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Understanding the structure and practices of research ethics committees through research and audit: a study from Mexico

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Abstract

This paper reports on a series of studies that were conducted at the Mexican Institute of Social Security (IMSS) between 2001 and 2002 to determine the role, structure and workings of their local research ethics committees (LRECs).

The IMSS, unlike other Mexican health institutions, has a formal system of committees. Such committees operate under a regulatory system and are charged with scrutinising all research proposals in order to ensure their scientific validity and to protect the rights and well being of research subjects [Instituto Mexicano del Seguro Social. Dirección de Prestaciones Médicas (México). Manual de Investigación Médica en el IMSS: Instituto Mexicano del Seguro Social; 1999]. The organisation wanted to know how the committees were functioning and if the work of the committees needed to be improved.

The problems that were encountered included issues with the composition of the committees, the process of project assessment, the continuing review process, and a lack of motivation of staff. In addition a qualitative study [Valdez-Martínez E, Turnbull B, Garduño-Espinosa J, Porter JDH. Descriptive ethics: a qualitative study of local research ethics committees in Mexico, Developing World Bioethics, 2005, in press] highlighted the focus of the committees on rules, regulations and the law with little understanding of the important individual role of members in complementing and adding to these structures and perspectives.

The paper suggests that, to support staff and to protect research subjects, the organizational structure, management and decision making process of the IMSS's LRECs ought to be assessed regularly through audit cycles. In order to support the further development of the committees, the aim of the audit cycles should be focused on education and development of the vision, perspectives, values, and working processes of each LREC.

Keywords: Local research ethics committees; Ethics; Audit; Health research; Mexico

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1. Introduction

1.1. Local research ethics committees in the global context: where is the research?

The Helsinki Declaration and the International Ethical Guidelines for Biomedical Research (CIOMS) establish that LRECs exist to ensure, first, that proposed research will not expose participants to unacceptable risks and practices; second, that the potential participants can evaluate the expected consequences of their involvement and decide for themselves whether to participate [3,4]. The fascinating world of LRECs is comparatively under-researched, although there are increasing numbers of international publications that address a variety of the facets of committees including: structure, process, monitoring, regulation and training [5–10]. The role of LRECs for many is a mystery, and there are expressed concerns that the increasing guidelines, regulations and bureaucracy being created through the development of LRECs is not improving the overall purpose of these committees which is to protect human subjects [10–13]. LRECs are increasingly becoming a 'hurdle' that researchers need to cross rather than an important process within research that protects human subjects and at the same time improves the ethics of proposals and the research work that is eventually conducted. Many of the current publications come from industrialised countries where LRECs have been functioning for a number of years. There is a lack of information from middle and low income countries who are increasingly witnessing and experiencing the increased 'ethics' bureaucracy associated with international research collaborations [14,15].

Research committees in the Mexican Institute of Social Security (IMSS) exist to scrutinise all research proposals in order to ensure that they are scientifically valid with rigorous methodology and to protect the rights and well being of research subjects [1]. The proliferation of IMSSs committees throughout the country in the 1990s has been followed by an attempt by the institution to improve the work of its committees. This paper reports on a series of studies that were conducted in the IMSS (Fig. 1) to look at the role of LRECs. The studies included a survey [16], an audit, and a qualitative study to describe how LRECs consider and apply research ethics in the evaluation of research proposals [2]. The paper highlights the importance of both research and audit of LRECs and suggests that there are indispensable pathways within audit cycles to strengthen the functioning of LRECs.

1.2. The history of research ethics and the creation of guidelines: more is not enough

The story of the ethics of medical research begins in the early 19th century – the age of "experimental medicine" – when medicine began to reap the fruits of the previous century's scientific advances [17–19]. Medical ethics had already a history of more than 2000 years; however, during the previous centuries research ethics was a field rarely discussed. First, because it was an inactive field, ethics codes mostly addressed medical etiquette [20,21]. And second, since Hippocrates' time to the nineteenth century, experimentation was not clearly distinguished from practice [17–20].

The turning point in the story of medical research ethics was World War II. In that wartime environment, human experimentation was guided by utilitarianism: the idea was to pursue "the greatest good for the greatest number" through medical research. Following the Nazi doctors' trial at Nuremberg, at the end of the war, came a new era of efforts to improve conditions for human research subjects: a series of international agreements (i.e., the Code of Nuremberg, Helsinki Declaration, Belmont Report, CIOMS/WHO guidelines, etc.) were generated, together with the creation and development of research ethics committees. All of these changes in the research realm were intended to regulate research and to prevent the occurrence of abuses from ever happening again. Regrettably, despite the international ethical agreements and guidelines, and the growing number of LRECs worldwide cases of research misconduct continued to occur over the course of the time. This situation raises the argument that regulations are not enough in themselves; that International Ethical Guidelines and regulations are only actions, and require both sagacity and discretion to be applied [22–24]. Discretion is, of course, not without dangers: professionals, researchers, committee members, etc. cannot be totally dispassionate about their work; they cannot be immune from the jumbled and often intense conflict pressures that envelope them [25–27]. The application of regulations within a LREC involve a complex social setting as pictured in Fig. 2, which not only encompasses the principles and details of the