European CF Registry Steering Comittee meeting, Jan 26th 2009

Eitan Kerem, Anil Mehta, Gita Mehta, Ulrika Sterky, Martin Stern, Hanne Olesen, Laura Viviani (as statistical expert). Apologies from Linda Foley, Bruce Marshall, Angelika Preftitsi and Milan Macek.

Benni Assael represented IERFC,and and Patrizia Iansa represented the Azienda Ospedaliera di Verona

Update on PortCF

The UK version of PortCF has been installed and tested at the University of Milan. A small pilot with 5 centres has been done and some issues have been identified. All the necessary supportive software licences have been bought.

1. Administration
    a. Three layers of administrators
        i. Global administrator: Sets up usernames and passwords and assigns the EU centre number. Gita Mehta will be responsible for assigning the centre numbers and assigning usernames/passwords. Patrizia Iansa will get the center numbers from Gita in case she needs it to help out a center (=on a need to know basis). Laura Viviani will need to know in which country the centre is located (without knowing the name of the centre), in order to group data belonging to each country. The centre code is essential for PortCF, because data are entered on a center level, which for small centers means that anonymity may be compromised (this does not happen for data from national registries where data are pooled on a national level and can therefore be stored with country identification).
        ii. Centre Administrator: One per center. Administrator of usernames for the single center. Do not have direct access to data.
        iii. User: Up to several per center. Put in data and can see data from the center. Can make queries.
        NOTE: User and centre administrator can be the same person.
2. Data protection problems
    a. We are not allowed to store data that allow the patient's identification (i.e. name/surname) on the server in Italy
    Solutions:
        i. Encryption at center level, so that the centers can see the names, but they will be encrypted when stored into the server. This imples that an encryption programme will be added. We will need a quote from USi for this. THIS SOLUTION IS THE IDEAL ONE.
        ii. Alternatively, we change the labels of the fields "name" and "surname" to "center id" and "patient id", so that the centers don't get tempted to put in name. If they still do we may have a problem with the Data Protection Agency. It has to be investigated whether this solution is acceptable for the EU/Danish/Italian data protection codes.
    b. Patientcode

i. should this be a randomly created code or one that the centres create by themselves. Some centres may already have a patient code which will be easier for them to use, and risk less faulty entries because of mistaken identity.

c. Excessive data: The data protection laws state that stored data should not be *excessive in relation to the purposes.* There was general consensus, that even though PortCF stores more data than the core data we ask for ECFR the data are not excessive, since they are all disease relevant.

3. Fields with problems:
   a. Ethnicity and race: These fields are compulsory in PortCF. We do not aim to collect them for the ECFR, therefore they should be made non-compulsory.
      Long term solution: Could be greyed out and set to Caucasian for default (because PortCF uses them to calculate FEV-1).
      Temporary solution: put unknown in both fields

   b. Decimal numbers: PortCF uses full stop for decimal numbers (both CFF and UK version). Putting in a comma instead does not work since the comma just disappears.
      Long term solution: change numberformat
      Short term solution: none – we need a quotation from USi for this change.
   c. Date format: PortCF uses mm/dd/yyyy format, which is not compliant with most European countries. For date of birth the field is marked with "mm/dd/yyyy". For encounter date this is not the case which leaves us open for errors.
      Long term solution: have USi change the date format
      Short term solution: add "mm/dd/yyyy" to the encounter date field label
   d. Country of birth: Right now only UK counties to choose from. In order not to lose the anonymity of the center code this needs to be left out.
      Long term solution: delete this field
      Short term solution: put unknown
   e. Logo, contact details etc:
      Need to be changed
   f. Pancreatic status: PortCF only collects data on enzymes yes/no and whether the patient had a fecal fat measurement done. For the definition of PI/PS we need to know if the fecal fat or fecal elastase was pathological
      Long term solution: add a field for PI/PS according to definitions for each annual assessment
      Short term solution: only collect data on enzymes yes/no

