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FROM THE EDITOR

There is a strong feeling in the field that it is 'back to the drawing board' on prevention in HIV. Perhaps the most compelling possibilities going forward involve the use of antiretrovirals for prevention. Without doubt, next to prevention of vertical transmission the most emotive reasons for prevention include the immediate use of antivirals to prevent infection in those recently exposed. A large part of this spring edition is dedicated to post-exposure prophylaxis (PEP). The reduction of mother-to-child transmission is evidence that antiviral therapy at the time when infection is occurring can abort the establishment of that infection. The PEP guidelines as they appear in this edition may be thought of as controversial, and we welcome comments in this regard. There is an equally controversial legal take on the risks of HIV transmission in sport by Verrier and Tuson, and a short report on the importance of counselling and support for rape victims who are taking antivirals after rape. The issue also includes an account of the local experience of engaging with traditional healers in HIV programmes by Wreford and Esser, and some recommendations for completing death notification forms in the HIV era by Smith. Woods *et al.* describe the challenges of training health professionals, in particular nurses, to manage HIV, and present an innovative methodology for training. Finally there are two instructive clinical case studies, one on rhabdomyolysis following a drug reaction in an infected patient by Ramogi and the other the all too common problem of concurrent treatment of tuberculosis and HIV by Conradie, with a second opinion from Meintjes.

It has been said that a week in politics is a lifetime, and this can seldom have been better illustrated than by the past few weeks in South Africa. The political turbulence in our country has also seen the closing of the 'Manto' era, and many, activists and practitioners alike, have voiced an array of sentiments about this in the last few days. Those of us (and thankfully there are many) committed to seeing the countrywide, successful roll-out of PMTCT, antiretrovirals, testing and a variety of prevention strategies, as well as solid operational research, wish Health Minister Barbara Hogan and her team strength, wisdom and tenacity in taking us forward with bold new steps.

LINDA-GAIL BEKKER

Editor

TRIBUTE

MICK GRAHAM

Several extraordinary people have been involved in taking the HIV Clinicians Society from a small group of interested clinicians to one of the largest medical interest groups in the world.

Mick Graham arrived in South Africa four years ago from drizzly London, and has made it his home. Originally deployed to help non-governmental organisations sort themselves out, through the British-based Volunteer Services Organisation (VSO), Mick joined the Society during a staffing crisis. On his first day he was tasked with getting the Society back on its feet, especially as we had just been given a major grant to help establish a range of new projects. Deftly negotiating the complex politics that bedevil everything around HIV, Mick efficiently improved on the organisational structures of the Society while building up the staff complement to the stage where it is now self-sufficient.

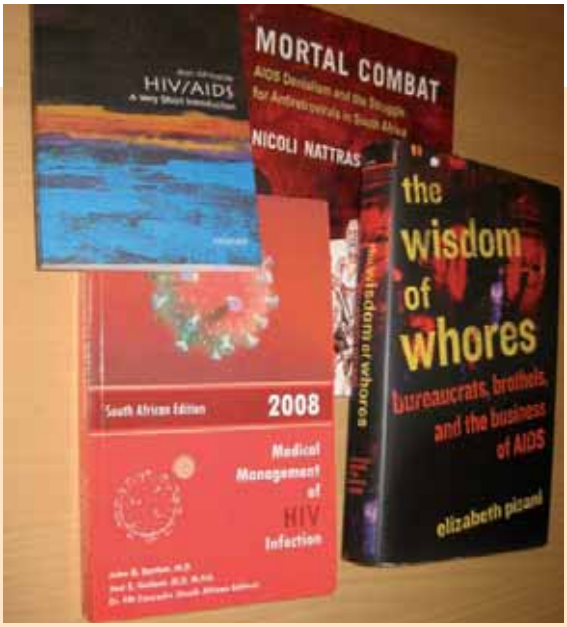
Mick's keen negotiation skills, honed while a justly feared trade union representative in his home country, were put to good use in getting great deals from publishers, sponsors and advertisers, all for the good of the Society. In a very short time he established the Society as a viable operation, with the *Journal*, *Transcript*, the guidelines and much of our commercial communication rapidly gaining financial independence. Mick's attention to organisational process has ensured that today the Society is a much stronger and more robust organisation, well positioned for the challenges of the future.

Mick will always be the ideal dinnertime companion. Conversations are liberally sprinkled with 'As my good friend George Bernard Shaw said ...', when not regaling us with his lunches with Prime Minister Tony Blair and stories from Northern England's steelworks.

We owe Mick a large debt, and will miss his contribution to fighting HIV, less than efficient contractors, and bad white wine. The Society, the general manager and the Executive wish him well in his semi-retirement.

Francois, Fatima, Pat, Natalie, Jean, Chloe, Kerry, Linda-Gail

MESSAGE FROM THE EXECUTIVE



We suddenly seem to be surrounded with books about HIV and AIDS. International books challenging HIV figures in Asia and the orthodoxies of transmission have shaken up the AIDS establishment and challenged large institutions such as UNAIDS. The debates about health systems, AIDS exceptionalism and funding levels have been at the top of the controversy circuit in the last few months, most notably at the huge AIDS conference in Mexico in August.

Locally, we have seen the publication of Jonny Steinberg's wildly successful and controversial *Three-letter Plague*, a look at the complex relationship between identity, stigma and HIV status in Mandela's birthplace. As HIV stakes claim to part of South Africa's heritage, we will probably see the rise of more books looking at how human beings deal with this scary virus. Steinberg's other books tend to take an alternative view and this one is no exception, having raised hackles among local clinicians and organisations.

Nicoli Nattrass's excellent examination of Mbeki's AIDS denialism, *Mortal Combat*, has been out for over a year. The book is liberally illustrated with Zapiro's cartoons, as Nattrass chronicles the curious and tragic evolution of the governmental response to AIDS, and the severe consequences for the debate around public health.

On a more clinical note, Francesca Conradie, one of our most respected doctors, has led the rewriting of the internationally renowned *Medical Management of HIV Infection*, with the support of the Foundation for Professional Development. Known also as the Hopkins book, the Bartlett book, or the Red (and, as editions change colour, Blue and Yellow) Book, this is the text that every HIV clinician yearns for – a quick and easy reference to all locally available drugs, with up-to-date disease management guidelines. The FPD have generously made copies available to selected Society members who have done their HIV course, and many of you should be receiving these in the post soon.

Elisabeth Pisani's *The Wisdom of Whores* tackles conventional wisdom on HIV transmission, and has caused an international stir, as she worked for HIV agencies in the developing world and has the insider track on how the response to the epidemic in Asia was constantly undermined by politically correct rewriting of epidemiology. Pisani's book is not for the sexually squeamish, as she explores the drivers of the epidemic in the back alleys of Indonesia, Cambodia and Vietnam – 'I do sex and drugs for a living'. Her book has been portrayed in various reviews as a savage criticism of the AIDS bureaucracy, but my reading of it suggests a more complex interplay looking at sexual networks and IV drug use. She demonstrates that the Asian epidemic calculations were chaotic (any researcher will go pale at the comical descriptions of mislabelling blood specimens) but well intentioned, not the careful and calculated manipulation of statistics claimed by some wild-eyed journalists and public health commentators. Her discussion on the southern African epidemic is frustratingly less in-depth (her experience is largely in Asia), and I hope she can come over and explain why our prevention programmes have been such a failure.

Finally, Professor Alan Whiteside's *HIV/AIDS: A Very Short Introduction* is a surprisingly readable introduction to the disease. It is particularly useful for people who do not have a firm biological background, as he has a gift for making science understandable. The sections on epidemiology are a good reminder as to how reliable some of our local statistics are. Journalists in particular should find this a quick and easy entry into our world.

Your spring reading list should now be complete. No place for frivolous thrillers or bodice rippers. Hurry, as Doug Wilson's excellent and much anticipated 2nd edition of the *Oxford Handbook of HIV Medicine* will be out soon.

FRANCOIS VENTER
President

OPINION

THE GHOST OF AIDS DENIALISM: MANGUZI HOSPITAL AND DUAL LOYALTY

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This boy is Ignorance. This girl is Want.
Beware them both, and all of their degree, but most of all beware this boy,
for on his brow I see that written which is Doom,
unless the writing be erased ...[1]

On 19 November 2003, the South African Cabinet approved the 'Operational Plan for Comprehensive Treatment and Care for HIV and AIDS'. After years of international protest, court action and unnecessary deaths, the South African government committed itself to a plan 'that provide[d] for Anti-retroviral Treatment in the public health sector'.[2] Many activists believed that this event heralded the end of AIDS denialism and what Nattrass terms 'the associated rejection of scientific authority in the regulation of medicine, ... Thabo Mbeki's initial questioning of AIDS science and ... his Health Minister's characterization of ARVs as 'toxic' and her support for alternative, scientifically untested therapies'.[3,2] Recently, the Department of Health claimed that 478 000 people with HIV/AIDS (PWAs) were accessing ARVs by end of April 2008 and triumphantly noted that South Africa was the country with most people initiated on ARVs in the world.[4]

To initiate almost half a million people onto ARVs in a few years is no small feat, and much of the success of South Africa's ARV programme can be attributed to committed and principled private and public sector health care professionals. These statistics could also be viewed as evidence of government-level refutation of AIDS denialism and its associated phobia about ARVs. Yet recent events at Manguzi Hospital have prompted people to recall the years 2000 - 2003, when AIDS denialism – and the concomitant ethical difficulties that principled health care workers faced in adequately treating and preventing HIV – was at its peak.

In this article, we will first explore Manguzi Hospital, outline the prevention of mother-to-child transmission (PMTCT) programme controversy, and suggest that divergent views existed concerning senses of urgency in the face of the suffering caused by HIV/AIDS. Unpacking the case of Dr Colin Pfaff, we then look at some of the goals of medicine and argue that the actions of Pfaff and his colleagues were morally praiseworthy. Then we will identify the way in which the spectre of AIDS denialism re-appears in the case of Manguzi Hospital. Finally, we show how health care professionals are once again caught up in the phenomenon of dual loyalty.

MANGUZI CASE STUDY

Manguzi Hospital is situated in the Umkhayakude Health Ward, a deep rural area that is 'under ruling of Inkosi M.I. Tembe and the Municipality of Umhlabuyalingana'.[5] The HIV prevalence rate in the hospital's antenatal clinic was between 24% and 28% in 2007. By October 2007 the hospital was laudably treating over 2 600 adults and children with ARVs.[6]

In July 2006, the World Health Organization (WHO) released its new guidelines on PMTCT, which recommended the use of dual therapy where indicated.[7] Despite advocacy efforts to urge the National Department of Health to revise its PMTCT guidelines in line with WHO recommendations, the 2002 guidelines remained in force. In the public sector, scores of pregnant women with HIV/AIDS therefore received the less efficacious monotherapy.

Pfaff, Chief Medical Officer of Manguzi Hospital, as well as other concerned doctors in the province, investigated national and international PMTCT programmes, noting that in KwaZulu-Natal 23% of women with HIV/AIDS on the existing single-therapy PMTCT programme transmitted HIV to their infants. This was in contrast to, for example, a less then 5% transmission rate in the Western Cape province where dual therapy had been in use since 2004.[8] Gravely concerned, in May 2007 Pfaff and his colleagues wrote to the KwaZulu-Natal Department of Health requesting permission to start rolling out dual

therapy in the Manguzi PMTCT programme: 'We cannot sit in silence any longer'.[8]

When the Department failed to keep its promises concerning dual therapy implementation, Pfaff and his colleagues took the initiative and raised funds from an international donor in order to purchase dual therapy. In August 2007, Pfaff began to implement the 2006 WHO dual-therapy programme at Manguzi Hospital.

Six months later, on 25 January 2008, the National Department of Health (NDoH) released its new PMTCT guidelines. These guidelines followed the WHO recommendations for the use of dual therapy for HIV-positive pregnant women. Here it should be noted that, as in all bureaucratic processes, a lag-time does exist from policy to implementation, so to censure the NDoH for delay might be considered unfair. Sibani Mngadi, a spokesperson for South Africa's Health Department, acknowledged that the government took the time needed to review the data and consult various players after the WHO recommendation. 'There were a number of issues to be debated,' Mngani commented.[8] Agreed – policy implementation requires logistical sorting, and some delays are inevitable. However, we suggest that the magnitude of the problem should have been sufficient to warrant a much greater assignment of urgency.

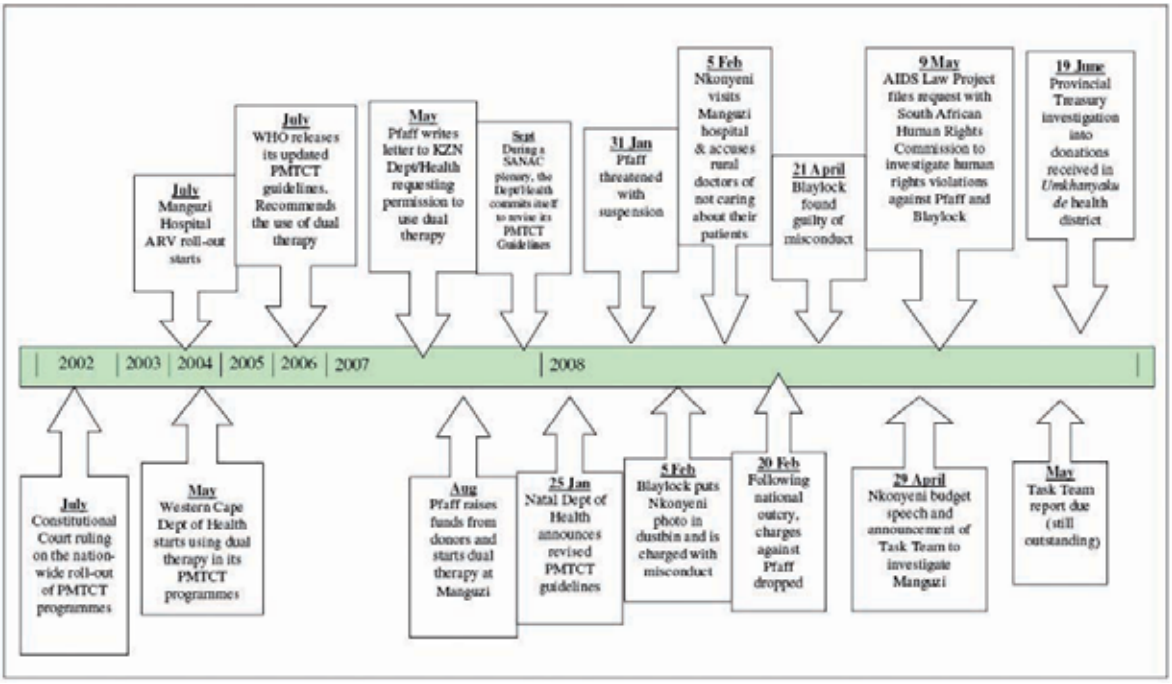
So far, we have outlined the PMTCT problem and have suggested that the NDoH did not respond with the necessary urgency. However, we admit that some hindrances in bureaucratic processes are plausible allowing for some delay in implementation. We have noted that Pfaff, backed by colleagues, stressed the immediacy of need to the provincial authorities. Failing to receive what was considered a reasonable response, the initiative was taken to secure dual therapy for pregnant women with HIV/AIDS in Manguzi Hospital at no cost to the government. What is obvious here is that we have two entities with apparently polar opposite approaches to a 'sense of urgency'.*

SENSES OF URGENCY

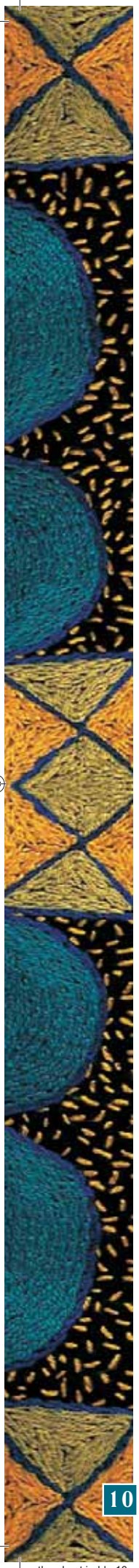
It is well acknowledged that the practice of medicine revolves around the doctor-patient relationship. Professional values such as honesty, integrity, and compassion, a respect for persons, dedication to a patient's welfare, and commitment to continuing scientific learning are some facets that are integral for doctors to hold as custodians of this bond. The truism that disease destroys the wholeness and integrity of the body while pain and suffering can destroy the wholeness of the person is a fact of medical practice. With this in mind, it is a doctor's moral responsibility to use her medical competence, knowledge, and technical skills in tandem with her patient's wishes to create overall a greater amount of benefit over harm. The cure of disease (when it is possible to cure), prevention of untimely or premature death, and the relief of suffering are some examples of long-time held medical goals.[10]

'Suffering occurs when an impending destruction of a person is perceived; it continues until the threat

*For example, concerning AIDS orphans, in 2001 there were an estimated 660 000 AIDS orphans in South Africa. By 2010, the AIDS orphan population is expected to reach nearly 2 million.[9] Moreover, these figures should be viewed in the context of poverty and the lack of available social services to communities in which the orphans are homed. The HIV infection rate for pregnant women in KwaZulu-Natal is 4:10.[8]



Important events relating to PMTCT programmes and Manguzi Hospital.



of disintegration has passed or until the integrity of the person can be restored in some other manner', writes Cassell.[11] It is an unfortunate fact that the *idea* of suffering and its relief and its *personification* are viewed differently on the part of some policy-makers and health care professionals on the ground. Policy-makers are usually removed from the experience of suffering. Moreover, they may recognise that a problem exists (for example, there are many pregnant women with HIV/AIDS in KwaZulu-Natal) but their myopic lens may fail to see, acknowledge or support those involved in the moral practice of medicine. For example, health care professionals have a *prima facie* duty to relieve the suffering of their patients. By a *prima facie* duty, we mean all things considered duty. For example, a *prima facie* duty to do X gives me a valid moral reason to do X, and in the absence of countervailing moral considerations, implies that I must do X.[12] If we accept that health care professionals have a *prima facie* duty to relieve suffering, to ignore this is to be less than one can and should be; it is more than an action which 'should be good to do', it is morally obligatory.

