

Minutes from the Business meeting of the EULAR Standing Committee on Epidemiology and Health Services Research (SCEHSR)

Excel Center London, Thursday, 26.05.2011, 17:00 to 18:00, Room S06

Present: Johan Askling (S), Nekati Cakir (TR), Loreto Carmona (E), Marco Cimmino (I), Luc de Clercq (B), William Dixon (UK), Bruno Fautrel (F), Francis Guillemin (F), Merete Lund Hetland (DK), Oili Kaipiainen-Seppänen (FIN), Koray Tascilar (TR), Estibaliz Loza (E), Ines Luis (P), Gary MacFarlane (UK), Kaleb Michaud (US), Ingemar Petersson (S), Raquel Lucas (P), Adrian Richter (D), Carlo Alberto Scire (I), Deborah Symmons (UK), Duruoz Tuncay (TR), Tiraje Tuncer (TR), Till Uhlig (N), Hassan Yazici (TR), Angela Zink (D)

Chair: Angela Zink; incoming chair: Loreto Carmona

Report on meetings of the Executive Committee and the SC chairmen relevant to the SCEHSR

On its way to greater transparency, Eular has worked on written and available Standard Operating Procedures for the Standing Committees. They will soon be available on the web and you will be notified.

A new research call on Pain should be posted on June 1st on the EULAR website.

Report on responses to and timelines of EULAR proactive call on patient-reported outcomes

Based upon expert opinions gathered at a EULAR workshop in November 2009, a proactive call on research proposals in the field of patient-reported outcomes (PROs) was launched in November 2010. It covers the areas of cross-cultural validation of existing instruments as well as the development of new PROs or personal life impact measures.

Until February 15th, 2011, 28 letters of intent for research projects were sent to the EULAR secretariat. They were reviewed by three members of the Executive Committee and one patient representative. 21 proposals fulfilled the criteria of the call, and the applicants were therefore encouraged to send a full proposal until June 1, 2011. These proposals will receive external peer review from experts in the field. A decision on funding will be made in September 2011.

News for epidemiologists from the European Medicines Agency (EMA)

The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP) has developed the Guide on Methodological Standards in Pharmacoepidemiology. It reviews existing methodological guidance for research in pharmacoepidemiology and pharmacovigilance, and contains useful links. (Available at:

www.encepp.eu/public_consultation/documents/ENCEPPGuideofMethStandardsinPE.pdf

Additionally, ENCePP has revised the Clinical Trials Directive 2001/20/EC, especially with regard to non-interventional trials and type-A trial (low risk). The revised directive should ease the implementation of observational studies in Europe.

Project update: Eumusc.Net

The project is in fair progress. Work package (WP) 4 already has a deliverable, which is the list of Health Indicators that will be used first to map Europe and then to monitor regularly. It can be downloaded from the eumusc.net web at www.eumusc.net/publications.cfm.

Some of the indicators will be obtained from questions that will be included in the European Health Interview Survey (a political achievement of the project!). The next deliverable, an atlas of musculoskeletal health will be published this June. The researchers need desperately help from these countries from where no data were available. Countries where additional data are needed: Bulgaria, Cyprus, Greece, Luxembourg, Latvia, Malta, Slovakia. If you know of anybody who could provide health data, please let the researchers know: (Josephine.Erwin@Cornwall.NHS.UK). WP5 and 6, on standards of care of RA and OA, and on Quality Indicators of RA and OA, respectively, are on their way and will deliver this year. WP7 on barriers and facilitators will start next year.

Implementation workshop of Task Force on Biologics Registers

Will Dixon presented figures from the Workshop held in Zurich last January. Topics included practicalities and logistics regarding registers, sharing of experiences made so far, specific issues pertaining to epidemiological analyses of register data, considerations when reporting the results and possibilities of concerted data analyses. The workshop aimed at communicating the recommendations to a wider community and at supporting persons all over Europe in planning and implementing biologics registers. Further, it aimed at giving hints on the challenges connected to those data.

No formal experience of registers or of epidemiological data analysis was required; both younger research fellows as well as clinicians with an interest in registers were invited. The invitation was distributed via the EULAR secretariat. The response was enormous: Around 60 delegates expressed interest to participate which was far beyond the budget. Therefore, it was decided to invite one person from each country which caused considerable disappointment in those who could not come. In total, there were 39 attendees, including 27 delegates and the faculty of 12.

The workshop received a very good response, and it was expressed by many participants that discussion on methodological issues and collaboration would be very welcome on a regular basis. Collaboration could be facilitated by an extension to the EULAR Task Force within the Standing Committee on Epidemiology. It is therefore planned to implement a study group on biologics registers within the SC. In addition, EULAR could take a more active role in bringing the European registers together.

Eular as an umbrella for registers

As a result from the above report on the biologics taskforce, Angela Zink inquired the Executive Committee and it was decided to hold a strategic meeting in Berlin in August to foresee the role of Eular with the registers. Angela proposes two actions: 1) a Study group for methodology (difficult statistical analysis, joint analyses); and 2) some service / support from Eular.

The Standing Committee is then prompted to summon their opinions on the matter. These were the reactions:

- Eular could be a tool for supporting the establishment or improvement of registers in some member states. It could create a facilitator structure based upon an open call for proposals.
- EULAR should not aim at getting hold of the raw data from the countries but rather encourage and support collaboration and joint analyses on specific questions.
- EULAR could offer a central infrastructure with FAQs and a sort of forum/network to ask "Who has data that can answer this question?"
- Establishment of a specific, joint Eular registry would need a specific hypothesis which can only be tested by this approach. A pilot study would be needed.
- Participation has to be voluntary and independence of the national registers should be maintained. There should be some incentives. Having other sources of support besides industry is nice.
- In the US, a similar experience ended-up with a reconciliation of electronic medical records.
- A previous SCEHSR workshop on ethical issues in international research stated that any transnational data collections and analyses have to comply with European and with the individual member states rules. This makes it sometimes very difficult.
- Asking the companies for support of a EULAR approach could influence the financial support of individual registers.
- Exchange of experiences may help to develop registers in other diseases (e.g. checklists for data collection, essentials for data analysis).
- Concerted data analyses could cover issues related to the individual health systems or comparisons of costs and cost-effectiveness across countries. Other questions that could be dealt with trans-nationally are those related to equity
- It has to be clarified that drug specific registers should not be included
- This idea of collaboration is not new and could be linked to the repository.

- Prerequisites for pooling or concerted data analyses should be further elucidated in a study group within the SCEHSR. Will Dixon and Johan Askling are asked to start such a study group.

Report on Task Force “Long-term extension studies”

The taskforce members met in Zurich in March and conveyed to develop points to consider when analyzing and reporting results from LTE. During the meeting, several discussion groups were held. Based on the discussions, the items of a Delphi questionnaire were developed. This is now under analysis. The taskforce will be finished much sooner than projected.

Loreto Carmona