



African
HEALTH MONITOR

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Traditional Medicine

Our Culture, Our Future

- **An Overview of the Traditional Medicine Situation in the African Region**
- **Integration of Traditional Medicine into National Health Systems**
- **Implementing the Regional Strategy on Traditional Medicine**
- **Enhancing Traditional Medicine Research & Development in Africa**
- **Accelerating Local Production of Traditional Medicines in Africa**
- **Pharmacoeconomics of Traditional Medicine**

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From the Regional Director's Desk

For all the revolutionary and dramatic improvements in human health care in the 21st century, life in much of Africa begins with, and is sustained by, the support of traditional medicine.

In many parts of Africa, the number of traditional health practitioners far outnumber that of medical doctors. The estimated average ratio of traditional health practitioners to the population is 1:200, and that of conventional health practitioners to the population is 1:25,000. It is also estimated that from the cradle to the grave, about 80% of Africans rely on traditional medicine for their health care needs.

Thus, from the Cape to Cairo, and from Dakar to Djibouti, Africans seek traditional health care along with, or even before approaching, modern medical services. This practice affirms the *de facto* existence of medical pluralism, irrespective of whether or not it is acknowledged at the formal level. In other words, Africans have a long tradition of using these two systems of health care, singly or in combination, thus rendering

'integration' - the formalization or incorporation of traditional medicine into national health services - a reality at the grassroots level.

Not only is traditional medicine popular and accepted in many African communities, it is the only system available in most, as Western or Orthodox medicine is too costly and inaccessible.

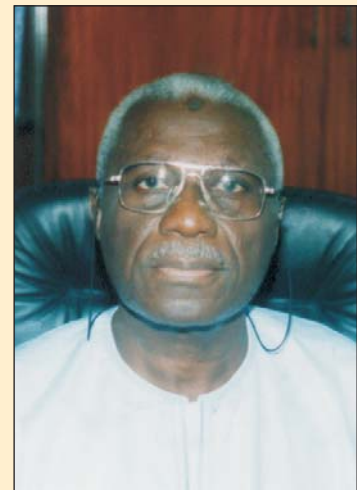
The question therefore arises: why don't we promote what is accessible and acceptable to us, and institute measures to nurture and manage it?

The arguments in favour of traditional medicine development and utilization in Africa are, indeed, legion and compelling: it is cheaper than modern medicine; it is widely available in practically all our communities; it is part of the medical culture of our societies, and its practitioners are highly regarded and socially-sanctioned with well-established clientele.

How has traditional medicine fared in Africa? Is it effective? If so, what is the evidence? How should issues of safety, efficacy, quality, standardization,

regulation and intellectual property rights be handled? Is commercial production feasible and desirable? Above all, should traditional medicine be institutionalized and "integrated" into mainstream health systems and services? Why is integration necessary? How can it be achieved?

These issues and related subjects are examined in this fourth issue of the *African Health Monitor*, which I recommend for your reading.



Dr Ebrahim M. Samba
Regional Director

Message of the WHO Regional Director for Africa, Dr Ebrahim Samba, on the Occasion of the first African Traditional Medicine Day - 31 August 2003

Today, 31 August 2003, Africa commemorates the first African Traditional Medicine Day.

The theme for the inaugural commemoration of the Day is *Traditional Medicine: Our Culture, Our Future*.

Why commemorate an African Traditional Medicine Day with a theme woven around culture, one may ask.

Since time immemorial traditional health practitioners have played crucial roles in combating multiple and complex conditions affecting people in the Region.

Traditional medicine was the only system available for health care for centuries for the prevention, diagnosis and treatment of social, mental and physical illnesses. Despite the official stigmatization of the system during the colonial era, it continued to thrive, even if largely underground. The dawn of independence in the 60's saw the bold and open re-emergence of traditional medicine and traditional health practitioners.

Four decades after independence traditional medicine is staging a comeback due to a mix of cultural, psychosocial and economic factors.

Traditional medicine is a product of social institutions and cultural traditions that have evolved over many centuries to enhance health. The use of traditional medicine is

widespread in Africa, and its acceptability, availability and popularity is not in doubt as about 80% of Africans have recourse to it for their health care needs.

Diminishing national income, cuts in foreign aid and the search for effective treatment for common diseases such as malaria, and opportunistic infections associated with HIV/AIDS, such as tuberculosis, are driving renewed policy interest in traditional medicine in Africa.

WHO has been supporting and leading the process through technical support and policy advice to Member States.

The challenge now is for countries to carry the process forward by embarking on specific actions.

It is incumbent on Governments in the Region to reverse the erosion of the centuries-old traditional medical knowledge and practice. This way, they will be restoring the glory of traditional medicine to its pride of place and perpetuating the culture of its utilization. Africa's future-- that is Africa's children -- must be empowered through awareness creation and the development of the right attitudes.

For example, depending on their age and level of education, it has been suggested that school children should be empowered to recognize herbal medicinal plants, name and describe the five most common diseases in their communities, and

cite at least one treatment for each of them.

We would therefore like to use this occasion to exhort Member States to:

- Formally recognize the value of traditional medicine in health systems, particularly in primary health care through development of national policies to be implemented according to national health policies.
- Create an enabling environment for the practice of traditional medicine through development of legal and regulatory frameworks for the practice and registration of traditional medicines and qualified traditional health practitioners.
- Conduct research with the involvement of traditional health practitioners, to validate claims on safety, efficacy and quality of traditional medicines used for treating common diseases, using WHO protocols and guidelines.
- Undertake documentation of inventories of effective traditional medicine practices and the development of national formularies on traditional medicines with evidence of safety, efficacy and quality.
- Carry out large-scale cultivation and conservation of medicinal plants with involvement of traditional health practitioners and the local communities.
- Create an enabling political, economic and regulatory environment for increasing local

production from small-scale to large-scale manufacturing of traditional medicines that are safe, effective and of good quality.

- Actively promote, in collaboration with all partners, the protection of intellectual property rights and traditional

medical knowledge in the field of traditional medicine.

There is need to produce a solid body of knowledge that will assist countries in formulating national medicine policies in which medicines of plant-based origin that are safe, efficacious and of good quality are

used to their full potential for improving people's health, now and in the future. African Traditional Medicine is our culture, and our future. Thus only we, as Africans, can determine whether this valuable resource continues to be used to promote and sustain the well being of our people.

Institutionalization of Traditional Medicine in Health Systems*

One of the principles on which the Regional Strategy on *Promoting the Role of Traditional Medicine in Health Systems* is based is **the** institutionalization of traditional medicine (TM) with the aim of contributing to the achievement of health for all through optimization of the use of TM. The term "institutionalization" is used here as synonym of the term "integration" which has come to be widely used to express the formalization and official incorporation of TM into national health systems and services. The setting up or strengthening of structures for TM is essential for optimizing its use and should therefore be based on a thorough analysis of the prevailing systems with the involvement of relevant stakeholders particularly the traditional health practitioners (THPs) themselves and communities.

Some of the organizational arrangements required for institutionalizing TM in health systems and services include:

- The establishment of a multi-disciplinary national body (e.g. National Expert Committee, Management Body, a National Council) responsible for the coordination of TM; the formulation of a national policy on TM, and establishment of legal and regulatory frameworks on TM vis-à-vis recognition, regulation and development of both the practice and products (e.g. the Bill for the practice of THPs and guidelines for registration of TMs)
- The allocation of adequate resources; the development of strategies and plans for improving the political, economic and regulatory environment for the local production and rational use of

TMs; and greater protection of intellectual property rights and traditional medical knowledge.

- The setting up of professional TM bodies to enhance discipline in areas such as the drawing up of a code of conduct and ethics to ensure the quality of services provided; the development of norms and standards; the establishment of mechanisms for the official recognition of TM, including the identification, registration and accreditation of qualified practitioners.

Improving mechanisms of collaboration between conventional health practitioners (CHPs) and THPs in areas such as referral of patients, establishment of structures for information sharing at local level and for interface between the two systems of medicine, giving impetus to research in order to improve the safety, efficacy and quality of herbal medicines and the wide distribution of improved TMs, promotion of the participation of THPs in health-related meetings, and inclusion of TM in the curricula of CHPs.

Mechanisms to facilitate the strengthening of collaboration between THPs and CHPs include:

- Establishment and strengthening of dialogue between THPs and CHPs.
- Establishment of an environment of mutual trust in order to facilitate dialogue between THPs and CHPs.
- Establishment of a legal system
- Establishment of a system of information sharing through seminars, workshops and meetings between the two categories of practitioners, and thereby developing a spirit of openness and

transparency amongst practitioners.

- Giving impetus to research in order to produce evidence on the safety, efficacy and quality of herbal medicines, and widely distributing the evaluated and improved traditional medicines
- Setting up of TM practice centres as a matter of urgency in the districts to encourage collaboration between traditional and conventional health practitioners, and promote the use of TMs
- Ensuring the participation of THPs in health-related meetings
- Inclusion of TM in the curricula of CHPs
- Encouragement of simultaneous consultation of patients as is the case in Ghana, Mali, Swaziland, Senegal, etc., to strengthen collaboration between THPs and CHPs
- Citing the names of THPs in medical journals
- Promotion of the use of relevant AFRO guidelines and research tools by Member States including:
 - › *Formulation, implementation, monitoring and evaluation of a national TM policy;*
 - › *Legal framework for the practice of TM;*
 - › *Code of ethics for THPs;*
 - › *Formulation of a national master plan for the development of TM;*
 - › *Registration of TM,*
 - › *Regional framework for protection of traditional medical knowledge and intellectual property rights;*
 - › *Generic guidelines for documenting data on ethnomedical evidence of TM, and*
 - › *Evaluation of TM used for the treatment of malaria, HIV/AIDS, sickle-cell anaemia, diabetes and hypertension.*

* Contributed by the Traditional Medicine Programme at ARFO

An Overview of the Traditional Medicine Situation in the African Region

By



Dr Rufaro Chatora*

Introduction

The World Health Organization (WHO) defines traditional medicine (TM) as “the total combination of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating physical, mental or social diseases and which may rely exclusively on past experience and observation handed down from generation to generation, verbally or in writing”. TM is indeed Africa's culture, future and heritage because the Region has a rich bio-resource base: about 6,377 plant species are used in tropical Africa, more than 4,000 of these as medicinal plants. It is estimated that 90% of TM in Africa is plant-based.

The important role of TM in global health care systems has long been recognized. This is evidenced by the Alma-Ata Declaration of 1978 on Primary Health Care (PHC), which recognizes the role of TM and its practitioners in achieving health for all. Since then, a number of resolutions have been adopted by various sessions of the WHO Regional Committee for Africa – WHO's Governing Body in the Region – on the use of traditional medicines (TMs); legislation governing TM practice, the promotion and development of TM, and research into medicinal plants.

In recent times, African leaders have demonstrated a renewed political commitment to promoting TM through the adoption of resolutions and declarations that have heightened the profile of TM in the Region. Examples of these are the adoption, by the 50th session of the

WHO Regional Committee for Africa (RC50) in 2000, of a resolution on promoting the role of traditional medicine in health systems; the April 2001 OAU Declaration in Abuja, Nigeria, which identified TM as a research priority, and the designation, by the OAU in 2001, of the period 2001-2010 as the *Decade of African Traditional Medicine*. At the request of Member States, WHO, in 2003, instituted an African Traditional Medicine Day to be commemorated on 31 August of every year, with effect from 2003.

Information resources for the situation analysis

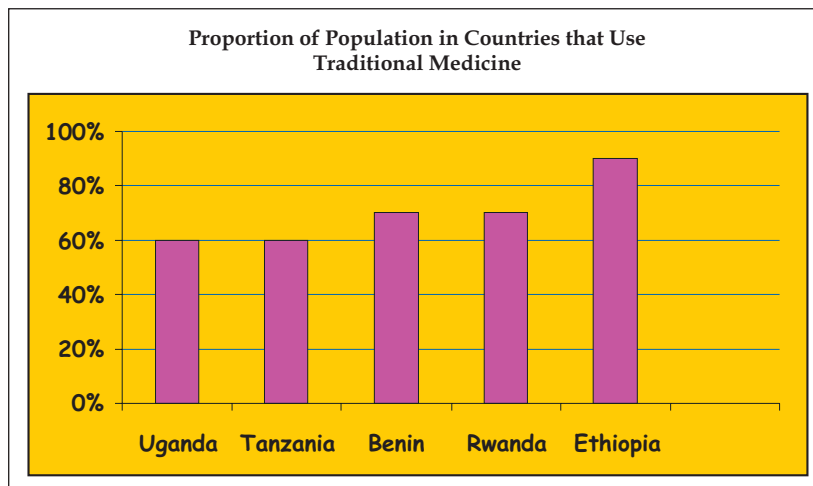
Information for this situation analysis is based on data from governments and WHO Reports (such as the World Health Report 2002), a 1999 survey conducted by the WHO Regional Office for Africa

(AFRO) in which 30 (65%) out of the 46 countries participated, and a global survey on TM in 2002, in which 36 (78%) of the countries participated.

A summary of the situation with respect to utilization, accessibility and the role of traditional health practitioners (THPs) is shown below.

The survey data has been analyzed taking cognizance of the implementation of the priority interventions proposed in the Regional TM strategy. These are policy formulation, capacity building, research promotion, local production and intellectual property rights at country and regional levels.

Figure 1: Use of Traditional Medicine in Some African Countries



Utilization, accessibility of African TM and the role of THPs

The estimated total population of the WHO Africa Region in 2001 was 655,477,000. Over 50% of this, mostly the poor and disadvantaged, do not have access to existing essential medicines. TM however continues to

maintain its popularity for historic and cultural reasons, as about 80% of the people living in the region depend on it for their health care needs. However, this percentage varies from country to country. Reports from Member States to WHO show TM use in Uganda and Tanzania at 60%, in Benin and Rwanda at 70%, and in Ethiopia at

90%. (Figure1).

In many parts of Africa, THPs far outnumber Conventional Health Practitioners (CHPs). Thus, they are more accessible to the population. Table 1 compares the ratio of THPs and medical doctors to the population in some African countries.

Table 1: Sample ratio of THPs compared with the ratio of medical doctors to the population

Traditional Medicine and Practitioners are a Major Source of PHC in African Countries		
Countries	Ratio of THP to the population	Ratio of Medical Doctor to the population
KENYA Urban (Mathare)	1:833	1:987
Rural (Kilungu)	1:146-345	1:70,000
ZIMBABWE	1:600	1:6,250
SWAZILAND	1:100	1:10,000
NIGERIA (Benin City)	1:110	1:16,400
National Average	No data	1:15,740
SOUTH AFRICA (Venda area)	1:700-1,200	1:17,400
GHANA	1:200	1:20,000
UGANDA	1:700	1:25,000
TANZANIA	1:400	1:33,000
MOZAMBIQUE	1:200	1:50,000

Policy formulation

An analysis of the two surveys referred to above reveals that several countries in the region are currently developing legal frameworks for TM practice. For example, 16 (53%) of the 30 countries that participated in the 1999 survey indicated that they had legislation for the practice of TM. A national management or co-ordination body for TM activities existed in 17 of the 30 countries (57%). Twenty-two countries (73%) indicated that associations of THPs had been established, and ten countries (33%) indicated that a directory of THPs existed (Figure 2).

