



CARDS

Cardiology Audit and Registration Data Standards

Background Paper

For the

Cardiology Audit and Registration Data
Standards (CARDS) Conference during
Ireland's Presidency of the European Union





Executive Summary

The Minister for Health and Children aims to agree EU data standards for priority modules of cardiovascular health information systems during Ireland's Presidency of the European Union. To achieve this, the Presidency is working in partnership with the European Commission, the European Society of Cardiology, European Union Member and Accession States, and the Irish Cardiac Society.

The aim of the Cardiology Audit and Registration Data Standards (CARDS) project is to achieve consensus on data standards for use in Europe for three modules of cardiovascular health information systems – acute coronary syndromes (ACS), percutaneous coronary interventions (PCIs) and electrophysiology (EP) (pacemakers, implantable cardioverter defibrillators [ICDs] and ablation). Three Expert Committees selected approximately 100 variables per module.

Member States aim to provide high quality health services which are responsive and accessible, which use resources efficiently and are accountable. Health information systems are essential to monitor the extent to which the aims of the health services are being achieved.

The data standards developed by the CARDS Project will facilitate the evaluation of clinical guidelines and risk management protocols for ACS. Coronary intervention and EP services are resource intensive, and the patient population and indications for these services are increasing. The CARDS Project will promote quality assurance in these high technology cardiology services.

Cardiovascular health information systems can be sophisticated, with electronic patient records and integration of hospital and cardiology clinical records.

Many hospitals maintain a cardiology database for clinical audit and research and may submit data to surveys such as Euro Heart Surveys and registries.

Other sources of data relevant to cardiovascular health information systems include national and international registries of adult and paediatric cardiothoracic surgical procedures. Data standards for cardiac rehabilitation are also relevant. Registers of patients with cardiac conditions are also maintained in general practice. There will be scope for agreement on variables which are common to registers of patients with other conditions, including heart failure, stroke and diabetes.

Other relevant data sources include mortality statistics, health behaviour and health examination surveys. There is a strong history of standardisation of cardiovascular survey methods, with international collaboration. Data from patient registries complement the information available from other sources.

A consultation questionnaire is being circulated to Member States with the invitation to attend this CARDS conference. This aims to collect information on relevant databases and registries, in place or planned, throughout the EU.



The standards documents set out the proposed data variables (or fields) for systematic data collection in the chosen areas of cardiology practice. A definition and a coding system are proposed for each variable. Further explanations about the content and information on the source documents are provided in the introductory sections of each of the standards documents.

The CARDS project will disseminate the data standards to all EU Member States. The extent and pace of implementation will be a matter for each country. Only the data standards are covered by CARDS. The choice of software, hardware and overall system design will be a matter for health service management at national and local level in each country.

Some countries already have many of the hardware, software, communications and staff requirements to fully implement CARDS. A minority of locations may have an integrated cardiology system, with the capacity to transfer data between the modules and with other information systems in the hospital setting. Some countries or hospitals may choose to implement each module separately, on a phased basis.

Data are already collected on patients with pacemakers and ICDs and many centres send data to a national registry. Data on PCI are also collected electronically in many centres but using different data sets. The chain of ACS care services is complex, involving pre-hospital care, the emergency department and coronary care staff and quality assurance is essential. If complete coverage of all ACS patients is not possible, registration may be carried out for specified time periods.

Data collection in the EU is subject to EU Directive 94/46/EC, as transposed into law in each Member State. Depending on national legislation, consent from the patient or next of kin may be required to record and store data electronically. Every effort must be made to ensure the security of the system, with appropriate arrangements for back-up and to prevent unauthorised access. The confidentiality of all stakeholders must be maintained.

Full implementation of CARDS in the EU would result in the establishment of cardiology registers in all acute hospitals providing PCI or EP services. These would collect data on all procedures performed and transmit data to a central national data centre. Registration coverage for ACS requires discussion in view of the resources required for data collection.

Members of the Expert Committees intend to pilot each of the data standards to test feasibility. The data standards and accompanying descriptive information will be published. The European Society of Cardiology will support this process, using its network of national cardiac societies and speciality working groups.

There are important benefits for the health services of Member States, for cardiologists and for device manufacturers and software companies from implementing CARDS. There is potential for co-operation at European level in the development of staff training materials and training courses, and in the collation and analysis of registry data.



The Minister for Health and Children aims to agree EU data standards for priority modules of cardiovascular health information systems as a major initiative under Ireland's Presidency of the European Union. To achieve this, the Presidency is working in partnership with the European Commission, the European Society of Cardiology, European Union Member and Accession States and the Irish Cardiac Society.

Aims of this Background Paper

This background paper uses a question and answer format and aims to achieve the following:

- (1) to introduce the CARDS Project, its aims and objectives;
- (2) to set the CARDS project into the broader context of quality assurance for health services in Europe;
- (3) to provide information on cardiovascular health information systems;
- (4) to provide information on CARDS, European data standards for ACS, PCI and EP;
- (5) to describe the potential benefits of CARDS for patients, cardiologists, planners and researchers;
- (6) to consider the implementation of cardiology data standards at local and national level;
- (7) to consider the implementation of cardiology data standards in Europe and
- (8) to provide a summary of the information on CARDS.



