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Menopause and hormone therapy – how confused are you?

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Where hormone therapy in the menopause is concerned a line was drawn on 9 July 2002 between two eras: the pre- and post-Women's Health Initiative study.¹ On this day the combined oestrogen-progestogen arm of the largest randomised controlled trial (RCT) was discontinued prematurely at just past 5 years. Unusually, the lay media reported on it before it was published and doctors were caught on the back foot when irate patients started calling their rooms to find out about their increased breast cancer, heart attack, stroke and pulmonary emboli risk that they had read about.

The primary aim of the WHI RCT study was to test the effects of hormone therapy on postmenopausal women's risk for coronary heart disease, breast cancer and hip and other fractures. The study was launched in 1991 and included 10 735 women in the oestrogen-only arm and 16 608 women in the oestrogen-plus-progestogen arm. The age range of the women in the study was 51 - 79 (16 608 women), with an average age (63.3) at least 12 years later than the average woman would normally have presented with menopausal symptoms and need or request hormone therapy.

In the words of Jacques Rossouw, principal investigator of the WHI study: 'The Women's Health Initiative study results tell us that during one year, among 10 000 postmenopausal women with a uterus (as opposed to those who have had the uterus removed) who are taking oestrogen plus progestogen, 8 more will have invasive breast cancer, 7 more will have a heart attack, 8 more will have a stroke, and 18 more will have blood clot in the lungs and legs, than will a similar group of 10 000 women not taking these hormones. This is a relatively small annual increase in risk for an individual woman.' The study did,

however, show a reduction in colon cancer and hip fracture risk in the oestrogen-plus-progestogen arm.

Up until 2002 almost reflex scripting of hormone replacement therapy for menopausal women was common among doctors, irrespective of whether a woman was symptomatic or not, and therein lies part of the reason for the patient backlash against the allopathic approach to management of the menopause. Prior to the WHI study we assured women that, in addition to symptomatic relief and prevention of osteoporosis, a small increase in breast cancer was offset by the 50% reduction in heart disease risk shown in observational and epidemiological studies.² We were now being accused of possibly being instrumental in causing cardiovascular deaths.

Cardiovascular disease

The *age of initiation of hormonal therapy* has given rise to the concept of a window of cardiac opportunity around the time of the menopause, thus giving credence to the earlier observational and epidemiological studies.

Some of the many roles of oestrogen before that final menstrual period include keeping arterial walls free of atherosclerosis by maintaining a favourable lipid profile, ensuring vascular wall relaxation and dilatation and preventing insulin resistance, which are all cardio-protective functions. The menopause heralds a dramatic reduction in oestrogen production with a concomitant increase in cholesterol deposits in arterial walls with trapping of cells which become calcified. Thickening of the arterial walls and associated calcified plaques contribute to the development of atherosclerosis as we age and the assumption is that the increased cardiovascular events seen in the WHI represent hormone-induced effects on unstable plaques. Exogenous hormone therapy is considered to stimulate arterial inflammation with subsequent plaque rupture, clot formation around dislodged particles which can block vessels, resulting in myocardial attack or stroke. The Heart and Estrogen/progestin Replacement Study (HERS) Research Group (I and later II) studies in women who had known pre-existing cardiovascular disease initially raised questions about the increase in heart attacks in the first year of hormone therapy use, but it was the publication of

the WHI few years later that raised the alarm.³

Venous thromboembolism remains a risk, especially in smokers, women with previous deep vein thrombosis and/or pulmonary emboli. The transdermal route of administration may be important in decreasing this risk in selected women. Bypassing entero-hepatic circulation by using 17-beta-oestradiol on its own or with progesterone in women with uteri is recommended for this at-risk group.⁴

Breast cancer

Women generally fear breast cancer more than they do cardiovascular disease and could simply not *hear* that only one arm on the study had been discontinued (oestrogen-progestogen therapy) and that women with hysterectomies (oestrogen therapy), by default, were at a distinct advantage where breast cancer and cardiovascular disease were concerned.

