A Situational Analysis of Competences of Research Ethics Committee Members in Review of Research Protocols with Complex and New Study Designs in Uganda

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Abstract

BACKGROUND Over the past two decades, Uganda has experienced a significant increase in clinical research driven by both industry and the need to combat the emergence and re-emergence of infectious disease epidemics. This has broadened the spectrum of research proposals that need evaluation by Research Ethics Committees (RECs) with associated requirement for new expertise. We assessed the competencies of REC members in review of research protocols with complex and new research study designs to guide development of a training curriculum to improve the quality of review.

METHODS This was a cross-sectional study design, with quantitative and qualitative data collection methods. We used a structured pre-coded questionnaire to collect data on competencies of REC members in review of research protocols with complex and new research study designs. Research Ethics Committee members were also asked to outline a list of additional topics for which they needed training. Data from coded questions was entered into Epidata Version 3.1 and then exported to STATA Version14.1 for analysis. Descriptive analysis was performed for quantitative data and findings were presented using percentages and frequencies.

RESULTS We enrolled 55/97 REC members from 6 RECs, majority of whom were males (56.4%, n= 31/55). The level of competence for review of selected study design was lowest for Controlled Human Infection Model (6, 10.9%) and reverse pharmacology design (6, 10.9%,), and highest for cluster randomized study design (29, 52.7%) and implementation science research (29, 52.7%).

CONCLUSION There is lack of competence in review of research protocols with complex and new study design and our analysis suggests that additional training in this area is an urgent priority.

Background

Clinical research remains cardinal in advancing our knowledge of disease, human biology and behavior and informing our health care practice(1). There has been a surge in clinical research driven by both industry and the need to combat the emergence and re-emergence of infectious disease epidemics in Uganda, including HIV, hemorrhagic fevers, tuberculosis, malaria, neglected tropical diseases, non-communicable diseases and the recent Severe Acute Respiratory Syndrome Corona Virus-2 that causes Corona virus disease-19 (COVID-19)(2–5). This has broadened the spectrum of research activities in the quest for solutions to improve health and wellbeing. Clinical research, especially that involve invasive procedures and interventions, may carry risks to human health and safety or may compromise the rights, values and interests of research participants or volunteers(6). Nonetheless, human participation in clinical research is important, and every effort should be made to minimize harm to research participants(6).

With the introduction of antiretroviral therapy, scientists in Uganda embarked on clinical trials with adherence and long-term efficacy monitoring (7, 8). In the recent past; there has been increasing interest in HIV vaccines research and investigations into a cure for HIV (9). These research interests to develop

novel preventive, investigational and treatment strategies need to be supported by efficient RECs to review the science and ethics, approve and monitor research regulatory compliance with assurance for safety and wellbeing of humans as research participants.

Members of RECs review the science and ethics of research proposals, approve research protocols and oversee the conduct of clinical research with the aim of minimizing risk to humans and ensuring respect for the research participant's rights, values and interests (10).

It is therefore important, to ensure that members of RECs have the competence to review research protocols to protect the safety, rights and welfare of research participants while advancing knowledge through high quality research. Therefore, this study aimed to assess the competencies of REC members in review of research protocols with complex and new research study designs, in order to guide development of relevant training curriculum for REC members.

Methods

Study design, site and population

This was a cross-sectional study among REC members from 6 accredited RECs located in Makerere-Mulago Hospital complex. The RECs include; School of Health Sciences REC (SHSREC), School of Medicine REC(SOMREC), School of Biomedical Sciences REC (SBSREC), School of Public Health Sciences REC (SPHREC), Mulago Hospital REC (MHREC) and Uganda Cancer Institute REC (UCIREC). School of Health Sciences REC, SOMREC, SBSREC, SPHREC, MHREC and UCIREC comprise of 14, 20, 16, 21, 13 and 17 REC members respectively. All REC members were eligible to enrol into the study if they were willing to participate.

