

History

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Research ethics and ethical review committees in Sri Lanka: a 25 year journey.

In 1981, the Faculty of Medicine, University of Colombo, became the first institution in Sri Lanka to establish an institutional Ethical Review Committee (ERC). Dissanayake VHW, Lanerolle R, Mendis N. Ceylon Med Journal 2006 Sep;51(3):110-3.

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Introduction

The aim of this article is to give an overview of the biomedical research ethics scene in Sri Lanka. It is confined to activities of statutory bodies and established institutions in Sri Lanka, because only these could have any meaningful long term impact on the ethical conduct of biomedical research in the country.

The first committees for ethical review of scientific research in Sri Lanka, were set up in some of our medical schools in the early 1980s. In spite of this early beginning, an editorial in the Ceylon Medical Journal (CMJ) in 1988 lamented: "It is a melancholy fact that there is a singular lack of awareness on the ethical review mechanism for human research conducted at the institutions in the Ministry of Teaching Hospitals and the Ministry of Health" (1).

The foundation for ethical conduct is enshrined in the culture of our country because Buddhism, the religion of the majority, emphasises a positive approach to ethics; Buddhist morality lays much emphasis on the necessity of cultivating wholesome character traits for the well-being of the individual as well as of the society (2, 3). What was required perhaps was to put in place and strengthen mechanisms for ensuring ethical conduct in research which the author of the above mentioned CMJ editorial himself initiated in 1991 through the National Science Foundation (NSF) of Sri Lanka, then called the Natural Resources Energy and Science Authority (NARESA) (3).

National Ethics Committees

An unofficial committee, set up in 1991 at the NARESA, drew up draft codes for scientific research, animal experimentation, biomedical research on humans, and social sciences research (3). They were discussed in detail at a workshop held in 1992 by NARESA and published for "dissemination for wider consideration

by the scientists” (4). But these never received wide acceptance, nor did it lead to the establishment of an apex national ethics committee as had been envisaged at that time.

Since then, several organisations at national level have taken the initiative to set up “Ethics Committees”. They are summarized in Table 1. Some of them are standing committees that continue to function, whereas others are committees that were set up at various times to deal with specific assignments.

The National Bioethics Committee (NBC) of the NSF, set up in 2002, is the apex committee in Sri Lanka that fulfils the role of a National Ethics Committee for scientific research at the present time. It does not however, have any statutory powers.

Institutional Ethics Committees

The number of institutional ethical review committees (ERC) in Sri Lanka has increased rapidly over the past several years due to the increasing requirement that ethical review be mandatory for presentation and publication of research. It also appears that there is a watchful ethics lobby that is eager to step in when ethical boundaries are transgressed (7).

This has led to overlap and duplication of effort among the committees, especially when some institutions such as teaching hospitals come under the purview of both University and Hospital ERCs. Researchers are often baffled as to whom they should submit their work, and confused by the fact that ethical approval has often to be sought from more than one committee.

The ERC of the Faculty of Medicine, Colombo undertook a review of ERCs in Sri Lanka in 2005 and a directory based on this review has now been published (8). A summary of this information is given in Table 2.

Bioethics Education

Medical education, based on a western system of allopathic medicine was established in Sri Lanka in the year 1870 with the setting up of the Colombo Medical School [currently the Faculty of Medicine, University of Colombo], the second oldest medical school in Australasia. It is not clear when ethics became a part of the medical curriculum in this Medical School, the only one in the country for the next 90 years.

Medical ethics, in Sri Lankan medical schools, was traditionally taught by members of the Departments of Forensic Medicine. In the early 1990s it was recognised that what was taught was thoroughly inadequate for dealing with modern (medical) ethical issues (9). Some even argued for a change in the way in which ethics is taught to medical students in Asian countries (10).

