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National Registries in Europe: present and future

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CURRENT STATE OF NATIONAL REGISTRIES

In March 2000, representatives of national End Stage Renal Disease (ESRD) registries met in Amsterdam to discuss the future collaboration within the European Dialysis and Transplant Association (EDTA). Over the last five years, the number of national registries has steadily increased and so has their capacity to gather data on the treatment of ESRD patients at a national level. There are now registries in many European countries, including Eastern Europe. Within the larger European countries, the efforts to create registries at a national level are gradually achieving more concrete success. The coverage of the English registry is increasing. In England they have made an explicit choice to aim for the collection of a wide range of data. This decision will enable the development of an in- depth system of quality improvement. On the other hand, the intention to gather an extensive data set, makes it more difficult to cover all the centres where ESRD treatment is being supplied. In Germany, Quasi Niere is making progress to implement a new system of data collection. The German system is unique because it uses smart card technology to ensure that patients can give explicit consent to transfer of data concerning their treatment. In France there seems growing consensus about the creation of a national ESRD registry, and hopefully concrete progress will be made in the near future.

Smaller countries such as those comprising Scandinavia as well as Belgium, Austria and the Netherlands seem to be successful in maintaining national ESRD registries. In larger countries, regional registries are flourishing in many instances but in general they seem to have more difficulty integrating the data flows of the higher number of centres within one national decision-making framework. In Spain and Italy therefore, several regional ESRD registries are following a course involving integration of registry data at regional level.

THE EDTA REGISTRY

While regional and national registries were developing rapidly, the registry at European level declined. The course of events surrounding the European registry shows how difficult it is to combine the different kinds of expertise that are needed to run a registry successfully. For example, medical insight has to be combined with up- to-date knowledge in a variety of other areas like information and communication technology, statistics, and information logistics. Of course combining these different types of expertise in a healthy organization requires a decision-making structure that can acquire appropriate funding and also allows the benefits of a European registry to be produced economically.

In the beginning of the nineties, there was a lengthy period where the EDTA registry was an example to others of good registry practice. At that time, the nephrologists in the United States did not have access to nationwide ESRD data. In the meantime, the positions have reversed and the United States Renal Data Systems has taken the lead. One important reason for this development was that the USRDS is directly funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in conjunction with the Health Care Financing Administration (HCFA). Europe lacks such a source of funding and so the European Registry has been run on a shoe string. In Europe however, many parties have an interest in a well run continent-wide ESRD registry. Among those parties, the European nephrologists are foremost, since the profession needs the epidemiological information to keep its house in order. The industry also needs surveys of developments in the market to be able to assess performance. In the long run, Europe cannot function without a European health policy. End Stage Renal Disease is an area where patients cross national borders. Given the high annual costs of treatment, national governments will want to be able to allocate scarce resources, such as donor kidneys in an appropriate way and for this they will require insight into international developments.

As has been pointed out, the European registry declined because it turned out to be impossible to combine the different kinds of expertise necessary to run a successful registry. Generally there was insufficient

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synergy between information technology expertise, statistical and scientific knowledge and organizational know-how. This created a crisis in the registry which dragged on for a number of years. This crisis deepened because of the sheer magnitude of data at a European level. This large flow of information cannot easily be handled in a centralized way. To do so, it requires strictly-planned logistical procedures. An organization that moves from one crisis to another is not able to maintain those procedures. Once the rhythm in the flow of information is broken and more importantly, once the feed back by way of surveys stops, the goodwill upon which every registry relies dries up quickly. At the end of the twentieth century the old files of the EDTA registry still have historic value but cannot be considered to be relevant for real decision-making in the twenty first century.

The new Amsterdam office of the EDTA registry started its activities in the first half of the year 2000. An important turning point was the acknowledgement that the European registry is primarily a federation where data is supplied by national registries. Therefore absolute priority has been given to the accumulation of a European database consisting of the relevant parts of the files of national registries that in turn consist of the integrated data files of regional registries. Much depends on the ability of the council of the EDTA to provide the office of the EDTA registry with sufficient funding to organize themselves at the minimum level required to run the registry and of the capacity of the staff in Amsterdam to get the machinery going.

The registry committee established at the EDTA meeting in Madrid and the staff of the EDTA registry in Amsterdam have decided to leave the old datafiles as they are and to concentrate on the integration of information elicited from national registries. If this (complicated) process can be carried out in half a year, first results of the new EDTA registry database might be available in Nice in September.

NEW TECHNOLOGY

The rapid growth in technological know-how provides exciting perspectives for the organization of registries on the one hand, but the lack of a stable perspective creates high risks on the other. If development in the application of information and communication technology knowledge is extremely rapid, the danger exists that everyone, including even high-level technology experts, become over-optimistic about the technological opportunities in the near future. This occurred during one of the crisis stages of the EDTA registry, where a decision was made to organize the database of the EDTA registry using Microsoft Office software. Datafiles of national ESRD registries tend to become rather large once they are integrated. Even the data on patient transitions arising from a relatively small country such as the Netherlands, contains too many records to be handled within the maximum capacity of an Excel spreadsheet. With the benefit of hindsight, the decision to use Microsolf Office software was incorrect. The decision to choose a new technology capable of handling files about all the European end stage renal disease patients is a difficult one.