Study procedure

The REC Chairs were contacted and informed about the study. The list of REC members was obtained from the REC administrators with contact details: email and phone number. Convenience sampling was used to enrol participants. Participants were selected based on availability and willingness to take part in the assessment. A notice was sent to each participating REC member and an appointment for the study interview made. Written informed consent form was obtained from the participants before the conduct of the face-to-face interview. However, due to the COVID-19 lock-down restriction measures enforced by the Uganda Ministry of Health, the data collection method was changed from face-face paper based-questionnaire to an online survey using KoBoToolbox. An email with a link to the online Informed Consent Form and the survey were sent to REC members inviting them to participate in the survey. In order to increase on the response rate, email and telephonic reminders were sent for participants who had not filled the survey after 7 and at 14 days of sending the survey.

Data collection

Data were collected using a pre-coded questionnaire developed for this study in English language. The questionnaire consisted of demographic characteristics and questions on competence in review of research protocols with complex and new study designs (adaptive, ecological, phase I, phase II, implementation science, step wedged design, cluster randomized design, controlled human infection model, reverse pharmacological design, and evaluation of studies with new technology/devices). The questions assessing the competence were on a Likert scale with four alternative responses with 1=not competent, 2=somewhat competent, 3=competent, 4=very competent. We used open-ended questions to collect data on other study designs that were not included on the list and a list of additional topics for which they needed training. The study coordinator checked the complete survey questionnaires for completeness.

Data management and analysis

Data was entered into the study data base developed using Epi data version 3.1 released by Epi data Association, Odense, Denmark with in-built quality control checks. The final dataset was exported to STATA version 14.1 released by StataCorp for analysis. The competence of REC members were further categorized into two categories: competent (competent and very competent) and not competent (not competent and somewhat competent). Descriptive analysis was done and findings were summarized using frequencies and percentages.

Ethical consideration

The REC chairpersons were informed about the survey before administering the survey to REC members. Informed consent was obtained before administering the questionnaire. The study was approved by School of Medicine Research Ethics Committee (#REC REF 2020-024) and Uganda National Council for Science and Technology (HS542ES).

Results

Social demographic characteristics of the participants

A total of 55 out of the 97 contacted REC members filled the survey giving a 56.7% response rate. All REC members (23/23, 100%) that were contacted physically completed the survey. A total of 32 out of 74 REC members contacted through email completed the survey. Of the 55 respondents, 56.4% were male. Participants had diverse expertise in the areas of social sciences, bioethics, epidemiology and biostatistics, psychology, dentistry, education, medicine, oncology, public health, basic sciences, nursing and pharmacy as shown in table 1 below. Majority of the participants had attained a PhD degree (31/55, 56.4%). School of Health sciences REC had the highest number of participants (14, 25.5%).

Competency in Review of Research Protocols with Complex and New Study Designs

Generally, most of the REC members reported they were not competent in reviewing research protocols with complex and new study designs. The level of competence for review of selected complex and new

study designs was lowest for controlled human infection model (6, 10.9%), reverse pharmacology design (6, 10.9%) and highest for cluster randomized study design (29, 52.7%), implementation science research (29, 52.7%) as shown in figure 1.

Additional Areas that Pause Challenges during Review of Research Protocols

Some REC members reported difficulty in review of research protocols for genetic studies; studies involving longitudinal large data, Investigation New Drug applications and New technology/devices. They also reported difficulty in review of herbal medicine research as well as management of ethical dilemmas that arise with complex and new study designs.