1. Introduction to the CARDS Project and the CARDS Conference

1.1 Why was the CARDS Project established?

Data related to patient care in cardiology are collected in many European hospitals. Such databases may serve purposes within the institution, to track the types of patients and number of procedures. Furthermore, data may be provided to national registries and national health authorities, as well as to international registries and survey programmes, such as Euro Heart Surveys.

Existing cardiology databases share similar aims but there is no European agreement on which variables to collect in specific service locations and no agreed definitions for most of the data fields. As a consequence, the important benefits of collation and comparison of data from different sources are lost. The CARDS Project set out to agree European data standards, to provide a basis for the collection of comparable data in cardiology databases and registries.

1.2 What are the aims, objectives and working methods of the CARDS Project?

The aim of the Cardiology Audit and Registration Data Standards (CARDS) project is to achieve consensus on data standards for use in Europe for three modules of cardiovascular health information systems – acute coronary syndromes (ACS), percutaneous coronary interventions (PCIs) and electrophysiology (EP) (pacemakers, implantable cardioverter defibrillators [ICDs] and ablation).

To achieve this, a Management Committee, a Co-ordinating Committee and three expert committees were established in September 2003 and a European CARDS Conference is scheduled for 10th and 11th May 2004. The Expert Committees include cardiologists and other health professionals with an interest in these types of databases and registries from a number of EU countries. The committees have met to discuss the issues and have also communicated by e-mail. For each of the three topics, existing databases and registries have been reviewed and collated into a matrix. From these inclusive data matrices the Expert Committees have selected approximately 100 variables per module which may be used for one or more of the following purposes: clinical audit, service planning and epidemiology.



The Expert Committees have worked to achieve the following objectives in advance of the CARDS Conference:

- To develop data standards (variables, definitions and coding) for each module and to review and adapt them following consultation with other national and international expert groups,
- To ensure consistency of definitions and coding for variables which are common to the three modules, and
- To review the adequacy of the proposed data standards for clinical audit, health service planning and epidemiological surveillance.

The objectives of the CARDS Conference are:

- To provide information about and reach agreement on the draft European data standards to representatives of Health Ministers of the Member States, including health service planners and professionals, and
- To discuss the dissemination and implementation of the data standards and to report to EU Health Ministers on their use to support cardiology practice in Europe.



2. Setting CARDS in the context of quality assurance in health services in Europe

2.1 What is the purpose of the CARDS Project?

The Department of Health and Children in Ireland, working in partnership with the European Society of Cardiology, the Irish Cardiac Society and EU Member and Accession States, aims through the CARDS Project to secure agreement on European standards for the data to be collected in priority areas of cardiology practice.

The information from cardiology registers using these European standards may be used by cardiologists, service planners and researchers to improve the quality of patient care and the efficiency of cardiology services. The collection and analysis of comparable data throughout Europe would provide a context in which to interpret local and national data.

2.2 Why is this project important for health services in Europe?

Ireland's Health Strategy is called 'Quality and Fairness'.¹ The title summarises its main aims, to provide high quality health services which are responsive and accessible to the whole population, regardless of social class or geography. The efficient use of resources and accountability are also essential. These underlying principles of health service provision are shared by other EU Member States.

Health information systems are essential to monitor the extent to which the aims of the health services are being achieved.

'Health information is fundamental to assessing and implementing quality programmes. It is also vital to the wider areas of value for money, information for management, information for the public, knowledge management systems and knowledge bases.'

Quality and Fairness. A Health System for You. Health Strategy, Ireland, 2001¹

2.3 How will the CARDS Project contribute to improved quality of cardiology services in Europe?

The most basic form of health service planning involves drawing up and agreeing budgets, and monitoring of expenditure and activity levels. In order to develop high quality services and to ensure efficiency, it is also necessary to consider:

