

ETHICAL AND REGULATORY ISSUES SURROUNDING AFRICAN TRADITIONAL MEDICINE IN THE CONTEXT OF HIV/AIDS

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African traditional medicine, HIV/AIDS, ethics, regulations

ABSTRACT

It has been estimated that more than 80% of people in Africa use traditional medicine (TM). With the HIV/AIDS epidemic claiming many lives in Africa, the majority of people affected rely on TM mainly because it is relatively affordable and available to the poor populations who cannot afford orthodox medicine. Whereas orthodox medicine is practiced under stringent regulations and ethical guidelines emanating from The Nuremburg Code,¹ African TM seems to be exempt from such scrutiny. Although recently there have been calls for TM to be incorporated into the health care system, less emphasis has been placed on ethical and regulatory issues.

In this paper, an overview of the use of African TM in general, and for HIV/AIDS in particular, is given, followed by a look at: (i) the relative laxity in the application of ethical standards and regulatory requirements with regards to TM; (ii) the importance of research on TM in order to improve and demystify its therapeutic qualities; (iii) the need to tailor-make intellectual property laws to protect traditional knowledge and biodiversity. A framework of partnerships involving traditional healers' associations, scientists, policy makers, patients, community leaders, members of the communities, and funding organizations is suggested as a possible method to tackle these issues. It is hoped that this paper will stimulate objective and constructive debate that could enhance the protection of patients' welfare.

INTRODUCTION

Plants have been used as sources of medicine for many centuries. For thousands of years, traditional

healers have been playing a major role as providers of primary health care to the majority of people in Africa. With the advent of orthodox, scientific, medicine early in the 19th century, traditional medicine (TM) began to be viewed as unconventional because active components had not been scientifically identified and proved to be efficacious. Although this led to the replacement of TM by orthodox medicine as

¹ The Nuremburg Code. 1949. *Trials of War Criminals Before the Nuremburg Military Tribunals Under Control Council Law*. Nuremburg, October 1946–April 1949. Washington, DC: US Government Printing Office: No.1; Vol.2: 181–182.

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the mainstream medicine in developed countries, in the developing world it has remained the first port of call for the majority of people.

The role of TM has been recognized by the World Health Organization (WHO): if the setting up of an office to specifically deal with the development of TM is anything to go by.² WHO defines TM as:

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.³

Thus, whereas orthodox medicine is arguably based on the axiom of Aristotle's dualism,⁴ which separates the spirit from the body and focuses on the latter, TM is based on both spiritual and physical components of personhood.⁵

The spiritual aspect is the basis of the supernatural dimension of TM,⁶ which tends to make it a taboo to question or attempt to fathom the intricacies of TM. The superstitious TM involves necromancy, which is the act of 'consulting' ancestral spirits for diagnosis and treatment.⁷ Unlike the supernatural component, herbalism is a branch of TM based on phytochemical components of herbs that have medicinal properties. For instance, artemisinin, which is derived from the plant *Artemisia annua*,⁸ has been tested scientifically and is recommended for treatment of malaria by WHO. In western Africa, extract of *Cryptolepis sanguinolenta* is an

established and widely used traditional medicine for malaria.⁹ Scientific studies have demonstrated the main alkaloid of *Cryptolepis sanguinolenta*, cryptolepine, to be a promising anticancer agent because it intercalates DNA and inhibits DNA synthesis in B16 melanoma cells¹⁰ and has cytotoxic effect on HL-60 leukemia cells.¹¹ Such medicinal properties were demonstrated in laboratories in the absence of magical or spiritual powers.

Since the emergence of the HIV/AIDS disease, many traditional medicines have been widely used by people living with HIV/AIDS (PLWHA),¹² in spite of the fact that no properly designed trials were conducted to identify any side effects and prove efficacy. In some cases, there are claims that the medicines can actually treat, or cure, HIV/AIDS.¹³ Since HIV/AIDS is a relatively new disease, the implications of this scenario are that: (i) the traditional medicines were 'revealed' through necromancy; and/or (ii) traditional healers have been 'testing' their medicines, probably through trial and error in some cases, on patients 'assumed' to be infected with HIV, with neither ethical approval from ethics committees nor informed consent from the patients concerned. Whereas it is illegal to prescribe conventional

² World Health Organization (WHO). 2003. *Traditional Medicine*. Geneva: WHO. Fact Sheet 134. Available at: <http://www.who.int/mediacentre/factsheets/fs134/en/> [Accessed 5 June 2006].

³ Ibid.

⁴ M. Cohen. 2003. *Aristotle's Metaphysics*. Stanford, CA: Stanford Encyclopaedia of Philosophy. Available at: <http://plato.stanford.edu/entries/aristotle-metaphysics/> [Accessed 5 June 2006].

⁵ A. Kleinman, L. Eisenberg & B. Good. Culture, Illness and Care: Clinical Lessons in Anthropology and Cross-cultural Research. *Ann Intern Med* 1978; 88: 251–258.

⁶ K. Little. 1954. The Mende in Sierra Leone. In *African Worlds. Studies in the Cosmological Ideas and Social Values of African Peoples*. D. Forde, ed. London: Oxford University Press: 127–128.

⁷ The Mystica. 2006. *Necromancy*. Online: The Mystica: An On-line Encyclopedia of the Occult, Mysticism, Magic, Paranormal and More. . . . Available at: <http://www.themystica.com/mystica/articles/n/necromancy.html> [Accessed 5 June 2006].

