EQUAL treatment

Magazine for the Treatment Action Campaign December 2009

Making sense of science

Why people believe in quack remedies

Traditional healers and HIV

What you need to know about cervical cancer

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Cover photo: Lee-Ann van Wyk from Bioanalytical Research Corporation (BARC) lab holds up a test tube of blood that has been separated in a centerfuge. Spinning blood in a centerfuge separates plasma, white blood cells and red blood cells in layers from lightest to heaviest. Photo by Samantha Reinders

Special thanks to Dr Ben Goldacre, Professor Lynette Denny, Dr Justine Davies, Dr Linda-Gail Bekker, Nathan Geffen, Sense About Science, Christie Heiberg and the Desmond Tutu HIV Foundation Clinical Trials Unit, and Yvette Kramer and the BARC lab, Cape Town.

Distribution: Kagiso Seleka

Layout: Designs4development, www.d4d.co.za

Printing: CTP Book Printers

TAC is committed to providing people with HIV, their families and caregivers accurate information about life-saving medicines and treatment. TAC and its leaders are independent of the pharmaceutical industry as well as of the natural and alternative medicine industries and have no financial interests with them.

Equal Treatment is published by the Treatment Action Campaign.

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CONTENTS

Issue 31 - December 2009

Editorial

A quack is someone who promotes medicines that have not been tested properly. It can be a dangerous practice. Quacks make money from people's fears and illnesses. At their worst they can deceive you to death. Across South Africa there are thousands of quacks selling untested remedies for AIDS and other diseases. They carry on doing this even though they often act illegally.

The Treatment Action Campaign (TAC) has taken action against many quacks. For example:

- We obtained a court order to stop Matthias Rath from promoting his multivitamins as a treatment for AIDS. Rath claimed that antiretrovirals (ARVs) are toxic and that multivitamins alone can treat AIDS.
- We also got a court order against the former Minister of Health, Manto Tshabalala-Msimang. She was told by the court to investigate Rath's experiments on people with HIV. Under Tshabalala-Msimang the government supported many quacks. Thankfully, this sad period in our history seems to have come to an end, but the damage that she and other government officials did will last a long time.
- We have lodged many successful complaints against quacks with the Advertising Standards Authority (ASA). Recently the ASA ruled against the adverts of Zeblon Gwala, who sells an untested AIDS remedy called uBhejane to desperate people for about R300 per month. The ASA regulates advertisements. If adverts make false claims, for example about AIDS, the ASA has some power to stop such adverts.

People with HIV are often scared of taking ARVs because they do not know enough about them or they have heard exaggerated stories of their side effects. This creates opportunities for quacks to sell them false hope. Many people have died unnecessarily because instead of starting ARVs they have wasted time taking quack remedies.

The actual quack remedies themselves are often harmless. What is dangerous is that precious time is lost trying such medicines instead of using scientifically proven ones like ARVs. However, sometimes the ingredients in quack medicines are dangerous. Indeed, many people are poisoned every year by untested medicines. Also, some alternative medicines, like garlic in very high doses or St John's Wort, can interact badly with ARVs.

The public health system is only supposed to give people medicines that have been properly tested and then approved by the Medicines Control Council. But one of the main reasons why people with HIV try quack remedies is because they are often treated badly by the public health system. Long queues, medicine shortages and angry overworked nurses make people not want to use their local clinic. Instead, they turn to the false hope offered by a friendly quack. A recent study showed exactly this: patients who have a bad experience at their clinic are more likely to seek the help of quacks.

This is why if we want to fight quackery, the best way to do it is to build a public health system that is much more effective and is less likely to trample on people's dignity.

Nathan Geffen
TAC Treasurer

Sources: Goudge, J. et al., Centre for Health Policy, School of Public Health, University of Witwatersrand "Affordability, availability and acceptability barriers to health care for the chronically ill: longitudinal case studies from South Africa" *BMC Health Services Research* (2009) http://www.ncbi.nim.nih.gov/pubmed/19426533.

quackery is all around us

By Marcus Low

Quackery and pseudo-science come in many forms and are not limited to any particular country or culture. They are not Western or African, but universal.

The sister of Nolunthando Magwebu, a person living with HIV in Khayelitsha who died in 2005 after experiencing side effects from taking treatment offered by the Dr. Rath Health Foundation, headed by notorious quack Matthias Rath. Here her sister reflects on Magwebu's death several years later. Magwebu was told that the Foundation's pills would 'make the HIV much better.' Nolunthando's husband, Zodani, told Health-E News Service that a week after starting the pills she had negative side effects and died several weeks later. Photo and story Anso Thom/ Health-E News Service.

The false AIDS cure uBhejane that you get in Kwazulu-Natal is unproven, just as detox foot pads or homeopathic medicines that you can buy in London or New York are unproven. What all these remedies have in common is that people claim that they can do things that they cannot. UBhejane or Revivo tea cannot cure AIDS, and detox foot pads have not been proven to help your body to detoxify. Your body does that very well by itself.

Just as quackery is not Western or African, scientific testing is not Western or African, but simply the best way we know to find out what works and what does not work. People in the West use it, just as people in Africa are using it. We can use scientific methods to test whether Revivo tea works, just as we can use them to test the latest antiretrovirals (ARVs).

Scientific testing can save lives. It is through testing that we first learned that ARVs save lives – and since then they have saved many lives. Scientific testing is also helping to develop ARVs with fewer side effects.

Scientific research does not only happen across the waters in Europe or America. More and more research is being conducted in Africa, by Africans. The knowledge we gain from these tests empowers us to make informed decisions about our health.

Quacks do not like to have their products subjected to scientific testing, and often use the excuse that scientific testing is not appropriate for the remedies they sell. This is probably because they are afraid that testing may show that these remedies do not work. Some quacks keep on believing in their products even after testing shows that they don't work.

By contrast, science progresses by researchers testing products and being open to whatever the findings are. Learning that a specific treatment is not effective is just as valuable to researchers as learning about something that does work. This is why findings are published openly in medical journals. Other researchers can then repeat the tests to see if the product really works.

Pseudo-science can be deadly

Under former President Thabo Mbeki and Minister of Health Manto Tshabalala-Msimang the South African government was very slow to introduce ARVs in the public health system. Instead, they promoted false cures like the quack remedy Virodene and supported charlatans like Matthias Rath. Researchers estimate that this delay in making ARVs available within the public sector led to over 300,000 preventable deaths.

Every quack who tells people not to take ARVs or who gives or sells people untested treatments is putting lives at risk. ARVs are the only treatment proven to fight HIV. It is important that HIV-positive people take their medicines as prescribed by their doctors or health workers.

Zodani Magwebu with his two children. The Magwebu family lost their wife and mother, Nolunthando, in 2005 after she began taking pills from the Rath Foundation which would supposedly 'help' her HIV. "Since my wife moved on, things have been bad here. It is increasingly difficult for me to look after my children," he says. Zodani said that despite the charges brought against Rath by TAC, no one has ever contacted him about his wife's death. "Rath must be arrested as he carries responsibility for the death of my wife and many other people… If government knew what was happening and they did nothing, they need to be held accountable." Photo and story by Anso Thom/Health-E News Service.

Drug interactions

Some medicines, quack remedies and vitamin supplements can interact with your antiretrovirals (ARVs) and make them less effective. This is why you must only take these remedies if your doctor or health worker says it is ok.

Many quacks do not know this and encourage people to take their remedies alongside ARVs or instead of ARVs. This is very irresponsible and can put people's health at risk. You should only take the medicines advised by your doctor or health worker.

Why people believe in quack remedies

By Marcus Low

It can be very hard to come to terms with having HIV, cancer, or diabetes. It is understandable that we sometimes hope for a miracle cure. When someone promises that his or her concoction can heal us, it is very tempting to believe them.

Quacks know this, and that is why they often make such promises. They know that we are feeling desperate and that we might be willing to try anything. They then give us untested treatments and charge us high prices for them. Not only are they taking our money, they are also selling us false hope.

Why we actually feel better

Many illnesses, like the common cold, get better without us having to take any medicines. Our bodies can fight these diseases by themselves. Nevertheless, when a cold is at its worst, we might go to the doctor or the sangoma, or perhaps take some vitamins and painkillers. When we then get better, it is easy for us to think that our recovery was because of the vitamin pills or the painkillers. We would be wrong though, since the cold was going to get better anyway.

Similarly, our health never stays perfectly stable. With most chronic diseases our health will still fluctuate over time – some days we will feel good and other days not so good. When something happens before we feel better, we don't necessarily

feel better because of that thing. The fact that a cold goes away the day after you had very salty pap for breakfast does not mean that salty pap cures colds.

Many quacks will tell you that your cold went away because of the herbs or vitamins they gave you, while in fact your cold would have got better anyway. Thinking that you feel better because of the quack remedy makes as much sense as feeling better because of salty pap. That is why we can say that quacks often take credit for what nature would have done anyway.

Claiming that quack remedies can cure colds is not all that harmful, but when quacks say that they can cure more serious diseases, it becomes very dangerous. HIV, cancer, or diabetes don't just get better by themselves. For such diseases we have to be certain that the treatments actually work, and the only way to do this is to put them through proper scientific testing.

Through testing, we can find out if it is actually the salty pap or the tea that made the cold go away, or whether our body would have fought it off anyway.

The placebo effect

When scientists test a new medicine, they often give half of the people in the study the new medicine and the other half a sugar pill that looks just like the new medicine. This sugar pill is called a placebo. (Placebos can also be saltwater injections or other sham treatments.) In these studies the participants do not know if they are getting the real pill or the placebo. The scientists can then see if the people getting the new pill are doing better than those getting the placebo. (See pages 14–17 for more on clinical trials.)

Scientists have noticed that sometimes people say they feel a bit better or worse even if they were only given the placebo. This is known as the placebo effect. The placebo effect happens when you experience a small effect because you are expecting a treatment to work – and not because of the treatment itself. It is another reason why people often believe in quack remedies.

Interestingly, the placebo effect seems to be linked to cultural expectations. It has been shown, for example, that green sugar pills are a more effective treatment for anxiety than red sugar pills. This is not because of anything that the green pills contain, but because of cultural meanings associated with the colour green.

Similarly, studies have found that saltwater injections can be a more effective placebo treatment than white sugar pills – not because there is anything particularly useful about saltwater injections, but because the 'ceremony' of performing an injection is a far more invasive, authoritative and dramatic intervention. In the same way, some quacks or traditional healers use elaborate ceremonies to convince us that their treatment will work.