Certain oestrogen-progestogen hormonal therapy combinations are associated with an increase in breast cancer. It may, however, be dependent on whether it is given as a continuous combination versus a sequential regimen, how long it is given, at what dose and how it is administered, as well as which progestogens are used. Medroxyprogesterone acetate has been maligned since WHI, but norethisterone acetate has been implicated with a higher risk of breast cancer. Recent Finnish data negate the general consensus that oestrogen alone does not increase the risk of breast cancer, neither does the addition of testosterone to oestrogen therapy.⁵

Recent studies support the notion that hormonal therapy promotes pre-existing lesions which are generally detected early, run a less sinister course and do not result in an increased mortality rate due to breast cancer when compared with non-users of hormone therapy. It is also reassuring that risk returns to that of the background population within a few years of stopping hormone therapy and that the risk increase with oestrogen-progestogen therapy does not occur before 3 - 5 years of use.

Osteoporosis

Results of the WHI showed that the use of conjugated equine oestrogen (CEE, 0.625 mg daily) together with medroxyprogesterone acetate (MPA, 2.5 mg daily) reduced the risk of hip and

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clinical vertebral fractures by 34%, and the overall risk of fractures by 24%, compared with placebo. (These percentages are calculated from the associated hazard ratios reported in the study.) This risk reduction amounted to 5 fewer hip fractures per 10 000 women per year.

Where are we going to?

Since 2002 newer, lower-dose hormone therapy preparations, both oral and transdermal, have come into the market and are starting to find their niche. Parallels may be drawn with the evolution of the now safe, efficacious and mainly metabolically neutral low-dose oral contraceptive pills which now have the added advantage of significantly decreasing the risk of both endometrial and ovarian cancer and can be used quite safely in smokers up to the age of 35.

All controversies spawn new approaches and we will soon be able to use non-hormonal therapy for vasomotor symptoms. Neuroleptic agents and selective serotonin and serotonin-norepinephrine re-uptake inhibitors are already being used extensively in women who choose not to use hormone therapy or have a contraindication for the use thereof.

Position statements abound globally and are under constant review. The South African Menopause Society published its revised statement on menopausal hormone therapy in 2007.⁶

The principles of the lowest effective dose for the shortest necessary duration rule.

According to the South African Menopause Society guidelines, oestrogen therapy does not increase the risk of breast cancer, but increases the risk of endometrial cancer in non-hysterectomised women.

Indications for hormone treatment

- Treatment of vasomotor symptoms and associated sleep disorders.
- Treatment of symptomatic urogenital atrophy.
- Prevention of bone loss in women aged between 50 and 60 who are at the risk of fracture, with or without vasomotor symptoms, while recognising that there are other proven non-hormonal modalities of treatment for osteoporosis.

It is generally accepted that women with premature ovarian failure should be offered hormone therapy until at least the average age of expected menopause, which is considered to be 51 years.

Previously hormonal therapy was also hailed as having such a beneficial effect on cognitive function, that Alzheimer's disease progression could be retarded. Hormone therapy, however, is not indicated for the treatment of Alzheimer's disease.

Contraindications to hormone therapy

- Current, present or suspected breast cancer.
- Known suspected oestrogen-dependent tumours.
- Undiagnosed genital bleeding.
- Untreated endometrial hyperplasia.
- Previous idiopathic or current venous thromboembolism.
- Known arterial coronary heart disease.
- Active liver disease.
- Porphyria cutanea tarda is an absolute contraindication.

Profiling women

By now it must be abundantly obvious that the 'one size fits all' approach of the past can no longer continue. Indications, dose, duration of treatment, current and future co-morbidities should all be considered prior to initiation and reviewed on at least an annual basis.

Initiation of hormone therapy in women over the age of 60 years should be avoided. Prerequisites prior to initiation of therapy include a full general, systemic and gynaecological examination which ideally includes a pelvic ultrasound examination to exclude pre-existing gynaecological pathology, a baseline mammogram and a fasting glucose level and lipogram.

Bone mineral density assessments depend on the patient profile and whether she chooses to use hormone therapy or not. Recognising the development of insulin resistance and being on the look-out for thyroid dysfunction all form part of a menopausal risk assessment.

Given the metabolic and mental impact of a dwindling ovarian reserve, the perimenopause and menopause present an ideal opportunity to intervene on multiple levels to ensure increased longevity and quality of life of women in a comprehensive manner.