⁸ D. Klayman. Qinghaosu (Artemisinin): Antimalarial Drug from China. *Science* 1985; 238: 1049.

⁹ C. Ansah & N.J. Gooderham. The Popular Herbal Antimalarial, Extract of *Cryptolepis sanguinolenta*, is Potently Cytotoxic. *Toxicol Sci* 2002; 70: 245–251; M. Willcox, G. Bodeker & P. Rasoanaivo. 2004. *Traditional Medicinal Plants*. Boca Raton: CRC Press.

¹⁰ K. Bonjean et al. The DNA-intercalating Alkaloid Cryptolepine Interferes with Topoisomerase II and Inhibits Primary DNA Synthesis in B16 Melanoma Cells. *Biochemistry* 1998; 37: 5136–5146.

¹¹ L. Dassonville et al. Cytotoxicity and Cell Cycle Effects of Plant Alkaloids Cryptolepine and Neocryptolepine: Relation to Drug-induced Apoptosis. *Eur J Pharmacol* 2000; 409: 9–18.

¹² Food and Agriculture Organization of the United Nations (FAO). *Living Well with HIV/AIDS*. Geneva: UN. Available at: <ftp://ftp.fao.org/docrep/fao/005/y4168E/y4168E00.pdf> [Accessed 7 June 2006]; Health24.com. 2006. Beetroot, Garlic, Onions and Aids. Cape Town: Health24. Available at: <http://www.health24.com/dietnfood/General/15-742-775,30354.asp> [Accessed 8 June 2006]; Herald. 2005. 900 People Undergo Herbal Therapy. *The Herald (Zimbabwe)* 5 September. Available at: http://www.zimbabwesituation.com/sept7_2005.html [Accessed 8 June 2006]; Mail & Guardian Online. 2005. Bogus Aids Cures Flood Swaziland. *Mail & Guardian Online* 30 December. Available at: http://www.mg.co.za/articledirect.aspx?articleid=39732&area=%2fbreaking_news%2fbreaking_news_africa%2f [Accessed 4 June 2006]; IRIN-NEWS.Org. 2005. *ZIMBABWE: Traditional Healers Make a Killing as Healthcare Costs Rocket*. Online: IRINNEWS.ORG. Available at: <http://www.irinnews.org/report.asp?ReportID=48781> [Accessed 4 June 2006].

¹³ A. Abdulbaqi (trans. I. Alayoubi). *HIV Cure Gives Folk Medicine the Upper Hand*. Doha: Islam Online. Available at: <http://www.islamonline.net/English/science/2002/11/article07.shtml> [Accessed 4 June 2006].

medicines that are not registered with the relevant national drug regulatory authorities, there seems to be no such regulatory requirement for African TMs.

However, it should be acknowledged that some progress has been made in terms of efforts to regularize the practice of African TM, by forming national and international organizations to register traditional healers and coordinate their activities.¹⁴ Although the formation of such organizations is a step towards creating ethical and regulatory frameworks that could facilitate efficient monitoring and standardization of African TM, a lot still needs to be done to bring it to a par with orthodox medicine, not only in terms of efforts to incorporate it into mainstream primary health care systems but also in terms of sensitizing traditional healers, policymakers, health practitioners, bioethicists, patients, and ordinary people about the need to equally scrutinize African TM. The aim of this paper is to highlight some major ethical and regulatory issues surrounding African TM that tend to be ignored or treated lightly, in spite of their potential to compromise the welfare of patients, especially PLWHA.

AFRICAN TRADITIONAL MEDICINE IN GENERAL

Supernatural TM

African TM has two main branches, one of which is based on occult or supernatural powers.¹⁵ To practise supernatural TM, one is supposed to be a spirit medium, so that ancestral spirits can diagnose the cause of illness and reveal the right treatment. In this branch of TM, health problems are believed broadly to be caused by invisible forces such as witchcraft, curse, former existence (re-incarnation)

or aggrieved ancestral spirits rather than biological causes.¹⁶ Consequently, supernatural TM is characterized by sacredness; the traditional healer is the one who knows, after necromancy, what is good for the patient. Thus, the ethical issues such as informed consent, potential risks and benefits of the treatment are perceived to be irrelevant.

While it is appreciated that supernatural processes could be beyond the comprehension of humans, it is the practice of combining the magical branch of TM with ordinary herbalism that complicates application of ethical and regulatory guidelines. For instance, some ordinary herbs are combined with some rituals that are intended to take care of perceived spiritual causative agents of illness. In light of HIV/AIDS, some innocent children have been raped by adults as part of cleansing processes, which some traditional healers believe can get rid of the disease.¹⁷ Rape of children increases the risk of spreading HIV infection to innocent minors. Some fanatic believers of supernatural TM go to the extent of killing people in order to obtain body parts for rituals.¹⁸ The dividing line between rituals for

¹⁶ P. Geschiere & F. Cyprian. Domesticating Violence: Witchcraft, Courts and Confessions in Cameroon. *Africa* 1994; 64: 323–341; Little, *op. cit.* note 6; C.W. Ford. 2003. African Myth Search for the Sacred Within: Literal Enactment Deeply Misguided. *Cape Times* 15 October. Available at: <http://www.capetimes.co.za/index.php?fSectionId=271&fArticleId=260964> [Accessed 4 June 2006]; Mail & Guardian Online. 2001. Zimbabwe Healer Moots Magic Chastity Potion. *Mail & Guardian Online* 10 October. Available at: http://www.mg.co.za/articledirect.aspx?articleid=227089&area=%2farchives_Online_edition%2f [Accessed 4 June 2006].