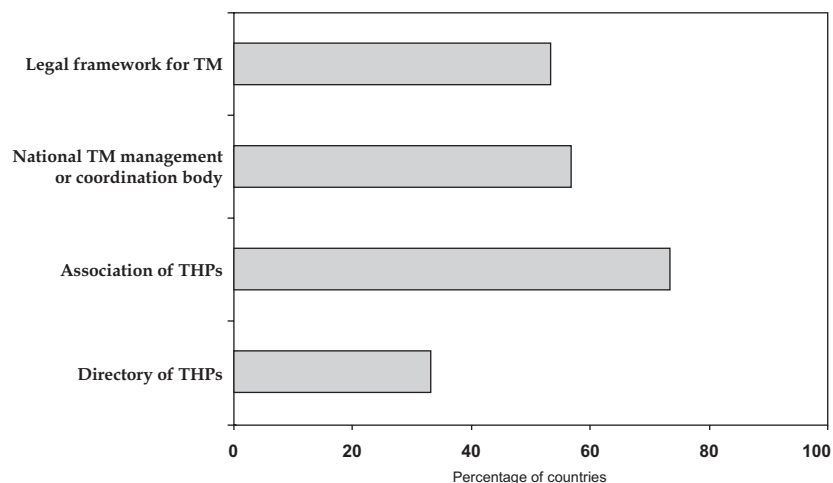
Research promotion

At country level, 20 countries (67% of the 30 who responded to the 1999 questionnaire) indicated that they had institutions conducting research on TM. The following countries

indicated that they were conducting clinical evaluation of traditional herbal medicines used for the treatment of malaria: Burkina Faso, the Democratic Republic of Congo (DRC), Ghana, Kenya, Madagascar, Mali, Nigeria, Tanzania and

Zimbabwe; for HIV/AIDS: Benin, Burkina Faso, DRC, Ghana, Cote d'Ivoire, Kenya, Madagascar, Mali, Nigeria, South Africa, Tanzania, Togo, Uganda and Zimbabwe; for diabetes: Benin, Burundi, Ghana, Madagascar, Mali, Nigeria and

Figure 2: Percentage of countries that indicated existence of structures to support traditional medicine (N=30)



Tanzania; for sickle-cell anaemia: Benin, Burkina Faso, Togo and Nigeria, and for hypertension: Cote d'Ivoire, Ghana, Kenya, Madagascar and Mali.

At Regional level, research institutions in Ghana and Madagascar were assessed with a view to designating them as WHO Collaborating Centres. Five research guidelines and protocols are currently being developed to support countries in the generation of evidence-based safety, efficacy and quality of TMs used for the treatment of the five priority diseases: malaria, HIV/AIDS, sickle-cell anaemia, diabetes and hypertension. Two regional workshops, one on the evaluation of TMs used for the management of HIV/AIDS and another on TMs, research, development, intellectual property rights and biodiversity were organised in Madagascar, in November 2000, and in South Africa, in September 2003, respectively.

Capacity building

At country level, 17 countries that participated in the 1999 survey indicated that they had initiated training programmes to improve Traditional Birth Attendants' skills and PHC knowledge. Some of these countries also provide training in TM for pharmacists, doctors, nurses and THPs. For example, Kenya has established a School of Alternative Medicine and Technology in Karati, and an Institute of Complementary and Alternative Medicine in Nairobi, Kenya. The Zimbabwe National Traditional Health Practitioners Association has established a School of Traditional Medicine in Harare, while the University of Zimbabwe is offering courses leading to the award of a Bachelor of Science degree in Natural Medicine. In Nigeria, there are institutions which offer diploma courses for traditional Mental Health practice, traditional bonesetters and

THPs involved in the preparation of traditional herbal medicine.

At Regional Level, two training manuals are being finalized to be used by countries in capacity building. These are a *Training Manual on PHC for Traditional Health Practitioners* and a *Manual on Traditional Medicine for Conventional Health Practitioners and Health Science Students*.

Development of local production

Some countries in the Region are producing, on a pilot-scale, various plant-based preparations for diarrhoea, constipation, cough, eczema, ulcers, hypertension, diabetes, malaria, mental illness and HIV/AIDS. Some of these medicines have been registered and included in the national essential medicine lists, such as in Mali. Fifteen out of the 30 countries (50%) that responded to the questionnaire indicated that there was local production of TM, and 17 countries (59%) indicated that they had a botanical garden or cultivate arboreta for medicinal plants. Promotion, conservation and cultivation of medicinal plants are ongoing in some countries such as Cote d'Ivoire, Ghana, Madagascar and

Tanzania.

At Regional level, a situation analysis of the local production of TMs was undertaken in Benin, Burkina Faso, and Côte d'Ivoire, Ghana, Kenya, Mali, Madagascar, Nigeria and South Africa. A plan of action for local production of TMs is being finalized and will be used for advocacy in countries to create an enabling economic, political and regulatory environment for the local manufacture of standardized African traditional medicines. Support is being provided to countries to assess their needs for possible local production of standardized products, as well as the conservation and cultivation of medicinal plants in order to ensure sustainability of raw materials.



A Traditional Health Practitioner picking herbs

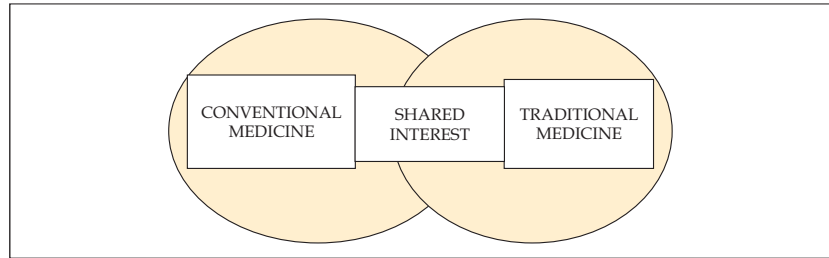
Issues of Intellectual Property Rights (IPRs)

Some countries such as Kenya, Mozambique, South Africa and Zimbabwe are reviewing their legislation to conform to the Trade Related Aspects of Intellectual Property Rights (TRIPS) and the African Union's legislation on protection of traditional medical knowledge of indigenous people. At Regional level, a document for supporting countries to document African Traditional Medicine and a regulatory framework for accelerating the protection of traditional medical knowledge and IPRs of TMs is being developed. WHO is collaborating with relevant organizations dealing with IPRs for the establishment of mechanisms for greater protection of traditional medical knowledge, preservation of biodiversity, and equitable sharing of benefits or proceeds accruing from the appropriate utilization of indigenous biodiversity. These organizations include, but are not limited to, the African Union, the African Regional Industrial Property Organization (ARIPO) and African Organization for Intellectual Property Rights (OAPI).

Challenges

Despite the fact that the role of TM in health care delivery is well recognized, some major challenges persist. These include disrespect for, and denial of, the role of TM and THPs by policy makers and CHPs, insufficient data on safety, efficacy and quality of TM, and inadequate regimes for the protection of traditional medical knowledge and

Figure 4: Diagramme Attempting to Demonstrate the Shared Interests between Conventional Medicine and Traditional Medicine



intellectual property rights. These challenges hamper the “integration” of traditional medicine into national health care systems. Furthermore, the concept of “integration” continues to be elusive. There is failure to recognize that given the huge spheres covered by both Conventional Medicine or Traditional Medicine, shared interests may only cover part of these two spheres (Figure 4).

Conclusion

This situation analysis shows important differences between the countries in the Region in the degree of organization and integration of TM into mainstream health systems. On the basis of country responses, it can be concluded that while some countries have no structures in place, others have considerable organization and integration is being achieved.

It has to be noted, however, that the content of the questionnaires was limited to eliciting responses on the existence of structures for the practice of TM, research, local production and training. The quality and the actual functioning of the structures have not

been addressed. WHO will continue its support to countries to produce standardized information that takes into account the quality and functional aspects related to the priority interventions outlined in the Regional Strategy on Promoting the Role of Traditional Medicine in Health Systems adopted by the WHO Regional Committee for Africa in 2000, and the Global WHO Medicines Strategy 2002-2005, adopted by the 56th session of the World Health Assembly held in May 2003.

Hopefully, these efforts will go a long way in facilitating the production of evidence-based standardized information on the use of TMs for the treatment of priority diseases in the Region. It is also hoped that this will lead to wider acceptance and acknowledgement of the critical role of TM in health care systems.

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Integration of Traditional Medicine into Health Systems in the African Region - The journey so far

What is integration?

The Regional Strategy on Promoting the Role of Traditional Medicine in Health Systems defines the term "integration" as increase of health coverage through collaboration, communication, harmonization and partnership building between conventional and traditional systems of medicine, while ensuring intellectual property rights (IPRs) and protection of traditional medical knowledge (TMK). That Strategy promotes the integration into health systems of traditional medicine (TM) practices and products for which evidence on safety, efficacy and quality is available, and the generation of such evidence when it is lacking.

Indeed, partnership building between traditional health practitioners (THPs) and conventional health practitioners (CHPs) will increase health care coverage. Surveys conducted by WHO and other organisations show that the number of THPs in many parts of Africa far outnumber CHPs. For example in 1982, Hedberg et. al.,¹ reported that there were about 30,000-40,000 THPs in Tanzania, and 600 medical doctors. Similarly, in Malawi, there was an estimated 17,000 THPs and only 35 medical doctors. A similar situation prevails in other countries. Bringing together the two systems of medicine will enable THPs and CHPs to complement each other, and thereby

promote and enhance management of diseases and disorders. In addition, THPs will be more knowledgeable about Primary Health Care while CHPs will be more knowledgeable about TM. This acquired knowledge by the two systems of medicine will enhance mutual respect, mutual understanding and productive collaboration.

Systems of integration

Historically, the relationship between modern and traditional medicine has taken four broad forms.

These are the:

Monopolistic or exclusive system

In a *monopolistic* or *exclusive* system, only modern medical doctors have the right to practice medicine. Currently there is no country in the African Region that falls into this category.

Tolerant system

A *tolerant* system or one of co-existence where THPs, while not formally recognized, are permitted to practice in an official capacity. Most of the countries in the region have not formulated national policies, legal and regulatory frameworks for regulating the practice, practitioners and products (medicines) as a *de facto*

By



Dr Luis G. Sambo*

sign of formal recognition of TM. However, in all African countries TM is practiced.

Inclusive system

A *parallel* or *dual health care model* or *inclusive* system is a system where both modern and traditional medicine are separate components of the national health systems. This means that national authorities officially recognize TM, but some aspects of it are not yet incorporated into the national health care system. In some cases, the national authorities are developing the appropriate frameworks for TM-related policy, regulation, practice, health insurance coverage, research and education.

Examples of countries in the Region practicing the inclusive system of integrating TM into their national health care systems are Benin, Burkina Faso, Cameroon, Equatorial Guinea, Guinea, and Cote d'Ivoire, the Democratic Republic of Congo, Equatorial Guinea, Niger, Nigeria, Madagascar, Mali, Mozambique, Swaziland, Tanzania and Zimbabwe.

Integrative system

In this situation, TM is fully recognized and incorporated into all

¹ Hedberg, O. and al., Inventory of Plants used in Traditional Medicine in Tanzania, Journal of Ethnopharmacology, 1982. See also <http://www.rbgekew.org.uk/peopleplants/wp/wp1/africa1.htm>

areas of health care delivery including national medicines policy; registration of TM products; regulation of TM practice; establishment of TM hospitals; inclusion of TM in national insurance schemes as reimbursable items; establishment of relevant research institutions on TM, and training of TM practitioners at all levels of education, including universities. Integration also subsumes visibility of TM in national health programmes, and its reflection in national planning and budgeting schemes.

Globally only four countries - the People's Republic of China, the Democratic Republic of Korea, the Republic of Korea and Vietnam - have integrated TM into their national health care systems in an integrative fashion. No country in the WHO African Region has yet established this integrative system regarding the incorporation of TM into national health care systems.

The role of WHO

At global level a WHO Traditional Medicine Strategy 2002-2005 that was launched at the fifty-fifth session of the World Health Assembly (WHA55) was adopted through a Resolution on Traditional Medicine by the WHA56. At Regional level the AFRO Strategy was approved and adopted through a Resolution on *Promoting the Role of Traditional Medicine in Health Systems: A Strategy for the African Region* by the 50th session of the WHO Regional Committee for Africa (RC50) held in Ouagadougou, Burkina Faso, in 2000. Both strategies promote the integration of TM into health systems. The WHO Regional Strategy has five priority interventions that Member States are implementing. These are : policy formulation, capacity building, research promotion, development of local production of traditional medicines (TMs) and protection of IPRs. WHO

has developed and is working on additional documents which can be used as tools for institutionalizing and hence integrating TM into health systems. Some of these tools are on policy; research for generation of evidence on safety, efficacy and quality; education and training; registration, regulation, legal framework for the practice of TM; code of ethics; quality control, and good agricultural and collection practices.

Inherent challenges

Still, challenges abound for the integration of TM into national health care systems. These include: lack of political recognition of TM; lack of regulatory and legal frameworks for practice of TM; inadequate protection of IPRs and biodiversity; lack of mechanisms for registration of TM; inadequate data on scientific and clinical validation of TMs; and issues related to prescription and marketing of TMs, and partnership with the private sector.

The Journey So Far

Political recognition

The adoption by RC50 of the Regional Strategy and the resolution earlier referred to was a significant step forward regarding the integration of TM into mainstream health systems.

That resolution requested the WHO Regional Director to propose to Member States the institution of an African Traditional Medicine Day for advocacy. This position was further strengthened by African Heads of State and Government who, at their April 2001 summit in Abuja, Nigeria, declared that TM research should be made a priority. In July 2001 the same forum of African leaders in Lusaka, Zambia, declared the period 2001-2010 as the *Decade of African Traditional Medicine*. On its part, WHO has instituted 31 August on its

calendar with effect from 2003 for the African Traditional Medicine Day commemoration.

African Health Ministers, meeting under the auspices of the African Union (AU) in April 2003 in Tripoli, Libya, adopted a Plan of Action (POA) for the *Decade* and appropriate implementation mechanisms. The POA, mechanisms for its implementation and the institution of the African Traditional Medicine Day were endorsed at the July 2003 of AU Summit of Heads of State and Government which took place in Maputo, Mozambique.

Policy, regulatory and legal frameworks on TM

The official recognition of TM is an important political issue which needs to be accompanied by the formulation of a national policy on TM and, subsequently, the formulation of appropriate regulatory and legal frameworks, for regulating the practice, practitioners and traditional medicinal products. Countries are at different stages of development of TM. Currently, only 11 out of 46 countries in the Region have developed a national policy; 12 have put in place laws and/or regulations on TM while 16 have established a legal framework for the practice of TM. WHO is supporting this process in Member States through the provision of guidance on these policy issues.

Registration of TMs

One of the ways in which the integration of TM into health systems can be manifested is the registration, marketing and rational use of TM products of proven quality, safety and efficacy for well defined diseases. In April 2003, AFRO, in collaboration with WHO/HQ organized a regional workshop in Johannesburg, South Africa, to review a draft document on the registration of TMs in the African region.

The document proposes to Member States a framework for facilitating the registration of standardized African TMs on the basis of the criteria of pharmaceutical quality, safety of use and therapeutic efficacy. The document also includes the minimum regulatory requirements for quality (plant raw materials and finished products), as well as the safety and efficacy of finished products. It is worthy of note that at country level, Ghana, Mali and Nigeria have already registered some TMs in accordance with their national regulations.

Intellectual property rights and biodiversity issues

Integration of TM into national health systems embraces both the practice

and medicines. Most TM products in the Region are based on indigenous biodiversity. THPs use their traditional medical knowledge to formulate various recipes for the management of the prevailing diseases within their localities.

Appropriate IPRs, regimes need to be formulated taking cognizance of the TMK possessed by individual THPs or communities with a view to ensuring equitable sharing of benefits or proceeds resulting from the commercial utilization of products based on their TMK.

It is important that biodiversity laws take into account the fact that many medicinal plants occur in ecological zones that span several countries.

Countries like Kenya, Mozambique, South Africa, Uganda and Zimbabwe seem to have done this, as they have initiated appropriate changes in their IPR, and biodiversity laws to enhance protection of TMK and equitable sharing of benefits which may accrue from the economic utilization of medicinal plants. WHO is working with organizations dealing with IPRs such as the AU, the African Regional Industrial Property and African Organization (ARIPO) and the Organization of Intellectual Property (OAPI) to develop mechanisms for the protection of TMK. A draft document on IPRs and biodiversity issues as they relate to TMK in Africa has been developed by AFRO and would be discussed at a regional workshop scheduled for October 2003 in Johannesburg, South Africa.



A Traditional Health Practitioner (right) checks the blood pressure of a patient (left) using a modern instrument

Scientific and clinical validation of TMs

TM products cannot be integrated into a national Essential Medicines List without evidence on standardization of the raw materials and finished products, clinical efficacy and safety.

