THE DEVELOPMENT OF A CENTRALISED CARDIOVASCULAR DATA COLLECTION ACROSS THE EUROPEAN UNION MEMBER STATES

To ensure effective service planning and quality of care for patients across the EU, there is an overwhelming need for a centralised, comprehensive European cardiovascular diseases registry. This would provide an important and effective tool for a patient-centred health care in the future.

I Cardiovascular diseases in the European Union

Cardiovascular (CV) diseases (CVD) (the principal forms of which are coronary heart disease and stroke) is the main cause of death in the European Union (EU), accounting for over 2 million deaths each year (42% of total mortality). Coronary heart disease itself is the single most common cause of death in the EU, leading to 741,000 deaths per year. CVD is also a major cause of death below age 65 accounting for 24% of all deaths, or just under 232,000 deaths. Coronary heart disease is the single most common cause of death before the age of 65 accounting for over 104,000 deaths, or 13%. According to research, a combination of disease prevention and improved treatment has brought about a decline in CVD death rates in recent years. Current lifestyle surveys indicate that for young and middle-aged adults there might be an increase in public health problems in the future. These issues need to be addressed now. Large differences in death rates due to CVD (and therefore large differences in life expectancy) are observed among EU member states. It is unknown to what extent this is due to the lack of prevention or to suboptimal care. Overall CVD is estimated to have cost the EU economy just under €192 billion in 2006, almost €110 billion of which are health-care-related and €82 billion from lost productivity and the cost of informal care.[1]

II The need

Today, real life data registries are needed. Across the EU member states, clinicians face important health-care decisions without adequate information. In many guidelines, a large proportion of recommended treatments have a level of evidence C, which means that the recommendation is purely based on consensus of the members of the guidelines committee and that reliable data on the recommended diagnostic modalities or treatments are not available in spite of the fact that they are given routinely to many patients. Furthermore, in many randomized, controlled trials specific patients groups are excluded, e.g. the elderly, women, patients with significant co-morbidity such as renal or liver dysfunction. These patients are frequently seen in daily clinical practice. A health system guided by better information about "what works" with an acceptable safety margin would have benefits for all who have a stake in national health systems. Patients would develop more confidence that the increasing complexity of diagnostic tests and treatments

[1] European cardiovascular disease statistics 2008 ; European Heart Network

could be tailored to meet their individual needs; physicians would have more certainty that their clinical decisions were evidence-based and serving patients well; health authorities would be reassured that their reimbursement system is cost-effective. Consequences of the lack of such information include wide geographic variations in treatments typically received for specific conditions and, with these variations, sizeable differences in related health care spending not accompanied by proportional differences in outcomes.

III What do patient registries bring to health care

A registry is a collection of a set of predetermined patient data on health status, consumed resources, demographics and socioeconomics. The data is placed in a central database and is available to be analysed as a whole or as a fraction of the collected data. The functions of a registry include recording management and outcomes of a disease, monitoring quality of care and providing a resource for further research. Patient registries are often utilised to track the pattern of a certain disease, the treatment provided, the effectiveness of methods of (secondary) prevention and the economic implications of different forms of treatment. Guidelines on diagnostic-therapeutic processes for CVD are provided to the medical community from different sources but if and how they are perceived and incorporated in clinical practice by physicians, and their impact in terms of outcome and cost is unknown.

In order for a register to be useful an underlying governing premise should be that the data is authentic and of good quality. Data sets must be comprehensive and representative, encompassing the different variables required for clinical audit, service planning and epidemiological research. Harmonised definitions of the variables must be in place to ensure comparability and transferability of data. Furthermore, in order to get a reliable picture of a specific disease in a specific region (country) all or nearly all hospitals should in principle be included in the registry or at the minimum a representative sample. In most registries only the best hospitals (clinicians) participate and, as a consequence, data are obtained which do not reflect the real impact of the disease or a treatment in a specific region (country).

IV Benefits of a centralised European CVD registry

Currently, there are national CVD registries and databases operational in a number of member states but there is no central European CVD registry. Throughout the EU, information on risk factors, incidence, prevalence and management of CVD remains patchy and there is very little data which can be compared between member states. Due to differences in the data standards, methods of collection and recording employed in the different member states, national registries do not provide comparable data and, in their current form, cannot be combined to meet the requirements of a centralised European CVD registry.

A comprehensive, uniform EU-wide data set would:

- Allow increased surveillance of CVDs and their components in a time of changing epidemiology
- Allow assessment of quality of care and patient outcomes

- Result in the expansion of the EU's clinical research capacity e.g. by identifying in the EU centres with a high incidence of a specific CVD or with a high use of specific diagnostic tools or treatments and thus facilitating European participation in international clinical studies
- Provide important information for health authorities on cost-effectiveness
- Avoid unnecessary duplication of work
- Be a valuable resource for maximising health resources and evolving standards of care with changing epidemiology
- Allow comparisons between hospitals within a country and between EU countries
- Enable comparison of data on an international level
- Provide a reliable tool for audit
- Provide a reliable tool for systematically monitoring use and effects in clinical practice for new (and old) medical devices and medications over time, including the possibility of rapid recall in the event of concern about a product
- Provide data on geographic variations in the severity of CVD around the EU.