¹⁷ B.L. Meel. The Myth of Child Rape as a Cure for HIV/AIDS in Transkei: A Case Report. *Med Sci Law* 2003; 43: 85–88; N.E. Groce & R. Trasi. Rape of Individuals with Disability: AIDS and the Folk Belief of Virgin Cleansing. *Lancet* 2004; 363: 1663–1664; C. Smith. 2004. *Rape has become a Way of Life in South Africa: Police Reported this Week that they were Achieving Success in Combating Most Crimes, but Not Rape*. Durban: Health Systems Trust. Available at: <http://www.hst.org.za/news/20040511> [Accessed 5 June 2006]; G. du Venage. 2002. Rape of Children Surges in South Africa: Minors Account for About 40% of Attack Victims. *San Francisco Chronicle* 12 February. Available at: <http://www.aegis.com/news/sc/2002/SC020203.html> [Accessed 5 June 2006]; P. Govender. 1999. Child Rape: A Taboo within the AIDS Taboo; More and More Girls are being Raped by Men who Believe this will 'Cleanse' them of the Disease, but People don't want to Confront the Issue. *Sunday Times (South Africa)* 4 April. Available at: <http://www.aegis.com/news/suntimes/1999/ST990401.html?FACT-Net> [Accessed 5 June 2006]; The Body: The Complete HIV/AIDS Resource. 2003. *Rise in Child Rapes in Zambia Traced to AIDS Cure Myth, Some Say*. Menlo Park, CA: Henry J. Kaiser Family Foundation. Available at: http://www.thebody.com/Kaiser/2003/dec22_03/child_rape.html?m29o [Accessed 5 June 2006].

¹⁴ G. Bodeker et al. A Regional Taskforce on Traditional Medicine and AIDS. *Lancet* 2000; 355: 1284; Guardian. 2000. Traditional Medicine Practice and Practitioners are Accorded Formal Status in the Nigerian National Health System, and will Contribute to the Fight against HIV/AIDS. *The Guardian (Nigeria)* 6 December. Available at: <http://www.worldbank.org/afr/ik/guardart.htm> [Accessed 4 June 2006]; Biore-sources Development and Conservation Programme (BDPC). 2006. *Drug Development: Science for the Common Good*. Washington, DC: BDPC. Available at: <http://www.bioreources.org/prog2.htm> [Accessed 4 June 2006]; Abdulbaqi, *op. cit.* note 13.

¹⁵ Little, *op. cit.* note 6.

supernatural healing purposes and witchcraft is hazy but what is clear is that such practices are not only unethical but also inhuman and illegal. It should be noted that national and international organizations of traditional healers have since condemned such inhuman practices, attributing them to bogus traditional healers.¹⁹ It is therefore important to demystify diagnosis and therapy if TM is to meet minimum ethical and regulatory standards that would facilitate its incorporation into mainstream primary health care systems.

Herbalism

The other branch of TM is herbalism, which is based on the premise that some herbs have botanical components with therapeutic properties. The indigenous knowledge about medicinal herbs is passed on from one generation to another without documentation. However, the herbs are generally used as crude mixtures without adequate information about safe dosages and potential harmful side effects. Even when the traditional healers are not certain about the safety and effectiveness of particular herbs, such doubts are not revealed to patients. Thus, patients may be used for 'experimentation' without their knowledge or consent. Consequently, the practice of TM, without standardization, could be perceived as perpetual, poorly designed 'experimentation' with human patients.

The fact that efficacy of a treatment is not sufficient to justify its use but that harmful side effects

are equally important should be emphasized in medicine, traditional or orthodox. For instance, although aspirin is a common registered drug that has been used widely, its anti-haemostatic properties that increase post-operative blood loss were observed in the early 1980s.²⁰ Aspirin has also been reported to cause a rare but lethal condition in children called Reye's syndrome, which is characterized by damage to the brain (encephalopathy) and liver.²¹ Similarly, some traditional medicines could have potentially harmful side effects, even if they are efficacious. If the side effects are known, no matter how rare they may be, then, firstly, appropriate precautions can be taken whenever possible and, secondly, patients can make informed decisions pertaining to proposed treatments.

A paternalistic, numinous approach in the practice of traditional medicine violates ethical principles of autonomy, beneficence and non-maleficence. If patients are not given information pertaining to a treatment, allowing them to make voluntary informed decisions whether or not to undergo prescribed treatment, then the principle of autonomy is not upheld. To uphold the principles of beneficence and non-maleficence, the therapeutic benefits of the treatment have to be maximized while making an effort to minimize the potential harms. However, if the potential harms are not known, it becomes difficult to try and minimize them. Gathering information about the side effects of herbs requires properly designed studies to be conducted, rather than relying on anecdotal observations by individual traditional healers on individual patients treated.

Privacy and confidentiality of patients should be ensured, especially when dealing with sensitive diseases such as HIV/AIDS. Consultations at the traditional healers usually involve families rather than individuals. In some cases, the sick person does not go to the healer but family members go on his or her behalf. Thus, the privacy and confidentiality of the patient could be compromised.

