



## The ethics of improving African traditional medical practice: Scientific or African traditional research methods?

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### ABSTRACT

The disease burden in Africa, which is relatively very large compared with developed countries, has been attributed to various factors that include poverty, food shortages, inadequate access to health care and unaffordability of Western medicines to the majority of African populations. Although for 'old diseases' knowledge about the right African traditional medicines to treat or cure the diseases has been passed from generation to generation, knowledge about traditional medicines to treat newly emerging diseases has to be generated in one way or another. In addition, the existing traditional medicines have to be continuously improved, which is also the case with Western scientific medicines. Whereas one school of thought supports the idea of improving medicines, be they traditional or Western, through scientific research, an opposing school of thought argues that subjecting African traditional medicines to scientific research would be tantamount to some form of colonization and imperialism. This paper argues that continuing to use African traditional medicines for old and new diseases without making concerted efforts to improve their efficacy and safety is unethical since the disease burden affecting Africa may continue to rise in spite of the availability and accessibility of the traditional medicines. Most importantly, the paper commends efforts being made in some African countries to improve African traditional medicine through a combination of different mechanisms that include the controversial approach of scientific research on traditional medicines.

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### 1. Introduction

Traditional medicine (TM) is found virtually on all continents where it has been practiced for many centuries. In most developing countries TM is easily accessible and affordable to the larger proportion of the populations relative to Western medicine (WM). In Africa, it is estimated that about 80% of the populations rely on TM for their primary health care needs (WHO, 2008). In the developed world TM is used by a relatively smaller proportion of the populations than the proportion that relies on WM. Consequently, in the developed countries TM is referred to as "complementary" or "alternative" medicine (CAM) since it complements WM which is accessed by a larger proportion of the populations. According to the World Health Organisation (WHO, 2008),

"Traditional medicine refers to health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being."

One major characteristic of African traditional medicine (ATM) is that it has spiritual and non-spiritual components (Jolles and Jolles, 2000). The non-spiritual component is generally referred to as herbalism. It should be made very clear that this paper is not discussing the spiritual component of ATM that involves divine healing based on religious faith which is believed to involve supernatural spiritual powers. However, in most cases in practice there is lack of clarity as to whether a Traditional Healer is practicing as a herbalist or as a divine healer. It is such ambiguity that tends to shroud the practice of ATM with so much sacredness that any attempt to question anything associated with the practice is perceived by some people not only as a taboo but also as one of the manifestations of neocolonialism.

A paper that touched on some ethical and regulatory issues surrounding African TM in the context of HIV/AIDS (Nyika, 2007) stimulated some debate in the public domain (Knapp van Bogaert, 2007; Tangwa, 2007). According to Tangwa, ethical principles that emanated from atrocities committed by Western medical practitioners should not be used to assess whether some actions of African traditional practitioners are right or wrong because they did not take part in the atrocities (Tangwa, 2007). The current paper, which focuses on ATM, will address the issue of whether or not the African Traditional Healers conduct any research, be it scientific or 'African traditional', before they come up with new treatments. If

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they do, then there are ethical requirements pertaining to conduction of research in patients which should be met (CIOMS, 2002; World Medical Association (WMA) Declaration of Helsinki, 2008). Two case studies that capture research approaches that were used during Edward Jenner's era in Western medicine and approaches that are currently being used by some African Traditional Healers will be discussed. The aim is to highlight firstly the need for properly designed research to improve both traditional and Western medicines and secondly, to flag some ethical issues surrounding the practice of and 'research' in ATM. The case studies illustrate the fact that research methods that were considered acceptable centuries of years ago should always be reviewed and improved as part of efforts to enhance protection of the well being of patients in particular and mankind in general.