Many quack treatments for HIV make use of the placebo effect. The person providing the remedy keeps telling you that the treatment will work, until you yourself are convinced of it. But whereas the placebo effect can make you feel a bit better or worse for a while, it cannot cure any diseases. That is why uBhejane or homeopathy will never be able to cure HIV or treat it as well as antiretrovirals (ARVs). ARVs do not depend on the placebo effect because they work physically on your body, not on your beliefs.

Some people convince themselves that a quack treatment is working. They may even feel a little better for a while. This is even more likely if there is a friendly quack encouraging them and telling them that they should feel better. For this reason we sometimes get people testifying that this or that quack remedy has helped them so much. Sadly, though, if these people stop taking their ARVs, their CD4 counts drop and they soon become very sick.

Feeling a bit better is not a cure

If an HIV-positive person's thrush or diarrhoea goes away and that person starts to feel better, quacks may claim that they have cured the person of HIV. Any such claim would be untrue. The HIV will still be in the person's body and will make that person sick again if he or she does not take ARVs.

It is important to keep taking your ARVs or TB medicines as prescribed by the doctor or health worker. If you do not take your medicines as prescribed, you might get sicker than you were in the first place.

Parts of this article are reworked from Ben Goldacre's book *Bad Science*. Goldacre also reviewed the article.

Interesting sources: Ernst, E. and A.R. White "Acupuncture for back pain: a meta-analysis of randomised controlled trials" *Archives of International Medicine* 158 (1998); Kaptchuk T.J. et al. "Sham device v inert pill: randomised controlled trial of two placebo treatments" *British Medical Journal* (2006).

Immediate results!!!

EIGHT WAYS TO SPOT A QUACK

1. PERSONALITY CULT

Quacks often put their own personalities at the centre of their businesses. Some name their businesses after themselves. They also like to say that they have been shown the truth, while other people do not know what they are doing.

2. DISLIKE OF ARVS

Dr Matthias Rath

Quacks often speak out against antiretrovirals (ARVs). They seldom understand how side effects work or that you can change your ARV regimen if you experience bad side effects. They also do not recognise that ARVs are the only proven treatment for HIV and that without them, people will die much sooner.

3.REMEDIES NOT REALLY TESTED

Quacks often say that their quack remedies have been tested, when in fact they have not been tested. Thus, when they say that it works, they do not really know that it does, but only hope so or convince themselves that it works. When you ask them, they cannot refer you to studies published in reputable journals showing that their products work.

4. SECRETIVE BEHAVIOUR

Quacks are often secretive. Many do not want to say what ingredients are in their remedies. This is because they know that very few people would buy them if they knew what these remedies contained. Quacks do not want to have their remedies analysed in a lab or scientifically tested.

5. UNJUSTIFIABLE PRICES

Quacks often charge high prices for their products even though they are only selling water or common herbs. This is because many are simply interested in getting rich. A minority of quacks, however, do not make a lot of money. Usually these people actually believe that the remedy they are selling works, while it doesn't really. Many of these individuals do not like to consider the possibility that they may be wrong.

6. TOO GOOD TO BE TRUE

Many quacks claim that they can cure a wide range of diseases – from HIV and diabetes, to arthritis and erectile dysfunction. Some even claim to be able to help you with legal or marriage problems. If it sounds too good to be true, it probably is. Quacks know that we sometimes feel desperate, and they exploit this for their own financial gain.

Suggesting HIV can be cured

7. PRETENDING TO KNOW

Quacks often say that feeling worse is a sign that you are getting better. This is a way for them to cover themselves: if you feel better, they claim the credit for it, and if you feel worse, they say that it was to be expected. This way they can claim to know what is happening with your health even if they have no idea.

QUACK!
QUACK!
QUACK!

8. MAKING THEMSELVES THE HEROES

Quacks often claim that they are being suppressed by mainstream medicine or powerful interests who want to keep their product off the market. This does not make sense. If the quack remedy actually worked, companies would be lining up to help sell it and make money.

REMEDIES THAT CURE ALL PROBLEMS

don't blame makhuma

Some traditional healers deny the existence of HIV. These quack healers are acting irresponsibly and putting lives in unnecessary danger. Adam Malapa *visited one in the town of Tzaneen.*

Mapungubwe is a traditional healer who practices alongside a small river in Tzaneen. He says he can cure HIV because according to him, HIV and AIDS do not exist. "AIDS is Makhuma", he said, emphasising that AIDS is Makhuma in an African way. "You get HIV and AIDS because you have not been following the ancestral way of doing things. This is just a punishment from the ancestors so that you get back to your ancestral way." (Usually, Makhuma means not having been cleansed after someone in the family has died.)

"When a person comes [to see me] for the first time, I take out my snuff and communicate with my ancestors. I can also speak to my snake, which is found inside this water." Mapungubwe said that his ancestors tell him what kind of treatment he must give to the patient. According to him, the person will start showing changes within three days of treatment. If the person has been ill for three months or more it might take a month for him or her to be healed.

Patients get the quack remedy in 1-litre bottles. They are told to drink one cup in the morning, half a cup in the afternoon and a full cup in the evening. These remedies include African potato, aloe roots and leaves mixture, some powdered mixture and ashes. Mapungubwe says that the medication will clean a person's blood and they will get back to their normal state.

Mapungubwe, a traditional healer who practices in Tzaneen, claims that he can cure HIV because he believes that HIV and AIDS do not exist. Instead he believes that these illnesses are Makhuma, or occur because a person has not been following the ancestral way. While traditional healers are an important part of South African society, such claims are false and the "cures" that Mapungubwe and others try to sell will not work as a treatment for HIV. Photo by Adam Malapa.

We know that AIDS exists and that it is caused by HIV. This has been confirmed in countless laboratory studies and is as true in Africa as it is in Europe or Asia.

Whereas traditional healers can provide social and psychological support, they cannot cure or treat HIV and it is irresponsible for any of them to claim that they can. The only effective treatment is antiretrovirals (ARVs), and even ARVs cannot cure HIV.

Why traditional medicines must be tested

By Poppy Riddle

It does not matter whether medicines are Western or African. It matters whether they are tested or untested.

Photo by Samantha Reinders.

Many traditional medicines have been scientifically tested. Some have been shown to help cure diseases or treat symptoms. Others have been found to be dangerous to humans. Some traditional medicines have been shown to be harmless to people, but useless for treating illnesses. This is why traditional medicines must be tested, just like any other medicines. Testing allows us to ensure that the drugs we take when we are sick will actually help us.

A success story

The malaria medicine **artemisinin** is an excellent example of an effective treatment that started out as a traditional remedy. Today it is widely used to treat Plasmodium falciparum malaria, the most common type of malaria in the world. Artemisinin is an active compound (substance) that can be found in certain species of the plant ***Artemisia annua*** (annual wormwood). For more than a thousand years, the *Artemisia* plant has been used by Chinese traditional healers to treat many illnesses, including malaria.

In the 1960s, Chinese scientists tested nearly 200 traditional Chinese medicines, all of which had been used by traditional herbalists to treat malaria. *Artemisia* was the only one that was found to be effective. It was shown to clear malaria parasites from the body faster than any drug had ever done. Nevertheless, scientists found that the human body couldn't absorb artemisinin very easily, reducing its effectiveness. So doctors conducted more tests. They developed forms of artemisinin that were easier for the body to absorb. But the problem with these forms was that after one to two hours in the body their effectiveness decreased dramatically. So scientists carried out further tests and found that this problem could be countered by giving artemisinin together with another, long-lasting anti-malarial drug.

This example shows that traditional medicines can be very valuable in the fight against disease. However, the history of artemisinin also shows the importance of testing medicines – including traditional medicines.

Of the 200 traditional remedies for malaria that Chinese scientists tested, only one was effective in treating the disease. Furthermore, this drug had to be modified and used in combination with other drugs in order to make it truly useful as a cure for malaria. Scientists and doctors could not have known this about artemisinin without proper scientific testing of the drug. Without these tests, the world would have been deprived of one of the best anti-malarial drugs that we have today.

Chinese Traditional Medicine Shop

While plants and herbs have been used as remedies for centuries, it is essential that all plants and other alternative remedies and treatments are scientifically tested for both safety and effectiveness. Photo by Tony Wills.

Between a poison and a cure

The testing of medicines is also essential to determine correct dosages. With any medicine, if a dose is too high, the substance may harm or kill you; if too low, the medicine may not work.

The substance digoxin, from the foxglove plant, is a good example of this. Hundreds of years ago, traditional doctors used foxgloves to treat heart disease. It wasn't until many years later that scientists discovered that the useful substance in this plant was digoxin. However, they found that whilst digoxin treats heart conditions in small doses, it can kill people if the dose is too high.

When using a plant it is difficult to get the dose right (in this case because some parts of the plant contain more digoxin than others). So, scientists carried out tests which enabled them to purify digoxin from the foxglove. They were then able to work out exactly the right amount needed to treat people without killing them.

Today, doctors administer digoxin to patients in tablet form, to ensure that the dosage is just right. Had scientists not tested the foxglove, doctors would still be unsure about how to treat certain heart conditions safely.

When we are sick, we want to get better. We want a medicine that we are sure will work. This is why testing medicines, including traditional medicines, is so important. The problem with some traditional medicines is that they have never been scientifically tested, and so we aren't sure whether they work. Why take something you don't know will work if you have another medicine that you know will make you better?

Whereas we know, thanks to scientific testing, that artemisinin is a safe and effective treatment, we cannot say the same about many of the untested remedies being sold in our communities.

Untested medicines are dangerous

The false AIDS cure uBhejane, a herbal remedy developed by Zeblon Gwala, is a good example of just such an untested remedy. Gwala says that uBhejane is a cure for HIV/AIDS. He advises his patients to stop taking antiretrovirals (ARVs), medicines which have been scientifically tested and shown to treat HIV, and instead use his treatment, which he sells for roughly R340 a bottle. It is impossible to test uBhejane properly because Gwala refuses to say what its ingredients are. All scientists could find out was that the mixture was not toxic to cells grown in test tubes. The Treatment Action Campaign (TAC) made a successful complaint against Gwala to the Advertising Standards Authority of South Africa, for advertising a fake AIDS cure.

