LETTERS

Ethics approval: a challenge for public health researchers in India

There is increasing impetus, interest and opportunity for people working in public health programmes in India to carry out operational research (OR) around relevant programme issues and then publish that in peer-reviewed publications (1,2). These published researches are valuable in analysing, documenting and advocating for locally generated evidence to inform policy and practice. Ethics review and approval is an essential step in the process of OR but is often viewed as a barrier rather than a prerequisite of good practice in OR. Journals and peer reviewers are also increasingly requiring approvals from local institutional ethics committees (IECs).

IECs are not always accessible outside the realms of traditional research institutions within a given country and this poses the greatest challenge in obtaining ethics approval for research. All institutions that fund and implement research in India are expected to set up their own institutional ethics board and these local bodies are set up to conform to guidelines elaborated by the Indian Council of Medical Research (ICMR) (3). Since public health programmes do not have their own IECs, programme personnel coordinating OR often seek collaboration with local research institutions and attempt to obtain ethical approval from the related IEC. Obtaining an ethics approval from a local IEC involves many challenges ranging from the actual process to issues related to the structure, functioning and knowledge of ethics of OR by members of the IEC. Process issues include the reluctance of local IECs to consider accepting submissions from programme researchers unless staff from the respective research institution are part of the OR team. This compromises the independence of the OR team as often demands are made to revise research protocols to suit the local research institution's own strategic priorities or directions. Requests are also made to add additional members to the research team. This is unfair and there is a risk that studies may get hijacked and study objectives and outcomes get derailed from an "operational" to an "academic" angle. Programme researchers who are really the principal investigators may thus be no longer able to control the final content. Additionally, local IECs do not meet regularly or often enough, and this can seriously delay the conduct/ relevance of OR.

The constitution and structure of local IECs tends to reflect the local research institution's expertise which may be restricted to specific domains. To the best of our knowledge, though there are standard guidelines for the composition of the IEC, there are no specific criteria to become a member of an IEC. For instance, medical colleges may include their faculty members who may have limited knowledge of ethical issues or the priorities of programme-related OR. Membership to a local IEC is most often through "nomination" with limited transparency of the actual process. To gain a wider perspective, it is essential that IECs represent all stakeholders including members of the community where research is coordinated. It is also not clear how local IECs maintain independence from their affiliated institution with respect to their role in the review and approval of protocols.

The function of the local IEC and their approach to OR is often aligned to reviewing clinical trials. Since, most requests for ethics clearance from public health researchers are focused on field-based studies (mostly OR), local IECs often deny approval to a submission stating that these are not hospital-based (clinical) studies. They are also often very hesitant to review/ provide approval for studies involving new models of care, or pilot projects - the *raison d'etre* of OR at the programme level. Local IECs are also not clear about their role beyond providing ethics approval at the proposal stage, and do not exercise any further influence on encouraging policy and practice impact and eventual benefits to patients and communities. This clarity is imperative given the recent controversy over the vaccine trial led by an independent international non-governmental organisation (NGO) after "clearances" from the relevant authorities (4). The new regulation for registration is for all IECs doing ethics review of drugs/devise trials protocols (covered under Schedule Y) and not for the IECs reviewing protocols for any other research to be registered. There is neither registration nor accreditation of IECs doing review of non-drugs/devices research in India. India produces a considerable amount of scientific knowledge through academic institutions; but there is a considerable gap between the generated knowledge and what we do with it – the so called "know-do" gap. Bridging this gap requires OR and it is time to adapt and empower IECs that can help ensure that research is generated to benefit health services and communities.

Sharath Burugina Nagaraja, *Department of Community Medicine, Employees State Insurance Corporation Medical College and Post Graduate Institute of Medical Sciences and Research, Bangalore, India,* ***Ritesh G. Menezes,*** *College of Medicine, King Fahd Hospital of the University, University of Dammam, Dammam, Saudi Arabia (KSA),* ***Rony Zachariah,*** *Médecins Sans Frontières-Brussels Operational Centre, Luxembourg,* ***Nevin Wilson,*** *The Union South-East Asia Office,*

New Delhi, India. Author for correspondence: Sharath Burugina Nagaraja e-mail: sharathbn@yahoo.com

References

1. India Tuberculosis-Diabetes Study Group. Screening of patients with tuberculosis for diabetes mellitus in India. *Trop Med Int Health*. 2013;18:636–45.
2. India Diabetes Mellitus-Tuberculosis Study Group. Screening of patients with diabetes mellitus for tuberculosis in India. *Trop Med Int Health*. 2013;18:646–54.
3. Indian Council of Medical Research. *Ethical guidelines for biomedical research on human participants* [Internet]. New Delhi: Indian Council of Medical Research; 2008 [cited 2012 Mar 26]. Available from: http://icmr.nic.in/ethical_guidelines.pdf
4. Mudur G. Indian MPs criticise HPV vaccination project for ethical violations [Internet]. *BMJ*. 2013 [cited 2015 Apr 7];347:f5492. Available from: http://www.bmj.com/content/347/bmj.f5492 (published on September 06, 2013).

