

KEMRI BIOETHICS REVIEW

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From the Editor In Chief



Thank you for reading this issue of the KEMRI Bioethics Review. Our newsletter features articles addressing ethical matters/ debates or concerns in health research. This particular issue's theme is on **public health research and ethics**. It features pieces on a wide range of topics, including medical screening, traditional medicine and ethics and culture in research.

Public health is, by its very nature, a public, communal good, though its burdens and benefits often appear to fall unevenly on different groups of the population. This raises a particular set of challenges that public health ethics has to address: who is public health good for? Whose health are we concerned with, and what sacrifices is it acceptable to ask of individuals in order to achieve it? And why is public health research good and worth promoting? Any answer to these questions has to take into account the fact that public health measures are often based on the long term prospects of benefits to individuals as opposed to immediately securable benefits.

KEMRI's commitment to improve health through research presents particular challenges. As the editorial committee, we aim to develop a publication in which researchers engage in writing thought-provoking articles based on dilemmas from the field of health research and subsequently formulate their opinions on relevant bioethical issues. We also hope to create a publication that engages readers and encourages new persons to explore the field of bioethics. We invite you to become an active participant in the rapidly growing field of bioethics by writing or responding to these articles, or on raising any topics you may want discussed or addressed in this newsletter for the future.

Enjoy and be informed.

*Dr. Elizabeth Bukusi,
Deputy Director Research & Training
(DDRT), KEMRI*

Editor in Chief:

Dr. Elizabeth Bukusi

Production Editor:

Mr. Timothy Kiplagat

Editors

Ms Everlyne Ombati

Dr Charles Obonyo

Dr Sera Gitome

Design/layout: Gamer Ent.

For questions and queries write to:
The KEMRI Bioethics Review
ADILI-The KEMRI Bioethics Center
P.O. Box 54840-00200
Nairobi, Kenya
Email: DDRT@kemri.org

Word from Director KEMRI



“ Should their wish to not be tested and their desire not take treatment be honored? ”

*Prof Solomon Mpoke, PHD
Director KEMRI*

Welcome to this issue of KEMRI Bioethics Review. There is a growing interest in the ethical, legal, and social aspects of public health research and practice. KEMRI has a national mandate to provide leadership in health research in Kenya and beyond. This includes a responsibility to define and investigate the incidence, prevalence and determinants of major diseases of public health importance; closely tied to this is the translation and dissemination of health research findings for evidence-based policy formulation and implementation for improved public health.

In the implementation of public health, scientific considerations may cause raise concerns and questions of autonomy, the rights of an individual, justice for the community, the common good, the norms of research, and multi-cultural values may arise. Consider, for example, an individual with – multi drug resistant tuberculosis (MDR TB), who does not want to be tested, even though they may have defaulted treatment several times and puts themselves and others at risk. Should their wish to not be tested and their desire not take treatment be honored? A clear mechanism to handle this delicate balance of ethics vis a vis an individual rights as enshrined

in our constitution, other peoples rights of protection against preventable and treatable communicable diseases is critical.

KEMRI will continue to remain committed not only to upholding the principles of research ethics, but also to unpacking those principles in a culturally appropriate and sensitive manner. We shall continue to review our current research regulation system with the ultimate goal to strengthen the ethics and scientific review, including fostering an environment and culture that supports and develops ethical practices in every aspect of our work.

As Kenya devolves to systems that provide healthcare at the county level, KEMRI must also decentralizes her activities to ensure that we are able to provide the counties with the research support they need to be able to respond to the health needs of the citizenry within each county while prioritizing concerns unique to their constituents. The presence of KEMRI support in every county is consistent with our role as a national research institute, and serves to promote our motto, “In search of better health “ for our people.

Ethics of screening in public health

Dr Charles Obonyo, PhD
Principle Research Officer CGHR

Introduction

Screening is the presumptive identification of unrecognized disease or condition by the use of tests, examinations or procedures that can help identify apparently well individuals who have a specified disease or a disease precursor.

The word “screen” originally meant to sieve—a screening test should act as a kind of apparatus that separates or sorts out the healthy population from those who are likely to have some specified disease or its precursors. It’s important to note that screening tests are usually preliminary and further investigation is most often required to verify that those who screen positive really have the abnormality and require treatment (true positives), and to eliminate those who test positive but do not actually have the abnormality (false positives). Those invited to participate in screening programs are not unwell or sick and many may never become unwell.