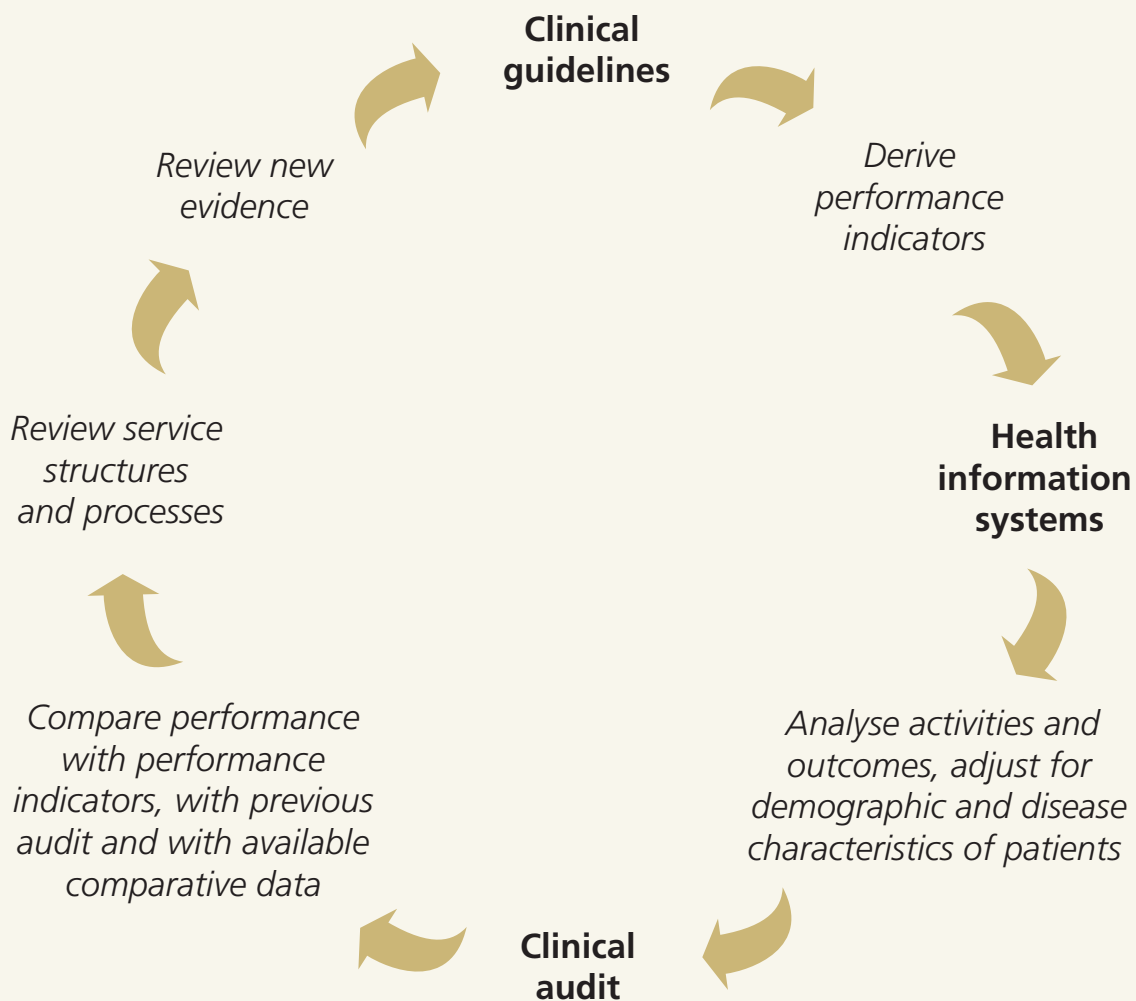
- health service structures - where care is provided and how different components of the service provide care at different times during the course of an illness,
- the processes of care - what services are provided, when and by which professional(s), and
- patient outcomes - extent of recovery, complications, referral for further investigations or procedures.



For common conditions, such as an ACS (suspected heart attack), clinical guidelines set out the investigations and treatments for which there is evidence of benefit. Professional societies, such as the European Society of Cardiology, convene expert committees to prepare, publish and update clinical guidelines. Relevant guidelines in this context include those for the care of patients with different types of heart attack (ACS with or without ST elevation) and for the care of patients with syncope who may require an EP procedure, such as the implantation of a pacemaker.^{2,3,4,5}

European guidelines may be adopted at national level or may be adapted to reflect the needs of patients or health service structures in a particular country. At regional or hospital level, European or national guidelines may be 'localised' to take account of local circumstances and to encourage ownership and implementation of the guidelines.

Figure 1. The professional audit 'quality cycle'





When guidelines are developed, clinical targets are set, for example, that patients should receive a particular treatment or medication unless there is a specific contraindication. These clinical targets provide the basis for performance indicators. Information systems (either ongoing or special surveys) are utilised to estimate the extent to which the service is achieving the key performance indicators and thus delivering the service in line with the clinical guidelines.

Clinical and professional audit is therefore an essential component of the 'quality cycle'. Teams of professionals review their performance in the context of the agreed guidelines. Where performance standards are not being achieved, the process of care is reviewed. The necessary actions to improve the quality of the service are agreed and incorporated into local guidelines, operating procedures and staff training. The extent to which the service has improved and is achieving quality indicators is reviewed in the next round of the professional audit cycle.

Increasingly, health services are undertaking risk management to focus on steps in the care process which are prone to error. This can be 'enterprise wide', that is it may cover all locations within the service, for example, procedures for dispensing medication. Other risk management initiatives identify crucial links in the chain of health care for a particular condition, for example, the role of each component of the service and of each type of professional to ensure timely assessment and appropriate administration of thrombolysis in patients with a suspected ACS.

'Outcome research requires specific information on large groups of patients, with different characteristics and managed with different treatment strategies.'

The Cardiology Information System. M. Simoons et al, 2002⁶

Access to timely, accurate and relevant information is essential for quality improvement through clinical audit and risk management. The CARDS project includes data standards for ACS. Rapid and appropriate investigation and treatment is essential for these patients, to minimise complications and to maximise cardiac function and quality of life after the event. Adoption of the proposed European data standards for ACS will facilitate the evaluation of clinical guidelines and risk management protocols for ACS.

The CARDS Project is also preparing data standards for PCI and EP. Coronary intervention and EP services are resource intensive, and the patient population and indications for these services are increasing. The appropriate use of resources and assuring best patient outcomes are essential aspects of a high quality service. By facilitating clinical audit and the collection of comparable data, the CARDS Project will promote quality assurance in these high technology cardiology services.



3. Cardiovascular health information systems

3.1 What types of cardiovascular health information systems are already in place in cardiology services in Europe?

A number of 'building blocks' have been described which contribute to a comprehensive cardiology information system:⁶

Building block 1: cardiology information systems

Building block 2: the hospital information system

Building block 3: journals, textbooks, guidelines and educational material - the knowledge base

Building block 4: cardiology news

Building block 5: registries and surveys.