## 2. Case studies

### 2.1. Case study 1: discovery of vaccination by Edward Jenner

When Edward Jenner tested the concept of using cowpox virus as a vaccine against small pox, he used a small boy, James Phipps, as an experimental subject ([http://en.wikipedia.org/wiki/Edward\\_Jenner](http://en.wikipedia.org/wiki/Edward_Jenner)). There was a serious outbreak of measles, and as a medical practitioner whose duty was to save human lives, he used his observation that milk maids exposed to cowpox virus were less susceptible to infection with small pox virus as the rationale for testing cowpox virus in the small boy. Edward Jenner used his experience and knowledge in his capacity as a medical practitioner and demonstrated the concept of vaccination. He became very famous and globally, vaccines have contributed towards successful control of many diseases such as measles and polio.

However, research methodologies for the development of vaccines have since evolved and the approach used by Jenner is now considered to be poor scientific design and unethical. Instead of one person conducting the research, multidisciplinary research teams conduct research so as to minimize the risks of bias and errors in the research process as well as in the analysis of collected data. In addition, a research protocol has to undergo review to ensure minimum acceptable scientific and ethical standards before the research starts.

### 2.2. Case study 2: discovery of HIV/AIDS treatment and cure by a Traditional Healer

A well-known, highly respected African Traditional Healer used to treat many patients suffering from a variety of illnesses. When the HIV/AIDS pandemic started affecting his country, he also started 'diagnosing' HIV infection in some of his patients. Using his knowledge and experience as a Traditional Healer, he tried some of his traditional medicines on his HIV/AIDS patients but without informing them that the medicines were being tested. After the 'trials', the healer was convinced that the medicines were effective not only for treating but curing HIV/AIDS patients. Since his medicines were very affordable compared with the Western medicines, he soon became the first port of call for many patients seeking treatment and cure for HIV/AIDS. He became a very rich and famous person in his country and in neighbouring countries.

However, the Traditional Healer was totally against the idea of subjecting his medicines for HIV/AIDS to any form of tests involving other stakeholders and insisted that his observations and deductions were sufficient to guarantee safety and efficacy. The Traditional Healer and those who shared his view argued that scientists and pharmaceutical companies wanted to hijack the traditional knowledge for their own commercial benefits. On the other hand, people calling for properly designed scientific research to be conducted on the traditional medicines argued that if the traditional

medicines that were being claimed to treat or cure HIV/AIDS were truly effective, the ever rising disease burden and mortalities due to HIV/AIDS in Africa would have been brought under control since the traditional medicines were widely accessible to those who needed them. Most importantly, they argued that the risk of bias in the observations and deductions made by the healer who would benefit from payments by patients was unacceptably high.

## 3. Historical and current methodologies in the development of new treatments in WM and ATM

### 3.1. Western medical practice and research: from Edward Jenner type of research to randomised controlled trials

Case study 1 captures research methodology that was used ages ago, and was acceptable then but is no longer acceptable nowadays. Today, a single medical doctor may not simply decide to test something in a patient or in patients without involving other people with relevant expertise that the doctor may not have. There is now a requirement that any testing of anything in human beings should be explained in a protocol in order to enable peer review (CIOMS, 2002 guideline 2; World Medical Association (WMA) Declaration of Helsinki, 2008). The review of the protocol is meant to ensure that firstly there are no flaws in the planned methodology that may compromise the usefulness of the findings and secondly that the safety of the humans who will take part will not be compromised. The most important requirement for research nowadays is the informed consent. Many international and national ethical guidelines or legal frameworks clearly stipulate that obtaining informed consent is a prerequisite for research. For instance, the CIOMS guideline 4 states that

"For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee (CIOMS, 2002)."

Thus when a patient presents to a medical doctor seeking treatment and the doctor happens to be involved in a study that is testing an alternative treatment, the doctor must inform the patient so that s/he decides whether to take part in the study or not. The patient may decide not to take part in the study but should still be given the standard treatment. If there is no proven standard treatment for the disease, then the doctor has to explain to the patient that the medicine available is still being tested. That is the distinction between medical practice and research. Indeed, both the treatment and research may be done in the same hospital settings, but the patients must be informed if they are to be used in a study.