For uBhejane to be recognised as a treatment for HIV/AIDS, it would need to be compared to existing treatments (ARVs) in many hundreds of patients. This has not been done. Therefore we have no reason to believe that uBhejane is anything but a quack remedy. For Gwala to advise people to stop taking ARVs is extremely irresponsible and could lead to unnecessary deaths. If he really wants to cure people, Gwala should encourage testing of uBhejane and be open about its ingredients.

Some people say that medical doctors use Western drugs, whereas traditional doctors use African remedies, which they say are more trustworthy. However, the examples above show that medical drugs are not Western or non-traditional (Artemisinin was discovered by the Chinese, foxglove/digoxin was used by traditional herbalists).

Many so-called Western drugs use natural products which have been used in the past by traditional doctors. Some of the earliest protease inhibitors (used in ARV drug combinations) were derived from the soy protein found in soya beans. However, these natural products are only used in scientifically developed medicines if they have first been tested. If you are given a drug by a medical doctor, she or he will prescribe it for you because scientific tests, carried out on hundreds of people, will have shown that this is the best known way to treat your illness.

Reviewed by Dr Justine Davies, Sense About Science and University of Dundee.

Many popular alternative treatments advertise that they have healing powers because they are derived from or include plants in their ingredients. Sometimes plants are advertised on their own as having healing properties. While historic use suggests that some plants do have healing effects, it is important that any such treatments undergo thorough scientific testing – just as other alternative remedies, traditional healing methods, or indeed any medicines must be tested. Without testing, we cannot be sure that plant treatments are effective or safe for human consumption. Photo courtesy of www.mediaclubsouthafrica.com.

Sutherlandia

Common names: Insiswa, Unwele, Mukakana, Phetola, Lerumo-lamadi, cancer bush, kankerbos, kankerbossie.

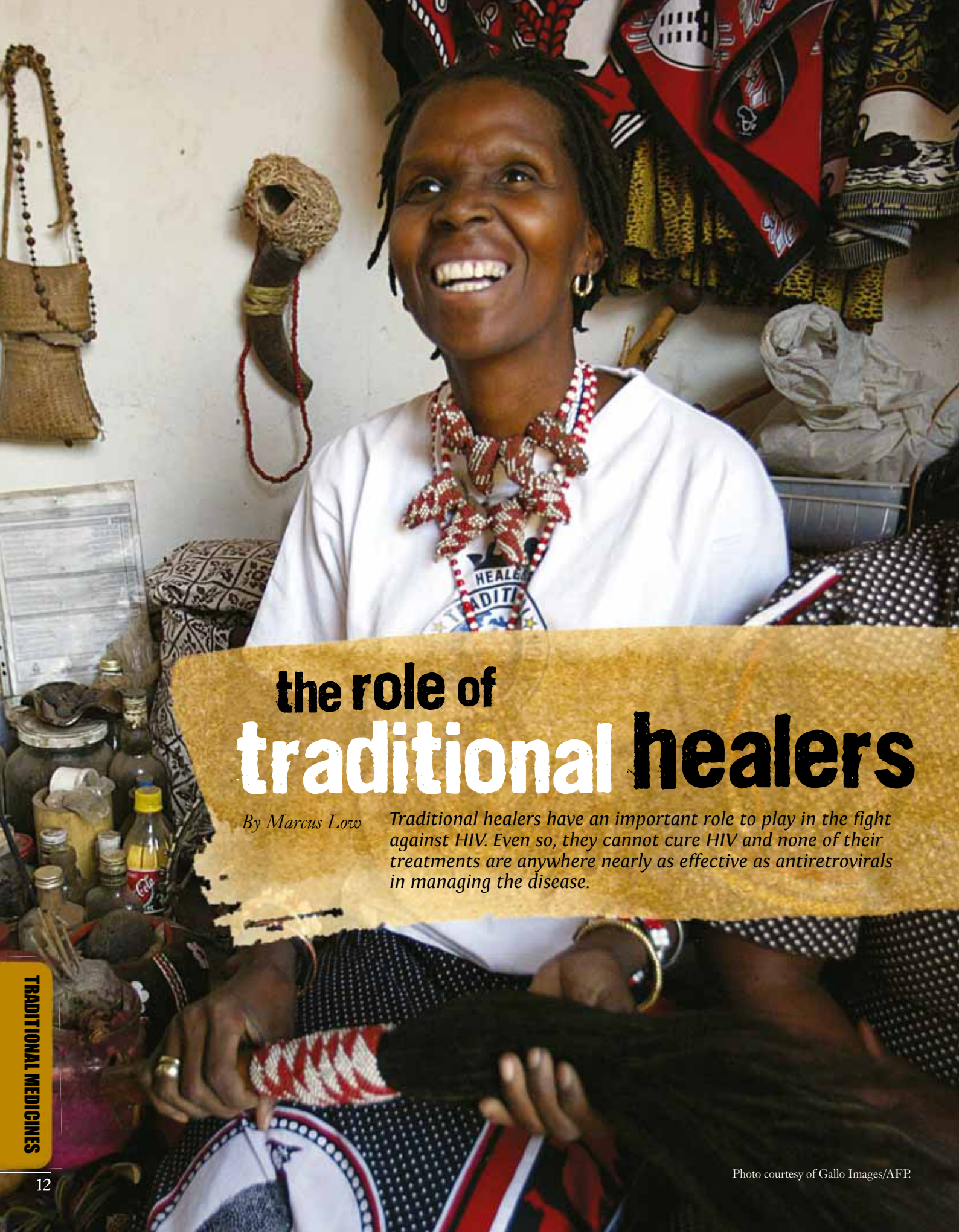
Sutherlandia has been used by some traditional healers to treat many diseases including cancer, tuberculosis, diabetes, influenza, arthritis and HIV. There is, however, no reason to think that sutherlandia can cure any of these diseases and claiming that it can is extremely irresponsible.

Currently, scientists are testing sutherlandia, to see if it is useful in treating certain illnesses. They are trying to understand what sutherlandia contains, in order to see which parts of it may be useful. Scientists are also testing sutherlandia on animals to see whether it is harmful to them and if it has any beneficial affects.

Early tests have shown that sutherlandia may have some useful effects. However, there is also evidence suggesting that compounds in the plant may interfere with ARV treatment, in particular with how ARVs are metabolised (processed) by the body.

Many more tests are needed to determine if and how sutherlandia works. As with artemisinin, it will have to be tested to see if it is dangerous, if it is effective in treating any conditions, and what the ideal dosages would be.

Photo by Michael Wolf.



the role of traditional healers

By Marcus Low

Traditional healers have an important role to play in the fight against HIV. Even so, they cannot cure HIV and none of their treatments are anywhere nearly as effective as antiretrovirals in managing the disease.

Photo courtesy of Gallo Images/AFP.

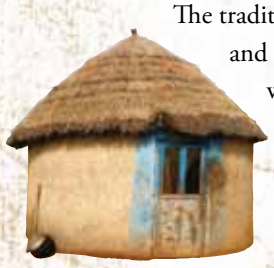
South Africa has roughly 190,000 traditional healers and it has been estimated that as much as 70% of the population use their services. Though these numbers may not be very reliable, we do know that many people consult traditional healers and that they therefore have an important contribution to make to healthcare in this country. Some surveys suggest that the number of people visiting traditional healers has fallen slightly in recent years.

Many people consult both medical doctors and traditional healers. Whereas doctors tend to focus primarily on the body, healers often stress a variety of social, cultural and religious issues. So, for example, HIV infection can sometimes be blamed on an evil spirit or on the ancestors being unhappy. We know however that antiretrovirals (ARVs) are the only way to effectively manage HIV. Any traditional healer who disputes this fact or who tells people not to use ARVs is a quack. It is hoped that the Traditional Health Practitioners Act might help to weed out such charlatans.

Traditional healers as part of the solution

Some studies have suggested that traditional healers can play a valuable role in helping TB patients to take their medicines as they should. In a related initiative, some traditional healers are being trained to recognise the symptoms of HIV and TB infection so that they know when to refer patients to medical doctors.

It is vital that traditional healers refer to the clinic any patients that they cannot effectively treat. Serious diseases like HIV or cervical cancer should be treated by a doctor as soon as possible. In some cases early treatment can make the difference between life and death. Traditional healers can save many lives by referring people to the clinic as soon as they spot dangerous symptoms.



The traditional healer can still provide socially and culturally relevant support to those who need it. Given the relative lack of psychological services in the public sector, this help could enable some patients to cope and stay positive.

The Traditional Health Practitioners Act

The purpose of the Traditional Health Practitioners Act is to: (a) establish the interim Traditional Health Practitioners Council of South Africa, (b) provide for the registration, training and practices of traditional health practitioners, and (c) serve and protect the interests of people who use the services of traditional health practitioners.

However, the details of regulation and accreditation are still unclear, and most sections of the act are not yet being enforced. Once the act does become enforced, traditional healers will have one year to register. If they fail to do so, they will no longer be allowed to practice as traditional healers. Healers who are not registered will be guilty of an offence if they claim that they can cure HIV, cancer, or other terminal diseases.

What is traditional health practice?

The Traditional Health Practitioners Act defines traditional health practice as "the performance of a function, activity, process or service based on a traditional philosophy that includes the [use] of traditional medicine or traditional practice" and which has as its aim —

(a) to maintain or restore physical or mental health or function; or

(b) to diagnose, treat or prevent a physical or mental illness; or

(c) to rehabilitate a person, enabling them to resume normal functioning within the family or community; or

(d) to physically or mentally preparare an individual for puberty, adulthood, pregnancy, childbirth and death.

Source: Traditional Health Practitioners Act.

How science works

Our ability to gain knowledge, pass it between people and improve on it may be the skill that most clearly separates humans from other animals.

Photo by Samantha Reinders.

By Eduard Grebe

We have been doing this since the beginning of time. What we call 'culture' is basically knowledge and habits that have built up over many thousands of years. However, science is a special kind of knowledge that only came about quite recently in human history. It involves a methodical search for knowledge using disciplined research, which is carried out according to the 'scientific method'.

The 'scientific method' means making hypotheses about how things work and then testing these ideas using controlled experiments. (A hypothesis is a formal description of how something is thought to work.)

Medical research applies scientific method in order to make human life better. It can discover what causes a disease and which treatments work. Unfortunately the medical field can also be affected by all kinds of non-scientific practices and claims. Understanding the science of medicine can help us to tell the difference between treatments that are supported by scientific evidence and the many 'remedies' that are based on faith alone.