4. Other issues to be solved:
   a. Decide domain name
   b. It should be clear for the centers which will be the variables to be sent to the registry. Ideally, the fields could be highlighted (Anil suggested to have them in a separate table).
      Minimal solution: to give the centers the list.

c. Language issues: Gita thinks there will be no problems. However she suggested to have the definitions translated.
Minimal solution: user manual in English

d. Finalise the letter of appointment ECFS/IBSUM – on data protection issues for PortCF (awaiting solution to the above data protection issues)

e. Write the user guide for the centers who want to join PortCF – including the ECFS definitions when needed and which fields to leave out /fill in differently. For now it will be in English. The countries can have their own translation done if they want

5. Schedule for implementation
   a. Obtain permission to use PortCF with patient ID without encryption from Italian data protection authorities
   b. Obtain quotation from USi on the suggested changes – especially the decimal number issue.
   c. Obtain a lasting version of PortCF from USi
   d. When the above issues are solved contact centers who have expressed an interest in starting PortCF to get their confirmation that they have national permission to transfer data to PortCF
   e. Ask centers that will use PortCF to have 1 person in charge of data-entry process at the centre, that will be the contact person (at least at the beginning)
   f. Start including centres one by one in order to calculate the necessary resources for help desk etc.

How to go on from here

We discussed also the future of the registry. PortCF has some limitations, and since any changes will be very expensive according to our previous quotations from USi and the contract that will not allow us to do any changes to the software ourselves, we will have to look forward.

The general opinion was to start working on our own software, so that we would be independent from other registries. We will of course continue working with CFF, UK Trust, Australia etc to try and make the registries as compatible as possible for comparison.

For this purpose a thorough specification of our needs must be done, so we can get reliable quotations from software companies.

The offer from Chiesi together with the ongoing funding from IERFC allows us to develop this software.

Transition from EuroCareCF

EuroCareCF is almost finished. The data, mostly demographic, supplied by the participating countries are now stored in Dundee and the plan for transfer of the data to ECFS (= IBSUM, who hosts the rest of the ECFR data) is as follows:

1. Joint letter from EuroCareCF/ECFS to the participating countries/centers (except those centers/countries that send data directly to the ECFS from national registries etc) for their permission to transfer the data to the ECFS part of the project. There will be the following options:

   a. The country/center allows us to transfer the data directly from Dundee, thereby taking advantage any data cleaning already done.
   b. The country/center sends their original data sheet directly to the ECFS
   c. The country/center does not allow the transfer
2. In the same letter we will include an invitation to supply new data from 2007 via an excel® spreadsheet as supplied (including the newest variables according to the definitions group)

Gita is working at the moment on the demographic report on the entire data set and hope to have a few slides ready for presentation in Brest.

Definitions group

The registry definitions group met Jan 25th 2009 defining 4 further variable groups: Pancreatic status, ABPA, Liver disease, complications at birth. Furthermore, we finalized the list of data that should be collected from the national registries (and other interested countries/centers) this year.

Six further variables need definition before being included (DIOS, CFRD, CF related bone disease, Pancreatitis, Nasal polyps, GFRD). This will be finished at the next definition meeting later this year.

The new definitions and the list of variables will be distributed as soon as possible to all registry contacts (via Gita, Milan and the national registries) for comments.

Update on annual reports and further analyses

The 2004/5 report has been approved by the national registries involved and is put up on the internet today. The 2006 report is currently at the national registries for comments and will hopefully be published soon. Data for the 2007 report will be collected during February/March and hopefully some core data will be presented at Brest.

For the presentation in Brest we will be doing some more detailed analyses on the 2006 data – e.g. gender or genotype comparisons to show that ECRF data can be used for other purposes than annual reports.

In Brest Hanne will participate in a session on improving data for the registry, including some of the definitions work.

International comparison of data

Brief discussion of the possibility of supplying data to CFF for analysis in order to compare to the US values. This has been done by the Australian CF registry with great success. General agreement that this should be done and that we can contact Bruce Marshall about it in Brest.

Feb 10th, 2009

Hanne Vebert Olesen