In the future, clinicians may access all of these sources of data and information from a single workstation.⁷ At present, few systems are in place at this level of sophistication. A small proportion of hospitals have electronic patient records, with integration of hospital and cardiology clinical records. Such integrated cardiology systems may access demographic data from hospital administration systems and the results of diagnostic tests, such as radiology and biochemistry laboratory results, from relevant electronic records systems. The results of basic or more sophisticated cardiology tests may also be accessed electronically and drawn into the electronic patient record.

A subset of data from an integrated electronic patient record can in turn be extracted for hospital reporting systems, including for assignment of diagnostic related groups (DRGs). Data can also be extracted for export to national or international registers or to surveys such as Euro Heart Surveys.

While few facilities have fully integrated electronic patient records in cardiology, a larger number have made some progress in this direction, with some integration between cardiology records and patient administration systems, and extraction of data from cardiology records for submission to national and international registries.

Many hospitals which do not have electronic records to support patient care maintain a cardiology database for clinical audit and research, and may submit data to surveys and registries.

3.2 What other sources of data are relevant to cardiovascular health information systems?

CARDS involves data which are collected in the acute hospital setting, in coronary care, in catheterisation and EP laboratories. There are national and international registries of adult and paediatric cardiothoracic surgical procedures, including patients undergoing coronary artery bypass graft surgery. There is some overlap in the types of data collected in surgical databases and those in CARDS. There is scope in the future to move towards agreed data standards for those common variables.



Prior to the commencement of CARDS, the Irish Association of Cardiac Rehabilitation (IACR) had started to agree data standards for use in practice in Ireland. There have been discussions on the draft standards between the IACR and their counterpart organisations in the UK and in Europe. The draft CARDS standards have been made available to the cardiac rehabilitation practitioners, to encourage consistency of variable definitions and coding where there is overlap in the data being collected.

Some data on the early stages of ACS relate to pre-hospital care but are recorded in hospital-based ACS databases. Registers of patients with cardiac conditions are also maintained in general practice to support the ongoing care of such patients, including treatment to reduce risk of recurrent events. In future it is likely that registers will be established to support the care of patients with chronic heart failure, and may be shared between the hospital and general practice settings. There will also be scope for agreed data standards for variables which are collected in registers of patients with other cardiovascular conditions, including stroke and in patients at high risk, such as those with diabetes.

In addition to patient registers, epidemiologists and health service planners use a number of data sources to get a picture of the current burden and likely trends in cardiovascular disease in a population⁸. These include mortality statistics which are coded using an international classification system. Other sources of data to estimate levels of sickness or morbidity in a population include hospital discharge statistics and population prevalence surveys. In addition to estimating disease prevalence, population surveys can monitor trends in lifestyle risk factors. Health examination surveys measure biological risk factors such as blood pressure and blood cholesterol levels.

There is a strong history of standardisation of cardiovascular survey methods, with international collaboration. WHO published the first edition of 'cardiovascular survey methods' in 1968, the second edition in 1982 and a further edition was published recently.^{9,10} Standardised survey and registration methods were also utilised in the WHO MONICA Project (Multinational MONItoring of Trends and Determinants in Cardiovascular disease), supported by instruction manuals, staff training and data validation procedures.¹¹ The MONICA Project registered coronary heart disease and stroke in defined populations (community and hospital events) and, at its peak, encompassed 38 populations in 21 countries in 4 continents.

'It has become clear that the value of these studies may be greatly increased if different groups can agree to use some of the same methods, for in this way findings in different populations may be compared.'

Introduction, Cardiovascular Survey Methods, 1982.⁹

Data from patient registries complement the information available from other sources, to provide a clearer picture of trends in risk factors, morbidity and mortality, as well as in the characteristics of patient populations and the outcomes of treatment.



3.3 The purposes of cardiology registries

The main purposes of cardiology registers are:¹²

- to describe patient characteristics, investigations and treatments,
- to estimate morbidity, mortality and resource utilisation,
- to examine trends over time in patterns of disease and therapies, and
- to compare patient care with the evidence base, with clinical guidelines and with care in other places.

In addition, questions arising from analysis of registers can be researched in special studies and information from registers can contribute to the design of clinical trials.²⁷ The process of data collection can itself be a learning exercise and discussion of registry reports can form the basis for educational discussions in the health services. Reports from registries can raise public and political awareness, for example, of the need to seek care soon after the onset of symptoms of ACS, or of groups at increased risk.

In addition, cardiology registry data can provide a basis for health service planning and for epidemiological research.

3.4 Cardiology registries in Europe

A complete description of cardiology databases and registries is beyond the scope of this paper. Selected examples will be provided. Reports from some registries may be circulated for local use and may not be accessible through searches of the medical literature.

A consultation questionnaire is being circulated to Member States with the invitation to attend this CARDS conference. One of the aims of the questionnaire is to collect information on relevant databases and registries, in place or planned, throughout the EU.

There have been a number of national and international surveys of ACS, of myocardial infarction and ischaemia. There have been three such national surveys in Ireland.^{13,14,15} There have been other national surveys, for example, in the United Kingdom (SAMII and PRAIS-UK),^{16,17} as well as Europe-wide surveys (ENACT and Euro Heart Survey ACS).^{18,19} The Global Registry of Acute Coronary Events (GRACE) involves 95 hospitals in 14 countries in Europe, North and South America, Australia and New Zealand.²⁰

The value of such registers has been recognised.²¹ Differences in treatments are found, for example, the frequency of utilising some medications or the level of interventional therapies in some countries compared to others. There is then scope to examine the extent to which patient outcomes are different and the relationship between treatments and outcomes.