V Meeting the agenda of the European Commission

There is currently growing support from EU policy makers to engage in this endeavour, both from the public health angle and the Information & Communications Technologies (ICT) portfolio:

- In December 2010, Mr John Dalli, the EU Commission for Health, wrote to MEP Ioannis Tsoukalas and indicated that "The Commission is also developing comparable indicators for cardiovascular diseases monitoring, and cardiovascular mortality comparable data"[2].
- In January 2011, Ms Neelie Kroos, Vice-President of the European Commission responsible for the Digital Agenda, told participants of the 2011 Continua Personal Connected Health European Symposium that "the Commission indeed calls for a minimum common set of patient data that can be accessed or exchanged electronically across Member States"[3].

The need for exchange of medical data is crucial and goes far beyond the EU borders. The European Union recently signed a Memorandum of Understanding with the USA to promote a common approach on the interoperability of electronic health records and on education programmes for information technology and health professionals.

The Memorandum is in line with the Digital Agenda for Europe objectives:

- to promote the use of eHealth technologies,
- to improve the quality of health care,
- to reduce medical costs, and

[2] E-9548/10EN
[3] http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/11/19&format=HTML&aged=0&language=EN&guiLanguage=en

» to foster independent living, including in remote places.

Finally, the objective of one centralised CVD registry at European level meets the objectives of the Cross Border Healthcare directive, which encourages the European Commission and Member States to work on interoperability of health data, whether it concerns patients, prescriptions or treatments and procedures.

VI What has already been done

Much of the work towards agreeing on data standards has already been done by the Cardiology Audit and Registration Data Standards (CARDS) in Europe. The CARDS project was undertaken and its standards were adopted during Ireland's presidency of the EU in 2004. The goal of CARDS was to have an agreed common European lexicon for describing the management and outcomes of patients with cardiac disease. The CARDS project was co-financed by the Irish Department of Health and Children which worked together with the European Commission, the ESC and the Irish Cardiac Society on the project. The aim was to achieve comparability and to prevent conflicting definitions. It aimed to agree data standards for priority modules of cardiology health information systems. By facilitating clinical audit with the collection of comparable data, the CARDS project promotes quality assurance. The CARDS project agreed on standards for three priority modules of cardiovascular health information systems: acute coronary syndromes, percutaneous coronary interventions and clinical electrophysiology (pacemakers, implantable cardioverter/defibrillators and ablation procedures). Content data on demographics, past history, risk factors, presenting symptoms, procedure/event, outcomes and discharge details were common to the three modules.

European Community Health Indicators (ECHI) developed by the European Commission and the Member States produced a few CVD related indicators[4]:

» Mortality due to ischaemic heart disease and diseases of the circulatory system;
» Hospital discharges for acute myocardial infarction and diseases of the circulatory system;
» Number of surgical operations and procedures: coronary angioplasty;
» Use of medicines: hypertensive diseases

In addition, the EUROCISS[5] projects co-funded by the European Commission seek to develop indicators related to cardiovascular disease surveillance and prevention.

The American Heart Association and the American College of Cardiology have recently developed a new set of Data Standards for acute coronary syndromes and chronic coronary heart disease. Furthermore, a new, industry-independent, EurObservational Research Programme on all major CVDs has been launched recently by the European Society of Cardiology based on a methodologically robust platform, and structured in European networks representative of the European health care in the different countries and with the participation of CV national medical

[4] http://ec.europa.eu/health/indicators/indicators/index_en.htm
[5] http://ec.europa.eu/eahc/projects/database.html?prjno=2003118

societies Thus, the scientific work performed by the large cardiac societies in the world (ACC, AHA and ESC/EHN) will facilitate a centralised EU registry.

In terms of centralisation of data in Europe, the European Commission is currently developing a web-based portal dedicated to health information data in Europe, called Heidi[6], which allows experts to upload their data and knowledge on health statistics in Europe.

VII What is still needed

To take the EU registry forward, the following formal actions are needed:

- The establishment of a coordination and operation committee
- The development of a facility to allow for local, national and international analyses and report generation
- The development of audit capability
- The introduction of a unique European patient identification number
- The development of a system of governance ensuring compliance with data protection

The implementation at national level of compulsory data collection or through incentives is a necessary condition to guarantee completeness and continuity.

Formal collaboration between national and European Societies (ESC and EHN) to agree on uniform data items and data definitions will be needed. Close cooperation will also be established with project leaders of existing initiatives (see above) to avoid duplication and encourage synergies.

One of the main obstacles is (will be) the sovereignty of member states that may have developed their own health data systems. There is an urgent need to promote the adoption of common standards by member states on a voluntarily basis. Health professionals in the field of cardiology already represent a unique integrated European community sharing a common professional ground. In spite of their efforts to promote common data standards such as CARDS, their adoption and implementation have been poor indicating a great need of support from national health authorities.

VIII Conclusions

All stakeholders in cardiovascular health in the EU will benefit from a centralised database not least the health authorities in the different EU member states. The final aim is to agree on and to implement a standardised cardiovascular data collection platform which later could possibly serve as a local hospital file if accepted by national health authorities. To achieve this ambitious goal the support of the EU commission, parliament and national health authorities will be needed.

[6] http://ec.europa.eu/health/heidi