The ultimate aim of screening is to detect disease earlier in its progression, prior to the onset of any symptoms or illness, with the hope that early implementation of an effective treatment may improve prognosis and lead to lower morbidity and mortality from the disease among those screened. Screening is also considered a type of secondary preventive intervention.

There are several types of screening programs. Universal screening involves screening all individuals in a certain category (e.g., children of a certain age). Mass screening involves the application of screening tests to a large unselected population. Case finding or targeted screening involves screening a smaller sample of the population based on presence of risk factors.

In Kenya, screening programs exist for a number of conditions.

Some of these include: blood smear for malaria, HIV tests for HIV infection, pap smear for cervical cancer, mammography for breast cancer, mantoux test for tuberculosis, the measurement of blood pressure for hypertension, testing of blood sugar for diabetes, and weight measurements for malnutrition.

Because screening procedures are not risk-free and are applied to large, apparently healthy populations, they almost always raise ethical issues. Some of these include, doing more harm than good, the role of informed consent and information, and equitable distribution of the benefits and harms of a screening program. This article presents a brief review of the scientific and ethical issues that should be considered in the implementation of screening programs.

Scientific and policy considerations in screening

World Health Organization (WHO) has proposed a set of ten principles for mass screening programs (see Table 1). The principles relate to the adequacy of the scientific evidence, the balance of risks and benefits, the availability of an effective treatment, the acceptability of the screening test, and the costs and resources required.

Ethical considerations in screening

Like all medical tests, screening procedures are associated with both beneficial and harmful effects. Screening raises a number of important ethical issues; these include the need for informed consent, protecting privacy and confidentiality, balancing risks and potential benefits, and issues pertaining to targeted screening of higher-risk persons (distributive justice). Other issues may relate to the cost of screening and how best to allocate limited public resources for screening. Some of these issues are discussed below.

Principles of mass screening

1. The condition sought should be an important health problem
2. There should be an accepted treatment for patients with the disease
3. Facilities for diagnosis and treatment should be available
4. There should be a recognizable latent or early symptomatic stage
5. There should be a suitable test or examination
6. The test should be acceptable to the population
7. The natural history of the condition should be adequately understood
8. There should be agreed policy on whom to treat as patients
9. The cost of case-finding should be economically balanced in relation to possible expenditure for medical care as a whole
10. Case-finding should be a continuing process and not a “once and for all” project

Table 1 Courtesy of http://whqlibdoc.who.int/php/WHO_PHP_34.pdf

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Informed consent and informed decision-making

The principle of respect for the autonomy of persons supports the right of individuals to informed consent prior to screening. This should ensure that individuals who undergo screening receive balanced and relevant information to enable them make informed decisions regarding the available screening options.

In addition, it should encourage health providers to interact responsibly with patients. Persons undergoing screening require quality and understandable information to facilitate the making of free personal choices. The information should include details of the procedure, the meaning of a positive or negative test result, and any risks or potential harms and benefits. Specifically, they should understand the risk of a false positive (or false negative) test result and the procedures that may follow it.

Table 2 shows the four characteristics proposed by Sheridan et al (2004) that facilitate an informed decision in relation to screening.

Voluntary versus mandatory screening

The screening programs for most diseases are generally voluntary in order to respect the individual autonomy, to encourage public participation and to increase the number of people who “need to know” their disease status. However, there are a limited number of diseases where the public health system has established mandatory screening programs in order to prevent death or other serious harm to the affected individuals.

Benefits and risks of screening

Screening is undertaken for important public health problems (in terms of morbidity and mortality) and for conditions for which early detection and treatment has been shown to be effective in reducing mortality or serious disability. The potential benefits of screening therefore include the early detection of disease and the prevention of serious illness or disability and improved survival.

These benefits can be considered from either the perspective of the individual or the perspective of the population. A screening test may be considered beneficial if it has an impact on a common disease that substantially burdens the community, or on a rare

condition that poses a significant burden at the individual level. Screening involves cost and the use of scarce medical resources for people who may never need treatment. Screened populations may undergo some diagnostic procedures that would never have been done and also receive earlier implementation of treatment for persons with incurable disease. Evidence from randomized trials is usually used to evaluate the effectiveness, the potential benefits, and risks of screening. Similarly, decisions on screening costs and how to allocate public resources is almost always based on scientific evidence.