There are several examples of national registries of PCI, as in France,²² Germany,^{23,24} Denmark²⁵ and Spain.²⁶ Most collect data on an ongoing basis and include all patients undergoing a PCI procedure.



Records are maintained of patients receiving a pacemaker or ICD, so that patients can be contacted in the event of a suspected problem with a particular model. The European Pacemaker Identification Card was originally designed in 1978.²⁷ Registers may record demographic and clinical data as well as information on the type of device implanted. National registration centres send aggregated data to the European Working Group on Cardiac Pacing.

Some countries, including Sweden and the U.K., have national registers covering areas of cardiology practice, including those addressed in CARDS. The Swedish Cardiovascular Registry is based at the Uppsala Clinical Research and Registry Center (www.ucr.uu.se). It has been recognised as an official national quality register since 1995. RIKS (Register of Information and Knowledge Sweden) uses Internet-based technology and allows password-controlled interactive access to data and statistics.

The Central Cardiac Audit Database in the U.K. is managed by the NHS Information Authority and covers seven 'domains'. (www.ccad.org.uk) It builds on registers developed by the British Cardiac Society and the British Cardiac Intervention Society, the National Pacing Database and databases in other domains of cardiology and cardiac surgery. It is also Internet-based, using NHS Net, with security precautions to control access and ensure patient confidentiality.

Both Sweden and the U.K. have unique personal identifiers which permit linkage of the cardiology database to the national population or health service register. Patients in the cardiology registers can be 'flagged' in the population register and their death can be notified to the cardiology register, permitting mortality follow-up of those registered.

Thus there are a number of national and international cardiology registries in operation in Europe, particularly for ACS and PCI. Some countries have a national central facility to collate data for several clinical modules, to support clinical audit. Other countries are planning national registries and central research support facilities. The CARDS Project will facilitate the efficient development of cardiology registries in Europe.

'In conclusion, registry data is valid, interesting, and useful to physicians, clinical investigators, and health care administrators. Meticulous attention to methodology improves the quality of the data. Interpreting the implications of a particular registry's data requires a thorough understanding of the techniques employed to collect the information reported.'

Are data from clinical registries of any value? J.S. Alpert, 2000.²⁷



3.5 Are cardiology registries in Europe achieving their full potential?

At present in Europe some hospitals have a comprehensive cardiology health information system but data collection is not carried out in all hospitals. Where an information system is in place, similar types of data are collected but the definitions and coding systems may be different.

Therefore, the present system makes it difficult or impossible to compare the care of patients in different hospitals. Clinicians can use their data to analyse the care they provide for patients. However, the findings of such clinical audits are difficult to interpret. Being able to compare findings in one hospital or country with those in other places facilitates clinicians in the interpretation of findings in their own hospital.

The current system is inefficient. The collection of similar but not identical data in different locations increases the costs of developing software. Agreement on data standards means that software companies could develop a basic suite of software for use in cardiology practice throughout Europe.

The current system is inefficient also for medical device manufacturers. When a pacemaker is inserted into a patient, the clinician must register the patient and the pacemaker serial number. This patient record is updated during routine check-ups. The patient register can be used to track all patients who received a particular type of pacemaker should a problem be suspected with the product. At present different data may be collected for this purpose in different parts of Europe, increasing the registration costs for the manufacturers of pacemakers. The situation is similar with regard to implantable cardioverter defibrillators (ICDs) which are inserted in patients with irregular heart rhythms at risk of cardiac arrest.

Demographic and epidemiologic trends, along with technological developments and additional treatment indications are likely to result in increased demand and higher costs of cardiology services. This is particularly challenging for those services which are resource intensive, for example, PCI which is used to treat lesions in the coronary arteries without cardiothoracic surgery. Health service planners and managers need high quality data to track the volume and quality of service being provided. Collection of data on an ongoing basis and comparable to that in other locations would greatly increase the value of the information for planning and evaluation.

'Together the industries, health care providers and medical professional organizations can develop data standards to be collected / registered for patient care, as well as the standards for access to the knowledge base and registries. The dream which some of us had 30 years ago can now be realized.'

The Cardiology Information System. M. Simoons et al, 2002⁶



4. The CARDS Project

4.1 What cardiology patients, conditions or treatments are included in CARDS?

Three modules of a cardiology health information system were chosen for the development of cardiology data standards in Europe. These will support data collection on:

- (1) Patients admitted to hospital with suspected acute coronary syndrome (ACS), including acute myocardial infarction (heart attack) or unstable angina,
- (2) Patients in a catheterisation laboratory undergoing a percutaneous coronary intervention (PCI), such as an angioplasty procedure to improve blood flow in a coronary artery, and
- (3) Patients in an electrophysiology laboratory in whom a pacemaker or implantable cardioverter defibrillator (ICD) is implanted, and in those undergoing an ablation procedure.

The CARDS project will agree the data standards. Implementation of the data standards in cardiology health information systems and registers will be a matter for health service managers and cardiologists in each EU country.

4.2 What is being proposed by the CARDS Project?

The three standards proposed by the CARDS Project's Expert Committees are being circulated with this Background Paper.