Table 1
Demographic characteristics of the participants

Variable	Frequency (percentage) (N = 55)
Sex	
Male	31(56.4)
Highest level of education	
Certificate	01(01.8)
Diploma	01(01.8)
Bachelors	01(01.9)
Masters	21(38.2)
PHD	31(56.4)
REC membership	
SHSREC	14(25.5)
SOMREC	09(16.4)
SBSREC	08(14.6)
SPHREC	09(16.4)
UCIREC	08(14.6)
MHREC	07(12.7)
Area of expertise	
Medicine	11(20.0)
Nursing	03(5.5)
Social sciences	05(09.1)
Bioethics	04(07.3)
Basic sciences	06(10.9)
Public health	15(27.3)
Epidemiology and Biostatistics	04(07.3)
Dentistry	02(03.6)
Psychology	01(01.8)
Education	02(03.6)

Variable	Frequency (percentage) (N = 55)
Pharmacy	02(03.6)

Discussion

We assessed the competencies of REC members in review of research protocols with complex and new research study designs to guide development of a training curriculum to improve the quality of review. The response rate amongst REC members in this study was slightly higher compared to 52% in a similar study in a similar setting (11). The ratio of male to female participants was almost equal, which could be attributed to the guidelines by the Uganda National council for Science and Technology which encourage RECs to have diverse membership, including consideration of gender(10). Majority of the participants had a master's degree or higher qualification. This is attributed to the national guidelines requirement that the REC to be sufficiently qualified through the experience and expertise in different specialty areas (10).

Most participants reported that they were not competent to review research protocols with complex and new study designs. Our findings are in agreement with the discussion highlighted during the 10th Annual National Research Ethics Conference, that emergence of new study designs like Controlled Human Infection Model, studies with digital intervention and genetic studies present enormous scientific and ethical challenges for review by REC members(12–15). The lack of competence in review of research protocols with complex and new study design could lead to a longer or delayed research review process, poor quality review and rejection of important studies. The lack of competence reported could be due to broadened spectrum of research emanating from significant increase in clinical research that is driven by the changing disease patterns.

Limitations Of The Study

There may be some possible limitations of this study. The small sample size which we attribute to the impact of COVID-19 restrictive measures affected our analysis and conclusions. In addition, the RECs involved are situated in the capital city of Uganda, Kampala, where most research institutions are located thus the results may not be generalisable to all RECs in the country due to differences in the volumes and scope of the research received by these RECs and the academic environment.

Conclusion And Recommendation

There is lack of competence in review of complex and new study design among the REC members studied and additional training in this area is an urgent priority. Results of this study will inform development of a training curriculum for REC members in Uganda.

List Of Abbreviations

REC Research Ethics Committee

SOMREC School of Medicine Research Ethics Committee

SHSREC School of Health Sciences Research Ethics Committee

MHREC Mulago Hospital Research Ethics Committee

UCIREC Uganda Cancer Institute Research Ethics Committee

SBSREC School of Biomedical Sciences Research Ethics Committee

SPHREC School of Public Health Research Ethics Committee

COVID-19 Corona Virus Disease-19

Declarations

Ethics approval and consent to participate: The study received ethical approval from School of Medicine Research Ethics Committee (#REC REF 2020-024) and Uganda National Council for Science and Technology (HS542ES).

Written consent was obtained before the survey was undertaken for the surveys that were collected using a paper-based form of data collection. For the online survey, the e-consent form provided detailed information about the survey. Individuals who voluntarily choose to participate clicked on a box “I agree to participate” and those not willing will click on “I do not agree to participate”. E-consent was not taken as a “full signature” but rather an indication of accepting to participate in the survey.

Consent for publication: Not applicable. The manuscript does not contain data from any individual person’s data.

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on a reasonable request. All data generated or analyzed during this study are included in this published article.

Competing interests: Authors declare that there are no competing interests

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Authors' contributions:

AP Participated in writing the protocol, acquiring regulatory approvals and data collection, performed the analysis, drafted, revised and finalised the manuscript

BC conceptualised the idea, participated in writing the protocol, revised and finalised the manuscript

SO Conceptualised the idea, revised and finalised the manuscript

AJW Conceptualised the idea, revised and finalised the manuscript

RPR Conceptualised the idea, participated in writing the protocol, revised and finalised the manuscript

PBK Conceptualised the idea, participated in writing the protocol, acquiring regulatory approvals and data collection, cross checked the analysis, revised and finalised the manuscript

