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### News from the 6th South African AIDS Conference

### **By Lesley Odendal**

## South Africa introduces tuberculin skin test for IPT eligibility in new guidelines

The South African Department of Health launched new guidelines on isoniazid preventative therapy (IPT) for HIV-infected individuals at the 6<sup>th</sup> South African AIDS conference held in Durban in June this year. The greatest change in the IPT guidelines is the introduction of the tuberculin skin test (TST) for people living with HIV to determine the duration for which isoniazid should be taken to prevent TB disease.

Previous South African IPT guidelines issued in 2010 dropped the requirement for TST, based on World Health Organization (WHO) recommendations. Current WHO guidelines state that "TST is not a requirement for initiating IPT in people living with HIV," in order to simplify the operational delivery of IPT. Tuberculin skin testing requires refrigerated supplies of tuberculin which may not be feasible in many settings, for example. However, in some settings where it is feasible, TST can help to identify those who would benefit most from IPT, according to the WHO.

The new South African guidelines state that all people living with HIV should be initiated on IPT after active TB has been ruled out. In those eligible for antiretroviral treatment (with a CD4 cell count of less than 350 cells/mm<sup>3</sup>), IPT should begin after ART initiation, and once active TB has been ruled out.

The main reason for the inclusion of TST in the TB screening algorithm for IPT in South Africa is because many health care workers do not feel confident using symptom screening alone to exclude active TB in people living with HIV. This prevented more people from being initiated on IPT. The Department of Health believed that the introduction of TST would provide an alternative, more accurate method of ruling out TB.

Tuberculin skin testing is used to determine whether a person has been exposed to TB. A positive result shows that the person is mounting an immune reaction to the presence of TB and may be latently infected. Isoniazid preventive therapy significantly reduces a person's subsequent risk of developing active TB.

A negative result can mean one of two things. Either the person has very poor immune function, in which case they may be unable to mount a reaction to the skin test despite being exposed to TB, or they may not have been exposed to TB.

The Botswana IPT trial showed that people with HIV who received IPT had no significant reduction in their risk of developing active TB if they were TST negative prior to starting IPT. (Samandari).

According to the new South African guidelines, the introduction of TST will be phased in as soon as health care workers are trained to read TST results and after demonstration projects have identified any operational problems that need to be addressed. People should still be initiated on IPT using previous guidelines until the health system is able to implement TST for all people living with HIV.

According to the guidelines, people with HIV should take IPT for six months if TST is not available and if active TB has been excluded. The same applies if a person tests TST negative and is not on antiretroviral therapy. However, if a person tests TST negative and is on ARVs, they should continue IPT for 12 months. The latter recommendation is based on <u>the results of a South</u> <u>African study</u> conducted in Khayelitsha which found that a 12-month course of IPT in people taking antiretroviral therapy reduced the risk of developing active TB by 37% during a follow-up period of at least 12 months. In that study TST was not required and so there is no information about the relative performance of IPT according to TST status in South Africans taking antiretroviral therapy. (Rangaka).

Those who test TST positive should take IPT for 36 months, regardless of whether or not they are also taking ARVs. Pregnant women should not be excluded from receiving IPT, and the same guidance should be followed for pregnant women.

The Department of Health has already started training health care workers on the new guidance.

One of the main barriers to implementing the scale up of TST is that patients need to return to the health facility 48 hours after the test is done to have the result read. This burden often results in a loss to follow-up with patients not returning to have the results read.

According to the South African guidelines, if there are no signs of TB, all people living with HIV should be started on IPT unless the person is using alcohol or if there are adherence or side-effect concerns. In 2011/12, the South African Department of Health initiated 373,073 people on IPT and 91% of all people living with HIV were screened for TB.

However, as highlighted in a study conducted within the provincial Eastern Cape Department of Health in South Africa, also presented at the launch of the guidelines, there were already problems in the implementation of the previous IPT guidelines in South Africa. The study showed that the IPT guidelines are not known about and that many doctors and consultants are not committed to the implementation of the guidelines.

One of the main barriers is that TST is only conducted by TB nurses as most nurses are not confident to read the TST results. Also, there is not enough focus on training nurses already responsible for antiretroviral treatment initiation and monitoring to read TST results.

Furthermore many health care workers have fears regarding isoniazid toxicity and resistance and are hence reluctant to initiate patients on isoniazid.

One of the recommendations made in the study was to develop TST standard operating procedures where all patients could receive TST on a Monday and all nurses would be able to read the results on a Wednesday or Thursday morning at allocated times. This could reduce the waiting time for patients who spend hours waiting to have their TST results read at the health facilities.