In view of the inherent variations in the chemical components of medicinal plants, which are influenced by the environment, soil chemistry, season, weather, time of the day etc., efforts have to be made to standardize the raw materials and the various production processes involved. On this score, the desired aspects of standardization activities to be considered relate to botanical, chemical, and biological questions. Application of Good Laboratory Practice (GLP) ensures that all experiments are properly conducted, documented and supervised so as to generate quality and reliable research data. This is a painstaking but desirable process requiring special equipment and expertise. AFRO in collaboration with WHO/HQ is planning – several Regional training workshops aimed at building capacity of countries in the scientific and clinical validation of TMs during the 2004-2005 biennium.

Furthermore, clinical validation of TMs is crucial regarding their consistent quality, safety and efficacy. AFRO is developing protocols to guide researchers in documenting ethno-medical evidence and conducting clinical validation of TMs used for the treatment of priority diseases such as HIV/AIDS, tuberculosis, malaria, sickle-cell anaemia, hypertension and diabetes. AFRO is also providing technical guidance to some institutions in Member States

involved in Research and Development activities on TMs, including clinical investigations.

Prescription and marketing of TMs

It is expected that at the conclusion of scientific and clinical studies, the products will be registered, marketed and rationally used. These will no doubt constitute an important element in the integration of TM into national health systems.

Collaboration and partnership arrangements

THPs, biomedical researchers, the private sector as well as governments of Member States hold the key to the success of integrating TM into national health systems. In the case of THPs, if they decide to withhold the secret formulae and the names and parts of the plants being used, no meaningful progress can be achieved regarding the integration of TM into national health systems. They should therefore be brought into partnership arrangements as equal partners because trust among collaborators is crucial. The use of appropriate legal agreements can be instrumental in building such mutual trust.

Research institutions need to be more proactive in initiating these arrangements. Scientific data, which can be used to attract the interest of the private sector, have to be carefully generated by the researchers following GLP principles. Governments need to promote the appropriate regulatory and legal environments to facilitate such partnerships between the private sector, researchers and THPs. National Associations of THPs should be involved in the

development of these partnership arrangements. To facilitate this, AFRO is developing a generic Memorandum of Understanding and Legal Agreement between biomedical researchers and THPs, which can be adopted and adapted to country-specific situations.

Conclusion

As long as there is denial by both policy makers and CHPs of the role that TM and its practitioners play particularly in PHC, the pace of integration of TM into health systems will be slowed down. Integration or harmonization of African Traditional Medicine does not have to be in the fashion of the Chinese, Koreans or Vietnamese. Member States have to find and develop systems of harmony between the traditional and conventional systems of health care in the African context, with the minimum of threat to either. Member States working jointly with all stakeholders have to develop systems that will ensure economic survival and social acceptance of both systems of health care to promote health care coverage to the majority of people.

However, with the strong political will demonstrated at the highest level in Member States, and the technical and other support provided by WHO and other development partners, all bringing their comparative advantages into play, it is hoped that the integration of TM into mainstream health systems in countries of the Region may be achieved sooner than later.

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Progress Report on the Status of Implementation of the Regional Strategy on Promoting the Role of Traditional Medicine in Health Systems

By



*Dr Jean-Marie Trapsida**

Introduction

The Alma-Ata Declaration recognized the role of Traditional Medicine (TM) for the achievement of "Health for All", and recommended that proven (TMs) and practices should be incorporated into national essential medicines programmes for Primary Health Care (PHC). Despite this recommendation, TM practices and medicines have not been sufficiently integrated into health systems and services in most WHO Member States. This is mainly due to denial by policy makers and Conventional Health Practitioners (CHPs) of the contribution of TM to the development of health systems and services. This has led to the unavailability of governmental policy frameworks, and mistrust between CHPs and traditional health practitioners (THPs). In order to address these concerns, and aware of the fact that about 80% of the African population depend on TM for their health care needs, the 50th Session of the WHO Regional Committee (RC50) held in 2002, in Ouagadougou, Burkina Faso, approved a TM strategy for the Region. The strategy document is titled - *Promoting the Role of Traditional Medicine in Health Systems: A strategy for the African Region*. The Regional Committee is WHO's Governing Body in the African Region.

The objectives of the strategy are to:

- develop a framework for national policy formulation, capacity building and integration of the positive aspects of TM into health systems and services;
- promote research and development into the quality, safety and efficacy of TMs;
- establish mechanisms for the protection of cultural and intellectual property rights (IRPs) of THPs;
- develop viable local industries to improve access to TMs, and
- strengthen national capacity for the mobilization of stakeholders to formulate and implement relevant policies.

Policy formulation

RC50 requested the WHO Regional Director for Africa to, among other things:

- establish a regional mechanism for supporting Member States to effectively monitor and evaluate progress made in the implementation of the strategy;
- convene a Regional meeting which would bring together CHPs and THPs to exchange experiences and learn from each other;
- propose to Member States the institution of an African Traditional Medicine Day for advocacy;

- establish a budget line for TM and strengthen human resources at the Regional level;
- increase technical and financial support to Member States, and
- encourage Member States to develop mechanisms for enhancing collaboration between CHPs and THPs.

In response to the above, the Regional Director established a 12-Member WHO Regional Expert Committee on Traditional Medicine in May 2001, with members drawn from Burkina Faso, Cote d'Ivoire, the Democratic Republic of Congo (DRC), Ghana, Kenya, Madagascar, Nigeria, Uganda and Swaziland. The Expert Committee held its inaugural and second meetings in Zimbabwe and Gabon in November 2001 and 2002, respectively. At the two meetings, members of the Committee adopted nine documents developed as tools for institutionalizing TM in health systems in countries of the Region.

The July 2003 Summit of the Heads of State of the African Union (AU) -- the successor body to the Organization of African Unity -- endorsed the institution, by WHO, of an African Traditional Medicine Day, for advocacy in Member States. The Day is to be commemorated on the 31 August of every year, with effect from 2003.

Two WHO-organized meetings in 2001 and 2003 helped to provide

perspective on issues on TM policy formulation to participants. To date, 12 countries have developed national policies on TM, and another 12 have established a national TM office in their Ministries of Health. The WHO Regional Office for Africa (AFRO) has stepped up efforts to mobilize resources for assisting countries to implement, monitor and evaluate the strategy on TM with the support of partners. A good example of support from partners is demonstrated by the Canadian International Development Agency (CIDA), which will spend 10 million Canadian Dollars (about US\$6.5) over a five-year period to strengthen traditional health systems for malaria prevention and control in the Region.

Research and promotion

The 2001 and 2002 sessions of the

WHO Regional Committee for Africa adopted specific resolutions on research into medicinal plants, promoting their use in the health care delivery systems, and the generation of evidence on safety, efficacy and quality of TMs.

To implement these policy orientations, AFRO organized a *Regional Workshop on Evaluation of Traditional Medicines* in Madagascar in November 2000. Significantly, the workshop agreed on a methodology for the evaluation of TMs used for the management of HIV/AIDS and malaria. Other research tools are being developed by WHO/AFRO to support countries in the generation of evidence-based safety, efficacy and quality of TMs used for the treatment or management of sickle-cell anaemia, diabetes and hypertension. These protocols have been adopted and are being used by a number of

countries for the evaluation of TMs used for the treatment of the indicated priority diseases: malaria, HIV/AIDS, diabetes, sickle cell anaemia and hypertension.

Capacity building

A situation analysis conducted in 1999 and 2002 revealed that four countries had a training programme on PHC for THPs. The analysis also indicated as follows: Botswana, Côte d'Ivoire, Gambia, Guinea, Senegal, and Zambia had training programmes for traditional birth attendants; and training modules on TM were indicated to be included in the training programmes for pharmacists in Burkina Faso, Côte d'Ivoire, Ghana, Mali, Nigeria and Zimbabwe. Similar modules were indicated to be included in the training programmes of nurses in



Bottled herbs

Ethiopia, Ghana and Zimbabwe; and of doctors in Ghana and Zimbabwe. It is worth noting that some aspects of TM have been incorporated into the curricula of some training institutions in countries such as Nigeria, Ghana, Kenya and Zimbabwe.

AFRO is developing a Manual on PHC for THPs, and a Training Manual on TM for CHPs and Health Science students. These manuals will support countries in the development of national capacities in this area.

Development of local production

Issues related to the development of mechanisms and improved economic and regulatory environments for the local production of TMs are addressed by AFRO through the development of a plan of action for local production of TM.

This plan will be used for advocacy and to encourage countries to create enabling economic, political and regulatory environments for the local manufacture of standardized African TM, which can be included in the national list of essential medicines. A needs assessment for local production of TMs has been undertaken in Benin, Burkina Faso, Côte d'Ivoire, Ghana, Kenya, Mali, Madagascar, Nigeria and South Africa. In the same vein, a report and a concept paper on the situation analysis for local production of TMs were produced in collaboration with the African Development Bank

AFRO and the African Initiative and the Centre for Development of Enterprise and Industry of the European Union organized a joint mission to Benin and Mali in October and November 2001 to provide technical support for local production of TMs used for the treatment of sickle-cell anaemia and

malaria. Support for feasibility studies in terms of availability of raw materials, equipment for large-scale production and distribution of TMs, IPRs issues and partnership with the private sector was provided to Benin, Burkina Faso, Mali, Nigeria and Tanzania between 2001 and 2003. Also worth mentioning is the collaboration between the Government Research Institute of Thailand and AFRO for the local production of TMs and of antiretroviral medicines. Similarly collaboration between China and African countries was developed at a China-Africa Forum on Cooperation and Development of TM held in Beijing in October 2002. Senior health officials from 23 African countries attended the Forum. The cooperation covers also issues related to policy, research, capacity building, IPRs and traditional medical knowledge (TMK)

Issues of IPRs and TMK

Most countries have not developed or reviewed their legislation to include the safeguards provided for in the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. However, a few countries such as Kenya, Mozambique, South Africa and Zimbabwe have amended their legislation on Industrial Property to conform to the TRIPS Agreement.

To carry this process further, AFRO has developed two documents to support countries in documenting African TM practices and protection of TMK. It has also supported Angola, Burkina Faso, Ethiopia, Gabon, Ghana, Madagascar, Mali, and Nigeria in documenting TM.

WHO will continue to work in close collaboration with organizations dealing with IPRs issues particularly the African Union, the African Regional Industrial Property Organization (ARIPO) and the African Organization for Intellectual Property (OAPI) to disseminate information, and to support

countries to understand the implication of the TRIPS agreement as it relates to TM.

Perspectives

Despite the progress made so far, TM is not sufficiently integrated into national health systems and services in the Region. More countries need to be involved in conducting research on safety; efficacy and quality of TMs used for the treatment of priority diseases using WHO protocols and guidelines. There is a need for more countries to incorporate aspects of TM into training the curricula of health professionals, embark on continuing education and skills development programmes, and encourage the development and use of information, education and communication strategies to advantage in relation to TM.

Many governments have yet to play the key roles of creating enabling political, economic and regulatory environments even for small-scale manufacturing of TMs. There is also an urgent need for countries to accelerate the implementation of other aspects of the Regional Strategy on TM by countries.

WHO, for its part, will continue to advocate for, and stimulate the development of, national policies on TM; promote the acquisition of knowledge and skills by facilitating the exchange of experiences; support the development of training programmes and training materials, and undertake advocacy for countries to develop local production of standardized TMs for inclusion in national essential medicines lists.

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Enhancing Traditional Medicine Research and Development in the African Region

By



Dr Ossa M J Kasilo

Introduction

In 1964, the Organisation of African Unity (OAU), now the African Union (AU), set up the Scientific and Technical Research Commission (OAU/STRC), which organised the Inter-African Symposium on the Development of African medicinal plants in Dakar in 1968. The Symposium decided that the efficacy of herbs used by traditional health practitioners (THPs) should be evaluated.

The 49th and 50th sessions of the WHO Regional Committee for Africa – WHO's Governing Body in the African Region – adopted a number of specific resolutions in 2000 and 2001 related to traditional medicine (TM) research. The resolutions called on WHO to support countries in carrying out research on medicinal plants and promote their use in the health care delivery systems; urged Member States to produce and undertake relevant research for evidence on safety, efficacy and quality of traditional medicines (TMs), and requested that WHO Collaborating Centres and other research institutions be strengthened to carry out research and disseminate results on safety and efficacy of TMs.

The OAU Summit of Heads of State held in Abuja, Nigeria, in April 2001, declared that research on TM should be made a priority. Later in the same year, the same body decided in Lusaka, Zambia, that the period 2001-2010 be designated the *Decade of African Traditional Medicine*. A plan of action for implementation of the decade was endorsed at a Summit of Heads of State of the AU held in July

2003 in Maputo, Mozambique. It is against this background that this article attempts to provide a status report on TM research and development (R&D) in the Region, outline the main challenges emanating from the analysis, and propose interventions and discussion points for the purpose of enhancing R & D into TM in the African Region.

Situation analysis

In implementing the above-mentioned decisions and resolutions, the AU, WHO, UNIDO and other institutions have undertaken a number of initiatives which have enhanced the development on R & D on medicinal plants. Among these are: the production of an African Pharmacopoeia, the conduct of ethnobotanical surveys in search of ethnomedical evidence; addition of value to some TMs; clinical observational studies and clinical evaluation of the safety, efficacy and quality of TMs; standardization of some TMs into tablets and capsules, and local pilot scale local production of some of TMs.

In November 2000, the WHO Regional Office for Africa (WHO/AFRO) organised a *Regional Workshop on Evaluation of Traditional Medicines* in Madagascar. The meeting agreed on a methodology for evaluation of TMs used for treating malaria and people living with HIV/AIDS (PLWA). Since then, AFRO has developed other research protocols and guidelines for evaluation of TMs for treating diabetes, sickle cell anaemia and hypertension. These protocols were reviewed at the *Regional Meeting on*

Integration of Traditional Medicine in Health Systems: Strengthening Collaboration between THPs and CHPs held in Harare, and adopted by the WHO Regional Expert Committee on TM in November 2002.

Some institutions in Member states have conducted pilot scale clinical trials on TMs using the protocols developed by AFRO. Preliminary collated results from the evaluation of TMs used for the treatment of HIV/AIDS, malaria and sickle cell anaemia are very encouraging and show that some of the TMs contain pharmacologically active ingredients. Some countries such as Mali, have gone further to include TMs in their National Essential Medicines List. WHO is currently supporting research on evaluation of traditional medicines (TMs) used for treating malaria in Kenya and Nigeria using WHO protocol.

The results of pilot clinical trials in which a study group was given TMs and a control group was given conventional medicine, show that TMs could clear malaria parasites within seven days of treatment in most of the patients in the study group, without any observable side effects. Further investigations are in progress. Similar results have been reported in Burkina Faso, the Democratic Republic of Congo (DRC), Madagascar, Mali and Tanzania. The work of the Malagasy

Institute for Applied Research (IMRA) on malaria has resulted in the discovery of a new medicine which is effective against chloroquine-resistant strain of *P. falciparum*. This medicine is still being developed. Similarly, WHO is supporting research on HIV/AIDS in Burkina Faso and Zimbabwe where, apart from baseline CD4/CD8 and viral load, values measured at the inception of the study and re-assessed every three months, liver and kidney function tests are being undertaken, using WHO research protocols.

Improvements have been noted in the quality of life and clinical conditions of patients treated with TMs. Blood tests to monitor the level of immunity (CD4 and CD8 counts) of patients, have shown a marked increase in blood cell counts. In some countries such as Burkina Faso, a weight gain of up to 20 kilogrammes has been noted in some patients within four months of treatment. Similar results have been reported from DRC, Ghana, Cote Ivoire, Nigeria, South Africa, Tanzania, Togo and Uganda. Research by a team at the National Institute for Pharmaceutical Research and Development (NIPRD) in Abuja, Nigeria, has led to the development and standardisation of two TMs called *Dopravil* and *Cornavil* that THPs claim to be effective for the management of HI/AIDS. Also NIPRD has standardized a TM known as *Niprisan* used for the management of sickle cell anaemia. Similar studies on sickle-cell anaemia are being conducted in Benin, Burkina Faso and Togo. Research on diabetes is being conducted in Burundi, Benin, Ghana, Madagascar and Mali. A similar exercise is being undertaken on hypertension in Côte d'Ivoire, Ghana, Kenya, Mali and Madagascar.