The standards documents set out the proposed data variables (or fields) for systematic data collection in the chosen areas of cardiology practice. A definition and a coding system are proposed for each variable. Further explanations about the content and information on the source documents are provided in the introductory sections of each of the standards documents.



Figure 2. Example of data standards. Extract from ACS data standards – section 2, past history relevant to coronary artery disease

Past History relevant to Coronary Artery Disease - Previous history may be documented in the patient medical notes, GP letter or other referral letters or the patient or the patient family may have positive information from medical professionals that confirm history.

	Field name / prompt	Short code	Field content	Definition	Definition of field options	Data format
ACS 2.01	History of previous myocardial infarction (MI)	1	No	Indicate if the patient has had at least one previous myocardial infarction before this admission.	Patient has no history of a previous myocardial infarction.	Code n1
		2	Yes		Patient has had at least one myocardial infarction previously	
		9	Unknown		Information missing	
ACS 2.02	Prior angina	1	No	Indicate if the patient has a history of angina and / or has been treated previously for angina by a physician.	Patient has no history of angina	Code n1
		2	Yes		The patient has a history of angina	
		9	Unknown		Information missing	
ACS 2.03	History of congestive heart failure (CHF)	1	No	Indicate if the patient has a history of congestive heart failure and/or has previously been treated for congestive heart failure by a physician.	Patient has no previous history of congestive heart failure.	Code n1
		2	Yes		The Patient has a history of congestive heart failure.	
		9	Unknown		Information missing	
ACS 2.04	History of stroke	1	No	Indicate if the patient has a history of cerebrovascular accident (CVA) / stroke, as evidenced by a persistent neurological deficit due to ischaemia.	Patient has no previous history of stroke	Code n1
		2	Yes		Patient has a history of stroke	
		9	Unknown		Information missing	



5. The potential benefits of CARDS for patients, cardiologists, planners and researchers

5.1 What will be the main uses of data collected using CARDS?

Implementation of cardiology data standards will improve cardiology services for patients by enabling the collection of high quality data to meet the needs of three main user groups:

- (1) cardiologists and other health professionals for use in clinical audit,
- (2) health service providers, planners and managers for service planning and evaluation, and
- (3) epidemiologists for analysis of disease patterns.

5.2 How will patients benefit from the development and implementation of data standards?

Clinical audit using data collected according to European standards will improve the quality of care for patients suffering a heart attack or related condition. Cardiologists and other health professionals will be able to examine the service they provide on an ongoing basis. They will be able to set their performance into the context of their national data and the findings for other European countries.

European data standards for cardiology will support health service planners to study the volume and mix of their services and compare them with services in other places. They can study service quality and compare outcomes with key performance indicators. Better data will support the case of health service planners for additional or better use of existing resources to improve access to higher quality services and treatments. The benefits derived from extra resources can be calculated, so that those funding services can see the improved quality of care as a result of the investment.

Epidemiologists can use the data collected according to the standards to analyse differences in the rates of disease or characteristics of patients in different places or over time. Studies based on local data allowing comparison with other populations can raise awareness of health problems and can also be powerful motivators for behaviour change, for example, to reduce risk of heart attacks. Research questions arising from the analysis can be further examined using additional studies.

The potential benefits from use of the data standards by each of the main user groups are now considered in more detail.



5.3 How will the practice of cardiology benefit from the use of European cardiology data standards?

Health service reforms in many countries, including Ireland, are putting service quality at the top of the agenda. Many physicians and cardiologists assess the quality of their services through case conferences and *ad hoc* surveys. These can make valuable contributions to improving patient care and will continue to do so in the future. However, modern health services require a more systematic approach to assessing and improving the quality of patient care. Quality assurance of cardiology practice requires comprehensive collection and analysis of high quality data on an ongoing basis, linked to a process of clinical audit.

Euro Heart Surveys is a series of surveys co-ordinated by the European Society of Cardiology. The surveys are done across Europe on key aspects of cardiology practice and involve completing a clinical record form on consecutive patients meeting set criteria. A 'snap shot' is obtained of the care of patients in Europe and of the extent to which they are receiving evidence-based treatments. Each country can compare its findings with those for Europe as a whole, as well as with the clinical guidelines for the care of patients with the condition being studied. There are substantial benefits from collecting a large data set from a series of patients over weeks or months. However, the patients surveyed in a country may not be representative of patients in that country, so the findings on a national or local level may be difficult to interpret.

Clinical audit involves agreeing clinical guidelines for the care of a condition, collecting, analysing and examining data on patients receiving care, and comparing the extent to which the care provided is in accordance with the agreed guidelines. Key aspects of the process can be summarised and communicated through the use of performance indicators.

The 'audit cycle' analyses the data on patient care over a period of time. Clinicians and other professionals compare the care provided to patients with that recommended in clinical guidelines and against the performance indicators. High quality data and appropriate statistical analysis are necessary for this process, in order to ensure that the complexities of the data are appreciated and taken into account. For example, the outcome of patients in cardiology practice is affected by factors such as the age of the patient and the level of cardiac function, including whether or not the patient has heart failure.

Agreeing data standards nationally and internationally is essential to implementing clinical audit at local level. In units with small numbers of patients, patient characteristics, outcomes and adverse events can vary substantially from time to time. Interpretation of the findings of clinical audit is greatly facilitated if the data can be compared with those in larger data sets. Data which are comparable from place to place can be amalgamated into larger data sets and provide a context for the interpretation of clinical audit at local level.