Clinical research

Clinical research is the branch of medical science that deals with the development and testing of medical interventions like drugs and surgical methods. Generally, when someone suggests a new intervention, two things must be confirmed before it can be used: Firstly, that humans can take it safely (including the circumstances in which it should not be taken and any possible side effects) and secondly, that it does in fact work. There are well-established rules for researching the safety and effectiveness of drugs, methods of diagnosing illness and other new interventions. The most important type of research is called the *clinical trial*.

Clinical trials are not just good research practice, they are vital to the way most countries regulate medicines. Before a new drug can be made available, evidence on its safety and effectiveness must be given to the appropriate authorities. In South Africa, all drugs, diagnostic tests, medical equipment, etc. must be registered with the

Medicines Control Council (MCC). The MCC reviews clinical trial results and other scientific data before approving a new drug for use.

It is important to understand that not all clinical studies produce evidence of the same quality. How much value we should attach to the results of a study depends on a number of factors. One of these is the type of study that is done. For example, a well-designed clinical trial that tests an intervention experimentally produces stronger evidence than an observational study. An observational study is one that tries to find the effect of a treatment by looking at information obtained through routine record-keeping. The quality of evidence is also affected by whether a study follows the rules for good study design and practice. Other factors include the number of people taking part in a study, and the outcome, or end-point that it measures.

Clinical trials of new drugs

The development of new drugs requires a huge amount of research. Once a promising substance has been found, it is studied in the laboratory and put through pre-clinical studies. These include studies on animals to discover whether the drug is likely to work in humans, and how toxic it is. Before studies on humans can begin, approval must be obtained from regulatory authorities, which review the data from the pre-clinical studies. At this point the drug is known as an investigational new drug (IND). Clinical trials must also be approved by an ethics committee or ethical board. These groups review the research protocol (the formal research plan) to make sure that human volunteers are not exploited or put in undue danger.

Clinical research on new drugs is usually carried out in four stages:

Phase I: Safety studies are done using a small number of healthy volunteers. Participants are usually observed around the clock. In addition to making sure the drug does not have dangerous side effects, other features of the treatment are studied. These might include its 'pharmacokinetics' (how much the body absorbs, how long it takes to process and excrete the drugs, etc.).

Photo by Samantha Reinders.

Phase II: If the IND seems safe in Phase I trials, researchers test how well it works in a larger group of volunteers (usually 20-300). These trials also help to decide optimal doses and to confirm the safety of the medicine.

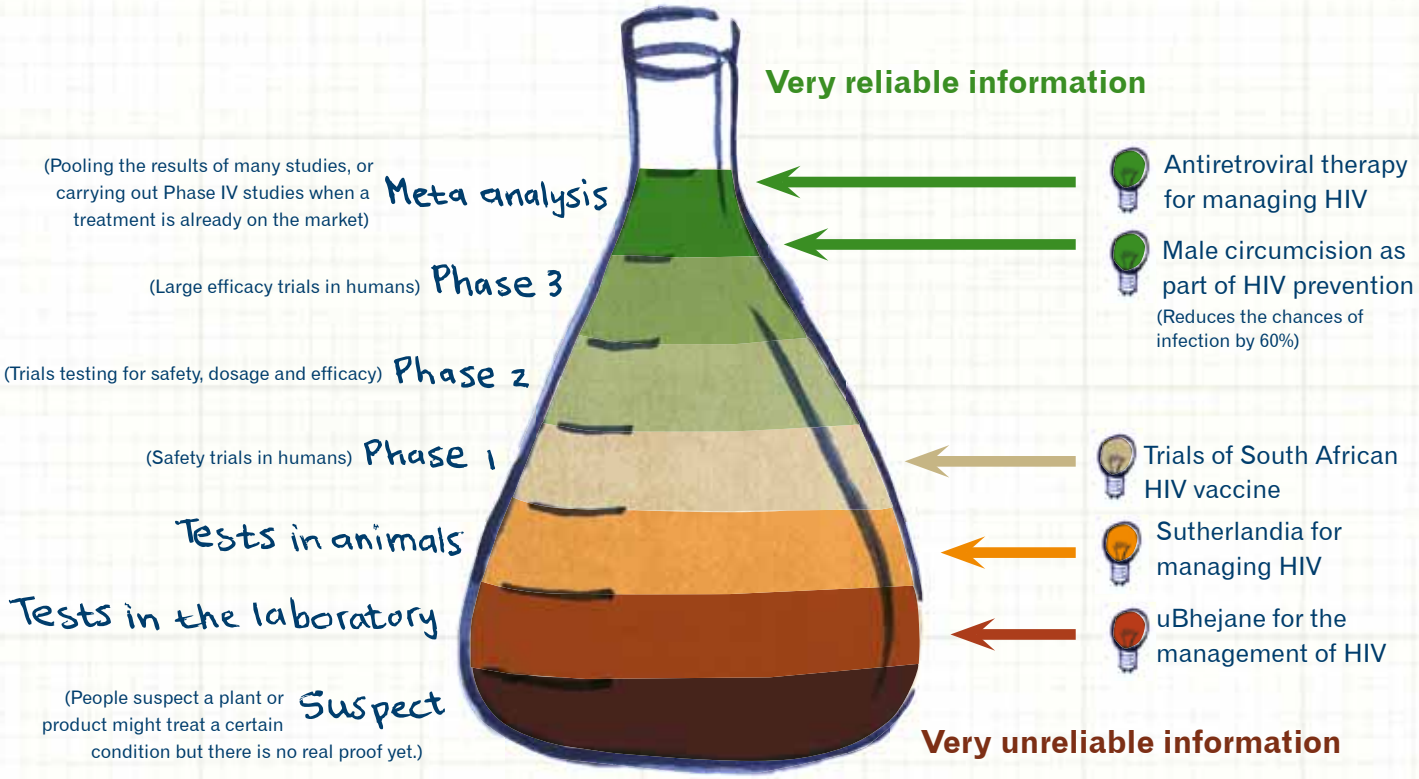
Phase III: This research usually takes the form of 'randomised controlled' trials (see page 17). They are done in multiple locations and with much larger patient groups (usually 200 to 3000 or more). Phase III trials are designed to assess beyond doubt how effective the treatment is compared to the best treatment currently used. Regulatory approval usually requires more than one successful Phase III trial.

Phase IV: These are also known as 'post-marketing surveillance' trials. They are designed to monitor new drugs after they become generally available. The trials look for rare harmful effects and other safety concerns. Sometimes these trials result in drugs being limited to smaller numbers of patients. Very rarely, they can lead to a drug being withdrawn from the market.

Clinical trial design

Not all clinical studies produce evidence of the same quality.

Clinical trials are arguably the most important type of clinical research, because they are used to decide whether treatments are safe and effective. It is therefore extremely important that clinical trials are well designed so that we can trust the results. A trial should have a detailed protocol - a document that explains exactly how patients will be chosen and treated, how records will be kept



By the time a treatment or health intervention reaches the top of this ladder, we can say with a very high degree of certainty whether it is effective or not. Many treatments drop out in the laboratory phase, when it becomes clear that they are not feasible, or in the safety phase, when risks are picked up.

etc. This is especially important for a trial that is carried out in multiple locations. Otherwise, there is a strong possibility that research practices could vary.

In most cases, the best study design is a 'randomised double-blind controlled trial'. Most Phase II and Phase III drug trials are of this kind. See the box for a detailed explanation of this kind of clinical trial.

Clearly, because clinical trials are experiments on people, they raise difficult ethical questions. For example, taking a placebo when there are treatments that are known to work is bad for a patient's health. In some cases this issue is dealt with by using an "active control" instead of a "placebo control". This means that the test treatment is compared to the standard therapy currently in use, rather than a fake treatment. When new antiretrovirals (ARVs) are tested, they are compared to the currently available ARVs.

There are ethical guidelines and legal rules for clinical trials, such as the requirement to get informed consent from all patients. Also, ethical boards sometimes stop trials when it becomes clear that a treatment works and that it would be unacceptable to continue giving some patients placebos.

Statistical significance

In order to show that a treatment is beneficial, there must be a "statistically significant" difference in the outcomes between the treatment groups and placebo groups in the trial. There are well-developed mathematical measures to decide statistical significance. The most common of these is the *p*-value linked to a particular result. The *p*-value measures the likelihood that the difference between two groups of patients could have happened purely by chance. A lower *p*-value therefore shows that people can have greater confidence in the result. The number of participants in a study has a big impact on how reliably we can detect and measure the effects of a treatment. This is known as the statistical power of a trial. However, larger trials are also more expensive.

Randomised double-blind controlled trials are designed to eliminate any possible sources of bias or factors that can create the false appearance that an intervention is effective when it is not (or the other way around). The key elements of these trials are:

Control: Researchers need to separate the effect of the treatment being tested from all other factors. In order to achieve this, the people taking part in a trial are divided into a 'treatment group' that receives the treatment being tested and a 'control group' (these are known as 'arms'). The process of receiving treatment (whether the treatment itself has any effect or not) make many patients feel better. This is known as the placebo effect. In the ideal situation, the control group receives a placebo or 'fake' treatment (such as a sugar pill or a saline injection). Such trials are 'placebo controlled'. In other cases, the treatment is compared to the standard therapy currently in use, rather than to a fake treatment. This is known as an 'active control'. Some trials, such as those comparing different dosages or ways of using existing treatments, have multiple treatment arms.

Blinding: If the patient knows whether he or she is getting the real treatment, the effect of the treatment cannot be separated from the placebo effect. It must therefore be impossible to tell the real treatment from the placebo. The patient must not know which they are getting. It is also a good idea to hide from the trial workers whether they are giving patients the real treatment – otherwise they may unconsciously reveal this to patients. This is known as double-blinding.

Randomisation: Each patient is randomly assigned to an arm (i.e. to a treatment or control group). This ensures that all groups, if they were given nothing, would be equally likely to get better or worse. If the study is not randomised, any difference in outcome between the groups could be for a reason other than whether they received a treatment that works.