Challenges

A number of challenges face traditional medicine R & D activities in the Region. Among these are:

- lack of coherent national health research policies;
- deficient health development plans for R & D;
- insufficient data on evidence-based safety, efficacy and quality of TMs as well as on cost-effectiveness;
- lack of adequate mechanisms for the protection of traditional medical knowledge (TMK) and intellectual property rights (IPRs);
- weak linkages of networking and collaboration of research institutions;
- lack of coordination among institutions undertaking R & D on TMs, and
- lack of a critical mass of researchers with an interest in TM.

Proposed interventions and discussion points

Health research policy

Three elements constitute the cornerstone of any serious national health research effort. These are: a coherent policy that will provide guidelines for R & D in TM, allocation of financial and other resources with clearly defined objectives, and equity in health - which is a fundamental challenge in health research, and should underpin actions to strengthen health systems research. In recognition of this, WHO has developed draft guidelines on the formulation, implementation, monitoring and evaluation of national policies of TM for adaption by countries.

Other pertinent issues to be addressed in the area of health

research policy are: the sensitization of policy makers to formulate national health research policies which include research into TM; forging closer links between the TM research community, health services and policy makers, in order to facilitate the utilization of research results in policy making, and the integration of research in TM into national health research and development plans.

Cultivation of medicinal plants

Sustainability of the raw materials for R & D is a key consideration in planning for the production of TMs on any meaningful scale. In some cases, agronomic studies may be required to establish the best conditions for cultivating valuable medicinal plants. Training in good agricultural and good harvesting practices will ensure that more sustainable techniques are employed. The success of home-based herbal medicines for common complaints associated with HIV/AIDS and malaria depends primarily on the cultivation of home gardens by THPs and other individuals. These gardens should be linked to appropriate research institutions to ensure the supply of the best varieties of seedlings. Research institutions should also provide technical support and organise training workshops for farmers and THPs. WHO has planned a series of such training sessions on good agricultural, collection and conservation practices for THPs for the 2004-2005 biennium.

Still, the questions may be asked: how can home gardens of THPs and subsistent farmers be made a reality? Should governments and research institutions assist communities in this area? What roles should WHO and other development partners play?

Identification of centres of excellence for R & D

There is need to identify regional centres of excellence for R & D on TM where meaningful research findings can be produced for use in decision-making. Such centres should play a role in determining the needs, capacities, capabilities and sustainability of TM raw material production. Centres of excellence so identified should strengthen or establish research and ethics review committees; conduct research and disseminate information using WHO guidelines and protocols in collaboration with THPs and conduct placebo-controlled randomized clinical trials in accordance with WHO protocols. International collaboration in health research should help in strengthening local institutions and health services as well as addressing the issue of economic benefits for local communities which are sources of material for TM production.

Capacity building for research and development

Very few countries in the Region, have a systematic plan for developing and building capacity in TM research. Fewer still have a 'critical mass' of researchers with an interest in TM. The need for capacity building for R&D will vary from country to country and this is an issue that should be immediately addressed through, for example, support to THPs. The inclusion of TM in the curricula of medical training institutions should be encouraged and training materials on TM should be developed.

In summary, specific issues to be addressed in building capacity for research and development include: the identification, training and retention of researchers in TM, the elaboration of the role of regional

collaboration in support of TM research, and the generation of interest in TM research among policy makers, health workers, community groups and other stakeholders.

The protection of IPRs and TMK

Although patentable research results from R&D on TM are available, many of them have not been exploited commercially. Knowledge about intellectual property rights (IPRs) and traditional medical knowledge (TMK) is limited even among the elite in Africa. There is therefore the need for the dissemination of basic information and the creation of awareness about patenting to researchers, THPs and policy makers. WHO is currently working with organizations such as the World Intellectual Property Organization (WIPO), the African Organization for Intellectual Property (OAPI), the African Industrial Property Organisation (ARIPO) and the African Union to develop a regional framework for protection of IPRs and TMK.

Issues to be addressed with regard to IPRs and TMK protection include: mapping out strategies for use in protecting TMK and biodiversity in order to establish a fair and equitable sharing of benefits; the inclusion of issues related to IPRs in international research collaboration, and advocacy for the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement to promote easier access to TM for the health care needs of African countries?

Collaboration /networking/ information dissemination

The following actions will enhance collaboration, networking and information dissemination on R& D in TMs: regular update of the AFRO Website on TM research; the creation

and synthesis of databases; the dissemination of information, and the strengthening of existing regional and sub-regional networks; the organization of annual events to commemorate the Decade of African Traditional Medicine including TM exhibitions; the establishment of an *African Journal of Traditional Medicine*; the promotion of collaboration between CHPs and THPs through organisation of workshops for the exchange of experiences, and the definition of a framework for referral between the two systems.

Issues to be addressed here include: forging closer links between THPs, CHPs and policy makers, strengthening inter-African co-operation among the THPs, and enhancing the capacity for local production of traditional herbal medicines used for the treatment of priority conditions.

Dialogue with the private sector

Once TMs have been evaluated for their safety and efficacy, they would have to be produced on a large scale for their sustained availability, effectiveness and affordability. Continued dialogue between the private sector, THPs and other stakeholders is necessary. WHO should facilitate and foster partnerships between the pharmaceutical industry, research institutions and individuals for commercial production of TMs. Furthermore, the private sector would have to be persuaded to invest in TM, while the research community pursues dialogue with the private sector, including THPs, on TM research and development.

Support and respect for traditional health practitioners

Registration and licensing accreditation of qualified THPs are crucial if charlatans are to be eliminated and excluded from practice. Training for THPs in special practices and techniques, in TM research methodologies, concepts, diagnosis and treatment are also essential. The following actions would facilitate support and respect for THPs by CHPs: the setting up of TM centres in districts, the establishment of an enabling environment for mutual trust between THPs and CHPs, the establishment of structures for information sharing through

seminars and workshops, and the organization of meetings between CHPs and THPs. Here again, some pertinent questions arise: how can support and respect for THPs be promoted in hospitals, universities and research communities? What mechanisms should be put in place for the official recognition of TM, including identification, registration, licensing and accreditation of qualified practitioners?

Conclusion

Evaluation of TMs by selected centres of excellence is crucial. Collaborating institutions for building capacity for R&D in TMs should be identified and strengthened. Coherent national health research policies should

include TM research policy. Countries need to take advantage of the political momentum that is building up in the Region as demonstrated by actions being taken by the continent's leaders, raise the profile of TM in the Region and facilitate its integration into mainstream health systems. Answers to the discussion points raised in this article should help stakeholders to take the required action regarding R&D for African TMs, thus contributing to the ultimate goal of integrating TM into national health care systems.

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Traditional Medicine: CIDA, WHO/AFRO Collaborate*

The WHO Regional Office for Africa (AFRO), with the support of the Canadian International Development Agency (CIDA), is developing training modules, guidelines and model protocols aimed at enhancing the quality of interventions by traditional health practitioners (THPs) and conventional medical practitioners (CHPs) in the prevention and control of some priority diseases in the African Region.

The CIDA-WHO/AFRO collaboration is within the framework of a five-year 10 million Canadian Dollars (about US\$6.5 million) CIDA-funded Plan of Action on *Strengthening Traditional Health Systems for Malaria Prevention and Control in the African Region*.

Among the tools currently being developed by AFRO are guidelines for registration of traditional medicines (TMs) in the WHO African Region, a tool for documenting African Traditional Medicine, a Manual on Primary Health Care and malaria for THPs including traditional birth attendants and a Training Manual on Traditional Medicine for CHPs and Health Science Students.

Also being developed are model protocols for documenting ethno-medical evidence and clinical evaluation of safety and efficacy of traditional medicines used for treating priority diseases such as malaria, HIV/AIDS, sickle cell anaemia, diabetes and hypertension.

These model protocols will assist Member States to produce inventories of effective practices as well as evidence on safety, efficacy and quality of TMs, and to undertake further relevant research.

Using WHO protocols, some institutions in Ghana, Kenya and Nigeria are already conducting systematic research on traditional medicines used for the management of malaria. Preliminary research results of pilot-scale clinical trials, which are quite promising, were evaluated in March 2002 during the WHO Review Meeting of antimalarial herbal medicines, co-sponsored by WHO/HQ and AFRO. Further studies are still going on.

"I am convinced that, these protocols will go a long way in supporting countries to evaluate the quality, efficacy

and safety of traditional medicines used for treating malaria so as to facilitate access to standardized African traditional medicines" comments the WHO Regional Director for Africa. Dr Ebrahim M. Samba.

As part of the implementation of the CIDA-funded project, AFRO has also developed a tool for documenting African TM. This tool will assist countries to document TM practices, information and their sources; history of TM; TM regulation, structures and institutions; intellectual property and infrastructure and traditional home remedies used for the treatment of priority diseases including malaria.

CIDA's support to AFRO's activities in the area of traditional medicine is aimed at contributing to the reduction of morbidity and mortality associated with malaria and other communicable diseases through community-based activities and traditional systems of medicine.

* Contributed by the Traditional Medicine Programme at AFRO

Accelerating local production of Traditional Medicines in Africa

In the African region, traditional medicines (TMs) are used for the management of both chronic and acute diseases in rural and urban areas. In most cases, the herbal preparations are formulated by the traditional health practitioner (THP) upon a visit by a patient. In urban areas, very limited preparations, especially in powdered form, are routinely dispensed. Validation of the claims of THPs has been one major requirement prior to commercial production in Africa of standardized African Traditional Medicines (SATMs). The World Health Organization (WHO) is currently supporting clinical validation of some TMs used for the management of some priority diseases in the Region. This article will briefly look at some challenges, the rationale, and the way forward for accelerating local production of TMs in Africa.

Challenges

There is a dearth of reliable information on herbal preparations which are being used successfully for the management of prevailing diseases in various African countries, and this poses an important challenge in this sector especially for intending investors.

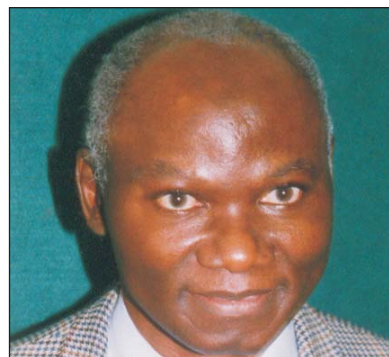
The issue of the protection of traditional medical knowledge (TMK) and biodiversity is a crucial one, which requires urgent attention. This issue is further complicated by the fact that in some cases, TMK is owned by a family, a community

or communities, while the plants used for formulating the TMs may be found in different communities and, indeed, in many countries. Furthermore, funding for the various aspects of the mandatory research and development activities of TMs is a limiting factor. This may be responsible for the limited commercial production of SATMs especially for those herbal recipes included in the African Pharmacopoeia, which has been published since 1985.

The capital outlay for production machines and accessories is very high for potential investors. Also, the socio-political environment in some countries in Africa is not generally conducive for investment, especially for the commercial production of TMs. Cultivation of medicinal plants is another challenge, given that some preparations may contain active ingredients from more than five different indigenous plants. In some cases, acquiring large hectares of land for cultivating the desired plants could be a serious limiting factor while local expertise for commercial cultivation of medicinal plants is limited.

Furthermore, the safety of the herbal preparations may constitute an obstacle to some health personnel who, understandably, demand both scientific and clinical evidence of safety, efficacy and quality before registering, prescribing or dispensing such products. The

By



*Dr Charles Wambebe**

scientific validation of various herbal recipes following standard protocols is quite demanding and requires some expertise. Product formulation and process technology development also pose some challenges to those in this field. The need for clinical validation of SATMs is overwhelming and expensive, and requires special expertise, which is in short supply in Africa. Furthermore, the marketing of any new herbal product requires special techniques and strategies to ensure that people believe in its efficacy and use it.

Rationale

Growing interest in use of natural-based products

The increased use of TMs worldwide offers a unique opportunity for their commercial manufacture and marketing, primarily for economic benefits. Indeed, the sales of herbal medicines are booming in Europe, the USA and elsewhere around the globe. For consumers, their reason for patronizing TMs is different. Most of them desire to determine, according to their conviction, what they choose to take for their health complaints. They prefer a more personalized control over their health. The constantly evolving field of

information technology has made available vast amounts of valuable data on TMs on the Internet. Consumers are exposed to several options for the attainment of a higher quality of life. From the economic point of view, the significant increase in the global use of herbal medicines justifies the promotion of their commercial production.

Treatment of chronic diseases

A review of 18 randomized controlled trials of 2,939 patients suffering from benign *prostate hyperplasia* who were treated with *Saw palmetto* showed that the treatment significantly improved urological symptoms and flow parameters more than did placebo. In fact, *Saw palmetto* was found to be clinically more effective than *finasteride* - the orthodox medicine used for such medical indication. This meta-analysis supports the general belief that some herbal medicines appear to be more effective, and much safer and cheaper for the management of some chronic diseases than orthodox medicines.

Treatment of some priority diseases

It is possible to discover new therapies from African biodiversity for the treatment of HIV/AIDS, malaria, sickle cell anaemia, diabetes and hypertension. Progress reports on the clinical evaluation of traditional medicines for the management of these priority diseases in the African region are very encouraging.

Poverty reduction and gender issues

Poverty reduction and gender issues are crucial elements for promoting sustainable economic growth. Promotion of local production of

herbal medicines will create new jobs and earnings in both local and foreign currencies, with multiplier effects on the national economy, community development, family support systems, technical expertise and socio-economic status of employees.

It will also impact positively on poverty reduction and enhance the empowerment of women in the rural areas through acquisition of new skills (e.g. medicinal plant cultivation, harvesting and post-harvest processing, improved earning capacity, contribution to economic growth and elevated social status). Promotion of local production of SATMs will facilitate acquisition of valuable human, natural, physical, financial and social assets by rural dwellers, especially women.

It is common knowledge in Africa that women are very active as THPs. They serve as Traditional Birth Attendants (TBAs), paediatricians, gynaecologists and general practitioners. Such activities enhance the economic potential of women leading to a higher quality of life. Since it is generally believed that African women are poorer than their male counterparts, partly due to entrenched traditions and gender discriminatory ownership regimes, improving the earning power of women may have profound effects on their self worth, status, economic liberation and the general well being of their families. Evidently, therefore, local production of herbal medicines is an appropriate intervention, which will contribute immensely to poverty reduction and impact positively on the role of women in development.

The way forward

In some African institutions, THPs and individuals have already developed herbal preparations for the treatment of malaria, HIV/AIDS, sickle cell anaemia, diabetes and

hypertension, etc. However, due to financial, technical and/or regulatory constraints, little or no commercial production is in progress yet.

WHO needs to assess the peculiar needs and missing links in each case where the preliminary clinical data is promising. For example, in Tanzania, the plant source of *artemisinin* (a very potent anti-malarial medicine) is grown, harvested and exported to Europe for processing and pharmaceutical formulation, which is subsequently imported to the country and sold at an unaffordable price. WHO is in the process of collaborating with Tanzania to facilitate the acquisition of the appropriate process technology so that the medicine could be produced locally. Similar missing links from promising research and development projects with the potential to foster commercial production will be identified and bridged appropriately by WHO so as to promote local production of SATMs.

Additionally, feasibility studies should be undertaken to assess the viability, sustainability and cash flow projections of identified projects. Three levels of development of traditional medicines for specific intervention include: home-based remedies at community level using mainly food plants which also possess medicinal values for common ailments like skin rashes, cough, fever, diarrhoea; SATMs already being used for some priority diseases like HIV/AIDS, malaria, sickle cell anaemia and hypertension, but which require clinical trials and commercial production prior to their registration; and herbal products at the research and development stage. Specific interventions at these three levels of development will require partnership and collaboration with local communities, THPs, national institutions, indigenous

pharmaceutical companies, NGOs, the WHO Regional Office for Africa, relevant UN agencies and other development partners and institutions. In terms of prioritization, the second level of intervention needs the most urgent attention. The Box below shows factors that can sustain the local production of TMs in Africa.