Phlebotomy consent: ethical concerns

Phlebotomy is one of the common invasive procedures carried out all round the globe (1). The practice of phlebotomy varies widely. In terms of the technique, the procedure may involve the use of a syringe or a vacutainer, and as for the technicians, some are not specifically trained to perform the procedure and others are qualified phlebotomists. Finally, some may receive training on the job, while others undergo formal, focused training. However, the underlying ethical principles of respect for autonomy and informed consent do not change (2). This commentary, which is supported by data collected during training in phlebotomy, reflects on the ethical issue of obtaining consent for the procedure.

The programme

In a tertiary hospital, a training programme was conducted on best practices in phlebotomy for nursing staff and laboratory technicians. The programme, which was spread over three sessions, included a pre-test and post-test to assess the efficacy of the programme. The technical questions were in the form of multiple-choice questions. The questions on ethical practices, such as obtaining consent and ensuring patients' safety, were in the form of true or false statements, e.g., "Consent is not required to collect samples – True / False." In all three sessions, both the pre-test and post-test included questions on ethical practices. The responses were evaluated to understand the awareness of the ethical issues related to consent for phlebotomy.

A total of 95 staff members participated in the training. These were 76 staff nurses, 15 technicians, and four phlebotomists . Forty-two (45%) of all the staff members had marked the correct responses both in the pre- and post-test. This percentage increased to 65 in the post-test administered after the training. Twenty-six (28%) of the staff members selected wrong responses both in the pre- and post-test. Two did not respond to the questions. One of these was a technician and the other, a phlebotomist. Seven of them marked the correct responses in the pre-test and incorrect responses in the post-test.

Commentary

The WHO guidelines emphasise that verbal consent be obtained from the patient. They stress that patients have a right to refuse the test at any point before the blood sampling and it is important to ensure that they have understood the procedure (2). If a person presents his/her hand or arm to the phlebotomist, it indicates an implied consent to phlebotomy. Implied consent is acceptable. Many of the participants were not aware of this and hence, felt that consent is not required. The fact that more than 25% of the participants selected wrong responses is reflective of the lacunae in ethics training. The increase in the percentage of people who selected the correct answers following the practical training underscored the need for ethics programmes.

Much emphasis is laid on medical ethics in the curriculum of undergraduate medical students (3). However, the same cannot be said of the training of nurses (4). Also, in the case of paramedical staff, there is no regulatory body similar to those for the medical or nursing cadres. All organisations which impart training to paramedical staff/nurses should make sure that the training includes the basic concepts of ethics, as this will enhance the development of the individual and ultimately lead to an improvement in the care of patients.

Karuna Rameshkumar, *Professor, Department of Pathology, Justice KS Hegde Hospital, Nitte University, Deralakatte, Mangalore, 575 018, INDIA e-mail: karunark@yahoo.com* ***Chandrika Rao****, Assistant Professor and Blood bank officer, Department of Pathology, Justice KS Hegde Hospital, Nitte University, Deralakatte, Mangalore 575 018, Karnataka, INDIA*

References

1. World Health Organization. Guidelines on drawing blood: the best practices in phlebotomy [Internet]. Geneva: WHO; 2008 [cited 2015 Mar 10]. Available from: http://www.who.int/injection_safety/sign/drawing_blood_best/en/
2. World Medical Association Ethics Unit. Declaration of Helsinki [Internet]. Geneva: WMA; 2003[cited 2015 Mar 10]. Available from: http://www.wma.net/e/ethicsunit.
3. The Indian Medical Council regulations, 2002, amended up to 2010 published in Part II section 4 of the Gazette of India. *Issues in medical ethics* 2002;10:66–70.
4. Indian Nursing Council. Curriculum [Internet]. Date unknown [cited 2015 Apr 3]. Available from: http:// www.indiannursing council.org/.