Since screening usually involves large numbers of apparently healthy people, it is important to consider the potential harms and risks that may arise from screening. There may be risks associated with the test itself (e.g., discomfort, stress, anxiety, chemical or radiation exposure) or with the test result (false-positive or false negative). For instance, during screening of asymptomatic individuals, the occurrence of minor complications or rare adverse events that would be acceptable in the treatment of a severe disease, become extremely important and needs a careful balance to ensure that potential benefits still outweigh these risks.

There is also potential harm arising from the psychological impact of a test result on the individuals undergoing screening. For instance, screening may cause anxiety or over-diagnosis—the identification of disease that would not have produced signs or symptoms before death. False negative results may offer a sense of security which may delay the final diagnosis. Screening programs should protect the privacy and confidentiality of information collected from those undergoing the procedures to minimize the risks or potential harms from discrimination and stigma.

Ethics of targeted screening

Targeted screening focuses the program on subgroups of the population with a higher prevalence of a disease or condition. This approach should be accompanied by the availability of accessible and affordable diagnostic and treatment facilities. Targeting high-risk individuals is important for lowering the costs to the screening program, improving the specificity of a screening test and minimizing the number of false-positives. However, this approach has the increased potential for stigmatization of the targeted persons.

Characteristics of an informed decision

The patient must:

1. Understand the risk or seriousness of the disease or condition
2. Understand the preventive service, including the risks, benefits, alternatives, and uncertainties
3. Have weighed his or her values regarding the potential harms and benefits associated with the service
4. Have engaged in decision making at level he or she desires and feels comfortable with the decision.

Table 2

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Distributive justice

The ethical principle of justice requires equitable distribution of healthcare resources such as screening services. For screening, justice holds that each person should share equally in the distribution of the potential benefits of screening services. This implies that for the whole community to benefit from these services, the needs of the medically underserved and socially disadvantaged populations should be addressed. This principle holds the community responsible to correct inequalities in the distribution of resources to ensure that affordable screening services are accessible to those who are least well off.

Conclusion:

In summary, frameworks for addressing ethical and policy issues in public health screening should consider the adequacy of scientific evidence, the balance of benefits and risks, the availability and affordability of an effective treatment, the acceptability of the screening test, provisions for obtaining informed consent, patient preferences, protecting privacy and confidentiality, avoiding discrimination and stigmatization, as well as the costs of screening and access to screening programs

by socio-economically disadvantaged persons. The benefits of screening include prevention of serious illness or disability and improved survival. On a societal scale, mass screening may potentially give rise to a population of the 'worried well' individuals.

Further reading

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Picture source - zaindarling.blogspot.com

The Role of Traditional Medicine in Public Health

By Festus M. Tolo, Ph.D.,

Ag. Head, Traditional Medicine and Drug Development Programme (TMDDP), KEMRI

One may be excused for asking what role traditional/herbal medicine (or complementary/alternative medicine as often referred) may play in the health and well-being of the public in the 21st century, given the advances in pharmaceutical medicine. Although long an integral part of the health systems of societies all around the globe, and especially in Africa, public health and traditional or indigenous health practices have not often been compatible in most parts of the continent. Yet the question of the proper role of traditional medicine in the health of the public remains, perhaps, the most important one to be asked by many since answers are sometimes not easy to come by.

According to the World Health Organization, one third of the global population has no regular access to essential modern medicines, and in parts of Africa, especially the sub-Saharan Africa, about half of the population faces shortage of minimum healthcare. This is attributable in part to inadequacies in health care financing by the African states which has led to a situation of highly limited material and human resources for healthcare services. External resource oriented, foreign technology based and vertically designed healthcare programs have been a major stumbling block for not achieving the desired health outcomes in the region.

This has been worsened by the heavy burden of communicable diseases such as HIV/AIDS, malaria and other parasitic diseases, pneumonia, diarrhea,

tuberculosis, coupled with growing numbers of those with chronic diseases such as diabetes, asthma, hypertension which continue to rise in prevalence in the region. High maternal and child mortality, rapid demographic changes and urbanization, ineffective health support systems for poor populations, migration of medical professionals, environmental changes and related epidemics are some other major public health concerns in such economies.

