ECFS Patient Registry Newsletter

YEAR 2011, ISSUE 1 May, 2011

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1. THE FIRST ISSUE

The purpose of this Newsletter is to give Colleagues and Friends in the CF field a regular update on the activities of the ECFS Patient Registry (ECFSPR).

In this edition we summarise the results achieved by the collaboration of EuroCareCF and the European CF Registry, now joined into the new ECFS Patient Registry. The governance of the registry is now agreed and the key principle is one of patient consent. We have published this recently in the Journal of Cystic Fibrosis as an open access document (*EuroCareCF: Report on the demographics of cystic fibrosis in 35 European countries*, European Coordination Action for Research in Cystic Fibrosis; EC FP6 project no. LSHM-CT-2005-018932, Journal of Cystic Fibrosis Volume 9, Supplement 2, December 2010). This sets out what can be done with the data and how it can be used for patient benefit, as defined in the consent itself.

2. THE ECFSPR ACTIVITY 2006-2010

The ECFSPR is a project registered under the Danish Data Protection Agency. The data are stored on a secure server, situated in secure premises at the University of Milan and are managed according to Danish, Italian and EU Data Protection laws.

The database includes one record per patient per year, each record comprising 47 variables carefully selected and defined by the Registry Steering Committee after two years of consultation with stakeholders across Europe. Patients' inclusion criteria and variables definitions can be found at ECFSPR webpage http://www.ecfs.eu/projects/ecfs-patient-registry/Variables-Definitions.

From 2006 to 2009, centres and national registries willing to participate in ECFSPR were asked to send us their database using a pre-formatted spreadsheet according to agreed patients' inclusion criteria and variable definitions.

Table 1 shows the number of patients registered in the ECFSPR since year 2006.

Table 1: number of patients reported to the ECFSPR from year 2006 to year 2009

year	data referring to year	number of participating countries	number of patients registered
2006	2003	7 countries	10,752 patients
2007	2004	5 countries	15,339 patients
	2005	4 countries	6,609 patients
2008	2006	10 countries	14,101 patients
2009	2007	16 countries	20,204 patients

Each year we summarised the demographic and main clinical characteristics of CF patients into an annual report and presented them at the annual ECFS conference. Copy of the annual reports can be downloaded from ECFS website at the link http://www.ecfs.eu/projects/ecfs-patient-registry/annual-reports. The annual report is fundamental, but it would be of little use if not integrated and supported by special studies fostered by the registry data. Examples of studies recently carried out include abstracts presented at the 2010 ECFS Conference in Valencia on *Differences in disease severity of F508del homozygotes across European Countries*, on *Burkholderia and Stenotrophomonas infections among different European countries* and on *Lung Function in the ECFS Patient Registry*. Copy of these abstracts can be browsed here: http://www.ecfs.eu/meetings/ecfs.

The collaboration with the EuroCareCF project allowed to compare the demographics of CF patients across Europe, as published on The Lancet 2010; 375:1007-1013 by J. McCormick et al. on behalf of the European Registry Working Group: *Comparative demographics of the European cystic fibrosis population: a cross-sectional database analysis*.

Furthermore, the ECFSPR works closely with the ECFS Clinical Trial Network (CTN), e.g. when clinical trials involve identification of patients for targeted trials.

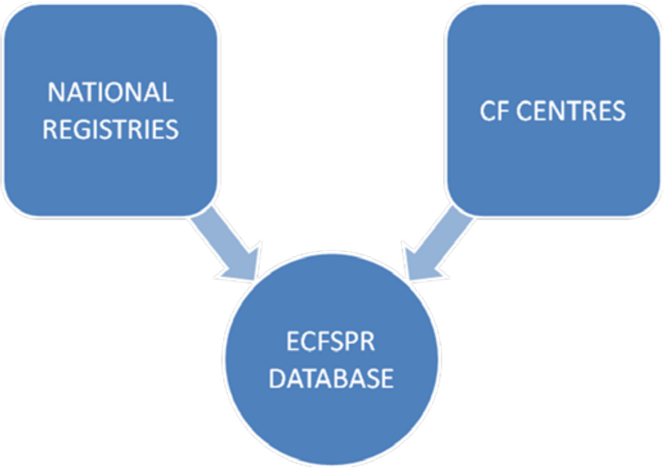
3. THE NEW ARCHITECTURE OF THE ECFSPR

The use of spreadsheet templates for data collection did not efficiently address the technical aspects of data coding, such as control of variables' content. Different national settings resulted in non-uniformity in dates/decimals specifications that needed to be addressed in a customised way.

