Report on the 3 days training on ethics of HIV care and service provision for Teachers of medical and dental students in Nigeria

By:

New HIV Vaccine and Microbicide Advocacy Society

With funding support from

SIDACTION

Table of content

Executive summary

The training on ethics of medical care and service provision for teachers of medical and dental students was held on 21st through 23rd September 2010 at the Development Support Centre Ibadan.

The training aimed at building the capacity of the lecturers on medical and research ethics so as to be able to teach and mentor students on how to conduct ethical research

A total of 30 participants were in attendance. Twenty three were teachers of ethics in medical and dental schools. Most of the teachers who teach ethics in the medical and dental school had never had formal training on ethics.

The participants were extensively engaged, analyzing the current situations in the medical and dental schools and proffering solutions to bridge the gaps identified.

A participatory learning process was employed. This included slide presentation, brainstorming, plenary discussion, group work and case studies.

The interactive learning process afforded the participants opportunity to acquire new ideas, share experience, and identify ethical dilemmas and best practices in medical care and service provision. The training also afforded them the opportunity to network.

A communiqué was developed at the end of the workshop which will be distributed to the medical and dental council, media and other relevant authorities.

The workshop evaluation indicated that participants had increased knowledge: pretest and post test average scores were 69% and 82% respectively. The 22 plenary sessions were also scored very high. The overall evaluation of the workshop was rated high in terms of content, logistics and the conduct.

The quality of the training was rated very high, 53% rated it excellent while 47% rated it very good. All the participants indicated that the workshop achieved its objective. A workplan post the workshop was developed. The workplan shall serve as a monitoring tool over the next 5 months of the training. Most of the participants wanted an extension of the workshop duration and also getting more of the stakeholders trained.

Next steps: This include wide circulation of training report to stakeholders recommended by trainees; publication of communique; a post workshop evaluation of use of knowledge, skills and tools acquired at the workshop. A second meeting of trainees to evaluate what steps to take as definitive measures to move the agenda forward nationally.

Background information on the project

The 2007 global statistics about the HIV pandemic continues to show the explicit need for continued efforts at addressing the global epidemic: there are renewed epidemics in regions of the world where the epidemic was once under control. HIV infection also continues to have a woman face with driving forces such as inequitable access to health, human right abuse and poverty continuing to be the social and economic context in which the epidemic occurs.

Current treatment and behavioral prevention efforts - such as including condom education and promotion, peer counseling, needle exchange interventions, safe blood transfusion, and interventions to reduce mother-to-child transmission - have slowed the spread of HIV, but have not stopped it. While great strides have been made in the availability of cheaper treatment for people living with HIV, problems of adherence, drug resistance, side effects, poor medical infrastructures and associated huge cost outlay make access to treatment still difficult for many. Moreover, the best treatment available do not cure; at best, they merely slow the progression of the disease

In the light of these, in many countries of the world, intensive research is being undertaken to develop new technologies for HIV prevention. Vaccines, microbicides, Pre exposure Prophylaxis, early diagnosis and treatment of HIV infection, and prompt STI prevention and management are among the most promising technologies. Huge resources have been invested in these research efforts over the last 10 years.

Due to the HIV epidemic in Nigeria (Nigeria being the 3rd worst affected nation by the HIV epidemic), there has been a huge mobilisation for HIV treatment in the last 6 years. ARV access sites have increased with lots of efforts at moving ART services closer to the people. Secondary and tertiary health institutions provide ART services, ensure opportunistic infection treatment and faciliate care and support of PLWHIV.

In recent times, in a bid to strategically address the epidemic, Nigeria as a country has focused on its most at risk populations – men who have sex with men, male and female sex workers, intravenous drug users, uniformed service men, incarcerated persons, and long distance truck drivers. While the national constitution may not recognise the independency of MSMs and sex workers, the newly revised national HIV policy and the new National Strategic Framework for addressing HIV/AIDS (NSF II) recognises the needs of these populations and addresses their needs in terms of access to HIV prevention services, treatment, care and support.

The field of HIV research, treatment, care and support has grown and is growing rapidly. Unfortunately, while the field is growing, there is very little commensurate efforts at growing the capacity of local persons to engage actively in the field. One of these are the trainers of researchers and service providers. Many of the lecturers in the universities and medical schools who train the medical service providers (doctors, nurses, dentists, physiotherapists) were trained way back before the evolution of the epidemic. Many have had access to update courses and so continue to be left behind. Unfortunately, this equally has impact on the students.

An informal evaluation conducted by NHVMAS in the medical schools in Southwestern Nigeria shows that ethics is not thought to postgraduate students. In the few undergraduate schools were ethics is taught, the focus is exclusively limited to addressing medical misconduct: nothing is thought on the ethics of research nor is anything thought on the ethics of patient's clinical care. Yet these undergraduate and postgraduate students conduct research and provide HIV clinical care services in various settings: they simply learn on the job.

The current situation calls for urgent local action. While the national government recognizes the need to improve and build current capacity to facilitate HIV research relevant to address the national epidemic – recognizing its peculiar country relevant context – as well as ensure appropriate and ethical service provision for those that require HIV prevention, treatment, support and care services, the national response in this direction is very slow. NHVMAS intends to contribute to this national effort through the training of key actors in the field.

Often times. What happens in the field is that medical service providers graduate from medical, dental and nursing schools without the appropriate knowledge set and skills to manage HIV research related issue. The ethics of research, including HIV research is continuously breeched. The rights of people who access HIV care services are abused. Most at risk persons are also stigmatised when their identity are revealed when accessing medical care. A few specialised HIV treatment, care and support centres try to address these gaps in undergraduate and postgraduate medical, dental and nursing students' training by helping these staff to access short training courses on HIV prevention, treatment, care and suport research conduct and service provision. Unfortunately, many of these trainings are conducted outside the country and at huge costs. While these efforts might help build the capacity of few medical service providers, many still remain ill trained to address the needs within other health care service centres like the private, tertiary, secondary and primary health care centres.

NHVMAS tries to address this gap. NHVMAS plans to train lecturers who teach students on ethics in the 23 medical, 10 postgraduate, and 6 dental schools around the country. In so doing, it will be addressing a gap needed within the health care services to build skills and capacity needed to ensure effective health care delivery based on ethical and human rights principles. Also, this training will further help to build a foundation of good research ethical practices that can be inculcated into undergraduate and postgraduate medical and dental students' research culture even as they plan the conduct of their undergraduate and postgraduate researches.

NHVMAS will not only train these lecturers and build their skills and knowledge, it shall also, in consultation with the lecturers, develop sets of slides that can be used for teaching on relevant topics on the ethics of HIV research and the ethics of HIV clinical care service provision for both the undergraduate and postgraduate students. These tools will help make it easier for the lecturers to incorporate relevant lecture topics into their training curriculum. In addition, the tool will help faciliate consistency in content of the topics being taught for undergraduate and postgraduate students through a consensus building process.

This will be the first of such efforts in the field. Till date, there has been no formal training of lecturers who train undergraduate and postgraduate medical and dental students on the ethics of HIV research and clinical care service provision. These crop of personnels will therefore be having access to new frontiers of skills and knowledge for the first time in their career.

Chapter 1: Pre workshop preparations

On the 30th of July, 2010, a Technical Committee meeting was held to plan the implementation of the workshop. Attached is the minutes of the meeting of the technical committee meeting. The dates and venue were decided, the training content revised and facilitators asigned topics.

Based on increasing cost of logisitcs, 35 trainees were identified for the workshop – 5 less than the initial proposal. All 35 were contacted via emails, telephones, sms, multiple personal office visits and referrals from past NHVMAS ethics trainees. Multiple swoops of recommended personnels were made as we the office realised that nominees were actually not teachers of ethics. A large number of medical schools did not teach ethics as a course. Rather, there were a few individuals, who because of their past training on ethics, incorporate ethics into their student's lecture schedules.

As a next effort, Provost and Deans of medical schools were then asked to make nominations of teachers to attend the courses. By the 3rd week in September, we had received confirmation from 25 participants to attend the workshop.

Reading materials were sent upfront to these participants. The training curriculum was also sent to all participants for inputs. The date of September 21st 2010 ws set for the 3 days training.

Chapter 2: Report on the Training Workshop

2.0. DAY ONE- 21st September, 2010

2.1. Workshop Introduction

The training sessions started at 8:30 am with an introduction of the training objectives. Participants and facilitators introduced themselves. Each individual shared with other information about the roles in ethics and expectations from the workshop. Most of the participants were directly involved in the teaching of ethics to undergraduate and postgraduate medical and dental students. A few were involve with ethics committees. Six participants were present to learn about how to start an ethics curriculum in their school.

Training objectives

- Improve knowledge of trainees on research ethics
- Improve the capacity of trainees to teach and mentor students on how to conduct ethical research
- Help trainees develop plans on how to teach or integrate ethics into existing training programs for health sciences students

Participants' expectations from the training:

- To broaden knowledge and have update on ethics
- To acquire knowledge so as to be able to teach ethics of research and not only ethics of medicine
- To have enough knowledge on ethical issues in research
- To interact with my colleagues and learn more on ethics.
- To increase the passion for teaching of ethics to medical students.
- To broaden biomedical ethics in medical students curriculum

2.2. Introduction to the training

A brief introduction to the training was made. Ajustification for the training which included among others the fact that medical service providers graduate from the medical, dental and nursing schools without adequate knowledge on ethics, especially HIV research related issues. At the end of the training, participants were expected to have acquired new knowledge on biomedical ethics in research and clinical care, new skills for teaching biomedical ethics for medical and dental student at the undergraduate and postgraduate levels, networked, and together as a team, developed tool for the teaching of ethics in medical and dental schools.

2.3. Ground rules

Participants set the acceptable code of conduct throughout the workshop duration.

2.4 Presentations

The topics presented for the day included:

- Ethical principles and codes of conduct for research practices
- History of ethics and research conduct
- Research integrity and misconduct
- Research obligation for undergraduate and postgraduate medical and dental students
- HIV prevention and treatment research
- Understanding the terrain for conducting HIV prevention and treatment research in Nigeria
- Group work on a practical look at the field: what can we change?

2.4.1 Ethical principles and codes of conduct for research practices by Dr. Ajuwon: The session provided participant with an understanding of research ethics, the need for standard in research and the principles of research ethics. Participants were made to understand that data from unethically conducted research is useless and more so, abuse of the rights of research participants creates a public perception that researchers cannot be trusted with safety of persons involved in research. There was extensive discussion on the principles of research ethics which included respect for persons and community, beneficence, non-maleficience and justice.

Discussion: There was consensus that just about 20% or less of people in theresearch field were aware of the principles of research. Awareness is low. For those that were aware, about 60% apply them in practice.

Factors identified for non-compliance with these principles include:

- Settings for research conduct. When conducting research in military setting, resepect for autonmy may be difficult.
- Low level of knowledge in the research communities; If the communities are knowledgeable they can challenge the researchers and that can facilitate the application of the principles
- Researcher may forget to apply the principle. Some of the participants argued that researchers cannot forget to obtain inform consent if it was part of the research proposal.
- Partial blame was attributed to the IRBs. However the question was, how many IRBs are funded, how many are functional and how many in practice monitor research approved.
- There was extensive discussion on the position of oral consent in informed consent process.
- A life story was shared where oral consent was obtained for a study that involved screening of members of sports club for hepatitis. The participants were later asked to sign a written consent form in retrospect for documentation. Just abouty 60% accepted to sign while 40% refused though they earlier gave an oral consent.
- There was a consensus that what is not documented is not done and it is subject to denial. A written consent will protect the research participants and the researcher. In clinical trial informed consent must be written.
- Other issue raised was the fact that funding may be an obstacle to applying the principles including obtaining written informed consent. Researchers were encouraged to look for good funding to do good research.