Nevertheless new technology is increasingly available that has the potential to allow for great improvements in the integration of databases containing information on ESRD patients. In recent years, technological progress has focussed to a large extent on the *organization* of databases. It is now feasible for every centre to organize elaborate sets of information on ESRD patients who are being treated in a particular centre in a local database. There has accordingly been improvements in the functioning of databases in many dialysis centres. For instance, in the Netherlands currently about 40 of the 50 dialysis centres are using DIAMANT software. The structure of that database software in the centres is broadly the same. The database contains information on global treatment, but also on many detailed variables like laboratory values, logistics for home dialysis patients, planning and realization of dialysis sessions for haemodialysis patients, recording of visits of peritoneal dialysis patients, complications etc. In the United Kingdom, a number of dialysis centres are using CCL software, which also covers a wide range of data. The situation is different in different parts of Europe. However over the last years, progress has been made in regard to the development of software to manage data for dialysis centres and it can be expected that in the near future, many centres will be using some kind of database functionality.

In transplant centres, databases have been in use for a considerable length of time. These data bases will often be part of the general database of the hospital, but at least they contain information on the status of the patients. It is known that the follow-up of patients living with a functioning graft is difficult, because the follow-up is event driven at patient level. Therefore it is difficult to keep track of patients who are living with a functioning graft and who are fortunate not to be faced with a continuous stream of complications. In these cases, the frequency of communication with the patients is less and sometimes the medical responsibility for those patients is transferred to nephrologists or internists outside the transplant centre. In these cases, it is difficult to gather the follow-up data about the patients. However the technical mechanisms to keep the data in an electronic database are available. The problem is to collect the data, not to store them.

Major technological advances have been made over the last three years, which provide a positive perspective for ESRD registries and for communication between centres treating ESRD patients. These developments are a result of the more general harmonization of data transfer that has been agreed within the governing structure of the world wide web. The world wide web connects computers with different characteristics containing different databases running on different systems. Over recent years therefore, great effort has been invested in the development of standards to connect those computers in a safe and reliable way and also in the development of tools to maintain the connection once a communication channel is established.

Harmonization on the word wide web

It is now a common experience to download HTML pages from computers providing information worldwide. In the past, this information had to be organized within the limits of the Hyper Text protocols. The committee which governs the standardization of protocols on the world wide web has now agreed to a more powerful language called XML. XML provides the option to define data transfers in an organized way. Data transfer is effectively realized by means of profiles. For instance, a profile could cover all the data relating to a transition of a patient moving from a centre where he/she has been treated up to a certain date, to another centre, where the patient is going to be treated. Of course that profile has to be agreed by the parties who are responsible at both sides and much work has still to be carried out to standardize that information. However once the nephrological community in a certain local area, region, country or continent reaches agreement in regard to profiles, associated with certain events, the technology is available to transfer that set of information from one centre to another or from one centre to a regional or national registry, or from a regional registry to a national registry or even from a national registry to a European one.

CORBA

CORBA stands for common object request broker architecture. It is a set of specifications that enables us to make a connection between two computers and to transfer data between those two computers. For instance, if two centres or all the centres collaborating within the framework of a regional or national registry, have agreed to a certain profile to describe the data about a patient transition in a standardized way, the transmission of the data defined by the standardized profile can be organized using CORBA specifications. To provide the required security, the connections between computers are effectively made via secure tunnels and do not allow an outsider or a computer managed by an outsider to gain insight into the data. These tunnels are named secure socket layer (SSL) connections.

In the future it will be possible to connect computers to transfer information that is organized in certain profiles from one place to another in a safe and secure environment. That transfer of information might take place via the internet, using appropriate encription protocols, or via dedicated communication lines assumed to be safer than the internet. Therefore it would be possible to send information about a patient transfer at certain fixed times, during the night for instance, or triggered by an administrative procedure carried out once a decision has been made in a centre to transfer a patient to another centre.

Database connectivity

Standards have been agreed about the definition of data according to profiles and about the transfer of data in a secure manner conforming to the CORBA specification. The missing link is the connection between the data available in databases in dialysis and transplant centres and the set of data associated to a profile that has to be transferred. This is called database connectivity and basically implies that routines have to be written to distil the information in these databases into a profile which can be transferred later on. These routines can be written in JAVA which would have the advantage that they could be applied by computers using different operating systems, such as UNIX or Windows NT. The ideal situation would be to distil the information into XML format.

NDSnet

Over the last three years, a project (nephrological data systems or NDnet) has been carried out, subsidised by the European Telematics Programme, to explore the potential of the new technology described above for the nephrological community. This project has resulted in a demonstrator which is able to establish a connection between a computer in a dialysis or transplant centre and an ESRD registry and to transmit information associated with a patient transfer. It is hoped that the experience of the partners in the NDSnet project can be shared with many other parties involved in registries of ESRD data. In the not too distant future, the application of this technology promises dramatic increases in the capacity of the nephrological community to collect data and to use these data to improve the quality of ESRD treatment and to share responsibilities. There is now an obligation on everybody involved in the work of ESRD registries to ensure all these technologies work for the benefit of the patients.