¹⁸ AllAfrica.com. Ghanaians Killed for Rituals as Government Delegation Dumbfounded. Online: AllAfrica.com. Available at: <http://allafrica.com/stories/200508190871.html> (Subscription) [Accessed 5 June 2006]; R. Mweninguwe. 2005. *Ritual Murder Mars Women's Day*. Nairobi: News From Africa. Available at: http://www.newsfromafrica.org/newsfromafrica/articles/art_10175.html [Accessed 5 June 2006]; E. Barry. 2005. *The Witchcraft Murder*. Washington, DC: National Geographic. Available at: http://blogs.nationalgeographic.com/channel/blog/2005/03/explorer_witchcraft.html [Accessed 5 June 2006]; Daily News. 1999. Couple in Alleged Ritual Killing Granted Bail. *The Daily News* 30 March: 2; Standard. 1991. Too Old to be Sacrificed. *The Standard* 18–24 April: 1; Sunday Mail. 1999. Ritual Murders and Trade in Body Parts on the Increase. *The Sunday Mail* 18 April: 2.

¹⁹ United Nations (UN). 2002. *United Nations Rights Expert Calls for Measures Aimed at Child Victims of Sexual Violence in South Africa*. Press Release, 14 October. Geneva: UN. Available at: <http://www.unhcr.ch/hurricane/hurricane.nsf/0/7EEF5A26FEC5AAF4C1256C48003259EB?opendocument> [Accessed 5 June 2006].

²⁰ L.F. Prescott. Post-operative Bleeding Caused by Aspirin. *J Dent* 1980; 6: 207–208.

²¹ National Reye's Syndrome Foundation. *Reye's Syndrome*. Online: National Reye's Syndrome Foundation. Available at: <http://www.reyessyndrome.org/> [Accessed 5 June 2006].

AFRICAN TRADITIONAL MEDICINE IN LIGHT OF HIV/AIDS

Detection of HIV infection

There are no scientifically proven traditional methods of detecting HIV infection. Thus, patients presenting to traditional healers either do not know their HIV status or they know their status from voluntary counselling and testing (VCT). Since the traditional healers are the ones expected to make a diagnosis, it becomes immaterial whether or not the patient knows his or her HIV status. In light of the HIV/AIDS epidemic, failure to detect HIV infection as soon as possible means that infection may have spread to any sexual partner(s) by the time the correct cause of the illness is known. Such a scenario would increase HIV incidence rates, which would worsen the situation in Africa, especially sub-Saharan Africa, where 3.1 million new infections in 2004 increased the total number of people living with HIV/AIDS in the region to 25.4 million.²² Although the population of sub-Saharan Africa is about 10% of the world's population, 60% of people living with HIV/AIDS globally are in this Third World region.²³ Thus, no stone should be left unturned, including African TM, as efforts are made to ameliorate the devastating effects of the HIV/AIDS epidemic.

It should be noted that, in both TM and orthodox medicine, causation of any illness should be correctly established if the correct treatment is to be prescribed. An incorrect diagnosis, or incorrectly attributing causation of ill-health to mystical spiritual forces, means that wrong and irrelevant medication would be prescribed to the patient concerned. Thus, the condition of the patient would worsen while getting wrong and ineffective treatment. This would not only be unethical, but could also have public health implications.

²² AVERT.ORG. HIV & AIDS in Africa. *The HIV & AIDS Epidemic in Africa*. Horsham: Avert. Available at: <http://www.avert.org/aidsinafrica.htm> [Accessed 5 June 2006].

²³ Ibid.

Misinformation about herbs used by some people living with HIV/AIDS

Although antiretrovirals (ARVs) have been proved to be effective,²⁴ use of traditional medicines is predominant in developing countries due to various socio-economic factors. Information about herbal treatments and remedies that some traditional healers and PLWHA believe to be beneficial has been widely publicized.²⁵

Traditional 'treatments' for HIV/AIDS that have gained popularity include the African potato (*Hypoxis* species), virgin olive oil, onions, beetroot, aloe, and ginger.²⁶ These and other herbs are loosely described as 'treatments for HIV/AIDS' by traditional healers and by ordinary members of the community. Some controversial government officials have publicly endorsed such herbs, regardless of lack of scientific evidence of their efficacy,²⁷ and in some instances clinics²⁸ or companies²⁹ have been established to dispense or market the herbs. Since they are cheap and available, some desperate PLWHA may first resort to using these 'treatments' and, thus, delay seeking ARV treatment which has been shown to be effective treatment for HIV infection.³⁰ Patients who consult traditional healers have the same rights as those of patients presenting to

²⁴ F.J. Palella et al. Declining Morbidity and Mortality among Patients with Advanced Human Immunodeficiency Virus Infection. *N Engl J Med* 1998; 338: 853–860; C. Kabugo et al. Long-term Experience Providing Antiretroviral Drugs in a Fee-for-service HIV Clinic in Uganda: Evidence of Extended Virologic and CD4+ Cell Count Responses. *J Acquir Immune Defic Syndr* 2005; 38: 578–583.

²⁵ Food and Agriculture Organization of the United Nations, *op. cit.* note 12; Health24.com, *op. cit.* note 12; Mail & Guardian Online, *op. cit.* note 12; IRINNEWS.Org, *op. cit.* note 12; Abdulbaqi, *op. cit.* note 13.

²⁶ Food and Agriculture Organization of the United Nations, *op. cit.* note 12; Health24.com, *op. cit.* note 12.

²⁷ News24.com. 2005. *Manto Sticks to her Guns*. Online: News24.com. Available at: http://www.news24.com/News24/South_Africa/Aids_Focus/0,6119,2-7-659_1700396,00.html [Accessed 5 June 2006]; News24.com. 2005. *Dr Garlic Defends Aids Work*. Online: News24.com. Available at: http://www.news24.com/News24/South_Africa/Aids_Focus/0,,2-7-659_1700492,00.html [Accessed 5 June 2006].