For these reasons, we developed *ECFRecord*, the software for data collection customised for the ECFSPR. This software allows to have uniformity in format and content of the variables and to perform controls of internal coherence of the data.

ECFRecord allows national registries to directly upload their database and CF centres to use the data-entry feature of the software (Figure 1).

Figure 1: data flow-chart



The data-entry feature of *ECFRecord* stores the patients' data on a local PC and, after cryptography, automatically sends clinical data, without identification, to the ECFSPR server. Data quality controls are automatically performed by the software, which warns the user by means of coloured fields whenever discrepancies or missing fields are found. *ECFRecord* fosters the creation of national registries where they still do not exist. In fact, if all the centres within one nation use the *ECFRecord*, the registry is spontaneously activated. It can be easily institutionalized if the centres appoint a national coordinator, allowing him to access all the participating centres data.

The national registries are asked to extract the data from their database according to the agreed specifications in terms of variable definitions and formats and to create an XML (eXtensible Markup Language) file. They can upload this file through the upload feature of *ECFRecord*, which performs the same data quality controls performed by the data-entry feature.

In order to facilitate work of the centres and registries, we set up a helpdesk service. Once the data are successfully transferred to the server, all further contacts with centres and national registries (requests for clarifications, data coherence corrections) are managed through the helpdesk.

After the necessary data cleaning process, the data are analyzed by the statistics team at the University of Milan and an annual report is delivered. Further data analyses for specific projects are performed after approval by the ECFSPR Scientific Committee, according to the ECFSPR guidelines (http://www.ecfs.eu/projects/efcs-patient-registry/guidelines).

4. WHO DOES WHAT/1 – THE ECFSPR GROUPS

To ensure that all countries are represented and their views heard, the national representatives of the countries that actively supply data to the ECFSPR are members of the ECFSPR Steering Group, which assembles once a year at the ECFS annual conference, and from which the members of the ECFSPR Executive Committee are elected every 3 year. The ECFSPR Steering Group also elects a ECFSPR Scientific Committee to review any requests for data from the registry.

Furthermore, we support an ECFSPR Interest Group, which anyone with an interest in the registry can participate in. This group also meets once a year at the ECFS annual conference at an open meeting.

The updated list of members of ECFSR Steering Group and Executive Committee can always be found at http://www.ecfs.eu/projects/ecfs-patient-registry/steering-committee.

5. WHO DOES WHAT/2 – THE UNIVERSITY OF MILAN

Anna Bossi, Ivan Cortinovis, Laura Viviani and Anna Zolin are the statisticians of the University of Milan who are involved in the ECFSPR project in different areas, but the tasks of the team concentrate mainly in the data management and statistical analysis.

The statisticians perform data quality controls in terms of data coherence and detection of missing data. To improve data quality for the future, they write data quality reports, tailored to each participating centre/country and sent to the data providers for acquaintance and discussion. They carry out statistical analysis of the registry data and summarise the results in tables and graphs, published in the annual report and in scientific papers.

6. WHO DOES WHAT/3 – THE HELP-DESK

The helpdesk provides support to all people who send or plan to send their data to the ECFSPR. Patrizia Iansa and Alice Fox are located in Verona (Italy) from where they manage technical assistance to CF centres and national registries that already use *ECFRecord*, or want to join the ECFSPR.

After having met the national and European data protection requirements, the centers and the national registries are issued user ID and password that can be used to download and install the software to start entering data. Given the peculiarities of every hospital computer system, local centres most often need help to establish the correct procedure to connect to the ECFSPR server through their hospital firewall system.

The helpdesk further provides two-way communication between the University of Milan and the local centres/national registries.

7. CONTACTS

These are the contact details for the most common queries. The updated list of contacts can be found at http://www.ecfs.eu/projects/ecfs-patientregistry/contact.

Data protection	Hanne Vebert Olesen: hanne.olesen@ecfregistry.eu
Helpdesk	Patrizia Iansa/ Alice Fox: helpdesk@ecfregistry.eu
Scientific aspects	Anil Mehta: a.mehta@dundee.ac.uk Hanne Vebert Olesen: hanne.olesen@ecfregistry.eu
Statistical aspects	Laura Viviani: laura.viviani@unimi.it

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