Accelerating the local production of SATMs will require WHO to provide technical guidance in appropriate research methodologies, generic clinical protocols, regulatory, legal and registration frameworks, and partnerships involving all stakeholders, among others. WHO is already pursuing various elements of these activities. It is anticipated that with continued support to Member States, SATMs of proven quality, safety and efficacy will not only be locally produced and marketed within Africa, but also exported to the rest of the world in the next few years.

Key elements in the Sustainability of Local Production of Traditional Medicines in Africa.**

Promotion of this sector can be sustained if there is political will on the part of the governments of Member States to ensure that the enabling environment is created. For example, appropriate legislation, access to loans, tax breaks, credit for investors and a commitment to registering and using proven TMs. THPs have significant roles including their willingness to enter into partnerships with interested

researchers and investors. In such cases, appropriate legal documents with unambiguous provisions on royalties, benefit-sharing formulae, responsibilities and rights of the parties etc will facilitate the smooth implementation of the projects. Furthermore, clauses on the perpetuity of the benefits derivable from such partnerships will enhance full cooperation of the THPs. Governments will generally serve to protect the interest of the community and the THPs in addition to ensuring that the framework for monitoring the various activities are well established, while the resources for the government agency charged with such responsibility are provided at the right times.

Cultivation of the desired plant species is mandatory for the sustainability of this activity. In fact, the raw materials (i.e. plants), constitute the most critical factor in sustaining the business. It is therefore significant for governments of the Member States to legislate appropriate laws, which will enhance access to large hectares of land for the cultivation of valuable medicinal plants. Once the rural farmers are adequately encouraged to participate in the cultivation, they will easily realise the economic potentials of this activity. This, in turn, will facilitate their continued participation since they will regard such medicinal plants as valuable economic assets.

It is even possible to assist farmers to start the medicinal plant farms by providing them with the

materials and resources they require to take off. Thus, the plants will belong to them while the harvested parts of the plants are sold to the research establishment involved in the standardization of the raw materials and subsequent product formulation. The farmers can repay the loans (with no interest) using a convenient payment schedule. The renewable nature of the raw materials is a unique advantage in this business. In fact, it offers a competitive advantage over synthetic drugs, which rely on fossils and petrochemicals for their basic raw materials. Such raw materials, unlike plants, are not renewable. This competitive advantage will facilitate the sustainability of the local production of traditional medicines in Africa.

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** (Extracted from the Keynote Address on Policies and Directions for Traditional Medicine and Medicinal Plants: The Way Forward in the Next Decade by Professor Charles Wambebe). Proceedings of the 15th Meeting of the Inter-African Experts Committee on African Traditional Medicine and Medicinal Plants, Arusha, Tanzania, 15-17 January 2002. Organization of the African Unity/Scientific, Technical and Research Commission. 2001-2010: OAU Decade for African Traditional Medicine.

Pharmacoeconomics of Traditional Medicine

By



Dr Jose M. Kirigia*

Introduction

Neither individuals nor governments have enough resources to tackle priority diseases such as HIV/AIDS, malaria, diabetes, hypertension, and sickle cell anaemia. It is therefore impossible to avoid making choices concerning how best to use the available resources. In the context of traditional medicines (TMs), pharmacoeconomics, a sub-discipline of health economics, is concerned with identifying medicines and practices that yield best value for money. It focuses on the efficiency with which patients utilize, and traditional health practitioners (THPs) produce and supply, traditional medicine (TM) into the market. This article describes the scope of pharmacoeconomics of TMs (Figure 1).

Measurement and valuation of effects of TM on health (Box A)

Diseases predispose individuals to

sub-optimal quality of life (QoL) and length of life (LoL). Thus, health indices such as the quality adjusted life year (QALY) and the disability adjusted life expectancy (DALE) should combine changes in both QoL and LoL due to administration of specific TM. The effect of any TM is the difference between total expected QALY (or DALE) with therapy and total expected QALY (or DALE) without therapy. Therefore, pharmacoeconomics delves into the measurement and valuation of the effects of TM on health.

Determinants of demand for TM (Box B)

In the context of TM, an individual faces various choices: as a sick person, should I seek treatment from modern health facilities or a THP (herbalist or a spiritual healer)? If I choose to consult a herbalist, which one should I visit? Which herbal preparation should I use? Should I comply fully with the prescribed herbal preparation or not?

Concerning the abovementioned choices, economics tells us that individuals will choose the alternative for which they believe the net gain (utility) to be the greatest. Choice of a particular commodity or course of action (e.g. whether or not to consult a specific THP) is usually assumed, in pharmacoeconomics, to be a function of personal socio-economic characteristics (e.g. age, marital status, religion, health education, secular education, income, risk attitudes, health status, etc), and commodity-level attributes (e.g. commodity price, prices of other commodities, travel cost to service source, waiting time at the source, perceived effectiveness of service, etc). Demand analysis information is

Figure 1: The scope of pharmacoeconomics

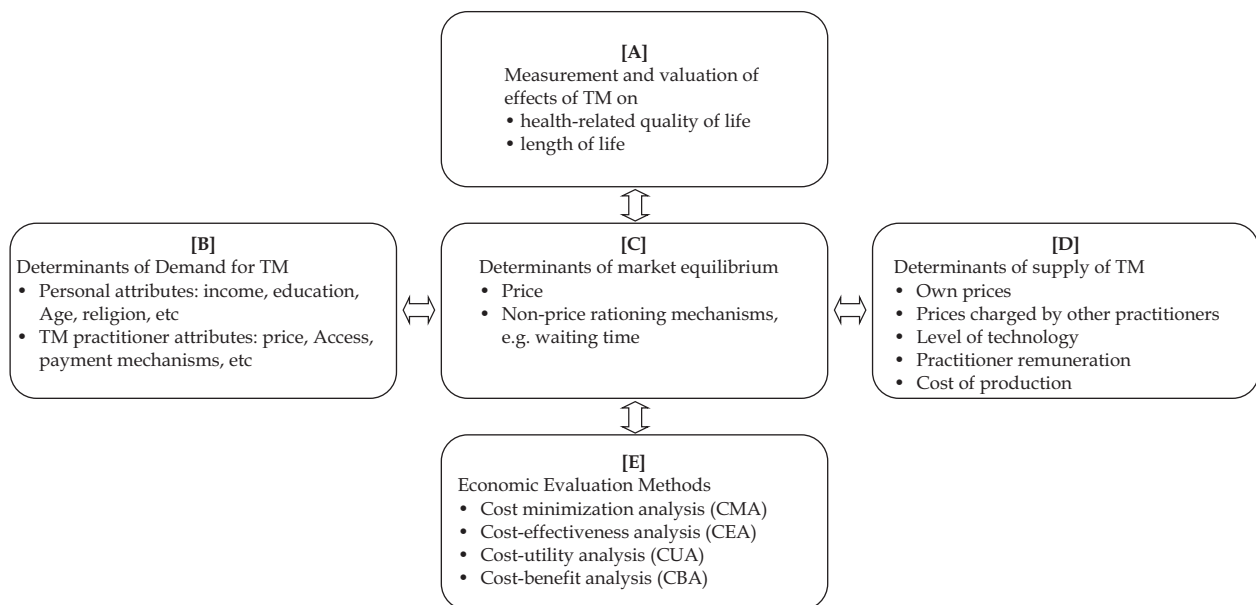
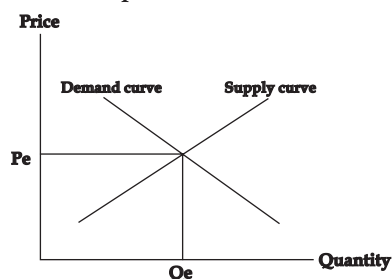


Figure 2:
A simple TM market model



important in pricing of traditional therapies (and practices) and in explaining compliance or non-compliance with prescribed TM.

Determinants of supply of TM (Box D)

Supply refers to the maximum quantity of health services THPs are able to produce and are willing to sell at the going market prices. A higher (lower) price gives profit-motivated THP the incentive to increase (decrease) production. In addition, in the short run, the quantity supplied is affected by input prices, technology and prices of substitute medicines. Underlying the supply of any good or service is the production function, that is, the relation between the output of that good or service and the inputs (e.g. healers' and assistants' time, herbal medicines).

Determinants of TM Market Equilibrium (Box C)

If the TM market were perfectly competitive, there would be one unique price (P_e) where the quantity supplied (Q_e) by THPs would be equal to the quantity demanded (Q_e) by patients (see Figure 2). The market may fail due to: information asymmetry between patients (least informed about effectiveness) and the THPs (relatively more informed); unquestioning reverence of THPs; and existence of monopolies in certain rural areas.

Economic evaluation Methods (Box E)

There are four main *economic evaluation methods*: cost minimization analysis (CMA); cost-effectiveness analysis (CEA); cost-utility analysis (CUA); and cost-benefit analysis (CBA).

CMA identifies the least costly TM when there is evidence that alternative therapies under consideration are equally effective in improving health status of individuals. It is appropriate when the question to be answered is: "From a societal perspective, assuming that *N'diribala*, *Namor*, *Mist Nibima*, *Massy Totaquina*, and *Niprimal*¹ traditional therapies for malaria are equally effective, which treatment regimen is least costly?" CMA decision criteria require choice of the TM with lowest cost.

CEA compares costs and outcomes of two or more TM, measuring the inputs in monetary terms and the outcomes in natural or physical units, e.g. deaths or cases averted. CEA is relevant when the problem facing a decision-maker is: "From the viewpoint of THPs, is it more cost-effective to treat diabetics using *Mist INDICA*, *Mist BREDINA*, *Madegilucyl* or *Diabetisane* traditional therapy?" CEA decision criteria require choice of the therapy with the least incremental cost-effectiveness ratio.

CUA compares costs and consequences of two or more TMs, measuring inputs in monetary terms and the outcomes in a health index, e.g. QALY or DALE. It is appropriate when the problem facing a decision-maker is: "From the viewpoint of both the traditional medicine practitioner and HIV/AIDS patients, does *Sutherlandia*, *St. Camille*, *Paludrine*, *Projects St. Dominique (CSRPM/WCC)*, *Winnie Cure*, or *Canavil* herbal preparation promise the highest health improvement per unit cost?" CUA decision criteria entail choice of the TM with the lowest incremental cost-utility ratio.

CBA identifies, quantifies, and values in a common yard-stick (usually local currency) all important costs (direct, indirect, intangible and externality costs) and consequences (benefits) to society of any TM. It is appropriate to use when the problem facing a decision-maker is: "From the social perspective, is it *worth* continuing the status quo sickle cell anemia treatment instead of either *VK500*, *Mist Morazia*, *Fagara*, *Niprisan*, *Nifadin*, or *Drepanostate* traditional therapy? The CBA decision rule dictates that any TM whose net present value (NPV) is greater than zero is worth using. And, when there are two or more worthwhile TM, the one with the highest NPV should be preferred.

Concluding remarks

Pharmacoeconomics is critically important in: the process of measuring health impacts of TMs; evaluating the causal-effect relationship between health care-seeking behaviour and individuals and THPs specific attributes; pricing of TMs and practices; advocacy for utilization of TMs that prove to be cost-effective; the estimation of the statistical association between patient compliance with treatment regimen and personal as well as therapy-specific attributes; establishing individual THP's magnitude of inefficiency in resource use; and guiding choice of TMs for specific diseases, i.e. identifying the best buys.

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¹ Hedberg, O. and al., Inventory of Plants used in Traditional Medicine in Tanzania, Journal of Ethnopharmacology, 1982. See also <http://www.rbgekew.org.uk/peopleplants/wp/wp1/africa1.htm>

Building a Regional Initiative for Traditional Medicine and AIDS in Eastern and Southern Africa

Introduction

In sub-Saharan Africa, the majority of people living with HIV/AIDS (PLWA) continues to depend greatly on traditional health practitioners (THPs) and herbal treatments for health information and care, because THPs and herbs are far more available and accessible in their communities than modern doctors or medicines. Yet, traditional medicine (TM) still lacks recognition and credibility among the medical establishment, policy makers and donors alike.

The Regional Initiative on TM and AIDS

The Eastern and Southern African Regional Task Force on Traditional Medicine and AIDS was created at the conclusion of a Regional Consultation on TM and AIDS convened in 2000 in Kampala by UNAIDS and the Association for the Promotion of Traditional Medicine (PROMETRA), based in Dakar, Senegal. A Ugandan NGO, the Traditional and Modern Health Practitioners Together against AIDS (THETA) was selected to serve as the Task Force's Secretariat. THETA has proposed to build a Regional Initiative of users, THPs and conventional health practitioners (CHPs), implementers, policy makers and scholars to establish minimum standards of practice regarding six key aspects of TM in relation to AIDS. These are: prevention and care; evaluation of TM treatment; processing/packaging of herbal

medicine; and protection of indigenous knowledge and intellectual property rights (IPRs).

The broad aim of this initiative is to strengthen the voice and credibility of African TM as the primary health system that the majority of Africans continue to access. The plan is to come up with a consensual strategy (phase 1), test it (phase 2) in a limited number of pilot sites, and evaluate it (phase 3). If successful, the initiative should be scaled up in a following cycle in additional sites in Africa.

In order to develop a consensual and credible strategy, the Task Force Secretariat visited potential partners in Kenya, Malawi, Rwanda, Tanzania, Uganda and Zambia to share the concept of the initiative and invite potential partners to participate in a regional workshop which was held in Kampala in May 2003. The workshop's main intent was to develop minimum standards of practices for the different areas of TM summarized above.

The workshop participants drafted the following minimum standards:

Evaluation of Traditional Medicines

- Evaluation of TMs should be guided by information gathering with clients and THPs on the potential value of herbal preparations.
- Observational studies should be conducted to further confirm safety and assess indicative

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- efficacy. Minimum methods were outlined for the conduct of the study, including enrolment and follow-up of participants, treatment administration, and care for side effects and referral.
- It was agreed that randomized clinical trials should not be part of the minimum standards as

they require technical capability and resources that defeat the purpose of evaluating the numerous preparations already in use by millions of PLWA throughout Africa.

- Results should be shared and documented with the primary beneficiaries of the studies (PLWA and THPs) and disseminated to communities and stakeholders involved.
- Accessibility to tested preparations should be ensured through the use of local ingredients and their preparation in a low-cost standardized form suitable for ease of packaging, storage and administration.

Spiritual Healing

- Spiritual medicine was defined as a process carried out through powers of the spirit/divine, not associated with use of medicine or physical body manipulation, unless so directed/instructed by spirits. It was stressed that spiritual healing is not witchcraft;
- Characteristics of the spiritual healing practice include acceptance by the community, absence of negative social aspects, and gratuity of services whereby community/clients only make voluntary contributions;
- The service should include guidance, counselling, healing, review of cultural practices, peace promotion, security (protection from malevolent spirits), and advocacy for good practices;
- Personal attributes of the spiritual medium/healer were defined as a person or animal chosen by the spirits (hence not predictable);
- Ethical standards of the practice include the observance of confidentiality, the option for

clients to make appointments and the dependence of the healer on her/his guiding spirits;

- The healer's shrine can be any place recognized by the spirit, but the place should be recognized and respected by the community and be freely accessible without fear.

Prevention and care

Communities, clients and practitioners (THPs, CHPs) should be trained/empowered in a number of issues related to prevention and care.

Referrals should be emphasized both ways (THPs to CHPs and CHPs to THPs), referral forms should be introduced in programme areas, and CHPs should be encouraged to refer cases such as chronic skin conditions, mental illness, epilepsy, spiritual cases

As a minimum output, THPs should be able to give correct information on Sexually Transmitted Infections, HIV/AIDS and TB to clients and community members, promote adequate prevention methods, identify danger signs and symptoms, refer patients to appropriate health facilities, and demonstrate skills in counselling and information sharing. BHPs should demonstrate positive attitudes towards THPs/TM.