In light of all these, and the increased utilization of complementary and alternative medicine (CAM) in recent years, there is an increased possibility that CAM approaches could prove to be important factors in public health, particularly if used within an integrative framework together with mainstream medicine. There exists a defined need for research to explore the integration of conventional health care and traditional/CAM approaches, as well as define mechanisms of CAM-based therapies to facilitate such integration. Essential to these goals is the accumulation of a database derived from outcomes-based pre-clinical and clinical investigations for evidence base to fast-track traditional/CAM medicine into the mainstream health care system.

It is important to note that even in contemporary rural Africa, there is nodoubt about the efficacy of herbal medicine. Many Africans, especially rural people and the urban poor, rely on the use of herbal medicine when they are ill. In fact, many rural communities in Africa still have areas where traditional herbal medicine is the major, and in some cases, the only source of health care available.



A Herbal Medicine Research exhibit at a past Nairobi Trade-Fare by researchers Ms Joyce Ondicho and Ms Ruth Nyag'acha of CTMDR, KEMRI

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Modern health care has never been, and perhaps in the foreseeable future is unlikely to be, adequately and equitably provided anywhere in Africa, due to financial limitations related to rapid population growth, political instability and poor economic performance, to mention only a few. For instance the problem of ensuring the equitable distribution of modern health care has become ever more serious, as the gap between supply and demand has continued to widen. Hence, the majority of people lack access to health care, and even where it is available, the quality is questionable. The role of traditional medicine for the good health of the public in Africa can therefore not be ignored or wished away.

Scientifically, herbal medicine is defined as, “a system of medicine which uses various remedies derived from plants and plant extracts to treat disorders and to maintain good health”. Traditional Medicine on the other hand can be defined as health practices, approaches, knowledge and beliefs including plant, animal and mineral-based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to diagnose, treat and prevent illnesses or maintain well-being.

However, these two terms are often used interchangeably to convey the same message. What then, constitutes an “acceptable” herbal/traditional medicine product? It is important to note that a medicinal plant is not a drug or a medicine until it has been converted, through a pharmaceutical process, to satisfy the criteria of identity, efficacy and safety. At best, the plant is only the raw material. The design or formulation of a traditional medicine does not necessarily mean extraction of active ingredients.

It means the preparation of the medicinal product according to African traditions in a standardized and reproducible manner. Some herbal products, which are currently in commercial circulation within the country and region, may not meet these criteria in order for the physician can prescribe them.

However, it is possible to integrate the African traditional medical know-how with modern pharmaceutical science to produce acceptable therapeutic products. The WHO/AFRO has designed guidelines for achieving these objectives.

Our challenge therefore in the scientific arena on herbal medicine research is to ensure preparation of herbal products that the African medical doctor can feel confident to prescribe. We can then make these traditional medicines

accessible and affordable to the people living within the region and beyond. It is only then that we can move towards achieving the Regional Strategy as developed by the WHO Regional Office for Africa, COMESA and the East African Community.

Further reading

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3. *World Health Organization, WHO Traditional Medicine Strategy 2002–2005, World Health Organization, 2002.*
4. *Lettington R, (2000): The protection and Promotion of Traditional and Marginalized Medicinal knowledge: Romantic Dream or Twenty-First century Necessity? Regional Conference on medicinal Plants, Traditional Medicines and Local Communities in Africa: Challenges and opportunities of the New Millennium, Nairobi, Kenya.*

The challenges of Ethics and culture in Research: Points to ponder

By Dr. Elizabeth Bukusi

This is Kenya's Jubilee year. Fifty years since independence. What has changed about Kenya? In particular, what has changed about health research? From early attitudes where health research was largely viewed as those from the Western world 'using' Kenyans as guinea pigs, there is more understanding about what research for health is and how it benefits development. Specifically, there is growing interest in medical research recognizing that we have to prioritize our health needs and not wait for someone else to set a health research agenda for us. But what makes researchers ethical? Sometimes the question is raised that researchers grow rich on the 'blood' of the poor and marginalized. Who participates in medical or health research?