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### ARV and TB drug supply issues threaten South Africa's ARV programme

HIV activist groups in South Africa are calling on the Minister of Health to address drug supply chain problems which are causing HIV and tuberculosis (TB) drug stock-outs in the country's Eastern Cape province.

According to a report launched at the 6th South African AIDS Conference by a coalition consisting of the Rural Health Advocacy Project (RHAP), Doctors Without Borders (MSF), the Treatment Action Campaign (TAC) and SECTION 27, 40% of the 70 facilities surveyed by MSF and TAC during May 2013 in the Mthatha catchment area in the Eastern Cape province had experienced HIV and/or TB drug stock-outs. More than 100,000 people, on antiretrovirals (ARVs) or TB treatment, depend on 300 facilities served by the Mthatha depot.

Medical staff at 24% of the affected facilities were forced to send patients home without treatment because they experienced stock-outs of essential HIV and TB drugs. These stock-outs were reported to last, on average, 45 days at a time and have been ongoing since October 2012. The organisations estimated that at least 5494 adults were not able to take some of their ARVs and 561 children were sent home without treatment since September 2012 when the drug supply issues began.

Lamivudine (3TC), tenofovir, nevirapine, efavirenz, paediatric ARV formulations and *Rifafour* (a fixed-dose combination of four TB drugs) are the main medications affected.

"This situation is catastrophic. It means many thousands of people living with HIV have risked treatment interruption for months now. The stock-outs consequently undermine clinical benefits of life-saving ARV treatment. Over time, more deaths will occur as a result and the likelihood of increased drug resistance is significant," says Dr Amir Shroufi, Deputy Medical Co-ordinator for MSF in South Africa. There have been a number of reports of patients receiving dual or even monotherapy in the Eastern Cape and Gauteng.

"I have been taking ARVs since 2008. Each year this [a stock-out] happens at least six times. I go to the clinic and they tell me there is no medication for me," said a 36 year-old unemployed man who lives in a rural village in the Eastern Cape.

### "The national Department of Health should create an emergency team to respond to stock-outs – given the extent, importance, and frequency of essential drugs stock-outs nationwide." John Stephens, SECTION 27

"It is very difficult for patients. We are telling them to adhere, but when they arrive at the clinic, which can take up to two hours to access by car in the rural Eastern Cape areas, they are told there is nothing for them and that they must come back another time," said Vuyokazi Gonyela, the TAC Eastern Cape District Organiser.

On 10 October 2012, staff at Mthatha depot in the Eastern Cape staged a strike, following which 29 individuals were suspended, leaving the depot with only 10 working employees. Coupled with chronic supply chain issues, this precipitated widespread drug stock-outs in the region.

The survey followed an intervention by MSF and TAC volunteers during December 2012, which continued for three months, to

respond to the burgeoning Mthatha depot crisis by supporting staffing, managing and ensuring drug delivery at the depot. This intervention helped to clear the backlog of drug orders and to bring the depot closer to normal levels of functioning.

"The MSF/TAC emergency intervention in the Mthatha depot from December 2012 to March 2013 has shown that it is possible to correct a disastrous situation with limited resources, even if the impact remains short-lived without large systemic changes and action from the provincial Department of Health", said Gonyela, who led the intervention.

The main causes for the drug supply problems are the lack of an early warning system for facilities to be able to report potential shortages, drug suppliers failing to meet tender quotas, government failing to pay suppliers, and poor ordering practices at health facilities and medicine depots.

South Africa has one of the largest ARV programmes in the world with over 2 million people initiated on ARVs in the public sector. However, drug stock-outs are occurring across the country and are not limited to HIV and TB medication, but extend to other basic chronic medication such as hypertension (blood pressure) and diabetes medication, according to Dr Francois Venter, Deputy Director of the Wits Reproductive Health and HIV Institute (WHRI). This was reiterated by a number of healthcare workers attending the conference.

"The national Department of Health should create an emergency team to respond to stock-outs – given the extent, importance, and frequency of essential drugs stock-outs nationwide," said John Stephens of SECTION 27.

The organisations are recommending that when stock-outs are identified, the underlying reasons must be established for each and appropriate action undertaken, and the individuals responsible for the stock-outs must be clearly identified.

In response to the drug supply problems, the organisations have set up a civil society monitoring group which will focus on solving the drug supply problems and continue monitoring drug supply across the country.

"We are aware of the drug stock-outs across the country and share your concerns," said Helecine Snyman, Head of Affordable Medicines at the South African Department of Health.

