

WAB



Newsletter



West African Bioethics

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A Newsletter of West African Bioethics Training Programme

About WAB

The West African Bioethics is program for teaching, service and research in International Bioethics

The West African Bioethics training program is unique because it uses the opportunity afforded by its location in West Africa to research and train in Bioethics in English and French languages, both of which are widely spoken in the West African subregion.

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**WAB wishes you all a Merry Christmas and
a Prosperous New year**

Closing Remarks

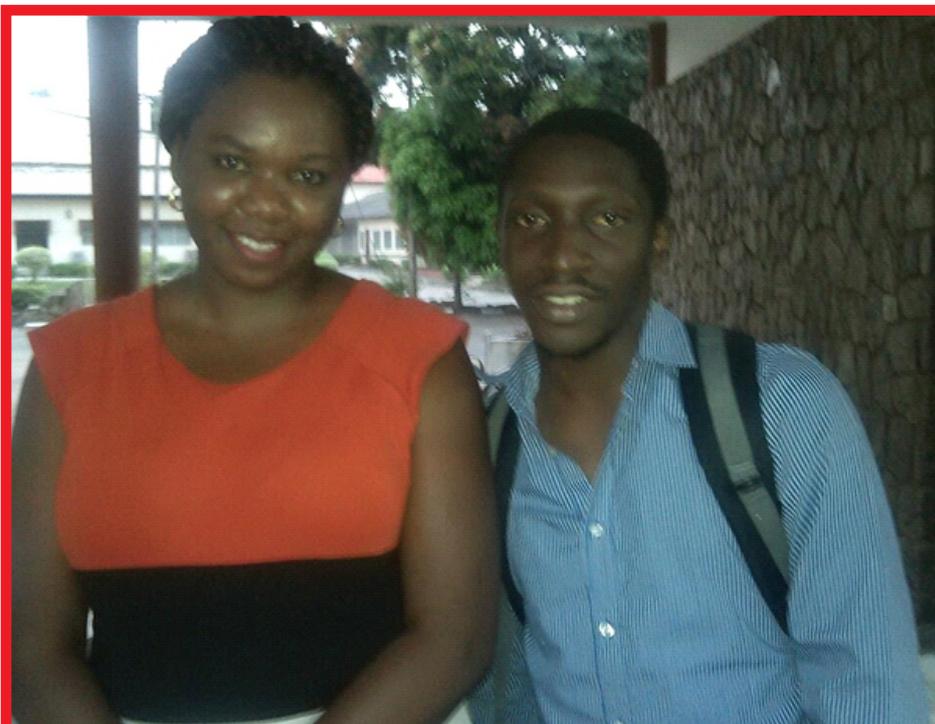


2013/2014 WAB Trainees (MSc Bioethics Program)

This current session, WAB awarded two students scholarship to study MSc Bioethics; a taught Master's degree program domiciled in the Department of Surgery, College of Medicine, University of Ibadan, Nigeria. The trainees are:

1. Dr. Aderonke Adedayo: She is a Medical Officer in Ibadan with strong passion for research ethics. Her area of interest is in research on vulnerable population.

2. Barr. Olorunfemi Owoyemi: He is a Research Assistant at the Oyo State High Court in Ibadan. His area of interest is in research on assisted reproduction.



Dr. Aderonke Adedayo and Barr. Olorunfemi Owoyemi



Bioethics Seminar Meeting – The Ethics of Ebola Drug Trials: to give or not to give?

The September 2014 Bioethics seminar meeting was held on Thursday, 25th September 2014 at the Seminar room, Department of Surgery, University College Hospital, Ibadan. In attendance were West African Bioethics (WAB) Training Program faculty and students, as well as consultants, residents, lecturers and students from various departments within the University. A total of 52 people were in attendance, including the presenter, Dr. Mrs. Ebuoluwa Oduwole, a philosopher and a bioethicist at the Department of Philosophy, Olabisi Onabanjo University, Ago-Iwoye, Ogun state. She presented the topic “The Ethics of Ebola Drug Trials: to give or not to give”.



