

Bioethics in Sri Lanka

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الأخلاقيات البحثية من منظور إقليمي: تقرير من سريلانكا
آثولا سوميتاباتا

الخلاصة: تسير الأخلاقيات البيولوجية بخطى بطيئة في سريلانكا، وإن كان هناك الآن لجان للمراجعات الأخلاقية في العديد من كليات الطب والمنظمات الوطنية. وتقوم جميع كليات الطب بتدريس بعض الأخلاقيات الطبية، وإن لم يتوافر عدد كاف من المدرسين المدربين. ولا يوجد أي قصور في الدلائل الإرشادية الوطنية المعنية بأخلاقيات البحث. وقد تم تشكيل منتدى البحوث والتطوير بُعْثَ بناء ثقافة جديدة للبحوث الأخلاقية. وتشتمل مبادرة الأخلاقيات البيولوجية هذه على ما يلي: التوعية بأهمية الأخلاقيات البيولوجية؛ والأنشطة التعليمية وبناء القدرات؛ والتبشير بهذا المفهوم؛ وإعداد الدلائل الإرشادية للسياسات. ويهدف القائمون على المنتدى إلى توعية المجتمع العلمي، والجمهور عموماً بالمبادئ الأخلاقية، والقانونية والاجتماعية التي توجه السلوك البحثي المسؤول.

ABSTRACT Bioethics took off slowly in Sri Lanka, but now there are ethics review committees in many medical schools and national organizations. All medical schools teach some medical ethics but there are not enough trained teachers. There are no national guidelines on research ethics. The Forum for Research and Development was formed with the aim of building a new ethical research culture. The bioethics initiative includes: awareness-raising; education activities and capacity building; advocacy; and the development of policy guidelines. We aim to raise awareness in the scientific community and the general public on ethical, legal and social principles guiding the responsible conduct of research.

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Introduction

In terms of measurable health indices, Sri Lanka is very much comparable with the industrialized countries. Our public health system is very good: during the tsunami of December 2004, for example, we did not have a single disease outbreak because the system worked so well.

There is, however, no overarching research culture, although we have some very eminent, internationally renowned researchers. Therefore our actual research output is low, less than that of India, Pakistan and Bangladesh, and just marginally above that of Nepal.

With this background, it is not surprising that bioethics has not taken off rapidly in Sri Lanka. Bob Simpson, who did some work in the country, came to the conclusion that bioethics was in a very early stage of development: there were no formal teaching or training or advanced training courses entirely dedicated to research ethics or clinical medical ethics [1].

Now the situation has totally changed. There are ethics review committees in 5 medical schools and in the Sri Lanka Medical Association. The association also has an ethics committee. Interest in medical ethics is, however, more or less confined to universities. The National Science Foundation has a national committee for bioethics, although it is not universally considered “national”, and it is certainly not truly multidisciplinary. The Sri Lanka Association for the Advancement of Science has an ethics committee, but it is not a review committee. The Medical Research Institution has an ethics review committee but it is not clear whether it is functioning. The National Institute of Health Science also has an ethics review committee.

Teaching and training on ethics

Although all the medical schools in Sri Lanka teach some aspects of medical ethics to undergraduate students, the contents of the curricula vary. Most medical schools teach medico-legal aspects of ethics in the forensic medicine department. The University of Peradeniya has been teaching medical ethics in the Department of Forensic Medicine. The course deals with medical issues relating to resource allocation and health policy but not very much on clinical ethics or research ethics as such. However, at Colombo Medical School, the Department of Psychological Medicine has started a formal teaching programme. They have a very innovative behavioural medicine programme running across 5 years, in which ethics is included. However, they have only 60 hours of contact time—6 lectures, seminars and small group discussions and assessment of 2 structured essays in the examination. There is one dedicated senior lecturer and they appointed another lecturer recently. The course content includes history of medical ethics, principles of medical ethics and informed consent.

Other faculties, e.g. the Faculty of Medicine in Ruhuna, which is in the south of the country, have a limited amount of input. Two other universities around Colombo also give some input on ethics, although it cannot be considered adequate.

Ethical review and ethical review bodies in Sri Lanka

When it comes to research ethics, there are no national guidelines: there are limited guidelines covering *in vitro* fertilization but nationally accepted, widely discussed guide-

lines do not exist. The Faculty of Medicine at Colombo Medical School was probably the first institution to start formal ethical review in Sri Lanka. That was in the 1970s, and they review about 35–40 submissions annually using international guidelines. Peradeniya University started their ethics committee in 1984. However, most of the members are not formally trained in ethics committees.

There are a number of shortcomings and problems associated with the teaching of medical ethics. Specific problems include lack of a research culture, lack of trained medical teachers to teach medical ethics, lack of adequate time on the curriculum, lack of teacher motivation to emphasize ethical aspects during teaching, and lack of interest from the students.

