CASE STUDY - Choosing a Research Ethics Committee system amongst the existing models? Critical decision of a middle income country (Chile).

BACKGROUND: In September 2006 a law was enacted in Chile setting the ethical framework for biomedical research in the country. Now, regulations following this law are being generated, one of which should define how Research Ethics Committees (RECs) will be organized and articulated as a network at a country level.

The law mandates the Ministry of Health (MoH) to establish this set of rules. To this end, a Task Force within the MoH was appointed to make a proposal that will serve as a working document to stimulate the debate within all players involved across the country i.e. members of current existing RECs, investigators engaged in biomedical research involving human subjects, research sponsors (public and private), academia, scientific societies, and social organizations like associations of patients, research professionals, etc.

We are still on a preliminary phase of the planned discussions. We have mainly received feedback from members of RECs currently functioning in academic and public health institutions. These early discussions have shown that there are different conceptions coexisting which we have identified with different "models" of REC systems. Thus, our case study will present some key points addressed by the MoH proposal and we propose to discuss them from a model analysis perspective.

Issue 1 – Should RECs be centralized or locally-based? Based on regions / centralized or on institutions?

- The US model of Institutional Review Boards (IRBs) represents the pioneering strategy of "local" review of research (i.e., review within the institutions in which the research will take place). Set up by regulation in the US in the late 70's, the IRB model has been adopted in Latin America nearly in every country, although even the US authorities from the Department of Health and Human Services recognize that after more than 20 years the IRB system is in need of deep reform (1). Probably the main difficulty with the IRB model is that they can face conflicts that threaten their independence because of the increasing importance of research as a source of revenue on the institution operating budget. Another criticism has come from the fact that the US regulatory requirement, which has been adopted in Latin America extensively, calls for only one nonscientific member. This minimum requirement has maintained lay members and citizens as a whole away form the supervision of research. Generally speaking, the local IRB model is supported by those who believe that the main task of RECs is to assess the investigator scientific and ethical behavior and the community willingness or appropriateness to host the research.
- One of the products of the project funded by the European Commission framework 5, "Privireal", who examined the role of ethics committees, is a document (2) that summarizes some of the best national practices across Europe. Here, the authors conclude that it is advisable "for countries having the chance to start from scratch – to create a regional system instead of an institutional one from the very beginning". They argue that democratic lay representation is better achieved through committees linked to political and administrative regions. They point out another disadvantage of the "institutional model" which

is that not all research is done within an institution (e.g. epidemiological studies, vaccine field trials, studies on health and environment, etc.), thus the institutional IRB model leaves an important portion of research uncovered. Supporters of centralized or regional RECs seem to believe that the main mission of RECs is to assess research from a more big-picture perspective, widening the horizons to a more diverse membership, putting the accent in the social relevance of the research projects.

- In Chile we have currently a mixed model. There are local RECs in many academic faculties (e.g. medicine, psychology, dentistry, etc.), in research institutions, private hospitals, etc. In addition, there are non-local RECs linked to some (to the ones with more research activity) of the MoH territorial administrative divisions.
- The UK experience is interesting since they established a mixed model. Local research ethics committees (LRECs) were established in 1991 and Multicenter research ethics committees (MRECs) were created in 1997. MRECs are responsible for reviewing proposals taking place within the boundaries of five or more LRECs. Approval given by a MREC has national acceptance. LRECs must then consider the study only with respect to issues that may affect acceptability locally. Rejection from a LREC, according to a NHS Executive guidance issued in 1998, can only be for local reasons i.e. suitability of the local researcher, of the site, of the subjects and adequacy of the patient information sheets and consent forms to locally appropriate language. Judging by the number of papers discussing or criticizing the mixed model (4), it seems that a two-tier model like this must ensure that the realm of each type of REC is clearly defined and that bureaucracy is avoided at any rate.

In summary, we would like to raise a similar question as Coleman and Bouësseau (3) but in relation to a middle income country as Chile: is the local IRB model or the regional Danish or the mixed UK model worth copying? How can we pick up the best aspects of each model and adapt them to our reality?

Issue 2 – Should REC members be part-time volunteers or dedicated professionals?

We have found little guidance to sort out this complicated issue. The "local model" answer to this question is easy, since members are employees from the same institution; they can dedicate time to the REC as needed. In some places were regional REC are implemented, membership is considered a "civic duty". Thus, members are administratively "on secondment" participating in the RECs activities. However, it seems that in Latin America, members are more frequently volunteers with no official assignment. Nonetheless, the advantage of volunteers is that they can feel freer when giving unpopular opinions about a particular research. On the other hand, it is somewhat inconsistent to demand REC members to be held responsible for something they dedicate a few hours per month. As research grows in volume, increases in sophistication, the amount of information that needs to be processed becomes overwhelming and it is impossible not to have a secretariat (1-2 persons) dedicated intensively to the various tasks involved (reviewing and following up of protocols, safety information, etc.) To properly function, a REC should review at least 100 projects annually (2), so this is another point in favor of some sort of full dedicated members of RECs. There are probably other considerations we are

missing and more discussions are needed to have a comprehensive picture of this matter.

Issue 3 – What could be the pros and cons of a two-tier review system based on the investigator and/or sponsor assessment of potential risk prior to REC review?
Maybe the boldest aspect of the MoH proposal for regulation of a REC system in Chile is the one that intends to establish a two-tier review system. The rationale for this two-tier system comes from the scarce resources available to set up a national system which could guarantee a proper and timely review and follow up of all biomedical research, as the new law calls for. Consequently, having two types of RECs: one (RECs I) reviewing research involving only minimal risk and another (REC II) reviewing research involving more than minimal risk, may allow the MoH to allocate some funding to a limited network of RECs type II and maintaining the current local RECs as RECs type I, in charge of reviewing less bureaucratically demanding research. Particularly, RECs II would have a full employed secretariat (2 persons) financed by the MoH budget. On the other hand, the MoH would have to ensure a training program in bioethics for research to be carried out for all RECs members i.e. RECs I and II members. This model has no rationale in itself, it only pretends to be a pragmatic way of allocating scarce resources. We would like to believe that this two-tier system could be a transient system until a robust culture of ethics in research is set up and no economical constrains will show the two-tier system to be useless.

REFRENCES

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