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### Higher CD4 threshold for ARV initiation did not overwhelm HIV clinics in Khayelitsha, South Africa

Successive expansions in eligibility for antiretroviral therapy in South Africa have not resulted in sharp increases in ART initiation in Khayelitsha, South Africa, a large township outside Cape Town,

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according to a study presented by Médecins Sans Frontières (MSF/Doctors without Borders) at the 6<sup>th</sup> South African AIDS conference.

In 2010 the WHO revised the adult ART guidelines and raised the ART initiation threshold to "secure the greatest likelihood of survival and quality of life for the greatest number" of people living with HIV. The new guidelines were implemented incrementally in South Africa with all pregnant women and TB/HIV co-infected people being initiated on ART at a CD4 of 350 cells/mm<sup>3</sup> from April 2010, and all people with a CD4 below 350 cells/mm<sup>3</sup> being initiated on ART from August 2011. In April 2012 eligibility for treatment was extended to all HIV-positive people diagnosed with tuberculosis.

In June 2013 WHO issued new guidelines recommending that all adults with CD4 cell counts below 500 should receive antiretroviral treatment. Concerns have been expressed regarding the new guidance, such as the substantial increase in demand for ART, displacement of patients in urgent need of treatment due to exhaustion of limited treatment budgets, saturation of the capacity of health services and exposure of patients to ART for longer.

In order to evaluate the impact of guideline changes on the demand for treatment and service utilisation in an area with a very high prevalence of HIV, researchers from MSF Khayelitsha and the University of Cape Town carried out a cross-sectional study comparing the uptake of ART across four time periods related to the changes in South African treatment guidelines outlined above. Khayelitsha has a population of approximately 500,000 people with 16 health facilities providing HIV and drug-resistant TB care. There are 25,875 patients on ART at the moment.

The researchers found that the increase in the number of ART initiations has remained steady, with the median increase per year being 20% between 2007 and 2012.

However this average conceals considerable variation. The biggest year-on-year increases in treatment initiation occurred in 2008 and 2009, before South African treatment guidelines expanded treatment eligibility beyond a CD4 cell threshold of 200 cells/mm<sup>3</sup>.

The number of people initiated on treatment actually fell by 2% in 2011. The small decrease in initiations in 2011 may be due to stabilisation of coverage under these guidelines. Another possible explanation is capacity constraints; the nurse mentoring programme was being scaled up during 2011 to enable more nurses to initiate patients on ART.

The study also found that the average CD4 cell count at which people initiated treatment rose from 135 cells/mm<sup>3</sup> to 221 cells/mm<sup>3</sup> between 2008 and 2012. Yet, although the proportion of people initiating treatment with symptomatic WHO stage 4 HIV disease fell from 21% to 11%, the total number remained stable. In other words, although the proportion of seriously ill people starting treatment declined – meaning that the vast majority of people starting treatment now have less complex requirements – the number of seriously ill people starting treatment remains the same, implying that the burden on clinical services has grown substantially.

"Our concern should not only be about initiating patients at a higher CD4 count, but to find ways to get patients to access care earlier when their CD4 counts are higher," said Gabriela Patten of MSF.

### Decreased time to ART initiation after nurse midwife HIV and Antenatal care integration

MSF also found a decreased time to ART initiation in pregnancy when HIV and antenatal care became integrated in Khayelitsha. The

median time to initiation was 7 days after integrating services, compared to 36 days to initiation under previous arrangements.

The proportion of women initiating ART before delivery also increased from 55% in women at the same service, using doctors on specific days of the week, to 85.6% when women were initiated on ART by nurses.

2670 women were booked for antenatal care from May to November 2012. Excluding women with known HIV-infected status and who were already on ART, 95% of women tested for HIV (2286 of 2670). Of those who tested at booking, 36% were diagnosed HIV-positive (562 of 2286). HIV prevalence (among all women) was 31% (834 of 2670). 48.2% of women who tested in pregnancy were eligible for ART at a CD4 count of less than 350 cells/mm<sup>3</sup> (271 of 562). Of these women who were eligible for ART, 85% initiated prior to delivery and 95% of all initiations were done by two midwives authorised to initiate ARV treatment.

The median time to initiation was seven days (IQR 5-12 days). 60% of women initiated within one week of eligibility and 78% within two weeks. Some of the reasons for delay in ART initiation were lack of readiness for ART or not having disclosed their status to their partners (18%), obstetric complications or transfer to a referral hospital (16%), work or travel schedule (11%) or being at less than 14 weeks of gestation (6.8%).