Standardization, processing and packaging of herbal medicine

Minimum requirements for harvesting, processing and storage of TM include

- proper selection and botanical identification of raw material;
- documented harvesting geographical area, month, date, time;
- controlled conditioning for temperature, moisture content, light exposure, and drying method, and

- controlled storage conditions including good ventilation, protection from light/ultra violet rays, adequate temperature, and wooden racks

Accurate selection and identification of correct plants for particular usage should be guided by a THP taking into account season, time, and geographical region.

Minimum extraction standards include ensuring hygiene for mechanical extraction devices and using appropriate methods for volatile and non-volatile products.

Minimum standards for packaging and labeling of TM preparations were differentiated for individual THPs and commercial preparations. Additional standards for commercial preparations include avoiding the use of polythenes, using air-tight containers, and sterile glass containers for suspensions, solutions and injectables. In addition to what is required from THPs, labeling should include the botanical/scientific names and quantities of each ingredient, the date of manufacture and expiration, contraindications, different dosages for adults, children and infants, and other warnings as appropriate.

Indigenous Knowledge

- African traditional medical knowledge (TMK) relates to the spiritual, herbal and technical knowledge, rites and practices that have been developed and used for generations to heal and alleviate all sorts of physical, emotional and spiritual ailments in Africa.
- TMK comprises a number of 'specializations' including, but not limited to: spiritual healing; preventive traditional medicine; traditional counseling; traditional midwifery; bone setting / surgical procedures;

nutritional advice; herbal medicine, including the use of animal and mineral products (often used in combination with any of the other practices)

- The protection of herbal medicine as TMK also implies the development of sustainable and traditionally acceptable practices for its cultivation, harvesting, processing, utilisation and dissemination
- The protection of the various practices that constitute TMK require that each 'specialty' be documented, analyzed, evaluated, validated, and attributed (ownership).

Intellectual Property Rights (IPRs)

- Protection of IPR requires information on community needs, incremental documentation at various levels, and the design of model agreements

Although the minimum standards for legal protection of IPR will vary depending on specific national laws, the following universal practices / approaches were recommended:

- Sensitize THPs and communities about their rights
 - National / local heritage should be given priority, e.g. protection of traditional sites/areas
 - Use available legal instruments to protect sources (including providers/THPs), processes and products
 - Use the OAU Model Law to advocate for adoption of appropriate national/local legislation to protect TMK
 - Use innovative mechanisms to allow for settling complex issues involving multiple key players such as the establishment of Community Trusts for TMK ownership and benefit sharing,
- In any case,
- Communities or individuals should not sell IPRs, but license them under legal agreements.

- Public and community health and wealth should prevail over individual and corporate interests!

Resolutions taken

It was agreed that in order to strengthen the Regional Task Force, participants will form country chapters and devise collaborative projects based on, and designed to test, the minimum standards developed. The Task Force is to use its combined network and credibility to mobilize funding for the projects.

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WHO Supports Process Technology Development for Local Production of Dihydro-artemisinin in Tanzania.

The World Health Organization through its Regional Office for Africa and the Tanzanian Ministry of Health will soon sign a technical agreement *vis-à-vis* a research project on "Feasibility Study for Domestic Production of Dihydro-artemisinin for Treatment of Uncomplicated *P. falciparum* Malaria in Tanzania"

This project will be executed by the National Institute for Medical Research of Tanzania's Ministry of Health as the focal institution, and the Government Chemist Laboratory Agency as the collaborating institution. The project will involve extraction of *artemisinin* from *Artemisia annua*; purification and

hydrolyzation of *artemisinin* into *dihydro-artemisinin*; and pilot production of *dihydro-artemisinin*.

The general objective of the project is to develop the process technology for the local production of *dihydro-artemisinin* - a potent anti-malarial medicine using *Artemisia annua*, a medicinal plant of Chinese origin which is grown in Tanzania's northern and southern highlands. The plant-based medicine is known to have the highest cure rate for malaria.

WHO has expressed interest in supporting Tanzania to embark on

commercial production of the medicine. This could mean a drop in price from the current \$6 to \$7 per dose to a more affordable \$2 per dose for the anti-malarial medicine which is currently imported from Europe where it is processed with raw material grown in Tanzania.

Experts from the WHO regional office, after a recent field visit to Tanzania, concluded that the production of the medicine locally was a viable option, particularly given the fact that the local variety of *Artemisia annua* was 10 to 15 times more potent than the varieties found in China and Thailand.

** Contributed by the Traditional Medicine Programme at ARFO*

Evaluation of Traditional Medicine for the management of Sickle Cell Anaemia in Nigeria

By Prof. Shingu Gamanuel*

Introduction

Sickle Cell Anaemia (SCA) is an inherited blood disorder which mainly affects Africans and some people of Middle Eastern and Asian origin.

Symptoms include fatigue, breathlessness, bone and joint pains, body weakness and susceptibility to infections. People affected with SCA also experience what is known as 'crisis'. These are severe attacks which can encompass the aforementioned symptoms as well as jaundice, fever and vomiting. A crisis usually leads to hospitalization, and in some cases a blood transfusion is needed. Repeated crises can lead to liver, lung, kidney damage and other severe medical conditions.

There is no cure for the disease but daily medication and regular hospital check-ups keep SCA manageable. People with the condition are able to go to school, college or work but, of course, may have to take time off for periods of illness.

SCA in Nigeria

About 2% of Nigerians suffer from SCA, while another 25% of the population has sickle cell trait. It is estimated that 10% of infant mortality is due to SCA complications. On a yearly basis, about 100,000 babies are born with SCA. Those who survive infant death usually experience recurrent painful crises leading to the death of most of them from bacterial infection, malaria or complications of SCA before attaining 40 years of age. In Africa, there is no medicine

available for the routine management of SCA. Consequently, most SCA patients resort to traditional health practitioners (THPs).

Since the early 1990s, SCA topped the list of priority research projects of the National Institute for Pharmaceutical Research and Development (NIPRD) – a Federal Government-owned research agency – based in Abuja, the capital. In 1993, the Institute received credible information that one Reverend, P.O. Ogunyale, a traditional health practitioner (THP) based in Oyo, in the western part of the country, was managing SCA patients. Subsequently, NIPRD established a collaboration with the THP, resulting in a study which was undertaken by NIPRD between 1993 and 2001.

Clinical observational study

The study design involved 20 SCA patients who used the traditional medicine (TM) prepared by the THP for six months. The effectiveness of the TM was assessed by the number and severity of SCA-related painful crises, frequency of blood transfusion and absence from school or work. Safety of the medicine was evaluated by measuring both kidney and liver function enzymes, and any reported side effects by the patients. These parameters were measured before treatment, and monthly, during therapy. The patients were clinically assessed at the NIPRD clinic prior to administration of the medicine, and then weekly thereafter. The results indicated that the patients benefitted from the medicine on all the parameters tested without any side effect.

Laboratory studies on the quality of NIPRISAN

Based on the promising data of the clinical observational study, NIPRD took over the research and development of the TM and called it *NIPRISAN*. The scientific parameters for the quality of the raw plant material, extract and product were established. Pharmacological and toxicological studies conducted indicated that *NIPRISAN* was safe and manifested a potent anti-sickling property against red blood cells. Furthermore, the technical processes regarding the extraction, formulation and dosage of *NIPRISAN* were determined. Subsequently, scientists at the Children Hospital of Philadelphia, USA, reported on the efficacy and safety of *NIPRISAN* using animal models of SCA which corroborated the clinical data of NIPRD scientists.

Patents

In order to protect the ownership of *NIPRISAN*, it was patented in 46 countries in Africa, Asia, Europe, the Americas and West Indies between 1998 and 2000. *NIPRISAN* is jointly owned by NIPRD and the THP (Reverend Ogunyale) who prepared the original recipe from which it is developed. The funds for patenting and conducting research and development of *NIPRISAN* were provided by the United Nations Development Programme (UNDP).

Controlled clinical trials

A controlled randomized clinical study was conducted at the NIPRD clinic in Abuja, using 100 SCA

patients. A clinical trial followed at the Military Hospital in Yaba, Lagos, involving 30 SCA patients, using an open design. The duration of the studies was 12 months. The study at the Military Hospital was done between 1995 and 1996, while the NIPRD study took place between 1997 and 1998. The study design for the two studies is similar to that used for the clinical observational studies, except that the patients served as their own controls and visited the clinic/hospital monthly, while *NIPRISAN* was formulated and standardized by NIPRD into capsule dosage form. Furthermore, the laboratory tests were done on monthly basis at the Department of Chemical Pathology of the Lagos University Teaching Hospital, located in, Nigeria's commercial capital.

The results of the two studies showed that about 70% of the patients did not experience any major painful crises

during the study period as compared to a yearly average of three painful crises before treatment with *NIPRISAN*. None of the patients was transfused while school/work attendance significantly increased during the study period. The data also showed that *NIPRISAN* had no harmful effect on either the kidney or liver.

Licensing, registration, local production and marketing of *NIPRISAN*

In July 2002, *NIPRISAN* was licensed to XECHEM Inc., a pharmaceutical company based in the USA by the Nigerian Federal Ministry of Health. The licensing agreement specified that the THP (Reverend Ogunyale), and NIPRD, would share the royalties accruing from the sale of *NIPRISAN*.

NIPRISAN is expected to be registered, launched and marketed

by XECHEM Nig Ltd (a subsidiary of XECHEM Inc.) in Nigeria in 2003 as a prescription phytomedicine. Indeed, XECHEM Nig. Ltd has already commenced the local production of *NIPRISAN*.

Conclusion

The story and journey of *NIPRISAN* – from a plant extract to medicine in capsule dosage form – has had a happy ending because of collaboration between NIPRD and Reverend Ogunyale, the grant from UNDP, the collaboration of the clinicians and participating hospitals, the patenting of the product, and the enabling environment created by the Federal Government of Nigeria for all these.

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Evaluation of Traditional medicines for the management of HIV/AIDS: The Experience of Burkina Faso

By Dr Jacques Simpore*, Dr Jean Baptiste Nikiema* and Dr Daboga Sia*

Introduction

HIV/AIDS is both a major public health problem and a developmental concern in Burkina Faso. In 2002, the United Nations Joint Programme on HIV/AIDS (UNAIDS) estimated the prevalence rate in Burkina Faso as 6.5%, with 600,000 people infected, and 100,000 of these in need of antiretroviral treatment.

The situation is even worse in rural areas where traditional medicine (TM) is the only medicine available for health care.

Needless to say, antiretroviral treatment still eludes the majority of people living with HIV/AIDS (PLWA) in Africa in spite of efforts being made to procure them, and the resolutions and recommendations adopted in various fora.

Since HIV/AIDS made its debut in Burkina Faso, Traditional Health Practitioners (THPs) have provided treatment to infected persons. Due to the absence of data on the services provided by the THPs, the Ministry of Health signed an agreement with the *Centre Medical Saint Camille* under which the institution would evaluate the efficacy and safety of traditional herbal medicines in the management of HIV/AIDS.

This accord led to the establishment, in 1999, of a Phytotherapeutic Unit, essentially made up of a hospital and a laboratory for biomedical analysis. The study presented below summarizes the experience of the *Centre Medical Saint Camille* in the management of HIV/AIDS with traditional herbal medicines after a three-year period.

1- Study protocol

1-1. Selection of patients

1-2.

Inclusion criteria of persons:

- Over 18 years old
- Infected with HIV1
- With a CD4 count of 200/microlitre or more
- Who consented in writing for inclusion in the study

Exclusion criteria of persons:

- Less than 18 years of age
- Concurrently infected with HIV-1 and 2
- Pregnant women
- With pulmonary tuberculosis
- With cardiac or renal problems, or who are suffering from serious hepatitis
- Undergoing antiretroviral treatment

1-2. Method of clinical and biological follow-up

The following clinical and biological parameters were carried out as baseline prior to commencement of the study and there after repeated every three months:

- An HIV confirmatory and discriminatory test (HIV1/2)
- Monitoring of immunity level CD4/CD8/CD3 (FACS count)
- Estimation of the viral load (Kit amplicor HIV-1 de Roche) at baseline and once every 6 months
- Estimation of creatinine transaminases
- A clinical examination at

beginning of study, and once every three months. There was a dose follow-up (monthly physical examination) of patients with CD4 count below 300

- X-ray of the lungs

1-3. Selection of THPs and of treatments

THPs were selected from all over the country, with account taken of their experience in managing PLWA. Surveys were based on the testimonies of patients, and health personnel, and complemented with interviews with THPs. The most promising traditional herbal medicines were used, according to their pharmaceutical qualities and safety.

11- Results

A total of 1,246 patients were registered for the study. Of these, 723 were regularly monitored for at least a one-year period during which they received treatment: twenty-two (22) of them died, while 82 were able to undergo CD4 count estimates. The detailed results concerning these 82 patients are as follows:

- The CD4 count of 62 patients (75.6%) increased significantly
- The CD4 count of 9 patients (11.0%) dropped significantly, and remained at the same level for 11 patients (13.4%)
- The viral load of 56 patients (68.3%) dropped significantly, while it increased for 26 patients (31.7%)
- 52 patients (63.4%) simultaneously showed an increase in CD4 count and a significant reduction of viral load

- In 1 patient, the virus was below detectable level

The patients monitored showed a clear physical improvement as early as in the first month of treatment. This improvement was accompanied by a decrease of the viral load and an increase in CD4 count.

111-Discussion

The results of the study showed that the traditional herbal medicines used in these clinical investigations brought about a positive impact on the quality of life, accompanied by a

significant drop in viral load (68.3%). This decrease in viral load occurred at the same time as the CD4 count increased, demonstrating that the immune system of the patients had been boosted. However, the effect of the traditional herbal medicines used is less significant when compared with the effect of antiretrovirals available on the market.

While the viral load dropped significantly in the majority of patients, the virus was below detectable level in one patient after three successive counts taken over a one-year period during which he was

receiving treatment. This patient joined the study with a relatively low viral load (20,000 copies/ml). These traditional herbal medicines should not be used for bed-ridden patients.

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Who Establishes Regional Expert Committee on Traditional Medicine*

The WHO Regional Office for Africa has established a Regional Expert Committee on (TM) to support the monitoring and evaluation of the progress made in the implementation of the Regional Strategy on *Promoting the Role of TM in Health Systems* in the African Region.

The Committee was set up in May 2001 in response to a resolution adopted by the Health Ministers at the 50th session of the WHO Regional Committee for Africa in 2000 in Ouagadougou, Burkina Faso, requesting the Regional Director to, inter alia, establish a regional mechanism to support the monitoring and evaluation of the progress made in the implementation of the Regional Strategy.

Since its establishment two years ago, the Committee met in November 2001 and 2002 respectively, and has reviewed 12 and approved 10 documents developed as tools that could serve to raise the profile of TM in Africa, speed up its official recognition, and serve as the cornerstone for the development of policies for its institutionalization and integration in the health systems of countries in the Region.

The documents were on:

- Guidelines for the formulation, implementation and evaluation of national strategies on TM,

- Legal framework for the practice of Traditional Medicine: Model Traditional Medicine Bill for traditional health practitioners in the WHO African Region,
- Model Code of Ethics for Traditional health practitioners in the WHO African Region, and
- Model Protocols for evaluation of traditional medicines used for the treatment of priority diseases.
- Guidelines for the formulation of a national master plan for the development of traditional medicine
- A tool for documenting African traditional medicine
- General guidelines for documenting data on ethnomedical evidence of traditional medicines
- Guidelines for registration of traditional medicines in the WHO African Region
- Regulatory framework for accelerating protection of intellectual property rights of traditional medicines and traditional medical knowledge

They have also adopted a number of recommendations. Principal among these are the establishment or strengthening of TM Programmes in WHO country offices, greater involvement by WHO Country Representatives in TM activities, organization of a Regional workshop on

intellectual property issues for the protection of traditional medical knowledge and equitable benefit sharing of the industrial utilization of medicinal plants and the use of Africa's biodiversity. The Committee also adopted the theme *Traditional Medicine, Our Culture and Our Future* for the inaugural African Traditional Medicine Day as

Members of the Regional Expert Committee, two of whom are Traditional Health Practitioners, are: Prof. O' Penge (Democratic Republic of Congo), Prof. Kwabena Francis Oppong-Boachie (Ghana)**, Prof. Abayomi Sofowora (Nigeria), Dr. Jean Baptiste Nikiema (Burkina Faso), the late Prof. Ettiène Yapo (Cote d'Ivoire), Dr. Donna Kabatesi (Uganda), Dr. Jacques Ranaivoravo (Madagascar) Mr. Nhlavana Maseko (Swaziland) Dr. J. K. Ghitae (Kenya), Dr. Kofi-Tsepko (Kenya), Prof. Rabodo Andriantsiferana (Madagascar) and Prof. Charles Wambebe (Nigeria), now Short-Term Professional with the Traditional Medicine Programme in WHO/AFRO.