²⁸ Herald, *op. cit.* note 12.

²⁹ S. Tsiko. 2006. Launch of Traditional Medicine School a Milestone. *The Herald (Zimbabwe)* 8 May. Available at: <http://allafrica.com/stories/200605090194.html> [Accessed on 6 June 2006]; Herald. 2005. *Moringa Oleifera Miracle Tree that Boosts Immune System*. *The Herald (Zimbabwe)* 5 June.

³⁰ Palella et al., *op. cit.* note 24; Kabugo et al., *op. cit.* note 24.

conventional medical practitioners. Patients are entitled to full disclosure of information about the proposed treatment so that they can make informed decisions. Patients should also be free to ask traditional healers any questions without fear of prejudicing relationships, not only with the traditional healers but also with their relatives who may consider such questioning disrespectful or taboo.

Implications of delay in seeking proven ARV treatment

Any delays by HIV-infected people in seeking proven and effective treatment create various problems that need to be addressed if the fight against the HIV/AIDS epidemic is to be effective. Firstly, such delays pose a public health problem since HIV-infected people taking these 'treatments', which have not been shown to lower their viral load, could fuel the spread of the virus if they do not practise safe sex. Secondly, the delay in seeking ARV treatment means that the progression to full-blown AIDS could take place unabated, leading to loss of productivity and high costs of caring for terminally ill relatives. Thirdly, people whose lives could have otherwise been prolonged by taking ARVs early die prematurely, leaving orphans and elderly people to fend for themselves.

Use of both traditional medicines and ARVs

Potential risk of developing ARV drug resistance due to reduced ARV adherence

Emergence of ARV-resistant strains has been reported by various authors³¹ and their potential

³¹ F.M. Hecht et al. Sexual Transmission of an HIV-1 Variant Resistant to Multiple Reverse-transcriptase and Protease Inhibitors. *N Engl J Med* 1998; 339: 307–311; D. Boden, A. Hurley & I. Zhang. HIV-1 Drug Resistance in Newly Infected Individuals. *JAMA* 1999; 282: 1135–1141; S.J. Little, E.S. Daar & R.T. D'Aquila. Reduced Antiretroviral Drug Susceptibility among Patients with Primary HIV Infection. *JAMA* 1999; 282: 1142–1149; S. Yerly et al. Transmission of Antiretroviral Drug-resistant HIV-1 Variants. *Lancet* 1999; 354: 729–733; H.B. Gershengorn & S.M. Blower. The Impact of Antivirals and the Emergence of Drug Resistance: HSV-2 Epidemic Control. *AIDS Patient Care STDs* 2000; 14: 133–142.

transmission pose a serious public health problem.³² One of the factors that contributes towards development of drug resistance is non-adherence.³³ Concomitant use of ARV treatment and traditional medicine for HIV/AIDS could compromise compliance as one may switch from one to the other at certain times. Some proponents of alternative 'treatments' for HIV/AIDS have gone to the extent of publicly condemning ARVs as poison in order to discourage PLWHA from using them.³⁴ Such public campaigns by proponents of alternative treatments for HIV/AIDS undermine VCT and ARV roll out programs at population level and compromise ARV drug compliance at individual level. If the magnitude of the public health problems associated with drug resistance is not appreciated not much effort will be made to understand various factors that could lead to development of ARV drug resistance.

Beliefs and practices that could potentially affect adherence to ARV treatments, therefore, need to be understood in order to reduce the risk of development of ARV drug-resistant HIV strains. In a study conducted in South Africa, 35% of respondents believed that missing ARV doses did not lead to faster progression of the HIV/AIDS disease.³⁵ Therefore, effective behavioural interventions and treatment strategies depend to a large extent on the realization of the fact that some HIV/AIDS patients who are on ARV therapy also use traditional

³² M.A. Wainberg & G. Friedland. Public Health Implications of Antiretroviral Therapy and HIV Drug Resistance [Special Communication]. *JAMA* 1998; 279: 1977–1983; H. Salomon, M.A. Wainberg & B. Brenner. Prevalence of HIV 1 Resistant Antiretroviral Drugs in 81 Individuals Newly Infected by Sexual Contact or IDU. *AIDS* 2000; 14: F17–F23.

³³ World Health Organization (WHO). Drug Resistance: HIV/AIDS. HIV Drug Resistance to Antiretroviral Drugs. Geneva: WHO. Available at: <http://www.who.int/drugresistance/hivaids/en/> [Accessed 5 June 2006].

³⁴ M. Merten & N. Deane. 2005. Vitriolic Dr Rath Attacks TAC. *Mail & Guardian Online* 15 March. Available at: http://www.mg.co.za/articlePage.aspx?articleid=199867&area=/insight/insight_national/ [Accessed 5 June 2006]; L. Gedye. 2005. UN Condemns Raths HIVAids Advertisements. *Mail & Guardian Online* 4 April. Available at: <http://www.mg.co.za/articlePage.aspx?articleid=200811&area=/insight/monitor/> [Accessed 5 June 2006]; Mail & Guardian Online. 2005. Harvard Researchers Condemn Rath. *Mail & Guardian Online* 10 May. Available at: http://www.mg.co.za/articlePage.aspx?articleid=237722&area=/breaking_news/breaking_news_national/ [Accessed 5 June 2006].

³⁵ J.B. Nachega et al. HIV/AIDS and Antiretroviral Treatment Knowledge, Attitudes, Beliefs, and Practices in HIV-infected Adults in Soweto, South Africa. *Acquired Immune Defic Syndr* 2005; 38: 196–201.

medicines, and an understanding of their beliefs and practices in the context of HIV/AIDS is important.