Forum for Research and Development

Against this background of no research culture and no adequate ethics, the Forum for Research and Development was formed 4 years ago, with the main aim of helping build the nation through research. The Forum is trying to integrate indigenous knowledge and scientific development for national development. We are working to achieve a paradigm shift in the thinking and actions of the scientific and academic community to create a new strategic alliance among scholars, professionals, and especially the public: work at grass-roots level is crucial.

We aim to build a new ethical research culture in Sri Lanka. In doing this, our mission is to bring Sri Lankan scholars—there are about 2 million Sri Lankans all over the world—from diverse disciplines, not only medicine, living anywhere in the world to create a research culture in Sri Lanka and to

foster evidence-based, informed decision-making for national development. Although the Sri Lankan academic community displays a degree of intellectual richness and variety, structure and form is inadequate, even though there are many organizations contributing positively. Lack of a research culture is reflected in the scientific research output per capita in Sri Lanka in terms of measurable indicators. Unfortunately, only around 0.2% of our gross domestic product is spent on research and development. There was a plan for it to be increased to 1% during the current budget. It is expected to come through in the next budget.

The Forum for Research and Development has a different focus and emphasis in terms of research and ethics. We will, however, collaborate and network with all the institutions and individuals involved in research and development in Sri Lanka to address this challenging task. Our organization does not work for ownership, it works for partnership. We have expatriate forums, local professional forums and student forums. We also work to promote networking for strategic partnerships; development of an ethical framework; development of leadership qualities, commitment and dedication; awareness raising; and collaboration with the public and with the media.

We believe researchers have a duty to bring together different stakeholders. We do not believe that researchers are only researchers, and we do not see research and ethics as opposing disciplines or as rivals. We very much believe that ethics is an integral part of research, a friend of research rather than an enemy. We have capabilities, expertise and dedication to ethics but we do a lot of research as well: we hold 9 Wellcome grants for different projects. Current activities include setting up a genetics laboratory and training people in statistics

and writing skills. A holistic approach is used—trying to create scientists as opposed to separate ethicists and separate researchers. We believe in converting research into policy and practice. That is the sum of our mission and agenda.

In the local professional forum, one of the main arms is the bioethics initiative, and a multidisciplinary group is involved in educational activities and research. We have actually converted philosophy into action. Our bioethics initiative covers 4 areas: awareness-raising; education activities and capacity building; advocacy; and the development of policy guidelines from a developing world perspective.

Education

When the word “exploitation” was first used, it was considered a political word, but even so, it is used because exploitation happens in research as well. The foremost objective in our educational activities is awareness-raising, within the scientific community as well as the general public, particularly on ethical, legal and social principles guiding the responsible conduct of research in Sri Lanka. So our strategy is to train a critical mass of mid-career faculty members to take a leading role in cultivating interest among the wider scientific community.

To bring this about, we ran our first workshop in 2003 over 7 days. We advertised 30 places, and did not expect to fill them as this is considered an uninteresting subject by some people, so we did not expect there would be many applicants. In the event, it was a very popular course. We ended up having 150 applicants and had to increase the intake to 50. Representation came from all universities, but again mainly mid-career academics—some of the senior people did not want to know about it. We had representation not only from medical

faculties but many other faculties. It was a very successful initiative.

Another of our activities is promoting bioethics among schoolchildren because we think they are still unspoiled: it is better to catch them early and plant the seeds early.

Our initiative attracts people from different universities, from the medical community, education, nursing, veterinary science, law—a very mixed group. We do not review research projects, we work on capacity-building in ethics to elevate the level of review.

Advocacy and policy

We have drafted a set of guidelines, “*Research ethics from a developing world perspective*”. Rather than the end product, the document itself, the most important thing was the process involved in drawing it up. We circulated the proposal as widely as possible among the scientific community nationally and internationally, allowing people to discuss and develop the local guidelines.

We have also contributed to international guidelines, including documents from the Nuffield Council of Bioethics. When it comes to ethics, we believe that we have to research ethics as well. It should also be evidence-based, otherwise it would be based only on philosophy or personal prejudice, and this would not be the best way.

We did a study on the informed consent process, a qualitative study carried out with participants from many parts of the world. Basically, it elaborated on issues which are part of the informed consent process. A theme repeatedly appearing during this survey was conflict of interest during internal collaboration. It was published in the *American journal of bioethics* [2]. We have also contributed to the ethical issue of the global divide in other publications.

We are also carrying out a project on informed consent, mapping current practices and producing a leaflet on quality of information, consent forms and understanding the process. All these have implications for the ethics we practice in our part of the world. We believe in public engagement and consultation and there is discussion about what should happen after finishing a research project.

We have put forward the slogan to the international community “What should happen before you start research?” Consulting the public and other researchers is important. So we do public engagement work. Our informed consent project was presented to the scientific community in Sri Lanka, where it was discussed and the protocol altered.

