to module. For the ACS and PCI modules, this section is identical and includes survival status, events since discharge, and medication at follow-up. The EP modules have fewer follow-up variables: survival status as well as immediate and medium-term complications of the EP procedure.

The following sections provide further details on content specific to each of the data standards, in addition to the sections shared with other modules.

The data standards for ACS
The data standards for ACS include 83 variables on the patient, diagnosis, treatment, and outcome, and a further 25 on follow-up.

- Reperfusion treatment: the type of reperfusion, thrombolysis/PCI, date, and time reperfusion commenced, or the reason why reperfusion therapy was not administered.
- Other investigations, medication, and procedures: variables on investigations, medications, and procedures the patient underwent after the acute event, such as angiography, PCI, coronary artery bypass graft surgery, and electrical devices.
- Events during hospital stay: data such as recurrent infarction, stroke, episode of bleeding, and/or a cardiac arrest.

The data standards for PCI
The data standards for PCI include 87 variables on the patient and the procedure, and a further 25 on follow-up.

- Coronary angiogram: percentage stenosis of the coronary segments and the left ventricular function.
- PCI procedure: the date, time, and indication for the procedure. If the indication for the PCI intervention is an ACS, these details on the ACS are recorded: presenting symptom, date and time of symptom onset, date and time of arrival at hospital. Variables about the procedure include whether direct stenting was used, stent type and size, as well as diagnostic and therapeutic devices used during the procedure.
- Events during hospital stay: immediate complications of the PCI are recorded, for example, acute segment closure and side branch occlusion. Events such as myocardial (re)infarction, stroke, bleeding, and cardiac arrest during hospital stay are also included.

The data standards for clinical EP: pacemakers and ICDs
The data standards for clinical EP include 131 variables on insertion of pacemakers, 127 variables on ICDs, and 16 variables on follow-up.

- Procedure: details on the device implanted are included, such as the generator and lead manufacturer, model, serial number, and configuration.
- Repositioned/repaired/replaced/explanted: if a generator or lead is repositioned, repaired, replaced, or explanted, the type of procedure and the indication for it are recorded.
- Procedural complications: immediate and post-operative complications of the procedure, such as central venous complications, pneumothorax, haemothorax, and wound complications.

The data standards for clinical EP—ablation
The data standards for clinical EP–ablation have 130 variables and 18 on follow-up.

- Ablation procedure: date of the procedure, ablation target, total procedure duration, and ablation techniques.
- Procedural complications: immediate and medium-term complications specific to the procedure such as unintended AV block, unanticipated pacemaker implant required, pulmonary vein stenosis, and pericardial effusion. Data on if and when the arrhythmia recurred are also collected.

Discussion

The CARDS Project aimed to agree data standards for priority modules of cardiology health information systems. Rapid and appropriate investigation and treatment are essential for patients with suspected ACS to minimize complications and to maximize cardiac function and quality of life after the event. Adoption of the proposed European data standards for ACS will facilitate the evaluation of adherence to clinical guidelines and management protocols for ACS. PCIs and EP services are resource intensive, and the patient population and indications for these services are increasing. By facilitating clinical audit with the collection of comparable data, the CARDS Project will promote quality assurance in these high technology cardiology services. Systematic collection and analysis of comparable data throughout Europe will provide a context in which to interpret local and national data. Decisions in relation to the configuration of cardiology health information systems and on software will be made by local and national

health services, using the agreed European data standards. Variables included are deemed to be of high priority for the purposes of clinical audit, service planning, and clinical epidemiology. However, a local or national service may decide to collect additional information.

There was substantial discussion by the Co-ordinating and Expert Committees on whether variables on social class or ethnic group should be included. The accurate recording of social class is challenging and even more so in a European context, where different categorizations are in use in different countries. Some European countries consider it is essential to record ethnic group or to monitor equity of access to services by disadvantaged and minority groups. In other countries it is considered discriminatory and unacceptable to record such information. It was concluded that it would not be appropriate to include socioeconomic variables in European data standards at this time. Each country may, however, set its own national standards for such variables.

The three modules have a similar structure, with sections on demographics, history, risk factors, event/procedure, medication, outcome, discharge, and follow-up. As follow-up is resource intensive and health services vary from country to country, the Expert Committees decided that this section should be optional. The ACS and PCI standards have 83 and 87 variables, respectively. There are three EP data standards, for pacemakers, ICDs, and ablation. Due to the complex nature of EP procedures the number of variables exceeded the original aim of 100 per module. However, for pacemakers and ICDs, $\sim$70% of variables will only be applicable to a particular patient at any one time.

Implementation of the data standards will vary from country to country. For example, national cardiology registers and clinical audit systems are already in place in Sweden, the United Kingdom, and Denmark. Therefore these countries have the opportunity to adopt these data standards immediately. Prior to the conference, the Department of Health and Children in Ireland circulated a consultation questionnaire to the Health Ministries of Member States. The aim of the questionnaire was to collect information on relevant databases and registries, in place or planned, throughout the EU. Most countries considered the data standards to be relevant and that they would be likely to adopt them in future development of cardiology health information systems. The main challenges that were highlighted were inadequate hospital IT systems, resources for staff and equipment, and the variety of existing software already in use.

The ESC will act as steward of the CARDS initiative in the future, encouraging implementation of the data standards, acting as a source of information, and guiding the process of updates of the data standards. Dissemination of the data standards will be through the ESC networks of national societies, working groups, and associations (www.escardio.org). Providers of software for cardiology and hospital information systems will be contacted and facilitated to use the data standards in their systems.

The CARDS Project has agreed data standards for some areas of cardiology practice in Europe. Use of the standards will support local and national registries to evaluate the volume and standards of cardiology services, with the capacity to compare data between institutions and countries, and to set the findings into the context of services in other European countries. There is substantial scope to extend the development of European data standards for other areas of cardiology practice.

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