MINUTES

EUPHORIC PROJECT – WP5.2 MEETING

KARLOLINSKA INSTITUTET, STOCKHOLM
NOBELS VÄG 12A

10 SEPTEMBER 2008, 09:00 – 15:30
MEETING ROOM: 5TH FLOOR, MEB

PARTICIPANTS:

AB: **Unto HÄKKINEN** and **Persephone DOUPI**,
Centre for Health Economics at Stakes, Stakes Unit for eHealth and eWelfare (STAKES), Helsinki (Finland)

AB: **Weimin YE** and **Christina PERSSON**,
Karolinska Institutet (KAR), Stockholm (Sweden)

AB: **Gerold LABEK** and **Renate FECHTER**,
EFORT-EAR – Medical University Innsbruck (EAR), Innsbruck (Austria)

MEETING AGENDA:

1. **WELCOME**
   Christina Persson and Weimin Ye welcome the participants of the meeting.

2. **APPROVAL OF THE AGENDA**
   The agenda is approved by all participants; no modifications are made.

3. **QUALITY REGISTERS: DATA COLLECTION AND REPORTING – FINLAND PERSEPHONE DOUPI.**

   After briefly summarising the main aspects of her presentation from June, Persephone gives an overview of her activities since then and the current status of her draft report. Her focus in the present meeting is on the interim results achieved and those issues that are still to be clarified – including, inter alia, the structuring and presentation of findings in the final report and its synchronisaton with the Finnish report.

   Among other things, supplementary information is given regarding the connection to other databases (slides p. 5): linking is possible only after special permissions have been obtained, special procedures must be followed. Within STAKES, for instance, application for data is also obligatory, but decisions are rendered relatively fast (1 day to 1 week).

   As to the open issues, the >**redundant**< type of **data collection** is discussed in more detail. Persephone points out that there are different levels of redundancy: the kind/ nature of data as opposed to the redundant registration of data. In principle, the choice often is either extracting the data from existing sources/databases or collecting them anew. The method applied depends on what is more economical for the register;

ultimately, the infrastructure and size of the register is decisive. Smaller registers have to consider their limited human and financial resources; for some of them, data collection is even restricted to paper form before electronic processing can be carried out. And they have no means to push hospitals since the provision of data is on a voluntary basis.

Regarding the **presentation of findings, structuring, classifications**, etc. Gerold makes clear that he does not insist on the adherence to any formal guidelines but suggests that Persephone and Christina should preferably coordinate these questions with each other, particularly with respect to the comparison between the two countries.

One of the new topics Persephone has concentrated on is the **validation of data** (slides p. 7). Her findings suggest that data validation is generally understood as the control of data accuracy. In practice, it mainly consists of routine checks of outlier data in the annual input and cross-checking with data from other relevant registers, while more in-depth quality checks are confined to specific research work. In this context it seems worth looking at an additional aspect: to which extent does research work help the validation of data?

Other important areas dealt with more closely:

- **Data security measures** (slides p. 8);

- **Legal framework** (divided into general and register-specific laws; pages 9 and 10);

- **Evaluation** with regard to the **coverage of EUPHORIC indicators** (p. 11);

- **Data access** (p. 12);
  ➔ It is suggested to
  i) summarise in the form of a table (Unto) which data external parties can access and how they can do that,
  ii) also indicating the respective web page and/or the name of a contact person (Gerold).

  If possible, it would also be helpful to include the contact person's function in order to make it easier for potential users to identify this person or his/her successor when trying to get access to particular data.

  In the context of data access and the associated data protection regulations, Unto and Gerold also disuss a problematic aspect in the present situation of the actual **usage of data**: the fact that in Finland there is no possibility to go back to indentifiable data and it is therefore virtually impossible to find out the kind of arthroplasty the patient has had implanted, or the kind of cancer he suffers from, if he/she was treated in another hospital, to a certain extent limits the value of the data for surgeons and other potential users in practice.

