Detailed commentary on updated ART guidelines

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On 1 April 2010, South Africa adopted new guidelines for the clinical management of HIV/AIDS. On this date the following documents were published by the South African National AIDS Council (SANAC):

- **Clinical Guidelines for the Management of HIV&AIDS in Adults and Adolescents 2010**
- **Clinical Guidelines: PMTCT (Prevention of Mother to Child Transmission Guidelines) 2010**
- **Guidelines for the Management of HIV in Children 2010**

Copies of these documents can be found on the SANAC website at http://www.sanac.org.za/resources/art-guidelines

The guidelines for HIV counselling and testing (HCT) are also being updated but must still be finalized and published for distribution. South Africa will launch a massive testing campaign which aims to test 15 million people by July 2011. Through this campaign and the updated treatment guidelines, government aims to double the number of people on antiretroviral therapy (ART) in the next year.

Government will also be expanding its prevention efforts through the rollout of voluntary medical male circumcision (VMMC). VMMC will be immediately rolled out in KwaZulu Natal. VMMC will be rolled out in the Northern Cape and Mpumalanga by December 2010 and in all provinces by 2011.[1] South Africa?s VMMC policy must be finalized and made publically available for education and dissemination.

It is important for all people, particularly patients and healthcare workers, to become familiar with the updated guidelines and new policies to ensure that they are properly implemented in all facilities at a district and provincial level.

This is the first published update to the ART guidelines since 2004. Given that South Africa has more people on ART than any country in the world (nearly a million), this is unacceptable. An efficient and effective process for regularly updating the guidelines so that they are cognisant of scientific developments is needed. Expert clinicians should have much more say in the guidelines. There should also be community involvement.

Below is an overview of some of the key changes to be rolled out under the new guidelines.

1) Expanding Access to antiretroviral therapy (ART) and Integration of Services

The new guidelines must be implemented in all facilities that provide ART. Currently there are 496 facilities providing ART which government aims to expand to 4,333 facilities by March 2011.[2] To achieve this, the Department of Health (DoH) is working to accredit more ART sites. The DoH will also accredit all antenatal care facilities and TB testing and treatment centers to provide ART. To accelerate accreditation, the process has been decentralised from a national to a provincial level. Provinces have been given a facility readiness tool to assess whether facilities are ready to provide ART.

Lack of access to ART sites and prohibitive transport costs remain a serious barrier to treatment, particularly in rural

areas. The decentralization of ART provision will improve access to, uptake of and adherence to HIV treatment and care. Integration of services is vital in areas where patients struggle to access facilities.

2) Improving 1st line ART regimens

The updated guidelines will begin to phase out the use of stavudine (d4T) and start replacing it with tenofovir (TDF). While the use of d4T has saved thousands of lives it should be phased out given that there are now better drugs available with fewer side effects at competitive prices. Under the new guidelines all adults and adolescents initiated onto treatment will be given TDF, unless they have kidney problems. Also all patients experiencing side effects on d4T or zidovudine (AZT) will be switched to TDF. D4T side effects include lactic acidosis, lipodystrophy, neuropathy and facial wasting. TDF has been associated with kidney damage in a small percentage of patients and this must be monitored. Patients on d4T and AZT experiencing no side effects will remain on these regimens. TDF can be given once a day, as can 3TC and EFV, so patients starting ART can look forward to taking all their tablets only once daily.

Replacing d4T with TDF will reduce side effects and the need for treatment switches. Given the negative perception of the side effects associated with d4T, this should also increase uptake and adherence.

Government has also committed to purchasing fixed dose combinations and co-packs when possible in the upcoming tender.[3] This is an important improvement that will simplify regimens for healthcare workers and patients. A fixed dose combination combines all three in a regimen into one or two pills and a co package combines all of the drugs in a regimen into a single user friendly blister.

3) Nurse initiated ART for treatment and prevention

The new guidelines aim to enable nurses to initiate ARVs for treatment and prevention. To date 357 nurses have been trained to initiate and manage ART.[4] Through SANAC, TAC and other civil society organizations have long been advocating for the implementation of task shifting to reduce bottlenecks caused by human resource shortages. Allowing nurse initiated ART is essential to expanding access to ART and particularly in rural areas. Nurse initiated ART will also reduce waiting lists. Reducing waiting lists is necessary to implementing earlier treatment as currently the majority of patients in South Africa are only able to access treatment once their CD4 count has fallen below 100.[5] Nurse managed ART programmes in Swaziland and Mozambique have shown similar outcomes to doctor managed programmes.[6]

4) HIV and tuberculosis (TB)

TB is the leading cause of death of people living with HIV. At the same time South Africa is facing a drug-resistant TB epidemic. Under the new guidelines, TB patients will now be able to access ART at a CD4 count of 350. Patients with drug-resistant TB (MDR or XDR TB) will receive ART irrespective of their CD4 count. Early access to ART will reduce TB mortality. The integration of TB/HIV services is also particularly important to reduce mortality and improve TB cure rates.