Potential harmful interactions

Effects of interactions between some traditional herbs and ARVs are not fully known. However, preliminary studies have shown that such interactions could be detrimental to the health of people on ARV treatment. For instance, garlic, which is used by some PLWHA,³⁶ has been reported to lower blood levels of saquinavir, an antiretroviral medicine.³⁷ St. John's Wort has also been reported to affect negatively indinavir, a protease inhibitor used as an HIV drug, by reducing its blood level by about 57%.³⁸ St. John's Wort also interacts with nevirapine, a non-nucleoside reverse transcriptase inhibitor.³⁹ Such potentially harmful interactions could also occur between different traditional medicines prescribed to a patient.

Potential increase of risky behaviour due to optimism and complacency

Optimism and complacency due to use of antiretroviral therapy have been associated with increased high-risk sexual behaviour at population level among gay men.⁴⁰ Similarly, use of traditional medicines by people infected with HIV could lead to the same kind of optimism and complacency, which in turn could lead to an

increase in unsafe sex. In developing countries more than 70% of people living with HIV/AIDS do not have access to ARVs⁴¹ and the majority of them use TM. In light of the facts that some of the HIV/AIDS patients are made to believe that the TM they use can treat, or even cure, HIV/AIDS, and that the predominant mode of transmission of HIV in Africa is unprotected sex, the potential increase in risky sexual behaviour of PLWHA using African TM is a practical public health threat that could significantly fuel the spread of the epidemic.

Exploitation of desperate PLWHA

Although some traditional herbs could reverse some symptoms of opportunistic infections, it is unethical to claim that they treat or cure HIV/AIDS. Traditional healers have been reported to be making fortunes in the wake of the HIV/AIDS epidemic.⁴² Being trusted and respected members of their communities, some traditional healers have taken advantage of the desperation of PLWHA to enrich themselves. The absence or laxity of regulations governing the practice of TM has created an environment that is conducive to the exploitation of desperate PLWHA. Claims that traditional medicines can treat or cure HIV/AIDS are examples of deceit by people who have influence over ordinary members of society.

³⁶ Food and Agriculture Organization of the United Nations, *op. cit.* note 12.

³⁷ S.C. Piscitelli, A.H. Burstein & N. Welden. The Effect of Garlic Supplements on the Pharmacokinetics of Saquinavir. *Clin Infect Dis* 2002; 34: 234–238.

³⁸ S.C. Piscitelli, A.H. Burstein & D. Chaitt. Indinavir Concentrations and St. John's Wort. *Lancet* 2000; 355: 547–548.

³⁹ M.M. de Maat et al. Drug Interaction between St. John's Wort and Nevirapine. *AIDS* 2001; 15: 420–421.

⁴⁰ A. Larpote. A New Decline in Preventive Behaviours among Homosexual Men: The Role of Highly Active Antiretroviral Therapy? *Euro Surveill* 2002; 7: 15–16; International Collaboration on HIV Optimism. HIV Treatments Optimism among Gay Men: An International Perspective. *J Acquir Immune Defic Syndr* 2003; 33: 345–550; J.M. Stephenson et al. Is Use of Antiretroviral Therapy among Homosexual Men Associated with Increased Risk of Transmission of HIV Infection? *Sex Transm Infect* 2003; 79: 7–10; P. Van de Ven et al. HIV Treatment Optimism is Associated with Unprotected Anal Intercourse with Regular and Casual Partners among Australian Gay and Homosexually

Active Men. *Int J STD AIDS* 2002; 13: 181–183; J. Elford, G. Bolding & L. Sherr. High-risk Sexual Behaviour Increases among Gay Men between 1998 and 2001: What is the Role of HIV Optimism? *AIDS* 2002; 16: 1537–1544; M.C. Boily et al. Changes in the Transmission Dynamics of the HIV Epidemic after the Wide-scale use of Antiretroviral Therapy could Explain Increases in Sexually Transmitted Infections: Results from Mathematical Models. *Sex Transm Dis* 2004; 31: 100–113.

⁴¹ World Health Organization (WHO). 2004. '3 by 5' Progress Report, December 2004. Geneva: WHO. Available at: <http://www.who.int/3by5/progressreport05/en/> [Accessed 5 June 2006].

⁴² Mail & Guardian Online, *op. cit.* note 12; IRINNEWS.Org, *op. cit.* note 12.

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Patients should be protected, regardless of who is conducting research

The need to protect participants has resulted in controversies over drugs such as thalidomide,⁴³ trovan,⁴⁴ virodene,⁴⁵ and tenofovir.⁴⁶ This has been possible because modern medicines and drug trials are increasingly under scrutiny from scientists, politicians, ethics committees, drug regulatory authorities, patients and ordinary people. Thus, scientific rigour and high ethical standards are considered to be the cornerstones of protection of research participants and patients. Although lack of safety and efficacy information about some traditional medicines could endanger the lives of patients, stakeholders involved in protecting the welfare of people tend to bury their heads in the sand. A traditional healer can prescribe any herb without anyone asking for its name, contraindication, mode of action and/or evidence of safety.

The fact that traditional healers have 'discovered' traditional medicines for 'treatment' of new diseases like HIV/AIDS implies that they 'test' their herbs on humans, probably guided by necromancy or using inherited knowledge. Since such 'tests' are conducted out of the spotlight and there is no monitoring of adverse events, as is the case with ethically approved scientific trials, patients may be harmed without anyone noticing. In addition, patients are charged for such services in spite of being potentially uninformed guinea pigs. Could scientists or pharmaceutical companies do the same without causing an outcry? Such an action would constitute professional misconduct and/or negligence if committed by medical practitioners.