In this background in the mid 1990s when the Faculty of Medicine, University of Colombo became the first medical school in Sri Lanka to change over from a traditional medical curriculum to a new integrated modular curriculum, it took the opportunity for a complete overhaul of its ethics curriculum broadening its scope to include even ethics of new genetics and assisted reproductive technologies while emphasising on the core principles of ethics. It is likely that such input may have contributed to shaping the attitudes of future doctors in their early days in medical school towards issues that have ethical implications (11).

In spite of these developments in the undergraduate curricula, postgraduate curricula hardly deal with ethics. To fill this void the ERC of the Faculty of Medicine, University of Colombo conducted a successful series of ethics workshops for paediatric postgraduate trainees in 2005, with funding from the World Health Organisation (WHO). It is hoped to expand this programme to other training programmes of the Postgraduate Institute of Medicine, because it is the sole institution responsible for awarding all postgraduate degrees and diplomas acceptable to the ministry of health.

Bioethics Legislation/Guidelines

The existing provisions in Chapter III of the Constitution of the Democratic Socialist Republic of Sri Lanka that deals with Fundamental Rights (12) provide a firm foundation for further provision to be made by law for ethical conduct of research in Sri Lanka. Successive Sri Lankan governments have enacted legislation

to what they perceive as emerging 'threats' in the field of medicine emanating from the introduction of new medical technologies to the country. Provisions in such legislations, although not primarily intended to ensure ethical conduct of research, may do so indirectly. The Transplantation of Human Tissues Act is one such example (13).

Bringing about new legislation to cover other broader areas of research however, is not an easy task. The development of guidelines for researchers by an apex organisation, such as the NSF, has been advocated, to overcome that handicap and to promote ethical conduct of research. The first document intended for that purpose to be published was the SLMC's "Provisional code of practice for assisted reproductive technologies" (6) published in November 2005. NASTEC's "New genetics and assisted reproductive technologies – a draft national policy on biomedical ethics" published in April 2003 also contains good practice guidelines (5). Such guidelines are useful, even to ERC members, in dealing with contentious issues (14).

Bioethics Activities

Two national level organisations have taken the initiative in organising regular activities in bioethics. They are the Sri Lanka Association for the Advancement of Science (SLAAS) and the Sri Lanka Medical Association (SLMA). The SLMA gives high priority to research ethics. It was even the subject of a Presidential Address of the SLMA in 2001 (15). More information about the activities of these associations could be found in their annual reports and other publications.

What is noteworthy is that the activities of these two associations have had a direct impact on national policy in Sri Lanka. For example, the establishment of a study group by NASTEC to draw up draft national guidelines on biomedical ethics that relate to new genetic and assisted reproductive technologies was a consequence of an invited guest lecture delivered at the Annual Academic Sessions of the SLMA in the year 2000 which was titled "Genethics in Sri Lanka the slumbering sentinels".

In addition to these, at institution level, many medical schools, professional medical associations and other public and private organizations continue to conduct various ethics activities that are outside the scope of this brief review.

To stimulate further discussion on ethical issues in research, the ERC of the Faculty of Medicine, University of Colombo, conducted a series of "Open Forums" in the year 2004 with funding from the WHO (16). The committee is now in the process of planning and implementing follow up action based on this experience.

Networking and Future Directions

The need for networking has been recognized with the expansion of the number of ethics and ERCs in various organizations at national, regional, and institutional level. This has been facilitated by the Joint Forum of ERCs convened by the ERC of the SLMA. The ERC of the Faculty of Medicine, University of Colombo, took the initiative to strengthen this network further by organizing a joint meeting of representatives of these committees on 31 August 2005, with funding from the WHO, with the following aims:

01. To identify common issues faced by ERCs in Sri Lanka.
02. To identify solutions for those problems which could be sorted out by dialog and communication or by consensus between ERCs.
03. To make recommendations to the Ministries of Science and Technology, Health, and Higher Education on issues which require national direction and/or policy planning.

The meeting resulted in a consensus document, the recommendations of which are given below.