All authors read and approved the final manuscript

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Figures

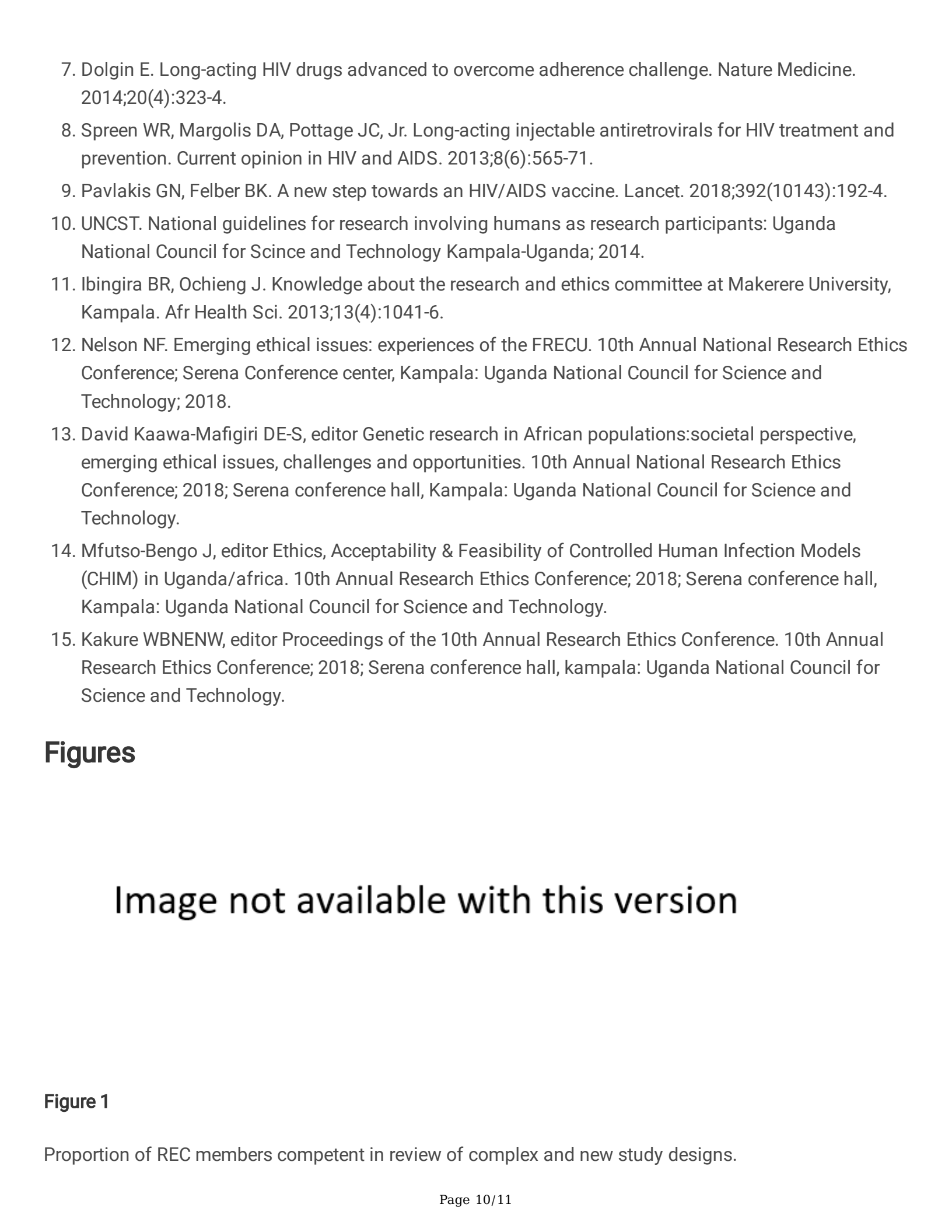

Figure 1

Proportion of REC members competent in review of complex and new study designs.

Supplementary Files

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- supplement1.docx
- supplement2.pdf