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## South African AIDS conference discusses new aspects of male medical circumcision

Three studies examining new aspects of Voluntary Medical Male Circumcision (VMMC) were presented at the  $6^{th}$  South African AIDS conference.

The first looked at the sexual practices of men accessing VMMC services, the second compared the outcomes of VMMC for HIV-positive and HIV-negative men and the third evaluated the acceptance of VMMC amongst secondary-school learners.

Randomised clinical trials conducted in Kenya, South Africa and Uganda have demonstrated that male circumcision reduces the risk of HIV acquisition by between 50% and 75% and that this effect is sustained for at least five years.

Circumcision programmes are being implemented widely as part of HIV prevention activities in southern Africa. Operational research is evaluating the perfomance of these programmes and their impact on sexual behaviour.

### Sexual behaviours among MMC participants

Abstinence from sexual intercourse during the wound-healing period after medical circumcision is presumed to be important for reducing the risk of HIV acquisition during this period through unhealed wounds.

A study in Kwazulu-Natal evaluated the resumption of sexual activity among men who underwent medical circumcision. 76.1 % of 775 men who received VMMC observed the six-week abstinence recommendation, with the remainder having post-operative coital

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activity by five weeks post-operation. Men with more than one partner were less likely to observe the six-week abstinence recommendation (p<0.001).

68.6% of the participants indicated that their sexual partners were unwilling to test for HIV - 46.9% of these already knew their status, while 22% were male partners who had already been tested prior to undergoing circumcision.

50.1% of the participants had a mean of more than one partner before circumcision. 65.6% of participants had used a condom at last sexual intercourse. Condom use began to decline eight months after the circumcision. At eight months, condom use had declined to 54.8% and to 52.1% at 12 months (p<0.001).

Among the study participants, the HIV incidence was 0.3% or 2.9 per 1000 person years, after 12 months. The prevalence of STI symptoms before circumcision was 18.4%. The incidence of STI symptoms was 0.7% or 1 per 1000 person years after 12 months.

### **Outcomes in HIV-positive men**

MMC has health benefits such as prevention of STI transmission and urinary tract infections that might facilitate HIV transmission. For this reason, MMC programmes should not discourage HIV-infected men from undergoing MMC.

The Perinatal HIV Research Unit (PHRU) compared circumcision outcomes (such as adverse events, specifically wound infection) in HIV-positive and HIV-negative men through a retrospective medical record review of all men circumcised in February 2011.

Prior to circumcision, 26 (3.9%) of the males were found to be HIV-infected. The median CD4 count was 323 cells/mm<sup>3</sup> (IQR: 270-449). Of all the HIV-infected males, none developed wound infection post-circumcision, but five of the 648 HIV-negative males did (0.8%).

#### VMMC uptake in secondary schools

Medical circumcision is most likely to reduce a man's risk of HIV acquisition if it takes place before he becomes sexually active, or as soon as possible after sexual debut. For this reason, targeting of young men through secondary schools is a key means of maximising the population impact of medical circumcision on HIV transmission.

Researchers reported on a male medical circumcision programme among secondary school learners in the Vulindlela rural district in KwaZulu Natal province, 170 km from Durban

Boys were recruited from 42 secondary schools in the sub-district through a three-phase recruitment strategy which involved community consultation, MMC awareness-raising in schools during break-time and peer recruitment.

Peer recruitment was implemented though a local NGO, Zimnandi Zonke.

4873 MMCs were performed between March 2011 and December 2012. Only one male experienced an adverse effect and this was minor and self-resolving. 3575 (73%) of the males circumcised by the programme were between the ages of 15 and 19. The acceptability of VMMC was high among this population of school learners.

HIV testing and counselling (HCT) was provided at the school or at the study clinic. Learners who tested positive were referred to the study clinic or a primary health care clinic. The MMC procedure took place on Saturdays and post-operative procedures were undertaken in schools to avoid disruption of schooling.

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### Linezolid effective in treating XDR-TB in Khayelitsha, including for those HIV co-infected

New evidence from South Africa demonstrating how the high-strength antibiotic linezolid is effective in treating extensively drug-resistant TB (XDR-TB), even in patients with HIV, was presented at the 6<sup>th</sup> South African AIDS conference.

<u>Preliminary results</u> of a study conducted in South Korea have shown that the addition of linezolid to a failing regimen for the treatment of XDR-TB resulted in culture conversion and no relapse after completion of treatment in 13 patients. Final results of this study in HIV-negative patients are awaited in late 2013.

Data are lacking on the use of linezolid in HIV-positive people, particularly in respect of efficacy and safety while taking antiretroviral therapy.

