Contents

1. Letter from the Chief Editor pg 3

2. A Word from the Director KEMRI pg 4

3 Research Ethics Committee and Hospital Ethics Committee: What is the Difference pg 5

4. A Human Heart in Clinical Practice pg 8

5. H3 Africa pg 9

7. Case challenge pg 10
Welcome to our second issue of 2016 on Clinical Ethics. In this issue we feature two articles on ethical issues within the clinical setting. One article focuses on the distinction between Hospital Ethics Committee and Research Ethics Committee. The second article is titled ‘human heart in clinical practice’; it briefly highlights some of the ethical dilemmas caused by health workers strikes. We also highlight some facts about the Human Heredity and Health (H3) in Africa project. Lastly, we provide an opportunity for our readers to participate and win on the ethics case challenge.

Clinical ethics is important as a basis for decision making in the medical profession; its significance is further reinforced by the importance attached to human life and the rising instances of medical litigation. Clinical ethics should therefore constitute everyday work in the clinical profession.

Technology has permeated every aspect of humanity, clinical sector included; in this day and age, telemedicine services like Sema doc have been embraced with ease thanks to the comfortable access of mobile devices. The roll out services such as doctors on call and the penetration of high speed internet on mobile devices have led to some patients consulting Google doctor based on symptoms before visiting the hospitals. As patients turn to technology to get answers to their medical problems, the dilemma is that these web sourced information may not be authentic; the pros and cons may not have been fully analyzed hence leading to misinformation. Similarly, trying to reach a consensus may eventually deny your client a more effective intervention. All this change in landscape has presented new challenges, dilemmas and opportunities to doctors in dealing with their ‘Medically Educated’ clients. However the enlightenment of patients has not been merged with proper development of clinical ethics and this leaves practitioners vulnerable because they face dilemmas in handling some patients.

Efforts towards improvement of ethical practice in Kenya have been focused mainly on research ethics, consequently enormous improvements have been made in building capacity and developing ethical guidelines in research ethics. These efforts have born fruits in supporting ethical conduct in medical research. The clinical ethics aspect has however not received as much attention it deserves. The current training of Clinical ethics in medical schools and other allied clinical health care training facilities may be insufficient to prepare young doctors and health care workers for practice in the real and very modern technological world. It may be important for regulators, practitioners and other stakeholders to come together to find ways of promoting ethical and reflective practice and ensuring healthcare practitioners are equipped in making of “right” choices and decisions in the delivery of health.

In the wake of information overload that threatens to compromise effective delivery of treatment, the main area of focus to start with is on principle based frameworks for ethical decision making in clinical setting. Training that is holistic and allows not only teaching by mentoring but also via example will enable newly graduating doctors and other health care workers effectively compare the aims of treatment, the available alternatives and the consequences of each alternative against the an existing code of conduct of ’doing no harm’ to the patient and seeking the best interest of the patient at all times. An appropriate framework for decision making will go a long way in ensuring doctors and other health care workers articulate their decisions to patients, learn and practice good communication skills and implement a treatment plan in way that is ethical and effective to the benefit of their patients.

Dr Evans Amukoye
Ag DDRD and Editor in Chief.
Welcome to this issue on Clinical Ethics. Clinical Ethics is the process used by healthcare professionals to evaluate, decide and justify right or wrong, good or evil in clinical practice. Clinical ethics forms an important component of our healthcare system. Research ethics in Kenya is already well developed but more remains to be done in ensuring that all levels of healthcare have formal and informal provisions to support health professionals on ethical issues arising from their clinical practice.

There is evidence to suggest that health professionals have limited access to ethics and legal advice, given the number of litigations involving suspected cases of negligence in our hospitals. While there is also evidence that more resources and efforts have been directed towards improvement of ethics in research through NACOSTI and other initiatives, clinical ethics has received less attention, and therefore, more needs to be done in the health sector, especially in regards to building clinical ethics capacity in Kenyan health care institutions.