⁴³ CBC Archives. Thalidomide: Bitter Pills, Broken Promises. Toronto, ON: CBC. Available at: http://archives.cbc.ca/IDD-1-75-88/science_technology/thalidomide/ [Accessed 5 June 2006].

⁴⁴ BBC News. 2001. *Nigerians Sue Pfizer over Test Deaths*. London: BBC News. Available at: <http://news.bbc.co.uk/1/hi/business/1517171.stm> [Accessed 5 June 2006].

⁴⁵ S. Mullholland. Virodene Saga a Lesson in how not to Conduct Affairs. *Sunday Times. Business Times* 30 August. Available at: <http://www.btimes.co.za/98/0329/columns/columns2.htm> [Accessed 5 June 2006].

⁴⁶ J.A. Singh & E.J. Mills. The Abandoned Trials of Pre-Exposure Prophylaxis for HIV: What Went Wrong? *PLoS Med.* 2005; 2: e234.

From animal models to human trials

The importance of well-designed scientific studies on traditional medicines has been acknowledged.⁴⁷ Such studies should address side effects, efficacy and standardization of herbal medicines. To date, scientific studies on some traditional herbs have demonstrated their medicinal value in animal models. For instance, cardiovascular-protective effects of crude methanolic extracts of *Harpagophytum procumbens*, a plant commonly known as Devil's Claw or grapple plant, which has been used to treat such health conditions as hypertension, diabetes mellitus, gout, fever, skin cancer and osteoarthritis,⁴⁸ were observed in experimental arrhythmias in rats and rabbits.⁴⁹ In addition, aqueous extract of *H. procumbens* was shown to induce dose-related decreases in arterial blood pressure and heart rate in laboratory animal studies.⁵⁰ Other studies demonstrated anticonvulsant and sedative properties of aqueous extract of *Passiflora edulis* in laboratory animals.⁵¹ Traditionally, *Passiflora* herbs have been used to treat health conditions of the nervous system such as epilepsy, insomnia, anxiety and headache.⁵² Safety studies of *Sutherlandia microphylla*, a traditional herb used by some PLWHA, have been conducted in vervet monkeys in South Africa.⁵³ Such laboratory findings help to demystify the medicinal properties of traditional herbs.

⁴⁷ C.O. Adewunmi & A.O. Ojewole. Safety of Traditional Medicines, Complementary and Alternative Medicines in Africa. *AJTICAM* 2004; 1: 1–3.

⁴⁸ B.E. van Wyk & M. Wink. 2004. *Medicinal Plants of The World*. Pretoria: Briza Publications: 164–167; J.M. Watt & M.G. Breyer-Brandwinjk. 1962. *The Medicinal and Poisonous Plants of Southern and Eastern Africa*. 2nd ed, London: Livingstone: 828–830.

⁴⁹ C.F. Circosta et al. 1984. A Drug used in Traditional Medicine: *Harpagophytum procumbens* DC. II. Cardiovascular Activity. *J Ethnopharmacol* 11: 259–274.

⁵⁰ I.M. Mahomed & A.O. Ojewole. Cardiovascular Effects of *Harpagophytum Procumbens* [Pedaliaceae] Secondary Root Aqueous Extract in some Mammalian Experimental Animal Models. *AJTICAM* 2004; 1: 30–40.

⁵¹ E. Ngo Buma et al. Sedative and Anticonvulsant Properties of *Passiflora Edulis* Dried Leaves Decoction in Mice. *AJTICAM* 2004; 1: 63–71.

⁵² C. Wolfman et al. Possible Anxiolytic Effects of Chrysin, a Central Benzodiazepine Receptor Ligand Isolated from *Passiflora coerulea*. *Pharmacol Biochem Behav* 1994; 4: 1–4.

⁵³ SAHealthInfo. 2006. *Traditional Medicines. First Toxicity Study of Sutherlandia Leaf Powder (Sutherlandia microphylla) Consumption*. Online: SAHealthInfo. Available at: <http://www.sahealthinfo.org/traditionalmeds/firststudy.htm> [Accessed 5 June 2006].

It follows, therefore, that research on TM should follow the same stages, that is, from animal model to human trials, as for conventional medicines. There should be ethical approval, first person informed consent, monitoring for adverse reactions and dissemination of findings.

Non-maleficence

Properly designed studies are important for the detection of harmful side effects of traditional medicines that may not be picked up by anecdotal observations on individual patients by traditional healers. Indeed, some side effects may only be detected after long-term meta-analysis studies. For instance, recent studies showed that use of ephedrine, a drug derived from three species of the genus *Ephedra*, namely *E. sinica*, *E. equisentina* and *E. intermedia*, is associated with high risk of cardiovascular disease and psychiatric symptoms such as autonomic hyperactivity and palpitations.⁵⁴ These findings led to the US Food and Drug Administration (FDA) advising consumers to stop using ephedra products.⁵⁵

Use of crude mixtures may expose patients to some toxic components, which may be harmless individually but fatal when in combination with other chemicals. Such a case was shown by phytochemical studies that revealed that poisonous properties of *Erythrophleum* species could be due to the combined toxicity of the constituent alkaloids, saponins, tannins and glycosides.⁵⁶ It is therefore imperative that constituent components of herbs be identified and characterized in order to minimize chances of inadvertently causing harm to patients.