It is more often those who are disenfranchised and who may not have options of medical care that would be eager to participate in research that may provide the much needed care. With estimates suggesting that up to 70 % of Kenyans live below the poverty line, can the educated, middle to upper class researchers know the real plight of the research subjects? The researchers, often well educated, well heeled individuals who had had the benefits of good education and were likely born with a silver (or at least some) spoon in their mouths have not had to deal with the rampant abject poverty found in the regions or sections of the country or communities devastated by the most debilitating diseases, childhood diarrhea and pneumonia, cholera, schistosomiasis, HIV and many other neglected tropical diseases.

When a participant enrolls in a research study and then does not tell the truth, and there are many examples of that in the field, from women who enrolled in two clinical trials of similar products simultaneously (even though the consent says you should not enroll if you are in a clinical trial) (CAPRISA 004) to those who say they will take some study product and do not take it (FEMPREP), are the researchers and the participants on the same page?

So what are these challenges of ethics and culture? How is truth defined? Is truth absolute in all cultures or do some cultures define truth in a different way. Does truth only occur in the situation of full disclosure? Does partial disclosure of information, as may be defined as "acceptable" especially in a cross-cultural, cross-power and cross-the-financial-divide relationships, still be considered as truthful?

Can two people define truth differently as per their' culture' which may be defined more by the social standing and upbringing, thus bringing about a situation of false

expectations and understanding, by only showing what will portray them in the light they want the individual who is not from their culture to see them? Culture cannot even be defined in the same way among the 'haves' and 'have nots', among those who eat because they are hungry or want to eat and those who eat only when there is some kind of food to be found.

I would suggest that 50 years after independence, researchers have the dilemma of being 'a child of two worlds'. This is particularly true for those who embrace the 'western culture' for the expediency of modernity and for work and yet live with an 'African culture' or world view in their day-to-day life that does not involve work. This changing African culture has evolved because of discrepancy of material wealth; it has changed from the village status of sameness and community of sharing of similar circumstances to one in the urban informal settlements that promotes a culture that suggests you must use your position and power to get all that you can gain materially to make you better than the next person. The season of equity has ended.

The season of community when everyone looked out for the welfare of those around them is over. It is now everyone for himself and every person is busy trying their best to run away from poverty and indeed even those who seem wealthy, were possibly poor in the last generation. The older folks driving big expensive 'German' cars probably went to school barefooted. The expansion of the interactions with others not of their immediate family and ethnicity brought about by the transition from rural to urban communities also means there are a lot of 'not our own, not part of us' relationships and so pitting families and communities against each other with challenges of clashes in ethnic diversity and scramble for scarce resources. So what values have emerged in this kaleidoscope of culture and modernity?

Firstly, power. The one with the Conch shell is King. The one with the most material wealth has the respect and can move on, regardless of how the wealth or materials are obtained.

Secondly, our value systems have therefore probably changed. Truth and honesty as we define them are a western concept even though the basic fabric of moral behavior and fairness and justice was in built into African culture. But the absolute truth telling and honesty as valued as it is for the western world has not seemed to pan out in much of modern Africa.

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The Missionaries and the slave traders and the colonizers seem to have had the same 'modus operandi' to some extent. They did not study the culture enough to change value systems in a transition that would have allowed the best of all cultures to emerge and enable deeply seated and held values to be the end product. They imposed and in that they did not treat those they colonized fairly. Thereafter, those who had not been treated fairly were asked to treat each other fairly as it is the right thing to do. Yet they did not get that same fair treatment, and sadly sometimes those who preached this gospel did not live up to the standards they voiced. They talked the talk, but did not walk the walk.

Thirdly as a result of these lost values, there has been a paucity of self regulation in the general sense within the emerging 'African cultures', depending on regulation from external resources. The 'regulation' from the political powers does not happen as many times those who are to the regulators are the first to break the regulation as often their goal is to ensure their own political gains are met at whatever cost. The values of honesty and truth depend on a personal basic core which when not nurtured from an early age are very difficult to inculcate in an adult.

Fourthly, I would suggest that the deeper understanding of research remains limited, even among those who conduct research for long periods of time, it sadly remains a job. Those who truly have egalitarian goals in research are probably the sheep among the wolves.

Fifthly, in dealing with research subjects who are materially poor, the guilt born by those who 'have' when dealing with those who are 'have nots', remains a divide and is a difficult one to overcome. As it is always a secret weapon, where one feels 'you do not understand the circumstance'.

