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# Heathcare Ethics

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The **KEMRI Bioethics Newsletter** is an iniative of the ADILI Task Force with full support of KEMRI. The newsletter is published every 3 months and hosted on the KEMRI website. We publish articles by KEMRI researchers and other contributors from all over Kenya. The scope of articles ranges from ethical issues in **biomedical science, healthcare, technology, law , religion and policy.**

The chief editor encourages submisssion of articles as a way of creating awareness and discussions on bioethics

please write to ddrt@kemri.org

# Letter from the Chief Editor

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Welcome to our second issue this year on Healthcare Ethics. In this issue we feature three articles on ethical issues within the healthcare setting. One article focuses on palliative care and the ethical issues surrounding end of life issues by a health practitioner in Aga Khan University Hospital. The second article reviews HIV and Ethics, where the Family AIDS Care and Education Services (FACES) Director offers his views on the top ethical challenges affecting HIV treatment and care. Lastly, Dr Mike English, Principal Investigator and consultant physician, writes on research and service improvement comparing Kenya and United Kingdom. We continue with the introduction of new SERU reviewers and also highlight the work of the SERU archive team.

Ethical issues in healthcare constitute everyday work for healthcare providers; just about each decision made has an ethical spin on it. The implications are even greater considering the health and lives of patients are at stake. There is a vast range of ethical issues that arise in the field of healthcare today. Occasionally we encounter cases of medico-ethical misconduct and litigation highlighted by the mass media.

Our healthcare system encounters many other challenges outside the ethical issues. We however need to build capacity in bioethics which is a wide field that is made up of research ethics but also includes clinical ethics. Bioethics is a salient field that has not been a focus for the healthcare field in the Kenya. It is our intention as an Institute to promote the training in clinical ethics through creation of awareness on ethical issues in health care and ignite discussion on the ethical issues which arise in the healthcare field. This will equip the health care providers and patients with the basic knowledge in ethics needed to improve how services are delivered to the patients and help patients know what they should expect.

Autonomy - one of the three cardinal ethical principles underscores significance of providing information enabling voluntary decision making. This is very pertinent in the healthcare field. Do the patients have their right to make a choice on treatment matters or they are at the mercy of the providers? Do our providers consider it important to let patients (or their relatives) decide when they have options?

The other aspect of autonomy is the right of professional healthcare providers to exercise their skills to the best and acceptable level of standards of good healthcare and good medical practice. The providers should be viewed as neither servants nor masters to the patients but professionals with a duty to discharge; nevertheless, the providers are obliged through the oath of practice to act in the best interest of the patient. Where negligence is evident, it is expectation of many that due process and justice is served to avoid simi-

lar cases in the future. Thus concerns over the quality of care, and of regular hospital audits should be part and parcel of what health care facilities undertake.

Justice is another primary ethical consideration. Justice in health care is concerned with fairness or equity in healthcare. Justice means ensuring that as far as possible the patients seeking health services(in private and public health sector) have equal access to basic and affordable healthcare and that all sections of a community get their 'fair share' of health resources. Devolution of health services in Kenya has so far been bitter sweet, some counties have better healthcare than others, and other counties still grapple with the huge task of trying to balance quality and efficiency in the new system. Other issues are linked to building and sustaining the healthcare workforce for the counties. Cases of patients suffering due to staff strikes or lack of essential drugs or equipment have already been reported is some counties. It raises a real question about whether the right values are driving our focus in our healthcare system even while recognizing that the health care workers do deserve their basic needs taken care of.

The nation's health care policy developers must not only consider the input of health specialists of various disciplines but should also consult with ethicist especially in the context of scarce health care resource to ensure justice and equity. Article 43 of the 2010 Kenya constitution explicitly states *"Every person has the right to the highest attainable standard of health, which includes the right to health care services",* It thus prudent for all the stakeholders to come together to ensure the intention of article 43 is implemented fully ensure access to basic care which is the hallmark of any civilized society.

Hospital ethics committees are emerging in Kenya and a number have been set up for example Aga Khan University teaching hospital and Jaramogi Oginga Odinga Teaching and Referral hospital. It would be important for these committees to clearly map out their roles which should be distinctly different from those of research ethics committees. Consultation on ethical challenges like "End of life" and "Do Not Resuscitate" (DNR) decisions should be among the concerns that these committees should address. They should also be part of the discussion on resource allocation made by evidence based decision on data collected within the health care facility or on the county or sub county levels.

Health care ethics or clinical ethics remains an aspect which will contribute to the well being of any nation, and our health professional training institutions should ensure that they instill these values both in the training and by emulation of examples.

Health care ethics will be important to any of us, should we have any health concern or have a relative with a health concern and improving awareness and raising the quality of this aspect of care will go a long way to help us reach our Motto of ***"In search for better health"***

***Prof Elizabeth Bukusi***

# A word from the Director KEMRI

Prof Solomon Mpoke, PhD, MBS
Director, KEMRI

Welcome to this issue on Healthcare ethics. Healthcare ethics is an interdisciplinary field that involves clinical, organizational, professional, and research issues related to biomedical science, social science, law and policy. Healthcare provision is the primary mandate of the Kenya Government via the National and County structures, and a core mandate of KEMRI; as our mission is to improve human health and quality of life through research, capacity building, innovation and service delivery.

The Health system is majorly composed of; the health work force, information resources, financing and the pharmaceutical and diagnostics products. These are the areas that KEMRI investigators focus on a daily basis when conducting research. Research is obviously crucial as a foundation for defining evidence-based decision making in matters of healthcare. Over the years, KEMRI has made immense contributions to healthcare policy at both the national and international levels through basic, applied, social and translational research. The promulgation of the Kenyan constitution in 2010 resulted in the devolution of healthcare, which subsequently led to KEMRI realigning its strategies to be able to provide its services to the County governments.

As outlined in our 2013-2017 strategic plan, KEMRI has a new framework composed of seven (7) regional clusters. This is the platform on which KEMRI provides research for health support to the country's forty seven (47) counties. These regional clusters play a pivotal role in planning and providing support for implementation of research projects and programmes aimed at identifying the unique health research needs of the counties, , translating findings into policy formulation and building capacity for research and service delivery. The ultimate goal of the focus on counties is to use research findings in the production of new interventions that can be applied to improve healthcare at this level. Furthermore such interventions can be commercialized, thereby generating much need revenue for the Counties. There exist many health challenges deep at the grass roots level where KEMRI can share findings from research to improve health care practice and health outcomes at the community level.

KEMRI endeavors to harness the knowledge from research into meaningful policy and ensure application of this knowledge to produce new drugs, devices, and treatment options for patient. However, we must be cognizant of the healthcare ethical issues that are bound to arise. For example, informed consent is not just an issue for research but also crucial for the patient at every point and more so for health care provision within the county health management level. The ethics of health care include important aspects such as workplace ethics, handling of medical records and concerns of confidentiality of records. Do the counties and indeed National Government have an explicit policy of ownership, retention release of records either for research or any other relevant use and destruction? Healthcare ethics also reflects on the allocation of scarce healthcare resources. In an environment of scarce financial resources, what is the objective system of allocation across and within the counties?. Is it the pre-term new born child and a new born ICU that is a priority, or is it that there should be no stock out of drugs for malaria? Is a new maternity wing more critical than a radiotherapy machine if funds cannot get both at the same time? To help find solutions to these challenges, we are in the process of positioning KEMRI as an important source of training capacity in Bioethics in Kenya, which shall include capacity building on ethics in health research and health care.

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In conclusion, we urge the KEMRI scientific community, with support from relevant stakeholders, to dedicate and tailor make our research priorities and attention into problems that affect citizens in different counties in order to identify solutions that directly or indirectly improve healthcare at the county level.

# Center for Biomedical Ethics and Culture

**Sindh Institute of Urology and Transplatation, Karachi Pakistan**

**Now accepting application for Postgraduate Diploma in Biomedical Ethics (PGD)**
**Admission for PGD, Class of 2016**

Application Form available on http://www.siut.org/bioethics/CBEC%20Application%20PGD%20Form%20full%20final.htm

**DEADLINE FOR RECEIVING DOCUMENTS IN CBEC: AUGUST 15, 2015, 5.00 PM**

The Centre of Biomedical Ethics and Culture (CBEC) offers a year long Postgraduate Diploma (PGD) in Biomedical Ethics, a program which was launched in 2006. The degree is awarded by the Sindh Institute of Medical Sciences (SIMS), and is recognized by the Higher Education Commission of Pakistan. The PGD was the first comprehensive program to be offered to healthcare related professionals in Pakistan. Its primary objective is to enhance bioethics capacity among healthcare related professionals, and to provide them with basic knowledge and skills to initiate and / or enhance ethics related activities in education, clinical practice, and research within their institutions. The sixty one professionals who have graduated to date constitute a network in public and private institutions involved in research and healthcare delivery services across the country. For details about the alumni, please visit the alumni pages on http://siut.org/bioethics.

This one year long program is specifically designed for busy working professionals. It consists of four modules taught in CBEC interspaced with Distance Learning components in the intervening months. The first Foundation Module is of approximately 2 weeks whereas the subsequent three modules are 8 to 10 days in length. The last module includes a written examination and presentation by students of an "Ethics Project" which they are required to initiate and execute in their parent institutions following graduation.

**For futher assistance on application, Please contact the office of the Deputy Director Research and Training, KEMRI**

**All those interested must forward their names to the DDRT office by COB 15th July 2015.**

# Ethical issues in PALLIATIVE Care Practise

BY Dr. John Weru
Consultant in Pain & Palliative Care
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Palliative Care is defined as holistic care for patients and families facing life-limiting illnesses and it encompasses all the aspects of health: physical, social, psychological, spiritual and cultural, WHO (2008). There is often conflict between doctors, nurses, other healthcare team members, patients, and family members about what constitutes appropriate care and how much and what kind of care makes sense, especially as patients approach death. Decision-making is a major source of ethical dilemmas in palliative care even as the field continues to grow exponentially globally, Weru (2013).

Medical ethics, as applied in medical practice, provide guidelines and codes for doctors as they go about with their duty, responsibility and conduct. The guiding principles in medical ethics are: Respect for autonomy – Respecting autonomy means ensuring the informed patient's right to participate in medical decision-making. Beneficence – The principle of beneficence mandates that doctors act in the best interests of their patients. Non-maleficence – The principle of non-maleficence is the instruction for doctors to first, do no harm. Justice – Justice requires that all people be treated well and fairly, and also that health resources be used equitably. In addition to the four principles, there are basic aspects which are important in medical practice and much more so in palliative care:

*Dignity - the patient and the persons treating the patient have the right to dignity*

*Truthfulness and honesty - the concept of informed consent and truth telling*

All these together constitute the six values of medical ethics but their inadequacy in guiding palliative care is often evident, which could be due to:

- Rapidly evolving medical technology leading to multiple treatment modalities and involvement of multiple teams
- An increase in legal cases between patients and healthcare providers
- Longer life expectancies, including in patients with a life-limiting illness/or functional impairment
- Increased awareness of patients' rights and duties especially right to information coupled with the very sick nature at the time patients are referred to palliative care

## CASE SCENARIO

For example, palliative care physicians seeing a patient in pain and fatigue in the background of metastatic cancer, for the first time after referral, may decide that the patient must be told that the cancer is incurable to enable him make informed decisions and use his remaining time well. However, the family may be of the opinion that the patient should not be told because they believe that knowledge will rob him of the will to live, with the argument that the family will feel guilty of the patient's death. In such a situation, the principles of respect for autonomy and the principle of non-maleficence are at odds. So, who decides what happens with the patient? What treatment is the doctor legally allowed to continue with even if there is no straight forward decision maker? The oncologist may have felt that continuing with treatment will be a futile venture that may not be beneficial to the patient, but rather will cause more harm while accelerating the cost of care. This could have informed the decision to refer the patient to a palliative care centre.

We can discuss the following ethical issues arising from this scenario

### Medical decision making and advance care planning

### Pain treatment

### Issues of futility

#### Decision making

The cardinal principle of autonomy holds that patients have the right to accept or reject healthcare recommendations made by clinicians, Cerminara (2011). However, this does not mean that the patient has the right to demand interventions which are not medically indicated or legally unacceptable e.g. euthanasia. Definitely, this is with the belief that the patient makes a decision following timely, quality and complete information or informed consent, Beauchamp and Childress (2001). Respecting autonomy recognizes the fact that other influencers are important such as values, goals, experiences and social relationships.

In palliative care, the process of decision making becomes even more complicated when patients are unable to speak for themselves and decisions must be made jointly by health professionals and family members who may have different views and various vested interests or cultural demands. This is a common occurrence and can only be overcome by the society embracing the culture of advance directives, where the patient, when still able to make decisions, gives instructions on their preferred latter care, Joseph (2006). In the absence of this, decision making often requires the clinician to give voice to what would be in the patient's best interest by reviewing the benefits and risks of each reasonable intervention, including how each would impact the quality of life. This should be coupled with weighing the risk and the degree of suffering and pain associated with an intervention, including the clinician's ability to lessen any suffering encountered, Schumann and Alfandre (2008).

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When patients are unable to make their own decisions, individuals in their life who can provide guidance either based on actual knowledge of the patient's wishes or on their understanding of what is in the patient's best interest are called upon to assist. In our setting, the biggest challenge is to select who this person is, due to the fact that the next of kin indicated in the medical records may not be the main decision maker in the family based on socio-cultural factors e.g. the medical details may indicate the spouse of a patient as the next of kin but in some cultures the first born son is the main decision maker, or there could be a hierarchical determination. As such, discussions around the surrogate decision-maker for the patient need to take place earlier in the trajectory of the disease. However, when evaluated, there does not appear to be a high degree

of correlation between what a surrogate decides when compared with the patient, Shalowitz, Garett-Mayer and Wendler (2006) but despite low-quality evidence, surrogate decision making is thought to be more accurate than a clinician acting alone without the benefit of a surrogate, Sheunemann, Arnold and White (2012). The accuracy of the surrogate's understanding of the patient's wishes and values is a significant concern and shared decision making between the clinical team and the surrogate usually minimizes this. A big challenge that follows use of surrogates in decision-making is the heightened sense of burden, stress and fear of isolation following the decisions made and this has actually been associated with depression in some cases, Schenker, Crowley-Matoka and Dohan (2012).

**Advance care planning**

Advance directive is a written or verbal documentation in which a person indicates health care preferences while he or she is cognitively and physically unable to make decisions, the process of doing this being referred to as advance care planning. All patients under palliative care need such a decision but few of them have them made or even have discussions around this, Beauchamp and Childress (2001). This makes it difficult to make decisions acceptable to all parties concerned or even quote the patient's preference. Factors that inhibit preparation of advance directives include poor education, religion, culture, legal framework and failure of the physician to initiate the discussion, Pope (2012). A critical limitation of advance directives is having a basis or even assessing the patients' attitudes about health conditions that they have not yet experienced. Futile medical practice- can be defined as excessive medical interventions (both in terms of effort required or financial resources utilized) that stands little prospect of changing the ultimate clinical outcome, Ditto, Jacobson and Snucker (2006). In palliative care, this scenario is very common as there are general feelings that as the end of life approaches, medical intervention needs to be minimized or withdrawn or withheld as the benefits are thought to be minimal. Worse still, in resource-poor settings, the competition for scarce amenities is frequently quoted as a support for this undertaking. While it may be tempting for clinicians to refuse to provide potentially futile therapies on the basis that doing so would preserve precious resources for other patients, this kind of bedside "rationing" does nothing to ensure just health care, Swetz et al (2014). That is, there is no reason to think that refusing to treat a specific patient will result in better (or more) care for other patients who stand a greater chance of benefit. In addition, the stage at which futility sets in is still a very gray area. While there is broad consensus that health professionals are not obligated to participate in care that they find morally objectionable, it is advisable that health care institutions put in place mechanisms

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**Pain management**

One of the major concerns and beliefs by patients and families facing life-limiting illnesses is that pain will definitely occur and will be untreated or will be poorly controlled. One of the cardinal definitions of palliative care is prevention and control of suffering especially pain with this symptom being recognized as the 5th vital sign, Lynch (2001). General under-treatment of pain, lack of use of strong pain medications such as opioids, regulatory factors in opioid accessibility and availability, all compound the ethical dilemma around pain treatment. Furthermore, pain is a subjective, multidimensional symptom, which at onset, is associated with the disease, but as it persists, extended meaning arises such as no more activities of daily living, it is the will of God etc.

To compound the ethical dilemma, effective and efficient pain control in palliative care is usually achieved through the use of opioids, which may, if titrated aggressively without proper assessment and use of the WHO pain treatment ladder, hasten death thus negating the principle of non-malefescence. As such, it suffices to ask the question, does this justify the doctrine of double effect in use of opioids? (The double effect holds that med-

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ication intended to achieve pain relief is justified even if a hastened death may result, so long as pain relief, not death, is the intended outcome). This ethical dilemma may be avoided by proper pain assessment, knowledge of the pharmacology characteristics of analgesics, use of

the WHO pain treatment ladder to decide what medication to use and most importantly individualizing care. Initiation of pain treatment early with the aim of timely control is an ultimate endeavor. The fear of addiction, dependence and tolerance is so common in palliative care that some patients refuse to take these analgesics.

## CONCLUSION

There are many ethical challenges in the practice of palliative care and this arises from its holistic nature, the so important aspect of family engagement in any decision made and the fact that patients are very sick when they access palliative care. There are questions regarding how much and what kind of care is ethical, legal and makes sense based on the limited life expectancy of the patient. The guiding principles in medical ethics: respect for autonomy, beneficence, non-maleficence, and justice are not adequate in palliative care and there is a need to individualize the care provided and be proactive in recording and documenting patient's preferences early on in the disease trajectory. Use of advance care planning is recommended as a way of pre-empting conflicts. It might be argued that autonomy overrides the other principles of medical practice as it guides in respecting patient's dignity and responsibility to self. However, respecting a patient's autonomy includes providing the patient with the opportunity to defer decision making to another individual, the surrogate, who might be or might not be a relative to the patient or the next of kin. Defining whom this person is is therefore a key role of palliative care practitioners.

*The guiding principles in medical ethics: respect for autonomy, beneficence, non-maleficence, and justice are not adequate in palliative care and there is a need to individualize the care provided and be proactive in recording and documenting patient's preferences early on in the disease trajectory.*

*It is important that institutions have frameworks of dealing with such difficult ethical questions e.g. a Hospital Ethics Committee has a mandate to guide the doctor when such an issue arises with the aim of coming up with ethically and morally viable solutions. Early referral and engagement of palliative care teams minimizes the daunting task of transition.*

Futile medical practice presents more of a moral decision than a legal question. Transition from aggressive treatment to comfort care may, to the patient and the family, be interpreted as failure of health care/professional and be associated with a guilt feeling by the clinician. In order to deal with this, all involved parties need to negotiate and agree upon specific goals for treatment, openly and honestly. Though this is not always possible, with compassion and expertise it is frequently achieved. It is important that institutions have frameworks of dealing with such difficult ethical questions e.g. a Hospital Ethics Committee has a mandate to guide the doctor when such an issue arises with the aim of coming up with ethically and morally viable solutions. Early referral and engagement of palliative care teams minimizes the daunting task of transition.

There is a need to use a double-pronged approach to actualize quality pain treatment. Practitioners' knowledge of pain medications, pharmacology and pharmacokinetics need to be enhanced. It is important to approach pain management multi-dimensionally. Patients and families need to be educated so that they comprehend pain as an association of the disease and also understand that pain can be managed effectively and efficiently with drugs and non-drug modalities. Being proactive in educating patients about drug effects and the interventions on experiencing the same is an important assurance that the drugs are not dangerous.

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# SHIPMENT APPLICATION PITFALLS AND HOW TO AVOID THEM

By James Nguya
SERU Secretariat Member

KEMRI/Scientific and Ethics Review Unit (SERU) reviews and approves requests for exportation of Biological samples or specimens. Currently SERU only process shipment requests for research studies reviewed and approved by KEMRI. Sometimes the Principal Investigators (PIs) encounter delays in getting approval due to various reasons that are related to non-adherence to SERU shipment requirements. Outlined are some common pitfalls and how to avoid them.

**1. Failure to indicate clearly in the protocol that samples will be shipped for further analysis outside Kenya.**

The PI needs to have indicated in his/her project proposal that they would ship samples out Kenya for further analysis. Delays in shipment happen when the PI fails to indicate this within the protocol as the PI will have to file for a protocol amendment which will take more time (at least a month) for the process s to be completed.

**2. Failure of the PI to state the aspect of shipment in the informed consent documents**

PI should point out the aspect shipment of blood and other human body samples in the Informed Consent Document (ICD). This proves that the participants consented to shipment of the samples. In addition, for both biological and non-biological samples to be collected in participant's samples homes, Consent must be sought and indicated on the ICD. Therefore, the PI must always attach an ICD that shows that participants were informed about impending shipment and they consented to export of samples.

**3. Failure to fill shipment form 7/14 duly and completely.**

SERU Shipment Form 7/14 is available online on KEMRI website. The PI must duly fill this form to be permitted to ship samples. Poorly filled form delays shipment of samples. Some of the common reasons for deferment of approval related to completion of the shipment form include:

i. Disparity in the quantity of samples to be exported between the cover letter, PART B (ii) of Form 7/14 and the certificate page or even failure to quantify the samples at all.

ii. Failure on the part of the PI to ensure that all required signatures are appended. The form has sections to be filled by the PI, Declaration by the recipient institution and the Centre Director. The PIs should note that form also has a section to be signed by the Centre Director on the Shipment Certificate page. Lack of one or more signatures causes delays since the application is sent back for that compliance.

iii. Failure to indicate the destination of samples on the Form.

iv. Failure to indicate the type of analyses to be conducted on the samples to be exported.

v. Indicating a longer storage period than the approved period (there should no long term storage of samples in overseas institutions except under special circumstances).

**4. Alteration of samples to be shipped from the samples indicated in the informed consent forms**

The PI must ensure that they apply to ship the type of samples that they had sought consent for in the ICD and the proposal. For example it is inappropriate for a PI to request to export serum samples whereas consent was sought for plasma samples.

**5. Applying to ship samples to a different destination from the one indicated originally in the protocol.**

The PI must ensure consistency in the destination of the samples to be exported. The PI should only seek to ship samples to the destination which was indicated in the approved protocol, if a change is a must, an amendment will be necessary. For example, an application seeking for shipment of samples to University of Navarra, Spain while in the informed consent document and project proposal the study participants consented to the samples being sent to Friedrich Loeffler Institute, Germany will not be approved.

**6. Failure to attach the required supporting documents in the application.**

Shipment application is considered complete only if the following documents are attached:

i. A cover letter requesting t export samples.

ii. A duly filled SERU Shipment Form 7/14.

iii. A copy of the current ERC/SERU approval letter.

iv. A copy of the ERC/SERU Amendment letter if an amendment was sought to enable shipment of samples.

v. A copy of the SSC Approval letter for studies approved by the SSC.

vi. A copy of the ICD documents showing evidence of consent of shipment of samples.

vii. A copy of the ERC/SERU project proposal for some applications (e.g non-blood biological samples)

**7. PI requesting to export samples when the study approval period has expired.**

An application for shipment is valid only if the protocol is active. Delay may occur because the PI will have to first seek renewal before the application for shipment is processed.

# RESEARCH & SERVICE IMPROVEMENT

*Author*
*Prof Mike English*
*Group Head / PI, Consultant Physician and Fellow*
*KEMRI-Welcome Trust Program*

## Are we making it too difficult for health care staff and researchers to engage in work to improve health services?

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The Kenyan Ministry of Health's goal is 'Attaining equitable, affordable, accessible and quality health care for all'. To help achieve this goal the MoH has developed a Monitoring and Evaluation Framework that is "aimed at providing a common platform for health sector performance , monitoring and evaluation that will guide all actors at both the national and county level." However this framework acknowledges the 'weak culture of data demand and use of information for decision-making' within the health sector and 'lagging capacity in the analysis of health sector performance'.

Monitoring health service performance is a concern of all countries. Such monitoring requires data and these data are typically derived from patients who use services or from staff who provide services. In high income countries such as the United Kingdom data for some monitoring approaches are collected routinely and automatically. Researchers helped develop the performance indicators to be used, the processes of collecting these data and the methods to analyze them and determine what it may be appropriate and useful to measure. As systems became routine, the same skills continue to be used but the work is no longer research, it is part of mandatory performance management strategies. As a result it is now possible for any citizen (indeed anyone in the world) with internet access to view the health services performance data. For example, you can examine the performance of a particular hospital and review its mortality rate (Figure 1) or the performance of a named surgeon and the mortality rate of the patients they operate on (Figure 2).

The Kenyan Ministry of Health has for some years also conducted 'research' to assess health care services. Using research study tools such as questionnaires, structured interviews and observations, Ministry of Health staff visit facilities, collect data, enter it into databases and analyze these data to produce reports such as the 'The State of Health Service Delivery (2014)' (Figure 3). The forms for health service and health care assessment described above do not require approval of an ethical research committee in the United Kingdom, the patient data that is used to generate the performance reports

But what if employees of a research institution or a university were to join government efforts to undertake an evaluation of service provision? What if the researcher wanted to publish a report using these data? Would the researcher need ethical approval when their Ministry of Health colleagues do not?

are anonymized and patients are not asked to consent to its use. The public health benefit (of efforts to improve health services) are in the public interest just like the efforts to improve the management of publicly funded health care – and wouldn't any good manager wish to use information on how their services are provided to improve them in the same way as a bank or a mobile telecommunications company might? Similarly evaluation of health services conducted by the Kenyan Ministry of Health is not subject to ethical review and consequently no consent is sought from staff or patients who might contribute information. But what if employees of a a research institution or a university were to join government efforts to undertake an evaluation of service provision? What if the researcher wanted to publish a report using these data? Would the researcher need ethical approval when their Ministry of Health colleagues do not? What if a clinician or a nurse wanted to use data from a facility for evaluation – for example to measure the post-operative complication rates in a hospital or to see how frequently incorrect drug doses were given. Does this qualify as research? Do these people need ethical approval? What if it is not the hospital doctor or nurse but a researcher or a university student who wishes to tackle such questions about the way care is provided and whether it is of high quality?

Researchers aim to develop skills that enable them to answer questions that, in biomedical research, have the ultimate goal of improving individual or population health. The range of questions to be tackled is very large. As researchers engage with efforts to improve health services and work with colleagues who define policy on healthcare and those who manage or deliver these services.They may use many techniques common to many research fields: sampling strategies, development of data capture tools, management and analysis of data. Similarly, health care professionals may use the same techniques emulating good research practice to provide the best possible answer to their question. However, it seems too often it is the institutional background of the person doing the 'research' and not the nature of the 'research' that determines whether ethical review is required and whether or not consent for data collection is required. This is inappropriate, it should be the nature of the research that is important. Here is a brief description of 'research' that may not require ethical approval – and may still be work that can be published in research literature. The ways in which clinical audit and service evaluation may be differentiated from research are outlined in Table 1.

## Clinical Audit

This is defined in the UK as: "Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implement-

Figure 1. Information available on the MyNHS website that aims to provide Data for Better Services (https://www.nhs.uk/service-search/performance/search). In this screenshot highlighted in the red box are summary reports on hospital mortality for named hospitals

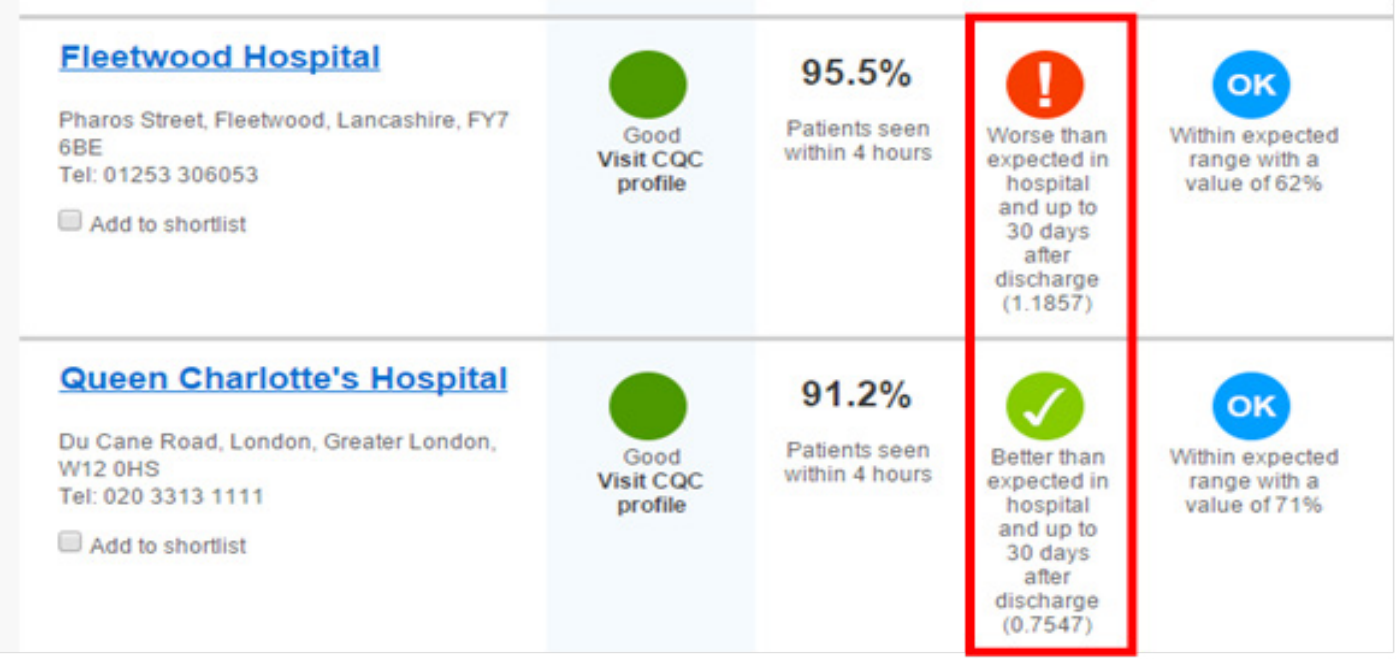
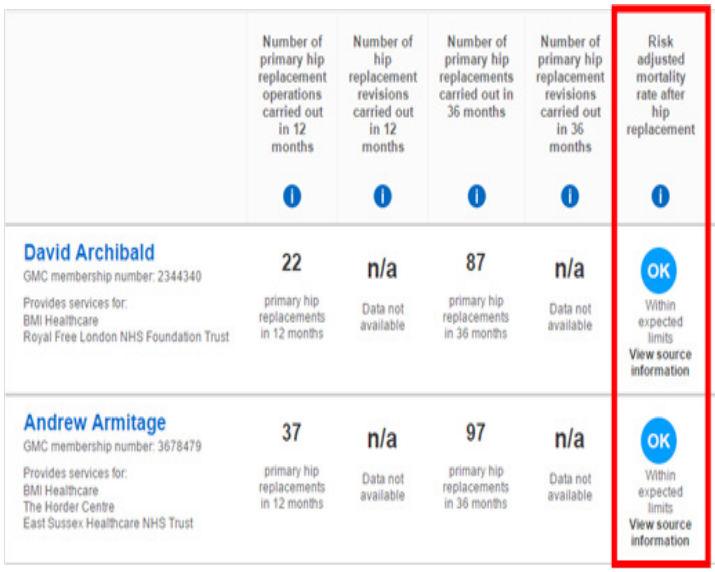


Figure 2. Information available on the MyNHS website that aims to provide Data for Better Services (https://www.nhs.uk/service-search/performance/search). In this screenshot highlighted in the red box are summary reports on the mortality of patients after hip replacement operations for named surgeons.



| | Number of primary hip replacement operations carried out in 12 months | Number of hip replacement revisions carried out in 12 months | Number of primary hip replacements carried out in 36 months | Number of primary hip replacement revisions carried out in 36 months | Risk adjusted mortality rate after hip replacement |
|---|---|---|---|---|---|
| **David Archibald**<br>GMC membership number: 2344340<br>Provides services for:<br>BMI Healthcare<br>Royal Free London NHS Foundation Trust | 22<br>primary hip replacements in 12 months | n/a<br>Data not available | 87<br>primary hip replacements in 36 months | n/a<br>Data not available | OK<br>Within expected limits<br>View source information |
| **Andrew Armitage**<br>GMC membership number: 3678479<br>Provides services for:<br>BMI Healthcare<br>The Horder Centre<br>East Sussex Healthcare NHS Trust | 37<br>primary hip replacements in 12 months | n/a<br>Data not available | 97<br>primary hip replacements in 36 months | n/a<br>Data not available | OK<br>Within expected limits<br>View source information |

ed at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery". The conduct of clinical audit requires collection of data typically from patient records or other health care documents (e.g. theatre lists, laboratory results books, clinical registers etc). However, audit is part of clinical governance within the health system and is not regarded as research – it therefore does not require ethical approval or patients consent for their information to be used. Instead audit projects should be evaluated and approved by the health care system (for example the hospital board or other oversight body). This process should ensure the activity is an audit, that the exercise is a good use of resources and that it will be useful. There is no reason why the results of an audit cannot be published if they have merit. Audit is one tool that can be used in quality improvement. Improvement emphasizes the cyclic approach to 'plan, do, study, act' to keep using measurement to check that improvement is occurring. Such quality improvement approaches might also be published if they have merit and again would not typically require ethical approval if using only routine data.

## Service Evaluation

Service evaluation is broader than audit. As indicated, the Ministry of Health has conducted service evaluations in many programme areas, such as HIV, malaria or family planning, health ministries may also conduct extensive evaluations of health care provision relevant to programme goals using methods that would be familiar to many researchers. These typically examine whether things are being done (to a standard) and base this evaluation on available information resources (facility records, patient records) and even basic interviews (for example to determine health worker's knowledge). Such service evaluation should be reviewed – and there are clear rules on de-identifying data where relevant – but if the activities are clearly of less than minimal risk and meet the service evaluation criteria, then there should be a system to waive formal ethical review. The examples in Figures 1 and 2 are from the United Kingdom's routine service evaluation approach.

## Operational Research

This is the discipline of applying advanced analytical methods to help make better decisions according to the Massachusetts Institute of Technology. This often requires use of routine data and engagement in discussion with people who are managing or implementing services. These discussions may not be formal, in depth interviews exploring people's perceptions they are typically focused technical conversations on what is or not working. This replicates the kind of day to day activity many good managers would typically be undertaking to ensure their programme or facility is working well but does this more systematically and formally so that the best health care delivery decisions might be made. Data collection is commensurate with the aims – one would not tape record conversations but you might make notes; you would not use quotations but you would use the technical or 'ground level' insights into what is or not working to develop a solution based on a detailed understanding of the situation. If

continued pg 15

Figure 3. A screenshot of the cover of the Ministry of Health's 2014 report on health services.

Table 1

| Research | Clinical Audit | Service Evaluation |
|---|---|---|
| The attempt to derive generalisable new knowledge, including studies that aim to generate hypotheses, as well as studies that aim to test them. | Designed & conducted to produce information to inform delivery of best care | Designed & conducted solely to define or judge current care |
| Quantitative research - designed to test a hypothesis. Qualitative research - identifies / explores themes following established methodology | Designed to answer the question: "does this service reach a predetermined standard?" | Designed to answer the question: "what standard does this service achieve?" |
| Addresses clearly defined questions, aims & objectives | Measures against a standard | Measures current service without reference to a standard |
| Quantitative research - may involve evaluating or comparing interventions, particularly new ones Qualitative Research - usually involves studying how interventions and relationships are experienced. | Involves an intervention in use only (the choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference). | Involves an intervention in use only (the choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference). |
| Usually involves collecting data that are additional to those for routine care, but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. | Usually involves analysis of existing data but may include administration of simple interview or questionnaire. | Usually involves analysis of existing data, but may include administration of simple interview or questionnaire. |
| Quantitative research - study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications | No allocation to intervention groups: the healthcare professional and patient have chosen intervention before clinical audit. | No allocation to intervention groups: the healthcare professional and patient have chosen intervention before service evaluation. |
| May involve randomization | No randomization | No randomization |

done by a management team, would this require ethical approval? If done by a researcher, would it require ethical approval?

Researchers could be valuable partners to national and country governments using their skills to tackle important questions about how health services are being provided, their performance, and how to improve them. However, researchers' ability to engage in such work and to respond to government needs in a timely mannermay be undermined by requirements that they get ethical approval when in fact this may not be necessary. Researchers need better guidance on work that they might undertake by that might be exempt from ethical review. Plans should be reviewed to ensure they are in fact clinical audit or service evaluation (see Table 1) by a relevant authority and this review documented – but this should be a rapid process. This might encourage researchers to engage more with county and national governments and play an important role in developing or improving health care services to produce broad, public health benefit.

# Meet the SERU Archive team



As part of restructuring of research regulation system at KEMRI, 7 Assistant Research Officers (SERU Interns) were recruited to assisist in archiving duties in November 2014. The team started the process by transferring all the documents previously preserved at CCR, ESACIPAC and former ERC and SSC offices to the new archive office. After the assembling of all the files. the filling process began with identification and categorizing of all the protocols as per their SSC numbers, this process has been completed with over 3000 protocols filed. The team is currently working on a database developed by IT team which will make easy assessing and search of information. Besides filling the archives team have been involved in data abstraction and assisting the SERU secretariat staff in some of their work.

Files at old ERC office

Asembling process

Sorting & Categorization

Filing completed- New archive office

**Geoffrey.K. Ngasura** Sang holds a Bachelor degree in Business Information Technology degree from Mount Kenya University. He graduated in 2013.

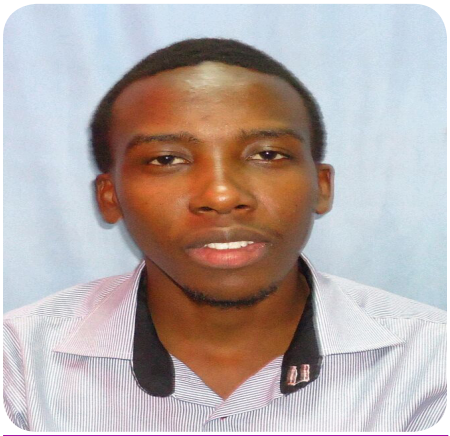
**Austine Odwuor,** is a gradute of Moi University. He holds Bachelor of Science degree in Environmental Health. He completed his studies in 2014

**Gideon Cornel Msee** holds a Bachelors degree in Biochemistry and Zoology. He graduated form Kenyatta University in 2014

**Judy Ngure** holds a Bachelor of Science degree in Biochemistry and Zoology. She graduated from Egerton University in 2014

**Kisienya Odhiambo Cyprian** holds a Bacher of Science degree in Biotechnology from Guru Nanak Dev University – Amritsar Punjab, he graduated in 2006

**Lilian Achacha** holds a Bachelor of Science degree in Microbiology and Biotechnology from University of Nairobi. She is currently pursuing master's degree in Medical Parasitology and Entomology, at ITROMID



**Evans Atoni** holds a Bachelor of Science degree in Medical Microbiology from Jomo Kenyatta university of Agriculture and technology. He completed his studies in 2013.

## SERU Secretariat Member

## Papias Mwangi

Papias Mwangi joined SERU in September 2014. He holds a Bachelor of Science degree in Microbiology and Biotechnolgy from the University of Nairobi. Papias is involved in reviewing continuing review reports, preparation of agenda for SERU Commitee meetings and drafting letter templates. He has also been involved in development of SERU SOPS. Papias has developed interest in science and ethics and hopes to further his studies in this field.

# ETHICAL ISSUES THROUGH THE CASCADE OF PUBLIC HIV CARE


Author
Dr Patrick Oyaro
Director FACES

HIV services in Kenya within the public health sector started actively in 2004, more than a decade ago following external donor support. This makes the HIV program mature enough enabling the implementers to share best practices, experiences and challenges aimed at improving these services.

There is a mix of issues that cut across good intentions versus bad outcomes or repercussions which may fall under ethical/non ethical practices. Having worked in the HIV management sector for more than a decade within the Ministry of Health (MOH), Faith Based Organization (FBO) and now Non-governmental/ parastatal organization, I have experienced the entire cascade of HIV management through the different program areas of HIV prevention, treatment and Research.

Adherence to bioethics ensures that the welfare of the patient being served is taken care of in the best possible way without unnecessary infringing on their rights. Activity or lack of activity should not in any way negatively affect the quality of service and outcome of a patient under the care or supervision of a health professional or anyone who interacts with the patient in any way

The aim of my write up is to expose the potential areas of conflict between good intention towards taking care of a patient and infringing into patients' rights and privileges

## HIV MANAGEMENT CASCADE

Several HIV strategies have been discovered, most are already being implemented while others await adoption by various countries despite evidence being shown that they work. Without any specific categorization these include HIV testing, behavioral interventions, biologic interventions like; use of condoms, pre- exposure prophylaxis, post exposure prophylaxis, use of highly active antiretroviral therapy and ART prophylaxis and Voluntary Male Medical Circumcision.

The HIV Care and Treatment cascade involves finding those who are infected, linking them to enrollment and care, providing treatment, retaining them and ensuring they attain Viral load suppression. In all these strategies and points in the cascade, there are potential areas of ethical or unethical behavior based on the ultimate outcome for the patient.

## HIV TESTING/FINDING and LINKING

An effort towards finding /HIV testing in the population when executed well helps in identifying those who are HIV positive. This is a crucial step that facilitates enrollment and treatment to improve life by reducing morbidity and mortality and foster prevention amongst those tested negative, however if offered with coercion, without parental consent(in case of children), or without confidentiality of testing and giving of results or with unauthorized disclosure it becomes unethical. Once one test positive they are linked to the health facilities for early enrollment which will ensure that they get treatment as soon as possible, more importantly, the patient will need proper post- test counseling to be able to make informed choice on when to enroll and be

linked to a health facility of choice without feeling coerced.

## HIV TREATMENT

After effective linkage to an HIV clinic, patients go through the triage and enrollment process before they are attended to by the clinicians. The triage process of HIV care involves determination whether they are ready for enrollment on the same day or another day depending on their readiness or the workload of the day and moreover whether there is a suggested health facility by the health worker based to proximity to the patient's residence. Sending patients back without enrollment for whatever reason may lead to loss to follow up. It is therefore wise to enroll a patient in a health facility near their homes. In some cases a patient feels comfortable in a health facility far away due to fear of stigma and other associated reasons, ***would failure to enroll them in this facility of choice amount to being unethical?.*** On enrollment proper counseling and education on the procedures that will be undertaken in the clinic is important to ensure the patient adheres to them, consequently failure of provision of that education in a proper manner is not acceptable. Patients go through baseline laboratory testing that involves phlebotomy and those too need to be conducted well after explanation without causing harm.

Patients are then taken through adherence processes in preparation to the initiation of ART and this may involve need to get a treatment buddy to support the patient in the adherence process and this need to be done well without coercion for one to disclose their status when they are not ready. Concerns are that for married couples who have not disclosed, what's the balance between confidentiality and protection of the HIV negative partner?

*"The guidelines on ART initiation have evolved over time and the trend is that people are being initiated on ART at higher CD4s/ immunity status and probably soon we will adopt the Test and Treat Approach. Does the patient still have a right to refuse treatment if they feel they are still healthy?*

The guidelines on ART initiation have evolved over time and the trend is that people are being initiated on ART at higher CD4s/immunity status and probably soon we will adopt the Test and Treat Approach. ***Does the patient still have a right to refuse treatment if they feel they are still healthy?*** Whereas the antiretroviral therapy will boost ones immunity and provide better life as a result, how do we balance that with the possibilities that the earlier one starts the treatment, the longer they will be on treatment and the higher the chances of adverse drug effects?

When initiating patients on treatment, it is critical for healthcare providers to give proper explanation on drug choices, side effects and adherence. Patients may raise concerns if they experience the side effects of drugs that could have been avoided or well explained during the ART initiation process. Patients are expected to adhere to their appointment and pill uptake. ***Then how do we address and assist those who fail to do this without negative effects?*** We need to provide grounds to explore reasons for this and assist them adhere. Pediatric cases are more challenging because they depend on the actions of the parents and/or guardians and there are possibilities of poor adherence and poor health outcomes due to negligence of the parents and guardians which infringe into the rights of the children to good health. Handling such cases poses challenges as one may think of options for legal redress to force the parents to ensure the children keep appointments to clinic and are given their medications without failure. For children who acquired HIV through MTCT, disclosure to them is a delicate balance because the children have a right to be gradually disclosed to from a certain age based on maturity. Secondly, the mothers worry about the children blaming them for transmitting HIV to them. Therefore in providing assisted disclosure these need to be looked into. Finally ensuring adherence and retention will ultimately ensure positive health outcomes. Interventions such as patient reminders through phone contact and home visits are implemented help patients adhere to treatment, however such interventions should always be done with the patients consent to ensure confidentiality, avoid unwarranted disclosure and stigmatization during these procedures.

## PREVENTION OF MOTHER TO CHILD TRANSMISSION(PMTCT)

Certain processes within the PMTCT related services are similar to those in the HIV care and treatment cascade. There are potential areas of ethical issues in all the 4 prongs of PMTCT. Primary prevention for all women of reproductive age is critical in elimination of Mother to Child transmission so the prevention services need to be available and accessible to them. This should be much easier amongst the adults who can easily make independent decisions but is still a challenge to the adolescents and mature minors who are sexually active or fall within the reproductive age group but may not be able entirely independent decisions. The current question and debate is whether condoms should be provided to the youth including in schools. ***How do we strike a balance between discouraging the adolescents from engaging in sex and prevention of HIV infection and teenage pregnancy?*** Adolescents under 18 years (unless they are mature minors) cannot also consent for HIV testing yet. At what point should they have a right to consent for their testing yet they are sexually active? Another PMTCT prong is on the prevention of unplanned pregnancies amongst the HIV positive women. This needs

to be done without coercion and only after educating this women and providing them with acceptable legal options or choices. Remember that HIV is not a deterrent to desire for children so the rights have to be respected as much as access to the contraceptives should be optimal. There have been newspaper stories on cases of women getting tubal ligation (sterilization) without consent. Another ongoing discussion here is on the reproductive and sexual needs amongst the adolescents with poor uptake and provision of the contraceptives amongst the sexually active adolescents.

## VOLUNTARY MEDICAL MALE CIRCUMCISION (VMMC)

VMMC is one of the latest HIV prevention strategies; its scale up in Kenya has been majorly in the traditional non circumcising communities. The introduction of VMMC had to be done cognizant to the traditions and culture of these communities especially during mobilization. Mobilization for these services require proper education on the health benefits of VMMC and creating demand for the services, facilitating access without coercion of any nature. The current targeted age group is boys and men of ages between 10 to 65 years and once again those below 18 years need parental/guardian consent before the procedure is conducted. Being a surgical procedure, adverse events are bound to occur but these need to be minimized through proper training of the service providers, proper care during the procedures, proper education to the clients on wound, adherence to these instructions on wound care by the clients and timely follow ups post operation.

## OTHER PREVENTIONS AND GENERAL ISSUES

Post Exposure Prophylaxis (PEP) has been used overtime to prevent HIV infection amongst those exposed through occupation and al non occupational ways. Before PEP is provided there is need to determine the source of the possible infection which may require HIV testing of the source. The victim should also be tested for HIV to rule out any prior HIV infection and provide the best intervention. This should be done with consent and the victim should not be denied the intervention. There are situations whereby the victim reports occupation exposure whereas the exposure was actually non occupational (intentional and consented sexual exposure) and the debate has been on whether to offer the intervention in such case or not. The guidelines are clear that the PEP should be provided. In relation to non-occupational exposure due to common reasons like condom burst and rape there are aspects of stigmatization and medico-legal factors that need to be addressed as PEP is being provided.

The latest intervention that has been tested and found to work is PreP (Pre exposure prophylaxis) which involves use of antiretrovirals before exposure. Studies are ongoing to identify the feasibility of its implementation within the health sector and this will address most of the anticipated challenges for its implementation.