- For retrospective studies, researchers must seek for consent to waive informed consent. Such waiver covers for the researchers and the institution from liability.

What makes the conduct of research ethical?

- Research is designed and implemented in ways that generate the knowledge sought (value)
- There is a fair selection of study participants (justice)
- There is a favorable balance of potential benefits over risks to the participants (beneficence)
- Scientific validity: the design is methodologically rigorous (application of best practices; comprehensive review of literature, adequate sample, correct analysis)
- All scientifically flawed research are unethical
- Independent review of proposal and monitoring of research by a competent ethics committee
- Valid informed consent (understanding and voluntary) obtained from all study participants (respect for persons)
- Safety and well being of enrolled participants guaranteed during and after research is completed (respect for persons/beneficence/non-maleficence)
- Competent persons (investigators and their representatives) conduct the research
- Findings of study are disseminated appropriately (feedback to study participants, communities, local and international dissemination)

2.4.2 History of ethics and research conduct by Dr. Adejumo: Participants were taken throgh the history of research, research abuses and the evolution of research guidelines.

Discussion: is autopsy a research, if so is it benefiting to the patient (dead). What about the cultural factors?

- Scenario was shared, were some persons refused autopsy on their dead relatives because of myths associated with autopsys. There was consensus that the dead are not living and so the definition of person does not apply to them.
- The first consideration in research is the social value of that research. Research must be sensitive to the norms and values of the society and must be viewed from the lenses of culture. Researchers tend to cling to the scientific principles without focusing on the cultures of the community. It is unethical not to be sensitive to the cultures of the community in the practice of science.
- It was agreed that the ethics committee who are the watchdogs of research conduct should be strengthened and participants were encouraged to go back and strengthen their ethics committee.
- Other issues discussed were the fact that most students, especially postgraduate students, want to do research without ethical approval because of limited time to conduct the study. There was consensus that the lecturers need to start to get their students ready in time so as to submit their proposal to the research ethics committee.
- Research ethics committees need to develop research guidelines and inform their science community on how to submit research protocols for ethical review. They also need to provide oversight functions and also protect the investigators from possible liabilities.

The discussion was wrapped up with participants referred to National Health Ethics Codes. This addresses culture sensititvity. The code is been passed through the legislative arm for ratification since 2006.

2.4.3 Research integrity and misconduct by Dr. Ajuwon: Research, integrity refers to the ability of a researcher to perform his/her professional duties with honesty and truthfulness. Integrity is required in all stages of research process. It is the anti-thesis or direct opposite of misconduct. Misconduct in research challenges the integrity of the investigator, stakeholders and the research.

Case study: Dr Smith is a well known and well respected researcher. He has a graduate student that spent more than a year on a research that Dr. Smith had expected to provide impressive result. The research did not come out as expected and both of them felt disappointed. Dr. Smith had so much depended on the result from this study for abstract presentation at upcoming conferences. Both of them were certain that their hypothesis was correct but had not been able to figure out what had gone wrong with the experiment. Dr. Smith now handed the student materials from completed experiment that he had never before seen-the protocol, notebooks of data result and draft of conclusion for publication while he tries to figure out what went wrong. Participants were to assume the position of the student and state if they will accept or decline Dr. Smith's offer.

- Some of the participants said they will accept the offer while others could not make a decision on the ground that the student in this scenario was under the supervision of the lecturer and may not be able to decline the offer.
- There was a consensus that in practice, many will accept the offer.
- Refusal of offer was ethically required; clamming that work as his own would have been an example of plagiarism, a type of research misconduct.

Other forms of research misconducts shared included; fabrication, falsification, failure to publish, deceptive authorship, publication of paper with sections lifted from other papers without acknowledgement, publishing and resubmitting previously published data with minor alterations and no acknowledgements and breaking up papers from a single research work.

Question session: **If a research has so many variables that cannot be presented in one paper, does it amount to misconduct to break-up such paper?** There was consensus that the editor of the journal should be informed that part of the paper was part of a much larger study.

Can the raw data of a study bere-analyzed from another perspective than the original idea: If data should be analyzed, then the ethical committee should be consulted and if the content of the analysis is not in-line with study participants consent, the researcher has to revisit the informed consent. However, scientifically, secondary analysis of a data to address a question that was not identified as the primary objective of the study has its limitation for data interpretation purposes. This limitation must be identified in the write up. At best, the paper can only be a pointer to a possibility NOT established as a definite association of disease cause. This ie because of variable statistical parameters in sample size determination, methodology etc.

Other issues: The same article should not be submitted to different journals at the same time. A case of a single article being published in two different journals was cited. Researchers were dissuaded from this practice and also informed that abstracts are peer reviewed and can easily be

track if it has been published or submitted in other meetings or journals. An article must be withdrawn first from a journal before resubmission.

- Some of the lecturers publish students' research project without acknowledging the student. One of the participants shared experience of not knowing how to acknowledge the 10 student that took part in a study; she just decided to acknowledge only one person. Participant was made to understand that the ten persons could be co-authors and they can actually acknowledge up to 75 authors. For students' research project, lecturers or supervisors are co-authors while the students are the authors.
- Translating publications in other languages (e.g German language) to English and claiming ownership of the work. It was interesting to know that some of the people involved in this practice in our institutions were brought to book .
- Making research participants to pay for investigation for a condition not relevant to his care in the interest of research was identified as unethica;.

2.4.4 Research and ethical obligations for health sciences teachers and students by Dr. Ajuwon:

There are three major components of health research namely: protocol or proposal development, data collection and analysis and finally dissemination of findings. The session educated the participants on their Obligations in each of the three stages of health research. In protocol development, researchers are obliged to ensure approval of proposal by properly constituted Ethics Review Committee and show a commitment to implement the protocol as approved by the Committee. Researchers' obligation during data collection include among others: research must be conducted with the highest level of responsibility: avoid negligence, haste, carelessness and poor attention. Obligation for authorship included among others, ensuring results are published in an open, transparent and accurate manner, at the earliest possible time, unless intellectual property considerations justify delay. All authors, unless otherwise specified, should be fully responsible for the contents of the publication. Participants were discouraged from complimentary authorship.

Questions: The issue of complimentary authorship generate concerns from the participants and they shared experiences. It was reported that in one of the institutions, every paper generated from a department must include the name of the professor in the department for such article to be accepted for publication in international journals. His name probably gives integrity to the research work and that makes it acceptable internationally. An article was once submitted without his name and that was turned down and when the same article had his name as author, it was accepted and published. With this, it has become a tradition to have the professor's name in all abstract generated from the department.

There was consensus that if the research setting is such that the person contributed to the conduct of the study, then the person would be given authorship and the order of authorship in the manuscript need to be clarified prior to publication.

How do I get the community involved in a study to test the efficacy of a drug on patient with sickle cell disease, do I have to visit the Oba or Emir? The concept of community was clarified as not

limited to geographically bounded areas but group of people with a common interest. The community for the sickle cell drug study should be the sickle cell club. Community consultation should be conducted prior to the development of the research protocol. Experiences were shared on community preparedness for a trial to be conducted in Ibadan. Almost all the community members were aware of plan to carry out the study and it simply shows that the community was involved in protocol development.

What is the ethical implication of conducting a study to find out the efficacy of a herbal drug on hypertension? The drug is widely used and everybody in the institution attest to the efficacy. Scientific discoveries involve a process and that process must be followed. You have to know the composition of the herbal preparation, conduct study on laboratory animals before safety and efficacy study on humans.

2.4.5. HIV prevention and treatment research: ethical obligation by Dr. Ezechi: A brief overview of the global HIV epidemic and the disease burden in Nigeria was shared. The current challenge in prevention and treatment of HIV infection were outline and these included among other patients friendly drugs, HIV/TB co-infection, side effect of current drug, female controlled prevention options and most at risk populations friendly options. Researchers' ethical obligation in conducting prevention and treatment trial is to ensure that participants' rights are respected and available treatment is not withheld.

In a HIV prevention trials do researchers and sponsors have a moral obligation to provide life long ART to research subjects who contract HIV? There was consensus that life-long treatment should be provided. All research participants contributed to the success of the study and should be cared for when they contract HIV. The HIV infection contributes in a unique way to the study outcome. An example was shared wherein a research proposal on hepatitis B study was turned down by a researcher because the protocol stated that the entire patient with hepatitis B will be referred to a treatment centre. There was no treatment for hepatitis B in the treatment centre and the protocol did not provide an MOU from the treatment centre.

2.4.6 Understanding the terrain for conducting HIV prevention and treatment research in Nigeria: The session provided the participants with current HIV situation in Nigeria. There is need to prioritize prevention against treatment options for HIV/AIDS response in Nigeria. Concern was raised on government preparedness to sustain the PEPFAR driven treatment response upon disengagement. Corruption was identified as a key problem. There is need to redistribute HIV resources from the federal to the state and primary health facilities. Every doctor should be educated on how to treat HIV/AIDS just as malaria is treated. The Nigerian government especially at the state and local government need to be more involved in HIV/AIDS response. A culturally driven approach was recommended in promoting HIV education and behavioural change; this included the use of village town criers, native gong and drum to reach out to the community. Identified gaps in HIV prevention

and treatment option included low HCT uptake, low uptake of PMTCT, need for early detection, treatment and management of STI, and poor infrastructure and human resources.

2.4.7 Group work: Participants were divided into three groups. Each of the groups deliberated on the following questions;

1. What is the current content of ethics training curricular with respect to research?
2. Does it equip students to be able to address the challenges of practice in the field?
3. What can be changed and how?

2.4.7.1. Group One: The group identified 6 topics in research ethics and evaluated if it is the content of current curriculum. The topics are:

- History of research ethics
- Definition, scope and concept of research ethics
- Components of research ethics
- Principles of research ethics and misconduct
- International code of research ethics
- Role of IRB

In LUTH and BUK universities, none of the topics are taught except principles of research ethics and misconduct. Contrary, most of the topics were taught in ABSUTH, OAU, LAUTECH AND EBSUTH.

2.4.7.2. Group Two: There is no specific curriculum yet. Part of the lecture schedule in community medicine and medical sociology include:

- Ethics of medicine
- Research methodology
- Ethical issues in research
- Introduction to medical ethics
- Consent and legal aspect of anaesthesia
- Community in immersion

The topics equip the students to a variable extent. To make improve this, it is important to:

- Introduce research ethics
- Lecture and technique of teaching not sufficient: this should be broadened.

2.4.7.3. Group three: The members of the group shared experience from their various institutions.

Contents:

- In national postgraduate and medical college and West African college of Physician and Surgery, ethics training is just peripheral integrated in research methodology.
- However in LASUCOM, LAUTECH and Osun State University, there is an established curriculum. In LASUCOM, lecturers are expected to undergo online training.
- In LUTH and Edo State University Ekpoma, there is no established curriculum training is incorporated into research methodology for medical students.

The current training curriculum does not equip students to be able to address the challenges of practice in the field. Suggested possible changes include:

- Introduction of a separate course on ethics into undergraduate and postgraduate curricula
- The department responsible for medical student project should have ethical committee and train students on ethics of research
- Other departments should have committees that address ethical issues of research proposal.

2.5. Evaluation of Day One

2.5.1. Things participants liked: The session most liked was history of ethics and research conduct and reason was that it was quite revealing, things they have heard before was mentioned. What they liked for the entire program was active participation.

2.5.2. Things participants disliked: The session on understanding the terrain for conduct of HIV prevention and treatment research was least liked because no new information was gained from the presentation. What was least like for the entire program is fact that few individuals kept on talking and interrupting the sessions.