Edward Jenner conducted his experiment alone, which during his era was most probably acceptable to the communities, the medical fraternity and perhaps to the parents of James Phipps for medical practitioners to use their discretion to conduct 'research' as they saw fit without any peer review. It was fortunate that Edward Jenner's observations and deductions happened to be correct and that his 'experiment' yielded positive results without serious adverse reactions. But nobody knows whether or not he had conducted other 'experiments' detrimental to the health of his research subjects. Nowadays it is no longer acceptable, no matter how knowledgeable the medical doctor is, to conduct such tests using people without voluntary informed consent. We are in a new era in which people should be adequately informed to enable them to make informed decisions. Precautions should always be taken to safeguard the welfare of patients or research participants, and also

to be sure that the research methodology is such that the research questions can be answered objectively and accurately.

### 3.2. African traditional medical practice and 'research': scientific or 'African traditional' research methods?

It should be acknowledged that ATM has evolved over centuries of years, and has involved systematic methods of assessing medicinal or detrimental properties of herbs. Although one school of thought may want to refer to that systematic assessment of traditional herbs as 'African traditional research methods', it could be argued that the systematic approach was basically scientific, more or less similar to the approach that Jenner used, and was devised by the African Traditional Healers themselves. For instance, one approach used by the Traditional Healers long time ago was to observe herbs that were never eaten at all by animals, and such herbs were suspected to be poisonous and would be avoided by the Traditional Healers. Long time ago there were no means of testing toxicity; hence such an approach was logical during that era. The point is that centuries of years ago African Traditional Healers developed methods of assessing safety and medicinal properties of herbs that were logical and acceptable during that era, but the methods should change with time.

Traditional knowledge was therefore not gathered haphazardly, there were systematic ways of gathering the knowledge which was then passed from one generation to the next. Was this approach of gathering knowledge not scientific research methodology that was acceptable during that era, just like Jenner's approach? If it was not scientific but an African research methodology, should it remain the same as it was ages ago even when circumstances are changing and the diseases affecting Africa are dynamic? Just as there were limitations in the research methodologies used by Jenner, the research methodologies used by Traditional Healers had limitations which should be gradually overcome as time goes by. In other words, the research approaches used by Traditional Healers should be dynamic, the aim being to continuously improve and overcome limitations.

In contrast to case study 1 which depicts what used to happen ages ago in the context of WM, case study 2 shows what is still happening today in the context of ATM. In the advent of the HIV/AIDS pandemic, the African Traditional Healer in case study 2 tried some of his medicines in patients and came to the conclusion that his medicines were effective. The implication is that there was some form of research that involved testing of the traditional medicines for HIV/AIDS, albeit without disclosure of such 'research' activities to the patients. The traditional medicines that were being given to people living with HIV/AIDS were not free of charge; the Traditional Healer benefited financially from the sale of the medicines. It therefore means that there was conflict of interest since the Traditional Healer testing the medicines was the one who interpreted the findings and eventually benefited financially from the sale of the medicines. Although the medicines were affordable to the majority of the people needing them, the high prevalence of HIV/AIDS in most African countries meant that there were large numbers of people needing such medicines, which translated into huge financial gains for the healer relative to ordinary members of the community.

Another point to be highlighted is that when the traditional medicines are being tested, the patients are not informed about the testing aspects. It is important that any necessary procedural differences in the process of obtaining informed consent are allowed in order to respect different cultural and traditional practices. For instance, empirical studies conducted in some developing countries showed that most people prefer to discuss with their spouses or relatives before deciding whether or not to take part in health research (DeCosta et al., 2004; Nyika et al., 2009). Thus obtaining

informed consent should not be an event, but a process that allows ample time for consultations as per the wishes of the prospective participants.

Another issue is that patients have to buy the traditional medicines even if they are still being 'tested' and may have side effects. There is need to assess potential side effects, and such assessments may require laboratory tests in addition to clinical assessments that the Traditional Healers may perform. It is therefore critical that medical practice, be it traditional or Western, is clearly distinguished from medical research, especially when medical practitioners play both roles as service providers and researchers.