There is also a decided difference in reading about suffering and experiencing it, seeing, smelling, hearing and living it – a phenomenon often lost to bureaucrats removed from the scene. Nearly 80% of the children in the paediatric ward at Manguzi Hospital are HIV positive and suffer from wasting and a host of infections, pneumonias and chronic lung diseases.[13] Children experiencing these disease processes are uncomfortable, distressed, helpless and often in pain. Such suffering is not unique to Manguzi – it is repeated throughout South African hospitals daily.

For health care professionals it is a wrong to see an individual patient suffer. When compounded in visualising a dual burden of suffering – for example, mother and infant or child in the face of established preventable measures – the situation on the ground for health care professionals such as Pfaff becomes morally untenable. It is morally untenable because it could be otherwise. If we make a request to ameliorate or end suffering, it necessarily includes an appeal to whatever causal sequences will prevent it from happening. This is the crux of the problem such health care professionals faced: suffering ought not to occur when there are measures available to prevent its occurrence. In acting to procure antiretrovirals to prevent or reduce suffering, Pfaff and his colleagues acted in accordance with the requirements of morality.

Governmental health care systems (which of course are composed of individuals) should have moral ideals. Such ideals may not be wholly attainable and their total non-achievement should not be unnecessarily condemned. However, moral ideals are different from moral requirements. Government health care systems can be held accountable for doing what is morally required and certainly are obligated to avoid what is morally prohibited. With the burden of HIV/AIDS so heavy, one could rightfully ask why a similar sense of urgency did not thrust the NDoH into immediate action.

On the part of Pfaff and other health care professionals, we can say then that they were doing their moral duty. They investigated the situation and informed others of their actions through the proper channels of communication. Rebuffed, they sourced an alternative provider and through that beneficent action were able to provide their patients with greater hope of relief from suffering.

Concerning the KwaZulu-Natal Department of Health, their response becomes morally murky. We have noted that they were deficient in their lack of a sense of urgency; oddly this was followed by what can only be called display of 'muscle-flexing'. During the same month as the revised PMTCT guidelines were announced, Pfaff was threatened with suspension. Disciplinary action was taken against him in January 2008 because, as it was stated, he had 'allegedly acted beyond his authority in accepting a donation and implemented a Prevention of Mother-To-Child Transmission (PMTCT) dual therapy to pregnant mothers and newborn babies without prior permission of his superiors'.[14†]

In this statement repudiation by the government of the moral grounding of medicine is clear. One may also wonder what particular end the government had in mind in the threatening of suspension of a dedicated doctor. It may well be, as Schneider puts it, that 'Ultimately, policy contestation around AIDS in South Africa can be understood as a series of attempts by the state to legitimately define who has the right to speak about AIDS, to determine the response to AIDS, and even to define the problem itself.'[15] Pfaff and his colleagues informed the officials of their intentions, and we have argued that their intentions were morally praiseworthy. That they were not viewed by provincial authorities as such, does not speak well of any attempts to move towards a participative democracy. Indeed, it belies the government's advertisement of March 2003, 'Let's build a people's contract to fight HIV/AIDS ... Our energies should be spent fighting AIDS, not one another' (*Cape Times*, 20 March 2003, as quoted by Van der Vliet[16]). But there is more.

THE GHOSTS RETURN

To reiterate the whole history of factors and factions involved in delays of HIV treatment roll-out is beyond the scope of this article. Suffice to say that from its

†After an international outcry by health care workers and human rights activists, these charges were dropped later in the month.

onset, a denial of the epidemic seems to be linked to a denial of the behaviour that fosters it. Moreover, HIV fostering behaviour must be viewed in concord with South Africa's political history. Following apartheid and its brutal discriminatory practices, the onset of HIV/AIDS in South Africa as a racially differentiated, sexually transmitted epidemic came in tandem with the political upheaval needed to advance a rightful democratic process. It is not surprising that early on factors such as under-funded HIV budgets, fragmented NGOs, exorbitant therapy costs, and the unrealised scope of the epidemic led to poor service delivery.

Meshed within such complex processes emerged the well-known dissident views, all variants on the theme that HIV did not cause AIDS. The admixture of appeals to African-only solutions, to customary practices, conspiracy theories and racism, impeded the public's acceptance of the need for safer sex and HIV testing.[16] AIDS denialism, spearheaded by President Thabo Mbeki and his Minister of Health, Manto Tshabalala-Msimang, was espoused by lower levels of government and created a variety of obstacles to principled health professionals acting in the best interests of their patients and in line with best practice and international standards.

With time and the increasing availability and affordability of antiretroviral therapy to prevent transmission and treat HIV/AIDS from 1998 onwards, the resistance of some sectors of government to facilitating its access became commonplace. Disagreements followed between health professionals and Department of Health officials over the efficacy and necessity of prescribing ARVs for (*i*) preventing the transmission of HIV to rape survivors;[17,18] (*ii*) preventing transmission from pregnant mothers to their infants;[19] and (*iii*) treating people with HIV/AIDS.[3,20]

Although such rhetoric appears to have abated somewhat during more recent years it still exists, as does the confrontation between the moral duties of health care professionals and their obedience to the state.

In 2001, in the Western Cape's Khayelitsha township, triple therapy came into use and AZT was used 'off-label' for prophylactic treatment against HIV transmission to rape survivors. While 'off-label' use of AZT for rape survivors was covertly practised in many hospitals, it did not have national approval. The issue reached the public domain in 2001 - 2002 in the province of Mpumalanga, where an NGO called GRIP (the Greater Nelspruit Rape Intervention Project) set up their rape crisis centre at the Rob Ferreira Hospital in Nelspruit. Through generous donations from the public, they were able to supply antiretrovirals to rape survivors. Because they realised government officials did not approve of this,[†] the drugs were hidden in the bellies of stuffed teddy bears that lined the corners of the crisis centre – their presence known only to the staff and the doctors assisting them.

This situation became known to the then MEC of Health of Mpumalanga, Sibongile Manana, who was deeply suspicious of ARVs. For example, when interviewed in 2002 on the Constitutional Court ruling on PMTCT, Manana responded, 'we will implement [Nevirapine] because we are forced to implement ... I must give my people a drug that is not approved by the FDA.[§] I must poison my people' (L Garret, *Newsday New York*, 8 July 2002, as quoted by Van der Vliet[16]). As for GRIP, the accusation was that they were acting in contravention of the provisions of the Medicines and Related Substance Control Act (for 'off-label' use) and placing the health and lives of 'our poor black people' under serious threat. In addition, she suggested that GRIP was hypocritical in claiming to have 'poor black people's interests at heart' and that GRIP was politicising HIV/AIDS and 'trying to overthrow the government'.[22,23¶] The consequence of this was the closure of GRIP and suspension of Rob Ferreira Hospital's well-respected hospital superintendent Dr Thys von Mollendorf, who supported and facilitated GRIP's access to the hospital.[**]

Similar to the rhetoric waged at GRIP and von Mollendorf, comments attributed to the MEC of Health, KwaZulu-Natal, during a visit to Manguzi Hospital on 5 February 2008 clearly display a return of the ghosts of denialism and a blatant confrontational stance towards medical professionals:

> AZT is toxic and must be controlled. Dual therapy [for prevention of mother-to-child transmission for HIV] has not been agreed upon. We have a problem with doctors who work in rural areas. They do not care about people. It is all about profit not about caring for people. I have heard that ARVs have bad side-effects, especially for children.[24]

That claim that ARVs are toxic is not new. All drugs have side-effects. It is part of a medical professional's duty to have the scientific knowledge to understand a patient's physiological response to antiretrovirals and ameliorate, when necessary and as best they can, those effects which are adverse. The knowledge that HIV/AIDS is ultimately fatal if not treated is not new either. The point is to avoid further transmission of the virus and, if it is present, to delay the onset of AIDS – in other words, to avoid suffering. Concerning the allegation that doctors who

[†]Government policy at the time only allowed for ARVs to be prescribed for needle-stick injuries of health care workers to prevent HIV transmission from a possibly infected patient to a health care worker. Prescribing ARVs following sexual assault was not included in this policy.

[§]The manufacturer of nevirapine, Boehringer Ingleheim, suspended their application to the USA's FDA following reports that some aspects of their Ugandan trials were found not to have met certain record-keeping regulations. The validity of the study, however, was never in doubt.[21]

[¶]For additional information, see the AIDS Law Project complaint to the Public Protector on the conduct of Ms Sibongile Manana, the MEC of Health of Mpumalanga, dated 14 September 2001 – www.alp.org.za.

[**]GRIP re-opened shortly after this without the ARVs on site. For more information read Von Mollendorf's book Dare to Care (forthcoming).

work in rural areas care only about profit and not people, one is hard put to find any truth or relevance. Was the MEC referring to international conspiracy myths, for example that HIV was developed by imperialist countries in secret laboratories to ensure that South Africa would not become a world power,[25] or that antiretrovirals remain an international pharmaceutical plot, in which rural doctors are somehow involved? It is difficult to find any conceivable connection. One only needs to visit rural hospitals and see under what conditions doctors are obliged to live and work to prove this allegation false.

Scrooge learned from the visitations of his ghosts, but some government officials may '... walk the earth eternally after death, invisible among his fellow men, burdened with chains, seeing the misery and suffering he could have alleviated in his life but now is powerless to intervene'.[1] And who could plead more eloquently for the alleviation of HIV suffering than the health care professionals who have seen people live and die?

This tension between the ethical duties of health care professionals and their loyalty towards their employer, the state, is best expressed in the concept of Dual Loyalty.

DUAL LOYALTY

The International Dual Loyalty Working Group defines Dual Loyalty as 'simultaneous obligations, express or implied, to a patient and to a third party, often the state'.[26] Throughout the evolution of health care ethics, absolute commitment and loyalty to one's patient have been stressed. The Hippocratic Oath requires that a doctor be committed to the following maxim: 'That I will exercise the art of medicine solely for the cure of my patients ...', while the following extracts from the World Medical Association's International Code of Medical Ethics are particular applicable to patient commitment:

> A physician shall be dedicated to providing competent medical service in full professional and moral independence, with compassion and respect for human dignity. A physician shall act in the patient's best interest when providing medical care. A physician shall owe his/her patients complete loyalty and all the scientific resources available to him/her.[27]

The International Dual Loyalty Working Group has identified six areas within the medical profession where Dual Loyalty dilemmas could arise:

> (A) Using medical skills or expertise on behalf of the state to inflict pain or physical or psychological harm on an individual that is not a legitimate part of medical treatment
>
> (B) Subordinating independent medical judgment, in therapeutic or evaluative settings, to support medical conclusions favourable to the state
>
> (C) Limiting or denying medical treatment or information related to treatment to an individual to effectuate policy of the state in a manner that violates the patient's human rights
>
> (D) Disclosing confidential patient information to state authorities or powerful non-state actor
>
> (E) Performing evaluations for legal or administrative purposes in a manner that implicate human rights
>
> (F) Remaining silent in the face of human rights abuses committed against individuals and groups in the care of health professionals.[26]

Sadly, South Africa has had a very poor history of health professionals choosing patient loyalty over loyalty to the state. Under apartheid, a number of health professions conducted themselves in ways that fall under the six categories delineated above. The unethical conduct of health professionals were described in great detail during the Truth and Reconciliation Commission (TRC) hearings and documented in book format afterwards.[28] The final TRC report found that:

> the health sector, through apathy, acceptance of the status quo and acts of omission, allowed the creation of an environment in which the health of millions of South Africans was neglected, even at times actively compromised, and in which violations of moral and ethical codes of practice were frequent, facilitating violations of human rights [as quoted by de Gruchy and Rubenstein[29]].

With the advent of democracy, the emphasis on a culture of human rights and progressive health legislation such as the National Health Act created a clear expectation that Dual Loyalty dilemmas that forced health care professionals to choose between patient care and obeying an oppressive state, were something of the past. The goals of medicine are clear, as are the moral duties of doctors and other health care professionals. To go against the state when it is morally necessary is not easy matter, but it is a right and just action.

CONCLUSION

In this article, we have shown that the actions of Drs Pfaff and Von Mollendorf, their colleagues, and many other unnamed health care professionals in the face of AIDS denialism is morally praiseworthy. We have also suggested that there is a decided difference in perceptions of urgency between principled health care professionals and those who are removed from the daily cauldron of misery caused by HIV/AIDS. We have shown

that the early propagation of AIDS denialism is still with us, and we have outlined the nature of 'dual loyalty' in relation to this.

In conclusion, we suggest that medicine is a complex practice in its own right, and is best left up to those who are skilled in its practice. It is grounded as a moral enterprise in the very gift of a patient's trust and the health care professional's return of that trust – to do all that he or she is able to do for the patient's benefit, and not for that of the state or any other third party.

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OPINION

THE CHALLENGE OF PROVIDING HIV TRAINING TO HEALTH PROFESSIONALS

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The HIV pandemic in southern Africa has overwhelmed health services in the public sector and presents awesome challenges to the authorities responsible for providing nurses and doctors with the knowledge and ability to manage the many facets of patient care.

The quality of health care available to both adults and children depends on many factors including adequate numbers of well-trained, caring and motivated primary health care nurses, who form the backbone of clinic services in many poorly resourced communities. While basic training for these nurses is important, continuing education is essential to maintain a high standard of care. Failure to provide opportunities for lifelong learning stunts professional growth and impacts on service delivery and job satisfaction. Unfortunately the formal provision of post-basic training is often inadequate and the responsibility for continuing education is usually left to the individual.

TRAINING OPTIONS

As traditional methods of continuing training for nurses usually consist of in-service or centralised courses managed by teaching units in larger hospitals, participants from rural areas have to leave their families and places of employment for variable periods of time to attend such courses. Accommodation, travel and tuition are expensive. The content of courses in tertiary hospitals is often inappropriate to the needs in district and regional hospitals and clinics, while what is taught may not be applicable due to a lack of equipment and facilities. Moreover, many health carers are denied training leave owing to lack of replacement staff. Occasional lectures by visiting experts are no substitute for a carefully planned programme of ongoing education. While advanced courses in centralised hospitals have their place in a broader scheme of health care training for nurses, what is required is an innovative vision of affordable continuing education for all professional health care workers that avoids these obstacles.

A number of attempts to take teachers to outlying areas have had limited success. Teams of medical and nursing tutors meet groups of students in a rural venue for a few days. Formal lectures are given, discussion groups are supervised, audit sessions are arranged and selected skills are taught. While there are benefits to this model, it remains expensive in terms of teaching staff and travel. In addition, the exposure to teaching is only occasional and for a very limited period of time. The train-the-trainer model has also been popular, particularly with overseas funding agencies. However, good clinical staff do not necessarily make good teachers, and this method of training is difficult to sustain. While computer-based interactive learning is very attractive and has been widely used in many industrialised countries, the record of successful implementation in financially and educationally constrained areas is disappointing.

The ideal method would be one that is cheap, decentralised, and enables teams of health care workers to manage and take responsibility for their own continuing education with only limited outside support. The emphasis should be on learning rather than teaching. This exercise should be conducted locally without the need for formal teachers. However, regional facilitators to introduce and supplement the training programme with encouragement and some input would be beneficial. The course content must address real needs

and provide practical answers to common or important clinical problems. If possible the training course should reflect current clinical practice and assist the participants to improve their knowledge, learn new skills and correct negative attitudes. The goal is to improve the standard of patient care by stimulating and supporting professional growth, while also providing a sense of competence and career satisfaction.

PERINATAL EDUCATION PROGRAMME

The Perinatal Education Programme (PEP) has met many of these promises.[1] For the past 12 years it has provided self-help educational opportunities to 50 000 nurses, doctors and medical students in South Africa. It has also been used in other African countries. Prospective controlled trials, where groups of nurses managed their own continuing education courses in maternal and newborn care, have demonstrated significant improvements in cognitive knowledge, clinical skills, attitudes and patient care.[2-5] In addition, smaller field trials have documented an increased knowledge and understanding of maternal and newborn care in primary, secondary and tertiary settings.[6]

PEP is based on the belief that health professionals can take responsibility for their own ongoing education if they are given access to appropriate learning material. They are naturally inquisitive and want to learn. The process can be effective, easy and fun if groups of health professionals study together. This introduces the principles of peer tuition and co-operative learning. PEP uses a question-and-answer format that enables participants to learn a complex subject in 'digestible small bites' and emphasises the important lessons to be learned.

Groups of interested nurses and doctors buy the manuals at cost from a non-profit trust. Each group appoints a co-ordinator who arranges a time and venue for meetings every 2 - 3 weeks. Participants study one module at a time on their own and then discuss the contents at the group meeting. Groups of learners encourage and support one another, and this collective energy drives the process. The question-and-answer method of learning promotes problem solving and leads the student through all the required knowledge. Case studies at the end of each module help participants to integrate their newly learned knowledge into everyday clinical practice. Multiple-choice tests before and after each module allow each participant to monitor their own step-by-step progress through the course material. On completion the group finds a responsible person to manage a final theory examination. In this way the group is empowered to manage all aspects of their own course including the final evaluation. The pride and sense of success is theirs. By means of a retrospective bursary system, an overseas funder repays each successful examination candidate the small cost of their course book.

HIV EDUCATION COURSES

The Perinatal HIV course from PEP has been successfully used by nurses to improve their knowledge of HIV infection in pregnant women and their newborn infants.[7] It has recently been revised and republished in an attractive book format.[8] Additional books using the PEP format have been written to address the care of adults and children with HIV. The *Adult HIV* book[9] was developed for the Desmond Tutu HIV Foundation, while the *Childhood HIV* book[10] was written for Eduhealthcare, a not-for-profit organisation dedicated to the improvement of health care through self-help learning.

All three books provide courses for nurses and doctors caring for pregnant women, children and adults at a primary care level. The basic epidemiology and pathophysiology of HIV infection is spelled out, prevention and early diagnosis are stressed and all aspects of patient management are explored. The correct use of antiretroviral drugs and drugs to treat opportunistic infections is detailed, while the importance of positive living, a caring approach and palliative care are emphasised.

