

OA-002 **TRANSLATING ETHICS GUIDELINES ON COMPENSATION FOR RESEARCH-RELATED INJURIES INTO POLICY IN LOW-INCOME COUNTRIES: LESSONS LEARNT FROM MALAWI**

Patrick Kamalo,¹ Lucinda Manda-Taylor,¹ Stuart Rennie². ¹University of Malawi, Malawi; ²University of North Carolina, United States of America

10.1136/bmjgh-2016-000260.11

Background Injury to human participants in biomedical research is a known problem and despite a number of ethical guidelines advocating compensation for research-related injuries (RRIs), African countries do not have a unified approach for compensation. In 2012, Malawi introduced a policy mandating no-fault insurance coverage for RRIs. We conducted this study to explore the challenges associated with the implementation of this policy and what lessons can be learnt from Malawi.

Methods We conducted a qualitative case study through nine in-depth interviews with purposively sampled key stakeholders in research in Malawi: policy-makers, researchers, ethics committee members and insurers. Interviews were conducted by one researcher, recorded using a voice-recorder and later transcribed and verified for consistency. Manual data analysis was done using a word-table and pattern-matching. The study was approved by two ethics committees: in Malawi and South Africa.

Results Participants were in favour of compensation for RRIs through the insurance mechanism of no-fault type, although there was discordance in the understanding of the 'no-fault' principle. Some researchers felt this policy was instituted to punish them and stifle clinical research. In addition, we found that the local insurance industry was not in a position to cover clinical research. This deficiency in local capacity to provide insurance left some researchers feeling that Malawi would lose out by externalising hard-earned resources.

Conclusions All stakeholders in research in Malawi view the policy mandating no-fault insurance cover for RRIs as a positive step in research governance. However, certain challenges need to be addressed, such as the understanding of the concept of no-fault and local capacity to handle clinical trial insurance. Compensation for RRIs through no-fault insurance needs to be tried in other African countries and be adopted by the African Union in order to standardise and enforce compensation in Africa, where it is ethically acceptable based on the African ethic of Ubuntu.