It also means that there should be well thought out plans of how the research would be done, instead of anecdotal ways of testing medicines, be they Western or traditional. Most importantly, the experimental people should be informed that the medicines are being tested in them. Since no person is omniscient, there may be need to include people with expertise in various relevant fields in the research team. Instead of having a one-man research project, like the one Edward Jenner or the Traditional Healer conducted, bringing on board other experts such as Epidemiologists, Microbiologists, Statisticians, Pharmacists, Physicians and people experienced in conducting clinical trials could significantly increase the quality of research.

### 4. Availability and affordability of African traditional medicines versus disease burden: need to improve efficacy

The ultimate goal of health care systems is to reduce the burden of diseases and improve the quality of life. Thus it negates the purpose of having health care if availability and affordability of the health care do not effectively contribute towards the achievement of good health of people and reduced disease burden. It would be unethical to focus only on availability and affordability of African traditional medicines to the poor African populations relying on the medicines without assessing whether or not the disease burden of the populations is being reduced. It should be acknowledged that there are other factors such as poverty, poor nutrition and environmental factors that affect disease burden. However, if some African traditional medicines and some Western medicines can make positive impact even in the presence of such factors, then the aim should be to improve the medicines so that they can make as much impact as possible. The question that should be asked is whether or not the access to African traditional medicines by the estimated 80% of the African populations is effectively tackling the disease burden of the populations.

In the advent of emerging and re-emerging diseases, it is imperative that ATM keeps improving in order to rise up to the new challenges. Organizations such as the CDC have realized the need for public health systems to be ready for such diseases and are always working on prevention strategies in light of environmental, societal and technological factors (Centers for Disease Control and Prevention (CDC), 1998). Examples of emerging diseases are HIV/AIDS, Ebola, severe acute respiratory syndrome (SARS), multi-drug resistant tuberculosis (MDRTB) and extreme drug resistant tuberculosis (XDR TB). Examples of re-emerging diseases include plague caused by *Yersinia pestis*, cholera caused by *Vibrio cholerae* and dengue hemorrhagic fever caused by flaviviruses.

As is the case with Western medicines, research is needed to better understand potentially harmful side effects that may be associated with some traditional medicines. It should be emphasized that harms are not always caused deliberately; they may be caused inadvertently. Hence the need for checks and balances to minimize potential harms. In cases where crude mixtures of traditional medicines are used, the possibility of identifying and separating active components from other non-therapeutic

components which may have harmful side effects should be explored.

It means therefore that existing traditional medicines should be improved and new ones should be developed in order to match the dynamics in the disease burden of the global population. African traditional medicine should reach a stage where it competes with the Western medicines, thus becoming a source of revenue for countries that are bestowed with such valuable natural resources. Such competitiveness could go a long way in lowering the costs of drugs and making effective health care accessible to poor communities.

Africa should not bemoan the unavailability or unaffordability of Western medicines developed by pharmaceutical companies when African traditional medicines are abundantly available and accessible to the African populations to the extent that it has been proposed that ATM should be considered the 'orthodox/conventional' medicine for Africa (Tangwa, 2007). For instance, HIV/AIDS affects Africa more than other continents in terms of deaths and prevalence; this is in spite of the availability of affordable traditional medicines in Africa. Instead of scrutinizing the effectiveness of the abundantly accessible African traditional medicines, unavailability or unaffordability of Western medicines are sometimes blamed for the high prevalence and mortality rates prevailing in Africa.

It follows therefore that there is need for research in order to improve the efficacy of the African traditional medicines. If there are African 'traditional' research methods that are different from scientific methods of research but can improve the efficacy of the traditional medicines, then such methods should be used. What is important is to develop safe and effective medicines, and any method that is appropriate and effective should be used, provided people who participate in the process are informed. It could be argued that scientific research methods are the most effective, if the impact arguably being made by medicines developed by pharmaceutical companies is anything to go by.