Ethical misconduct in a healthcare setting usually leads to public scrutiny and most likely negative perception with adverse consequences in a healthcare system. The establishment of a Hospital Ethics Committee is essential in resolving unusual, complicated ethical problems involving issues that affect the care and treatment of patients within health care institutions. It is essential therefore, for the National and County Government bodies responsible for health to work together with the professional regulatory bodies to widely disseminate and entrench clear health sector regulatory ethics standards, and implement measures geared towards improvement of clinical ethics in the country. This may include but not limited to the establishment of Hospital Ethics Committees to deal with ethical dilemmas in the clinical setting, and appropriate training for those serving on such Committees. Hospital Ethics Committees will support the doctors and families of those concerned to make decisions based on sound ethics and peer support, and therefore, contribute to patient safety.

KEMRI has been instrumental in the development of bioethics in Kenya, and has indeed, contributed significantly to the improvement of research ethics in the country. The Institute is, in a position, and ready to contribute through research and policy development towards establishment and strengthening of clinical ethics as a core part of health systems support.
The sun! The moon! In retrospect, I remember the days my kindergarten teacher would ask me to draw a sun and a moon. Using my pencil which sometimes, unconsciously was my chewing stick, I drew a circle with protruding arrows and named it the sun. I drew an ovum with dull coloring and named the moon. The drawing gave a vivid distinction to this young innocent boy of what the sun and the moon were. Growing up contentiously and with a lot of curiosity, I came to know that the real difference between the sun and the moon was in two critical factors: that the moon is visible at night while the sun is visible during the day. And secondly on the actual source of the light that they emit, whether they are a source, or if they are reflective of light from a source. Well, for those who have not been blind folded for their entire life or those who have the gift of sight would likely have seen the sun and the moon share a day.

Taking you back in time as I am reminiscent about my childhood, I am reminded about the visibility of both the sun and the moon in a day- solar eclipse. This sets the stage for my discussion on the difference between, Research Ethics Committees and Hospital Ethics Committees. Just like the sun and the moon, Research Ethics Committee (RECs) and Hospital Ethics Committee (HECs) share a liaison which requires a bit of explanation. Like the sun and moon each has a distinct function and a responsibility to ‘shed light’ on ethical dilemmas in their specific fields. But the argument will not be on who intrinsically emanates light and heat and which it is that reflects it. The analogy is just to reflect the importance of each in their spheres of jurisdiction.

Definition and Historical Background
Ethics literally means right, but in expanded view it means more; as conduct it requires acting in the spot-on spirit, respect and concern for one’s fellow beings. Narrowing down, research ethics, and in particular involving human beings and that which involves all life sciences is collectively known as bioethics. The distinction between ethics in research and clinical ethics is that, ethics of research regulates the systematic and planned investigation which involves human subjects or in other words ‘research for health’, while ethics practiced in hospitals provides moral guidance for the ethical dilemmas that occur within the health care – primarily with regards to known medical practices in the provision of health care.

Earlier in the 1900s, there were no regulations regarding the ethical use of human as subjects for clinical practice or in the conduct of biomedical research. This lack of oversight and regulation provided an enabling environment for many macabre research practices and medical experiments exemplified during World War II and highlighted in the public sphere by examples of experimentation carried out by the Nazi doctors in German concentration camps. Examples given of such experiments included forcing prisoners to drink seawater to establish whether a man can survive without fresh water. After the end of World WAR II, investigations unearthed many unethical practices by many of the armies on the prisoners of war (not only the German forces) and led to recommendations for development of ethical guidelines or regulations for the conduct of biomedical research.

The first guidelines developed after WWII were the Nuremberg code, then followed the Declaration of Hel-
Hospital ethics committee is crucial for any hospital seeking international accreditation by Joint Commission International. The Joint Commission International accreditation Standards for Hospitals under the Governance, Leadership, and Direction section requires that before accreditation, a hospital leadership establishes a framework for ethical management that promotes a culture of ethical practices and decision making, addresses operational and business issues and professional conflicts that may not be in patients' best interests and ethical issues and decision making in clinical care. For hospitals that conduct research involving human subjects, the accreditation standards make it mandatory for the hospital to set up a committee or another way to oversee all research in the hospital involving human subjects.