01. The establishment of a central ERC by an Act of Parliament under the Ministry of Science and Technology with representation from Ministries of Science and Technology, Health, Higher Education, and representation from all ERCs in Sri Lanka (on a rotational basis to ensure ownership and participation of all ethical review committees). The NBC of the NSF was the choice for an apex body. Until such an apex body is formed it was proposed that the Joint Forum of ERCs convened by the ERC of the SLMA should function in this capacity.

The functions of the central ERC would be to:

- a. Develop general as well as certain institution specific guidelines for the composition of institutional ERCs and the training requirements of potential institutional ERC nominees.
- b. Accredite institutional ERCs that conform to stipulated guidelines.
- c. Develop guidelines for use by ERCs on matters of frontier research and issues where a national policy is required, and in the following areas which are of special significance:
 - research in reproductive medicine and genetic medicine.
 - research where genetic material or resource is transferred overseas.
 - research involving patient and intellectual property rights.
- d. Foster development of ERCs and their resource persons by organising regular training workshops and training programmes for new members and committees.
- e. Act as an appeals body for submissions rejected by other ERCs.
- f. Review projects involving multilateral or multicentre research and research involving foreign collaboration, and monitor progress of such research after the approval is given.
- g. Maintain a database of all projects received by all local ERCs.
- h. Encourage interaction between ERCs.
- i. Maintain a website.

02. The amalgamation of University ERCs with the ERCs of their affiliated teaching hospitals.

03. To encourage a wider representation of both medical and non-medical personnel in ERCs. In conclusion, research ethics and ethical review committees in Sri Lanka, have come a long way, since its humble beginnings a quarter century ago. But much more remains to be done. The recommendations outlined above can be the starting point in the next phase of this continuing journey.

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Table 1: “Ethics Committees” of National Level Organizations

Institution	Committee Name, Year Established	Main Activities/Outputs
Sri Lanka Medical Association (SLMA) http://www.slma.lk	Ethics committee, 1992	Information available on the website.
Sri Lanka Association for the Advancement of Science (SLAAS) http://www.nsf.ac.lk/slaas	Ethics committee, 1996	Information available on the website.
Ministry of Health http://www.health.gov.lk	National Health Research Council (NHRC) Functioning under the Education, Research and Training Division, 2000	One of the functions of the NHRC is to promote research ethics.
National Science and Technology Commission (NASTEC) http://www.nastec.lk	Study Group IX, 2000 to 2003	Publication of “New genetics and assisted reproductive technologies in Sri Lanka – a draft national policy on biomedical ethics.” (5).
National Science Foundation of Sri Lanka (NSF) http://www.nsf.ac.lk	National Bioethics Committee (NBC), 2002	Information available on the website.

Sri Lanka Medical Council (SLMC) Assisted reproductive technologies
http://www.slmedc.lk guidelines committee, 2004

Publication of a "Provisional code
of practice for associated
reproductive technologies." (6).

Table 2: Institutional Ethical Review Committees in Sri Lanka

Institution	Year Established
Faculty of Medicine, University of Colombo, Colombo.	1981
Faculty of Medicine, University of Peradeniya, Peradeniya	early 1980s*
Faculty of Medicine, University of Ruhuna, Galle.	1984
Faculty of Medicine, University of Jaffna, Jaffna	1985
Postgraduate Medical Centre, Kandy	1992
Faculty of Medical Sciences, University of Sri Jayewardenepura, Nugegoda.	1994
Faculty of Medicine, University of Kelaniya, Ragama	1995
Faculty of Dental Sciences, University of Peradeniya, Peradeniya.	1995
Sri Lanka Medical Association	1999
Medical Research Institute, Colombo	2000
Lady Ridgeway Hospital for Children, Colombo	2002
Sri Lanka College of Paediatricians	2002
Sri Jayewardenepura General Hospital, Nugegoda	2003
National Hospital of Sri Lanka, Colombo	2004
Colombo South Teaching Hospital, Kalubowila	2004

*has been functioning as the research and ethics committee, until a separate ethics committee was formed in 2003.