We also organized a qualitative workshop to be used in research in ethics, which we organized not only for medical scientists but also for sociologists and anthropologists. We have established a successful network with most parts of the world, and we formed the Asia Pacific Bioethics Network

We do not believe that ethics is merely a fashion; and ethics is definitely not just for intellectual debate—a self-gratifying exercise behind closed doors. Ethics is a mission. It has to come into the open and the public has to be involved. Certainly it needs to be removed from the hands of the medical profession and taken to the wider community.

We took the 2004 tsunami as an opportunity for policy development and sustainable capacity-building, e.g. we used the slogan “Prevent retraumatization of the traumatized” because we foresaw this as one of the serious issues that would come up. So we used the media quite heavily. We also launched a campaign for a national ethics framework for disaster-related research. We

managed to establish an ethics committee at the National Institute of Education. This was important because at that time a lot of children were approached by groups from different parts of the world to be exploited for easy, cheap research.

It was also proposed that a central ethics committee be established at the Ministry of Health but it did not come about. There are initiatives from the World Health Organization to have ethics committees throughout the country. We do not, however, believe in the mushrooming of ethics committees: it becomes counterproductive and these committees become heads not brains. So there has to be a balance between the need and the forming of ethics committees—it is not advisable to have an ethics committee under every tree. In any case, there should be accreditation of training. However, we felt that a central ethics committee at the Ministry of Health was important, particularly one dedicated to post-disaster research.

We have also worked with politicians, the top-down approach, not only bottom-up. We gave evidence to the parliamentary select committee to propose steps to minimize the damage from the disaster and highlighted ethical issues in addition to other work, including identification of the dead and the role of genetics. We used all these openings to try to convince people (top-down and bottom-up) to make this a national issue: it also needs to be a regional issue.

Networking is extremely important and we took things even further. We appealed to the international ethics community, journal editors in particular, to be vigilant about exploitative research, particularly after disasters, and urged them to insist upon ethical clearance. There is still some debate on how to do this and what to do, but we wanted to highlight the issue. If researchers allow their findings to be put in a library without

trying to convert research into policy and practice, that is an ethical issue. Not every researcher can do this, but there is a social responsibility to try.

Again, we have used the tsunami as a reason to convert into policy and practice research done over the past 15 years on medically unexplained symptoms, which are very common after disasters. We have done clinical trials using psychological intervention, which was efficacious not only when the therapy was done by a psychiatrist, but also when the primary care physician carried out the intervention.

Through a World Health Organization grant we have produced a poster on the use of psychological intervention which will be distributed throughout Sri Lanka. There has been a request from Pakistan to send it to the disaster areas there because they have found people are using psychotropic drugs for medically unexplained symptoms. In Sri Lanka we found people doing computerized tomography scans and magnetic resonance imaging when people present with medically unexplained symptoms. This is an example of how it is the ethical responsibility of a researcher to convert research into policy and practice.

We have also produced a manual, which will be distributed free of charge to local researchers as well as to the international community. We hold training workshops nationally, funded by the World Health Organization, and are happy to do them internationally.

Non-use of ethics in research

We say research is important but how can we ensure that research happens in an ethical framework? There are 2 main types of reasons why ethical obligations are not catered to, intentional and unintentional.

Unintentional reasons result from lack of awareness of ethical issues and lack of

sensitivity to specific ethical issues. The researchers simply do not consider ethical issues an essential component of research. By creating awareness among the research community this ignorance can be defeated. This can be done by guiding researchers to do quality research because they believe in the ethical framework: you should promote ethics because ethics produces good research and you should become an ethical researcher because you believe in it and not because somebody has started to police you.

Intentional reasons include conflict of interest, exploitation and lack of respect for survivors and for their dignity. This is more difficult to deal with. You have to draw on protective mechanisms such as guidelines and legislation, networking (in particular), public awareness, exposing those who do not comply with ethical obligations (a very important method), imposing sanctions on publications and exposing research fraud when it occurs.

One example serves to highlight this. After the tsunami, a foreign group collected blood samples in the southern district for a proteomic study on neurobiological markers of stress. One of the local medical officers confiscated the blood and reported it to the Ministry of Health and Centre for National Operation where we were dealing with psychological issues related to the tsunami. It was judged unethical and was stopped. Then a young researcher was recruited to become the applicant. He applied for authorization from the ethics committee, where his father headed the organization. Fast-track approval was given. The documents attached to those from the foreign group saying that they had ethical clearance (from their group) were for a completely different project, however, one which had been given ethical clearance in 2003. We considered it definite collusion. The matter

has been taken very seriously. The people involved should be held responsible and all measures taken to expose them, in addition to taking all professional steps to try to rectify the situation and safeguard the dignity of the ethics committee.

Finally, I would like to quote Abraham Lincoln, "To sin by silence when they should protest makes cowards of men."

References

1. Simpson B. Ethical regulation and the new reproductive technologies in Sri Lanka: perspectives of ethics committee members. *Ceylon medical journal*, 2001, 46(2):54-7.
2. Sumathipala A, Siribaddana S. Revisiting "freely given informed consent" in relation to the developing world: role of an ombudsman. *American journal of bioethics*, 2004, 4(3):W1.