In future, it is likely that professional practice will not just be audited by clinicians at local level. It is likely that formal systems of clinical governance will be put in place. Professionals will oversee the assurance of professional standards of practice. This may involve re-accreditation, whereby professionals must demonstrate that they are maintaining their skills and continue to have the competence necessary to do their jobs and provide the appropriate level of care to patients. Such a system of competence assurance and clinical governance will require high quality health information systems to examine the care provided by professionals and to set that care in a broader national and international context.

Thus agreeing European data standards in cardiology lays the foundations for assessing the quality of care, facilitating the assurance of professional competence and clinical governance, and supporting clinical audit at local, regional and national levels.

5.4 How will health service planning and evaluation benefit from the use of European cardiology data standards?

High quality services provide care to patients at the appropriate time, in the appropriate location, and to appropriate standards. From the perspective of the patient, care is not just for the treatment of acute symptoms, but includes rehabilitation, prevention to reduce risk of recurrence, and ongoing care for chronic conditions, as well as consideration of the health and social care needs of family members.

Hospital discharge statistics provide data on the numbers of patients treated, on disease conditions and on the procedures carried out. These data are important for service planning. If hospital discharge statistics are collected to a high standard, they provide information on the trends in hospital discharges with common conditions and on interventions, such as insertion of pacemakers. However, routine hospital discharge statistics do not provide data of sufficient completeness, accuracy or timeliness to adequately examine access to services, resource utilisation and the quality of the care provided.

Improved cardiovascular health information systems can support health service planners to examine whether patients have adequate and equal access to services regardless of their area of residence, gender, or socioeconomic status. Information on socio-demographic characteristics and disease manifestations can be used to make appropriate statistical adjustments when comparing treatments or outcomes in different facilities. Detailed data can support the case for additional resources to improve access to evidence-based treatments. Ongoing data analysis can demonstrate the benefits derived from increased resources.

Patient registers can be used to examine the quality of services. For example, health service managers need to work with community and hospital-based personnel to ensure that patients with acute chest pain receive thrombolysis ('clotbuster' medication) as appropriate and within the agreed length of time after calling for help. With standardised cardiology health information systems, each service can examine its own performance on 'call to needle' and 'door to needle' times. The findings are substantially more meaningful when performance can be compared with agreed indicators on an ongoing basis and compared with other similar facilities.



5.5 What benefits will be derived from the use of cardiology data standards for epidemiological research?

Epidemiologists study disease patterns in populations, looking at the number of people with a condition, what factors are associated with developing the disease, what influences outcome, what are the trends in the condition and how does the incidence (new cases) and prevalence (cases living in the population) compare with that in other places or over time. The aim of epidemiological research is to learn about the disease in order to prevent or reduce its occurrence. Epidemiological study methods can be applied in a clinical setting, providing data for clinical audit and for health services research.

There have been substantial changes in the epidemiology of cardiovascular disease in many developed countries. Death rates have been decreasing and the age of occurrence of acute coronary disease is increasing. By analysing data collected in different locations according to set standards, epidemiologists can identify areas with high incidence or with poor prognosis. Hypotheses can be generated as to why there are different disease patterns in some locations and these can be studied using specific studies established to address the hypotheses.

Cardiology registers using European data standards would complement other sources of data to build a comprehensive picture of the epidemiology of cardiovascular disease in EU Member States.



6. The implementation of cardiology data standards at local and national level

6.1 What are the information technology implications of implementing CARDS at local and national level?

The CARDS project will disseminate the data standards to all EU Member States. The extent and pace of implementation will be a matter for each country.

Only the data standards are covered by CARDS. The choice of software will be a matter for health service management at national and local level in each country. Likewise the hardware and overall system design will be decided and implemented in the context of the overall development of health information systems in each Member State. Issues for discussion at national level are whether databases will be distributed across each hospital registering data or whether data will be transferred to a central database.

Some countries already have many of the hardware, software, communications and staff requirements to fully implement CARDS. A minority of locations may have an integrated cardiology system, with the capacity to transfer data between the modules and with other information systems in the hospital setting. Some countries or hospitals may choose to implement each module separately, on a phased basis.

6.2 Are there differing resource implications in implementing the CARDS modules?

Patients with pacemakers and ICDs require ongoing follow-up to ensure optimum functioning of the device. Data are already collected on these patients and many centres send data to a national registry. The additional resources to implement CARDS-EP, including staff training and procedures to check data quality, would be justified by the added benefits of assuring data quality and comparability of data across Europe.

Given the projected increase in patient populations and the increased indications for PCI, including 'primary' PCI as a revascularisation treatment early in the course of a heart attack, there are strong arguments for implementing national and European registries using CARDS-PCI. The details of the procedure are recorded in the patient's records but the CARDS registers would do this in a standardised manner. Data are already collected electronically in many centres but using different data sets, according to whether or not they contribute to an existing PCI registry.

There are strong arguments to implement CARDS standards in those registers already in operation in Europe and to put software in place to provide data compatible with CARDS-PCI. Registration of PCI is likely to be a requirement for quality assurance of services and for competence assurance for cardiologists in the future. It would be appropriate for all PCI services to plan to implement such registers. Their benefits would be maximised by adopting CARDS-PCI.