The Department of Health will also expand access to isoniazid preventative therapy (IPT). Currently 8,000 patients have been provided IPT through the public sector. Government plans to increase this figure to 45,000 in the next 12 months.[7]

Under the new guidelines IPT will be given to patients for 6 months. Expanded access to IPT will reduce TB incidence although there is new evidence that IPT is more effective if continued for longer periods. A trial carried out in Botswana has shown that 36 months of IPT is more effective than 6 months for patients with latent TB. However, this intervention is not without complexity. The Botswana trial also showed that 36-month IPT is only beneficial to patients with positive Tuberculin skin test results (a means of diagnosing latent TB). It found significantly increased mortality in patients who tested negative for tuberculin and received IPT. But the new guidelines do not provide for tuberculin

skin testing, probably because these add cost and complexity in operational settings.

An expert consultation is needed to resolve these problems and the guidelines will probably need to be revised soon to reflect the outcome of such a consultation.[8]

5) Early initiation onto ART for pregnant women

South Africa continues to face unacceptably high maternal mortality rates. The maternal mortality ratio in the country is 400-625 per 100,000 live births.[9] Maternal mortality in South Africa is directly related to high HIV prevalence. Between 2005-2007, 59% of women who died maternal deaths were tested for HIV of which 79% tested HIV positive. The new guidelines provide ART for women with CD4 counts below 350 cells/mm3, an improvement from the earlier guidelines and should help reduce maternal mortality, as over 80% of all HIV related maternal deaths occur below this level of CD4.

6) Updated PMTCT regimens

The improved PMTCT regimens will initiate pregnant mothers onto a PMTCT regimen from 14 weeks instead of only 24 weeks, which is in line with World Health Organisation (WHO) recommendations.

Following delivery mothers will be given a single dose of TDF + emtracitabine (FTC). This is called ?the tail? and it is given to mothers to reduce drug resistance given that in time they will need treatment for their own health. A study carried out in Zambia has shown that this is a safe and effective method of reducing resistance.[10] This regimen is also recommended given its simplicity.

It is possible that there are more effective methods to reduce resistance requiring further research to assess the optimum regimen and duration. Further information is available at http://i-base.info/htb/1854.

7) Immediate ART for HIV positive infants

In South Africa high rates of infant mortality are closely linked with HIV. Further, in 2007, 57% of deaths of children under five were due to HIV. To reduce infant deaths it is necessary to reduce the number of infants born HIV positive each year but also to provide comprehensive, quality care to HIV positive infants.

The updated guidelines provide for infants to be given a PCR test at six weeks to determine their HIV status. Infants with HIV will immediately be given treatment. Early treatment of infants is in line with the results of a clinical trial carried out in South Africa showing a 75% reduction in mortality.[11]

First line regimens for infants and children have been updated to replace d4T with abacavir (ABC). This is an important improvement as d4T is not recommended by paediatricians due to its high rate of side effects, as in adults.

It is important to note that lopinovir/ritonavir (LPV/r) is widely used in the new guidelines and particularly in paediatric treatment. Yet, heat stable paediatric tablets are not yet available in the country. Abbott, the patent holder of LPV/r in South Africa submitted a dossier to the Medicines Control Council (MCC) in 2008 for heat stable paediatric LPV/r tablets (lopinovir 100mg ritonavir 25 mg).This has not yet been registered. The MCC must not be a barrier to implementing the new treatment guidelines and must fast track the registration of this formulation prior to the 2010 tender.

8) Pap smears and cervical cancer

Women living with HIV are at higher risk for cervical cancer and they often develop it at younger ages than women that are HIV negative. Cervical cancer is caused by infection of the cervix with the human papillomavirus (HPV).

Women with cervical cancer are 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.[12]

It is important that all women and particularly women living with HIV are able to access regular pap smears. Under the previous guidelines, women were only able to access pap smears every 10 years once they were over the age of thirty. The updated treatment guidelines call for all women that are diagnosed with HIV and have not received a pap smear in the past 12 months to be given a pap smear on their first visit and thereafter every three years if the pap smear is normal.

It is important for women?s health that access to pap smears will be expanded under the updated treatment guidelines.

8) Updated HIV Counselling and Testing Policy and HCT Campaign

The Department of Health will be launching a massive testing campaign on 25 April 2010. The campaign aims to test 15 million people over the next 12 months.

SANAC is finalising the updated HIV Counselling and Testing Policy. Under the new guidelines patients will be routinely offered a test when they enter a facility. It is important to note that the new policy does not support coercive testing and that patients that choose not to undergo HIV testing must still be able to access healthcare services.

9) Voluntary Medical Male Circumcision

With the launch of the updated treatment guidelines and HCT campaign government will also begin to roll out voluntary male medical circumcision (VMMC). SANAC is currently finalizing the VMMC policy.
Three randomized clinical trials carried out in South Africa, Uganda and Kenya have shown that VMMC reduces the risk of HIV transmission for heterosexual men by 60%.