2.5.3. Logistic challenges: Few participants expressed challenges on not getting accommodation within the training centre and lack of internet access.

2.5.4. Suggestion on how to improve the sessions: Facilitator should take control of the discussion and minimize interruptions during the presentation, also keeping to the time.

The general comment was that the program is very educative.

Lessons learnt from day 1

- There are still gaps in the understanding of research ethics in the field.
- Research ethics is not formally included in the training of undergraduate students in many medical schools. Where it is taught, it is included in lecture sessions by individual teachers who are interested in the subject matter.
- The is need for a forum where dialogues about research ethics can hold regularly.

2.6. Day 2- 22nd September, 2010. The day started with a recap of the day one sessions. Participants were able to recall what they had learnt and what has left a lasting impression.

2.6.1. Function of the ethics committee and relevance to undergraduate and post-graduate research by Dr. Ajuwon: The session provided information on Health Research Ethics Committee (HREC) and their roles. It was also noted that the committee should provide continue education to the community that it serves

Question, what happens if two similar or potentially identical proposals have been submitted to the HREC, whose protocol should be approved? The person that first brought the proposal should be considered as the original owner of the idea. The second proposal will be advised on how not to waste resources noting that such a research is been conducted in the institution. If it is a case of plagiarism, the committee needs to clarify who copied and from whom. The committee will then hand over to the appropriate unit. The committee cannot take over investigation and sanction of those whole violates the code of conduct. The committee can provide evidence that this research was approved and monitoring report was received.

What component of the protocol should be review? The science of the research and the ethics of the proposal.

Why should it bother itself with the science since it is an ethics committee? Bad science is bad ethics. The committee should be interested in both the methodology and the ethics of the research. In institution where there are 2 committees, science and ethics, the science review should preceed the ethics review because the science is the foundation of the research. Ideally the protocol review should be done by the committee however if there is no expertise within the committee to review the protocol, the committee can aske for external review.

Procedure for the recruitment of participants: Consent form must be signed by study participants. The consent form should be comprehensible to a JSS 3 student. In cases of people who are not literate, the informed consent will be translated into the local language. When training research assistants, there should be agreement on the common language to be used for specific scientific terms.

A proposal on validation of data on TB and will involve tracing those who are available. The information will be provided by phone if the person cannot be available in person to confirm that the data available is valid. What is the ethical issue? Tb is a stigmatised condition, the investigator will provide plan that the information of the patient will be protected.

What is the definition of a bad research proposal? This is because sometimes there are arguments on the scientific proposal. The proposal should conform to the require standard proposal format. The views of the ethics committee members are harmonized at the committee level as the decisions of the committee supersede the individual opinion.

How best can one deal with delays in review of proposal? Is there any way the members of the research community can pass a vote of no confidence to a member of the IRB that is found not to meet up with the expectation. The delays are dealt with by withdrawing the proposal from the reviewer and assigned to another person. Sometimes the reviewers may have to be blacklisted. It is only the members of the ethics committee that can pass vote of no confidence. There should be an administrative office of the ethics committee and a secretary to the committee. The secretary checks the proposal when been submitted using a check list. If every journal editors insist on ethical approval before publication, then it will send a positive signal for all researchers to follow. The committee may cancel an approval already given if there is bridge of the protocol during protocol implementation .

Issue to think about

- What is the ethical way to fund HREC? Charge fees, solicit funds from donors, rely on institutions)
- How best can member of HREC are rewarded for their services? Cash, kind or thank you letter

2.6.2 The ethics of clinical care and services provision for patient by Dr. Ukpong: The principles of ethics are universal and they apply to both research and patient care. The session stimulated the

participants to reflect on the principles of ethics in relation to patient care and services provision. These principles are individual autonomy and informed patient choice, distributive justice in commissioning care, beneficence and non maleficence. Respect for choice was emphasized. Medical service provider should provide the patient with options or information on treatment for the patient to make informed decisions.

How then will the doctors convince the patient on what is right treatment for him? Paternalistic medical practice is unethical. Doctors are encouraged to shift away from the authoritarian position and lay information for the patient to make informed decisions.

What is the ethical implication for a surgeon who refused to carryout an operation because he feels the patient will not benefit from the surgery, even when the patient insist on having the surgery – the life scenario here is for a of pt who first present at 1st stage tumour refused to go for surgery, presented 2years later with 4th stage Glycoma and is now demanding for an operation. In situation like this, the surgeon can refer the patient. In private institution, the medical practitioner has a right on whom he wants to see so also the patient decides on whom to see. The reverse is the case for public health institutions. In situation where patient refused treatment e.g. blood transfusion on religious ground, the doctor does not have any right to send the patient away. The patient can still provide access palliative care and be referred where necessary.There is low level of health education in Nigeria. Most patients do not know or understand the drugs they are taking. There was consensus that care providers need to educate and inform the patient on the details of their ailment and their treatment. The Nigeria Medical Association was identified as having a lot of work to do in promoting health education among the populace which they are not currently doing.

If a medical colleague who needs medical attention walks into a colleague's clinic, should he be attended to before other patient? There was consensus that as colleagues they need to be give attention while apology is given the patients on the cue.

How ethical is it to give preferential treatment based on affordability? Treatment options should be provided to all patient independent of cost or SES of patient. Patient should make decision on treatment option based on his or her ability to afford treatment options. Clinical cares are expected to delivered in a way that is sensitive to the needs of their local population and reducing inequity.

What is the ethical position of paying different consultancy fee for seeing a consultant, senior registrar and charity services? There is nothing wrong with the arrangement so long as the quality of care is not compromised. Charity care should not be of low quality. Health care providers are not mandated to take social responsibility.

Issues to think about

- Where does the patient right start and where the right of the doctor start?
- Does the doctor has the right to reject a patient
- Does the doctor has the right to refer a patient
- What does the doctor do with a patient who refuse treatment?

2.6.3 Understanding care needs of PLWHA by Olayide Akanni: Most concerns of PLWHA are enormous and often centred on stigma and discrimination. Some of the concerns outlined were; how to inform their partner, how to manage their drugs, and reproductive health challenges. In the early 2000, there were cases of unethical trials where HIV positive patient were made to pay as high as N60,000 for participating in treatment trial. The treatment was then withdrawn at the end of the trial. The uttermost standard of care has to be provided in HIV treatment research. The fact remains,

treat the people whether treatment is interated into general health care or not. Integrating HIV treatment into general practice will assist in addressing stigma. HIV stigma within the health system not only stigmatizes the patient but also the doctors. There is low HIV knowledge among workers in the health system.

Discussion: Stand alone HIV treatment centre in the health facilities gives room for stigmatization the need to decentralize the treatment unit was emphasised. LAUTECH experience on standalone STI treatment centre was shared. The STI centre was not accessed at the initial stage because it was a standalone unit and is stigmatized. However when the clinic was resituated so that the centre became hidden, people started accessing their services. The participants were encouraged to provided advocacy to their institutions and get them to know that stand alone clinic is not working.

2.6.4. Understanding care needs of MSM, IDUS, male and female sex workers by Dr. Ezechi: The session provided information on the most at risk populations and their health care needs. Doctors were encouraged to provide care to most at risk population especially men having sex with men (MSM) in Nigeria. The HIV prevalence is high and the community is a bridging population. If we discriminate on service provision for MSM because we think it is not right on religious grounds, then we continue to fuel and epidemic just based on stigma.

How do we protect our values while we respect the rights of the MSM? From a public health perspective MSM need to be provide with care irrespective of our beliefs and values.

2.6.5. Challenges of providing care and support in an ethical manner by Dr. Oyedeji: A case study was presented and analysed to elicit the ethical dilemma in proving care and support. The case study is on Mr. Jone a 47year old man with cancer who had both illectomy and a colectomy because his abdominal cancer was extensive. His nutritional status was maintained through the administration of hyperalimentation. Through this he was able to live a nearly normal life at home and even returned to work. However, Mr. Jones' insurance does not cover hyperalimentation and there are no social programs to help him. Mr. Jones was unable to pay his bills; therefore he was informed that his treatment will be discontinued. Mr. Jones tried his best but the bill is too high - he cannot pay.He asked "How can you take my food away? You'll be killing me. What right do you doctors have to take out my intestines so I can't eat and then starve me to death?" He was advised to quit working and be a destitute but he declined the offer rather he relied on the doctor to help him.

- What should the doctor do to help him?

- Should he point out that it is his choice, he can die of starvation or he can "qualify" for help.
- What other options, if any, are open to the doctor?

Lessons from the case study: Although limited access to scarce resources is not necessarily unjust, the issues involved are to important to be the sole decision of one health professional – or even a group of health professionals. Most of these situations have far- reaching implications for health care professionals, for institutions, for society and, of course, for patients. Therefore such decisions should involve special committees of laymen and women to consider and evaluate the situation vis a vis the cost to the society and the obligations of the society pertaining to the rights of individuals.

A woman gave birth to an encephalopia baby and after counselling the woman, she decided to abandon the baby. How do we handle it? The ethics committee and the hospital, management should be involved in such challenges. There should be a referral system in our institutions so that cases are directed to appropriate unit. Care is about helping to sustain life. The ethical dilemma in providing care and support health research include:

- Who defines the standard?
- What is best proven standard of care?
- What is the funding capacity-sponsor?
- For how long and who should bear the burden?

In Botswana, once participants are enrolled for vaccine or microbicide trial, they must be insured for life. The facilitator recommended the standard of care document developed by NHVMAS and called for its integration into the national code. The Nigeria National ethics code is a living document, participants were encouraged to make their contributions. Participants were encouraged to advocate for government involvement in research through counterpart finding.

2.6.6. The ethics of involving women in research by Dr. Oyedeji: The session provided participants with information on why women are excluded in research and also made a case for the need to include women in research. Most times women are excluded from research because of conflict between protection of research participants, versus the fairness of having appropriate information, and reaping the benefits of that. The historical concern with paternalism had led to a default position of excluding women from research; only including them when it was deemed absolutely necessary. This protectionist stance however is changing. There is need to include women in research and some of the reasons identified were; their different biology (size, body composition, metabolism, and hormonal fluctuations), women require proper information about the effects of drugs on their bodies and the fact that some conditions are unique to women e.g. (thrush in pregnancy). Men's "reproductive capabilities" may also be affected by some research; yet they are trusted to use condoms. Why not trust women to similarly avoid conception while in a trial?

A study on TB/HIV recruited participants and major exclusive criteria was pregnancy and over 200 was lost due to pregnancy which affected the validity of the study. Why does the research design not factor in the possibility for loss to follow up due to women becoming pregnant? There is need to power our research so that it can accommodate women who get pregnant while participating in trial and the validity of the study will not be affected.

2.6.7. Group work: Participants were grouped into 3 and each group deliberated on a specific issue.

2.6.7.1. Group one: Should ethics to be part of a curriculum or a separate course? What should be the minimal content in ethics?

- There was consensus that ethics should be part of the curriculum

- Ethics of medical practice should be taught in the first clinical year by Medicine Department
- Research ethics should be taught in the final year by Community Health Department prior to commencement of research

Minimal contents: Ethics of medical practice

- MCDN guideline
- Other Law
- Principles of medical ethics
- Hippocratic oaths

Minimal contents: Research ethics

- History of research ethics
- International codes of research ethics
- National codes
- Principles of research ethics

2.6.7.2. Group 2: How much ethics should be included in undergraduate-clinical and research? what should be minimum content on research ethics?