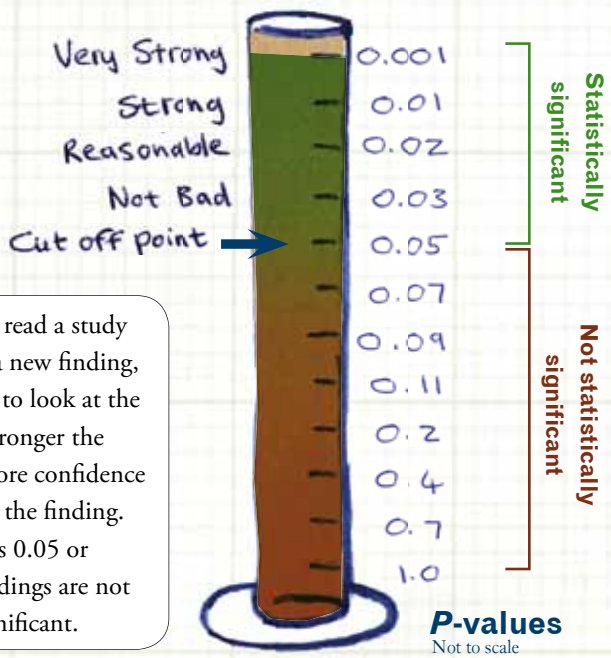
Systematic reviews

Systematic reviews or 'meta-analyses' of trials are studies that combine the results of several studies. All of the studies address a set of related research hypotheses. A systematic review of clinical trials – all measuring the effects of the same treatment – allows researchers to achieve greater statistical power than any of the individual trials. This gives them a better idea of the true size of the treatment's effects without doing a new and larger study.

Systematic reviews provide the most trustworthy results. They are an excellent way to establish the 'state of the evidence' on a particular question. These reviews sometimes have unexpected results. For example, they may show that a treatment works when most of the individual studies seemed to show the opposite (or vice versa). A respected source of systematic reviews of medical interventions is the Cochrane Collaboration. It has produced excellent systematic reviews which have heavily influenced clinical medicine practices. For example, a Cochrane Review pooled the findings of three big circumcision trials. It showed that circumcision reduced the risk of HIV infection in heterosexual males. This led to recommendations that circumcision should be offered as part of HIV prevention programmes.

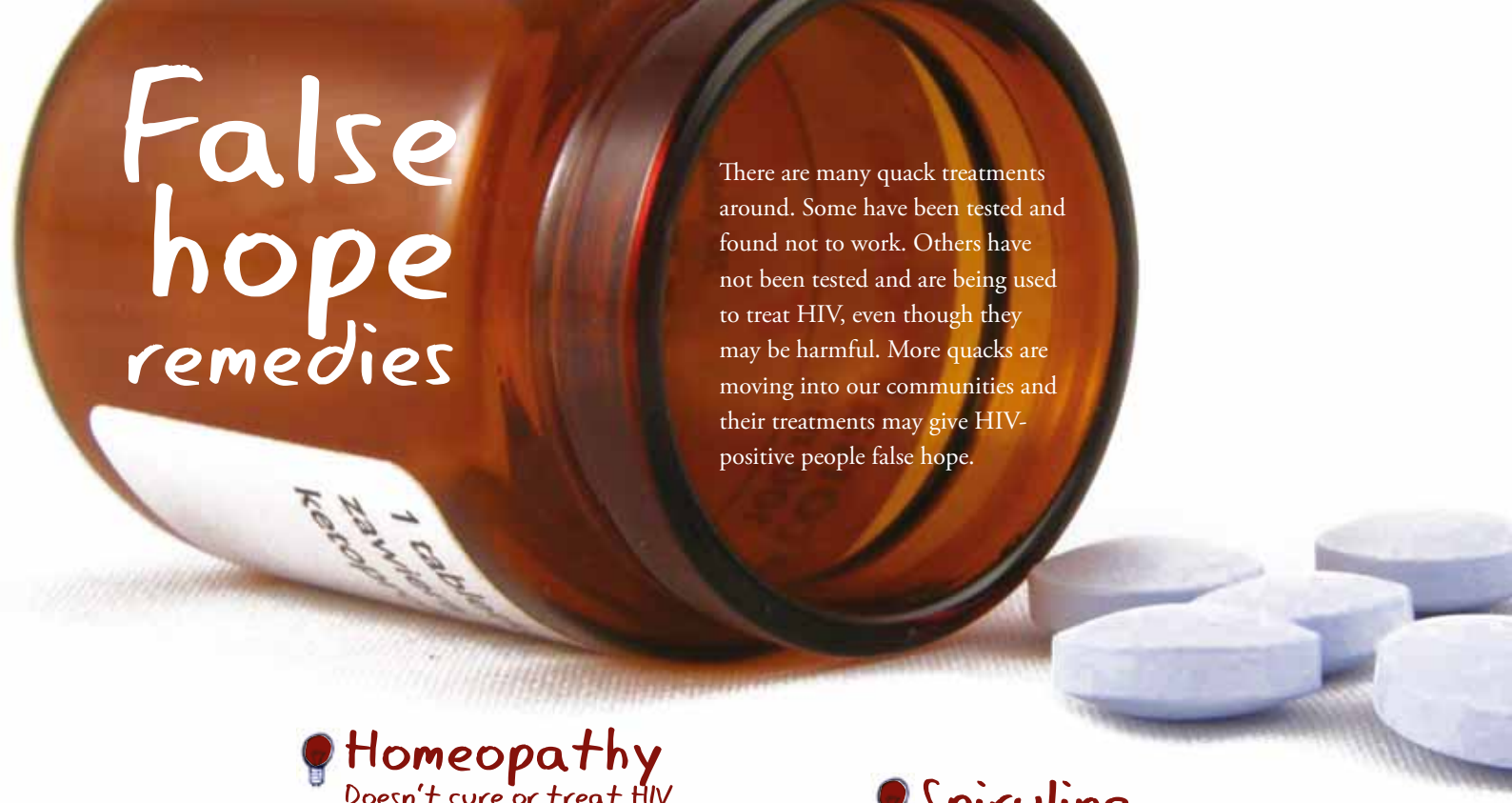
Science has provided us with the knowledge to substantially improve the length and quality of life for all people. In some cases this takes the form of sophisticated 'high tech' medicine, but there have also been many advances in public health based on relatively simple interventions, such as vaccinations and the treatment of drinking water. However, for far too many people the benefits of medical science have yet to arrive. It is our responsibility to ensure that all of mankind benefits from one of its greatest achievements.

Statistical significance is indicated by *p*-values



Whenever you read a study or hear about a new finding, it is important to look at the p-value. The stronger the p-value, the more confidence we can have in the finding. If the p-value is 0.05 or weaker, the findings are not statistically significant.

False hope remedies



There are many quack treatments around. Some have been tested and found not to work. Others have not been tested and are being used to treat HIV, even though they may be harmful. More quacks are moving into our communities and their treatments may give HIV-positive people false hope.

Homeopathy

Doesn't cure or treat HIV

Homeopaths believe that they can treat a disease by giving patients extremely small doses of a substance that they say will produce the same symptoms as the disease itself. Usually they do this by diluting the substance in water. They dilute it to such an extent that there is no longer any of the substance left in the water. Homeopaths sell this water for high prices.

The World Health Organisation recently warned that homeopathy cannot cure HIV, TB, malaria or flu. Homeopathy has never been shown to cure any serious diseases and studies have found that what little benefit some patients experience is probably because of the placebo effect (see page 5 for more on the placebo effect).

Revivo

Doesn't cure or treat HIV

The Advertising Standards Authority of Southern Africa recently ruled that advertising of the herbal supplement Revivo must be withdrawn in South Africa. Revivo advertising made unproven claims that the supplement acts against HIV, increases CD4 count and lowers viral load. Revivo has not undergone clinical trials in humans and there is no scientific basis for these claims. HIV-positive people are advised not to waste their money on Revivo.

Spirulina

Doesn't cure or treat HIV

Spirulina dietary supplements cannot cure HIV, nor is there any evidence that they can help manage CD4 counts or viral load.

Most of the research that has been done on spirulina was carried out in laboratories or on animals. We will only know whether spirulina supplements are of any use to HIV-positive people once large, placebo-controlled, double-blinded trials have been done in humans. Until then, there is no reason to think that it will do you any good, whatever the people who sell these supplements may say.

Acupuncture

Doesn't cure or treat HIV

Acupuncture involves putting fine needles into specific parts of a patient's body in order to relieve pain or to treat a specific condition.

Acupuncture cannot cure HIV. There is also no reliable evidence that acupuncture can ease symptoms or lessen the side effects of ARV treatment. Some studies, however, have suggested that acupuncture might help with certain conditions, but these findings are controversial. Where acupuncture does bring some benefit, it is widely thought to be because of the placebo effect.

Sources: Liu, J.P. and E. Mannheimer, M. Yang "Herbal medicines for treating HIV infection and AIDS" *Cochrane Database System Review* 3 (2005); Mills, E. and P. Wu, E. Ernst "Complementary therapies for the treatment of HIV: in search of the evidence" *International Journal of STD and AIDS* 16.6 (2005); Shang, A. and K. Huwiler-Muntener, L. Nartey, et al. "Are the clinical effects of homoeopathy placebo effects? Comparative study of placebo-controlled trials of hom0eopathy and allopathy" *Lancet* 366 (2005).

See page 10 for more on the quack remedy uBhejane and page 11 for more on Sutherlandia.

Quacks in Limpopo

The era of Mbeki and Tshabalala-Msimang's AIDS denial may be over, but on street corners and in markets all over the country, untested medicines are still being sold. *Lawrence Mbalati* reports from Limpopo Province.

The failure to effectively regulate untested medicines that are being sold to people with HIV is a major stumbling block in our fight against the pandemic. The Treatment Action Campaign (TAC) has challenged this lack of regulation. It has had several important victories, stopping prominent quacks from continuing to make false claims about their untested remedies. The challenge, though, is far from over. We still see many people openly selling concoctions in the streets without anyone stopping them.

Furthermore, in Limpopo, so-called hospices treat HIV-positive people using untested remedies. Despite many people having died in these circumstances, no one is being held responsible for their deaths.

Many residents of Limpopo Province make decisions about their health based on cultural, religious and traditional beliefs, rather than on scientific evidence. When people are sick, they often conclude that they have been bewitched, rather than seeking tests for HIV, TB or other chronic illnesses. These delays in getting medical treatment can have severe consequences for health and may even be deadly.