⁵⁴ US Food and Drug Administration (FDA). *Evidence Report/Technology Assessment Number 76. Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*. Rockville, MD: FDA. Available at: <http://www.fda.gov/bbs/topics/News/ephedra/summary.html> [Accessed 5 June 2006].

⁵⁵ US Food and Drug Administration (FDA). *Sales of Supplements Containing Ephedrine Alkaloids (Ephedra) Prohibited*. Rockville, MD: FDA. Available at: <http://www.fda.gov/ov/initiatives/ephedra/december2003/> [Accessed 5 June 2006].

⁵⁶ W.J. Griffin et al. Alkaloids of the Leaves of *Erythrophleum Chlorostachys*. *Phytochem.* 1971; 10: 2793–2797; N.J. Loder et al. Tumor Inhibitory Plants: New Alkaloids from the Bark of *Erythrophleum Chlorostachys* (Leguminosae). *Aust J Chem* 1974; 27: 179–185; B.A. Adeoye & O.O. Oyedapo. Toxicity of *Erythrophleum Guineense* Stem-bark: Role of Alkaloidal Fraction. *AJTAM* 2004; 1: 45–54.

Conservation and intellectual property issues

Research and campaigns to address conservation issues should be equally intensified. Use of traditional herbs is increasing due to domestic and foreign demand. The devastating impact of the HIV/AIDS epidemic on poverty-stricken communities is arguably causing the increase in local demand for traditional herbs. Although the majority of people in developed countries have access to primary health care, traditional medicine, which is referred to as 'complementary' or 'alternative' medicine (CAM),⁵⁷ is gradually becoming popular. In Canada and Germany, 70% and 90% of the population, respectively, have used CAM at least once in their life.⁵⁸ The annual expenditure on CAM by 2003 was US\$17 bn in the USA and US\$60 bn in the United Kingdom.⁵⁹ Consequently, international trade in traditional medicines has been on the increase. It is therefore imperative that conservation programs be implemented urgently to avoid extinction of some herbs. One possible way to achieve this is to make it an ethical and regulatory requirement for companies dealing in phytomedicines to plough back a stipulated proportion of their proceeds into conservation projects.

Intellectual property rights issues also need to be addressed if trust is to be enhanced between traditional healers, on one hand, and research scientists, regulatory authorities, pharmaceutical companies, and bioethicists, on the other. Without such mutual trust, unsubstantiated claims of safety and efficacy of some traditional medicines would continue to endanger the welfare of patients, especially PLWHA. Some stakeholders suspect that once a traditional herb has been taken into the laboratory and is commercialized, the traditional healers and their communities, who gave the leads in the first place, do not get any benefits. Consequently, increased bioprospecting activities by academics and pharmaceutical companies have raised fears of biopiracy.

Generally, inherited knowledge about traditional herbs and their use may not meet certain legal

⁵⁷ World Health Organization, *op. cit.* note 2.

⁵⁸ *Ibid.*

⁵⁹ *Ibid.*

intellectual property requirements, such as novelty and technical specification of active components. In addition, the patent process tends to be long, tedious and costly. This is further complicated by the fact that, in some instances, communities, in addition to the traditional healers, claim ownership of the traditional knowledge and the herbs. Such community claims led to royalty agreement between the San people of the Kalahari desert, on one hand, and Phytopharm and the South African government research agency (CSIR), on the other.⁶⁰ The case of the San people demonstrates how intellectual property laws could accommodate traditional healers and their communities by making them customary custodians of traditional knowledge and herbs, thus creating a legal framework for royalties to filter to the ordinary community members. However, it would be necessary to develop transparent and efficient mechanisms of benefit sharing. One possible mechanism is the formation of trust funds to which royalties could be channelled for developmental and/or conservational programs.

CONCLUSION

There are loopholes in the practice of African traditional medicine that have the potential to expose patients to harm. The fact that traditional medicines have been used for many centuries does not necessarily prove their safety and efficacy since not many

well-designed scientific studies have been conducted and their popularity could be due to relative affordability and/or availability. To a large extent, superstition attached to African TM slows down the process of bringing ethical and regulatory issues surrounding African TM under the spot light. When new diseases like HIV/AIDS crop up, the traditional healers tend to 'try' their medicines to treat the new disease. This 'testing' of existing medicines, based on an individual traditional healer's experience, inherited knowledge or supernatural powers is arguably poorly designed 'experimentation' on individual patients without ethical approval or informed consent. If scientific researchers have to have ethical approval to conduct studies on patients, and medical doctors have to prescribe registered medicines, then the same should be expected of traditional healers. Post registration surveillance studies should also be conducted in order to gather data on long-term risks and benefits of traditional medicines. In light of the fact that the majority of PLWHA are likely to be relying on traditional medicines, solely or in addition to ARVs, African TM is a major factor in the epidemiology of HIV/AIDS in Africa. Intellectual property laws need to be reviewed in order to protect indigenous knowledge and cultivate a sense of trust among traditional healers, patients, community members, scientists, policy makers, bioethicists and sponsors as a basis for the formation of partnerships in the health sector.

⁶⁰ UNC Kenan-Flagler Business School. 2005. *Corporate Responsibility in the Global Village. South Africa: Unilever Pays Bushmen to use Plant in Slim-Fast*. Chapel Hill, NC: UNC Kenan-Flagler Business School. Available at: <http://www.kenan-flagler.unc.edu/assets/documents/csr200501.pdf> [Accessed 5 June 2006].

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