attention to research ethics is given at the national and institutional level was sent to 15 representatives of the Clinical Research Strategic Network. This network comprised nine clinical research centres in Burkina Faso, Cambodia, Indonesia, Peru, RD Congo, Uganda, Zambia and Belgium, aims among others things to implementing essential ethical elements in clinical research. The survey was written in English and contained 21 questions about research ethics practices at the national level and within each institution. Eight institutions participated in the survey. In eight countries ethical approval is mandatory to carry out clinical research. However, research on human subjects is not regulated by a comprehensive law in at least two countries. Ethics committees (EC) are present in all eight countries, but their advice is only legally binding in seven. While the EC gives initial approval, it is otherwise not involved in the follow-up of the research. The follow-up of safety aspects or the possibility to interrupt the research based on ongoing results. Three institutions implement non-fault liability insurance for clinical trials. Two institutions only routinely execute the policy of the International Committee of Medical Journal Editors about registration of clinical research projects in a public database, as a prerequisite for publication. Most ECs do not have the possibility to follow up clinical research after the initial approval; also, there are no structural means to verify and ensure that the opinion of an EC is respected when the research is carried out, in both cases, probably due to lack of resources and at least in some countries due to the lack of a clear legislative framework regulating ethical review. Non-fault liability insurance seems to be a poor tool for academic researchers due to high costs and lack of model templates or guidelines. The International Committee of Medical Journal Editors about trial registration seems to be largely unknown. In general, more substantial investments are needed to strengthen national and institutional capacities in the field of clinical research ethics.

TIP2-03

Rationalising international approaches to ethical review: examining and revising the ethical review practices for clinical research funded, sponsored or carried out by Northern organizations in developing countries

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Various international recommendations state that clinical research sponsored, funded, or supervised by Northern organizations in developing countries be submitted for ethical review in the countries where the research takes place and in the country of the sponsor. In December 2008 a Network of researchers from Belgium, Burkina Faso, Cambodia, Cuba, the Democratic Republic of Congo, Indonesia, Nepal, Peru, Uganda and Zambia met at the Institute of Tropical Medicine in Antwerp, to build capacity for conducting health research that addresses the need of vulnerable populations, and to address the topic of 'double ethical review'. The discussion was based on the experiences of projects sponsored by ITM and carried out with partner institutions; protocols are routinely submitted to the ITM Institutional Review Board as well as to the ethics committee (EC) at Antwerp University Hospital and to the EC in the study’s countries. The workshop agreed that ‘double ethical review’ presented some challenges. In national, regional and private reports from northern countries the ‘requirement’ has not been substantially considered and there is often a sense of paternalism. There is a need to develop a systematic approach to ethical review that promotes respect and trust among research partners and improves the efficacy of international ethical review practices. Communication and education that cross traditional
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TIP2-05
Research ethics and international epidemic response: the case of Ebola and Marburg hemorrhagic fevers

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Outbreaks of filovirus (Ebola and Marburg) hemorrhagic fevers (HFH) in Africa are typically the theatre of rescue activities involving international experts and agencies. This is despite the fact that enforcing national authorities in clinical management, biological diagnosis, sanitation, public health surveillance and coordination. These outbreaks can be seen as a paradigm for its response to epidemic emergencies, through the convergence of such themes as isolation and quarantine, privacy and confidentiality, and the interpretation of ethical norms across different cultural settings. Our aims were to specify the nature of ethical dilemmas arising during epidemic response, as a result of tensions between clinical care, public health investigations and research, to review existing frameworks relevant to research ethics in emergencies, to review statements about ethical issues raised during public health responses to past HFH outbreaks, and to propose new approaches to research ethics in the course of epidemics. We did this through review and analysis of current normative documents on ethics in emergencies and analysing peer-reviewed publications describing past HFH outbreaks. We found that undertaking research during an ongoing outbreak poses considerable and specific ethical questions, often related to the blurred boundaries between research and public health practice. The scope of existing normative documents relevant to research ethics in emergencies has so far been limited by a main focus on informed consent and research ethics committees and lack of comprehensive regulatory documents endorsed at international level. Concerns over research ethics during past outbreaks of HFH have generally been poorly addressed or reported, suggesting a need for more systematic considerations of ethical issues related to the conduct of research in emergencies. For the longer term, we recommend the design of basic research protocols prior to emergencies, the establishment and strengthening of national or regional ethical review committees, and the advance involvement of potentially affected communities, including considerations to distinct ethno-cultural representations of illness and contagion.

TIP2-06
Clinical research in less economically developed countries: the ethical challenges

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The Directive 2001/20/EC on the implementation of Good Clinical Practices in the conduct of clinical trials applies not only in the EU but also in less economically developed countries. The clinical trials carried out in the later often contribute to the development of new drugs for usage in industrialized countries. The marketing authorization delivered by the European Commission can however be refused in cases of non respect of ethical principles as stipulated in the Directive 2001/20/EC. Our objective was to review the Directive 2001/20/EC focusing on the procedure for involvement of vulnerable people in clinical trials and its interaction to existing international legal norms. From the