VMMC will be available to men on a voluntary basis with informed consent. VMMC services will be prioritised for men ages 15-49 to ensure maximum effectiveness in reducing new infections. VMMC should also be routinely offered to infants. VMMC is not recommended during the ages of 6 months and 7 years.

Implementation of updated guidelines and policies

TAC supports government in its introduction of the updated policies. Through its district and branch structures, we will disseminate information on the new guidelines and educate members, communities and patients in the facilities TAC works in. We will also provide education on the importance of accessing testing, circumcision and pap smear services.

TAC will monitor implementation of the updated guidelines and policies. We will mobilize communities to respond to implementation gaps through TAC's community health advocacy programme. TAC has committed to inform the Department of Health of facilities that do not have medicines. You can assist TAC in this by reporting implementation problems to info@tac.org.za.

TAC recognizes that the updated policies reflect a new environment of political will and commitment at national level to implementing evidence based policies and meeting the targets set in the National Strategic Plan (2007-2011). This political will must be translated into action at district and provincial level.

Over the past year, through our resources for health campaign, TAC has called for the removal of a number of barriers to scaling up ART and improving health systems. These barriers must be addressed to successfully implement the updated policies. Below is an overview of some of the major issues to be addressed.

· To properly implement the new guidelines and ensure that the HIV Counselling and Testing campaign is sustainable

over time, government must address the shortage of healthcare workers. The updated guidelines allowing nurse initiation of ART are necessary to expanding access to ART. The new guidelines will be implemented at the same time as government launches its HCT campaign. To ensure that provider initiated testing is sustainable over time government should further implement task-shifting to expand the role of community healthcare workers.

Further government must end the ?dry-seasons? of non payment of lay counsellors. Lay counsellors often provide the counselling to patients receiving an HIV test and in cases where they are not present, patients have been turned away from facilities. The policy framework for community health workers (community care givers) is currently under development through SANAC. The policy must expand the roles of community healthcare workers as well as secure employment and wages.

· The upcoming tender is an important opportunity to access better, easier-to-adhere-to treatment regimens at lower prices. The new guidelines are necessary to improve regimens. Government needs to ensure that it purchases sufficient drugs in the upcoming tender to meet the need for treatment. Further government must use this opportunity to simplify regimens for patients, healthcare workers and procurement and supply chains through purchasing fixed dose combinations and co-packs. The MCC has been slow to register new drugs - particularly fixed dose combinations. The MCC must fast track the registration of new drugs and must not become a barrier to implementing the new treatment guidelines.

· Health services must be properly costed and budgeted so that available funding can be used effectively. Funding for HIV/AIDS has been expanded to scale up programmes. TAC is however concerned by the debt accrued by a number of Provincial Departments of Health and the lack of clarity as to how this debt will be financed. Payments of accrued debt must not be taken from budgets for healthcare delivery in the new financial year.

Further, it has been recognized that poor budgeting and poor financial management has led to weak health systems and healthcare delivery. TAC supports government?s move to support provinces to budget for health services through plans to establish a Provincial Finance and Budget Support Unit. TAC also calls for the public release of the Integrated Support Team (IST) reports on the financial and administrative management capacity of the Department of Health and provincial health departments, commissioned by Barbara Hogan during her tenure as Minister of Health in 2008/9.

[1] Health Minister Motsoaledi, ?Implementation Plan to Scale up HIV/AIDS Prevention and Treatment?, presented 17 March 2010
[2] Budget speech of Honourable Dr A Motsoaledi, MP, Minister of Health, delivered to the National Assembly, Parliament of the Republic of South Africa
[3] DoH, ?Presentation to the Portfolio Committee on Health: Strategic Plan and Budget 2010/11-2012/13?, 24 March 2010
[4] Message from Dr. Yogan Pillay, Expansion of HIV Testing and Treatment, 19 April 2010
[5] N Ford et al., Rationing antiretroviral therapy in Africa ? Treating too few, Too Late, NEJM 2008 November 20/ 359, 2233-44
[6] SANAC TTT on Treatment, Care and Support, Building the capacity of the Primary Health Care System for HIV/AIDS diagnosis, care and treatment in South Africa: Task Shifting Recommendation Document, May 2009
[7] Health Minister Motsoaledi, ?Implementation Plan to Scale up HIV/AIDS Prevention and Treatment?, presented 17 March 2010
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2010
[10] B Chi et al., Single dose tenofovir and emtricitabine for reduction of viral resistance to non-nucleoside reverse transcriptase inhibitor drugs in women given intrapartum nevirapine for perinatal HIV prevention: an open-label randomised trial. Lancet. Vol 370:1698-705.
[11] A Voilari at al., Early antiretroviral therapy and mortality among HIV-infected infants, NEJM 2008 November 20. 359, 2233-44
[12] E Shuh, All About Cervical Cancer, Equal Treatment Issue 31, December 2009

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