- Undergraduate should have enough knowledge to conduct basic research and clinical medicine ethically.
- They should understand the basic principle and concepts of research/Clinical ethics
- They should have a broad and in depth knowledge of clinical/medical ethics

Course content

- introduction to clinical and Research ethics- history, principle, ethical misconducts, national and international codes in ethics, patient bill of rights
- Doctor patient relationship- patient education, informed consent, Hippocratic oath,
- Consequences of unethical practice- legal implications of misconduct(medical jurisprudence)
- The roles and function of IRB (REC) - composition, functions.
- biomedical ethics and proposal writing- ethical considerations in research proposals

2.6.7.3. Group 3: How do you address the research methodology course contents in postgraduate training? How do we address ethics training for all postgraduate medical students?

Timing

- Residency- ethics course should be within 1st year of residency training
- Msc/PHD- ethics course should be within the 1st Semester

Content

- Medical ethics – this should include, health care ethics, health care institution ethics and biomedical research ethics
- Research methodology should include introductory part of biomedical research ethics

Duration

- Fellowship/residency- 3days-1week with certificate of attendance
- Prerequisite for part 1 exams
- Research questions in both part 1 and 11 exams

- PhD/MSc.- One semester course with exams

Potential setbacks

- Funding
- Transportation risks

The group proposed for online ethics course and the separation of research methodology from ethics. This will allow for an in-depth treatment of course, exposure to variety of researchers, sharing of ideals and networking

Way forward

- Advocacy to National University Commission
- Advocacy to postgraduate colleges of medicine through the college secretary and
- Advocacy to medical and dental council of Nigeria
- Reach out to individual through practices, departmental seminars
- Reach out to other healthcare workers including Nursing professional bodies and the Media
- Get a formal communiqué, A four member committee was constituted to draft a communiqué for the group. The members are: Drs Kanu, Umeora, Asoegwu and Dolapo

2.7. Evaluation of Day Two

2.7.1 Things participants liked: The participant liked most the session on understanding care need of MSM, IDUs male and female sex workers because of the practical orientation nature of the topic, it emphasised the need to care for people irrespective of their orientation. They also liked the interactive nature of the program

2.7.2. Things participants disliked: Most indicated none for the session least liked however a few mention challenges of providing care and support in an ethical manner.

2.7.3. Logistic challenges: The breakfast was cold and most people did not like it.

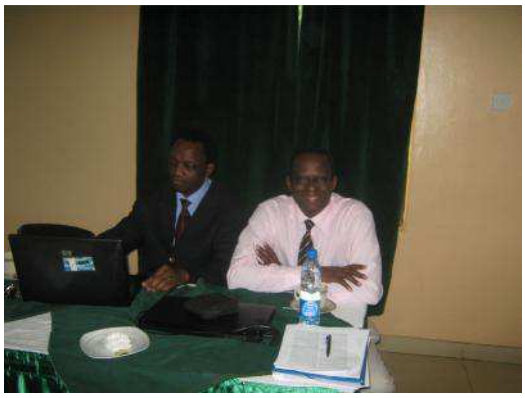
2.7.4. Suggestion on how to improve the sessions: Better time management

Lessons learnt on day 2

It is desireable to address the ethics of clinical care of patients. This is a gap not adequately addressed in the medical field. The examples shared and the issues that arose from discussions shows that discriminatory care and poor quality of service provision is rampant with no concerted effort to address this gap.

2.8. Day 3 - 23rd September, 2010: The day's activities commenced with a recap of day two sessions. Four topics were presented; these were comprehension, voluntariness and vulnerability, informed consent, medical ethics education and curriculum education, international regulations and codes for research ethics

2.8.1. Comprehension voluntariness and vulnerability by Adejumo: There is need for researchers to make themselves clear before their patient and research participants. Factors that predict comprehension of consent include; Age, education, reading ability, professional background, Mental illness and oversight. The NHREC guide to informed consent was outline. Emphasis was made on breaking down scientific terminologies into local language in order to achieve comprehension. Researchers should be able to use other technique other than didactic forms of teaching. The use of songs was recommended.



2.8.2. Informed consent by Dr. Adejumo: Many care decisions in times past were characterized by exploitation of patients of research participants. Health care decisions were made without adequate consent for nursing and treatment decisions. The purpose of informed consent is to protect patients from unauthorized interventions and researches, protect researcher and institution from litigations arising from patient participation in research and also serves as a statement of contract between potential research participant and researcher. Group responses are need for community engagement, but not a substitute to individual consent.

2.8.3. International regulation and codes of research ethics by Dr. Ajuwon: There was a review of the international regulation and code of research ethics, the Nuremberg code, Helsinki declaration, Belmonth report and the CIOMS. The international code recommended for proven prophylactic, diagnostic and therapeutic care for research participants. The question is who bears the responsibility –the researcher or the sponsor. This issue of who bear the responsibility should be discussed at the beginning of the study.

For TB therapy, why are we not using WHO best proven drugs, should there be double standard? Every country is advised to use its circumstances and available resources to meet their needs. International regulations stipulate that researches not acceptable in the West should not be done in the South. Ethical approvals are obtained from developed countries before they come to developing counties e.g. US and Italy. However not all developed countries do that.

Why are researches not approved in US being conducted in developing countries by US researchers? Example cited is the stem cell research conducted in India. The law does not protect people in the developing countries: one thing is having a guideline and another thing is for people to be aware of them and implement them. There is need for journalist to bring up the attention of unethical practice in clinical research and unless this happens it will continue to go on in our society.

2.8.4. How to integrate ethics into current training schedules by Ajuwon: Ethics of research and practice are not listed in existing curricula in many institutions in Nigeria. Students had learnt about ethics through mentoring and mentoring is not sufficient hence the need for ethics to be learnt formally while mentoring continues. There are three approaches, development of a new course-need a curriculum, extra curriculum approach using departmental seminars and integration approach using the contend developed at the meeting as minimum

2.8.5. Medical ethics education and curriculum development by Dr. Adejumo: Globally curriculum for medical education is culture specific, professional specific and institution specific. The participants were educated on the processes of developing curriculum for research ethics.

2.9. Content of the CD for ethics training for students

There was consensus on the following topics for integration into ethics training for undergraduate and postgraduate medical students**.**

- History
- Ethics principles
- Roles and function of IRBs
- National health research ethics code
- Principles of medical ethics

2.10. Communiqué

The committee presented the communiqué, outlining the ways to address the current deficit in ethics training at both the undergraduate and postgraduate levels. This was deliberated in the house and ratified (see appendix). The communiqué will be sent to the Medical and Dental Council of Nigeria, Colleges of Medicine in Nigeria, the Chief Medical Directors of the Teaching Hospitals, the media and other stakeholders.

2.11 Evaluation of Day Three

2.11.1 Things participants liked: The participant liked most the session on how to develop a course on ethics for undergraduate and postgraduate students, and session on informed consent. The sessions discussed topical issues and adapted local scenarios.

2.11.2, Things participants disliked: None.

2.11.3. Suggestion on how to improve the sessions: Hand on practice, providing more time for the sessions and projecting examples of curriculum which has been developed.

2.11.4. Lessons learnt

- Most of the medical/dental students do not have a formal course on ethics but ethics is target as part of existing course e.g. research methodology
- Most teachers of ethics have not had formal training on medical ethics
- Participants were eager to see ethics integrated into the curriculum
- There is need to merge plenary 8 and 7 into a single session to avoid repetitive and boring for participants

2.11.5. Recommendations

- There is need for follow up on training by having NHVMAS conduct site visits
- Advocacy to relevant authority for integration of ethics as a course in the medical and dental students curriculum
- Training of other paramedical and student teachers on ethics in order to avoid double standard in ethical practice in our institutions

Chapter 3: Action plan for institutions

Following the session on medical ethics education, participants are then paired according to institution to develop an action plan for developing curriculum on ethics or integrating research ethics in the existing curriculum. The action plan will become the yardstick for evaluating the participants during project monitoring and evaluation.

3.1. University of Port Harcourt Teaching Hospital / UNIPORT Group

Long term plan: Propose to the college of health sciences through the academic members OF UPTH IRB to:

- Expand the scope of lectures on ethics to include ethics on practice and ethics of biochemical research beginning from year 2 through final year of MBBS students
- Propose the core contents of these lectures
- Introduce the same series of lectures as part of physiology lectures for B.sc, M.sc students of Physiology Anatomy and Biochemistry

Later, health research ethics should be introduced as a course for B.sc and M.sc students

Short term plan: Provide a written report to the UPTH management and IRB:

- Propose a briefing [half-one hour] for UPTH IRB and propose
- Half-one day training on on ethical issues/regulations in biomedical research for:
  - All pre part 1 residents
  - All post part 1 residents
  - training for all new house officers during their orientation
- Seminar on ethical issues in practice and research for
  - Nursing staff/students
  - Medical laboratory staff/students

3.2. Ebonyi State University Abakaliki

Create awareness to integrate medical ethics and health research ethics into the medical students' course.

- Report of attendance and submission of communiqué of the workshop
- Survey all the current practice and knowledge, attitude to research ethics among institution workers
- Organize workshop in conjunction with REC
- Advocacy to include medical ethics and health research ethics in M.Sc curriculum

3.3. Amino Kano Teaching Hospital /University of Maiduguri Teaching Hospital

- Meet and inform the IRB of my centre about the workshop attended and raise up for discussion and consideration, the various aspects discussed at the workshop
- Stress the need to educate the community we are serving on:
  - Existence of IRB
  - Duties of IRB
  - The need for ethically based research

- To reach out to:
  - Undergraduate
  - Resident doctor
  - Post-graduates
  - Consultants
  - Nurses/other health workers

- How to reach the medical students
  - Organize workshops for faculty of medicine teachers and educate them through the dean.
  - Encourage teachers to emphasis ethical issues in teaching subjects
  - Encourage expanding the scope of research methodology substantial amount of ethical research

3.3.4. College of Medicine University of Lagos, Lagos University Teaching Hospital, National Postgraduate Medical College of Nigeria, West African College of Physicians / Surgeons

- Presentation of report of the training and communiqué to the national post graduate medical college of Nigeria and the West African college of physicians/ surgeons.
- Presentation of the report of the training and the communiqué to the Heads of the Departments, sub Deans and Deans of Basic Medical Sciences and Clinical Sciences of College of Medicine of the University of Lagos.
- Presentation of report of the training and communiqué to the Chief Medical Director, Lagos University Teaching Hospital.
- Delivering presentation on ethics of medical practice and biomedical ethics in various department of Lagos University Teaching Hospital.
- Presentation on ethics of medical practice and biomedical ethics in Lagos University Teaching Hospital ground round.