Médecins Sans Frontières (MSF/Doctors without Borders') carried out a pilot programme in which it evaluated the use of linezolid as part of community-based drug-resistant TB treatment in Khayelitsha. The data reported at the South African AIDS Conference concerned the outcomes of 16 patients treated with linezolid as part of a combination of drugs – including six HIV-positive patients – over a two-year period. To date, 71% of these patients have 'culture-converted' which is an early indicator that the two-year treatment regimen will be successful.

Nine of the patients had pre-XDR or XDR TB, seven patients had standard M/XDR treatment failure and the median treatment duration was eight months. Ten (71%) culture converted (three of which are HIV-positive), and are still culture negative and are receiving ongoing treatment. Three patients (21%), experienced treatment failure within the first nine months and are all now deceased. The time to death after treatment withdrawal was one to four months. One (8%) HIV-negative patient remains culture positive after three months and is receiving ongoing treatment.

MSF's linezolid pilot programme – one of the first in Africa to include patients co-infected with HIV – suggests that linezolid's efficacy is not compromised when patients are also taking HIV treatment.

MSF reported that the first patient to be cured of XDR-TB with a linezolid-containing regimen completed her course of treatment on 16 August 2013. Phumeza Tusile received treatment in a community setting at the Lizo Nobanda TB Care Centre in the Western Cape province.

"What makes Phumeza's story inspiring is that when she started, her chances of cure were even less than the 20% treatment success rate that we often associate with XDR-TB diagnosed patients who are offered the standard XDR-TB treatment regimen," said Dr Jennifer Hughes, MSF TB doctor and Phumeza's treating physician. "Phumeza's cure is nothing short of miraculous, and is

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due to access to a more effective drug and her sheer determination to beat the disease."

Yet access to the drug in South Africa is limited due to high prices.

Linezolid offers XDR-TB patients facing few treatment options new hope, but pharmaceutical company Pfizer is the only supplier in South Africa and holds several patents on linezolid in the country, resulting in high prices that prevent the wider use of the drug for DR-TB. A six-month supply can cost R123,000 (USD 12) in the private sector. The South African Department of Health pays USD 29 per 600mg tablet, which means that to treat one patient with linezolid daily for six months will cost USD 5; MSF must pay the private sector price of USD 58 per tablet.

"As linezolid is only one part of an already expensive treatment regimen, we've seen that the high cost in both the public and private sectors limits doctors' willingness and ability to prescribe the drug for their patients," says Julia Hill, MSF Access Campaign Advocacy Officer in South Africa.

A generic version of linezolid manufactured by the Indian pharmaceutical company Hetero costs US\$2.50 per tablet — over 90% cheaper. The product has been approved as a good-quality generic product by the Global Fund's Expert Review panel.

Local evidence of linezolid's use as a DR-TB drug is good news for South Africa, where over 10,000 people a year are diagnosed with the disease and whose chance of survival is typically less than 50% using the standard treatment regimen. Generally, between 5 to 8% of DR-TB patients are resistant to the few second-line drugs available and are considered to have pre-XDR or XDR-TB.

The MSF data from Khayelitsha contribute to a growing body of evidence on linezolid's effectiveness against DR-TB, with results similar to studies in the US, Europe and Asia, which have shown a combined treatment success rate of 68%. While linezolid, like most drugs used to treat TB, has several negative side effects with long-term use, it offers patients hope of treatment when other options have run out.

Dr Vivian Cox, Medical Co-ordinator of MSF's Khayelitsha project, urged the South African Department of Health to re-open its TB drug tender for linezolid to a broader range of bidders. She also urged that generic versions of linezolid should receive fast-track registration in South Africa, and encouraged the South African government to consider whether it can use flexibilities available under international trade agreements, such as compulsory licensing, in order to reduce the price through local generic manufacture.

### News from the 2nd International HIV Social Sciences and Humanities Conference

### **By Laura Lopez Gonzalez**

### South African couples living with HIV are missing out on safer conception advice

Clinicians and counsellors may understand the right of people living with HIV to have children, but that doesn't always mean they agree with their choices, according to new research that shows health workers may not be prepared to offer patients and couples living with HIV the best counselling on conception.

Research conducted among 25 doctors, nurses and counsellors at two antiretroviral (ARV) clinics in greater Durban, South Africa, has found that although clinicians and counsellors recognised HIV-positive people's reproductive rights, health workers are not proactively engaging with patients on reproductive health needs and tended to moralise about the choice to have children, for a wide range of reasons. According to Deborah Mindry of the University of California Los Angeles' Centre for Culture and Health, her study's results point to a need for training for service providers and more research into <u>safer conception options</u> for resource-poor settings.