Here are some of the untested remedies and services found in Limpopo:

Divine water

This is 'pure' water, charged at R100 per five litres. A faith healer prays for the water. When you finish drinking it, you have to pay for more, because the faith healer tells you to take the water for life. The healer is based in Seshego (Limpopo's biggest township),where he sells this water at Seshego Plaza and in the streets.

Whereas clean water is important, water - no matter how pure – cannot cure HIV, lower your viral load or increase your CD4 count.

This faith healer is clearly a quack who is exploiting people's sickness and lining his own pockets.

No-name concoctions

These are liquids sold inside dark cold-drink bottles. The producers do not reveal the ingredients used to make these concoctions. Therefore, the liquids could easily contain toxic substances that are harmful to our health. These 'remedies' are available in many areas and are sold on street corners at R80 per litre. There is no reason to think that these concoctions can help us. HIV-positive people should avoid putting their health at risk and wasting their money on these quack remedies.

Hospices

We have heard of two so-called hospices where taking antiretrovirals (ARVs) is discouraged. One is in Sekhukhune district and the other in Mhakweng. These 'hospices' are the homes of traditional healers, accommodating critically-ill people with HIV.

Churches that reject ARVs

As in other provinces, some churches in Limpopo – certainly not all – claim without any evidence that they can cure HIV. In areas of Modjadjie, certain churches discourage people from even talking about condoms, voluntary counselling and testing, or treatment. They appear to believe that what makes people sick is not HIV, but Makhuma (– they have not been cleansed after someone in their family has died).

TAC's *Charles Moponya* proves how easy it is to buy alternative medicines – and how much money it costs to buy so-called treatments that offer big promises they have not been scientifically proven to deliver. Here Charles walks *Equal Treatment* readers through an afternoon of buying quack treatments in South Africa. Photos by Moses Makhomisani.

Charles shows the R100 note needed to buy so-called 'divine' water, 'Phuma Health Drink'.

Charles receives the water and treatment instructions from it's seller. Charles is told that from now on he must drink only this water and that he will be drinking it for the rest of his life.

The unused so-called 'healing water', including a list of healing properties.

Regulating medicines in South Africa

By Jonathan Berger

Much of the global debate on medicines has focused on what can be done to ensure that their prices do not stop people from getting them. Much less, however, has been said about regulating medicines.

In South Africa, the denialism of Thabo Mbeki, Manto Tshabalala-Msimang and Thami Mseleku forced AIDS and healthcare activists to deal with medicines regulation. The denialism and quackery supported by all three figures proved that while it is necessary to bring medicine prices under control, doing so does not guarantee access to such medicines.

How South Africa regulates medicines

The Medicines and Related Substances Act 101 of 1965, which was amended most recently in 2008, is the key law that regulates how medicines are developed, registered and used in South Africa. Together with other laws, especially the General Regulations of 2003, the Medicines Act controls medicines from start to finish. It does this mainly by creating rules for the Medicines Control Council (MCC) to apply.

The MCC came into existence thanks to the Medicines Act. Its structure is decided mainly by the General Regulations. While the Minister of Health chooses its members, the MCC itself has the power to hire qualified people for its expert committees. The MCC makes binding decisions, but most of the work is done by committee members. They are helped by a secretariat (government administrative office) made up of Department of Health (DoH) officials.

This complicated set-up not only causes confusion about responsibilities, but it also undermines the work of the MCC. The secretariat, which is based in the DoH directorate that deals with regulating medicines, includes a Law Enforcement Unit (LEU) made up of inspectors who are chosen by the Director-General of Health. It is the LEU – and not the MCC – that has the power and the main responsibility to enforce the Medicines Act.

However, the MCC still has a role in making sure that the law is enforced. For example, section 2(2) of the Medicines Act empowers the MCC to "advise the minister or furnish a report to the minister on any matter referred to the council by the minister for consideration and arising from the application of [the] Act." In addition, section 35 gives the Minister the power to make laws "in consultation with" the MCC. In other words, they have joint authority to make regulations.

So where is the problem?

The MCC has no direct legal authority over the secretariat, including its LEU. It has no power to hire or fire people who work for the secretariat. It also cannot hold the Registrar of Medicines – the head of the secretariat and the link between it and the DoH – to account. This is because the Registrar – and his or her deputy or deputies – is chosen by the Minister "after consultation" with the MCC. In practice, the Registrar has historically been someone who works for the DoH.

This problem will be addressed if and when the South African Health Products Regulatory Authority (SAHPRA) is established. This is the new body that will replace the MCC. It is not clear when this will happen, for two reasons. Firstly, there are practical and constitutional problems with the 2008 amendment, which creates SAHPRA. Secondly, new laws and systems will have to be put in place to ensure that SAHPRA can carry out its legal mandate.

In the meantime

Part of the switch to the new authority involves sorting out the MCC's current challenges. A fair criticism coming from drug companies and activists alike, is that the MCC is extremely slow to register new medicines. This includes cheaper generic versions of existing products. The MCC is also criticised for the slow pace of its clinical trial authorisation. Without this authorisation, medicines cannot be sold or used in South Africa.

A full picture of the MCC's challenges was painted by the Medical Products Technical Task Team (MPTTT). MPTTT is an expert body set up earlier this year by the former Minister of Health, Barbara Hogan. Its role was to advise her on drug policy, including regulation and procurement (how medicines are sourced). The MPTTT handed its report to Minister Aaron Motsoaledi after he replaced Minister Hogan in May 2009. This report formed the basis of a series of actions – including a project to clear the registration backlog at the MCC.

In addition, preparing for the new authority includes a ministerial review of the 2008 amendment to the Medicines Act. The law signed by former President Motlanthe is a huge improvement on the version put forward by Tshabalala-Msimang. Nevertheless, it does not do enough to address some of the key concerns raised by the Treatment Action Campaign (TAC) and AIDS Law Project (ALP) during the parliamentary process.

What does this all mean for AIDS and health activists?

Under Minister Motsoaledi's leadership, the regulations – as well as how they are carried out – are receiving urgent attention. However, much of the damage done during the Mbeki/Tshabalala-Msimang/Mseleku years has yet to be repaired. Many of the charlatans who benefited from that period still do business unchecked. The LEU remains understaffed and underfunded.

Activists must remain alert to ensure that the Minister, his department and the MCC carry out their legal obligations. They must also play a role in making sure that industry obeys the law. Being active about medicines regulation – whether this means getting involved in the law-making process or in complaints to the Advertising Standards Authority – should remain firmly on the agenda.

Jonathan Berger is a senior researcher with the AIDS Law Project. The Minister of Health – Dr. Aaron Motsoaledi – appointed Jonathan to the MCC in June 2009. Earlier in the year, Motsoaledi's predecessor – Barbara Hogan – appointed Jonathan to the MPTTT. Jonathan writes for Equal Treatment in his capacity as an AIDS Law Project employee.

Photo courtesy of AFP.

How to lodge a complaint with ASASA

If you see advertisements making false claims about treating HIV or other illnesses then you can lodge a consumer complaint with the Advertising Standards Authority of Southern Africa (ASASA).

Lodging a consumer complaint is simple if the advertisement makes unfounded claims about treating or curing a disease listed in Appendix F of the code of advertising practice. This list includes HIV, cancer and diabetes, among others.

Simply write to ASASA, complaining that the advertisement is in breach of appendix F. Complaints can be sent to: Email: complaint@asasa.org.za Post: PO Box 41555, Craighall, 2024 Fax: +27 11 781 1616.

Photo courtesy of National Geographic/Getty Images

The search for a vaccine

HIV vaccines have been getting a lot of attention in the news lately, with almost 30 different products in various stages of testing. So far, however, HIV vaccine research has been slow and largely unsuccessful. *By Jennifer Reid*

A vaccine is not a cure

Vaccines control the spread of a pathogen (an agent that causes disease, for example a virus). But vaccines do not cure the disease that it causes (see footnote about therapeutic vaccines).

A cure for HIV infection could be achieved in two ways: by wiping out the disease using a vaccine for people not infected with HIV that prevented infection 100% of the time, or by having a treatment to cure HIV-positive people. Treatment for cure would require eradicating all traces of the virus from all parts of the body, even from the hardest-to-reach lymph nodes and other "reservoirs" deep in the immune system. Currently, treatment controls HIV infection but does not eliminate it. Therefore, no one up to now has been cured using available antiretroviral drugs.

Ideally, an HIV vaccine would prevent HIV-negative people from contracting the virus in the first place. Until this can be achieved, it would also be valuable to have a vaccine that may not prevent HIV infection completely but may, if the vaccinated person became infected, make the disease much milder than it would otherwise have been.

How vaccines work

Vaccines teach your immune system how to fight an infectious disease before you come into contact with it.

When you contract a virus, it enters your bloodstream and reproduces rapidly. Your body responds by sending out antibodies (virus attackers) and killer cells (infected-cell attackers) that have been specially created to fight that virus. The faster your immune system recognises the virus, the faster the parts of that system that control infection can work.

When you are vaccinated, a small amount of the virus or a copy of the virus (known as a subunit) is introduced into your blood in a weakened, killed or simulated version. Your body reacts by creating the right antibodies and killer cells. These stay in your bloodstream. As a result, if you were to be exposed to the real virus, the antibodies and killer cells would be there already, waiting to attack it.

Vaccines have been incredibly successful in fighting some diseases, like smallpox. After the smallpox vaccine was developed, a worldwide vaccination programme wiped out the disease. No new cases have

been reported since the late 1970s and vaccination against smallpox is now unnecessary.

Vaccines are safe

Some people fear that a vaccine will make them sick, but this is rare. It is only possible with vaccines that contain (always weakened) live versions of the virus. Even then, symptoms are typically very mild. For example, you may get a slight fever or a sore arm. It is important that a preventative vaccine is very safe and without side effects since it will be given to people who are free of disease. Many vaccines are not live and there is absolutely no risk of contracting the virus from these. HIV vaccine products will never contain live or killed viruses. They always contain only small parts of the HIV virus that cannot reproduce independently, ensuring that it is impossible to get HIV infection from being vaccinated with an experimental HIV vaccine product.

No effective HIV vaccine

Making an effective HIV vaccine is extremely difficult. HIV mutates very quickly. When your body produces antibodies, HIV can mutate and then you will need to produce new antibodies. Your immune system is always trying to catch up. This is why a standard vaccine model has so far been unsuccessful. With so many strains of HIV, scientists would need to find one feature common to all the strains on which to base a vaccine.