3.3.5. Obafemi Awolowo University Ife

- Training of University Research Management Team on Research Ethics.
- This could be done through the central office of research (COR)
- Then this could be followed by training of all University researchers (voluntary)
- Funds could be sought from COR / URC/ External Funders
- Protocol to this effect will be developed
- Sustainability of the project- floating a special elective course of 2 units to all undergraduates
- The special elective will be housed/achieved by COR/Dental Faculty/Institute of Public Health

3.3.6. Ambrose Alli University, Ekpoma

- Currently, there is a 1 Hour lecture on medical ethics to new clinical students. Introduce earlier in 200L as component of lectures. To include History of medicine lectures in community medicine – overview of medical ethics

- Currently, there is a 1 Hr lecture as component of rural posting in second clinical year of study. Focused series of lectures on clinical and research ethics along the lines such as:
    - Principles of ethics
    - National and International codes of ethics
- Assessment of ethics as compulsory component of student evaluation
- Develop training package and present to hospital ethics committee and CMD
- Develop curriculum to contain
    - Basic principles
    - Ethical misconducts
    - Others
- Develop training materials
    - For undergraduates
    - For resident doctors
- Develop and implement advocacy and communication of plan to faculty board of studies
- Develop Proposal to hospital to introduce ethical training on medical ethics to all doctors

3.3.7. Lagos State University College of Medicine (LASUCOM)

What we are

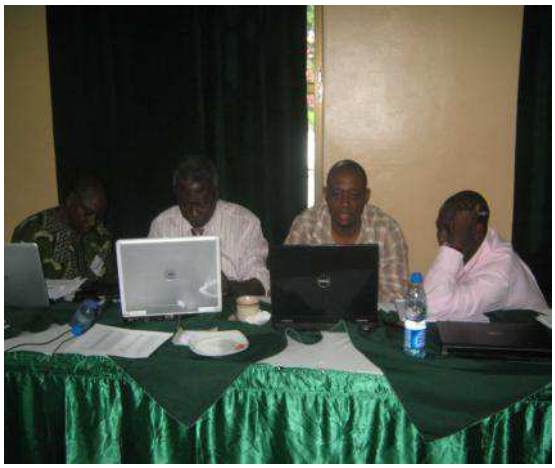
- A medical training and research community
- Tertiary health centre to disseminate best of service
- Train medical students and residents to do research

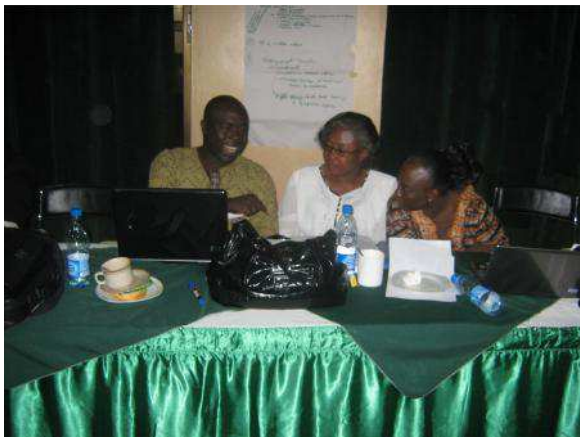
What we have

- HREC
- HREC guideline
- Medical school
- Departmental seminars
- Continuous Medical Examination

Proposed activities

- Write a report and submit the communiqué to the college
- Advocacy visits to HOD's for need in ethical training for residents and students
- Organize departmental seminars in ethics in clinical research
- Encourage wide circulation of IRB guidelines
- Encourage annual CME on ethics in research
- Facilitate the inclusion of ethics in research in medical students curriculum
- Mentoring of students and residents in the basic principles of ethical research





3.3.7. **Ladoke Akintola University of Technology /Osun State University**

- Upgrade and expand the already existing curriculum for undergraduate and postgraduate students
- Integrate introductory teaching in research ethics into the research methodology
- Organize a three day training course in the college for all identified stake holders e.g consultants etc.
- Integrate ethical issue topics into the departmental post-graduate seminars
- Identify lecturers who will teach ethics
- Collaborate with ethical committees
- Distribute communiqué to all relevant persons in the teaching hospital and college

4 months action plan fo Abia State University/Abia State University Teaching Hospital , Aba

Goal: To improve the knowledge and practice of research and clinical ethics among heathcare workers and trainees in the above named institution

S/No	Activity	Duration	Time line
1	Advocacy visit to College Provost & CMD and presentation of workshop communiqué	1 week	1st Month
2	Need assessment of for training for training of research and clinical ethics	1 month	1st Month
3	Mobilise and Strengthen the capacity of the ERC and Abia State University Research Group through 1-day training	1 week	1st Month
4	Development of guidelines for ethics for research and clinical care by IRB	2 month	2nd – 3rd Month
5	Commence the process of registration with NHREC	2 month	2nd – 3rd Month
6	Commence the process of review of the curriculum for training of Medical Ethics with the Department of Community Medicine	3 month	2nd -4th Month

Next steps

- Circulate the communique on NHVMAS listserv and the eforum
- Send out the communique to all CMDs and Provosts of medical colleges
- Send out a press release to journalists on NHVMAS data base
- Send out the report to all participants
- Send out specific action plans to stakeholders identified by participants
- Follow up participants and provide technical support
- Identify 10 active teachers and meet in February to discuss project and next steps.

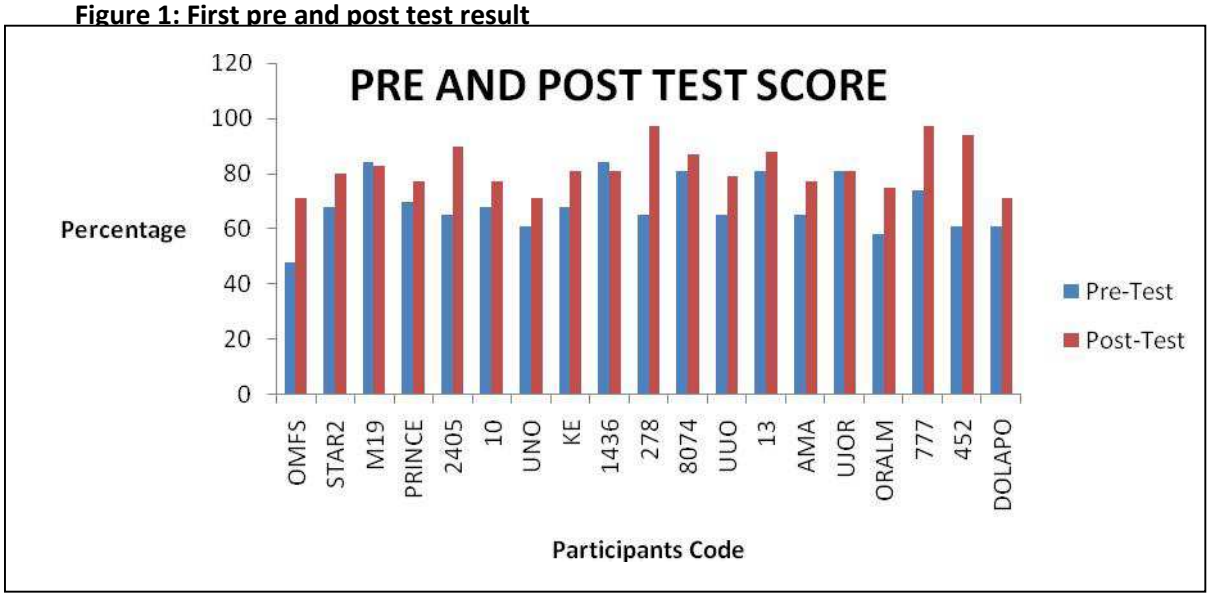
Chapter 4: Workshop Evaluation

4.1. Pre-test and post test questionnaire

There were two pre-tests and post-tests administered. One of the pretests focused on the ethics of research while the other address the content of the training. Results of both tests showed significant increase in knowledge among the participants.

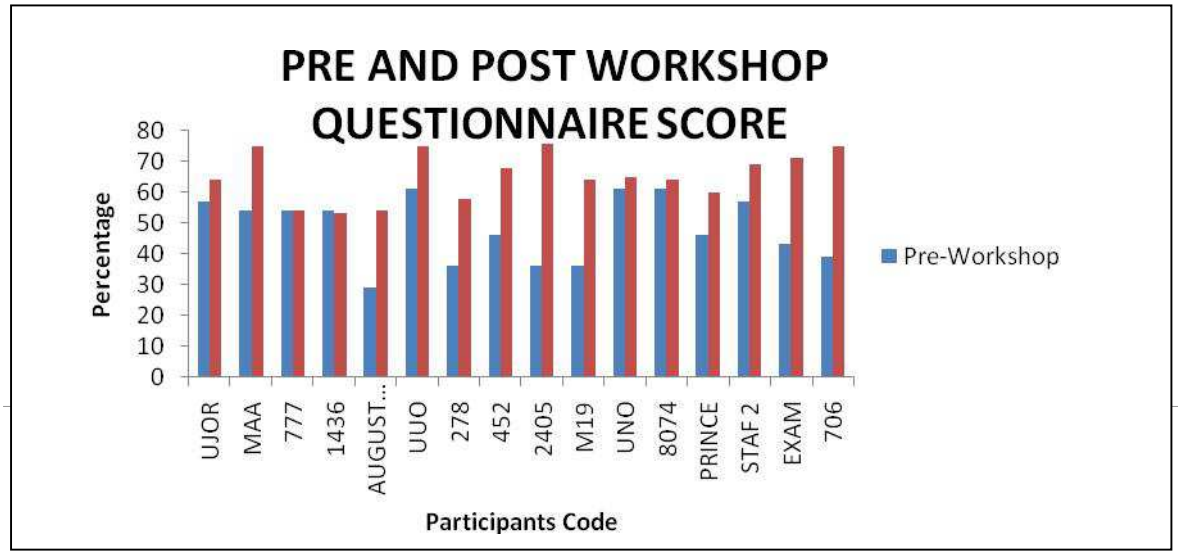
The average score for the first pre-test was 68.8 ± 2.2%. The scores ranged from 48% to 81% with 65%, 68% and 81% being the modal scores (3 persons each had those scores). The average of the post-test score was 81.9 ± 1.9% with scores ranging from 71% to 97%. The modal score was 81% (4 persons scored 81%). The pre and post test scores difference was highly statistically significant ($p<0.0001$). See figure 1.

Figure 1: First pre and post test result



The average score for the second pre-test which was based on case studies was 48.1 ± 2.6 %. The scores ranged from 29% to 57% with 54% and 61% being the modal scores (3 persons each had this scores. The average of the post-test score was 65.3 ± 2.0% with scores ranging from 53% to 76%. The pre and post test scores difference was highly statistically significant ($p<0.0001$). See figure 2.

Figure 2: Second pre and post test result



S/N	CODE NO	2ND EVALUATION		1ST EVALUATION	
		PRE-TEST (%)	POST-TEST (%)	PRE-TEST (%)	POST-TEST (%)
1	UJOR	57	64	81	81
2	MAA	54	75	65	77
3	777	54	54	74	97
4	1436	54	53	84	81
5	AUGUST 1 BADAN	29	54	-	-
6	UUO	61	75	65	79
7	278	36	58	65	97
8	452	46	68		
9	2405	36	76	65	90
10	M19	36	64	84	83
11	UNO	61	65	61	71
12	8074	61	64	-	-
13	PRINCE	46	60	70	77
14	STAF 2	57	69	68	80
15	EXAM	43	71	-	-
16	706	39	75	-	-
17	Doyin	50	-	-	-
18	2866	36	-	-	-
19	072	-	71	-	81
20	EK	-	64	68	81
21		-	-	-	94
	OMFS	-	-	48	71
	10	-	-	68	77
	8074	-	-	81	87
	13	-	-	81	88
	ORALM	-	-	58	75
	452	-	-	61	94
	DOLAPO	-	-	61	71
	Average	**48.1**	**65.3**	**68.8**	**81.9**

4.2. Plenary session evaluation: All the sessions were highly rated. None of the sessions was rated fair or poor. Table 1 shows a summary of the evaluation of the plenary sessions.