### **Unmet needs**

"With increased availability of ARV treatment, men and women with HIV are living longer and healthier lives," said Mindry, speaking at the <u>2nd International HIV Social Sciences and Humanities</u> <u>Conference</u> in Paris this week. "Many of these men and women are of reproductive age and are either having children or certainly are expressing desires to have children."

With the world's largest ARV programme, South Africa currently has more than 1.7 million people on ARVs and indications are that these people are living longer.

<u>Studies conducted in the country</u> have found that as many as half of all people living with HIV would like to have children, but only about 20% of HIV-positive women and 6% of men reported discussing these desires with healthcare providers.

In June 2011, Dr Linda-Gail Bekker of South Africa's Desmond Tutu HIV Foundation and colleagues published <u>guidelines</u> on safer conception for couples in which one or both partners are living with HIV. The guidelines outline several options for safer conception, depending on who in the relationship is living with HIV and stress that the starting point for clinicians is regular discussion with patients.

### **Patients and choices**

However, two years on, these guidelines haven't been officially adopted and service providers and healthcare workers aren't talking to patients about their options – instead they are waiting until their patients – generally female – approach them.

According to Mindry's research, which was conducted in one rural and one urban clinic, women living with HIV from urban areas were more likely to ask about conception options. Most people who knew about safer conception options had heard about them on television, rather than from clinicians.

Healthcare workers sometimes discouraged patients for a variety of reasons including marital or socioeconomic statuses, according to the research.

"I normally talk to them like a health educator and then talk again as a mother ...look at all the reasons why they would want to be pregnant," said one nurse in rural clinic surveyed by Mindry. "Like somebody who is unmarried or a single person and they want to have a child, I talk to them and discuss...maybe they end up seeing the importance of waiting for the right time to have a baby."

However, ultimately all of the healthcare workers surveyed by Mindry recognised that it was a patient's right to choose whether or not to have a child.

"We, as counsellors, we were not taught to decide; what we do is to give facts, and we ask those questions," said one counsellor surveyed in the research. "Then a client is able to tell you their story, but we can't judge and we cannot say you can't, but we give options

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and make sure that the patient is given all the information she needs."

Mindry also found that providers were more likely to support a patient having a first child than they were to support patients who already have multiple children, citing concerns for the children's health. This suggest that providers may need training not only on biomedical options for safer conception and catering for the emotional needs of serodiscordant couples around disclosure, but also about how to separate their own moral judgements from their work as healthcare workers.

While sperm washing is available in the South African private sector, it remains too costly for most in the country. Therefore, Mindry also called for research into how to make this safer conception tool less expensive and more available, as well as additional research on how to cater for infertility among couples living with HIV from resource-poor settings.

Reference

Mindry D et al. Providers balancing reproductive rights, needs, and safer conception knowledge. 2nd International HIV Social Science and Humanities Conference, Paris, session CS51, 2013. <u>View the abstract</u> and <u>download the presentation slides</u> on the conference website.

### What HIV self-testing may mean for couples

A study in Malawi is offering glimpses into why couples opt for HIV self-testing – including issues of trust and honesty – and what it may mean for their relationships. Moses Kumwenda from the Malawi-Liverpool Wellcome Trust Clinical Research Programme presented findings at the recent <u>2nd International Conference for the Social Sciences and Humanities in HIV in Paris.</u>

Self-testing for HIV, using the *OraQuick* oral HIV antibody test, has been found <u>highly acceptable in Malawi</u> and <u>other countries</u>. This option, in which people carry out the test themselves without a third party present, may overcome barriers such as the need to attend a health facility for testing, or fears of breaches of confidentiality. In Malawi, <u>it has also been shown to increase the</u> <u>uptake of HIV treatment.</u>

Launched in 2012, the Hit TB Hard study in Malawi investigates whether intensified tuberculosis (TB) case finding can curb new TB cases. As part of this five-year cluster randomised trial, HIV self-testing is offered in half of the trial's 28 clusters in order to facilitate targeted HIV/TB prevention.

To evaluate the impact of self-testing on care-seeking and couples' relationships, researchers kept in touch with 66 people, including seven serodiscordant couples, for a year after they had had an HIV self-test.

The researchers found that participants opted for self-testing for a number of reasons, including risk behaviour, mistrust within the couple, and a desire to either confirm an earlier HIV test result or check the effectiveness of local 'faith healing'. Some individuals used self-testing as an opportunity to disclose a previously known HIV status:

"We were not using condoms because I had not told my wife that I am positive. We were living normally as a family because she did not know and I was so afraid to tell her."