Dr. Oduwole during her presentation

In her presentation, she described Ebola Virus Disease (EVD) as a viral haemorrhagic disease that is severe and often causes fatal illness in humans. It is transmitted to human through wild animals like fruit bats, monkeys, gorillas and chimpanzees, and spreads in the human population through human-to-human contact. Symptoms of the disease include high fever, joint and muscle aches, sore throat, weakness, vomiting, diarrhoea and as the case worsens, internal and external bleeding. The incubation period of the disease is between 2-21 days. She described the current outbreak of the disease in West Africa as devastating, with the following statistics as of 22nd of September, 2014.

Country	Number of cases	Number of deaths
Guinea	1048	643
Liberia	3369	1779
Senegal	1	0
Sierra-Leone	1967	544
Nigeria	20	8
Total	6405	2974



Bioethics Seminar Meeting – The Ethics of Ebola Drug Trials: to give or not to give?

contd.

She explained that the EVD is associated with multiple concerns, among which are cultural, political, religious, economic, tourism and health, to mention a few. A major concern however, is the unavailability of licensed drugs or vaccine for this highly fatal disease. She said although there are few available drugs, they are not yet tested in humans, hence the need for clinical trials.

However, the process of completing the required clinical trials is cumbersome and takes time (can last more than a year or more). How do we solve this dilemma in the case of EVD outbreak and absolutely no time to conduct clinical trials? Dr.

Oduwole described four options;

- Do not give. Allow drugs and vaccines to pass clinical trials stage
- Give as emergency, without clinical trials
- Commence clinical trials immediately
- Give and commence clinical trials

She further described the current situation of Ebola trial drugs and vaccines. Examples of

available drugs are ZMapp (which she said has been administered to about seven cases and is currently out of stock), TKM-Ebola, Favipiravir, BCX4430 and Medivector. Available also are vaccines such as NIAID, VSV-EBV and Nanosilver. All these are manufactured by various pharmaceutical companies and are yet to undergo clinical trials, so the ethical justification to use them is questionable. Apart from this, other ethical issues that need to be considered include distribution of the limited drugs among patients, who gives consent for the use of these drugs, and who is responsible for the risks and benefits these drugs might cause.



Cross section of participants



Cross section of participants



Bioethics Seminar Meeting – The Ethics of Ebola Drug Trials: to give or not to give?

contd.

To consider also if clinical trial were to be conducted, what type of trial will be ethically justifiable? And again, with the issue of scarcity of ZMapp, are the pharmaceutical companies under obligation to produce more?

She further explained arguments against giving these trials drugs, which include; the fact that it is unethical and unscientific to administer drugs that has not been tested, any data collected at this stage will not be

scientific, the issue of obtaining valid consent from vulnerable population at a time like this and the fact that autonomy will likely be infringed upon. She however argues on three major grounds that it is ethical to use experimental drugs on compassionate grounds given the global outlook and deadly nature of this viral infection. In applying compassion then, informed consent should be a priority and must be properly scrutinized and taken into consideration before administering any drug. The use of Ebola trial drugs will also be ethical if it does not violate the fundamental principles of human research ethics. She concluded that giving trial vaccines on compassionate grounds in the face of Ebola outbreak can be universalized and this makes it ethical going by Immanuel Kant's proposal that an action is ethical if its maxim can be universalized. This is because in actual fact giving of such drugs to a selected few calls for moral questioning and should be discouraged.

She informed the house that the WHO also agreed that it is ethical to offer unproven interventions with cases such as the EBV outbreak, the following ethical criteria must however be applied: transparency about all aspects of care, informed consent, freedom of choice, respect for persons, preservation of dignity, involvement of community, mobile obligation for data collection and sharing.

She rounded up her presentation by stating the view of the National Health Research Ethics Committee of Nigeria (NHREC) on this issue. She said NHREC also supports the use of these trial drugs at a time like this. The National code classifies these drugs/treatments as innovative or non-validated treatments and can be used solely for the benefit of the patient.



Cross section of participants



Consultative Meeting on the Electronic System for Management of Nigerian Ethics



Group picture of the participants and facilitators

Chairman, National Health Research Ethics Committee of Nigeria (NHREC) Institutions around the world rely on effective information management systems to facilitate their strategic and operational activities. Institutions that typically handle large bodies of research, such as research ethics committees, ministries of health, research institutes and universities, frequently struggle to deliver an integrated information management environment. Key mechanisms for managing research ethics review such as issuing calls for protocols submission, filling in project information, registering projects, conducting ethics review and managing project data often rely on manual, paper-based processes or at times are electronically managed as separate and frequently 'unlinked' activities.