**Prof. Kwabena Francis Oppong-Boachie (Ghana) proposed the theme *Traditional Medicine, Our Culture* for the first African Traditional Medicine Day; his proposal was endorsed by other Members of the Regional Expert Committee and AFRO.

* Contributed by the Traditional Medicine Programme at ARFO

The Role of Traditional Health Practitioners in increasing access to HIV/AIDS Prevention and Care: The Ugandan Experience

By Primrose Kyeyune*, Dorothy Balaba* and Jaco Homsy*

Uganda had one of the world's highest HIV sero-prevalence rates in 1992, when two NGOs, the Ministry of Health and the National AIDS Commission launched an initiative called *Traditional and Modern Health Practitioners Together against AIDS* (THETA).

THETA's aim was to promote a lasting collaboration between traditional health practitioners (THPs) and conventional health practitioners (CHPs) in the areas of treatment, care, support and prevention of sexually-transmitted infections (STIs) and AIDS. The first THETA initiative attempted a collaborative clinical study to evaluate herbal treatments for HIV/AIDS symptoms, for which few or no therapeutic options were available in Uganda. When this study began, THPs were unwilling to discuss AIDS with their clients because they feared losing them if they pronounced a terminal diagnosis. These challenges motivated a second project to empower THPs for STI-HIV/AIDS counselling and education, with a particular emphasis on women clients in Kampala, where the prevalence of HIV had leveled around 30% in pregnant women.

In 2003, the overall HIV/AIDS prevalence in Uganda has dropped to 6.5%.

For a first study, 48 Kampala THPs were selected through home and clinic visits to answer a baseline questionnaire related to their knowledge, attitudes, beliefs and

practices surrounding STDs and AIDS. Following this survey, 17 THPs were recruited to participate in a 15-month training programme (for an average of three training days a month). The original training curriculum was developed in collaboration with an NGO known as The AIDS Support Organization (TASO), and with the input of both THPs and community women. The questionnaire focused specifically on STIs and AIDS, but also covered other topics such as cultural beliefs and practices, counselling, leadership, sexuality, gender, and legal issues.

THPs' overall performance was evaluated systematically. This was done through interviews with their clients and members of the local communities, oral and written tests, regular visits to the healers' workplaces, client follow-up interviews, and sit-in sessions (where a trainer observed a healer educating education or counselling clients).

Each healer was found to have applied the training differently, some using their new skills for community education, others for counselling and/or initiating PLWA, youth or women's support groups. Community education by healers proved to be very interactive with THPs designing their own training materials, developing and using unique approaches to convey their messages through story-telling, PLWA personal testimony, music, dance, poetry and drama. A preliminary assessment was conducted one year after the end of the training programme comparing

three communities where healers had completed the THETA curriculum. In one community no THP had been trained. The community members with trained healers showed increased knowledge of HIV/AIDS and reported increased condom use (50% vs. 17% where the THP was not trained), and reduced risk behavior. THPs' counselling was evaluated by interviewing 180 women clients who consulted nine such practitioners for HIV symptoms, STIs, or 'love' problems, and doing a follow up on them after three months (follow-up I) and six months (follow-up II) respectively. Both the proportions of women who reported having received counselling from their healer (45% to 72%) and having been tested for HIV (46% to 64%) had risen significantly by follow-up II. During counselling, women said the THPs discussed facts about AIDS, positive living and condom use. Condom knowledge, attitudes and use were found to significantly increase over time among these women, as was the increase in condom negotiation by women with their sex partners. However, at follow-up II, eight out of 39 (21%) women still said that one could tell someone had AIDS by his or her 'pale skin or eyes'.

In addition, within the first year of training, many of the trained healers spontaneously initiated the formation of PLWA support groups for their clients and THP associations, some of whom achieved local notoriety for their educational songs, drama and dance on AIDS. Based on these results, the THETA initiative has been expanded to seven rural

districts of Uganda using the framework developed in the Kampala pilot study. A participatory evaluation of THETA showed that:

- 125 THPs were trained for 18 months in the first five districts selected and over 400 THPs had been trained in all eight districts
- A conservative estimate shows that THPs receive about 15 clients/month and therefore about 72,000 community members are reached a year with improved services provided by THPs
- 60% trained THPs compared to 9% untrained THPs report distributing condoms
- 80% trained THPs compared to 40% untrained THPs report counselling patients
- 82% trained THPs compared to 42% untrained THPs report giving AIDS community education
- 97% trained THPs report referring patients to CHPs, clinics or hospitals

In Kamuli, a rural district of Uganda, 100 THPs were interviewed before training, and 90 THPs after training. The training programme involved 40 THPs. Results of the interviews showed that:

- 55% before vs. 95% after training talk to their patients about AIDS (condom use, prevention and referral)
- 63% before vs. 92% after training advise their patients to go for an HIV test
- 49% before vs. 95% after training discuss condom use with their patients
- 34% before vs. 69% discuss sex related issues.

Other benefits of training included: better management of patients through referral, better hygiene, record keeping, decrease in consultation fees, initiation of eight patient support groups, eight THP associations, and improved collaboration with conventional medicine.

In addition to training activities, THETA conducts clinical activities and has initiated the creation of a resource centre for TM and AIDS. Clinical activities have included a study assessing herbal treatments provided by THPs for specific HIV-associated symptoms, and a training of THPs on AIDS patient care.

The resource centre houses a library with material on TM medicine and AIDS, has produced two videos and a bi-annual newsletter, and conducts speakers bureaus where topics relevant to TM and AIDS are discussed and debated among THPs and CHPs as well as patients of both systems. The resource centre is also spearheading a regional initiative on TM and AIDS.

** Kyeyune, Balaba and Homsy collaborate with THETA in Kampala, Uganda*

Laboratory and Clinical Evaluation of Traditional Medicines for Care and Treatment of Malaria: Experience of the Malagasy Applied Research Institute

By



Dr Jacques Ranaivoravo*

Introduction

This article reports on recent research activities on traditional medicine (TM) and the use of Malagasy traditional plants for treating malaria. The Malagasy Applied Research Institute (IMRA) carries out research and laboratory tests on traditional medicines (TMS) prior to conducting clinical tests. The tests are preceded by the use of experimental models to confirm therapeutic activity and absence of toxicity in the plants to be used. All these activities involve the deployment of multidisciplinary competencies and the use of traditional health practitioners (THPs), botanists, chemists, pharmacologists and conventional health practitioners.

Methodology

In 1986, the IMRA scientific team initiated research on anti-malaria chemotherapy, using medicinal plants of Madagascar. After conducting surveys among villagers and THPs on how to treat malaria, and compiling a bibliography on plants traditionally used for treating the disease, the team succeeded in identifying and selecting plants used as anti-malaria medicine, to relieve pain or reduce body temperature in fever, or to enhance the effectiveness of chloroquine.

Botanical study and collection of plants

The botanist in the team then proceeds with the actual identification of the plants listed, classifying them according to family, gender and species. Plants for laboratory studies are always collected in the botanist's presence in order to avoid any possible confusion or error.

Phytochemical study

After drying and grinding the plants selected, the chemists in the team extract the quantities to be tested by the pharmacologist using experimental models available. In fact, phytochemical and pharmacological studies are done virtually simultaneously. The procedure is referred to as "bioguided fractionating". The aim is to isolate the active ingredient(s) of the plant studied.

Pharmacological study

Confirmation of the antiplasmodial activity and/or ability to reverse resistance to chloroquine is obtained from standard tests: *in vitro* antiplasmodial test on the erythrocyte phase of the parasite (a method developed by J. LEBRAS) and *in vivo* testing among rodents (a method developed by PETERS).

The *in vitro* tests are conducted, on the one hand, on a strain of *Plasmodium falciparum* sensitive to chloroquine and, on the other, on another strain that is resistant to chloroquine. The *in vivo* tests are conducted with either *Pl. yoelii*, or *Pl. berghei*.

Cytotoxicity tests

The safety of the plant extract was evaluated using standard procedures.

Acute and chronic toxicity tests

These are done respectively through single administration of a series of doses (for the acute toxicity test) and repeated doses (for chronic toxicity tests) of the plant extract studied.

Other tests

Other tests conducted include the study of plants reputed to be anti-malarial on the hepatic phase of the parasite (this is a new approach, which has just been added to the methodology). For the extracts and fractions that react positively to the *in vitro* and *in vivo* tests, some pharmacodynamic tests are conducted on isolated organs.

Clinical study

After comparing and analysing the data and results of all the stages detailed above, the clinical study was then conducted successively in two phases : a preliminary clinical study, and an actual clinical test. The first is an open and uncontrolled study, involving about 20 cases, while the second is a double blind randomized controlled clinical test. The study protocol adopted is the one developed by the Traditional Medicine Programme of the WHO Regional Office for Africa, and made available to countries in November 2002.

Results

The following genera with species endemic to Madagascar and reputed

to cure malaria were selected and used in the laboratory studies: *Asteraceae*, *Bignoniaceae*, *Hernandiaceae*, *Loganiaceae*, *Menispermaceae*, and *Rutaceae*.

Those that presented interesting biological activities benefited from further phytochemical study. So far, four species retained the attention of researchers of the department concerned because of their intrinsic anti-plasmodial activity and/or their ability to chloroquine resistance properties.

A double blind randomized controlled clinical test on a phytomedicine, or reverser of chloroquine resistance, was conceived and conducted in two phases in 2001 - 2002 in a region of the Central Highlands of Madagascar.

Some 317 patients, aged between six and 60, were selected for inclusion in each case for a period of 28 days.

Conclusions and prospects

The testing of extracts from plants of Madagascar for the research and as new candidates for pre-clinical studies is being pursued, particularly on species that are not threatened with extinction. Indeed, about 30 plants are tested every month at the *Laboratoire de Phytochimie et de Pharmacologie Cellulaire et Parasitaire*.

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Collaboration between Traditional Health Practitioners and Conventional Health Practitioner: The Malian Experience

By D. Diallo, M. Koumare, A.K. Traore, R. Sanogo and D. Coulibaly

Introduction

At the attainment of independence, Mali opted for the promotion of traditional medicine (TM) with a view to achieving two objectives: factoring traditional health activities into the national health policy, and actualizing the local production of medicines from locally available natural resources.

These promotional activities are coordinated by the Traditional Medicine Department (DMT) of the National Public Health Research Institute of the Ministry of Health in Bamako, Mali. Integrating TM into national health systems requires collaboration between traditional health practitioners (THPs) and conventional health practitioners (CHPs).

Principles underpinning collaboration

In Mali, a THP is defined as “a person recognized by members of his or her community as qualified to practise traditional medicine”. Such people abound in both the rural and urban areas of the country. The principles which underpin collaboration between THPs and CHPs include mutual respect, determination of limits of competence and voluntarism. THPs and CHPs agree to collaborate without receiving remuneration for services rendered.

Mutual confidence

Mutual confidence can only be established after a period of

observation of the use of traditional medicines (TMs) of THPs selected on the basis of results, and the actual practice by THPs of their profession. This promotes an enabling environment for a healthy collaboration as well as for the general investigation of traditional medical practice. Research into the TMs provided by the THPs is a major component of the collaboration between THPs and CHPs. Currently, introductory courses are organized for medical and pharmacy students pending the codification of the training. Just as a THP can refer patients to a CHP, the latter should also refer patients to a THP.

Determination of limits of competence

A THP who wishes to be officially recognized by the Traditional Medicine Department has to be evaluated.

The process of evaluation begins with a letter addressed by the DMT to a conventional health worker in the area where the candidate THP lives, inviting him or her to collaborate with the said THP, and to prepare a report on the collaboration.

Ethno-medical evidence or the THP's perceived “pharmacovigilance” is assessed over a four-month period during which the CHP is expected to follow up patients receiving treatment from the THP. Depending on the diseases treated by the THP, the evaluation should cover a minimum of 30 cases per disease.

In reporting back to the DMT, the health worker expresses an opinion on the candidate THP's professionalism, indicating the number of cases followed up, the kind of results obtained (whether good or poor), and cases for which no results were obtained.

Phytochemical analysis of recipes of THPs

The DMT conducts phytochemical analyses of the recipes supplied by candidate THPs. Results of the analyses remains the property of the THP who may use them to constitute a dossier in order to obtain a patent. So far, one THP in Mali has a patent for the formulation of medicines.

Seminars, workshops for THPs and CHPs

Several seminars and workshops have been organized for THPs and CHPs by the DMT on malaria, diabetes, asthma and HIV/AIDS. These workshops and seminars have facilitated collaborative exchanges on the classification of various diseases and the methods of managing them.

Associations of THPs

There are 51 associations of THPs in Mali. These associations have established a national bureau known as the Malian Federation of Associations of Traditional Health Practitioners and Herbalists (FEMATH). The Federation collaborates with the Traditional Medicine Department and organizes an International African Traditional

Medicine Week (SIMTA) once a year. This event, organized from 9 to 16 March, has since become a forum for the exchange of ideas and experiences among THPs in the West African sub-region.

The associations of THPs also organize orientation sessions for the training of their members by CHPs. For example, one association known as " Kènèya-yiriwaton ", in collaboration with the *Société Malienne de Phytothérapie*, (Malian Association of Phytotherapy), has organized training sessions on: the pharmaceutical preparations of THPs, paediatrics, cardiovascular diseases, and conditions associated with the inflammation of the lining of the stomach and intestines.

Malian THPs have expressed satisfaction with these training sessions, which have enabled them to

improve the preparation and packaging of their medicines and improved their knowledge of certain diseases.

Conclusion

Collaboration between THPs and CHPs is necessary for improvement of the health status of the general population. This is illustrated by the situation in Bandiagara, about 300 kilometers south of Timbuktu, where collaboration between THPs and CHPs has resulted in the decline of the rate of mortality caused by serious malaria, from 5% in 1997 to 2% in 1998. This kind of collaboration should serve to guarantee the relevance and impact of THPs on primary health care, as well as the safety of the patient.

In 1994 the Malian government promulgated a decree which spelt out

the conditions and regulations for establishing and running private traditional care consulting-rooms, herbalists' shops, and factories for producing improved traditional medicines.

In conclusion; we propose that it is desirable for countries in the African Region to recognize THPs and develop programmes for collaboration between them and CHPs. Such collaboration should make it possible for the work of THPs to be taken into account in the compilation of health statistics in the Region.

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Regulation of Traditional Medicine in the WHO African Region

The policy context of regulation

In considering the role of regulating traditional medicine (TM), three areas need to be addressed: the regulation of traditional health practitioners (THPs), the regulation of the practice of TM, and the regulation of TMs. However, before these three aspects are addressed, it would be useful to outline the policy context of regulation.

In recognition of the value of the world's resources of medicinal plants and the need for their rational use, the World Health Assembly has adopted resolutions relating to the cultivation and conservation of medicinal plants; quality control of medicines derived from traditional herbal medicines; an inventory and an assessment of medicinal plants; regulation and control of medicinal plant products, and their inclusion in the national formulary of

pharmacopoeia of remedies that are safe, effective and of good quality.

Similarly, the WHO Regional Committee for Africa, WHO's Governing Body in the Region, adopted a resolution in 2000 requesting that Member States be provided with technical advice on, among others: legislation for the practice of TM; the documentation of practices and medicines of proven safety, efficacy and quality, and the exchange and utilization of this information by countries. That resolution urged Member States to translate the regional strategy on TM into realistic national policies on TM, and to put in place appropriate legislations and plans for specific interventions at national and local levels.