- **Impact on stakeholders** (for details see slides, p. 13):
  In summary, the main beneficiaries are public health institutions and funding bodies, as well as those performing quality-related activities, while both patients and physicians have no direct benefit but profit indirectly.
  This is particularly a challenge with regard to the quality of data, since all more frequently it is physicians themselves who directly input the data that is later on used by registers. If register output is of no direct benefit to their work, then they may be less motivated to provide high quality data at the point of entry.

➔ As to the **structure of the report**, Gerold suggests **three levels**:

i) **2 descriptive reports**, written separately for each country;
ii) **1 common conclusive paper** for Finland and Sweden, mainly concentrating on the results (about 15-20 pages)*;
iii) **1 executive report for EUPHORIC** (essentially equivalent to an executive summary of ii); no longer than 5 pages) to be included in the EUPHORIC final report.

*Please note: Gerold stresses the importance of avoiding that the common paper is reduced to a mere descriptive summary of the two individual country reports, but should analyse and compare the strengths and weaknesses of each system including clear statements and a conclusion.

Persephone's PowerPoint slides are included in the annex to these minutes.

4. QUALITY REGISTERS: DATA COLLECTION AND REPORTING – SWEDEN CHRISTINA PERSSON.

Christina gives a detailed overview of how the different kinds of registers will be structured and described in the Swedish report (slides pages 2-7) and provides us with a thorough and vivid insight in the course and progress of her work illustrating it with several concrete examples.

In summary, six (out of a total of seven) nationwide registers ['nationwide' = run by the Swedish National Board of Health and Welfare] and twenty (out of 56) national healthcare quality registers have finally been selected for review. This accounts for a coverage of about 85 and almost 35 percent respectively.

For the quality registers the main inclusion criteria were a minimum age of 10 years and a minimum coverage of over 80 percent (pages 6 and 8).
➔ Gerold asks Christina to briefly describe the reasons for exclusion for both register categories in her report.

Referring to the 'Register on prescribed pharmaceuticals in Sweden' (founded in 2005) Unto mentions that this is done in Finland, too, but not in the form of a register.
➔ Gerold suggests to include this observation in the comparative report.

As to the actual status of her work, Christina reports that two thirds of the included nation-wide registers (p. 9) have already been completed while about half of the quality registers are still incomplete (pages 12/overview to 17). Christina presents several examples of completed and incomplete registers to give us an idea of what she has been doing. (Her examples actually are very illustrative and make us understand that fulfilling her task is all but a walk in the park …)

Many questions of the questionnaires that were sent out have not been or could not be answered, in some cases only an annual report was sent back instead of filling in the questionnaire, often it was difficult to get useable answers at all, even in the following telephone conversations. If the register does not run a website, even less information is available, and it is even more complicated to establish contact. Incomplete questionnaires must now be tried to be completed by phone contact.

Overall, the main problems in contacting register staff do not seem to have changed significantly from what was reported in June:

-difficulty to get in contact with the person responsible;
-reluctance of register staff to provide information (for lack of time or simple indifference);
-'the language barrier' (some staff members do not speak English at all, others do not understand all questions correctly and/or are reluctant to make efforts).

➔ It is discussed whether the questionnaire should be translated into Swedish and be re-sent. This would be quite time intensive and, according to Christina, might also bring some unmeant bias in (as a consequence of a 'quick' translation). It is therefore agreed to 'go the shorter way' for the time being and continue trying to get answers to the open questions on the phone instead. Translation should only be considered as 'a last resort'.

➔ Gerold suggests to include about one page dealing with these problems in the report since this could be of help to the Commission in building up an appropriate communication structure. (Note: no description per register but account in condensed/summarised form).

Slides #18 and #19 provide a brief overview of the missing pieces of information.

The issue of **data ownership** and the procedure of **data access** are discussed in more detail and also with respect to the country comparison. Since most registers in Sweden are state-owned, the respective authority and hence the society itself is to be considered owner of the data. The access and usage of the data is thus subject to the approval of an Ethical Committee.
➔ Gerold suggests to consider for the report whether there is a 'structured permission process' and fixed procedures have to be followed. And if so, to examine whether these apply to all interested parties, or if there are 'preferred partners'.