Couples struggled immediately after results to deal with feelings of blame and disbelief, with men in particular being less willing to accept results. This led some couples to re-test, as advised by both researchers and the *OraQuick* self-testing kits, but also prompted others to incorrectly assume that HIV discordance within longstanding relationships indicated resistance to infection among partners who had remained HIV negative.

"I told him that we should use condoms," reported one woman who had tested negative for HIV while her husband was HIV positive. "He told me, 'why is it that all this time you have not been infected? We should live the way we have been living.'"

Men, who accounted for 44% of all those opting for self-testing as part of the trial, generally had a harder time accepting the need to practice safer sex than women. The study found that, while self-testing increased the ability of HIV-negative partners within discordant couples to negotiate condom use in the short term, men largely wanted to continue practicing unsafe sex.

"We found that within discordant couples – regardless of which partner was HIV-positive – males still preferred unprotected sex while women were more concerned about preventing HIV transmission," Kumwenda said. "Some women reported trying to protect their marriages and the respect that they enjoyed in the community by accepting whatever their husband was telling them to do."

One HIV-negative woman said:

"When you say no to unprotected sex, he would ask you 'where should I go to have sex?' I married you to be my wife."

Social norms regarding definitions of a "good wife", including the need to sexually satisfy their partners and to bear children, were cited as some of the reasons that women continued to be coerced into unsafe sex – as were local beliefs that unprotected sex during pregnancy was important to infant development.

While couples also reported experiencing fears regarding the future of their relationships after self-testing, most couples were still together a year after learning of their HIV statuses. Separation and physical violence were only reported in one couple with a pre-existing history of domestic violence.

Preliminary results suggest that, while HIV self-testing may not introduce violence into relationships, it may exacerbate it in relationships in which it already exists. This may indicate a need for relationship counselling within HIV testing.

"There needs to be specialised counselling," Kumwenda said. "As testing is designed now, there is only pre- and post-test counselling but there is nothing to assist couples who already have issues."

Dr Nicola Desmond, also with the Malawi-Liverpool Wellcome Trust programme, said that a larger study into the relationship between gender-based violence and self-testing involving 300 participants is ongoing.

### Making the move to self-testing

The study comes as the World Health Organization works to develop guidelines on HIV self-testing following the first-ever WHO meeting on the subject in April 2013.

South Africa, Kenya and Malawi are currently considering adopting HIV self-testing to reach pockets that current testing campaigns continue to miss, according to Nicola Desmond.

"In Malawi, I think there's the realisation that HIV testing uptake is 'pocketed' in the sense that there are certain groups being missed either for initial or repeat testing," she said. "In Malawi, we have HIV testing campaigns once a year with door-to-door and mobile testing services but there are a lot of people who are being missed."

"We know that self-testing addresses (concerns) of convenience and confidentiality and that these are some of the key things that make testing attractive," she added.

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### Medical male circumcision campaigns face cultural challenges in southern Africa

Campaigns to circumcise tens of thousands of men in southern Africa are falling victim to lingering acceptability issues six years after the procedure was first recommended to help prevent HIV infection, according to speakers at the <u>2nd International Conference</u> for the Social Sciences and Humanities in HIV in Paris last week.

The World Health Organization (WHO) and UNAIDS began recommending medical male circumcision as an HIV prevention tool in 2007, following three large-scale randomised clinical trials. Conducted in Kenya, South Africa and Uganda, these trials found that medical male circumcision reduced a man's risk of contracting HIV by about 60%. Following international recommendations, high HIV-prevalence countries in both east and southern Africa announced plans for large-scale circumcision campaigns.

Now researchers say campaigns in Swaziland, Botswana and Malawi are failing due to concerns from men, communities and countries about whether medical male circumcision is appropriate for them.

### Programmes have paid insufficient attention to the social meaning of circumcision in different settings

Social scientists at the Paris meeting argued that those implementing medical male circumcision had paid insufficient attention to the social meaning of circumcision in different settings (it is often a marker of ethnic or religious difference, or associated with a particular form of masculinity). While there is evidence that the intervention has efficacy (in ideal conditions), it will only be effective (in real-world settings) in certain circumstances, when contextual factors including social networks, political debates and cultural values are favourable.

Biomedical researchers had "divorced any sort of understanding of the efficacy of these tools from how they operate in real people's lives", said Richard Parker of Columbia University. "That's what's missing from the evidence," he said, arguing for more social science research to shed light on the issue.