Numerous South African medical and nursing authorities in the field of HIV were invited to comment and contribute to the content of the courses, while every effort was made to incorporate provincial, national and international guidelines of management.

The content of the three books is also available on a free website.[11] Learning material can be printed for local use, while the course can be completed via the internet on a home or clinic computer. The website is structured in a 'wikipedia'-type format which invites comments and contributions. In this way the content can be continually widened and enriched. Because HIV medicine is a rapidly developing field the web-based format allows easy updating, keeping the learning material current.

These three HIV learning programmes for professionals are available in both book and web-based layout, and provide cheap, practical and up-to-date courses for all doctors and nurses in southern Africa who are faced with the daily needs of patients infected with HIV.[11] They promise to fill many of the educational gaps currently hampering the implementation of exciting new roll-out programmes for antiretroviral care. With adequate numbers of well-trained professional staff, the tide of the HIV epidemic can be turned. No primary care nurse or doctor needs to be deprived of an opportunity to learn about all aspects of HIV care.

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SHORT REPORT

INCLUDING TRADITIONAL AFRICAN HEALERS IN HIV PROGRAMMES: PRELIMINARY EXPERIENCE FROM THE WESTERN CAPE

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The potential advantages of co-operation between traditional and biomedical practitioners in Africa have been acknowledged,[1] and are especially important given the extent of the HIV pandemic.[2] Unfortunately schemes directly engaged in this process are still unusual. We report on an innovative pilot project in the Western Cape province, and describe some of the pitfalls and obstacles, but also some success. This is an extended version of a scientific letter published in the *South African Medical Journal* of May 2008.[3]

THE HOPE CAPE TOWN PILOT PROJECT

HOPE Cape Town (HIV Outreach Program and Education) is a non-profit organisation providing support in communities in the Western Cape province. HOPE Cape Town[4] was founded in 2001 and is linked to Tygerberg Children's Hospital and Stellenbosch University. HOPE Cape Town has trained and placed 20 community health workers (CHWs) in community health centres in the Western Cape to support HIV-related activities.

HOPE Cape Town established the first project in the Western Cape to include traditional health practitioners (THPs) in an HIV project in October 2005. The aims were to educate THPs about HIV, to discourage THPs from prescribing treatments that might interact with antiretroviral therapy (ART), and lastly to persuade more male clients to undergo voluntary testing and counselling (VCT) for HIV. Nine THPs were recruited to work with five HOPE CHWs in five Cape Town townships. The scheme commenced at Tygerberg Academic Hospital with a 6-week course of education in biomedical understanding of HIV/AIDS and its treatment. The THPs were specifically warned of the possible contraindications between some traditional remedies and ARVs[5,6] and advised to avoid invasive treatments where they suspected a depleted immune system. To monitor the success of referrals, the THPs learned how to complete referral forms, which clients were to present to the clinics, and instructed in how to maintain a client register while ensuring client confidentiality. Thereafter, the THPs underwent a VCT training programme for an additional 4 weeks. The THPs and CHWs then returned to work in their communities. This qualitative study is based on direct participation and observation of the HOPE Cape Town pilot and its implementation in the field. Data are taken from field notes, supported by in-depth interviews with participating THPs, CHWs, and staff employed at clinics and counselling organisations.

INITIAL RESULTS OF THE COLLABORATION

Three THPs are now successfully liaising with community health centres (CHCs) in Mfuleni, Wallacedene and Delft South. Since the project's inauguration in March 2006, 80 clients have been referred, and even these numbers may be understated as clients often opt to visit clinics remote from their homes where HOPE CHWs are not employed. These referrals also suggest that the THPs are a valuable connection between male clients and the clinics. Finally, the healers have established links with the clinics. Many staff now express support of the THPs' involvement and support the enrolment of more healers in similar initiatives.

SELECTING CANDIDATES

Collaborative projects are complex, time-consuming and rarely without difficulties.[7] One lesson from the HOPE Cape Town experience concerns the selection of candidates. Of the 9 THPs initially enrolled, 3 have successfully referred clients. The latter are graduate

healers with established practices and a trusted reputation within their community. The remaining 6 healers were discovered (only after the training) to be *thwasa*, or trainee healers. Like apprentice doctors they can work only under supervision, and they lack the social status required to attract their own clientele. The HOPE CHWs have intimate knowledge of their own communities, including valuable insights into the status and reputations of local healers. This information could be valuable if more THPs are recruited. The clinic staff and counsellors also later volunteered names of interested THPs. HOPE Cape Town has learned that only graduated THPs should be considered, and that future programmes should canvass more appropriately for suitable candidates.

LIAISON AND FOLLOW-UP OF THPs

The HOPE Cape Town project generally adheres to the pattern of other 'educative' collaborations,[8] distinguished by the combined training of THPs with CHWs, and the VCT component. Taken together these could be expected to encourage 'group solidarity' and a commitment to working together. In the frenetic environment of the clinics, however, working relationships have sometimes proved fragile, and the THPs often (albeit obliquely) express the need for more encouragement and support. They have, after all, stepped outside the conventions of their customary practice, and although their communities seem to respect this stance, they are vulnerable to criticism from healers less inclined to co-operate with Western medicine.[9] Apart from regular contact with clinic CHWs and occasional visits from other staff, HOPE Cape Town has left the THPs to their own devices. This is understandable: the costs of further liaison and the administrative responsibilities can be complex. But there are risks in this *laissez faire* approach, especially in sustaining education and commitment. From interviews with the THPs it is clear that although they can and do refer to their course notes when they are unsure about how to advise a client, without continued mentorship there may also be a tendency for them to revert to non-biomedical interpretations about HIV/AIDS. Regular training sessions for the healers will ensure that HOPE Cape Town and the THPs can be mutually secure about their contribution and so boost the THPs' confidence.

PAYING FOR THE SERVICE

Collaboration presents another problem, which frequently goes unreported. In resource-poor public health facilities where staff shortages are the norm, there is often a tendency to assume that traditional healers will work gratis.[10] This ignores the reality that THPs are self-employed professionals who depend on their clients for income. HOPE Cape Town recognised this, and had to decide how much the healers should charge for their VCT and referral services. The decision of R10 per session has, however, proved difficult. Clients offered several excuses to avoid paying even the R10, and these suggest something of the complexity of fee negotiations between healers and their clients. Clients argue that they can 'get this [counselling] for free at the clinic'. Clients visiting a THP are convinced that their illness has a cultural explanation, and expect a remedy accordingly. In these circumstances they are therefore often reluctant to utilise the clinic's services. Clients sometimes claim to have no money, or refuse to pay 'just for talking' (as counselling is popularly known). This is perplexing, because clients coming to a THP are generally expected to pay something towards that service. More importantly, the quality of a treatment (and therefore its efficacy) is often related to its cost. Viewed in this light, the 'bargain' fee of R10 might be construed by clients as evidence of inadequacy. Custom requires that clients receive *amayeza* (medicines) before paying; this further complicates matters, because, as a direct consequence of their HIV/AIDS training, the THPs are now reluctant to prescribe some of the purgative treatments customarily recommended for sexually related complaints.[11-13] The THPs are also rightly concerned that the clients, offered a less aperient *amayeza*, may feel cheated. Left in doubt as to its efficacy, they may visit another less aware THP to obtain the expected remedy. A compromise designed to resolve the fee issue is now in operation. The THPs continue to practise in their accustomed way, with a diagnosis (*ukuvumisa*) and the provision of a remedy including (non-invasive) *amayeza*. If, during a session, the healers recognise that VCT counselling is appropriate, they incorporate this into the consultation, and try to convince the client to visit the clinic for a test. The healers then request the fee they would normally expect to charge, with no extra for counselling.

TACKLING STIGMA

The common problem of the stigma attached to HIV/AIDS is considered here with the question of publicity for the HOPE Cape Town project. Although apparently disconnected, these issues have actually combined to complicate the successful collection of data to support the project. In relation to stigma, the THPs had expected to refer counselled clients to the HOPE CHW at their local clinic: from the start it became clear that in order to avoid the stigmatisation of HIV/AIDS, clients were resisting this option, preferring to visit other clinics – often very remote from their homes. The organisation's decision to limit publicity of the project created further obstacles for the scheme. The fact that clients could (quite correctly) choose which clinic to visit meant that HOPE Cape Town's referral forms appeared in public health facilities where they were not recognised. Alternatively, the counselling already done by the THP was repeated, wasting time and counselling resources. To overcome these obstacles four steps have been taken: the THPs have been given a list

of all the facilities in which HOPE Cape Town operates so that, with the client's consent, referrals can be made to a clinic staffed by the organisation; all HOPE CHWs have received guidance on the scheme and a standard operating procedure outlining their own tasks; meetings have been held with other counselling organisations to inform them of the project and outline how they should respond to referral forms; and finally, meetings have been held with clinic staff (supported by a protocol document) to ensure familiarity with the project. All of these should enable the number of referrals to be monitored more accurately, and lead to a more effective intervention.

CHANGING ATTITUDES

The HOPE Cape Town pilot project confirms that given positive and supportive responses from medical personnel, THPs feel more confident of their contribution.[14] Conversely, a negative response causes discouragement and loss of enthusiasm. This may seem obvious, but the organisation initially underestimated the importance of liaison with medical staff at the clinics. Even at the end of the first year many clinics were unaware of the aims and objectives of the project (a situation not helped by frequent staff turnover, especially at management level). Medical staff opinions of THPs can sometimes be suspicious, even hostile, and personnel holding such attitudes continued to discourage patients from visiting THPs, including those referred by HOPE Cape Town healers, undermining their confidence in the project. The positive responses of staff at the liaison sessions are expected to assist in remedying this situation.

WHAT CAN MEDICAL STAFF LEARN FROM THE THPs?

First, there is the importance of language, communication and mutual understanding. The majority of the South African population avails itself of the services of THPs at one time or another. They do so not out of stubbornness or ignorance, but because the THP speaks their language, and understands health and illness in a familiar ancestral context.[15] The THPs are trusted to make sense of illness. This situation is as relevant to HIV/AIDS as for other diseases. When asked whether patients might listen to THPs rather than Western-trained doctors, one healer replied: 'Yes. They will come because of our communication and the language, and ... because we stay together.' On a day-to-day basis, that the THPs live within the community ('we stay together') and speak the language of their clients is germane. But the 'communication' identified by this healer also encompasses an essential factor in traditional diagnosis: communication relies not only on a conversation with the client, but with the ancestral spirits who empower the healers' work.

A second benefit emphasised by the traditional healers concerns confidentiality, a question complicated by the stigma attached to HIV/AIDS. Safeguards in the clinics are variable; as one CHW reported 'some of them [clinic staff] are too easy about disclosing status'. Even to be 'seen' visiting the local health facility is enough to generate unkind gossip. In contrast, having diagnosed a person, THPs are bound to keep all the information they have received to themselves. As one healer put it: 'If you diagnose someone then whatever they should discover from that person you have to keep it to yourself because it's a secret. That person can then say "OK, I am able to come back to this person because this person can really keep confidential information". '

OTHER LESSONS AND POTENTIALS OF COLLABORATION

The HOPE THPs have each assumed additional responsibilities that coincidentally reflect the aims and objectives of the government's latest national strategy for HIV/AIDS.[16] There is enormous potential for the involvement of traditional healers in HIV/AIDS interventions – for example as relationship counsellors, promoters of responsible parenting, and advisers in matters of sexual debut. For instance, some clients (especially those newly arrived from the Eastern Cape) are reluctant to visit the clinic alone. The healers take it upon themselves to accompany them, and after the visits act as powerful advocates, encouraging the clients to adhere to treatment regimens and to return for aftercare. It is well known that disclosure of a positive HIV diagnosis may be hazardous for female clients, who are often threatened, abused or abandoned, while their partners continue to resist testing.[17,18] The THPs report intervening in such situations: one invited a couple to her surgery, where she was able to encourage a frank discussion of sexual behaviour and eventually persuaded the man to test. Another actually visited her client's household, although so far her arguments have failed. Children are especially vulnerable to HIV/AIDS, a situation that the THPs recognise and work to alleviate: one cares for several orphans while struggling to obtain social grants for their care, another has shared her home with women and children abandoned by their fathers. All the THPs report sharing their meagre food supplies with impoverished clients, whether or not they are on ARVs. Lastly, regarding behaviour change, the healers have become an important source of condoms within the community. They report a particular interest from young people appreciative of non-judgemental advice, a supportive role that might develop into discussions on related issues such as responsible parenting, drugs and violence. The THPs themselves have requested additional counselling training along these lines.

BENEFITS OF THE HOPE CAPE TOWN PROJECT

Some general benefits of HOPE Cape Town project are obvious: THPs are accessible, and available 'out-of-hours', their sessions are not time-constrained, and they are generally affordable. The HOPE Cape Town pilot scheme provides evidence for additional advantages. First, the healers' acceptance of the biomedical interpretations of HIV as (for the present) without cure, and their advocacy of ARV treatment, should ensure that these THPs will not offer bogus or harmful treatments. Second, the THPs can recognise the biomedical difference between symptoms of STIs and HIV/AIDS, and are unlikely to offer remedies that might treat the former but leave the virus untouched; nor will they employ remedies that might undermine an immunocompromised patient. Thirdly, they can act as conduits of all these new understandings to the community, and encourage other healers in their neighbourhoods to take up collaborative opportunities. Fourthly, their understanding of means of transmission makes them useful promoters of behavioural change, including the use and distribution of condoms. Finally, since men tend to consult THPs before biomedical doctors (particularly regarding STI symptoms), this reality, together with the benefits already described, should support women in their struggle for access to testing and treatment.

CONCLUSION

Although the advantages of improved co-operation between the traditional and biomedical paradigms in the time of AIDS has long been understood, schemes directly engaged in this process have been rare, perhaps because the success of building relationships with traditional African healers in HIV/AIDS rests on mutual trust and respect. This paper has provided a portrait of the early stages of one such project. The results so far are very encouraging. Three graduated THPs enrolled in the HOPE Cape Town pilot project are now acting in liaison with their local clinics in three townships. They have referred a total of 80 clients for HIV testing since the project's inauguration in 2006. The numbers of men referred by the THPs demonstrates that they can provide a valuable connection between male clients and the clinics. Finally, the healers have formed important bonds with clinic staff, many of whom now express approval of the THPs' involvement and support the enrolment of more healers in similar initiatives. This paper has also documented some of the problems experienced by HOPE Cape Town and described their resolution. In so doing, the paper hopes to provide guidance and insights for those considering the establishment of similar cross-sectoral efforts in HIV/AIDS work, and to provoke debate about ways and means of implementing future co-operative projects.

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SHORT REPORT

SUPPORTING RAPE SURVIVORS IN ADHERING TO POST-EXPOSURE PROPHYLAXIS (PEP) TO PREVENT HIV INFECTION: THE IMPORTANCE OF PSYCHO-SOCIAL COUNSELLING AND SUPPORT

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Eleven years after it was first mooted in 1996, the Criminal Law (Sexual Offences and Related Matters) Amendment Act (32 of 2007) came into effect in December 2007. Law-makers proudly lauded sections 28 and 29 of the Act, which set out how post-exposure prophylaxis (PEP) to prevent HIV infection should be made available to rape survivors.* These clauses are, however, neither particularly novel nor innovative, Cabinet having already approved (in April 2002) the provision of antiretroviral drugs to prevent HIV infection following rape.

Subsequent to Cabinet's decision, a few studies were conducted examining various facets of providing PEP as part of a health response to rape.[1-4] In theory, these findings should have provided legislators with some insight into what was required by rape survivors from a PEP service, particularly in relation to psycho-social support. This was not the case, as we will show in this article, which draws on unpublished findings from 67 interviews with rape survivors† exploring their adherence to PEP.

STUDY METHODS

Monitoring by the Gauteng Department of Health (GDoH) of the uptake of PEP by rape survivors during the period 30 June 2002 - 31 May 2003 found that just 16.2% of rape survivors provided with the drugs completed all 28 days of treatment.[5] Concerned by this low rate, GDoH commissioned research from the Centre for the Study of Violence and Reconciliation (CSVR) (where the two authors were based at the time) to explore factors affecting adherence to PEP in the aftermath of rape.

A number of different approaches were attempted to recruit rape survivors. Letters explaining the study purpose and requesting assistance with recruiting victims were sent to organisations that provide counselling to rape survivors. One PEP site in the province which kept records of patients' contact details also provided us with a list of 20 names and telephone numbers (many of which however turned out to be incorrect). Ultimately, 15 survivors were recruited either by health care staff or researchers for in-depth, semi-structured interviews.

Another 52 rape victims aged 14 years and older were recruited by researchers based at three PEP facilities in the province, two located in greater Johannesburg and one on the East Rand. Selection of these sites was based on convenience, as well as the high number of rape survivors they treated. Over a period of 3 months, amounting to 74 days in total, researchers spent every Monday and Friday at the selected sites. While stationed there they approached rape patients to ask if they would be willing to take part in a short interview around their experience of taking PEP. Of the 60 patients approached, 8 declined to be interviewed. The 52 patients participating in the study therefore represent 87% of all victims aged 14 years and older attending these health facilities on Mondays and Fridays during this period. Information obtained from the short, face-to-face standardised interviews was coded and captured for statistical analysis with SPSS.

*These clauses came into effect on 25 March 2008.
†We use the terms 'patient', 'victim' and 'survivor' interchangeably in this report. 'Victim' is used to recognise that a violent crime has been inflicted upon someone, 'survivor' to acknowledge the long-term work required to cope with rape, and 'patient' because rape survivors are also using a health service.

Both interview schedules focused on the following key themes: patient knowledge of the drugs and their use; drug side-effects and their impact on patients; and support and counselling received by rape survivors after the rape. Interviews were analysed according to these key themes.

The ethical challenges of obtaining consent from children to participate in research meant that they were excluded from the study, which therefore does not explore factors affecting adherence to PEP of children younger than 14. Further, it was very difficult to recruit rape survivors who had defaulted on their treatment. Our findings are therefore more characteristic of women who adhere to their medication than of those who do not.

