FINALLY – PMTCT *DUAL* THERAPY

The national health department on 25 January finally announced a new national protocol for prevention of mother-to-child transmission of HIV (PMTCT), adding AZT to the 5-year-old nevirapine-only regimen, but ignoring lamivudine.

Expert HIV paediatricians and clinicians consulted on the protocol had strongly recommended adding lamivudine to AZT for the 7-day postpartum course (known as 'cover the tail' strategy). They had also pleaded for the official PMTCT guidelines to include pregnant women beginning ART at CD4 cell counts of 350. Both recommendations were ignored.

With HIV now the leading cause of maternal mortality, continuing to initiate treatment for pregnant women at CD 4 count levels of 200 runs counter to some of the most compelling scientific evidence available. USA and European guidelines now recommend ARV initiation at a CD count of 350 for all patients. Lamivudine (aka 3TC) is a safe, effective and inexpensive addition to AZT and counter to nevirapine resistance and is included in the World Health Organization's (WHO's) PMTCT guidelines.

Patient loyalty comes second – again

A dramatic example of rigid and punitive national and provincial health bureaucracy came just 5 days after the new protocol was announced. Dr Colin Pfaff of Manguzi Hospital (Maputaland/KwaZulu-Natal) was given written notice of pending disciplinary action for having used dual therapy drugs. The remote Manguzi Hospital has been using dual therapy for PMTCT, the drugs purchased with directly donated UK funds, since August 2007.

By December last year Manguzi had rolled dual therapy out to all of its 10 clinics where 88% of women with high CD4 counts were starting AZT before delivery.

Pfaff's hospital CEO presented him with charges of 'misconduct', saying he was acting on instructions 'from higher up'. He was asked for a written admission or denial of the charges, the latter requiring an 'explanation' of his 'misconduct', within 5 days.

The news stirred up a hornet's nest on doctor internet discussion forums, with comments ranging from 'this is beyond comprehension' to 'interference with one of the few programmes that really works and which cost the DoH not a thing'.

The Southern African HIV Clinicians Society said the incident was 'symptomatic of the lack of initiative and crude politicking that still seems to plague our country's response to HIV'. The matter was expected to blow over by the time *Izindaba* went to print, but it scratched open several old wounds among state sector doctors victimised for leading the fight against HIV/AIDS.

Now available at around 30% of their official post complement in most rural state hospitals, doctors are also concerned that the new official PMTCT guidelines speak of AZT and nevirapine (schedule IV drugs) having to be 'prescribed by a medical officer'.

Task shifting – no grasping of the nettle

This implies that the policy on nurses and midwives (whom the National Strategic Plan on HIV/AIDS acknowledge as vital for the ART rollout to succeed) being banned from prescribing ARVs remains unchanged.[1] The exceptions are a minority of 'rebel' sites in KwaZulu-Natal, Free State, the Western and Eastern Cape – all of which are now world leaders in developing 'best practice'.

Nurses at these groundbreaking sites have appropriate VCT, adherence and drug training and have for years been using the very best and latest TB/HIV guidelines developed by top local clinicians. In the Free State they initially only wrote repeat ARV prescriptions but recently began initiating drug therapy for less complicated cases. The pragmatic 'task shifting' has resulted in dramatically accelerated ARV access, now up to 100% at one northern KwaZulu-Natal site. Careful monitoring has shown properly trained and equipped nurses to be meeting the best standards of professional ART and care.

For the majority of the population however it seems that waiting in long

queues to initiate ARV prescriptions whenever doctors are available at an accredited rural ARV site will remain a feature of South Africa's health care landscape.

The new PMTCT regimen sees pregnant mothers receiving AZT from 28 weeks, as well as the single dose of nevirapine administered during labour. Their babies will receive AZT for 7 days.

If the mother received AZT for less than 4 weeks, the infant will be given AZT for 28 days. Babies will be routinely tested for HIV in order to establish the efficacy of the new interventions, first at 6 weeks (PCR testing) and then an antibody test at 18 months. All pregnant women attending antenatal care clinics will be offered VCT on their first visit. Those who test negative will be offered a follow-up test at 34 weeks and those who test positive, a CD4 count and viral load test as soon as possible.