### 5. Progress of scientific research on African traditional medicines in Africa

The involvement of such organizations as the World Health Organization (WHO) and the African Union (AU) in promoting scientific research into ATM has enhanced conduction of various types of scientific studies aimed at improving the safety, efficacy and quality of traditional medicines (AACHRD, 2002). Consequently, several African countries are intensifying efforts to improve traditional medicines through scientific research. For instance, laboratory analyses have been done in WHO-supported scientific studies conducted on traditional medicines intended for treatment of HIV/AIDS in Burkina Faso and Zimbabwe (AACHRD, 2002). The laboratory analyses done include CD4/CD8 counts and viral load measurements to assess efficacy as well as liver and kidney function tests to assess potential side effects of the medicines.

In addition, in Ghana, Kenya and Nigeria WHO has sponsored pilot clinical trials to test the efficacy of traditional medicines used to treat malaria. The control arms in the pilot trials were treated with chloroquine or fansidar for comparison (AACHRD, 2002). The clinical trials of the traditional medicines are being conducted by African scientists based at institutions in African countries. It should be pointed out that informed consent is obtained from people who participate in the scientific studies testing the traditional medicines, which should always be done when anything is being tested in humans.

In an effort to regulate, promote, develop or standardize the practice of ATM, some African countries are reviewing existing legal frameworks or putting in place new ones (WHO, 2001). For instance, the South African parliament recently passed the

Traditional Health Practitioners Act, No 35 (Traditional Health Practitioners Act, 2004). There are also efforts in various African countries such as South Africa to promote collaboration between Traditional Healers and biomedical researchers (South African Medical Association Task Team, 2006), which could go a long way in enhancing ethical and scientific standards and sharing of knowledge.

### 6. Relevance of international and national ethical codes and guidelines to African TM

If a Traditional Healer is not sure of the efficacy of the herbs s/he wants to try/test on a patient, but believes for one reason or another that it should work, patients should be informed about the uncertainty. Informing the person whose body is to be exposed to the 'experimental' traditional medicine, which in most cases is not for free but is paid for, that the medicine is being tested demonstrates respect for the person. Whether we want to call the 'testing' of the traditional medicines in patients 'research', and the disclosure of such 'testing' informed consent or something else is a matter of semantics. The fact of the matter is that a patient or customer should be given such information in order to make an informed decision. When African traditional medicines are being tested in clinical trials, the participants are informed and they give informed consent; the same should be done when the traditional medicines are being tested by African Traditional Healers.

If it is unethical for 'Western' medical practitioners to conduct the Edward Jenner type of 'testing' (which was poorly designed research) in patients, it follows that it is also unethical for traditional medical practitioners to conduct the same Edward Jenner-type of 'testing' (which is similarly poorly designed research) in their patients without first obtaining their informed consent. If such an action is considered ethically and morally wrong when the moral agent is a 'Western' medical practitioner and the patient is a poor, desperate African person, it should not be considered ethically and morally right when the moral agent is an African traditional medical practitioner and the patient is the same poor desperate person. If the 'Western' medical practitioner was to secretly test the African traditional medicines in the poor desperate African patients without their informed consent would it be considered to be ethically and morally right?

The fact that most of the ethical codes and guidelines being used nationally and internationally were a result of human abuses committed by scientists in Western countries does not make them completely irrelevant to ATM in Africa. One argument put forward is that "African TM was not an accomplice in, let alone the one responsible for, the medical atrocities that resulted in the Nuremberg Trials and the Nuremberg code" (Tangwa, 2007). Do we need to first have an African version of the Nazi atrocities so that we can then develop African versions of the Nuremberg code and African versions of all the subsequent ethical codes and guidelines? Is some form of disaster a prerequisite for existing mechanisms of protecting the clientele of African Traditional Healers to be strengthened and/or new ones to be put in place? Is it ethical and logical to require that humans should be harmed by ATM first, in large numbers like in the Nazi atrocities, before precautions could be taken or enhanced? Would that be an objective, proactive and ethical way of protecting human beings?