At a country level, common information management problems related to research ethics review include:

- A number of disparate activities conducted by administrators, researchers and reviewers that are not effectively linked or coordinated
- Little integration or coordination between research ethics committees
- No clear strategic direction for overall research ethics governance
- Poor quality of information, including lack of consistency, duplication, and missing documents
- Reliance on a paper-based system for the submission and review of protocols
- Long time delays for the review of protocols



Consultative Meeting on the Electronic System for Management of Nigerian Ethics

contd.

The Nigerian Human Research Participant Protection System has been evolving from strength-to-strength following the reinvigoration of the National Health Research Ethics Committee of Nigeria (NHREC) in 2006. With NHREC as the apex regulatory and coordination body, Nigeria now boasts of more than 30 health research ethics committees (HRECs) in the NHREC database of registered health research ethics committees. These HRECs are mostly based in university teaching hospitals, with a few in research institutes including the Nigeria Institute for Medical Research (NIMR).

Experience from training HREC members as well as researchers in research ethics that have been solely and/or co-facilitated by WAB and NHREC revealed that HRECs in Nigeria are facing a number of challenges including:

- Adequate financing for smooth operations resulting in delays in convening meetings
- Limited office space for the HRECs operations
- Limited storage space for fulfilling HREC record keeping mandate (to keep records of all studies reviewed for a minimum of 10 years after the study had been completed)
- Lack of SOP and standardized processes for consideration of studies with varying degrees of risk

In order to overcome these challenges, WAB, in furtherance of its on-going collaboration with NHREC is supporting NHREC to identify, deploy, build capacity for users and provide maintenance services for an Electronic Web Based Health Research Ethics Committees' Management Solution (E-HREC Solution).

This E-HREC Solution package is an innovative customized web-based /cloud based system that not only manages research data, but oversees and automates the entire life cycle of the research ethics review process. From online registration and submission of research protocols, to circulating protocols to reviewers, to generating indicators for monitoring and evaluation, the E-HREC Solution maintains the research governance process. It prevents the loss of data, hence promotes accountability for HRECs and is accessible from anywhere.

The solution allows users to analyze progress and produce status reports at any stage. It stores all data in an easy-to-retrieve format, turning it into informative graphs, charts and maps at the touch of a button. It is a system that will provide the evidence needed to inform, promote dialogue and to make important research.



Consultative Meeting on the Electronic System for Management of Nigerian Ethics

contd.

WAB and NHREC decided that an initial consultation workshop be held that will focus on the following: an assessment of functionalities needed and the group of users' profiles; technical architecture design and project functionalities; information system architecture composition and definition of the main sections and level of access; web areas for linkage between NHREC and other institutions of interest, and building the project team and introduction and demonstration of the use of RHInno Ethics. Additional meetings and consultations will happen virtually or via teleconferences.



Working group members L-R Mr Kunle Oyafajo (IT Administrator, WAB), Ms Olubusola Onasile (Program Assistant, WAB), Ms Anne-Marie Maidment (Consultant, COHRED), Ms Boitumelo Mokgatla Moipolai (Consultant, COHRED), Mr Aminu Yakbu (NHREC Desk Officer, Federal Ministry of Health)

The first consultative meeting was held at 3J's Hotel, Utako, Abuja on April 1-2, 2014. It was organized by the National Health Research Ethics Committee Federal Ministry of Health (FMOH) in collaboration with West African Bioethics Training Program (WAB) and Council on Health Research for Development Africa (COHRED). In attendance were 27 participants who included individuals that represented research ethics committees from across Nigeria, WAB staff, FMOH staff and the COHRED team.



Modern Research Ethics Workshop for Trainees and Staff of the NFEELTP/NSTOP Program, Center for Disease Control, Abuja



Group picture of facilitators and participants at the training.

A two-day workshop on Modern Research Ethics for trainees and staff of (NFEELTP/NSTOP) was organized by the West African Bioethics Training Program (WAB), Ibadan in collaboration with Center for Disease Control (CDC), Abuja.