RESULTS

DESCRIPTION OF OUR SAMPLE: PEP FACILITIES

Fifty-two respondents, comprising 48 women and 4 men, were interviewed. Slightly under half of those interviewed were aged between 14 and 19 years (48%). Approximately 38% of patients were aged between 20 and 29 years and 12% were between 30 and 39. The majority of patients had reported the incident to the police (96%) and most (88%) waited less than 6 hours before being taken to a hospital. Of the patients seen, 4 were asked by hospital staff to first report the incident to the police before they could be treated – of these, 3 did not want to do so.[†]

More than half of the patients (24 or 56%) for whom information was available were completing their second week of PEP, while 10 (23%) were in their third week of treatment. Six (14%) patients had completed their first week of PEP and 3 had just completed all 28 days.[§]

While pre-test counselling was conducted with three-quarters of patients, only 58% received post-test counselling. Slightly more than one in three (19 or 37%) patients reported having missed pills at some point. In 5 cases treatment was stopped because patients had defaulted. Of this group, 3 stopped because they had skipped a number of pills, while the other 2 stopped because of side-effects.

IN-DEPTH INTERVIEWS

In-depth interviews were conducted with 15 survivors. The youngest rape survivor was 16 and the oldest 45, with most (9) being in their 20s. Four women were aged 19 or younger at the time of the interview, while 2 were over 30. All said they completed the entire treatment regimen, with 2 reporting that they had missed taking pills – one because she forgot and the other because she tired of the pills. It is very likely that a third patient may also not have adhered to her PEP. This patient, although maintaining that she did not miss any pills, said she took her pills only once a day which suggests that she did not understand how to take her pills and is therefore very likely to have missed a number of doses.

WOMEN'S KNOWLEDGE OF PEP

Women exhibited varying degrees of understanding of the treatment. Almost 9 in 10 (88%) of the PEP facility sample could not name the pills they had been given (although a small number thought they were taking nevirapine). Patients from one particular site, were however able to describe their pills accurately.

Asked how many pills they were taking daily, responses varied from between 6 pills to 15 pills. (In terms of the regimen prescribed by GDoH at the time, the correct number of pills would have been 8.)[¶] Approximately 1 in 3 (33%) reported taking the incorrect number of pills. One patient, for example, had not clearly understood that she was meant to take both 3TC and AZT and was taking two pills from only one of the packets instead of one pill from each of the packets.

One patient said the nurses did not explain to her how the pills needed to be taken. Another patient, thinking that the medication had only to be taken for a week, had stayed away from school for that week to ensure that she took her pills correctly and did not miss any doses. It was noticeable across the majority of interviews that patients did not know when the treatment was to end and were merely taking their medication from week to week with no clear understanding of when it would be completed.

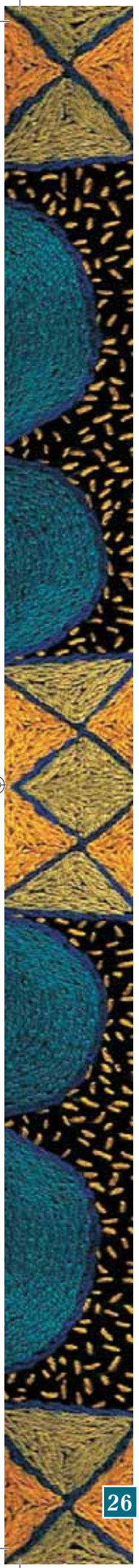
Women who participated in the in-depth interviews provided further insight into additional factors affecting their understanding of the drug regimen. At least 3 patients maintained that they had been in no state to listen to instructions about the treatment. Only after they went home were they able to sit down and determine from the package inserts how the pills should be taken.

> *Even if she explained, I wouldn't remember. You know, when something like this happens, you think about other things.*

[†]The one patient who did want to lay charges struggled to find someone willing to take his report. He first went to Site 3 where he was told to go to the police station to make a statement. (Apparently no police were on duty at Site 3 on this particular occasion.) When he went to the station closest to where he lived, he was referred to the station closest to where the incident occurred. Concerned that time was running out, he went back to the clinic but was once again turned away. He went to another police station and was finally taken to Site 7. This patient spent about 12 hours trying to access a PEP service.

[§]In the case of 9 patients it was not clear how many weeks they had completed.

[¶]This included two AZT pills at 6-hourly intervals and one 3TC tablet at 12-hourly intervals over one 24-hour period. This regimen should be repeated over 28 days.



No, I don't remember them explaining. I know I just had to get them and go home and sleep. At that time, I don't remember any explanations.

Some women were actively engaged in a process of repressing their memory of the rape. They could not recall the date or month in which they were raped and remembered little of what had happened in the immediate aftermath. At least one stated that she was deliberately trying to forget the entire experience.

SIDE-EFFECTS

Some 9 in 10 patients (46 or 88%) experienced side-effects, but only 14 (27%) told staff about these side-effects. Having been told to expect side-effects, they did not think they should mention them to the nurse. Of the 14 who reported the side-effects, 92% reported that nothing changed in their treatment. Only one patient was given other medication to help address the side-effects.

The most common side-effects were nausea and vomiting, with 34 survivors (65%) complaining of these. Tiredness and drowsiness were reported by 18 survivors (35%). Other side-effects included feeling dizzy and weak (14 or 27%), stomach upsets and soreness (10 or 19%) and headaches (7 or 13%). Twelve (23%) patients reported changes in their appetite, 9 losing their appetite while 3 thought their appetite increased. One reported painful lungs and another said she developed a rash around her genital area. Two reported changes in their periods, but this is likely to have been the result of the other medication they were provided with. Of the rape survivors 85% experienced more than one side-effect.

Like those women interviewed at the PEP facilities, almost all interviewees (14) experienced side-effects, with 12 suffering multiple side-effects. The presence of these side-effects tempted patients to stop their pills. One woman commented, 'The first week of tablets I vomited the whole week. I did not even go to work'. The degree to which these side-effects incapacitated survivors varied, some maintaining that it was constant throughout the 28 days and others saying that they experienced side-effects in the first week or two only.

The two rape survivors who did alert staff to the unpleasantness of their side-effects were not treated by the health facility but told to get medication from a pharmacy instead. One of these patients stated that she was not able to afford this medication and would have appreciated the hospital providing her with treatment. A third patient sought help for her side-effects from a private doctor.

Patients usually coped with the side-effects by changing their eating and drinking patterns, typically timing their pills with their meals (a particular challenge for those who had lost their appetite). One took sweets with her pills while 3 others added various types of drinks – tea, soda water and ginger ale – to their diets to help deal with the side-effects. A few patients stopped taking their pills until some of the side-effects had subsided and then started again.

FACTORS AFFECTING ADHERENCE TO PEP

Slightly more than 1 in 3 (37%) patients interviewed at PEP facilities reported having missed pills at some point. Forgetfulness was the reason most commonly cited for missing pills (6); this was linked to the next most common reason for skipping, i.e. patients not being at home when they were meant to take the pills (5). Four patients skipped pills to cope with the side-effects (one patient specifically excluding AZT), and one patient said she did not understand how the pills were supposed to be taken. Another reported that she could not get to the clinic to get more pills because she was at school.

More than half of patients (28 or 54%) interviewed at PEP facilities identified side-effects as the factor that made it difficult for them to take the pills. Two women who participated in the in-depth interviews provide very different reasons why side-effects could cause patients to default. One, a 17-year-old scholar, commented:

The smell was just making me sick when I open the container. And every time I walk into my bedroom I would just smell it and that was making me sick. … I vomited and then I saw the pills there and I was like, 'Oh no' … I just got this disgust feeling of 'No, I'm not going to take this any more.'

Because she had only 3 days left of her medication, she justified defaulting on the basis that she was very close to the end of her pill regimen and it would make little difference if she stopped now.

The other woman did not experience any side-effects in taking PEP, but having been told to expect side-effects, she assumed that their absence meant she was 'cured' of HIV and could therefore stop taking the drugs. A family member persuaded her to continue.

Over and above side-effects, there were other factors that made it difficult for patients to take the pills. These included not liking the taste and smell of the pills; finding the sheer number of pills overwhelming; and the role they played in reminding patients of the incident. Thirteen patients said they did not have any difficulties taking the pills.

Fear also emerged as a barrier to accessing PEP facilities, with a small number of women being frightened of leaving home to come to the clinic, particularly if the rapist/s were still at large.

When asked what helped them take their pills, 15 patients cited fear of contracting HIV as their motivating factor, while 11 maintained that family members reminding them made it easy. One interviewee stated that she reminded herself by setting her alarm clock when pills were meant to be taken, while 2 said nothing made it easier to take their pills.

COUNSELLING AND SUPPORT

Almost all of those interviewed reported having told someone about the need to take the pills. In all of these cases the survivor received support from those they had told, which included family members, school teachers, workmates and friends.

In one case where it appeared that the survivor's parents blamed her for the rape, her sister assisted her to take her medication and often kept her pills for her. Another patient was hiding her pills because she had not told her parents of the rape out of fear of their reaction.

Of the 52 patients interviewed, more than half (56%) had not been for any counselling. Patients at one particular site were most likely to have gone for counselling, mainly because there was a social worker at the facility.

At the time of the study, patients were collecting their PEP from the facility on a weekly basis. During the in-depth interviews, we asked survivors what they thought of this practice. With the exception of 3 rape survivors, most women were in favour of the weekly visits to the hospital for repeats, saying they encouraged them to continue taking their pills and provided an opportunity for their health to be monitored. These patients spoke of the psychological benefits of weekly visits to the clinic:

> *You actually hope that by going there they will make you feel better about the problems you have – I think every week – because somehow it gives you hope going back there, and I thought it would make me feel better.*

One patient remarked that she was very emotional when she visited the clinic. Staff at the site were helpful, allowing her to cry and encouraging her to continue taking the pills. Another patient thought that staff counselling and talking to patients when they came for weekly visits was essential in helping them move on. Survivors stressed the importance of ongoing support and counselling and suggested that more referrals be made to counselling services.

DISCUSSION

The interviews suggest that adhering to PEP is neither pleasant nor easy, and almost all of the rape survivors in this study required encouragement and support from health workers, family, friends and counsellors to do so. The interviews also illustrate how the trauma and distress caused by rape may affect adherence. Shock in the immediate aftermath of the event made it impossible for some women to recall what they had been told about PEP, while for others the drugs brought back unpleasant memories of the rape. Collecting PEP was also a fear-filled exercise for some women. The in-depth interviews also suggest that when women went to health facilities, they were not only hoping to be treated in relation to PEP but also wanted to be helped with their distress and trauma. However, it would seem that the health response to these survivors was primarily being shaped by concerns around HIV, rather than their health care needs globally after the rape.

Other studies have also highlighted counselling as an important component of a PEP service. One study investigated, from rape survivors' perspectives, what services they consider most necessary. They found that respondents most valued the availability of HIV post-exposure prophylaxis (with an HIV test) and having a sensitive health care provider who could provide counselling. They did not make choices based on travel time. The study suggests that patients are willing to trade off access to services (time travelled) for attributes such as HIV PEP, counselling, and a thorough examination.[2]

The second study sought to develop an integrated model for integrated post-rape care and HIV PEP. Among other things, the intervention focused on expanding the role of nurses in the management of sexual assault by equipping them to document the rape history, provide acute trauma debriefing, provide a stat dose of PEP, take a pregnancy test, dispense the treatment package and provide medication counselling and make follow-up referrals. Whereas 61.5% of patients found the health care worker's counselling helpful before the intervention, this number rose to 98.5% after intervention. PEP completion rates rose from 20.0% to 58.3% (although this was not due to the counselling alone).[6]

CONCLUSION

Taken together, these three studies highlight counselling, or emotional and psychological support, as an integral component of a PEP service. Yet in finalising the Sexual Offences Act, counselling services turned out to be what legislators were unwilling to provide. The South African Law Commission, in its discussion paper on reforming the law applicable to sexual offences, recommended that the State provide psychosocial support and health care to victims of sexual offences.[7] The Department of Justice and Constitutional Development did not accept this recommendation and excluded it from the Sexual Offences Bill introduced to Parliament in 2003. Removal of this clause minimises the seriousness of the physical and psychosocial trauma resulting from sexual offences

and ignores the currently differential availability of, and access to, services for wealthy and poor South Africans.

It is not necessary to pass legislation before psychosocial services can be provided to rape survivors. But in passing legislation which treated PEP as rape victims' only health service need, legislators reinforced the separation of HIV from other health concerns, rather than seeing them as intimately intertwined, and elevated HIV over other health concerns. It is to be hoped that health care workers do not repeat this error.

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SHORT REPORT

RECOMMENDATIONS FOR COMPLETING DEATH NOTIFICATION FORMS IN HIV-POSITIVE PATIENTS

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Death notification is a valuable tool for providing data on the HIV pandemic in South Africa, if it is done correctly. This article addresses common misconceptions regarding practical, legal, and ethical aspects of death notification form (BI-1663) completion in order to improve reporting and, ultimately, national statistics and policy-making.

INTRODUCTION

In order to plan effective health interventions in a country and in turn to monitor their impact, sets of uniformly and routinely collected health data are required. One important example of this type of data is the national cause of death statistics. These are compiled by Statistics South Africa from analysis of cause of death information completed on the death notification form BI-1663. These statistics give us an overview of the main underlying causes of mortality in our population overall, and in specific demographic categories (e.g. gender, age, etc.).[1]

Unfortunately, these statistics have poor accuracy, and this severely limits their value for the abovementioned purposes. This lack of accuracy can be attributed to errors made by health professionals in recording causes of death. Several studies performed recently in this country have shown very high rates of major (i.e. influencing the coding of the underlying cause of death) and minor errors in completed death notification forms.[2,3]

WHAT DO OUR CAUSE OF DEATH STATISTICS SAY ABOUT HIV?

The realm of HIV/AIDS statistical reporting has been fraught with challenges (whether ethical, political, or practical) since the beginning of the epidemic, and cause of death statistics have suffered just as much in this regard. According to the findings from the statistical report on causes of death in 2005, the top ranking cause was tuberculosis, followed by influenza and pneumonia, and intestinal infectious diseases. Certain disorders involving the immune mechanism were ranked 7th, while HIV disease was ranked 9th – classified as the underlying cause of death in only 14 532 deaths, or a mere 2.5% of the total.[1] Does this mean that very few people in the country die of HIV/AIDS, or does it mean that very few deaths due to HIV are recorded as such on the death notification form?

Groenewald *et al.*[3] in 2005 compared the trend in age-specific death rates for nine AIDS-related conditions (including tuberculosis and respiratory diseases) with age-specific death rates for HIV as predicted by the Actuarial Society of South Africa model (ASSA 2000), and observed a high level of correlation, concluding that these diseases account for the 'missing' HIV cause of death statistics, and showing that only about 40% of deaths due to HIV are recorded as such. Nojilana *et al.*[4] recently reviewed death notification forms completed at an academic hospital, and observed a similar percentage of HIV deaths as being officially reported on the death notification form.

There is much anecdotal evidence suggesting reasons for non-completion of HIV as cause of death on the BI-1663 form, including confidentiality issues and confusion as to whether or not it is 'legal' to write 'HIV' on the form. Furthermore, there are a significant number of instances on forms where a convenient euphemism (e.g. 'RVD', 'ELISA+', 'immunocompromised', etc.) is recorded in lieu of 'HIV'. It is of utmost importance for these issues to be addressed and the correct information supplied to medical practitioners countrywide if an improvement in the quality and accuracy of cause of death data is to be seen.

PRACTICAL POINTS TO CONSIDER WHEN NOTIFYING CAUSE OF DEATH[5]

Relating to opportunistic infections:

- Always specify the causative organism responsible for an infectious process, e.g. pneumonia, meningitis,

gastroenteritis. If the specific organism has not been cultured, specify the class of organism (e.g. viral, bacterial, protozoal, fungal, etc.) or record as 'organism unknown/unspecified'.

- When recording tuberculosis as a cause of death, avoid abbreviations such as 'PTB'. Always record the anatomical area affected by the organism, e.g. lung, kidney, etc.

Relating to HIV infection:

When recording HIV/AIDS as underlying cause of death, it must be stated as one of the following:

- Acquired immune deficiency syndrome/AIDS (acquired immunosuppression is also acceptable)
- Human immunodeficiency virus/HIV infection
- B24 (ICD-10 code for HIV – see below)
- If the diagnosis is based on clinical findings and not on laboratory diagnosis, the above can be prefixed by 'probable', 'clinical findings consistent with', '?', etc.

The following are not acceptable:

- Immunosuppression
- Immunocompromised
- Retroviral disease/RVD.

The above is necessary because the coders working at Statistics South Africa can only code what they see. They are not permitted to assume that you are referring to HIV infection when you use a euphemism such as 'RVD'. Immunosuppression/compromised is therefore coded under 'certain disorders involving the immune mechanism', and RVD under 'viral diseases unspecified' instead of under 'HIV disease', thus affecting the statistics (personal communication with coding staff at Statistics South Africa Data Processing Centre).

LEGAL AND ETHICAL ASPECTS

The widespread confusion on the ethical and legal aspects of death notification form completion has been fuelled by *inter alia* the widely publicised disciplinary hearing involving a prominent state pathologist. This arose from a complaint laid against him by the family of the deceased for writing 'AIDS' as cause of death. The charges were subsequently dropped as there was no evidence that any legal or ethical boundaries had been transgressed.[6,7]

The law requires you to complete the BI-1663 accurately, as it is an official document, and failure to do so in essence constitutes a criminal offence.[8] The HPCSA guidelines on confidentiality address the issue of disclosure of health information after a patient's death, and refer back to the law, stating that it is a legal requirement for the health care practitioner to complete the death notification form 'honestly and accurately'.[9] It is therefore illegal as well as unethical to omit HIV as cause of death in a patient who died of pathology resulting from this infection. However, the HPCSA also cautions health care practitioners to 'consider whether the disclosure of information may cause distress to, or be of benefit to, the patient's partner or family'.[9]

Although the second page of the BI-1663 form is required to be sealed in an envelope and attached to the first page before being handed to the family,[10] there are no systems in place to ensure this confidentiality. It is therefore conceivable that the family may see the cause of death written on the second page. If the cause of death is stated as HIV, this could cause the family distress if they were not privy to this information beforehand.

In such cases, where the practitioner feels that writing 'HIV' on the death notification form is not appropriate in light of the confidentiality situation, they may record 'B24' as cause of death. B24 is the ICD-10 code representing 'Unspecified HIV disease'. It will be understood perfectly by the coders, and not by anyone else who may happen to glance at the second page of the BI-1663. It therefore satisfies legal and ethical requirements for death notification form completion, protects the family from distress, and facilitates accurate statistical analysis.

CONCLUSION

If the above guidelines are followed when completing the BI-1663, great steps can be taken to improve mortality statistics in the country, providing policy makers with a clearer picture of the epidemic, and, in so doing, improve the interventions aimed at curbing its spread.

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FORUM

TRANSMISSION OF HIV IN THE FIGHTING ARTS

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THE FACTS

Two fighters, X and Y, engage in a bout. Unbeknown to fighter Y, but known to fighter X, fighter X is HIV positive. Fighter X fails to disclose his HIV-positive status to fighter Y before the bout. During the course of the bout both fighters sustain open wounds, fighter X bleeds into an open wound on fighter Y, and fighter Y is infected with HIV.

THE ENQUIRY

The enquiry is:

- Whether fighter X would be guilty of any crime for infecting fighter Y with HIV; and
- Whether fighter X would be liable to fighter Y for damages in delict consequent upon his infecting fighter Y with HIV.

DISCLOSURE

The right to privacy is enshrined in section 14 of the Constitution of the Republic of South Africa Act, 1996. However, neither the concept of 'privacy' nor the scope of the right to privacy is defined in the Constitution and it has therefore fallen to our courts, on a case by case basis, to attempt to define both the concept of 'privacy' and the scope of the right. (See, for example, *Bernstein v Bester* NO 1996 (2) SA 751 (CC) in para [77].)

Following, particularly, the Constitutional Court decision of *NM and Others v Smith and Others (Freedom of Expression Institute as* Amicus Curiae) 2007 (5) SA 250 (CC), the law is now clear that the right to privacy includes protection from disclosure of an individual's private and confidential medical information, including his or her HIV status. Put differently, there exists no general duty on an individual to disclose his or her HIV status, i.e. no one can be compelled to disclose his or her HIV status.

That said, where non-disclosure of one's HIV-positive status is coupled with conduct which results in, or causes, transmission of HIV to another, legal liability – be it criminal or civil or both – may follow; criminal liability flowing from the conduct through which HIV

CRIMINAL LIABILITY

is transmitted and civil liability flowing from the non-disclosure.

On the facts, two possibilities present themselves, namely attempted murder and assault with intent to do grievous bodily harm (assault GBH).

ATTEMPTED MURDER

On general principle, fighter X would be guilty of attempted murder only where, *inter alia*:

(i) He directly intended to kill fighter Y by infecting him with HIV, i.e. where he had intention in the form of *dolus directus*; or

(ii) He foresaw the possibility that he might kill fighter Y (by infecting him with HIV) and persisted in his conduct, reckless as to whether or not that result ensued, i.e. where he had intention in the form of *dolus eventualis.*

(See C R Snyman, *Criminal Law* 4ed at 180-185; Law, Race & Gender Unit, UCT, *Sexual Offences and HIV/AIDS – Challenges Facing the Magistracy* at 44-45.)

The Court would determine whether or not fighter X had intention, in the form of either *dolus directus* or *dolus eventualis*, as a matter of inference from the proved facts. If the only reasonable inference from the proved facts were that fighter X had the requisite intention, he would be convicted of attempted murder; if not, he would be acquitted. In order for the Court to draw the inference that he had intention in the form of *dolus eventualis*, it would merely have to be shown that the accused knew himself to be HIV positive, knew that HIV

could be transmitted by bleeding into an open wound on another, and knew that HIV could cause death.

(See *Snyman* at 186-187; unreported decision of *S v Nyalunga* [2005] JOL 13254 (T).)

Whether fighter X would be convicted of attempted murder would depend upon the facts. However, given the bare minimum of knowledge required of him to support a finding that he had intention in the form of *dolus eventualis*, it is our view that he would be likely to be convicted of attempted murder.

ASSAULT WITH INTENT TO DO GRIEVOUS BODILY HARM

Fighter X would be guilty of assault GBH only where, *inter alia:*

(*iii*) He directly intended to do grievous bodily harm to fighter Y by infecting him with HIV, i.e. where he had intention in the form of *dolus directus*; or

(*iv*) He foresaw the possibility that he might do grievous bodily harm to fighter Y by infecting him with HIV and persisted in his conduct, reckless as to whether or not that result ensued, i.e. where he had intention in the form of *dolus eventualis.*

(See *Sexual Offences and HIV/AIDS – Challenges Facing the Magistracy* at 46.)

It cannot be doubted that infection with HIV would qualify as 'grievous bodily harm'. (See *S v R* 1998 (1) SACR 166 (W) at 170.)

Further, given the competitive nature of a fight, fighter X would necessarily satisfy at least one, if not both, of (*iii*) and/or (*iv*) and, in the result, would be guilty of assault GBH.

The defence of consent (or *volenti non fit injuria*) may be raised by an accused to a charge of assault or assault GBH where the victim of the assault consented to the assault. Successfully raised, the defence has the effect of rendering lawful what would otherwise be an unlawful assault and is a complete defence to the charge. Indeed, the most common examples of cases in which the defence of consent is successfully raised are those in which the assault occurs during the course of a sporting event.

However, the defence of consent would not avail fighter X for two reasons, those being:

- The defence operates only in respect of injuries that are normally expected in the particular sport under consideration and there is no possible room for arguing that infection with HIV is an injury which might normally be expected in a fighting arts bout; and
- The person consenting must have been aware of the true and material facts regarding the act to which he or she was consenting and there is, likewise, no possible room for arguing that, absent disclosure to fighter Y of fighter X's HIV-positive status, fighter Y was aware of the true and material facts regarding the act to which he was consenting.

(*Snyman* at 123-128.)

DELICTUAL LIABILITY

In the event, fighter X would be convicted of assault GBH.

No case has yet come before our courts in which the court has been required to determine whether the transmission of HIV consequent upon non-disclosure by the defendant of his HIV-positive status to the plaintiff attracts liability for damages in delict. In our view, however, should such a case come before our courts, the defendant will likely be found to be liable.

In order for fighter Y to succeed in an action against fighter X for damages, he would have to prove each of the elements of delictual liability, those being causation, negligence, wrongfulness and actual loss, on a balance of probabilities. (See *Telematrix (Pty) Ltd t/a Matrix Vehicle Tracking v Advertising Standards Authority* 2006 (1) SA 461 (SCA) in para [12] at 468A-C.)

CAUSATION

Proof of the element of causation would require proof that fighter X's non-disclosure caused fighter Y's loss. In practical terms, that would require proof of two facts, namely:

- That, had fighter X disclosed his HIV-positive status to fighter Y, fighter Y would not have been infected with HIV, i.e. steps could and would have been taken to prevent his being infected with HIV; and
- That fighter X infected fighter Y with HIV.

The first of those facts could be proved fairly easily by way of medical and other evidence. The second, however, presents some difficulty inasmuch as it is impossible to prove, medically, how or from whom someone contracted HIV. The court would therefore have to decide, as a matter of inference from the circumstantial evidence, whether, on the probabilities, fighter X infected fighter Y. Relevant surrounding circumstances would include:

- Whether fighter Y was HIV positive prior to coming into contact with fighter X; and
- Whether fighter Y was likely to have contracted HIV during the 'window period' after being exposed to HIV by fighter X.

Whether or not fighter Y would be able to establish the

second fact would therefore depend on the evidence, and we are, for that reason, unable to express a definitive view as to whether fighter Y would succeed in proving the element of causation.

NEGLIGENCE

Proof of negligence would require a finding by the court that the 'reasonable person' in the position of fighter X:

- Would have foreseen the possibility that his non-disclosure would cause transmission of HIV to fighter Y; and
- Would have taken steps to guard against it.

(See *Kruger v Coetzee* 1966 (2) SA 428 (A) at 430E; *Minister of Education and Another v Wynkwart* NO 2004 (3) SA 577 (C) at 582.)

Snyman at 214-215 explains the attributes of the *diligens paterfamilias* or 'reasonable person' as follows:

'By "reasonable person" is meant an ordinary, normal, average person. He or she is the person "of ordinary knowledge and intelligence". He or she is neither, on the one hand, an underdeveloped person, or somebody who recklessly takes chances. The reasonable person finds himself or herself somewhere between these two extremes. The reasonable person is therefore not somebody who runs away from every foreseen danger; he may sometimes take a reasonable risk. ...'

On this authority, it is our view that:

- The risk of transmission of HIV to another could never qualify as a 'reasonable risk'.
- The reasonable person against whom the standard of fighter X's conduct would be judged would be the 'reasonable person' who has been diagnosed as being HIV positive and who is possessed of an average HIV patient's knowledge of HIV and its transmission.
- An average HIV patient, and therefore the reasonable person in fighter X's position, would have been aware:
  - that there existed a risk of transmission of HIV from him to fighter Y in the event of his bleeding into an open wound on fighter Y
  - that the prompt administration of antiretroviral therapy to fighter Y, post-exposure, would significantly reduce the risk of transmission of HIV
  - that HIV is progressively debilitating and, ultimately, fatal
  - that there is no known cure for HIV and/or AIDS; and
  - that patients infected with HIV face stigma, shunning and sometimes danger to life and limb.
- In order to prevent (or reduce the risk of) transmission of HIV to fighter Y, the reasonable person in fighter X's position would have disclosed his HIV-positive status:
  - to fighter Y, so as equip him to make an informed decision as to whether or not he wished to continue with the bout and thereby assume the risk of being infected with HIV; and/or
  - to the medical personnel at the ringside, so as to alert him or her promptly to administer antiretrovirals to fighter Y in the event of fighter X's bleeding into an open wound on fighter Y.
- Fighter X's conduct, i.e. his non-disclosure, would therefore have fallen short of the standard of conduct required of him.
- In the result, the court would find that the element of negligence had been proved.

WRONGFULNESS

Proof of the element of wrongfulness would require a finding by the Court that, as a matter of law, fighter X's non-disclosure was wrongful.

The question whether a particular act or omission is wrongful is a conclusion of law which the court will draw upon a consideration of the circumstances of the case, the legal convictions of the community, considerations of policy and constitutional norms, values and principles. (See *Van Eeden v Minister of Safety and Security (Women's Legal Centre Trust*, as Amicus Curiae) 2003 (1) SA 389 (SCA) in paras [9]-[10] and [12]; *Gouda Boerdery BK v Transnet* 2005 (5) SA 490 (SCA) in para [12] at 498G-499B; *Minister van Polisie v Ewels* 1975 (3) SA 590 (A); *S M Goldstein & Co (Pty) Ltd v Cathkin Park Hotel (Pty) Ltd and Another* 2000 (4) SA 1019 (SCA); *Local Transitional Council of Delmas and Another v Boshoff* 2005 (5) SA 514 (SCA).)

Fighter X's non-disclosure would therefore be found to be wrongful if, taking into account constitutional norms, values and principles, the Court considered that the 'legal convictions of the community and considerations of policy' determined his non-disclosure to be wrongful.

It is our view that, indeed, taking into account:

- the competing constitutional rights to privacy, dignity and equality of fighter X, on the one hand, and the rights to life, bodily integrity and freedom of association of fighter Y, on the other hand
- the fact that the prompt administration of antiretroviral therapy, post exposure to HIV, significantly reduces the risk of transmission
- the stigma, shunning and sometime danger to life and limb faced by patients infected with HIV

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- the progressively debilitating effects of HIV
- the fact that there is no known cure for HIV and thus the inevitable progression of HIV towards AIDS and, ultimately, death
- the emotional, financial and social consequences for the families of patients infected with HIV; and
- the fact that HIV/AIDS has reached pandemic proportions in South Africa and is having crippling effects on the country's social structure and economy,

there can be no doubt that a Court would find that 'the legal convictions of the community and considerations of policy' determined fighter X's non-disclosure to be wrongful.

ACTUAL LOSS/HARM

The element of loss – being, *inter alia*, fighter Y's medical expenses, loss of earning capacity and general damages – could fairly easily be proved by way of a combination of medical, actuarial and other evidence.

DEFENCE OF CONSENT OR *VOLENTI NON FIT INJURIA*

As in the criminal setting, a defendant in an action for damages for assault can raise the defence of consent or *volenti non fit injuria* where the plaintiff consented to the assault and, if successfully raised, this will be a complete defence to the plaintiff's claim. In *Boshoff v Boshoff* 1987 (2) SA 694 (O), it was held that the defence of *volenti non fit injuria* is, specifically, available in an action for damages arising out of injuries sustained in the course of a lawful sport or physical recreation.

Again, however, as in the criminal setting, fighter X would not succeed in his defence of consent as the defence does not extend to negligence on his part. In other words, while fighter Y clearly consented to assume the risk of being assaulted by fighter X, it cannot conceivably be said that he consented to assume the risk of the negligent transmission to him of HIV by fighter X. As expressed in *Vorster v Santam Insurance Co Ltd and Another* 1973 (2) SA 186 (W) at 191, fighter X's defence of consent would fail as, absent disclosure, fighter Y would not have known the 'nature and extent of the risk' he was assuming or 'appreciate[d] the risk to life and limb for himself' and the cause of his injury would have arisen from an element not covered by the *volens*.

CONCLUSION

In conclusion, it is our view – assuming that the evidence establishes causation – that fighter Y would succeed in proving each of the elements of delictual liability and would therefore succeed in his action for damages.

CLUB RULES

The option that immediately presents itself to a fighting arts club or association, as a means of protecting its HIV-positive fighters from the potential legal liability discussed above and of protecting its HIV-negative fighters from becoming infected with HIV, is for the club or association to invoke its constitutional right to freedom of association (as enshrined in section 18 of the Constitution) and to adopt a rule to the effect that each of its members is required to submit to a test for HIV and is further required to disclose the results of the test to the appropriate member or members of the association. (See *Taylor v Kurtstag NO and Others* 2005 (1) SA 362 (W) in paras [37] and [48] and *Bernstein v Bester* (*supra*) in para [77].)

It is not suggested that a member identified as being HIV positive should necessarily be excluded from fighting, but merely that knowledge of a fighter's HIV status is essential in order to place an HIV-positive fighter's opponent in a position to give his informed consent to participating in a bout with the HIV-positive fighter and in order to alert the ringside medical personnel promptly to administer antiretroviral therapy in the event of a situation arising in which his opponent is exposed to HIV.

It is our view that, although a rule of a fighting arts club or association requiring disclosure by members of their HIV status would necessarily constitute a limitation on the rights of its HIV-positive members to privacy, equality, dignity and freedom of association:

- Whether or not the limitation is justifiable would have to 'considered within the context' of section 36(1) of the Constitution, i.e. it would have to be considered whether the limitation was 'reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including' the factors set out in sections 36(1)(*a*) to (*e*).
- The rule would have as its object the protection of the right of the fighting arts club or association to freedom of association, as well as the rights of its HIV-negative members to life, bodily integrity and dignity (sections 31, 11, 12 and 10 of the Constitution, respectively).
- The right to privacy is inviolable only in the 'the inner sanctum of a person' or 'the truly personal realm' and becomes subject to limitation as the individual leaves behind the inner sanctum and enters into relationships outside of his or her 'closest intimate sphere'.
- Relationships between fighters would qualify as falling outside of the individual's 'inner sanctum' or 'closest intimate sphere' so that, in context, the individual

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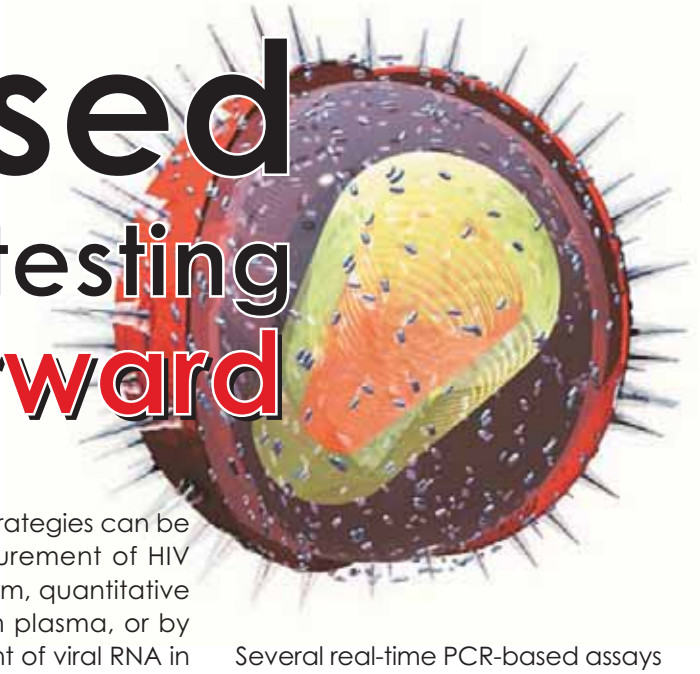

Human Immunodeficiency Virus (HIV) is the etiologic agent of the Acquired Immunodeficiency Syndrome (AIDS). Subsequent to its initial brief and non-specific clinical presentation, HIV infection is associated with a clinically stable, asymptomatic phase that can last for several years. During the asymptomatic phase of infection, viral replication and clearance appear to be highly dynamic processes. Production of viral particles and infection of $CD4^+$ T lymphocytes are offset by equally high rates of virus clearance. Continuous cell destruction and subsequent replacement ultimately results in comparatively stable levels of both plasma viremia and $CD4^+$ cells. During this period however, a steady depletion of $CD4^+$ T lymphocytes leads to severe immunodeficiency, multiple opportunistic infections, malignancies and eventually, death.

With the advent of highly active anti-retroviral treatment (HAART), it became critically important to accurately detect and measure HIV levels in peripheral blood in order to institute and monitor therapy.