Are the ethical and moral principles on which the 'Western' codes and guidelines are based different from the ethical and moral values that prevail in the African communities that rely mainly on ATM? Such African ethical and moral values may not be written or given the same terms as the Western codes, but they are practiced in the day-to-day lives of the communities. The ethical principles of autonomy, beneficence, non-maleficence and justice have been practiced in the African communities in the absence of the ter-

minology that was eventually coined by the West. What then is wrong if the same principles and guidelines are used to assess the actions of African Traditional Healers as they practice or test their medicines either to improve efficacy or to tackle new diseases? The paucity of documented harms caused by ATM does not necessarily mean that such harms never occur.

## 7. African traditional medicines as an economic natural resource for developing countries

The global trade in traditional medicines is increasing in both developing and developed countries. For instance, US\$17 billion was spent on CAM in 2000 in the USA alone, with the global market for herbal medicines being over US\$60 billion (WHO, 2003). Thus traditional medicines are natural resources which could be developed to a level that significantly complements exports that generate the much needed foreign currency for most developing countries. The ultimate goal should be to have the improved African traditional medicines developed and manufactured in the developing countries so as to export them as finished products. Efforts to develop African traditional medicines into value-added medicinal products are being intensified in some African countries. For instance, a pharmaceutical company in South Africa has developed a local traditional medicinal herb called *Sunderlandia* into standardized tablets (AACHRD, 2002). In Nigeria two traditional medicines, *dopravil* and *conavil*, that local Traditional Healers claim to be effective for the management of HIV/AIDS have been standardized and have reached clinical trial phase II (AACHRD, 2002).

The developing countries stand to benefit to some extent from employment created by such endeavours to develop traditional medicines. In addition, there could be significant financial savings due to reduced imports of medicines from developed countries. The challenge to protect the owners of traditional knowledge, who may not be adequately protected by the existing current intellectual property rights (IPR) frameworks, has been pointed out (Timmermans, 2003; Nyika, 2007), and there is need to review or expand the current IPR policies in order to address the peculiar nature of traditional knowledge.

## 8. Concluding remarks

The majority of the African populations rely on ATM because it is easily accessible and is affordable. This fact makes the need to ensure that ATM is made as effective and as safe as possible urgent because of the large numbers of people who make use of it in the wake of high disease burden. Efforts to improve ATM should not be perceived as evidence of condemnation of the practice of ATM or as neocolonialism because dynamics in the disease patterns and socioeconomic status of the global populations, including African populations, dictate that ATM has to respond to the changes in order to effectively serve the purpose for which it has been developed. The ultimate goal should always be to make various complementary efforts that are ethical and are aimed at reducing the disease burden in African countries. The efficacy and safety of African traditional medicines could be enhanced through well designed research that is conducted ethically in Africa.

Any methods, be they African, Western, Chinese, or any other, that are capable of further improving the safety and efficacy of the African traditional medicines should be used as a matter of urgency because diseases are wrecking havoc in Africa in spite of the accessibility and affordability of the African traditional medicines in their current state. If it so happens that scientific methods are the most effective in terms of improving the safety and efficacy of medicinal products, be they African or Western, then let African scientists and Traditional Healers use the scientific methods to improve the African traditional medicines. What is the point of African govern-

ments investing a lot of resources in educating Africans in sciences and then consider use of scientific research to develop African traditional medicines to be unacceptable? However, whatever methods are used to develop the African traditional medicines, patients should be informed that research is going on and secondly ways of protecting the custodians of the traditional knowledge should be put in place.

When the actions of scientists are subjected to scrutiny, it is not because scientists are all evil people whose aim is to deliberately harm patients or research participants. Similarly, scrutiny of African Traditional Healers should not be viewed as condemnation of the practice of ATM in its entirety. Whereas it is to a reasonable extent possible to distinguish between practice and research in Western medicine, it is generally not very clear in the context of African traditional medicine. If African traditional medicines are being tested in humans, the Traditional Healers should inform the patients that the traditional medicines are being tested for effectiveness against the diseases that the patients are suffering from. That is respect for the patients who have a right to know that they are in a study to test some traditional medicines.

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