This has been further perpetuated by HIV research in particular. It is good that HIV has helped the world realize the importance of involving those who are HIV infected to be part of their solution, something that had not happened for other disease conditions, but it also allows for an 'HIV rightism' where just the fact that one is positive or affected is what gives them the right to make decisions or take advantages of situations that one would not concede to for any other condition or circumstances. It is almost like the guilt of the survivor or the uninfected.

Lastly, the norms of socially acceptable behavior: silence as a defense or as a way of communication. How does one interpret silence? While the western world will assume a decision or an acceptance as they assume if there was a different agenda it would have been stated. Many African cultures DO NOT state things clearly.

Assumptions are made. People discuss issues in a roundabout manner and much digging and prodding is needed to actually understand what the real issue is. This speaks to judging others by how I view myself. If I do not tell lies, it is hard for me to think others are lying to me. Set a thief to catch a thief since there is no honor among thieves.



CASE CHALLENGE:

EVALUATING THE USE OF TRADITIONAL MEDICINES FOR DIARRHOEA

Adapted from: CASEBOOK ON ETHICAL ISSUES IN INTERNATIONAL HEALTH RESEARCH: Issues in study design. Pg 67

Hydrocotyle asiatica, or 'thankuni' is a plant common to South Asia which, when dried, ground up, and added to water, is reported to be effective for treatment of bloody diarrhoea. 'thankuni' is the main ingredient of a popular traditional medicine. 'ajorno' which is produced by a local company. This medicine is widely available, very popular, and quite inexpensive. A paper suggesting that 'thankuni' decreases bloody diarrhoea appeared in an unrefereed journal from an institute of traditional medicine in South Asia. However, no clinical studies have been conducted on this product, and the specific chemical composition has not been determined.

Dr Wabano, an investigator at an international research institution, is intrigued by this product, and wants to evaluate its clinical effectiveness. The present treatments for dysentery¹ (by far the most common cause of bloody diarrhoea in South Asia) are fluid intake and norfloxacin² an antibiotic that is clinically effective and bactericidal. Norfloxacin, however, is often unavailable outside the major cities (80% of the population is rural) and, even when it is available, is too expensive for many people to afford. Dr Wabano reasons that if the traditional medicine proves effective, therapy will be more accessible to everyone because of availability and cost.

The investigator submits a protocol to the study committee of the institute for a, double blinded study that compares

the clinical effectiveness and bactericidal properties of 'ajorno' with norfloxacin. Adult patients admitted or seen on an outpatient basis with a history of dysentery will be randomly assigned to one of the treatment groups after a rectal swab has been taken for a bacteriological diagnosis. 'Ajorno' which is in a powdered form will be put into a gelatin capsule so that it is indistinguishable from the antibiotic.

The ethics review committee meets, and votes not to approve the protocol for the following reasons:

- The specific chemical composition of 'ajorno' (i.e. "thankuni") is not known.
- The prior reports of effectiveness have been for "bloody diarrhoea" which might include any number of diagnoses, including dysentery and amoebiasis.
- No studies in peer-reviewed journals report that the traditional medicine is effective or suggest a mechanism for its reputed effectiveness.

Dr Wabano notes that it would be next to impossible to define all of the ingredients of this traditional medicine, and that if attempted, this would be a costly undertaking. He suggests that those on the review panel who voted against approval were biased against traditional medicines, and have denigrated the indigenous science of the country, and tried to impose their own 'western biases' on scientific research,

Questions:

1. In your opinion, was the research ethics committee correct in its assessment? Why or why not? Is there an alternative study design that the committee could recommend?
2. Is the investigator correct in his accusation that members of the committee who voted against the approval of the study are showing a "western bias" in their decision?
3. If the study were approved as presented above, would the committee have used a double standard in its assessment of the ethics of the design?
4. In circumstances where the researcher and the research ethics committee disagree, how might the situation be mediated?

¹Any of various disorders marked by inflammation of intestines, especially of the colon, and attended by abdominal pain, and frequent stools containing blood and mucus. Causes include chemical irritants, bacteria, protozoa and parasitic worms,

²An antibiotic used to (treat a range of bacterial infections,

The first five responses sent in will receive a prize. The first correct response will also receive a prize. Answers should be submitted to DDRT@kemri.org

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Partners:

