



# Are Ethical Clinical Trials Possible Without Formal Ethics Instruction In Medical Schools?



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## Background to the Study



- In most of the developed world, ethics training is now an established component in medical and public health sciences curricula;
- Mentoring and modeling ethical behavior are no longer considered sufficient;
- The need for explicit training in research ethics for scientists is widely recognized as necessary;
- In most of Africa however, consideration of ethics in medical and health sciences curricula is a very recent phenomenon;



## Background to the Study



- Lack of ethics training, lack of resources, lack of trained personnel and ineffective ethics review processes are common features;
- In Zambia in particular, the situation is even more critical;
  - Lack of ethics training in medical and related schools;
  - Lack of ethics expertises;
  - Limited ethics knowledge among researchers;
  - Limited ethics review capacity;
  - Public health research goes on without ethics review; etc.



## Background to the Study



- In 2006, then Minister of Health Dr Brian Chituwo acknowledged these shortcomings in the public health research sub-sector in Zambia;
- He particularly advised medical and health sciences training institutions in the country to help address this anomaly;
- It is in this context that this study was conceived;



# Objectives



- To examine the nature and level of integration of ethics training in medical and health sciences education in Zambia; and
- To capture perceptions (and/or attitudes) of medical and health sciences educators and other stakeholders on the importance of ethics training in ensuring the conduct of ethically prudent clinical trials.



# Methods



- Extensive review of relevant literature;
- Self-administered questionnaires targeting all 40 medical and health sciences training institutions in Zambia (33 responded);
- 30 in-depth interviews targeting a selected number of medical and health sciences training institutions (16) and other stakeholders in the field (14).



# Results (1)



- Very low formal integration of ethics in most of the institutions studied (7 out of 33 had dedicated ethics courses);
- Very low knowledge levels of ethics in the institutions;
- Marked lack of ethics training among medical and health sciences instructors (teachers);
- Of the 40 medical and health sciences institutions in Zambia, only 3 have institutional RECs (**There are six RECs altogether**);



## Results (2)



- However, there was widespread acceptance of the importance of ethics training among medical and health sciences educators;
- About 98% of medical and health sciences educators and other stakeholders said ethics training is critical for ethical clinical trials;
- 96% were supportive of more ethics training in medical and health sciences education in Zambia;



# Discussion & Conclusions



- Medical researchers cannot appropriately handle ethical issues that arise in medical research and practice without formal exposure to ethics training (ethics training should not be left to chance);
- The potential for misconduct, not necessarily because of malicious intent but rather, as a result of what has been termed “innocent ignorance” would be greater;
- Noncompliance to ethical standards based on a lack of understanding of regulatory requirements and consequences is more likely;



# Discussions and Conclusions



- Thus, while ethics training does not necessarily translate into ethical clinicians and researchers, it is critical if they are to act ethically, both in medical research and in practice;
- All medical and health sciences institutions in the country should therefore consider integrating ethics training in their core curricula;



# Future perspectives



- A workshop of stakeholders to discuss study findings and the way forward;
- Develop a generic ethics curriculum to be piloted in selected institutions in their current settings;
- Scale-up the pilot curriculum to all the 40 medical and health sciences training institutions in the country;
- Hopefully, help produce a cadre of ethicists & medical researchers who will become ethics champions in the country;



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**Thank you for your attention!**