The size of HECs should be consistent with the needs of the health institution but not so large as to be unwieldy (www.ama-assn.org/ama/pub/physician-resources/medical-ethics). The composition of HECs should be made up of members selected on the basis of their concern for the welfare of the sick and infirm, their interest in ethical matters, and their reputation in the community and among their peers for integrity and mature judgment. A crucial consideration is usually given to the experienced members of hospital or medical society committees concerned with ethical conduct or quality assurance. Preferably, for HECs the majority members should comprise of physicians, nurses, and other health care providers.

**Research Ethics Committee**

The responsibility of the Research ethics committees have been defined and refined over the last 60 years after the World War II. The mandate and composition are clearly defined in the Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance. RECs review a wide range of research, including research that falls into one or more of the following categories:

1. Clinical trials of investigational medicinal products research involving medical devices.
2. Research involving children, pregnant women and research involving prisoners or the vulnerable groups.
3. Research involving vulnerable populations including adults lacking capacity to give informed consent.
4. Establishment of research tissue banks.
5. Establishment of research databases, and in the more recent years, researches involving genetics and other complex biomedical concerns which include not just an individual but also communities. (www.hra.nhs.uk/about-the-hra/our-committees/research-ethics-committees-recs).

In reflection, while the HECs main concern is particular patients' welfare and what is in their best interest, RECs beneficiaries include a large group research participants, pharmaceutical and medical device companies; healthcare professionals; aca-
demic researchers, including students. HECs are defined within hospitals or health care facilities while REC can be found within any institution of higher learning or a research institution including but not limited to learning institutions like the universities.

In order to properly review a research proposal, REC members must be pooled from diverse backgrounds to allow them evaluate the many facets of a proposal under review. It is therefore mandatory that REC members be trained in research ethics and must be multidisciplinary as defined in international codes of regulation for research. The members should be of diverse cultural and gender background and willing to volunteer. It is noteworthy it is requirement for appropriately constituted REC to have a lay representative who is not of scientific background and who preferably represents the community. Hospital ethics committees are in contrast largely populated by clinical care givers and with some representation of ethicists, lawyers and hospital administration.

Just like the illustration above, even where the sun and moon may appear at the same time, but their responsibilities and functions are very different. HEC and REC have distinct and important roles to play in the modern world of biomedical research and health care provision.

Further Reading

I want you to imagine a system where doctors, nurses, public health officers, lab technologists and all the health care providers never go on strike. A scenario where patients’ views are respected and their rights always protected; a system devoid of rules and directives governing the same and where patients’ feelings and needs are put into consideration before all other serious medical decisions are made.

Many a times there have been instances of damages and even avoidable deaths of patients reported at the various health facilities in the country. Among the many causes of these deaths is negligence by some care providers. However, this remains a contentious issue with the physicians attributing the loss of life to poor working conditions, insufficient facilities and poor remuneration/motivation among others hence the question on who should be held responsible remains a puzzle. Should a physician remain adamant and watch a life get lost since he/she has not been paid their dues? Should the patients be allowed to harbor more pain just because they cannot afford the cost for medication? I rest that upon to you to ponder.

It is a fact our health system is not in good shape when it comes to working conditions of the physicians which affects their practice and this has led to some opting to quit working in public health facilities and focus on private practice. It’s not bad to have private practice but a majority of Kenyans cannot even afford decent meals and so what about quality care? The ratio of patients to physicians is not that good and so the need for the government to invest more in not only training the physicians but also ensuring they are well supported to execute their mandates. In securing a healthy nation, all the stakeholders should play their part so that we synergize our efforts. This fight for better health calls for sacrifice by all the parties involved be they policy makers, practitioners, the community and all sectors of the economy.

All that aside even as the physicians handle the patients, are they given the same treatment when it comes to important aspects like mutual respect, honesty, trustworthiness, compassion? Are our leaders in the health sector committed to pursue shared goals by the physicians of ensuring we secure our people better health?. As you know the practice of good clinical medicine requires some working knowledge about ethical issues such as informed consent, truth-telling, confidentiality, end-of-life care, pain relief, and patient rights. One important thing to note is that there are serious decisions that have to be made and so this knowledge informs how sound the final decision could be.