The training curriculum was accredited by the National Health Research Ethics Committee (NHREC/TR/31/07/2014). The aim of the workshop is to strengthen the skills of trainees and staff of NFEELTP/NSTOP on research ethics and how to obtain ethical clearance/approval for research studies. The training came up between the 4th & 5th August, 2014 at Gracious Hotel, Abuja. In attendance were 15 participants exclusive of 2 facilitators.

11 plenary sessions were taken. Sessions included History of Research Ethics and Research Regulation; Legal, Moral and Philosophical Foundations of Modern Bioethics; Elements of Informed Consent; The Consent Process-Comprehension, Voluntariness and Risk; Exploitation, Benefits, Inducements and Compensation for research injuries and vulnerable populations; Functions of the National Health Research Ethics Committee; Composition, Functions and Management of Institutional Ethics Committees; Operationalizing and Ethics Committee, Functions of the REC Administrator and Ethics Committee Reports and Records.



Modern Research Ethics Workshop for Trainees and Staff of the NFELTP/NSTOP Program, Center for Disease Control, Abuja

contd.



Prof. Jegede during his lecture



Prof. Adejumo during his lecture

The training used various participatory mechanisms to facilitate learning. These include: brainstorming, question and answer sessions, cases studies and plenary sessions.

The workshop evaluation showed that participants had indeed acquired new knowledge and skills. The mean pretest score was 64.9%, the scores ranged from 40% to 80%. The mean post test score was 75.5%. The scores ranged from 60% to 80% with nobody scoring less than 50%

Feedback from all participants was that they have gained knowledge that will improve the quality of their work. Some participants recommended more time to be allotted for discussions between the resource persons and the participants at the meeting.

Overall the training was judged as successful by both facilitators and participants. They commended the efforts of the organizers and encouraged future interactions.



November 2014 Graduation

In the recent graduation ceremony of the University of Ibadan, which took place between the 15th and 17th of November, 2014, two of our students graduated with the MSc. Bioethics degree. They both performed excellently well with a grade that enables them proceed to PhD without needing to do an MPhil. The students expressed their joy and satisfaction for finally completing their program in spite of the challenges they faced during the course of the training.

They expressed their appreciation to the West African Bioethics Training Program and Fogarty International Center of the United States' National Institutes of Health for supporting them in achieving this career goal. The graduands were;

Dr. John-Moses Maduabuchi: He is Physician and presently the Executive Director of the Society for



Quality Assurance in Nigeria (SQAN) and also the Coordination of the Association of Good Clinical Practice in Nigeria. He is actively engaged in organising and facilitating research ethics training among institutions in the South- East Nigeria where he resides.



Dr. Onochie Okoye: He is an Ophthalmologist at the University of Nigeria, Enugu, Nigeria. He has this to say:

The WAB-sponsored M.Sc degree program in Bioethics reminds one that there is yet so much to learn in life. The way the program is structured puts some structure and organization into one's thinking process, pushes one to think real hard and to respect the opinions of others. Prior to my participation in the program, courtesy of the scholarship provided by WAB, my responses on ethical issues could at best be described as impulsive, and premised largely on my religious persuasion and life experiences.

Undergoing the program turned out to be a life-changing experience for me. Apart from the highly intellectual and engaging interactions I had with the faculty and my course-mates, I had ample opportunity to forge close, respectful and enduring friendships with them. The entire course was captivating, deeply informative and, has provided me with a stronger foundation for life as a human being, clinician, researcher, teacher/trainer and of course, bioethicist. The Biostatistics module was most challenging for me, yet very illuminating.



November 2014 Graduation contd.

The invaluable tutelage I obtained, particularly in completing the dissertation work, has reinforced my commitment to pursue a career in bioethics. I now think, talk, eat, drink and act bioethics; if I may borrow the words of my senior colleague/mentor in ophthalmology. I have now become more active and influential in the Health Research Ethics Committee of my institution. Involvement in bioethics has actually opened a couple of doors and windows not just locally, but also globally. This M.Sc program far exceeded my expectations, and has definitely set the bar high for any future postgraduate education I may pursue.

The entire WAB family wishes you all

Merry Christmas

&

Happy New Year



West African Bioethics





CLOSING REMARKS

Thank you for taking your time to read the issue of the newsletter, Your comments about the current issue, and ideas for the next issue are what will keep the West African Bioethics Newsletter an interesting and lively newsletter!!

Please send contributions and suggestions to **admin@westafricanbioethics.net**

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