Several viral load strategies can be employed - measurement of HIV p24 antigen in serum, quantitative culture of HIV from plasma, or by direct measurement of viral RNA in plasma using nucleic acid amplification or signal amplification technologies. Culture and antigen detection methods are not only cumbersome and time consuming to perform, but may be vastly insensitive in asymptomatic patients. These methods are not suitable for routine use and are best suited for use in dedicated research facilities. Signal amplification assays have been largely successful for HIV viral load determination and are well suited for use in developing countries.

A major drawback of these methods is the relatively long incubation time needed to complete an assay, thus not being conducive to high-paced diagnostic environments. Although signal amplification methods have proved themselves as being robust and cost-effective, this technology is now largely being surpassed by polymerase chain reaction (PCR)-based nucleic acid amplification assays.

Several real-time PCR-based assays are currently available for commercial use and all methods are essentially based on three principles; i) isolation of HIV-1 RNA from a blood sample, ii) reverse transcription and formation of complementary DNA and iii) PCR-based amplification and detection of the required target sequence. Commercial real-time PCR detection platforms are designed for near-total automation, minimizing the risk for operator-introduced error. In addition to automated sample preparation, these assays contain carefully designed probes targeting different areas situated on the HIV-1 genome, making them highly sensitive and specific. Internal amplification controls minimize the risk of PCR-inhibition and simultaneously permit accurate quantitation of HIV-1 RNA in the sample. In addition to improved accuracy, rapid turn-around times are made possible through the use of automation and real-time PCR detection methods.

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fighter's right to privacy would become subject to limitation.

- On a delicate balancing of the conflicting rights of HIV-positive members and the rights of the fighting arts club or association, and 'considered within the context of section 36(1) of the Constitution', the individual fighter's rights would be required to give way to the rights of the club or association and the rule would be 'reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom' and thus valid and enforceable.

Although, perhaps, any fighting arts club or association might baulk at the idea of adopting a rule that circumscribes any of its member's constitutional rights, it is our view that, in the light of the gravity of the consequences of the negligent transmission of HIV (those being, the potential legal liability discussed above for the HIV-positive fighter, and, ultimately, death for his opponent), the adoption of such a rule would be not only legally but also morally defensible and, indeed, would appear to be the only option presently available to a club or association to protect its fighters against the risk of infection.

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CASE STUDY

SEVERE RHABDOMYOLYSIS FOLLOWING CO-ADMINISTRATION OF SIMVASTATIN AND FLUCONAZOLE IN AN HIV-POSITIVE MAN

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We report a case of rhabdomyolysis and acute renal failure in a 43-year-old man newly diagnosed with HIV and hepatitis B co-infection. Rhabdomyolysis was possibly induced by co-administration of simvastatin and fluconazole. Underlying hepatitis may have increased the risk of rhabdomyolysis by decreasing the metabolism of simvastatin. Few case reports link the development of rhabdomyolysis with the co-administration of these two drugs. This case calls for extra pharmacovigilance with proper patient education when prescribing drugs with potential for adverse interactions.

CASE REPORT

A 43-year-old man presented to our genito-urinary clinic with a 3-month history of weight loss, poor appetite and recurrent genital ulcers. He had a past history of ischaemic heart disease and non-insulin-dependent diabetes mellitus. His medications included clopidrogel, gliclazide, metformin, atenolol, ramipril and simvastatin. On examination he was cachexic and had oral candidosis and penile ulcers typical of genital herpes (subsequently confirmed by a polymerase chain reaction test). Other findings were unremarkable. He tested positive for HIV antibodies.

The patient was prescribed fluconazole for the oral candidosis and co-trimoxazole for prophylaxis against pneumocystis pneumonia. A follow-up appointment was made for 2 weeks' time. However, 7 days later he was admitted complaining of muscle aches and difficulty in walking. His temperature was 39°C. He was unable to get up from a sitting position. There was no muscle tenderness, but he had significant weakness of hip flexors and extensors. Power distally was normal. Knee reflexes were normal and ankle reflexes were depressed. He had no bladder or bowel symptoms. The upper limbs and cranial nerves were normal. A urine specimen was dark and dipstick urinalysis showed 3+ red blood cells (RBCs) with no casts or proteins. The blood pressure was 140/70 mmHg. Urine microscopy and culture showed nil RBCs and no growth. Laboratory evaluation revealed sodium 125 mmol/l, potassium 6.0 mmol/l, urea 35.6 mmol/l, creatine 280 µmol/l, phosphate 0.77 mmol/l, calcium 2.42 mmol/l, magnesium 1.05 mmol/l, alanine transaminase 418 U/l, gammaglutaryl transferase l 743 U/l, alkaline phosphatase 460 U/l, albumin 25 g/dl, haemoglobin 10.9 g/dl, white blood cells 12.10×10^9, platelets 312×10^9, creatine kinase 18 123 U/l, lactate dehydrogenase 1 608 U/l (normal 220 - 450 U/l), HIV viral load 334 120 copies/ml, and CD4 count 28 cells/µl (3.3%). Hepatitis B surface antigen was positive. Ultrasound scans of the ureters and bladder were normal.

The patient was started on intravenous fluid therapy. Simvastatin, fluconazole and ramipril were discontinued. Within 3 weeks his muscle strength had improved with normalisation of the creatine kinase level and renal function. He continued to be pyrexial with no obvious focus of infection and rapidly went into respiratory failure requiring ventilatory support. A chest X-ray showed extensive alveolar opacification with confluent consolidation. He was treated for presumed pneumocystis pneumonia with high-dose co-trimoxazole. *Mycobacterium tuberculosis* was eventually cultured from a bronchial aspirate, a bone marrow aspirate and an early-morning urine specimen. He commenced quadruple therapy for tuberculosis followed by antiretrovirals (Truvada and efavirenz) 2 weeks later. He made a full recovery.

DISCUSSION

Rhabdomyolysis is a musculoskeletal condition characterised by muscle weakness, an elevated creatine kinase level and myoglobinuria. The causes can be broadly classified into four categories, namely trauma related, excessive muscle activity, hereditary enzyme defects and medical causes. Medical causes include hypoxia, metabolic disorders, infections, temperature alterations and drugs.[1] Simvastatin is metabolised via the cytochrome P450 (CYP3A4) system. Concomitant administration of simvastatin and drugs that inhibit the CYP3A4 system can increase serum concentrations of simvastatin. Our patient developed rhabdomyolysis soon after commencing fluconazole. The underlying hepatitis coupled with the inhibitory effect of fluconazole on cytochrome CY3A4 may have led to increased serum levels of simvastatin leading to rhabdomyolysis. There are few case reports of rhabdomylysis developing after co-administration of simvastatin and fluconazole,[2] but rhabdomyolysis following primary HIV infection (PHI), infection with *M. tuberculosis* and treatment with high-dose co-trimoxazole has been reported.[3-5] Increasing life expectancy of HIV-positive patients will mean increasing co-morbidities requiring pharmacological treatment. Awareness of the potential adverse drug interaction between statins and the azoles, macrolides and antiretrovirals, especially in patients with underlying liver or renal disease, is important.

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CASE STUDY

MANAGEMENT OF RASH IN A PATIENT ON TB TREATMENT AND ANTIRETROVIRALS

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A 25-year-old man was diagnosed with tuberculosis (TB) on sputum testing. He had symptoms typical of TB – weight loss, night sweats and chronic cough. His baseline CD4+ count was 134/µl (12%). He was mildly anaemic, with a haemoglobin concentration of 11.3 g/l (normochromic and normocytic). Apart from mildly raised gamma-glytamyl transpeptidase (GGT) there were no other problems.

The patient was started on antiretrovirals (ARVs) (stavudine (d4T), lamivudine (3TC) and efavirenz (EFV)) only 11 days after the start of TB treatment. The ARVs were started at the same time as co-trimoxazole (Bactrim).

On day 24 of TB treatment, he presented for admission with the following:

- fever
- rash (macular papular) without involvement of mucous membranes
- cough as before
- increased GGT and alkaline phosphatase (now at three times the upper limit of normal) but normal transaminases.

DIFFERENTIAL DIAGNOSIS

- TB immune reconstitution inflammatory syndrome (IRIS) – while the timing suggests this, the presence of a rash is unusual.
- Drug reaction – the patient had fever. If we believe this to be a drug reaction, we need to stop the offending drug.
- EFV – reactions to this drug tend to occur on the 11th to the 14th day: after start of treatment, so in terms of timing it is still a possible cause. It is common and occurs in about 17% of patients. Less than1% of patients have a sufficiently severe reaction to warrant stopping the drug (Stocrin package insert).

- Co-trimoxazole – a rash is reported in about 3.5% of patients and is most common in those who are HIV positive. Of all the drugs this is the least important, as there are alternative drugs that can be used for prophylaxis. While dapsone is inferior to Bactrim as prophylaxis for *Pneumocystis jiroveci* pneumonia (PCP), it is still a viable option.
- TB treatment – rifampicin, isoniazid and pyrazinamide may cause a hypersentivity reaction with flu-like symptoms and uticaria. A rash from anti-TB treatment usually results from pyrazinamide, not rifampicin. If minor rashes and acneiform reactions to rifampicin occur, they are almost always self-limiting or can be treated symptomatically.

MANAGEMENT

Co-trimxazole was stopped, ARVs were stopped, TB treatment was stopped, and the patient was given antihistamines and steroids (prednisone 20 mg twice a day). The rash and fever settled.

The idea of drug challenge is to identify the drug responsible for the reaction. Drug challenge starts with a small dose of with the TB drug *least* likely to be responsible for the reaction (a small dose is used because if a reaction occurs it will be less severe than the reaction to a full dose). The dose is gradually increased over 3 days.[1]

- INH: is this the drug least likely to be responsible, so this is where to start.
- The procedure is repeated, adding in one drug at a time. A reaction after adding a particular drug identifies that drug as the one responsible for the reaction. There is no evidence that this challenge process gives rise to drug resistance.
- If the drug responsible for the reaction is pyrazinamide, ethambutol or streptomycin, TB treatment is resumed without the offending drug. If possible, the offending drug is replaced with another drug. It may be necessary to extend the treatment regimen. This prolongs the total time of TB treatment, but decreases the risk of relapse.

The patient tolerated this process well and did not develop a rash again. We concluded that EFV was the most likely offender. He completed his TB treatment and was then started on a protease inhibitor (PI)-containing regimen. He is now well.

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CASE STUDY – A SECOND OPINION ON MANAGEMENT

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Patients diagnosed with tuberculosis (TB) and then commenced on antiretroviral therapy (ART) are often on several drugs that can cause a hypersensitivity drug reaction. Such reactions may take the form of a drug rash (which may evolve to a Stevens-Johnson syndrome or toxic epidermal necrolysis), hepatitis, a drug fever or a combination of these. These reactions result in considerable morbidity directly and indirectly because they cause interruptions in optimal treatment for the TB and HIV.

Although recurrence of fever is a manifestation of TB IRIS, a maculopapular skin rash is not. In this case, the maculopapular rash represents a hypersensitivity drug reaction with associated fever. The patient described did not appear to have an associated drug-induced hepatitis, as this typically manifests with raised transaminases. His cholestatic liver function derangement was probably related to TB in the liver.

In this case the drugs that could have been responsible for the hypersensitivity reaction are co-trimoxazole, efavirenz (these are the two most likely culprits) and any of the TB medications (rifampicin, isoniazid, pyrazinamide, ethambutol and streptomycin can all result in hypersensitivity drug rashes). At our hospital we would follow similar principles of management to that followed by the author, but there are certain differences in our approach. While neither approach is necessarily more correct, a 'second opinion' on management of this case may be of interest to the reader.

The presence of fever in association with a drug rash means that the hypersensitivity reaction is severe and systemic. Administration of the drugs most likely to be the culprits must therefore be interrupted. In this case rather than interrupting all therapy we would interrupt only those medications that were the most probable culprits, as follows:

1. In terms of ART, we would stop efavirenz and continue the two nucleoside reverse transcriptase inhibitors (NRTIs), 3TC and D4T. It is possible to interrupt efavirenz (or nevirapine) for 5 - 7 days and continue the two NRTIs because of the long half-life of the non-nucleoside reverse transcriptase inhibitors (NNRTIs), which means that the patient is still effectively on three drugs for this period. Once the reaction has resolved (this usually occurs within this 5 - 7-day window) we would add Kaletra to the two NRTIs. (Kaletra would need to be increased to double dose once rifampicin was successfully reintroduced because of rifampicin's induction of lopinavir metabolism.)

2. We would interrupt all the TB treatment the patient was taking. If the patient was in the early stages of TB treatment, as in this case, we would put the patient on two or three alternative TB drugs that he was not on at the time of the reaction (e.g. streptomycin, ofloxacin, ethionamide) so as to continue TB treatment before rechallenge. Once the reaction had resolved, we would then use these drugs as a backbone upon which to rechallenge one first-line TB drug at a time at 3-day intervals starting with a low dose and increasing to full dose. We would use the following order: ethambutol, isoniazid, rifampicin, then pyrazinamide. The alternative TB drugs used as a backbone can be stopped if the first-line drugs are all successfully reintroduced.

When rechallenging after a skin reaction it is important to monitor the patient's temperature, observe his or her skin and ask about skin symptoms. Even *mild* skin symptoms such as burning or itching after a dose should alert the clinician that that drug should be avoided. The patient may be able to restart all TB medications in this situation, as co-trimoxazole and efavirenz are the most likely culprits. However, if a reaction occurs to one of the TB drugs on rechallenge, that drug will need to be avoided and TB treatment may need to be extended (e.g. to 9 months if pyrazinamide is omitted).

3. We would stop co-trimoxazole and not rechallenge it, given that it was being used as primary prophylaxis and the patient is now on ART which will restore protection against PCP with time.

Our approach in such a situation is therefore to interrupt the likely culprit drugs while continuing safer treatments for TB and HIV as the reaction settles and then rechallenge in a similar way to that described by the author. However, when a drug reaction is life threatening (e.g. severe hepatocellular injury with very high transaminases, hepatic encephalopathy or raised international normalised ratio (INR), or Stevens-Johnson syndrome) we would manage differently: ALL therapies the patient was taking at the time would be stopped in the acute situation.

For drug reactions we do not prescribe systemic corticosteroids. The evidence base for their use is controversial and contradictory. Some studies have demonstrated an increased risk of sepsis in patients with Stevens-Johnson syndrome, and as one cannot be sure that a skin rash will not evolve to this when a patient is first seen, we avoid them.

FROM THE EDITOR

There is a strong feeling in the field that it is 'back to the drawing board' on prevention in HIV. Perhaps the most compelling possibilities going forward involve the use of antiretrovirals for prevention. Without doubt, next to prevention of vertical transmission the most emotive reasons for prevention include the immediate use of antivirals to prevent infection in those recently exposed. A large part of this spring edition is dedicated to post-exposure prophylaxis (PEP). The reduction of mother-to-child transmission is evidence that antiviral therapy at the time when infection is occurring can abort the establishment of that infection. The PEP guidelines as they appear in this edition may be thought of as controversial, and we welcome comments in this regard. There is an equally controversial legal take on the risks of HIV transmission in sport by Verrier and Tuson, and a short report on the importance of counselling and support for rape victims who are taking antivirals after rape. The issue also includes an account of the local experience of engaging with traditional healers in HIV programmes by Wreford and Esser, and some recommendations for completing death notification forms in the HIV era by Smith. Woods *et al.* describe the challenges of training health professionals, in particular nurses, to manage HIV, and present an innovative methodology for training. Finally there are two instructive clinical case studies, one on rhabdomyolysis following a drug reaction in an infected patient by Ramogi and the other the all too common problem of concurrent treatment of tuberculosis and HIV by Conradie, with a second opinion from Meintjes.

It has been said that a week in politics is a lifetime, and this can seldom have been better illustrated than by the past few weeks in South Africa. The political turbulence in our country has also seen the closing of the 'Manto' era, and many, activists and practitioners alike, have voiced an array of sentiments about this in the last few days. Those of us (and thankfully there are many) committed to seeing the countrywide, successful roll-out of PMTCT, antiretrovirals, testing and a variety of prevention strategies, as well as solid operational research, wish Health Minister Barbara Hogan and her team strength, wisdom and tenacity in taking us forward with bold new steps.

LINDA-GAIL BEKKER

Editor

TRIBUTE

MICK GRAHAM

Several extraordinary people have been involved in taking the HIV Clinicians Society from a small group of interested clinicians to one of the largest medical interest groups in the world.

Mick Graham arrived in South Africa four years ago from drizzly London, and has made it his home. Originally deployed to help non-governmental organisations sort themselves out, through the British-based Volunteer Services Organisation (VSO), Mick joined the Society during a staffing crisis. On his first day he was tasked with getting the Society back on its feet, especially as we had just been given a major grant to help establish a range of new projects. Deftly negotiating the complex politics that bedevil everything around HIV, Mick efficiently improved on the organisational structures of the Society while building up the staff complement to the stage where it is now self-sufficient.

Mick's keen negotiation skills, honed while a justly feared trade union representative in his home country, were put to good use in getting great deals from publishers, sponsors and advertisers, all for the good of the Society. In a very short time he established the Society as a viable operation, with the *Journal*, *Transcript*, the guidelines and much of our commercial communication rapidly gaining financial independence. Mick's attention to organisational process has ensured that today the Society is a much stronger and more robust organisation, well positioned for the challenges of the future.

Mick will always be the ideal dinnertime companion. Conversations are liberally sprinkled with 'As my good friend George Bernard Shaw said ...', when not regaling us with his lunches with Prime Minister Tony Blair and stories from Northern England's steelworks.

We owe Mick a large debt, and will miss his contribution to fighting HIV, less than efficient contractors, and bad white wine. The Society, the general manager and the Executive wish him well in his semi-retirement.