Many scientists believe that in order to develop a successful vaccine, more needs to be known about HIV, how it works and why a small number of people seem to be immune to it.

An enormous amount of time and money is required to develop a vaccine, and it is hard to find new funding for vaccine research. Communication between different research groups is often limited. Some are reluctant to share important research before their achievements have been recognised. All of these challenges make it unlikely that an HIV vaccine will be available in the next 10 to 15 years.

History of HIV vaccines

In 1984, some researchers expected to have a vaccine by 1986. Over 20 years later, we have seen many trials and all have failed.

A vaccine developed by University of Cape Town researchers is being studied now in a first round of human trials in Boston in the United States, in Cape Town and in Soweto. The vaccine uses a new approach, with two vaccine candidates being used to both prepare and then build up the immune system. As with other candidates, only subunits of virus are used in these products and so people taking part in the study have no risk of contracting HIV. The trial is being carried out jointly by the South African AIDS Vaccine Initiative (SAAVI) and the US National Institute of Allergy and Infectious Diseases (NIAID). Within the next year, researchers will be able to tell if these trials are worth continuing. If they move to the next step (phase 2 human trials), within a few years they may be able to decide whether the vaccine is effective.

Very early results from a recent trial in Thailand show some promise that a vaccine is possible, but not necessarily close. (See box for details of this trial.)

At present, we still know much more about what will not work in an HIV vaccine than what will work. The next five to ten years will be vital for closing the knowledge gap on HIV biology and vaccine creation. Hopefully, the latest trial results are a step in the right direction.

Sources: Duerr, A. and J. Wasserheit, L. Corey "HIV Vaccines: New Frontiers in Vaccine Development" *Clinical Infectious Diseases* 43 (2006) http://www.journals.uchicago.edu/doi/pdf/10.1086/505979 ; Graham, B. and J. Ledgerwood, G. Nabel "Vaccine Development in the Twenty-First Century: Changing Paradigms for Elusive Viruses" *Nature Publishing Group* 86.3 (2009) http://www.nature.com/clpt/journal/v86/n3/pdf/clpt2009128a.pdf ; South African AIDS Vaccine Initiative "Questions and Answers: SAAVI 102/HVTN 073 HIV Vaccine Clinical Trial" (2009); Thomas, C. "Roadblocks in HIV Research: five questions" *Nature Medicine* (2009) http://www.nature.com/nm/journal/v15/n8/pdf/nm0809-855.pdf.

New vaccine findings

Recent findings from a trial (called RV 144) of over 16,000 people in Thailand have attracted a lot of attention. The first reports claimed that a combination vaccine cut the risk of becoming infected with HIV by 31.2%. Though weak, these findings seemed to be the first concrete evidence that an effective HIV vaccine is possible. However, a more careful analysis is being performed at the time of going to press.

The trial tested for protection against HIV subtypes B and E. In Southern Africa we mostly find subtype C. We do not know whether the vaccine will offer any protection against subtype C.

We will soon know more about the exact outcomes of this trial. In the meantime, all of these human clinical trials are adding to the body of knowledge that we need to eventually design and implement a safe and effective preventative vaccine.

Reviewed by Dr. Linda-Gail Bekker, Deputy Director at the Desmond Tutu HIV Centre and principal investigator of the Cape Town wing of the South African vaccine trials.

Most discussions on vaccines concentrate on preventative vaccines. These are the vaccines that prevent infection in uninfected individuals. More rarely, vaccines can be therapeutic – in other words, they ease some symptoms of chronic diseases. More research is also being conducted on these vaccines. This article only discusses preventative vaccines.

All about Cervical Cancer

By Émilie Shuh

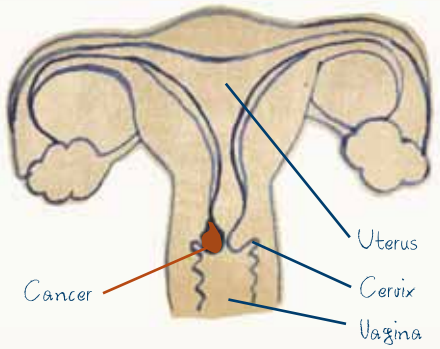
What is cervical cancer?

Cervical cancer is another name for cancer of the opening of the womb. The cervix is the lower part of the uterus (the womb) that connects with the vagina. This type of cancer develops when the cells of the cervix become abnormal and begin to grow out of control. It is easy to prevent and treat *if* it is caught early.

Cervical cancer is the most common cancer diagnosed among women living in developing countries. This is mostly because effective screening programmes (like the Pap smear test) to detect early changes in the cervix are either not in place or are not accessed by women.

What causes cervical cancer?

Infection of the cervix with 'high-risk' types of the human papillomavirus (HPV) is necessary for the changes in cervical tissue that could later become cervical cancer. Some people infected with HPV clear up the infection on their own without ever experiencing symptoms. Others do not; this is especially true of people living with HIV and those with poor immune systems. More importantly, women infected with HIV are also more likely to have HPV. They face a higher risk of HPV infections that are not easily treated and could return. And they are more likely to develop changes in the cervix that could become cancerous if left untreated.



You might have cervical cancer if you have:

- Bleeding after sex
- Pain in the lower abdomen
- Unexplained weight loss
- Abnormal discharge from your vagina

What is HPV?

HPV is a virus that is passed through vaginal, oral and anal sex and through skin-to-skin genital contact. This means that men are also at risk of HPV infections. These infections could cause genital warts or become cancers of the penis, anus or genitals. Men can also pass on HPV to their partners. Anyone who is sexually active is at risk. There are about 100 types of HPV. HPV types 6 and 11 can cause genital warts, and some 'high-risk' types, including types 16 and 18, can cause cancer. A vaccine against these two cancer-causing strains of HPV now exists.

The only way to detect HPV is by testing, for example through a Pap smear or HPV test. As mentioned above, people can be infected and not even know it, so testing is important. Currently, South African women can have three free Pap smears on the public health system during their lifetimes, starting at age 30. This

Remember: Cervical cancer can be prevented or treated if it is detected early. Don´t delay, have your Pap smear today!

test looks for abnormal cells in the cervix that could be harmful. Cervical cancer develops slowly, so frequent testing is not usually necessary. But for women living with HIV, cervical cancer is more aggressive, so if you are HIV-positive you should have a Pap smear, even if you are under 30 years of age.

What to do if you experience symptoms:

If you are worried about cervical cancer see your doctor or nursing sister immediately. They should offer you a Pap smear test, which is part of a woman's health check-up. The doctor or nursing sister will examine the mouth of the womb to check for signs of cancer. It should not be painful and only takes minutes. You will get the results a few weeks later. Depending on the results, you may need to return for another check-up a few months later, or you may need treatment. Cervical cancer can be treated with an operation to remove the cancer or with medicine and radiation treatments. Some women can be cured of their cancer.

It is important to access health services before symptoms appear or become worse. Of the approximately 80,000 women in Africa who develop cervical cancer each year, the majority seek medical care too late and already have advanced, incurable disease by the time they get to a clinic. Remember: you have a right to health!

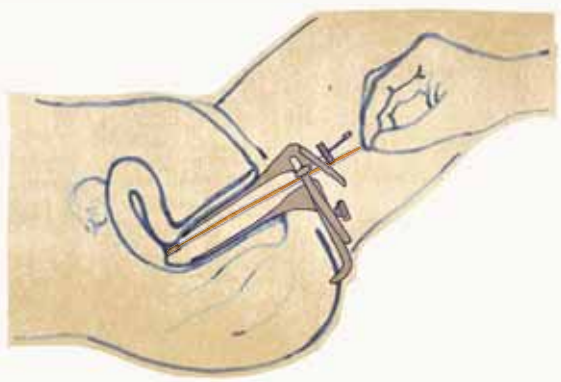
Sources: Batra, P. and E. Shuh "Treatment Action Campaign Policy Position Paper on HPV and Cervical Cancer Prevention in South Africa" *Unpublished* (2009); Denny, L. "Burden and natural history of cervical cancer in Africa" *Conference abstract*; Denny, L. "HPV and cervical disease in HIV infected women" *Conference abstract*: Padian, N. and A. Van de Straten, G. Rmjee, et al. "Diaphragm and lubricant gel for prevention of HIV acquisition in southern African women: a randomized controlled trial" *The Lancet* 370 (2007); Winer, R.L. and J.P. Hughes, F. Qinghua, et al. "Condom use and the risk of genital human papillomavirus infection in young women" *The New England Journal of Medicine* 354 (2006).

How to protect yourself:

- Get a Pap smear. This simple test will find early stages of cancer of the womb so that it can be treated.
- Always use a condom, and use it correctly so that it does not slip off or break. Consistent condom use reduces the risk of HPV infection. Diaphragms and lubricant are not a suitable method for preventing infection.
- Use a dental dam for oral sex.
- Limit your number of sexual partners.
- Stop and report sexual abuse of any kind.
- Know your HIV status. Women with HIV are more at risk for cervical cancer.
- Quit smoking. Smoking increases your chances of getting cancer.
- Ask about the HPV vaccine. This new injection can protect young women and girls from the HPV virus that causes cervical cancer. The vaccine works best if given before becoming sexually active. It is currently only available in the private sector.

Article reviewed by Professor Lynette Denny, University of Cape Town and Principal Specialist at Groote Schuur Hospital.

What is a pap smear?



The nurse or doctor will collect a tissue sample from your cervix and send it away for testing. You should get the results back in a few weeks. It isn't painful, takes only a few minutes and might save your life!

The vaccine that stops cervical cancer

By Émilie Shuh

The HPV vaccine can potentially prevent up to 70% of cervical cancer cases in sub-Saharan Africa, where it kills more women than any other kind of cancer. If the vaccine can save so many lives, why is it not available in the public health system?

Cervical cancer is a preventable and often curable disease. It can be prevented through vaccination and screening programmes and is curable when detected early and managed appropriately. In South Africa about 7,000 women develop cervical cancer each year. Thousands die because this cancer is not detected early enough and/or not treated properly. This is especially true for poor women and those living in rural areas, since access to health services may be complicated by transport problems, costs and a lack of knowledge about the disease. The worst part is, this cancer usually affects women between the

Photo courtesy of The Bigger Picture / Panos.

ages of 35 and 55 (earlier in women living with HIV), when they are essential to the social and economic stability of their families.