Have we had our minds clouded by quests for personal job satisfaction at the expense of quality ethical services? Is your institution having in place measures to equip the service providers with knowledge on good clinical ethics? It is time focus was shifted on ensuring that the medical service providers rediscover that they are not only pursuing a profession but that the profession they are in is a calling which requires selfless and a virtuous heart that puts the common good before self.

By Austin Odiwuor
ARO, SERU

A HUMAN HEART IN CLINICAL PRACTICE
(SPEAKING FROM THE HEART)
What is H3 AFRICA?
H3 Africa stands for Human Heredity and Health in Africa. It is an initiative of the US National Institutes of Health, Welcome Trust together with senior scientist in Africa. This initiative was launched in 2010 to fund population-based genetic studies in Africa.

Vision
H3 Africa vision is to create and support a pan-continental network of laboratories that will be equipped to apply leading-edge research to the study of the complex interplay between environmental and genetic factors which determines disease susceptibility and drug responses in African populations. Data generated from this effort will inform strategies to address health inequity and ultimately lead to health benefit in Africa.

Areas of focus to realize vision
1. Ensuring access to relevant genomic technologies for African scientists.
2. Facilitating the integration between genomic and clinical studies.
3. Facilitating training at all levels, and particularly in training research leaders.
4. Establishing necessary research infrastructure

Why genetics in Africa
1. African genomes contain more genetic variation than any other on Earth
2. African genomes are also much ‘older’ than European or Asian genomes
3. The genetic variants in African genomes are more clearly associated with certain regions of the genome than in Asian and European genomes making it easier to determine genetic pre-disposing factors that apply to all other populations worldwide
4. There are the studies that can only be done in Africa, such as those on certain neglected diseases

Funding agencies
- American National Institutes of Health (NIH)
- UK Welcome trust

Current funding opportunities
NIH is soliciting applications from foreign Institutions in African countries who wish to develop the study of genomic/genetic/environmental contributors of human health and disease within Africa to understand health and diseases affecting African populations

For more information on H3 Africa please visit http://h3africa.org/
Case challenge: Infomed consent and confidentiality in Clinical setting

**CASE 1: CONSENT AND COERCION**

Anne is 68 and has had multiple sclerosis (MS) for more than 20 years. As a result she is completely bed bound and requires full-time care in a nursing home. She saw her General Practitioner (doctor giving regular care) with a complaint of a change in bowel habits and rectal bleeding and was referred for a colonoscopy. Cancer was diagnosed and originally she consented to have surgical removal of the tumour. Anne has been listed for surgery. Anne’s adult daughter, Wendy, was her mother’s sole carer prior to her going into the nursing home and she visits Anne every day. Wendy has expressed to the consultant her concern that the operation is not in her mother’s best interests. She says that her mother lives a miserable life, in the past she expressed a wish to die and, as the cancer presents an opportunity for her mother to die naturally, intervention would be inappropriate. After Wendy’s visit the doctor speaks to Anne, who tells him that she has changed her mind and she no longer wishes to have the operation.

Questions

1. Should a change of mind about treatment be respected?
2. In what circumstances can discussion with family amount to coercion such that the patient’s decision is no longer valid?

**CASE 2: CONFIDENTIALITY**

Daisy is a nurse working on an orthopaedic ward. She has established a rapport with a patient, Janine, who has been admitted under the orthopaedic team for surgical repair of a fractured wrist. Janine told the consultant that her injuries were sustained falling down the stairs. However, during a chat with Daisy, Janine asks ‘is everything I tell you confidential?’ She then confides to Daisy that her husband has become increasingly violent and pushed her down the stairs. Daisy does not know if she should tell anyone.

Questions

1. Who is owed a duty of confidentiality?
2. In what circumstances can information be disclosed without consent of the patient?
3. Should Daisy disclose the fact that Janine has suffered domestic abuse?

Both cases adapted from 100 Clinical Cases book, second edition by Carolyn Johnston and Penelope Bradbury (2015)

Answers to both cases should be sent via email to the ddrt@kemri.org

The first correct response to each quiz will receive a prize