Francois, Fatima, Pat, Natalie, Jean, Chloe, Kerry, Linda-Gail

GUIDELINES

POST-EXPOSURE PROPHYLAXIS

KEY SUMMARY POINTS

- Southern Africa differs from other regions, particularly in terms of very high HIV and hepatitis B seroprevalence.
- Post-exposure prophylaxis (PEP) guidelines lack a substantive evidence base to guide advice. It is extremely unlikely that this will change, as randomised studies of different drug regimens for PEP are not feasible owing to the complexity of exposure, low event rate, and inability to ethically have a placebo group. Evolving basic science understanding, along with further studies on animals and prevention of mother-to-child transmission (PMTCT) findings, will continue to guide policy makers.
- Prior PEP guidelines are not user friendly, and rarely acknowledge the complex range of situations that occur with HIV.
- Selecting patients for appropriate PEP administration must be simplified. Algorithmic approaches for highly active antiretroviral therapy (HAART) regimens have simplified ARV management at the treatment and management levels. The same approach is needed for PEP regimens in this region.
- The approach to occupational, sexual and other forms of HIV exposure (bites, assaults, trauma, injecting drug use, etc.) is similar.
- Cases of exposure are often not simple, do not lend themselves to simple categorisation, and require an individualised approach. However, concepts to guide the attending clinician are relatively simple, and allow an effective intervention in most cases.

Convenor

Steve Andrews – Family Physician in Private Practice; Honorary Senior Lecturer, Division of Infectious Diseases, Department of Medicine, University of Cape Town; External Lecturer, Department of Primary Care and Family Medicine, Stellenbosch University

Expert Committee

Marc Mendelson – Head, Division of Infectious Diseases, Department of Medicine, University of Cape Town

Eric Hefer – Managing Director, Calibre Consultants

W D Francois Venter – Cluster Head, Reproductive Health and HIV Research Unit, University of the Witwatersrand

Ebrahim Variava – Principal Specialist and Head of Internal Medicine, Klerksdorp Tshepong Hospital Complex

Adrian Wulfsohn – Director, Ambulance Services, City of Johannesburg

Declaration of interests and support in the last 3 years (sponsors, managed care and pharmaceutical organisations)

Dr Venter is supported by PEPFAR, and has received travel and conference support from various pharmaceutical companies.

Dr Andrews has received conference travel and attendance support from Gilead Sciences, and training support from Aspen Pharmacare and MSD.

Dr Mendelson is supported by PEPFAR.

No other declarations of interests are reported.

The construction of Society guidelines is generally an uncontroversial affair. A panel of experts sits in a room for a few days, argues about a few usually minor issues, and hammers out a consensus document. This document then goes to external reviewers, both local and international, and then becomes standard of care for many organisations and helps inform regional governments' policy.

The post-exposure expert panel has indeed come to a consensus, after a long series of rewrites. However, two key recommendations – that of triple ARV prophylaxis, and treatment for all exposures – are very different from international guidelines, are definitely controversial, and have caused external reviewers to pause.

We have decided to publish the guidelines, and intend to give a detailed critique in the next edition. In future such critiques will be published together with the guidelines, allowing clinicians to see the debate. As with all guidelines, they guide practice, they are not tablets of the law.

We also hope that clincians will take note of the strength of these guidelines, namely the very strong emphasis on occupational prevention and simplified approaches, as well as side-effect and anxiety management, areas usually grossly neglected.

Francois Venter

President, Southern African HIV Clinicians Society

Clinical approach

- Animal data, case control studies and PMTCT data suggest that PEP is highly effective if taken correctly for the full prescribed duration.
- The key outcome in HIV PEP is successful completion of 28 days of uninterrupted appropriate prophylaxis.
- Side-effect management is critical to completion, and is often under-managed. Zidovudine (AZT) and protease inhibitor-based regimens are associated with significant side-effects.
- Anxiety management of the patient must be actively addressed.
- The number of drugs used to treat PEP is often the focus of clinician attention. While number of drugs and specific antiretroviral prescribing are important, completing the full course, through active side-effect and anxiety management, remains the cornerstone of successful management.
- Side-effects due to ART appear to be more common and severe in HIV-negative exposed people than in HIV-positive patients initiated on treatment, especially among health care workers.
- There have been few documented failures of PEP. Many of these failures have been associated with poor adherence, suboptimal dosing or delayed taking of ART.

Drug selection

- Where ART is felt to be justified, three drug regimens should be considered. However, this must never be at the expense of adherence. Monotherapy is known to be effective, and can confidently be used as an alternative where necessary.
- Nevirapine should never be used for PEP, owing to side-effects.
- Boosted protease inhibitors should be used in cases where ARV resistance is suspected, with nucleoside reverse transcriptase inhibitor (NRTI) choices based on medication the patient has not been exposed to. Expert guidance should be sought in these situations.
- Hepatitis B is often not considered after HIV exposure and must be part of any assessment.
- Follow-up must be actively pursued. Advice on further HIV and hepatitis testing, when it is safe to commence unprotected sex, and subsequent primary prevention, are critical. Post-exposure HIV status should be assessed through serial enzyme-linked immunosorbent asay (ELISA) testing. Polymerase chain reaction (PCR) testing does not currently have a role in PEP assessment.

Public health issues

- Occupational exposure is usually avoidable. All cases should be investigated with a view to improving infection control.
- All health and allied institutions where exposure is an occupational risk should have clear, public and accessible PEP protocols.
- Hepatitis B vaccination programmes must be encouraged in all occupational health settings, as primary prophylaxis is very effective.

1. INTRODUCTION

Current guidelines for post-exposure prophylaxis (PEP) are almost exclusively generated in the developed world, where HIV is far less prevalent than in the southern African region.[1] These guidelines largely reflect consensus opinion in regions where co-infection with hepatitis B and C is significantly different from that in our region. All the evidence on which these guidelines are based derives from developed world settings, and is seldom randomised or placebo controlled, except in certain of the prevention of mother-to-child transmission (PMTCT) prophylaxis settings. Much of these data rely on retrospective register analysis, as well as extrapolation from animal data and individual clinical case studies.

Existing guidelines differentiate between occupational and non-occupational exposures, with a strong emphasis on traditional health care settings. Recent guidelines have combined occupational with sexual assault guidelines, but do not address the broad array of other exposures that clinicians face on a regular basis. Given the very high background prevalence of HIV in the southern African region, HIV exposure risk outside the occupational setting is high and the distinction between occupational and non-occupational exposure less helpful for decision makers. Further complicating the problem is the high rate of sexual assault in the South African region, and the very large number of seroconverters within the community. The generalised nature of the epidemic creates differences in risk group demographics that must be accommodated by local PEP guidelines. Finally, 'non-traditional' exposures, such as pre-mastication, tattoos, roadside cuts from barber's shears and other exposures listed below, often require physician advice.

These guidelines do *not* deal with PMTCT settings, pre-exposure prophylaxis (PREP), or the comprehensive management of sexual assault. Local and HIV Clinicians Society guidelines should be consulted as appropriate.

2. SCALE OF THE PROBLEM: OCCUPATIONAL AND NON-OCCUPATIONAL INJURY

Reported occupational exposure to HIV in the USA alone exceeds half a million health care workers (HCWs) per year, with estimates that over 50% of these exposures are unreported. Data from the southern African region are poor. The largest study from three West African countries documented that 45% of HCWs had sustained at least one accidental blood exposure, over 60% of which went unreported.[2] In 2001, 69% of interns at Chris Hani Baragwanath Hospital in Gauteng, South Africa, had sustained at least one percutaneous injury and 45% had

sustained a mucocutaneous blood risk exposure.[3] Again in this cohort over 60% of exposures were not officially reported. At Tygerberg Hospital, 91% of junior doctors reported needlestick exposures in the prior year, three-quarters of these 'after hours' or during calls.[4]

Despite regulatory frameworks being in place in some countries, management oversight as regards occupational accidental blood exposure is largely lacking in southern African institutions, especially as far as the handling of sharps disposal and training in safe exposure practices are concerned.

In terms of non-occupational exposure, while there are data on many aspects of sexual assualt, with rape a tragic and everyday experience for women, children and many men, HIV transmission data are not as complete. There are almost no data on other forms of exposure; however, the continued high incidence of HIV in southern Africa among the general population suggests that exposure is ongoing and high risk. Advice is frequently sought from clinicians regarding PEP following assault, traffic accidents and other trauma-related events where blood exposure occurs.

3. CORE PRINCIPLES FOR PEP

- Occupational exposure prevention requires strong management oversight in all settings.
- Non-occupational exposure requires an understanding of core transmission principles, combined with clinical common sense.
- In the southern African setting, all unknown source exposure should be assumed to be HIV infected.
  - Evidence regarding occupational and non-occupational risks of transmission is limited.
  - Triple antiretroviral (ARV) regimens in treatment and PMTCT settings have been proven superior to mono- or dual therapy regimens.
  - It is recognised, however, that additional ARVs increase the potential side-effect and adherence burden. Risk of adverse effects and toxicities must be weighed against benefit in administering ARVs in the PEP setting. Side-effects must be treated rapidly, effectively and prophylactically.
- PEP should be administered as soon as possible after exposure; efficacy after 72 hours is highly unlikely.
- All PEP regimens must be administered for 28 days. Animal and case control studies suggest that administration for less than 2 weeks is associated with minimal efficacy; administration for more than 28 days confers no added benefit.
- Regimens need to be selected using locally available ARVs.
- A comprehensive infrastructure of counselling and support for the injured party is necessary to facilitate adherence to PEP regimens. Exposure is associated with substantial anxiety for the majority of people. This must be actively dealt with. In many cases, this is most significant for those who do *not* need PEP.
- Counselling must be available to deal with side-effects on an ongoing basis. Zidovudine (AZT) and protease inhibitors (PIs) are commonly associated with side-effects.

Exposure to HIV occurs in a bewildering variety of situations. Exposures where clinicians have requested advice regarding PEP, often where the source HIV and hepatitis status is unknown, include:

- Human bites or exposure to bloody phlegm during bar fights
- Exposure at schools, including biting in crèche
- Contact sports with blood exposure, such as rugby and boxing
- Sharing needles during recreational drug use
- Assaults with several people being stabbed with the same knife
- Bullets travelling through one person and lodging in another
- Animal attacks with repeated blood exposures on several people at once
- Roadside and emergency services exposure – often not just by ambulance staff; police, bystanders who help
- Exposure during home deliveries or during home-based care
- Consensual sexual exposure, burst condoms, mucosal exposure during non-penetrative sex
- Families, home-based carers
- Catering, preparation and serving of food with blood contamination
- Sitting on a needle in a movie theatre
- 'Venoterrorism' – public attacks with needles
- Unconscious drug addict found in a room
- Sex toy exposure.

It is beyond the scope of these guidelines to deal with PMTCT settings, PREP, or the comprehensive legal and clinical aspects of sexual assault.

4. PREVENTION OF EXPOSURE

Awareness of the risks and activities related to transmission of HIV as well as availability of PEP and support is critical, especially in an occupational setting. Health care workers in traditional exposure environments often receive training regarding this hazard. Other potential areas where PEP should be available include, but are not restricted to, home-based carers, day centres and crèches, schools and prisons, where PEP exposure and treatment training are often poorly available.

4.1 PREVENTION OF HIV EXPOSURE IN THE WORKPLACE

Prevention of exposure to HIV and other blood-borne viruses in the workplace is the responsibility of both

employer and employee. It is a legal requirement in many southern African countries for employers to provide a safe working environment and to ensure that employees are adhering to workplace guidelines for infection control.

South Africa has an extensive legal framework and comprehensive codes and guidelines dealing with this issue. Employers have specific and numerous responsibilities with regard to workplace safety and support of staff. The meticulous recording and reporting of incidents is critical and this responsibility usually rests with a medical practitioner. An example of legislation that covers exposure to blood-borne viruses is 'an employer is obliged to provide, as far as is reasonably practicable, a safe working environment'.

A broad range of professionals practising within the health care service and outside the Department of Health are at occupational risk of blood-borne viral exposure (see box below).

Persons at risk of occupational exposure to blood-borne viruses

Health care workers	Non-health care workers
Doctors	Firemen
Dentists	Commercial sex workers
Nurses	Teachers
Traditional healers	Prison warders
Phlebotomists	Bar bouncers
Laboratory workers	
Physiotherapists	
Occupational therapists	
Paramedics	

5. SPECIAL SITUATIONS: OCCUPATIONAL EXPOSURE

Occupational exposure involves potentially hazardous exposure to blood-borne viruses in the workplace.

- All occupational exposure should be regarded as preventable and hence deserving of investigation until proven otherwise.
- Standard precautions should be practised in every setting where blood or infectious body fluid contact is possible. Gloves should be worn, and where appropriate, protective eyewear.
- Clean water or saline should be available to immediately irrigate any mucosal exposure or percutaneous injury. Non-caustic soap should be used unless the exposure involves the eye.
- Needles should NOT be re-sheathed, and manipulation of the needle following withdrawal from the patient must be kept to the absolute minimum.
- Wherever possible, safety equipment for blood taking should be available, particularly in the hospital and clinic setting where the risk of exposure to HIV-infected blood is highest. It is imperative that the cost of cheaper equipment and disposal must be weighed against the potential increased risk of exposure that using such equipment entails.
- Needles and tools for any surgical practice, including traditional circumcision, should never be re-used without rigorous chemical disinfection/sterilisation according to national or local guidelines.
- All needles and sharp objects should be disposed of into a dedicated biohazard sharps bin. Syringes and other blunt instruments should NOT be disposed of in these bins, but rather in regulation biohazard bins for disposal of blunt biohazard objects.
- The number of sharps bins allocated to each workplace area will depend on the setting and the resources available. It is recommended that in hospital settings, designated areas of high throughput of patients who require a large number of invasive procedures, such as intensive care and casualty departments, should have a ratio of sharps bins to beds of either 1:1 or 1:2. Isolation rooms should have their own sharps bin, as should any clinic area in which blood-taking or invasive procedures are undertaken. The ratio of sharps bins to beds in open wards should ideally be 1:2, but be kept to a minimum of 1 bin per bay.
- Once ¾ full, the sharps bin should be sealed and disposed of to prevent obstruction of its orifice; overfull bins are a risk factor for injury during subsequent sharps disposal. In resource-poor settings where sharps bins are unavailable, the safest and most practical method of sharps disposal should be practised as per local or national guidelines.
- Within the hospital or clinic environment, it is the ultimate responsibility of that institution's infection control team to monitor and ensure that sharps bins are being sealed when ¾ full and disposed of correctly. However, on a day-to-day basis this responsibility falls to the nursing sister in charge of the ward or clinic.

Outside of the health care setting, employers must take responsibility for such monitoring and enforce standard practice as laid out above.

- Best practice should be enforced with the aid of unions within the framework of occupational law to ensure that employers and employees are creating a safe working environment with respect to prevention of blood-borne disease acquisition.

Post sexual exposure prophylaxis is indicated for those who present within 72 hours of unprotected risky sexual activity, including but not limited to insertive intercourse, and including but not limited to rape survivors. As a public health intervention equal access to treatment of persons who might otherwise not have been considered to have been raped, but who have definitely sustained a high-risk exposure, is essential to equality of therapy and minimisation of HIV transmission.

- There is often considerable variation in clinical presentation of exposure situations, making it almost impossible to establish standard operating procedures for control of exposure, as may be possible in occupational settings.
- The complications of criminal, civil and medico-legal elements, particularly in the case of criminally defined rape, are specialised elements of care that are beyond the scope of this guideline.
- Given the severe emotional and psychological trauma evinced by many of the patients who present after sexual assault, HIV-specific counselling may be appropriately delayed for 24 - 48 hours after onset of PEP regimens.
- It is recognised that the post sexual assault situation has a high rate of therapy default, complicating all aspects of management.
- The choice of ARVs when multiple other agents are being utilised for pregnancy prophylaxis, sexually transmitted infection (STI) syndromic management, and various medications to treat side-effects of trauma is complicated. Evidence in this setting is lacking, but anecdotal evidence from highly experienced practitioners (Dr A Wulfsson) suggest that the use of triple therapy HAART in this setting may compromise other therapy. Despite the strong empirical arguments for triple ARV therapy in this setting, a default to dual therapy with minimal short-term side-effects may be considered with full disclosure of the potential risk of this strategy to the patient. In addition, prophylactic management such as anti-emetics and anti-diarrhoeals should be considered as upfront therapy, given the high rate of therapy default.
- Issues of potential pregnancy in this scenario should be foremost in the clinician's mind, and use of efavirenz should be carefully weighed against its potential teratogenicity.

6.1 SEXUAL EXPOSURE OUTSIDE OF A RELATIONSHIP, WHERE DISCLOSURE ABOUT THE EXPOSURE IS NOT DESIRED

This is a common and thorny problem faced by clinicians, with ethical and social implications. Marriage and long-term relationships are almost always assumed within our society to be monogamous, although 'straying' from the relationship is very common in all communities. While a single episode of unsafe sex overall carries a low risk of HIV exposure, should the exposed partner become positive, they may have a very high viral load during the seroconversion phase, and unprotected sex will carry a very high risk to the regular partner, whether PEP is given or not. Sudden cessation of regular sexual relationships or introduction of condoms can cause relationship disruption, and the exposed partner may be reluctant to do this. This situation raises issues concerning the duty of the HCW to disclose to the partner, and requires a very careful and individual approach. Any decision to disclose against the wishes of the exposed person to the partner must be carefully discussed with colleagues, representative organisations and medical defence organisations. Patients may require help with strategies around disclosure.

6.2 CHILDREN

Principles around exposure for children are biologically similar to those for adults. However, consent issues are often complicated by legal requirements, and clinicians should be guided by local legislation. Children often do not give accurate histories, and anxious parents, especially in the context of possible sexual assault, may require significant counselling and careful referral.

Pre-mastication of food is commonly practised in both developed and developing countries, and several cases of transmission from caregiver to children have been described in the USA. This practice should be actively discouraged.

Another source of potential infection, through breastmilk, is using wet nurses, as well as milk kitchens (the practice

	Status of the Source		
	HIV Positive	Unknown	HIV Negative
Percutaneous exposure to blood or potentially infectious fluids	Triple therapy	Triple therapy	No PEP
Mucocutaneous splash or contact with an open wound, with blood or potentially infectious fluids	Triple therapy	Triple therapy	No PEP
Percutaneous exposure, mucocutaneous splash or contact with an open wound, with non-infectious bodily fluids	No PEP	No PEP	No PEP

Fig. 1. Selecting patients for PEP interventions.

of pooling breastmilk, and then transferring to bottles in health care facilities). These practices have been described in several local environments, and should be actively discouraged.

