supervision he or she is able to practise, the scope of practice being determined by that supervising physician.

As noted above, the issue of mid-level health workers was addressed in the Pick report of 2001. The decision to establish mid-level medical workers was taken in December 2002 at MinMec (now called the National Health Council) and confirmed in January 2004. Investigations and consultations have taken place since then with a wide range of stakeholders and role players including the health science faculties, professional organisations, and statuary councils including the South African Nursing Council. A large consultation conference held in March 2004 was attended by all the health science faculties, a large number of professional organisations including SAMA and Denosa, provincial health managers and district hospital managers and practitioners. The consensus decision at this meeting was that the implementation of the mid-level medical worker programme should continue with specific attention given to scope of practice. At that meeting the SAMA representative gave support to the undertaking. FaMEC (Family Medicine Education Consortium), which represents family medicine departments and rural health units of all the health science faculties in South Africa, assisted the Department of Health in the development of a scope of practice and training programme. Several workshops were held including a 2-day consultation with trainers of primary health care nurse trainers. Work on the scope of practice was informed by a study commissioned by the National Department of Health on the disease profile and skills needs in rural hospitals.[3]

The work started by FaMEC was continued by a ministerial task team who produced a report in August 2005. Since then five health science faculties have been working on further curriculum and training programme development.

With a focus on district health care, the decision was to create a team of clinicians for district health including the primary health care nurse practitioner, the clinical associate and the doctor. In this team the clinical associate will specifically assist the doctor in district hospitals (urban and rural) with procedures. The focus of the clinical associate will be on emergency care and on procedures, in support of hospital doctors. Regulation of the clinical associates will be under the Medical and Dental Board of HPCSA, and the draft regulations approved in 2006 state that the clinical associate will work under supervision.

Issues of inequity in health care in South Africa and the needs at district health level are important factors informing decisions. In the further development of the detailed curriculum, discussions about the scope of practice continue between the health science faculties and other stakeholders.

Rather than calling for the plan to be abandoned, in the face of the need in rural hospitals acknowledged in the editorial, the SAMJ should become actively involved in assisting the process to ensure the best possible outcome. The consultation process is still continuing and contributions are welcomed.

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I thank professors Couper, Hugo and Mfenyana for their responses to my 'diatribe' (definition: piece of bitter criticism; invective, denunciation). We have the same objectives but differ on how to achieve them. Imposing a solution by instructing various groups differs from informed consultation and debate. A responsibility of the SAMJ *is to inform the profession and the public, including through debates like this one. Nursing is the biggest crisis facing South African health care personnel. Nurses have demonstrated their 'pluri-potential' capacity, and our first priority must be to increase their numbers and to enhance their skills. And to improve the management of health care services, as so elegantly demonstrated in Professor Couper's recent article.*[1] – JPvN

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Medicines Control Council and registration backlog of antiretrovirals

To the Editor: Antiretroviral (ARV) medication must be taken faithfully in order to keep HIV in check. Some current regimens of highly active antiretroviral treatment (HAART) require taking many different pills, several times a day. Once-daily ARV formulations simplify dosing and could lead to better compliance.

On 12 July 2006 Bristol-Myers Squibb and Gilead Sciences announced that the US Food and Drug Administration (FDA) had cleared Atripla, their fixed-dose combination tablet containing Stocrin/Sustiva (efavirenz) and Truvada (tenofovir and emtricitabine). Atripla is the second once-daily HAART regimen taken as a single pill to be approved by the FDA. Of the three ARVs in Atripla, only efavirenz is currently available in South Africa. The first fixed-dose combination of ARV medications to be approved by the FDA in January 2005 was Aspen Pharmacare's generic combination of lamivudine,

zidovudine and nevirapine. It is a highly effective and widely used 3-in-1 combination, but unfortunately not available in South Africa as Aspen appears not yet to have applied for its registration with the Medicines Control Council (MCC).

When Aspen was asked in September 2006 whether it has applied to the MCC for registration of the generic combination of lamivudine, zidovudine and nevirapine, Gavin Wiggill, Product Manager for Aspen, provided an evasive equivocal statement from which it was unclear whether they had applied. If not, it is imperative that they do so immediately.