Table 1: Evaluation of the plenary sessions

Item	Excellent (%)	Very good (%)	Good (%)	Fair (%)	Poor (%)
Plenary 1: History of ethics and research conduct	35	55	10	-	-
Plenary 2: Ethical principals and codes of conduct for research practices	44	50	6	-	-
Plenary 3: Research obligations for undergraduate and postgraduate medical and dental students	35	45	20	-	-
Plenary 4: Breaching ethical conduct of research: understanding the nuances	33	56	11	-	-

Plenary 5: A practical look at the field: what can we change	20	70	10	-	-
Plenary 6: Students training needs on ethics	29	47	24	-	-
Plenary 7: HIV prevention and treatment research: ethical obligations	29	62	10	-	-
Plenary 8: Understanding the terrain for conducting HIV prevention and treament research in Nigeria	32	63	5	-	-
Plenary 9: The ethics of clinical care and service provision for patients	45	50	5	-	-
Plenary 10: Where does clinical care meet research obligation: what does the National Ethics Code say	27	64	9	-	-
Plenary 11: Group work: breeching the ethical codes of care and service provision in Nigeria – experiences in the field	38	50	13	-	-
Plenary 12: Understanding care needs of PLWHIV and PLWA	42	58	-	-	-
Plenary 13: Understanding care needs of MSM, IDUs, male and female Sex workers	50	50	-	-	-
Plenary 14: Students training needs on ethics	41	47	12	-	-
Plenary 15: Women and health research	40	55	5	-	-
Plenary 16: Challenges of providing care and support in an ethical manner	35	55	10	-	-
Plenary 17: Identifying our roles in changing the current paradigm	33.3	53.3	13.3	-	-
Plenary 18: Function of the Ethics Committees and relevance to undergraduate and postgraduate research	40	55	5	-	-
Plenary 19: Review of the training slides	36	64	-	-	-
Plenary 20: How to integrate ethics into current training schedules	58	42	-	-	-
Plenary 21: How to develop a course on ethics for undergraduate and postgraduate medical and dental trainings	50	44.4	5.6	-	-
Plenary 22: Informed Consent	67	27	7	-	-

4.3 Facilitators' evaluation: Table 2 shows a summary of the evaluation of the resource persons. None of the resource persons were perceived to have performed poorly.

Table 2: Summary of the evaluation of resource persons

Facilitators	Excellent	Very good	Good	Fair	Poor
Olayide Akanni	42	50	5.3	2.7	-
Oliver Ezechi	54	44	3	-	-
Adebayo Adejumo	51	47	2	-	-
Dr Ademola Ajuwon	50	50	-	-	-
Dr Oyedeji	28	56	11	6	-
Morenike Ukpong					

4.4. Workshop evaluation: The training received high rating. Tables 3 and 4 is a summary of the evaluation of the workshop. None of the logistic issues were rated poor. The conduct of the workshop was rated very high.

Table 3: Summary evaluation of workshop logisitics

Item	Excellent (%)	Very good (%)	Good (%)	Fair (%)	Poor (%)
1. Publicity for the training	24	47	23	6	-
2. Communication with participants prior to arrival	41	41	12	6	-
3. Preparation of participants for the training prior to arrival	29	35	8	18	-
4. Feeding	35	47	12	6	-
5. Hospitality	53	41	6	-	-
6.Responsiveness to logistic challenges	53	29	18	-	-
7. Quality of the training	53	47	-	-	-
8. Training Materials	41	41	18	-	-
9. Networking opportunity	18	59	18	6	-

Table 4: Summary evaluation of the training conducted

Please indicate your agreement with the following statements:	Please circle one				
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
This Workshop provided me with new insights about research ethics and patient management.	92	8	-	-	-
Participating in this workshop was a good use of my time.	85	15	-	-	-
I will be able to apply the content of this Workshop to my everyday work.	69	31	-	-	-
I made new contacts which will be helpful in my everyday work or everyday life.	46	54	-	-	-
Overall, the facilitation style was effective.	62	38	-	-	-
There was adequate time allocated for informal discussions among workshop participants.	46	31	15	8	-
The Workshop was well-organized.	54	46	-	-	-

Suggest changes recommended to make this Workshop better

- Assignment on comparison of various regulations guideline for research ethics
- Some of the statement in the questionnaire and pretest need to be rephrased to avoid ambiguity
- Provide materials a day prior to the lectures to enable better participation and discussion of issues. Material should be collated and made into a booklet before the training
- Introduction of more vegetables and plant based diet
- Create more time for interaction and group work
- Increase workshop duration

4.5. **Use of knowledge and skill acquired:** There were 11 medical schools represented and 2 postgraduate colleges. None of the postgraduate colleges addresses biomedical ethics in the training course content. Of the 11 medical and dental undergraduate programmes, 6 schools do not

teach ethics as a course though in some cases, ethics was integrated as part of lecture contents. Three schools noted that ethics was taken as a course though exams in ethics were only written in two schools (OAU and LAUTECH). Two of the schools had disparity in responses as to whether the courses were taught or not (University of Lagos, Abia State University). All respondents identified ways by which the knowledge and skills acquired will be disseminated. This include sharing of outcome of the training with colleagues who could influence curriculum change, holding of seminars with colleagues on the subject matter, update of course content on ethics, development of a curriculum on ethics in the medical school.

Chapter 5: Impact Assessment Outcome

NHVMAS conducted a capacity building training for 23 persons who teach medical personnel on the ethics of HIV research and service provision between 21st and 23rd September 2010. NHVMAS developed teaching slides for use by the lecturers that addressed the minimal components of ethics of HIV research and service provision that would be taught to undergraduate and postgraduate students.

The evaluation was specifically designed to assess how participants had utilized the teaching slides, with the possibility of integrating ethics into the training curriculum of the medical personnel.

A sample of about 8 persons (25% of trained persons) were randomly selected using a simple random method - balloting.

A structured questionnaire was administered through telephone interview and face to face contact of each of the selected trainees. The interview evaluated how skills, knowledge and training slides acquired from the workshop have been used in the training of medical personnel in their respective institutions.

The evaluation equally assess (i) challenges faced with the use of the teaching slides (ii) recommendation for modification of future trainings (iii) recommendations on how to integrate ethics into the medical personnel training curriculum (iv) recommendations on how best to introduce the training to a larger population of teachers of medical students.

Participants were randomly selected from the Lagos University Teaching Hospital (LUTH)- Dr CN Asoegwu and Dr TO Odugbemi Ambrose Alli University Teaching Hospital-Dr SO Abah University of Maiduguri-Dr O James LAUTECH- Dr OO Odu, Abia State University Teaching Hospital- Dr O Ugochukwu and Osun State university Teaching Hospital-Dr Mrs EO Asekun-. Two of the respondents were female, while five were male.

1. RESULT

All of the respondents agreed to have participated in the programme. They learnt about the trainings from their colleges, their institutional ethics committees. One of the interviewee learnt about the training from the West African College of Medicine.

2a. Did you provide an official report or feedback about the workshop to any one: All the respondents provided verbal reports of the training to their colleagues. One however prepared a position paper for the institution. These feedbacks were most often, given at the departmental level. As noted by some of the respondents:

- *Yes we gave the information at the departmental level and incorporated ethics in the orientation programme taught to new clinical students.-**Dr SO Abah***
- *It was an informal report presented to the secretary general of the College of Medicine.- **Dr CN Asoegwu***
- *I gave feedback to the College Board on the training and as a position letter.- **Dr O Ugochukwu***
- *I gave feedback to the HOD- **Dr O James***
- *I gave feedback. A formal report was given to the provost- **Dr Odu***
- *I gave feedback to the college secretary who selected me for the workshop – **Dr Odugbemi***

2b. Do you find the training relevant to the work your institution does: All participants reported to have found the training very relevant.

- *Yes the training has being of benefit to me and at the departmental level for the post graduate students**.- Dr Asoegwu***
- *Yes very relevant as a lecturer and in my practice.- **Dr Odugbemi***
- *Yes we gave the information at the departmental level and incorporated ethics in the orientation programme taught to new clinical students.- **Dr Abah***
- *Yes it was very timely, because we had issues with ethics especially in terms of informed consent; we were not use to getting it from study participants. Also, we had no knowledge on that we needed to write proposals before you begin your research. We just pick a topic and commence writing. I also learnt about the ethics of medical research**.- Dr James***
- *Yes it was very relevant. In my department, we organise community health programmes for the medical students. The students are expected to write and submit a project. I have been able to use the skills for the students in guiding their research write-up and implementation of their projects especially with regards to informed consent. Even as a member of the ethics committee, the skills were used in the review of protocol.-**Dr Odu***

2c. Do you think the training has impacted on the training of medical personnel in your institution?

- *Yes it has. I pass the knowledge acquired to the resident doctors I train. I also use it for discussion during journal review and other activities for the residents. Consequently, the residents are also acquiring knowledge.* ***Dr Asoegwu***
- *Yes, we used it for the clinical undergraduate students to expand the scope of their curriculum to include medical ethics.* ***Dr Odu***
- *I think so, because we have expanded the scope and time we use to teach ethics to medical students.* ***Dr Abah***
- *I shared the slides with the members of the ethics committee.* ***Dr Ogochukwu***
- *We intend to use it next year during the various scheduled lectures for students –* ***Dr James***
- *It has personally enchanced my work and improved my skills.* ***Dr Odugbemi***

2d. Have you used the skills, knowledge and teaching slides gained from the workshop to produce any educational materials? (i.e lecture notes, seminar, workshops etc). If so, please explain in details and provide any documentation as possible.

- *I have not used it to produce educational materials, but I have made sure that my residents, especially those of them working on HIV read the materials that we got. I have also made plans to start a formal discussion next year on ethics in research and provision of service.* ***Dr Asoegwu***
- *We intend to use the slides for the incoming undergraduate clinical students, as ethics is to be introduced and taught to them next year.* ***Dr James***
- *We have incorporated some aspect of the slides given to us into our already existing slides Also, I have found the slides very useful in my personal work.* ***Dr Abah***
- *Yes I have used it for lecturing and also shared the slides with the ethics committee members.* ***Dr Ogochukwu***

2e. Are there other ways you have used the skills and the teaching slides shared with you: Majority of the of the respondents (75%) could not identify new ways to use the skills. Some however note they will find use for the slide next year.

- *No, but the slides will form some of the discussion to be initiated next year on service delivery and ethics.-****Dr Asoegwu***
- *Yes personally, it has enhanced my work. I have used to improve my proposal writing skills.-* ***Dr James***
- *Very much so in very many aspects* ***Dr Odu***
- *No, except for my personal use-* ***Dr Abah***

2f. Have you kept up to date on new developments in the field of ethics of HIV research and service provision since the workshop? If so, how? (I.e. listservs, internet, reading journals): All participants answered that the keep updated from the information they get from NHVMAS.

- *I get information from you and read them.* ***Dr Asoegwu***
- *Yes mostly from the information sent from NHVMAS-* ***Dr Odu***
- *Yes, a number of updates have been sent by NHVMAS and I have being reading them. Also, I read journals.-****Dr Abah***
- *Yes, a number of update mails have been sent by NHVMAS, although I have not gone for any other training****. Dr Ogochukwu.***
- *Yes, I read the mails from NHVMAS and also attended the lagos training. –****Dr James***
- *Yes, from mails sent to my email by NHVMAS.* ***Dr Odugbemi***

2g. Did you have challenges with the use of the teaching slides you received: None of the respondents reported having any any challenges with the slides. *As noted by one of the respondents, '... subsequently, case studied should be added to the curriculum'*

2h. Do you have suggestions for improving future trainings?

- *I think you did well especially with the collaboration with NPMCN. More of those collaborations will have a wider reach.-* ***Dr Asoegwu***
- *Through institutional / hospital based partnerships.-* ***Dr Ogochukwu***
- *Through other bodies like MDCN and NMA. These bodies will be able to reach a larger audience; since they are the recognised associations that ahve continues education programmes.* ***Dr Abah***
- *You can conduct the training in an institution, which will have a wider reach.-* ***Dr Odugbemi****.*
- *To me, the best approach will be to conduct collaborative trainings on regional basis.* ***Dr James***
- *In collaboration with other institutions in states or on a regional basis, resource persons can come from those you have trained that are in the institution or in the region.-* ***Dr Odu***

2i. Do you have suggestions on how to introduce training to a larger population of teachers of medical personnel?