Finally, children are exposed to other children's behaviours which may theoretically have transmission risks, such as biting. Principles remain the same, although managing parent anxiety is often a huge challenge.

7. SELECTING PATIENTS FOR ARV INTERVENTIONS (FIG. 1)

7.1 POTENTIALLY INFECTIOUS MATERIAL

The following should be regarded as infectious material:

- **Blood** (and ANY bloodstained fluid, tissue or material)
- **Sexual fluids**
  Vaginal secretions
  Penile pre-ejaculate and semen
- **Tissue fluids**
  Any fluid drained from a body cavity, including ascites, embryonic liquor, cerebrospinal fluid, pleural fluid, pericardial fluid and wound secretions
  Breastmilk

Such exposure requires antiretroviral PEP intervention as described in these guidelines.

In the absence of super-contamination with the above fluids, the following may be considered non-infectious:

- **Sweat**
- **Tears**
- **Saliva and sputum**
- **Urine**
- **Stool.**

Exposure to non-infectious material requires reassurance but no PEP. A special circumstance involves human bites and punching. Where a bite or a punch has resulted in the opening of the skin, PEP should be advocated.

7.2 SELECTING ARV REGIMENS FOR PEP

7.2.1 PEP ARV regimens

The choice of NRTI combinations is based on available evidence in both PEP and treatment settings (including PMTCT), side-effect profiles, ease of use, local guidelines and availability.

Twice a day:

- Stavudine (d4T)* + lamivudine (3TC)
- AZT† + 3TC.

Once a day:

- Tenofovir (TDF) + emtricitabine (FTC)‡.

7.2.2. Third agents for PEP regimens

Twice a day:

- Lopinavir/ritonavir
- Saquinavir/ritonavir (400/100 bd).

Once a day:

- Efavirenz§
- Atazanavir/ritonavir
- Lopinavir/ritonavir (800/200).

NOT recommended:

- Nevirapine – owing to high risk of hepatotoxicity.
- Indinavir – this PI is associated with significant side-effects.
- Abacavir – risk of hypersensitivity reaction.

All PEP ARV regimens must be administered for a full 28 days.

7.2.3 Justification for three over two drugs, and for alternatives to AZT

This guideline is a significant departure from previous PEP recommendations, particularly in as much as where PEP is offered, 3 drugs should be administered. This recommendation is predicated on the following:

1. Current North American (Centers for Disease Control (CDC)) and UK guidelines are based on risk assessments in low-prevalence settings, with presumed exclusive clade B data. In contrast, the southern African situation is one of extremely high HIV prevalence (clade C), high volumes of patients, and an attendant very high number of exposures. The individual and cumulative risk of HIV transmission in this setting has never been quantified. There are limited data suggesting that clade C is more infectious in the sexual exposure setting. We assume that this risk is significantly higher than in other settings, and the person who has been exposed should therefore be treated appropriately.
2. While previous guidelines advocate two or three drugs based on clinician assessment of risk, this guideline recommends three drugs in all situations. There is no evidence backing the use of two drugs over the single agent AZT. We further note that the

*d4T is extremely well tolerated in PEP owing to the short duration of intervention.

†AZT is very poorly tolerated in PEP settings owing to headaches, fatigue and gastrointestinal side-effects. It has, however, the best available data for its use in PEP. D4T and tenofovir have been used successfully in PMTCT regimens, and tenofovir is commonly used for PEP in developed-world settings. While theoretically abacavir and didanosine may be used, these agents offer no benefits over the above, and carry significant short-term side-effects.

‡FTC is only available in the fixed-drug combination Truvada (tenofovir + FTC). FTC is not commercially available separately in sub-Saharan Africa

§Care with patients with pre-existing psychiatric illness and in PEP settings where ongoing severe anxiety predominates the clinical picture. Not to be used in pregnancy.

PMTCT trials suggest no added advantage of adding lamivudine to AZT, a finding replicated in various cohort PMTCT studies. However, the use of triple therapy HAART regimens has been shown to have significant benefit in comparison with dual therapy in treatment and PMTCT settings. While no evidence exists to support the use of such combinations in humans in PEP scenarios, all current PEP guidelines advocate triple therapy regimens in 'high-risk scenarios'. The argument is therefore not one of two or three drugs, but of what constitutes 'high-risk scenarios'.

3. Of particular contention are mucocutaneous exposures and oral sex scenarios, which are attributed with lesser risk. The current CDC guideline is based on a single known transmission out of almost 10 000 reported incidents. Once again, no evidence of risk is available in our setting, but evidence of significantly increased exposures in comparison to the US setting (blood spatters on eyeglasses, masks in low-, medium- and high-risk procedures) is available. Furthermore, blood risk exposures are chronically under-reported, a factor that is likely to be particularly true of injuries that are deemed to carry a lesser risk. Hence the incidence may be greater than we think. For these reasons, coupled with the known high background HIV prevalence, we advocate three-drug PEP in these scenarios.
4. Finally, the risk of side-effects increases when additional agents are added to PEP regimens. Three-drug regimens carry more risk of side-effects than simpler drug regimens, although arguably zidovudine-containing regimens carry such a significant side-effect profile that this agent should be avoided if possible. As there is no evidence that prevention of HIV transmission by AZT in the setting of PEP is due to anything other than its inhibition of viral replication, the use of d4T or tenofovir, the potency of action of which is equivalent to AZT, yet which is far better tolerated over 28 days of therapy, should be recommended as first line whenever possible. While the risk of adverse events is undeniably real, it must be balanced against the unquantifiable but equally real risk of transmission associated with high HIV prevalence, high individual viral load levels, and high levels of exposures in the occupational and non-occupational settings.
5. The guideline's powerful emphasis on appropriate choice of agents to minimise side-effects, on close management of the individual patient through the PEP process, and on the aggressive prophylactic and therapeutic management of side-effects allows a great deal of amelioration of the side-effect risk. This then tips the risk/benefit balance back towards the use of the most virologically potent regimen we have, i.e. HAART. Management guidelines to minimise exposure risk also form a large part of these guidelines, but once exposure has occurred, management of side-effects is almost always achievable, while the attendant risks are not.

8. ROUTINE BASELINE AND FOLLOW-UP INVESTIGATIONS

8.1 INVESTIGATING THE SOURCE INDIVIDUAL

The tests that should be performed on blood from the source individual are shown in Table I. If the source is found to be positive on any of the tests undertaken, they should receive post-test counselling and either be treated or referred to their local health care facility for further management.

- If the source individual is unknown, unavailable for testing, or refuses testing after appropriate counselling, the default position should be that the source is seropositive for all blood-borne pathogens.
- Hepatitis testing may not be available in some resource-poor environments. Hepatitis C testing of the source is recommended where resources are available, and omitted in the follow-up of the exposed person if the source is negative.
- If the source is found to be positive on any of the tests undertaken, they should receive post-test counselling and either be treated or referred to their local health care facility for further management.
- If a source individual is unable to give consent because of an impaired level of consciousness, national guidelines allowing testing in such circumstances should be followed.
- Testing of the source should be undertaken as soon after the injury as possible.
- Testing of needles, sharps or other samples that have been implicated in the exposure is not recommended, even when the source is unknown or refuses testing. Such investigations are unreliable and pose a risk of further exposure to the HCWs undertaking the testing.

TABLE I. TIMING OF BLOODS PRE- AND POST PEP

	Source	Exposed				
	Baseline	Baseline	2 weeks	6 weeks	3 months	6 months
HIV	√	√		√	√	√
HBV	√	√				√
HCV		√				√
Hb, WBC PMN		If AZT part of PEP	If AZT part of PEP			

- A nationally approved HIV test should be performed by a HCW who is trained in this procedure, with pre- and post-counselling, and formally documented.
- A positive rapid test should be confirmed, as per national guidelines, and the source patient managed as per guidelines.
- For source patients ON antiretrovirals, HIV RNA PCR should be performed where available. **If the viral load is elevated, genotypic testing should be considered.** This test should, however, not delay instigation of PEP. Raised viral load results should be discussed with an expert. If viral load testing and/or genotyping is not available, and if resistance is expected, a boosted PI should always be used as a third drug.
- Genotypic or phenotypic resistance testing of HIV from a source patient on or previously exposed to ARVs is not recommended in the setting of PEP.
- Testing of the source for HBsAg can be avoided when the exposed individual is known to be protected from hepatitis B acquisition by natural immunity or vaccination.
- In resource-limited settings where treatment for hepatitis C virus (HCV) is unavailable and seroprevalence within the population is low, HCV testing of the source individual can be omitted.
- Malaria blood films should NOT be routinely sent from source patients, unless there is clinical suspicion that the source has malaria.

8.2 INVESTIGATING THE EXPOSED PERSON

- Except under exceptional circumstances, it is strongly recommended that any investigation on the blood of an exposed person should be requested and taken by an independent third party.
- If infection is proven, baseline investigation for blood-borne viruses forms a vital part of any future compensation claim.

8.2.1 HIV testing

- Pre- and post-test counselling should be offered to all exposed persons at any testing facility.
- A baseline HIV (rapid or similar) test should be performed and the result carefully documented. As many cases have medico-legal or occupational claims implications, it is recommended that formal laboratory testing be done in all cases. Confirmatory testing of a positive result should be undertaken as per standard guidelines.
- Follow-up testing for HIV seroconversion should be undertaken at 6 weeks and 3 and 6 months. We do not advocate routine testing of an exposed worker at 12 months as seroconversion after 6 months is very rare. However, exposed individuals should be properly counselled in this respect and testing provided if the individual requests it.
- Viral load or p24 antigen testing is not recommended in the setting of PEP. Quantitative viral loads may yield false-positive results, and may cause substantial anxiety. Seroconversion on PEP is extremely rare and any exposed individual thought to be experiencing a seroconversion illness on PEP should be discussed with an HIV specialist physician for advice.

8.2.2 Hepatitis B virus (HBV) testing

- If the exposed worker has had natural HBV infection or has been vaccinated and is a known responder, then no investigation or post-exposure therapeutic intervention for HBV is required.
- If the source individual tests HBsAg negative and the exposed individual is not vaccinated or does not know their vaccination/antibody status, they should be referred to a local facility for testing and vaccination.
- In the case of exposure to an HBsAg-positive source, the options for management of unvaccinated individuals or those whose status is unknown are as detailed in Table II.

8.2.3 HCV testing

In resource-limited settings, HCV testing should be undertaken at baseline and 6 months only. There is no known prophylaxis.

8.2.4 Other blood-borne pathogens

Syphilis. Routine testing of source should NOT be performed.

Malaria. Routine testing of a health care worker who has been exposed to a source is NOT recommended unless the source is symptomatic.

8.3 MONITORING FOR ADVERSE DRUG REACTIONS

8.3.1 Co-morbidities

Patients with significant co-morbidities should have regular monitoring of any relevant investigations during therapy. No additional investigations are warranted in otherwise healthy individuals.

8.3.2 Medical co-morbidities and ARV selection for PEP (Table III)

Although many of the co-morbid conditions listed in Table III do not preclude the use of certain ARVs, increased monitoring of the co-morbid condition may be necessary during the 28-day course of PEP. Moreover, whenever a safer regimen is available with equal efficacy, that regimen should be used in preference.

8.4 KEY ISSUES RE COUNSELLING

8.4.1 Anxiety management

Anxiety should not simply be dismissed as baseless with simple reassurance. HIV remains a 'dread disease', despite the success of ART, because it is sexually transmitted, still accounts for significant mortality and morbidity, and has extensive stigma associated with it.

Anxiety management must be part of the adherence or follow-up support, and may need several interventions.

TABLE II. MANAGEMENT OF WORKER EXPOSED TO AN HBsAg-POSITIVE OR UNKNOWN SOURCE*

Vaccinated status of exposed worker	Anti-HBs	HBIG (0.06 ml/kg)	HBV vaccine	Comment
Previous vaccination and known responder	None	None	None	
Not vaccinated	If anti-HBs >10 mUI/ml, no treatment	If anti-HBs <10 mUI/ml, give stat HBIG and repeat at 1 month	1st dose stat and proceed to accelerated schedule 1-2-12 months	HBIG and HBV vaccine can be administered concomitantly at different sites
Incomplete vaccination or unsure	As above	Single dose stat	Complete depending on documentation or restart 0-1-2-12 months	As above
Vaccinated, but unknown response	As above	As above	Single booster stat	As above
Non-responder to primary vaccination	No	1 dose stat repeated after 1 month	1st dose stat and proceed to accelerated schedule 1-2-12 months	As above
Previously vaccinated with 4 doses or 2 completed vaccine series but non-responder		As above	Consider alternative vaccine	

* Adapted from European recommendations for the management of health care workers occupationally exposed to HBV and HCV (*Euro Surveill* 2005; 10(10): 260-264).

TABLE III. CO-MORBIDITIES AFFECTING CHOICE OF ANTIRETROVIRALS FOR PEP

Co-morbidity	Drug	Complication
Pregnancy	Efavirenz	Avoid in the 1st trimester due to teratogenicity
	Indinavir	Hyperbilirubinaemia and nephrolithiasis
Tuberculosis	Kaletra	Additional ritonavir dose of 300 mg bid needed or increase Kaletra dose to 6 tablets bid
Epilepsy	PIs	Increase levels of a number of commonly used anticonvulsants
	Efavirenz	Increased risk of seizures
Psychosis	Efavirenz	Increased risk of psychiatric symptoms
Insomnia	PIs	St John's Wort reduces all PI levels
Migraine	PIs	All PIs increase risk of ergotism with ergotamine co-administration
Renal failure	NRTI	Dose adjustments for AZT and D4T. Avoid tenofovir if creatinine clearance <60 ml/min
Hypertension	PIs	All PIs increase levels of calcium channel blockers. RTV increases beta blocker levels
Diabetes mellitus	PIs	May precipitate hyperglycaemia. Increase monitoring
Asthma	PIs	Decrease levels of theophylline
DVT/PE	PIs	Increase warfarin levels leading to risk of bleeding

Simple telephonic contact and reassurance is almost always adequate.

The intervention must be individualised, but broadly the following approaches should be integrated:

- Contextualise the risk: emphasise that acquisition of HIV is unusual through a single exposure, unless the injury is severe (sexual assault, blood transfusion of an infected unit, severe penetrating injury with infected tissue).

8.4.2 Risk-taking interventions

PEP is an ideal time to deal with risk-taking environments, whether unsafe sex (e.g. a one-night stand with unprotected sex), poor occupational health (e.g. overfull sharps bins) or other (e.g. injecting drug use).

Counselling should be non-judgemental. Addressing occupational risk must be practical (report over-full bins to infection control, do not tell an exhausted nurse to 'be more careful'). Harm to others (e.g. risk to a spouse after sex with a third party) must be solution focused.

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CASE STUDY 1

A man approaches his doctor 24 hours after having a one-night stand with an unknown woman at a conference. The man is married, and is having regular sex with his wife. He is tearful, and does not want to tell his wife what happened. He does not know the woman at the conference, and has no way of contacting her to determine her HIV status.

Initially, he volunteers that they had mutual oral sex only; the doctor elects not to prescribe PEP, as the exposure sounded very low risk. However, the doctor spends a long time extensively counselling the man, pointing out the severe danger he would put his wife in should he seroconvert and continue to have unprotected sex with her. The man is appalled, and tearfully agrees to see a counsellor.

However, he phones his doctor two hours later, and admits that he had unprotected vaginal sex with the woman. He is extremely anxious and tearful, because he anticipates that his wife will be expecting sex with him that night, as he has been away from home for several weeks. They do not use condoms, the sudden introduction of which is certain to make her suspicious. He asks whether the doctor can concoct a medical condition requiring condoms that may allow him to convince her that usage is legitimate; he also asks whether he could take PEP and therefore not use condoms.

The doctor explains carefully that even though the risk of transmission is very low after a single episode of unprotected sex, it is still present, and that it would have severe consequences for his wife. He suggests that he discuss the case with both of them together. The man is very angry, threatens litigation should the doctor discuss the issue with his wife, and accuses the doctor of scaremongering, as he has seen on the internet that HIV is not readily transmissible. He refuses HIV testing. The doctor elects to prescribe PEP (tenofovir, 3TC and lopinavir/ritonavir), and asks the man to start taking it immediately, promising to phone him immediately after the first dose. During this time he consults with two colleagues, both of whom advise him that he has an ethical duty to warn the man's wife. The doctor carefully documents all the advice and the clinical details.

He phones the man two hours later, under the pretext of asking about side-effects. In the interim the man has confessed to his wife, who is furious. The doctor offers to see the two of them immediately, and explains the threats of unprotected sex and the need for PEP. He also takes the opportunity to do an HIV test on both of them, and both are negative. He refers them to a marriage counsellor. The man develops diarrhoea one week after starting PEP, which does not respond to anti-diarrhoeal agents. However, it stops after the lopinavir/ritonavir is discontinued. The doctor stays in touch with him weekly during his PEP, and facilitates follow-up ELISA testing. The man reconciles with his wife, apologises to the doctor for his behaviour, and uses condoms for 6 months until his final HIV test returns negative.

CASE STUDY 2

An anxious couple arrives at the doctor's rooms with their two-year-old child. Their domestic worker has been looking after the child since soon after birth, and the parents have just found out that she has been chewing food for the child while weaning. The couple is terrified that their child has contracted HIV, despite not knowing the domestic worker's status, and she has refused to test, fearing that they will fire her. The couple demand PEP for the child.

The doctor calms the couple down, carefully explaining that while there is a very small risk, PEP during chronic exposures is not necessary. She tests the child immediately with a rapid test, which is negative. She volunteers to explain to the domestic worker why pre-chewing food is not acceptable, but refuses the couple's request to enforce an HIV test. She also carefully explains to the couple about the law, which in their country does not permit them to discriminate against their employee on the basis of HIV status. The couple is initially dissatisfied; however, after having the low risk of transmission explained, they agree to ask the domestic worker to see the doctor. The domestic worker agrees not to pre-chew food, but again refuses an HIV test. The doctor promises to keep all details confidential from the employers, who appear simply relieved that an independent and trustworthy party has been engaged.