Research indicates that stavudine, used as part of the standard first-line regimen in the Department of Health's HIV treatment guidelines, should be replaced by tenofovir, which is a potent, safe and well-tolerated ARV. Stavudine-related toxicity is one of the main reasons for discontinuation and/or changing the first-line regimen.

Few people on ARV treatment are accessing tenofovir in terms of the Medicines and Related Substances Act, as it is a time-consuming and onerous process to initiate that has to be reviewed every 6 months. Tenofovir is therefore effectively not available for treatment in public health clinics.

Both Gilead and Aspen pharmaceutical companies have applied for registration of tenofovir over the past few years but the MCC has yet to approve its registration, in spite of Aspen requesting fast-track review status for its registration in November 2005. On 24 September 2006 Aspen supplied additional information on tenofovir requested by the MCC, which has since indicated that tenofovir may possibly be registered by early 2007.

In a recent issue of the *Sunday Times*[1] Mandisa Hela, the MCC registrar, admitted that there is a drug registration backlog, with an average registration time of between 2 and 3 years for new drugs (including ARVs) entering the South African market. Experts working for the MCC indicate that this is largely owing to the exodus of skilled staff and increasing numbers of new drug applications. Reviews and evaluations of new drugs for registration are mostly outsourced to busy academics. The MCC therefore appears to be badly resourced and unable to cope with its mandate. Hela claimed that applications for registration of ARVs were automatically fast-tracked, but declined to comment on the pending tenofovir application saying 'that is confidential information'.

The MCC should review new drugs that are fast-tracked by first checking if the FDA and European Union (EU) have approved them. If so, the MCC should only check if there are any issues specific to South Africa that merit concern and then immediately register them. Atripla was approved in less than 3 months in the USA under the FDA's fast-track programme, and was made available within days following its approval. In spite of this good news about the availability of Atripla in the USA, it may take a long time before it becomes available in South Africa given the tardiness of the MCC in registering new medications, including ARVs.

Given the extent of the HIV/AIDS pandemic in South Africa, it is essential that the MCC facilitate the registration of these life-extending medications as rapidly as possible. The MCC should encourage pharmaceutical companies to apply for the registration of new ARVs as soon as they become available and ensure that the fast-track registration process is significantly improved to make these life-extending medications available much sooner.

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1. Registration backlogs block life-saving drugs. *Sunday Times* 17 September 2006.

Sources: http://www.aIDSmeds.com/drugs/atripla.htm, http://www.tac.org.za/newsletter/2006/ns30_01_2006.html, http://www.medpagetoday.com/InfectiousDisease/HIVAIDS/tb/3727, http://www.ciplamedpro.co.za/dyn_pdf/news/Triomune - Cape Times.pdf, http://66.249.93.104/search?q=cache:vzVN7skMW1AJ:www.haart4africa.com/oid1/pub_item.asp%3FItemID%3D249%26tname%3DtblComponent1%26oname%3DFront%2520page+emtricitabine&hl=en&gl=za&ct=clnk&cd=2, http://www.sundaytimes.co.za/Articles/TarkArticle.aspx?ID=2230774

Child abuse and our society

To the Editor: What do we as society do to combat the threat of trauma, crime and violence? Approximately half our population are children, the most vulnerable members of society. Physical, emotional and sexual abuse among the latter has reached epidemic proportions, with approximately 25 000 sexual offences reported to the South African Police each year. Since approximately only 1 in 9 rapes are reported to the police we can assume that the annual number of sexually abused children is around 225 000. Over the last 10 years we at Red Cross War Memorial Children's Hospital have treated approximately 1 000 children under 12 years of age for rape.

What factors in our society contribute to this crime against our children?

1. The perpetrator is usually not a sinister stranger, but rather a well-known friend, family member or breadwinner.[1]

2. In nearly all rape cases, there are important power roles. The perpetrator often has considerable physical, emotional, social or economic power over the victim, making sexual assault much more likely, especially since in 99% of all cases the perpetrator is male. These factors make it very difficult for the victim to disclose or report the crime. Nearly all sexually abused children do not disclose because they have been threatened, often with death.

3. Disclosure of the sexual abuse causes significant distress for the child and his/her family, and disrupts the home environment. Medical examination, hospital admission, contact with social workers and medical staff, antiretroviral therapy and policemen investigating the assault are all major disruptive forces for any rape victim, in particular in the life of a young child. The family often takes enormous strain trying to stay together and not disintegrate.