Both PreP and Highly Active Antiretroviral Therapy (HAART) are key biologic interventions to ensure the HIV partner in the HIV discordant relationship does not get infected and also contribute to the reduction of the chances of MTCT for those who desire to get a baby. One delicate balance is how to ensure the discordant couples get a baby as per their desire without HIV sero conversion of the HIV negative partner

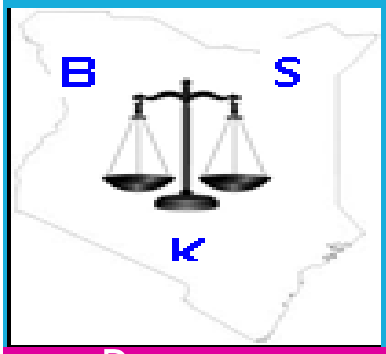
Finally, the issues above have mainly tackled the services within the public health sector. Most should also apply within the private sector, it is therefore in the best interest of the public that government ensures that the private sector follow the existing national guidelines. The private sector may

*"The private sector may be offering an opportunity for those who can afford the best available drugs and services but how does that affect the future options for these patients who go through the private sector. Are these patients provided with both immediate and future options or does the financial gains by the private health sector and the desire to provide the immediate best regimens over shadow the possible negative effects of future financial inability of the patients and failure to higher line ART regimens"*

be offering an opportunity for those who can afford the best available drugs and services but how does that affect the future options for these patients who go through the private sector. Are these patients provided with both immediate and future options or does the financial gains by the private health sector and the desire to provide the immediate best regimens over shadow the possible negative effects of future financial inability of the patients and failure to higher line ART regimens

With this summary of potential areas of ethical/unethical issues, one can then explore each service area with more details and provide measures to address them.

# BIOETHICS SOCIETY OF KENYA




## *MISSION*

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The Bioethics Society of Kenya is a self-governing organization whose main objective is to foster the development of bioethics in Kenya. The BSK is a not-for– profit, non-political, non-discriminatory, multidisciplinary organization. The society seeks to promote ethics in research, medicine and health care. Membership in the BSK is open to all Kenyans or persons residing in Kenya who shares the objectives of the BSK. Our mission is to support the development of ethics in the life sciences and diffusion of knowledge for equity and progress in health care.

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# New SERU Review Committee members

## Dr Beatrice Irungu, PhD.

Beatrice Irungu is a Research Scientist at Centre for Traditional Medicine and Drug Research (CTMDR), Kenya Medical Research Institute, Nairobi Kenya. She holds a Doctorate in Chemistry from the University of Nairobi. Her research interests are in drug discovery and development (synthetic and natural products) for management of communicable diseases. She has attracted a number of Research grants as a Principal Investigator from International Foundation for Science (IFS), National Council of Science Technology and Innovation (NACOSTI) and WHO/TDR. She is a member of CTMDR Centre Scientific Committee (CSC) and was recently appointed to be a member of KEMRI's Scientific and Ethics Research Unit (SERU) for a period of three years effective 1st March 2015. She has attended in-house training on research ethics and written online research ethics courses with Collaborative Institutional Training Initiative (CITI) by University of Miami (www.citiprogram.org). In an effort to improve her knowledge on research ethics, Beatrice sought for and was awarded a scholarship by the Centre for Research Ethics and Bioethics, Uppasala Universitet. This scholarship will facilitate a 10 weeks online research ethics training in August-November 2015.

## Dr. Mercy Karimi Njeru

Dr. Karimi Njeru holds a PhD in International health with a focus on health systems, from the university of Bergen in Norway. Her PhD thesis title is "HIV testing services in Kenya, Tanzania and Zambia: Determinants, experiences and responsiveness". She has extensive experience in the application of mixed methods and her work has recently received global recognition as one the best resources in mixed methods applications in health research. She is involved in various research projects mainly from a health systems perspective and has also been involved in mentoring and supervising graduate students. Dr. Njeru has participated in the developments of national guidelines as well as research involving other countries in sub-Saharan Africa. She has published in peer-reviewed international scientific journals and currently heads the health systems research unit at the Centre for Public Health Research in KEMRI. Her research interest is on Health systems and policy research

## Mr Tom Mokaya

Tom Mokaya has been an Assistant Research Officer at the Center for Infectious and Parasitic Research Control (CIPDCR) since 2007. He has previously worked in the pharmaceutical industry and Kisii District Hospital before joining KEMRI. His current research interests focus on fungi infections, HIV drug resistance and latent tuberculosis infection. Mokaya holds a Bachelor of Science degree from Doctor Bhim Rao Ambedkar University India and Post Graduate Diploma in Pharmacy from Central Institute of Management, India. He has been involved in bench work since 2007 and he is currently pursuing a Master of Science Student at ITROMID - Jomo Kenyatta University of Agriculture and Technology.

## Dr Elizabeth Echoka

ECHOKA Elizabeth is currently a Senior Research Officer at the Kenya Medical Research Institute (KEMRI), based at the Centre for Public Health Research. Elizabeth is also a part-time lecturer at the Institute of Tropical Medicine and Infectious Diseases (ITROMID) of Jomo Kenyatta University of Agriculture and Technology (JKUAT). She holds a PhD in Public Health from JKUAT, and over ten years public health research experience, with a focus on sexual, reproductive, adolescent, child health and nutrition.

# Case Challenge- A study to determine the value of postoperative radiotherapy

*Adapted from WHO CASEBOOK ON ETHICAL ISSUES IN INTERNATIONAL HEALTH RESEARCH, 2009, Case 26, pg 97*

Over an 11-year period, a well-respected cancer hospital in East Asia studied a much debated issue: whether the survival of patients with oesophageal cancer is improved by radiotherapy after resection (surgical removal of the cancer cells). The study did not receive an ethics review before it was started because at the time few research institutions in the country had research ethics committees.

Patients at the hospital who underwent radical resection during this period were randomly assigned into two groups: those who only had surgery and those who also received radiotherapy (treatment with radiation to kill any remaining cancer cells), beginning 3-4 weeks after their surgery. Clinicians told patients in the radiotherapy group that they were being given "innovative therapy". The clinicians provided complete descriptions of the probable risks and benefits of the treatment, after which patients had the opportunity to accept or refuse it.

None of the patients were told that they were participants in an experiment. The investigators believed that the population under study had such a strong, culturally rooted distrust of medical science that even simply using the term "research" would trigger a refusal by most patients to participate. The investigators reasoned that since the patients received all the information relevant to whichever intervention they were being offered and were free to accept or refuse that treatment, their oral approval was sufficient to keep the study in compliance with prevailing guidelines for informed consent.

The researchers submitted their results, which lent substantial support for postoperative radiotherapy in the treatment of oesophageal carcinoma, to a well-respected medical journal in the North America. After some deliberation, the journal's editor decided to print the paper but invited an editorial from a North American physician and ethicist who criticized the lack of informed consent and ethical review, adding that violations of human rights were frequent in the country where the study was done. The authors were not shown the editorial nor invited to reply.

**Questions**

1 Do you agree with the investigators' ethical justification of their decision not to tell patients that they were in an experiment? Why or why not?

2 What harm, if any, did the patients experience because they were not informed that they were participants in a study?

3 Though now widely introduced, formal mechanisms for informed consent and prior ethical review were not standard in the country when the study was done. Is it appropriate to use today's ethical standards to judge a study that began years ago?

4 Should the journal have printed a study that reviewers found unethical? When, if ever, is the scientific value of a study significant enough to justify publication despite ethical violations?

5 Should the authors have been given the opportunity to reply to the editorial?

6 Did the journal editor adopt an ethical approach by publishing an editorial against a published study without informing the investigators?

**The first three respondents in will receive a prize.**
**The first correct response will also receive a prize.**

***Answers should be submitted to ddrt@kemri.org***