- *Decentralize the training and collaborate with other bodies.- Dr James*
- *Make the certificate have CPD numbers and people will come as long as the cost is affordable.* ***Dr Asoegwu***
- *Collaborate with other bodies like MDCN and NMA. These bodies will be able to reach a larger audience since they are the recognised associations that have continues education programmes.-* ***Dr Abah****.*
- *Conduct it within and institution. Dr Odugbemi.*
- *Through institutional/hospital based partnerships you will reach a wider audience–****Dr Ogochukwu.***

2j. Do you have recommendations on how to integrate ethics into the medical personnel training curriculum

- *It should be adopted to the medical schools through the Head of Departments. You can target them for your next training and then they can move the agenda for including ethics in the curriculum of students.-* ***Dr Asoegwu***
- *Based on what we adopted as teachers at the Ibadan training, students should be taught and tested on ethics in medical practice.- Dr James.*
- *This can be done through the community health department of medical institutions and through the course on ethics during the orientation of medical students.-* ***Dr Abah***
- *This can be done through putting up a position paper through the Deans to the College Boards and through the community health department because students are questioned on ethics. Meanwhile, lecturers also need trainings on it****.- Dr Ogochukwu***
- *All the suggestions we gave at the training ie advocacy visits to National Medical Association, Medical and Dental Council of Nigeria*. **– Dr Odu**
- *Collaboration with the community health department, since medical students do projects during their postings in this department.-* ***Dr Odugbemi****.*

2k. Are there other things you would like to share with us in general?

- *I think you have done well. People have talked about the one you did in collaboration with NPCMN. Also I think the opportunity you gave us should be extended to others.-* ***Dr Asoegwu***
- *I did not know that the workshop would have been this meaningful and useful. It has really enhanced my work and that of the department.-* ***Dr Abah***
- *This training is really useful. It could be conducted for not only doctors but also lecturers in the university that teach students ethics****.- Dr Ogochukwu***
- *You are doing a good job. We are motivated by your activities to increase the knowledge of teachers and researchers on issues in medical ethics.-* ***Dr Odu***
- *You are doing a good work; especially on the ethics of medical research-* ***Dr James***
- *The training was very impactful and increased knowledge appreciably. Keep it up.-* ***Dr Odugbemi.***

CONCLUSION

The outcome of the impact of the training on the sampled participants show quite clearly that a 100% of the trainees had made good use of the training.

- Knowledge and skills acquired had been used to improve on the training and practice of ethics in the medical schools, undergraduate and postgraduate residents' training. There are evidence of ethics being introduced into medical and dental schools training curriculum.
- The CDs developed have been found useful by many of the trainees as there is evidence of the slides being used for multiple purposes including the teaching of students and personal updates.
- The updates provided by NHVMAS through its listserv training have been found useful by the trainees as this remain the main source of update for up to 100% of the respondents.
- There were no challenges with the use of the slides or the knowledge and skills acquired from the training.
- Respondents proposed that efforts should be made by NHVMAS to expand the training to others through collaboration with institutions such as the MDCN, Medical

Appendices

Appendix 1:

COMMUNIQUE ISSUED AT THE END OF THE WORKSHOP FOR TRAINING OF TEACHERS OF ETHICS FOR UNDERGRADUATE AND POTSGRADUATE MEDICAL AND DENTAL STUDETS/DOCTORS ORGANIZED BY THE NHVMAS AT THE DEVELOPMENT SUPPORT CENTRE, IYAGANKU IBADAN 20TH TO 24TH SEPTEMBER 2010

Introduction

Between 21st and 23rd of September, 2010, 21 Medical professionals and teachers drawn from 13 medical schools across the country, the West African Postgraduate Medical College and the National Postgraduate Medical College gathered in Ibadan, Oyo State at a three- day training of Teachers on Ethics workshop convened by the New HIV Vaccines and Microbicides Advocacy Society (NHVMAS) with support of SIDACTION.

Participants attending the workshop deliberated extensively on the current situation in medical and dental schools both at the undergraduate and postgraduate levels focusing on the quality, content and implementation of ethics training in the health institutions in Nigeria. Following their deliberations, the participants came up with the following recommendations as part of their communiqué:

Preamble

Recognising that the increasing international collaborative research in Nigeria, including clinical trials, requires knowledge of good ethical considerations and good clinical practice by Investigators/researchers, there is urgent need to address the current deficit in ethics training at both the undergraduate and postgraduate levels.

Specifically for undergraduate medical/dental students, the medical professionals recommend the following:

1. Ethics of medical practice and biomedical research ethics should be included as part of the curriculum of undergraduate medical education.
2. Ethics of medical practice should be taught to medical students at the inception of clinical training.
3. Health Research ethics should be taught to medical students at the beginning of research project training.
4. The Medical and Dental Council of Nigeria (MDCN) guidelines and other laws guiding ethical practice in Nigeria should be included in the curriculum.
5. The Hippocratic oath should also be taught to students before their graduation.
6. The content of the undergraduate ethics curriculum should include basic principle and concepts of research/Clinical ethics and should be emphasised so that medical students have thorough understanding and broad/ in-depth knowledge of clinical/research ethics. Students should be equipped with adequate knowledge to carry out basic research and practice clinical medicine ethically.

Recommended topics for inclusion in the undergraduate medical ethics curriculum are:

- Introduction to clinical and Research ethics History, Principles, Ethical misconduct, National and International codes in ethics, Patient bill of rights, Confidentiality, Conflict of interest

- Doctor patient relationship, doctor-doctor relationship (doctor's relationship with senior and junior colleagues including medical students) and doctors relationship with other paramedical staff
- Patient education, informed consent, Hippocratic oath
- Consequences of unethical practice - legal implications of misconduct (medical jurisprudence)
- The roles and functions of Health Research Ethics Committee - composition, functions.
- Biomedical Research ethics, proposal writing and writing for grants - ethical considerations in research proposals

Recognizing that the postgraduate students (irrespective of their level; MSc, PhD, Residency) ultimately get involved in research in the course of their training, it is important therefore to introduce and teach health research ethics and research methodology courses early in their programs to enable them imbibe the culture and ethics of research before setting out with design of research protocols.

For postgraduate medical/dental students, the medical professionals recommend the following:

- That Medical and Research ethics courses should be introduced as a separate course and mandatory pre Part 1 (residency) or before final examinations (Masters/PhD).
- The timing should be as follows:
    - Residency: Within the first year of their residency training
    - MSc/PhD: During the first semester
- The Course content should include the following:
    - Medical Ethics (as a separate course)
    - Health Care Ethics
    - Organizational/ Institutional Ethics
    - Biomedical Research Ethics

In addition, the Research methodology course presently organized by the National Postgraduate Medical College should include introductory parts and overview of Biomedical Research Ethics.

Signed by XXXX (State the names), (the members of The Communiqué drafting team) on behalf of Workshop participants

Appendix 2:

Pre and Post Test Questionnaire 1

Training workshop on ethics in research and Clinical Care

Directions for Completing this Questionnaire

Please select an identification number, symbols etc, and insert this in the space provided. Please not the same identifier should be used each time the questionnaire is completed.

Date _____ Identification number_____

1. Faculty _____ 2. Specialty _____
3. Highest professional/academic qualifications
    1. MSc.
    2. PhD
    3. MBBS
    4. FNCP, FWCP, FNCPH
    5. Others please specify_____
4. Have you ever attended any training program on research ethics?
    1. Yes 2. No
5. List the three most important ethical considerations in any research project involving human participants?
    1_____
    2_____
    3_____
6. List any three international guidelines or regulations that are supposed to guide the conduct of any research involving human participants?
    1_____
    2_____
    3_____

7. Which of the following statement is "True" or "False" about research ethics?

	True (1)	**False (2)**
1. Only research funded by an external agency should be submitted to the Ethical Review Committee for consideration.		
2. Once they are enrolled, participants in a research cannot withdraw from the study without prior approval or agreement from the principal investigator.		
3. The information in a consent form must be presented in a manner that is comprehensible to the research participants.		
4. Approvals from an Ethical Review Committee are for the duration of the		

research.		
5. It is the responsibility of the researcher to develop a scientifically sound research protocol.		
6. The main function of an Ethical Review Committee is to ensure the protection of participants who volunteer to take part in a research.		

Please write out in the space provided the principle of research ethics that best defines each of the following statements

8. The capacity and rights of all potential Nigerian research participants to make their own decision must be respected by the investigator _____

9. The special needs of vulnerable populations such as prisoners and children must be protected at all times _____

10. The protection of the Nigerian research participants is more important than the pursuit of new Knowledge by scientists' _____

11. It is the responsibility of researchers to maximize benefit and minimize risk of all persons who take part in a research _____

12. All segments of the Nigerian population must be fairly selected as participants in any research project _____

13. The use of poor Nigerian research participants for the exclusive benefit of more privileged Nigerians should be discouraged _____

14. Nigerian investigators have the responsibility of ensuring the physical, mental and social well-being of all Nigerians who volunteer to take part in any research project. _____

Please read the short stories below and answer the questions that follow.

Case study One: Professor Age Madral, a renowned dermatologist in a Nigerian University, owns a large stock in ABC Drug Manufacturing Company. He is approached by ABC to conduct a study to test the efficacy of a new drug for the cure of melanonia, a type of skin disease. Madral is expected to recruit patients from his clinic into the study. Madral is excited about this study because the drug offers new hope of effective treatment for treating many of his patients with melanonia. The company is offering N2,000 for each patient recruited in the study and a handsome honorarium to Madral for using his patients for the study. Madral agrees to collaborate and begins recruiting of patients for the study.

15. What type of ethics concerns exists in this study? (Please circle all that apply)

1. That Madral has a conflict of interest.
2. The study was not reviewed by an ethics review committee.

3. The amount paid to patients is acceptable or adequate.
4. All of the above

16. Which of the following statements do you "agree" or "disagree" with

	Agree (1)	**Disagree (2)**
1. Patients recruited into this study will definitely benefit from the new drug.		
2. Patients who participated in this study will definitely have access to the drug if it proven to be effective.		
3. The amount being paid to participants as compensation is acceptable or adequate.		
4. Madral may experience some tension between his interests as a scientists and his interest as a share holder in the company that sponsored the research.		

Case Study Two: A consultant physician in a local teaching hospital is interested in studying the prevalence of sexually transmitted infections (STI) among female sex workers in Moroka town. He has identified three brothels in which his potential research participants are located. He contacted the managers of each hotel as well as the landlady (the leaders) of the sex workers and obtained approval to conduct the study. Participants in this study will be tested for 3 common STI and interviewed about their sexual behavior. Blood will be drawn and physical examination performed. He provided free STI treatment for affected women at the hospital's STD clinic and paid N100 compensation for inconvenience and lost time. At the commencement of the study the manager summoned a general meeting of all sex workers and requested all of them to cooperate with the researchers. Although some of the women were initially reluctant to participate they agreed later because of the fear that the manager may sanction those who refuse to enroll in the study. The physician completed the study, published his findings and never returned to the hotel.

17. Which of the following statements are "True" or "False" about this study?

	True (1)	**False (2)**
1. The women provided completely voluntary consent consented to participate in the study**.**		
2. The payment of N100 was acceptable /appropriate as compensation for participation in the study.		
3. The investigator provided adequate feedback to the research participants.		
4. The researcher protected the safety of research participants in all ways.		
5. The women who participated in this study were not exposed to any risk.		