Regulation of THPs

A THP is defined as a person recognized by the community in which he or she

lives as competent to carry out diagnoses with local socio-cultural foundations, and contribute to the physical, mental, social, and spiritual well being of the members of the locality concerned. THPs can have various specializations such as traditional therapy, traditional midwifery, herbalism, psychiatry, paediatrics and spiritualism. Despite the contribution of THPs to health care delivery, TM has not been integrated into national health systems for several reasons. Among these are denial of the contribution of TM to the well being of people, and the lack of political recognition of THPs by policy makers and conventional health practitioners (CHPs).

There is therefore the need to empower THPs with proper training in Primary Health Care (PHC) matters, and through the introduction of legal and regulatory tools that can assist them to establish functional associations of THPs and

(continued on p. 40...)

Evaluation of Plant Medicines used in Ghana for the Management of Diabetes Mellitus

Introduction

Diabetes mellitus is a disease characterised by higher than normal blood glucose level. It occurs when the body is unable to control levels of blood glucose, derived primarily from sugars and starches (carbohydrates) ingested as food. Blood glucose level is controlled by insulin, a hormone produced by beta cells found in the islet cells of the pancreas. Insulin is required for removing glucose from the bloodstream into cells for energy production. Therefore, without insulin, cells are deprived of glucose and energy. The body attempts to correct this apparent glucose lack by converting body proteins into glucose (gluconeogenesis), thus further aggravating the diabetic state.

There are two major types of diabetes mellitus: **Type 1** diabetes where there is damage to the insulin-producing cells resulting in minimal or no insulin production, and **Type 2** diabetes where there is an apparent insulin lack. In addition to genetic factors, inactivity or obesity tends to predispose those susceptible to the Type 2 form of diabetes mellitus. Elevation in activated oxygen species (oxidative stress) levels also promotes diabetes and its complications through tissue damage (lipid peroxidation). Type 1 diabetes is primarily managed with daily insulin injections. The type 2 form is controlled through dietary manipulations and exercise or administration of oral hypoglycaemic agents. Inadequate

control of diabetes causes excess blood glucose to bind to proteins, cross-linking them to produce vascular damage and hence, complications involving the retina, nerves, kidneys and heart.

Herbal medicines are used widely to manage several diseases, including diabetes mellitus. In Ghana, the incidence of diabetes is increasing and becoming a public health problem. Many Ghanaian diabetics use plant medicines that are anecdotally claimed to be safe and effective in controlling and sometimes "curing" the disease. There are also published reports of herbal preparations with antidiabetes properties. Researchers at the Noguchi Memorial Institute for Medical Research have been investigating some anti-diabetic plant medicines to determine their effects on blood glucose and relevant biochemical parameters.

Method

We prepare herbal medicines for investigations as instructed by traditional healers, but we standardize the methods of preparation by documenting plant parts, weight and duration of extraction e.g. boiling or infusion. We freeze-dry extracts for either convenient storage or dose ranging studies. We also investigate the effects of the plant medicines in normal animals, type 1 (streptozotocin-induced) or type 2 (genetically obese) diabetic mice. We then perform oral glucose

By



Prof. David Ofori Adjei



Prof. Alexander Nyarko

tolerance test (OGTT) and measure fasting blood glucose (FBG), lipids, insulin release by isolated islet cells or circulating insulin levels, diaphragm uptake of glucose, glycogen deposition or glucose formation by liver slices (gluconeogenesis) and also oxidant levels and lipid peroxidation in control (water-treated group) or extract-treated animals (test group). We also assess the safety of these medicines and their potential to interact with orthodox drugs.

Results

Results from our human and animal studies show that some of the plant medicines significantly decrease blood glucose (about 50%) as illustrated in experiments performed with (test group; solid line) and without (control group; broken line) administration of plant medicines (Figure 1).

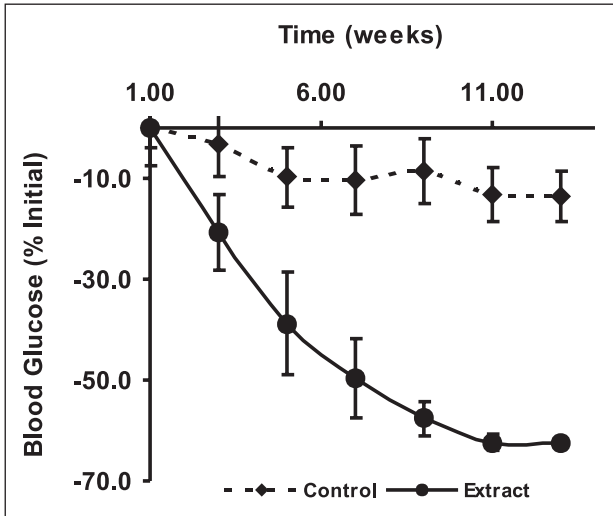


Figure 1: Lowering of fasting blood glucose (FBG) by an anti-diabetic plant medicine

Our studies also show (Figure 2) that the plant medicines, while decreasing fasting blood glucose levels (solid line), increase levels of circulating insulin (broken lines) as expected. We have subsequently showed with isolated rat pancreatic islet cells that some of the antidiabetic plant medicines promote insulin release (not shown), suggesting that these plant medicines will be more useful in managing **Type 2** diabetes. Indeed we have confirmed this in streptozotocin-induced diabetes that those herbal medicines do not lower glucose levels in **Type 1** diabetes mellitus.

Figure 2: Relationship of blood glucose and insulin in response to administration of anti-diabetic plant medicine

One of the anti-diabetic plant medicines also increases uptake of glucose by tissues as shown by diaphragm glucose uptake in Table 1. Most significantly, this plant medicine inhibits conversion of body proteins to glucose (gluconeogenesis) (Table 1).

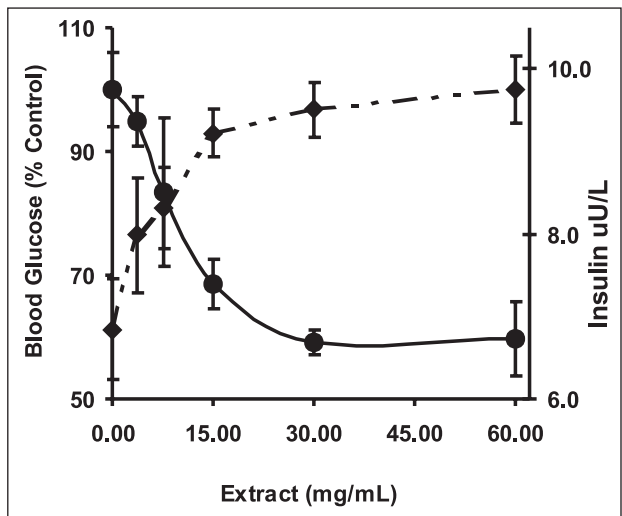
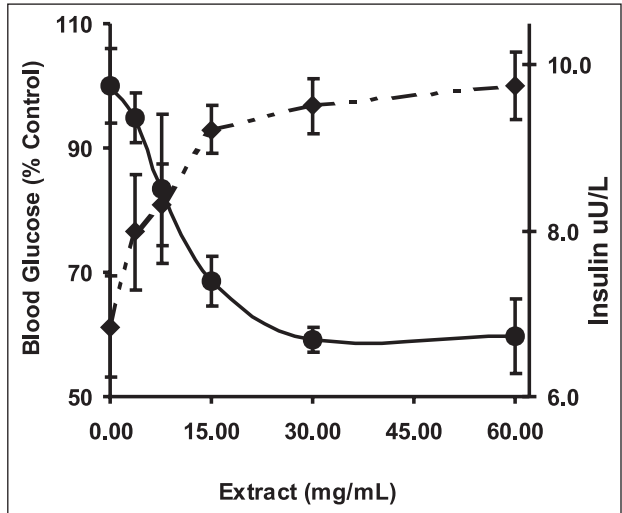
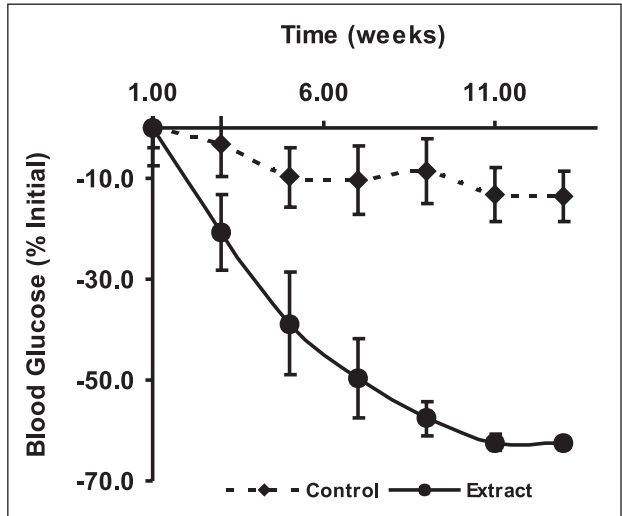


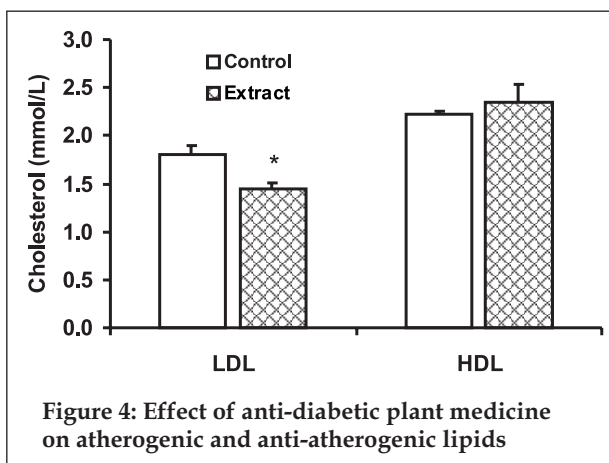
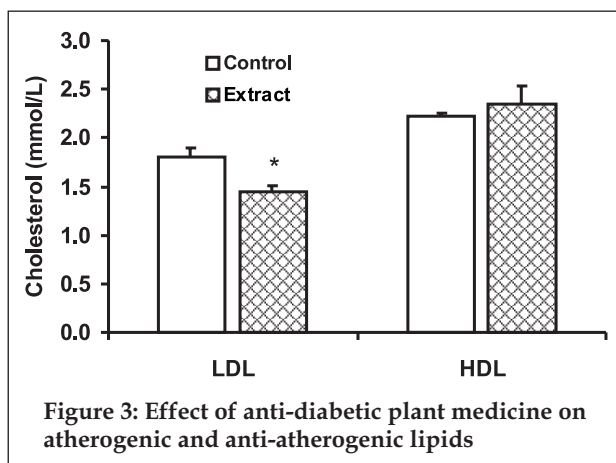
Table 1: Effects of anti-diabetic plant medicine on diaphragm glucose uptake, glycogen deposition and gluconeogenesis.

	Control	Extract
Diaphragm glucose uptake, (mmol/g tissue)	9.40 ± 1.23	15.26 ± 1.29*
Glycogen deposition, (nmol/g liver)	0.32 ± 0.03	0.45 ± 0.04*
Gluconeogenesis, (mmol/g liver)	16.14 ± 2.95	7.37 ± 1.62*

Figure 3 shows that some of the antidiabetic plant medicines decrease levels of low density lipoprotein (LDL). We have shown some of the medicines to contain polyphenolic substances that scavenge activated oxygen species (ROS) and inhibit tissue lipid peroxidation. Oxidation

of LDL promotes cardiovascular complications in diabetes. Our studies, using formation of thiobarbituric acid reactive substances (TBARS) as a measure of LDL oxidation, show that TBARS is significantly lower in incubations with plant medicine (16.91 ± 2.25

nmol/mg protein) than those without (43.06 ± 2.55 nmol/mg protein). These plant medicines may, therefore, protect against cardiovascular complications often seen in poorly controlled diabetics.



Acute and subchronic studies on one of the plant medicines did not reveal overt toxic effects. There was no indication of modulation of important drug metabolising enzymes, suggesting that this plant medicine will not affect the metabolism and hence elimination of concomitantly administered drugs.

Future prospects

Our studies suggest that some anti-diabetic plant medicines could be used to safely manage diabetes mellitus. Future research activities aim at identifying many of these medicines for their effects to be evaluated on **Types 1 and 2** diabetes. Diabetes mellitus is a chronic disease; therefore, the plant medicines used to manage it need to undergo acute and subchronic toxicity evaluation and their effects also studied on developing fetuses. Finally, there is need for further evaluation in humans with respect to selection of appropriate dose-range, safety and efficacy and drug interactions. Those with least or no risk-to-benefit profile can be developed for use in diabetes management.

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Regulation of Traditional Medicine

(...continued from p. 36)

Councils. These would lead to the establishment of appropriate legal frameworks. Membership of national associations of THPs should be based on accreditation, registration and licensing of qualified practitioners. Only 22 of the 30 countries that participated in a recent survey in the Region indicated that they had established associations of THPs. There is thus a need for countries to establish national associations which could form federations. WHO and other development partners could support this process. Indeed, WHO has already developed a *Model Code of Ethics for THPs in the African Region including Disciplinary Procedure* in order to ensure conduct in an honourable manner of THPs with their patients, the public and with other practitioners. The code could be adapted by Member States to their own specific situations.

Training of THPs will reduce charlatans, ensure good communication between THPs and conventional health practitioners (CHPs) on the one hand, and between them and their patients on the other. It will also enable THPs to provide proper information and guidance to consumers and the general public on treatment with TMs. To facilitate this, WHO has developed a *Manual on PHC for THPs and a Training Manual on TM for CHPs and Health Science Students*.

Regulation of the practice of TM

For the proper use of TM there is need for regulating THPs through a legal or regulatory framework for the practice of TM. The framework should include a

code of practice and minimum requirements for the practice of TM. Only registered THPs should be granted licenses for practice. Seventeen of the 30 countries that participated in the survey earlier referred to said that they had put in place a legal framework for the practice of TM, necessitating the need for more countries to develop such frameworks. WHO has developed a *Model Legal Framework for the practice of TM: A Bill for THPs in the WHO African Region and Guidelines for Minimum Standards for TM practice and Code of Practice*. These are separate chapters of the Code of Ethics for THPs mentioned above. Also developed by WHO is *Tool for Documenting African Traditional Medicines*, which countries may also adapt to suit their needs.

Regulation of traditional or herbal medicines

Generally, the use of herbal medicines in the Region is based on oral tradition within a family or a community. Most herbal medicines which are claimed to provide "effective cures" for various diseases lack scientific evidence for safety, efficacy or quality. Yet, they are openly sold in markets, stores, homes, and even in pharmacies as over-the-counter medicines and dietary supplements, with little -- if any -- advice offered on their use. Consumers may often be unaware of how and when herbal medicines may be safely taken, or of their potential side effects.

Most countries in the Region have not established safety-monitoring mechanisms for imported and locally produced TMs, as demonstrated by a survey conducted by WHO in 2002

which showed that only eight out of the 34 countries covered had regulations on TMs. This would seem to reflect the inadequacy of facilities for researchers in the Region for assessing the quality, safety and efficacy of TMs whose composition is usually complex.

Some major challenges facing the development and use of TMs in the Region therefore include inadequate data on scientific and clinical validation of many TMs; poor modes of prescription and marketing of those TMs for which evidence of safety, efficacy and quality exist, and lack of mechanisms for the registration of TMs. There is an absence of, or weak, intellectual property rights regimes on traditional medical knowledge (TMK) as well as deficient biodiversity laws on medicinal plants. Like conventional medicines, the criteria for evaluating TMs are quality, safety and efficacy.

In order to promote the registration and marketing of safe, effective and good quality TMs within the WHO African Region, the Organization has developed *Guidelines for Registration of Traditional Medicines in the WHO African Region*. The guidelines contain a classification of TMs, and minimum regulatory requirements for their registration vis-à-vis determination of quality, safety and efficacy by national drug regulatory authorities. Similar guidelines, protocols or regulatory frameworks have also been developed by WHO for assessing the safety, efficacy and quality of TMs, and for accelerating the protection of TMK and intellectual property rights.

* Contributed by the Traditional Medicine Programme at ARFO

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