### Threats to masculinity, tradition and sovereignty

In Swaziland, about one-quarter of all people between the ages of 15 and 49 are estimated to be living with HIV. With the world's highest HIV-prevalence rate, Swaziland was an early adopter of WHO recommendations. In 2009, the country developed plans to circumcise 150,000 males within two years. But by 2011, the country had only met about 12% of this target, according to Alfred Khehla Adams of the Universiteit van Amsterdam.

To find out why circumcision had been so unpopular among Swazi men, Adams interviewed men in the Kwaluseni district of Manzini, Swaziland through a mix of focus group discussions and interviews. He found that because men feared reduced sexual pleasure and possible adverse effects, Swazi men felt the procedure threatened their notions of manhood.

"A real Swazi man is defined as someone who has a wife and children, and is able to take care of family," Adams told the conference. "In order to have a wife and children, a man has to be sexually functional – the issue of circumcision introduced a threat to this."

Nonetheless, the three large randomised clinical trials found that only a small percentage, between 1.5 and 3.8%, of circumcisions resulted in complications such as wounds or swelling.

Men also reported that they did not see the value in medical male circumcision when continued condom use was still advised following the procedure.

"They tell you to circumcise and also use condoms, why?" said one uncircumcised man during a focus group. "This thing is not 100% effective so why don't you just leave the circumcision thing and condomise?"

Research from Botswana also points to lingering acceptability issues in the country, which in 2009 committed to medically circumcise 100,000 men each year. In 2012, the country was able to circumcise about 40,000 men, falling short of the targets that it is under pressure from the World Health Organization to meet, according to Masego Thamuku of the University of Bergen.

Conducting research in Mochudi, Botswana, Thamuku found that national circumcision campaigns that were initially well received by traditional leaders and communities had fallen out of favour. This was largely due to the way campaigns have been publicised and carried out among Tswana communities that already practice traditional circumcision via traditional initiation schools.

### Public campaigns breached notions of privacy and secrecy attached to traditional circumcision

"In 2009, three cohorts of initiation schools were brought into the clinic to be circumcised," said Thamuku during her presentation at the Paris conference. "In 2011, everything turned all around – the public campaigns had breached traditional privacy."

Not only had campaigns using radio and public events, as well as female nurses, breached notions of privacy and secrecy attached to traditional circumcision, but also they were seen to have eroded the kind of kinship fostered by traditional schools in which men learned the rules of manhood as part of a rite of passage. Following from this, Thamuku's interviews with men and implementers of circumcision revealed that there were doubts in the community as to whether medically circumcised men could be seen as "real men" alongside those who had been traditionally cut.

Justin Parkhurst of the London School of Hygiene and Tropical Medicine suggested that the government of Malawi had actively resisted international pressure to implement a prevention method imposed on it by donors.

While medical male circumcision is usually framed as a technical issue, Parkhurst said that it could be deeply political. In Malawi, information about circumcision was understood in the context of tensions between Christians and Muslims. Local knowledge – such as higher HIV prevalence in regions with high traditional

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circumcision rates – was privileged and the findings of international researchers questioned. Resistance to circumcision became part of a broader challenge to the country's dependence on Western aid.

#### **AIDS experts' ambivalence**

But while most speakers suggested that public health experts and international organisations had been unquestioningly enthusiastic about medical male circumcision, a very different analysis came from Ann Swidler of the University of California.

In her view, the attitude was much more awkward and ambivalent. Examining <u>a key WHO and UNAIDS document from</u> <u>2007</u>, she found the authors reluctant to accept the overwhelming scientific evidence, with the document full of caveats. The document insists that circumcision should be provided alongside a comprehensive package of HIV prevention interventions. Swidler argued that this obscures the fact that male circumcision has a proven efficacy whereas existing interventions such as voluntary counselling and testing or programmes to promote and distribute condoms do not.

### "The lack of enthusiasm for male circumcision has to do with the fact that it doesn't push any of our buttons" Ann Swidler

One reason for the reluctance around circumcision, she said, is that it touches on cultural sensitivities and anxieties, including those around about neo-colonial relationships between Europeans and North Americans, on the one hand, and Africans on the other.

But it goes beyond this. The empowerment struggles of women and gay men, as well as a broader aspiration to individual autonomy and self-determination in many contemporary societies, have powerfully shaped the "moral imagination" of people working on the response to HIV and AIDS, she argued.

"The lack of enthusiasm for male circumcision has to do with the fact that it doesn't push any of our buttons," she said. The intervention does not require sustained behaviour change or a transformation of gender relations. "We don't have to train people; we don't have to teach them to be different kinds of human beings," she said.

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