Appendix 3:

Pre and Post Test Questionnaire 2

Training of teachers of medical and dental student on the ethics of HIV Care and Service Provision
Development Support Centre, Iyaganku, Ibadan
20th to 24th September, 2010

Questionnaire

Please complete this questionnaire before the workshop. It should take you no longer than 15 minutes to complete. Your feedback will help us evaluate the workshop and inform future planning to advance our work on new prevention technologies. Your responses will be anonymous and confidential.

In order for us to match your pre-assessment and post-assessment, please provide us with a **code word** that you will use after the workshop.

CODE WORD:

1. Informed consent is important because

a) It enables understanding of vital information on the proposed trial
b) It provides the participant will all the information regarding remote risks
c) It enables the investigator to recruit participants of his choice
d) It promotes clinical research and paternistic care

2. Informed consent refers to:

a) Principle of autonomy
b) Voluntary but uninformed decision-making
c) A voluntary decision to participate in research, by a competent individual who has received and understood the necessary information
d) Permission to participate in research

3. The following are HIV Prevention related priorities in Nigeria except:

a) Preventon of mother to child transmission of HIV infection
b) Biomedical tansmission of HIV
c) Promotion of appropriate use of male and female condoms and lubrication
d) Male Circumcision

4. Which of following groups do not fall under the vulnerable groups diesciption in HIV research

a) Men who have sex with men
b) Prisoners
c) Care providers
d) People living with HIV

5. The following are the reasons for excluding women from health research except:

a) IrB policies supports protection of women, children anmd other vulnerable groups to the extent of excluding women in health research
b) Paternalism or protectionist stance
c) Women's reproductive cycle affect test results and male the research more complex
d) research on 'pregnable' women may affect the woman's reproductive capabilities
e) None of the above

6.The ethical dilemma in providing care and support in health research include:

a) Who determines the standard
b) difficulty in evidence on what is the best proven standard
c) Funding capacity – sponsors/Donors
d) For how long and who should bear the burden
e) All of the above

7. An unintended disclosure of a subject's HIV status could result in the subject's loss of employment or health insurance coverage not necessarily because

a) Confidentiality can be compromised through an unauthorized release of data, which could have a negative impact on the subjects' psychological, social, or economic status. For example:
b) release of sensitive information could erode patient's sense of security, self esteem and pride which could affect the patient's socio-psychological security
c) Patient's personal information and identifiers need to be guarded, not only for the patient's sake, but that of the family, and society
d) Insurance coverage and premiun is all about the undisclosed and latent personal and health risks.

8. A survey in which no identifiers are collected, and that are thus exempt from the remaining provisions of the regulations, such as the requirement for continuing review could be regarded as

a) low risk
b) moderate risk
c) high risk
d) no risk

9. What gives ethical validity to the procurement informed consent?

a) Detailed documentation of the process
b) Capacity of the participant to consent
c) Quality of the disclosed information
d) Quality of the interaction between the prospective participant and the recruiting physician/investigator

10. Which set of the following information need not be disclosed to a prospective participant to procure informed consent?

a) All the possible risks associated with participation; possibility of active deception by the investigators; confirmation that the study has an ethics review committee's approval
b) That the study involves research; sources of funding; anticipated benefits and potential risks
c) The discomfort that may be associated with participation; the right to withdraw from participation at any stage without reprisals; institutional affiliations of the researcher
d) Aims of the trial; methods to be used in the trial; possible conflicts of interest

11. Which set does not represent vital elements of informed consent?

a) Capacity to consent; voluntary decision to participate; adequate comprehension of the provided information
b) Ability to withdraw from the trial without reprisals; full comprehension of the provided information; documentation of informed consent
c) Full disclosure of relevant information; capacity to consent; voluntary decision to participate
d) Adequate comprehension of the provided information; capacity to consent; voluntary decision to withdraw from the trial at any stage

12. When is active deception of prospective participants and patients necessary?
a) Never
b) When no other method suffices
c) When deemed indispensable
d) For security reasons

13. Can the requirement for informed consent be waived?
a) Yes, at the discretion of the investigator
b) No, unless a designated ethics review committee approves
c) Never
d) Yes, with the consent of the participant

14. Who cannot consent to trial participation in Nigeria?
a) Healthy but poverty stricken volunteers
b) Healthy volunteers below the age of 18
c) Mentally stable but sick adults
d) Medical students

14. When is assent mandatory in procuring informed consent?
a) When the prospective participant is a minor
b) When the prospective participant is unconscious
c) When the prospective participant has a mental disability
d) When the prospective participant is a mature minor who is capable of making appropriate decisions about trial participation

15. Who gives consent in cases of minors who have no parents or guardians?
a) Consent can be waived, as it is not necessary
b) Nobody
c) A social worker
d) Legal guardians

16. Vulnerable populations are those best characterised as:
a) relatively poor persons
b) persons experiencing emotional distress
c) non-citizen residents of a foreign country
d) persons who stand in severely unequal power relationships with others
e) persons who are mentally incompetent

17. Research involving vulnerable populations must always:
a) leave the participants better off than they were before
b) address questions that cannot be answered by conducting research on other, non-vulnerable populations
c) follow local standards of care
d) involve participants residing in developing world countries
e) secure informed consent (directly or by proxy) from research participants

18. The following documents must be made available to the REC for review prior to trial approval:
a) trial protocol

b) written informed consent forms
c) information on serious adverse events from the Data Safety and Monitoring Board (F)
d) declaration of conflict of interest of the researcher where appropriate
e) participant recruitment procedures

19. Please answer these questions by placing 'True' or 'False' to the following questions
a) Which of these is not a principle of research ethics?
b) Respect for persons who participate in a research
c) Maximizing the benefits and minimizing the risks involved in a health research
d) Maintaining the confidentiality of a manuscript sent to a reviewer
e) Putting measures in place to protect the safety of vulnerable populations from exploitation
f) Ensuring that all persons involved in writing a manuscript are listed as authors of a paper

20. Which of these issues are not relevant for consideration by an Ethics Review Committee when reviewing a proposal for research

a) The procedures for recruiting research participants
b) The sample size for the study
c) The qualifications of the investigators
d) The process of receiving informed consent from potential and actual respondents
e) The plans for publishing the results for the study

1. Please provide us with some feedback on your experience of the Workshop:

Please indicate your agreement with the following statements:	**Please circle one**				
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
This Workshop provided me with new insights about research ethics and patient management.	5	4	3	2	1
Participating in this workshop was a good use of my time.	5	4	3	2	1
I will be able to apply the content of this Workshop to my everyday work.	5	4	3	2	1
I made new contacts which will be helpful in my everyday work or everyday life.	5	4	3	2	1
Overall, the facilitation style was effective.	5	4	3	2	1
There was adequate time allocated for informal discussions among workshop participants.	5	4	3	2	1
The Workshop was well-organized.	5	4	3	2	1

f) What changes would you recommend to make this Workshop better?

_____

_____

Any other comments?

_____

_____

Training of teachers of medical and dental student on the ethics of HIV Care and Service Provision
Development Support Centre, Iyaganku, Ibadan
20th September, 2010

Baseline and Post Training Evaluation Questionnaire

Please complete this questionnaire before the workshop. It should take you no longer than 1o minutes to complete. This is a baseline evaluation tool to help us assess the impact of the workshop on the impact of the training on teaching of biomedical ethics in medical and dental schools.

NAME:

MEDICAL/DENTAL SCHOOL:

1. **Does your school currently teach ethics formally as part of the student curriculum?**

2. **Do your students currently write examinations on biomedical ethics?**

3. **Is ethics integrated as a lecture in any of the courses being undertaken by students in your medical or dental school?**

4. **Do you teach ethics either as a course or as part of a lecture schedule to students?**

5. **Do you currently teach ethics to students in your medical or dental school?**

6. **Do you have the ability to inform curriculum content in your medical or dental school?**

7. **What are your plans with respect to the teaching of ethics in your medical or dental school?**

8. **How do you plan to make use of the lessons learnt from this workshop for the training of medical and dental undergraduate and postgraduate students?**

Participants at the Training of teachers of ethics training workshop, organised by NHVMAS, Ibadan. 20th to 24th September, 2010

	Name	Address	Email address	Phone number
1	SO Abah	Ambrose Alli University, Ekpoma	drsteveabah@yahoo.co.uk	08030647837
2	UM Agwu	EBSUTH, Abakaliki	vehgorsafeway@yahoo.com	08033037685
3	OUJ Umeora	EBSUTH, Abakaliki	oujair@yahoo.com	08039558074
4	Dr O James	University of Maiduguri	olutayo.james@gmail.com	07031271542
5	Dr Adesina O Adewale	University of Maiduguri	femmyadesina2000@yahoo.com	08035842203
6	Dr MR Akpa	UPTH, Port Harcourt	akpamac@yahoo.com	08083770898
7	Dr DC Dolapo	LUTH, Lagos	durodolapo@yahoo.com	08068923215
8	Dr UN Onwuchekwa	ABSUTH, Abia	unonwards@yahoo.com	08033171861
9	Dr TO Odugbemi	LUTH, Lagos	tomiodugbemi@yahoo.com	08037127858
10	Dr Olowo Samuel	Ambrose Alli University, Ekpoma	olowosamuel2003@yahoo.com	08034705278
11	Dr OO Odu	LAUTECH, Osogbo	borbordoc2@yahoo.com	08030784188
12	Dr Onyeonoro Ugochukwu	ABSUTH, Aba	hugouche@yahoo.com	08038726960
13	Dr CN Asoegwu	LUTH, Lagos	drnkiruasoegwu@yahoo.com	08037162405
14	Dr AO Dosunmu	LASUTH, Lagos	doyin_dosunmu@yahoo.com	08023369785
15	Dr A Gbadegesin	LASUCOM, Ikeja	gbade2000@yahoo.com	08023039807
16	Dr AI Olugbenga-Bello	LAUTECH, Osogbo	nike_bello@yahoo.com	08033839282
17	Dr Belonwu RO	AKTH, Kano	raybeloo@yahoo.com	08023040452
18	Dr Adedigba MA	OAU, Ife	ademich2002@yahoo.com	08037149761
19	Dr Abiodun Arigbede	UPTH,	arisabbey@yahoo.ca	07055736436
20	Dr (Mrs) EO Asekun-Olarinmoye	Osun State University	estoaskol@yahoo.com	08033602184
21	Dr O Okezie Kanu	LUTH, Lagos	daddykay143@gmail.com	08068918462
22	Dr Demola Ajuwon	UI, Ibadan	ajajuwon@yahoo.com	08034892561
23	Dr Oliver Ezechi	NIMR, Lagos	oliverezechi@yahoo.co.uk	08033065683
24	Dr Kola Oyedeji	NIMR, Lagos	kolaremi95@yahoo.com	08025187261
25	Dr Bayo Adejumo	UI, Ibadan	bisibayo@yahoo.com	08034919222
26	Olayide Akanni	JAAIDS/NHVMAS	olayide@gmail.com	
27	Morenike Ukpong	NHVMAS	toyinukpong@yahoo.co.uk	01-8195355
28	Aisha Adaranijo	NHVMAS	aishatuabdullahi@yahoo.com	08033738087
29	Florita Durueke	NHVMAS	chichiflorita@yahoo.com	08056445676
30	Augustina Amumuziam	NHVMAS	obyamuziam@yahoo.com	08032059188

Certificate of Completion

This is to certify that

XXXXX

Successfully completed a 3 day Training of Teachers of Medical and Dental Students

by

New HIV Vaccine & Microbicide Advocacy Society (NHVMAS)

On

The Ethics of HIV Care & Service Provision

With funding support from

SIDACTION France

@

Development Support Centre, Ibadan, Nigeria

.....

Dr. Morenike Ukpong

.....

Ms. Olayide Akanni