Another aspect to consider in connection with data access is whether or not and how one can access one's own data. This is reported to be possible without difficulty in Sweden. Patients also have an 'opt-out opportunity', i.e. they can decide not to be included.

In the context of data access also the issue of **charges and payment** is treated. It is revealed that in Sweden no fees are charged for the use of the data itself, but for the computer hours spent. In Finland, by contrast, some registers only charge for data use if it extends to more than an hour while others are not allowed to charge any fees at all. Another interesting finding resulting from the discussion is that some registers in Sweden get paid from clinics for data collecting work, which is not the case in Finland.
➔ Persephone suggests to adopt the whole issue as a topic, which is generally agreed.

A further point of discussion is the term **'size' of a register**. The crucial question is found to be: What do we understand by 'size'? Does it relate to the number of cases reported, or does it have to do with coverage? It is generally agreed that ultimately **coverage** is the important figure. In order to give a better sense of proportion, also the total number of cases included in the register, as well as the annual input of cases should be included, where available. Persephone gives the example of the HILMO register, where 1% of the forms are submitted on paper. Although 1% may seem small, in the case of this large register it translates to 1.5 million paper forms.
➔ This is also considered to be an interesting issue to be included in the report.

➔ With reference to the issues of **budget** and **external auditing**, Gerold suggests to include some information on what he calls >funders' auditing<.

- Do registers provide procedures enabling funders to check what their money is or has been used for?
- If this is not done routinely, is it at least required when registers apply for future funding?

Christina's slides are also part of the annex to the present minutes.

5. DISCUSSION OF REPORTS

As most of the content-related issues have already been discussed during or following the two presentations, the general discussion largely focuses on formal questions such as structuring, sharing structures, possible publications, etc., and on setting up a time table.

I. Publications:

- Scheduled official publications (to be published at the EFORT Congress in June 2009):
  i) EUPHORIC papers
  ii) Summary/Outline for orthopaedic surgeons
  iii) Guideline/Manual of how to organise a register
  (referring to arthroplasty or some sort of quality outcome register)

- Further possible publications:

It is discussed whether the collected material can be used to write several articles to have separate publications for every active participant.
Gerold suggests that one could go into more depth as regards organisation or content, or to go on the level of a single register, for instance.
Unto suggests that 'a really specific article' such as the country comparison between Finland and Sweden may be regarded as the most interesting subject for the European level.
Also the question of authorship is discussed.
➔ It is agreed to put off the decision about one or more publications as well as on the authorship issue until after the single reports have been finished. Then it will be clearer what sort of publishable material is available and which persons are able to take lead responsibility for which publications, depending on their schedules. The discussion can be handled by e-mail.
➔ It is underlined that the EUPHORIC project must be mentioned in the acknowledgements.

II. Suggested content and outline of summary report (Level ii):

A) System descriptions FIN – SWE

B) Aspects to be described:
-legal
-research
-funding
-quality of data
-etc.

C) Comparison

D) Model/Adapted model

□ All participants are invited to complement item B) by suggesting additional criteria; about 7-8 main topics should be treated altogether.

□ Re item D): If no final suggestion is possible, recommendations will be worked out based on the central points/findings of the report.

□ The item 'Legal Issues' may, for instance, include the following:
-owner of data;
-procedure to access data;
-online access possible?
-etc.
➔ Persephone suggests that it will be necessary to consult a lawyer for advice on this section, in order to ensure accuracy with regard to the applicable legal framework.

□ The research aspects may, for example, include:
-What can be done based on the data available?
-How can they be used?
-What is the added value for the health system as a whole?

□ It is suggested to consider also Persephone's presentation on 'Emerging Models' (see slides p. 14) for further topics and possible structuring.

□ Another issue of interest to be dealt within the comparative report is suggested during the discussion of the presentation of findings and in conjunction with the feasibility of direct comparisons of register data and data based on discharge records:
➔ ICD codes 9 and 10 are not structured identically in all European countries. In Sweden, for instance, they have four digits while five-digit figures are used in Finland.

III. Suggested structure for individual reports (Level i):

For the description per country, Persephone suggests to follow the structure of the questionnaire.
All details can be arranged between Persephone and Christina.