Mortality and complication rates associated with ACS are decreasing. Treatments for ACS are increasingly effective. The chain of ACS care services is complex, involving pre-hospital care, the emergency department and coronary care staff. The implementation of clinical guidelines, ongoing staff training and professional audit are essential for quality assurance.

A high quality information base is an essential component of quality assurance. Recording of a complete data set on all cases of suspected ACS is however resource intensive. If complete coverage is not possible, registration could be carried out for specified time periods. Particularly where clinical targets have been met, a minimum data set or data on a sample of patients could be recorded on an ongoing basis. This would provide a context for data collected during registration periods with a full data set and aiming to achieve complete coverage. Feedback of registry findings and their use in professional audit can contribute to staff motivation to maintain the ACS register with a high level of completeness and accuracy.

6.3 What will be the challenges in implementing CARDS?

In addition to resource implications, the establishment of cardiology registries presents many challenges and these will differ from country to country. Some countries have made substantial progress in developing cardiovascular health information systems. Some challenges will be unique to particular countries, for example, in relation to data protection.

Data collection in the EU is subject to EU Directive 94/46/EC, as transposed into law in each Member State. Depending on national legislation, consent from the patient or next of kin may be required to record and store data electronically. Consent may be required to transfer data to a central registry or to link data collected for different purposes. In other countries, consent is not required, particularly when the data are anonymised.

In all cases, every effort must be made to ensure the security of the system, with appropriate arrangements for back-up and to prevent unauthorised access. The confidentiality of all stakeholders – patients, professionals, and health services funding agencies and managers – must be maintained, in accordance with explicit agreements in advance of data collection.

All stakeholders have a responsibility to ensure that the registry data are of an acceptable quality. Initial and ongoing training, supported by manuals, is essential. A log of queries and proposed solutions should be maintained and manuals adapted as necessary. Data cleaning routines can check data quality. Cross checks can be carried out within data sets or with other sources of data, for example, with hospital discharge statistics.

The availability of European standards should support the development of registries, and facilitate the sharing of training materials and solutions to problems which arise.



7. The Implementation of cardiology data standards in Europe

7.1 What would happen if CARDS were fully implemented in the EU?

Implementation of CARDS in the EU would result in the establishment of cardiology registers in all acute hospitals providing PCI or EP services. These would collect data on all procedures performed and transmit data to a central national data centre.

Where there are ACS registers or where ACS surveys are being done, use of the European data standards would increase efficiency in planning, in software development. As well as improving comparability within countries and over time, a European context would be available for data analysis and reporting.

Those with sophisticated hospital information systems may be able to integrate cardiology registers using CARDS with patient administration and other hospital systems, for example, diagnostic or biochemistry laboratory systems.

Implementing CARDS will provide a solid basis for planning and evaluation of cardiology services, allowing comparability with other registers throughout Europe.

7.2 Will the cardiology data standards be adopted in all European cardiology registries?

The data collected in international, national and local databases were considered in the development of CARDS. There was considerable discussion and adaptation of variables, coding and definitions in developing and agreeing the draft standards, so the standards no longer resemble any particular registry. There has been consultation on CARDS with some of those already operating cardiology registries. It will be feasible at local level to add variables to the CARDS modules, so long as compatibility with the European standards is maintained.

Those with existing databases and registries will be encouraged to consider the software and record form changes necessary to implement the European standards. Such registries would require software to translate the existing database contents as far as possible into the new format so that data collected in the future can be compared with findings in the past.

Sweden has a comprehensive system of cardiology databases and plans to pilot the European data standards. It is hoped that other countries which have national systems in place will consider the alterations in software and record forms necessary to adopt the European standards. Countries which are considering the establishment of networks or national registers are likely to adopt the European standards.



7.3 What will be the next steps to implement European data standards in cardiology?

Members of the Expert Committees and others who have been consulted intend to pilot each of the data standards. This may be done using a paper-based system, primarily to test feasibility.

Translation from English will be discussed by the Co-ordinating Committee overseeing the process, Chaired by Prof. M. Simoons. Independent back translation into English will be considered, to ensure that the meaning has not been altered in the translation process.

The data standards and accompanying descriptive information including the progress and outcome of these pilots will be published and disseminated. The European Society of Cardiology will support this process, using its network of national cardiac societies and speciality working groups.

7.4 What will be required to implement CARDS at European level?

There are a number of stakeholders with an interest in implementing European databases for CARDS, for ACS, PCI and EP.

As described above, there are important benefits for the health services of Member States from implementing CARDS, particularly in relation to clinical audit, health service planning and epidemiological research. Cardiologists as represented by the European Society of Cardiology and national cardiac societies will benefit educationally and professionally from co-operation to implement CARDS at European level. There are benefits also for device manufacturers and software companies.

There is potential for co-operation at European level in the development of staff training materials and training courses, and in the collation and analysis of registry data.

7.5 Can the CARDS Project provide a model for the development of other European data Standards?

The CARDS Project during the Irish Presidency of the EU is addressing priority modules of European data standards in cardiology. There is scope for the agreement of further data modules in cardiology and related specialities, for example, in cardiac surgery, cardiac rehabilitation and heart failure services. Modules on other atherosclerotic vascular conditions and on related conditions such as stroke and diabetes could be developed, utilising similar formats where there are overlapping variables.

The development of European data standards in the CARDS Project provides a model for similar developments in other specialities.



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