Similarities and differences between REC's in Europe

Introduction

Eurecnet is a network that brings national Research Ethics Committees (REC) and its associations together at European level. The author is a member of this network. The Dutch association of REC's, the "NVMETC" organized a meeting for it's members in the end of 2012. One of the topics was the role and tasks of an REC now and in the future. The author was invited to give a presentation about this topic from a European perspective and to represent this perspective in a panel discussion. Therefore a questionnaire was sent out to the other participating Eurecnet countries. Answers were received from nearly all participants. For the specific questions raised in the questionnaire, please refer to annex 1. Annex 2 gives a tabular overview of the individual answers of the different countries. An analysis of the answers is given below.

Different types of REC's

Most countries have different types of REC's to judge different types of research. Most of the countries have one national and several regional REC's. The national committee does not have a supervisory role over the regional REC's, exceptions are the Netherlands and Denmark. In Germany some REC's are only legally competent for research on drugs and on medicinal products, whereas the other REC's are competent for all biomedical research.

Composition of REC's

The composition of REC's differs per country, but the principle of multidisciplinary committees applies to most countries. However, not all countries have compulsory requirements as to the number and or specific disciplines in a REC. For instance on basis on practicality, countries such as France, Austria and Norway have a nurse in their committee. Most European countries do not seem to have specific requirements for lay members. Striking on this accord is Ireland. Irish REC's that approve clinical trials, require a minimum of one third lay members and two third experts.
In France each REC consists of two colleges: the first college consist of 7 members from the medical field. The second college consists of 7 qualified members of the non-medical field, including 2 representatives of "an approved sickness association or a medical user association", 1 social worker and 2 qualified people regarding legal issues. In Sweden the REC consists of experts and 5 lay members (not specified as to competence). In the Netherlands only one patient representative (as lay member) is required. The definition for lay member differs per country.
In Norway REC's are required to have a health authority representative as member.
In Austria there a no special requirements regarding the different disciplines, but the composition of the REC should be balanced regarding gender. Denmark also mentions requirements as to gender. The Danish national REC also strives for gender balance in its committee. France and the Netherlands have strict rules with regard to the minimum amount of different disciplines and seem to have the most explicit requirements with regard to the composition of a REC.

Requirements for REC members

Within Eurecnet also the requirements for REC members differs. Most countries stipulate broad requirements as to novice REC members (for example descriptions like "qualified, duly qualified in their discipline, qualified researchers with an interest in ethical issues, experienced, experts, specialist"). In some countries there are no requirements, for instance in Finland members are mostly nominated for their general interest in the topic. The Netherlands seems to have the most detailed requirements for REC members.

Term maximum for REC members

There is a great variety in terms, both in years as in reappointment possibilities. Even within a country requirements can differ. In most countries members can be reappointed for a second term.

Supervision

Most REC's only have an administrative supervision system without inspections, exceptions hereto being the Netherlands and Austria. In most countries the administrative supervision of REC's is limited to their obligation to send in an annual report. This applies to Germany as well (annual report to their founding institutions), however there is no hierarchy within REC's, nor a system of appeal. In Sweden there is no supervision, behold the attorney general who oversees al governmental authorities. And though there is no standardized system of inspections, any individual can appeal to the attorney general.

REC an advisory role?
Many REC's give advice to the researchers before and/or after the meeting, except for Sweden and the Netherlands. The method and depth of the advice/consultation differs per country. The secretary or the chair often gives this advice.
Furthermore in Germany REC's are recommended to give researchers advice before they submit their request. The researcher may contact the office of the REC to learn the conditions for a favorable opinion on the request and is allowed to discuss specific questions with the concerning members. Actually, it's the opinion that this counseling does not taint the independence of a REC or its members. As a result of this advice the assessment period is shortened.
In Switzerland consulting before and hearings after the meeting are possible and often used by researchers. In Norway the REC's give advice before submission of applications, also in terms of counseling on specific aspects of protocol (like in Germany). After the REC meetings, the REC gives advice in order to facilitate and counsel to further the process. Researchers can also ask to meet the committee. These meetings usually take place as an equivalent dialogue, sometimes with clear advice as how to proceed.

Primary task of REC's
Most REC's consider Protection of participants as the most important task of REC's, but they mention that the scientific value of the trial is important too: "high science should be ethical". Four REC's mention both and one gave the scientific value as the most important task. It seems that scientific values tend to be gaining a more important role. "Good scientific quality of research is the main condition for the protection of participants". In Germany REC's also feel an obligation to protect researchers by advising them not to undertake projects that might be questionable with regard to scientific, legal and ethical issues. German REC's are only entitled to give a binding decision for research on medicinal products. In all other cases REC's give a noncommittal advice. This competence issue is an interesting topic for further research, as this seems to vary between the Eurecnet members.

Financial compensation of REC members
There is a big variety in compensations, but in general the members only receive a small sum. In some countries members are not compensated at all.

Non-therapeutic research with minors/incapacitated people
Research in this field is highly diversified with regard to regulations between the Eurecnet member countries. In most countries it's not forbidden with the exception of the Netherlands, Austria, Estonia, Latvia and Portugal. However, if research is not forbidden, there are national laws which regulate this kind of research. These laws mostly stipulate the regulations for research on drug and medical devices well, but leave other research more or less unregulated. In Norway there is no distinction between drug research and other research.
In Germany the legal representative (parents, guardian) may only authorize acts for the presumed benefit of the person concerned. This is not the case in research without a potential direct benefit for that person, so formally this kind of research is not forbidden, but in practice it is non-existent.

Training
In most cases, meetings are organized once or twice yearly by a national or regional REC or association of REC's. These meetings are mostly organized on a specific topic that is discussed in dept. Exceptions hereto are Austria, Portugal and the Netherlands who have systems of continues training for REC members. Most Eurecnet countries expressed that they wish to implement a systematical training scheme for REC members.
Particularly interesting is that next year Norway will start continuous education with special training for chairs and their deputies (special thanks to the UK National Research Ethics Service, which offers members training, who were so kind to share their knowledge in this matter). Members are expected to attend at least once a year.

Future
As result of the new EU-regulation most countries expect centralization of REC's in the field of medicinal product research. It is expected that the existing REC system will be maintained for the other types of research.

France expects changes with regard to number, tasks and requirements for REC's, because of a new law (since 2012). All research including observational research will have to be evaluated by a REC. Furthermore this law seeks to establish a National Commission for research ("Commission National de Recherches"). The role of this National Commission is not clear yet.
Norway does not foresee a change of tasks, though there is a motion towards REC's being given new tasks that have resemblances to ethics.
Switzerland expects a limitation of the number of REC's from thirteen now to seven within two years.
In Finland the number of REC's evaluating medical research has recently decreased from 25 to 9. The number of clinical trials has decreased; it certainly has impact in the evolution process.

Notable remarks
In Sweden a high court judge chairs the REC discussion. Some countries apply different ages for consent. Swedish and Norwegian children can give their consent already at the age of fifteen (when they are considered mature enough) in contrast to other countries where eighteen is customary. In Norway all decisions are publically available on the website of the REC.

General conclusion
There is a clear similarity between REC's in Europe, but there are also some differences. These differences deserve further analysis, so that we can profit from each other's specialties to optimize national REC's and harmonize REC systems in Europe. Eurecnet offers the ideal platform to strive hereto. This article offers an opening to start this discussion.

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