We must put pressure on GlaxoSmithKline (GSK) and Merck Sharp & Dohme (MSD) to drop the prices of their cervical cancer vaccines.

Two new vaccines (Gardasil® and Cervarix®) to prevent cervical cancer are available to South African women. Currently, these are only offered in the private sector. Pharmaceutical companies can charge a high price for new vaccines like these because of patent protection laws. These laws are meant to ensure that companies can make back the money they invested in designing and manufacturing the drug. But there is criticism that some companies make a lot more than they invested.

Furthermore, countries like South Africa are considered too wealthy to be eligible for vaccine funding through groups like GAVI (the Global Alliance for Vaccines and Immunisation). This means that the South African government will have to pay a high price if they want the vaccine to be available in the public sector. It is the same struggle over affordability that we saw previously with antiretrovirals (ARVs) and now see with second-line ARVs and the HPV vaccine.

The injection works by preventing the types of HPV contained in the vaccine. It can also offer some protection against other strains of the virus not contained in the vaccine. The immunisation works best if given to women *before* they are sexually active. That is why it is recommended for girls around 12 years of age. The vaccine is given as three separate injections in the arm, over six months. It is estimated that an HPV vaccine could prevent about 70% of cervical cancer cases in sub-Saharan Africa. But, there are several barriers to introducing the HPV vaccine to the South African public health care system.

Sources: Anorlu, R.I. "Cervical cancer: the sub-Saharan African perspective" *Reproductive Health Matters* 16.32 (2008); Cancer Research UK "Cervical Cancer Vaccine" (2008) http://www.cancerhelp.org.uk; Harries, J. et al. "Preparing for HPV vaccination in South Africa: Key challenges and opinions" *Vaccines* 27 (2009); Munoz, N. and F. Bosch, X. Castellsague, et al. "Against which human papillomavirus types shall we vaccinate and screen? The international perspective" *International Journal of Cancer* 111 (2004); World Health Organization " Human Papillomavirus and Cervical Cancer: Summary Report, South Africa" (2007).

Barriers to rolling out the HPV vaccine

- **Lack of awareness about HPV and cervical cancer.**
- **Lack of knowledge about how the vaccine works in HIV-positive individuals.** Research is being done, but data are still not available. These results will be important if the vaccine is introduced to the public health care sector, given the high prevalence of HIV in the country.
- **Lack of a population-based national cancer registry in South Africa.** This is necessary to track the number of cancer cases in the country to help monitor whether the vaccine and other interventions are effective.
- **Cost of the vaccine.** It costs about R2,100-R2,310 for all three required doses. Negotiations are underway with pharmaceutical companies to obtain price reductions in South Africa. One company, GlaxoSmithKline (GSK) has agreed to reduce the price to R450 per injection. While this price reduction is welcomed, the vaccine remains too expensive for most South Africans and for the South African government. There will also be costs involved in setting up a vaccination programme, delivering the vaccine and monitoring vaccinated girls for any lasting effects or safety issues, as this is a new vaccine.
- **Lack of coordination between groups that influence health decisions.** Offering this new vaccine will bring together groups of people that have not worked together in the past. Usually vaccines are given to infants and children, but this vaccine targets adolescents and young women.
- **The feasibility of vaccine delivery programmes.** It is a difficult task to ensure that three doses are given to each eligible South African female as this requires follow-up, made difficult in poorly resourced areas where health staff are not easily able to monitor their patients. Introducing the vaccine could put further strain on an already overwhelmed public system.
- **Continued need for cervical screening (e.g. Pap smear).** The vaccine will reduce but *will not eliminate* the risk of cervical cancer. This is because not all women will be vaccinated, and the vaccines only target the most common strains of HPV. It takes 10-20 years for cervical cancer to develop after infection with HPV (even less with HIV), so women will still need Pap smears in the future.

The Zihlangene family in August 2009, before TAC and other organisations intervened.

The Zihlangene's small dwelling, which housed 13 people.

Makers Plan manager Mrs. Xavuka with Mrs. Zihlangene.
All photos by Tandeka Vinjwa.

Report on the destitute family in Mcobothini, Lusikisiki

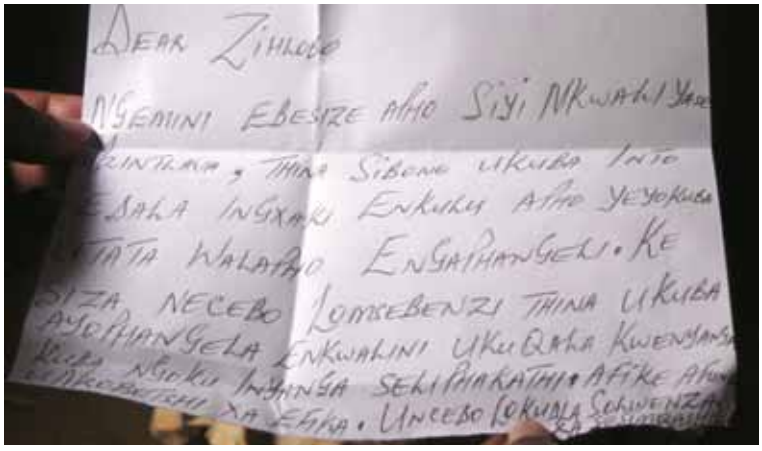
By Tandeka Vinjwa, Policy Communication and Research, TAC – Lusikisiki

TAC Lusikisiki Community Health Advocates found a family of 13 living in one house while they were doing a door- to-door campaign on socio-economic issues. The Sihlangene family lives in Mcobothini location, just 3 km away from Lusikisiki. When TAC found the family, both the wife and husband were unemployed and looking after their eight children and three grandchildren.

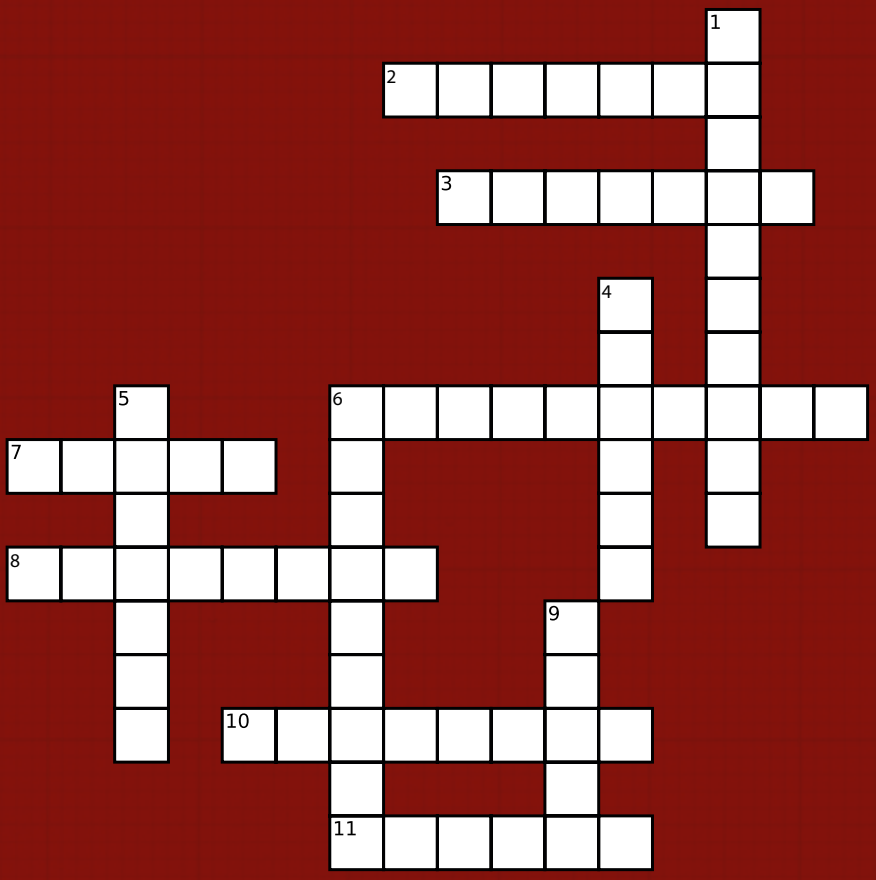
They were living on child support grants for two of the children. One of the children is disabled but was considered ineligible for disability assistance as her mother did not have a South African identity document. Only three children attended school.

In response to the family's situation, TAC Lusikisiki asked for help from organisations and individuals. Their story was presented at the local AIDS council meeting. Several organisations offered immediate assistance to the family, which helped to alleviate some of their basic material needs such as food and blankets. The Department of Home Affairs also provided an identity document for the mother of the disabled child, which will facilitate access to a disability grant. The family's father was also recently employed at Mzintlava Quarry.

This story reminds us of the poverty that affects thousands of families across South Africa, and the legal and employment issues they face that bar them from being economically stable. Outreach work by the TAC and other organisations is needed in order to help these families receive the help and support they need.



Equal Treatment's Crossword Puzzle



We will give a R200 Pick n Pay gift voucher to the first crossword drawn from a hat with all the correct answers. The answers can be found in this issue of *Equal Treatment*.

Winners from previous issues:
ET 27– *Social Grants* winner is Miss Linoiwe Nolovu
ET 28 – *Side Effects and Adherence* winner is Miss N.J. Mnyali
ET 29 – *Resources for Health*: no winning entries
ET 30 – *Women and Men* winner is David Poole

Congratulations to all our winners!

Fax or post your completed crossword, with your name, address and contact number.
Address: Equal Treatment, PO Box 2069, Cape Town 8001
Fax: 021 422 1720

Across

2 A sugar pill with no active ingredients

3 If participants in a trial do not know whether they are getting the real pill or the placebo, we say that the study has been _____.

6 ____reviews or 'meta-analysis' of trials are studies that combine the results of several studies.

7 Someone who promotes medicines that have not been tested properly.

8 Early results from an HIV vaccine trial in ____ recently made headlines across the world.

10 The most common cancer diagnosed among women living in developing countries.

11 In phase I trials researchers aim to establish the____ of a medicine.

Down

1 The World Health Organisation recently warned that ____ cannot cure HIV, TB, malaria or flu.

4 Vaccines teach your ____ system how to fight an infectious disease before you come into contact with it.

5 The medicine artemisinin is used is used to treat____.

6 ASASA stands for the Advertising ____ Authority of Southern Africa.

9 The substance digoxin is commonly used to treat ____ disease.

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