IV. AGREED TIME TABLE:

➔ **1st November 2008:** **Deadline for data input**

➔ **15th November 2008:** **'Sub-reports' from Finland and Sweden should be available to Gerold**

➔ **1st December 2008:** **Finalised draft version of comparison FIN – SWE**

➔ **By 10th December:** **Draft version of Executive Summary for EUPHORIC to be presented at the final project meeting in Rome**

➔ It is agreed that any data not available by the beginning of November will be excluded, the reason(s) for exclusion shall be described in brief.

6. MEDICAL DEVICE AUTHORITIES: UPDATE ON RESULTS

On the whole, all efforts have ended up with virtually no useable results.

■ Persephone reports that her second round with the main contact points (mostly directors, heads of departments, etc.) has yielded 'exactly the same result as in June': no answers at all. Moreover, almost no material is available in English.

■ Weimin presents an overview compiled by Fang Fang which contains websites in English and contact information on the medical device authorities of several European countries, amongst others the Swedish MPA, the Medical Products Agency (Karolinska). This overview is presently in review and will also be attached in the annex.

■ As to the German speaking countries, Gerold has made more or less the same experiences as before. He reports that the evaluations are not made even though the institutions would be legally obliged to; the reason they give for not fulfilling this obligation is as simple as astonishing: 'The data we get are not reliable.' Consequently, his report will consist of a summary of the >meager< results and the conclusion that, in fact, there is no chance to set up a standardised report.

➔ Gerold suggests that also Persephone summarises her results, and he will write a comprehensive summary including this information and the data obtained from the literature review performed on implant fractures.

It is further discussed that medical authorities will decide on an ex-post analysis since the existing data cannot be used for a prospective study, and that discharge records alone are not sufficient because they do not contain important pieces of information such as the reason for revision. For instance, it is necessary to know whether an implant fracture is due to medical device failure or has other causes.

7. CONCLUSIONS & FURTHER PLANNING

Having provided a good occasion for directly and personally discussing all matters of concern and open issues, the meeting is perceived as having been very fruitful for all participants.

It is discussed whether another joint meeting should be planned. The participants agree that this would only make sense after having finished work on the draft versions of all three papers and conclude that it is preferable to synchronise activities by e-mail contact. In case the necessity of a further meeting arises while preparation work is still ongoing, at least both country reports (due on 15 November) should be finalised and the comparative paper should be available in its finalised draft version (due on 1 December), thus the first week in December would be the only realistic period for another meeting to be arranged. In view of the difficulty in finding a date that suits all members of the working group at this early stage, it is decided to wait until Gerold has seen the draft versions of the country reports.

Unto suggests to arrange for a video conference instead of a meeting and to propose two or three dates for the last week of November or the first week in December to be able to discuss the drafts before preparing the final versions.
➔ Gerold and Renate will check if this is feasible and advise the others before long.

Another proposal to facilitate the work-flow is to ask Marina for an extra web page dedicated to the necessary coordinating work of the group.
➔ Renate promises to check this back with Marina. (Will be done by end September.)

A final discussion of the [pre-]final versions is scheduled for the final project meeting in Rome, which will be the last opportunity for 'fine-tuning'.

The importance of adhering to the agreed time frame is stressed once more.

8. ANY OTHER BUSINESS

In connection with the issue of funding Unto mentions a report by Pia Maria Jonsson that could be helpful as regards work on this subject.
➔ Unto is asked to send Gerold Mrs Jonsson's e-mail address to be able to request the Report for reference.
pia.maria.jonsson@ki.se

9. CLOSING OF THE MEETING

The meeting is closed at 15:30.

ANNEX:

- **POWERPOINT SLIDES – FINNISH REGISTERS, UPDATED VERSION (PERSEPHONE DOUPI)**
- **POWERPOINT SLIDES – SWEDISH REGISTERS, UPDATED VERSION (CHRISTINA PERSSON)**
- **OVERVIEW OF MEDICAL DEVICE AUTHORITIES (FANG FANG) (AVAILABLE ONLY FOR INTERNAL USE)**