The chorus of protest over government delays in introducing dual therapy reached a crescendo in mid-January.

AIDS chief explains

Dr Nomonde Xundu told *Izindaba* on 23 January that 'around R280 million' (up from the current R80 million for nevirapine only) has been budgeted for the 2008/9 financial year for the AZT/nevirapine drug combination. She said this would increase by 40% over the 'first few financial years', before the increases slowly flattened out. 'I'm not saying it will be drugs in the mouths of mothers (and babies) from April (2008) – we have to upgrade training of staff and patients first. The moment we get the signature from the national health council (headed by Health Minister Manto Tshabalala-Msimang) we'll go ahead'.

Pressed for an estimation of when implementation might come, Xundu refused to speculate but intimated that it would be well before the end of the year. The Treatment Action Campaign (TAC) accused national Director General of Health, Thami Mseleku, of having promised to make the updated dual therapy guidelines available 'within 2 weeks' of a South African National AIDS Council meeting in November last year (2007).

The council, chaired by Deputy President Phumzile Mlambo-Ngcuka, had recommended that provinces be allowed to implement the regimen in spite of its lack of endorsement at national level.

Xundu said things were now finally moving. 'Internally we've gone through all the processes, including deeper discussion with the minister about the guidelines and we've done all the costing'. The TAC and the Southern African HIV Clinicians Society expressed 'dismay' at the delays.

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Delays costing lives

Pregnant women were 'dying avoidably' from AIDS while over 60 000 children a year were being infected because of the inadequacy of current programmes. The government stubbornly dragged its heels in providing ARV drugs amid initial rampant AIDS denialism and claims of 'toxicity' at ministerial and presidential level.

Dr Francois Venter, chief of the HIV Clinicians Society, said it had been 7 years since the PMTCT guidelines were last revised, despite multiple subsequent revisions to recommended protocols by international agencies, including the WHO.

Paediatric HIV had almost been eradicated in many countries while poorer countries with far worse infrastructure than South Africa had made 'significant progress' in decreasing transmission. It was 'completely unacceptable' that children continued to become HIV infected due to the inability of the department to finalise a 'relatively simple change' in a PMTCT regimen that had international support and extensive local experience.

The Western Cape, which implemented dual therapy in May 2004, has reduced its mother-to-child HIV infection rate to about 8%. However, in KwaZulu-Natal, where nevirapine only was available, this infection rate stands at 22%. Venter said that with 1 in 3 pregnant South Africans HIV positive and the majority giving birth in state facilities, mothers having access to a sub-standard regimen for the protection of their children was 'a sad reflection on our health system'. He said that HIV testing, CD4 staging, opportunistic illness prevention and the initiation of appropriate ARVs remained 'unacceptably low' in both the public and private sectors.

Xundu said that as of October last year the number of hospitals and larger clinics accredited for voluntary counselling and testing (VCT) and ARVs stood at 345 (up from 143 sites in July 2005). This represented coverage of about 80% of the country's 184 health subdistricts, (translated as one facility in each district).

Xundu claimed that 57% of South Africans clinically qualifying for ART were now receiving it. By October last year the country's combined NGO, private and public sector services were reaching 488 000 patients out of the estimated 2007 'need' of 850 000. 'What attenuates it a bit is that there are lots of deaths, transfers out of an area and defaulters – but what our entire system was (accumulatively) able to enroll by October last year was 488 000,' she said.

However, figures from Leigh Johnson, a senior researcher at the University of Cape Town's Centre for Actuarial Research, put the national ARV (all service providers) percentage closer to 42%. This is based on projected rates of HIV/AIDS growth taken to October 2007 (390 000 on ARVs and 920 000 people living with AIDS).

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1. Pieper C. Addressing infant mortality. *S Afr Med J* 2005; 95: 492.

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