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Termination of pregnancy legislation in South Africa: Implications for health service providers

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Providing greater access to safe abortion reduces the public health burden of unsafe abortion, which in 2004 was estimated at 68 000 deaths and 5.3 million permanent or temporary disabilities per annum, primarily in developing countries.¹

The World Health Organization (WHO) defines abortion as a procedure for terminating an unintended pregnancy either by a person without the necessary skills or in an environment without the minimum medical standards or both.

Termination of pregnancy legislation

The advent of democracy in South Africa in 1994 created a unique policy environment for numerous new laws and policies to be legislated, including many within the sphere of women's reproductive health. Major changes in legislation and policy occurred in the area of termination of pregnancy (TOP). The South African Choice on Termination of

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Pregnancy (CTOP) Act of 1996 replaced the previously restrictive Abortion and Sterilization Act of 1975. The aim of the 1996 legislation was to promote a woman's reproductive right and choice to have an early, safe and legal TOP. As a result of the new TOP legislation, abortion-related morbidity and mortality have decreased significantly by 90%.²

The CTOP Amendment Act was first passed in 2004, then challenged in the Constitutional Court owing to a parliamentary process problem. Following nation-wide public hearings was reinstated in 2008. This has resulted in some confusion among health providers. The Amendment Act has, however, now been passed. The Act

- empowers provincial members of executive councils (MECs) of health, instead of the national Minister of Health, to designate abortion-providing facilities and make abortion-related regulations in their provinces
- allows suitably trained registered nurses to perform first-trimester procedures, and
- makes it an offence for a termination to occur at any undesignated facility.

Abortion is a time-restricted health service.

- The CTOP Act provides for abortion on request up to 12 weeks of gestation.
- In cases of socio-economic hardship, rape or incest, and for reasons related to the physical and mental health of the pregnant woman or fetus, terminations can be performed up to 20 weeks' gestation.
- From 20 weeks onward terminations can only be performed under very limited circumstances.
- Parental consent is not required for minors.
- First-trimester TOPs must be performed at a designated health facility by a trained midwife, trained registered nurse, or medical practitioner.
- Second-trimester TOPs must be done by a trained medical practitioner.

A health care provider has the right to refuse to perform an abortion – the right to conscientious objection. However, providers are obliged to inform a woman requesting a TOP of her rights according to the Act. In addition, a conscientious objector is legally and ethically obliged to care for patients with complications arising from an abortion, whether induced or spontaneous.

In 2001 the Medicines Control Council registered mifepristone for abortion use during the first 8 weeks of pregnancy. In combination with misoprostol, it has been shown to be a very effective medical abortion method when used early in the first trimester of pregnancy, and expands a woman's choice of an abortion method. Medical abortion is currently available in the private sector and guidelines are being developed for its introduction into the public health sector.

Challenges

Despite the new improved legislation, TOP services still remain inaccessible to many women. Barriers to women accessing TOP services include provider opposition to offering services, stigma associated with abortion, poor knowledge of abortion legislation, and a dearth of providers trained to perform abortions and facilities designated to provide abortion services.³⁻⁵ Increasing difficulties in accessing abortion services have resulted in women accessing illegal, unsafe abortions, i.e. outside designated health facilities.⁶

In recent years the number of abortions performed nationally and in each of the provinces has multiplied substantially, indicating increased availability and accessibility to abortion services.⁷ Despite this increase in demand and utilisation, challenges exist in the further expansion of services, particularly by trained nurse or midwife service provision up to 12 weeks' gestation. Service provision has been impeded by opposition among health care professionals to abortion services and to those providing them. Furthermore, there is a dearth of health personnel trained to provide abortions.⁴ The shortage of health care providers willing or trained to perform abortions undermines the provisions of the CTOP Act by limiting the availability of safe legal abortion, and has serious implications for women's access to safe abortion services and health service planning.

While the new legislation has greatly reduced maternal morbidity and mortality, gaps between policy and implementation need to be addressed. Strategies have to be developed with regard to these gaps in order for TOP legislation to contribute fully to improving women's health in South Africa.

Some of these issues could be addressed by exploring the following:

- An emphasis on quality of care is needed and would encompass all aspects of abortion provision and care. Similarly, the psychosocial needs of providers must be attended to as counselling and support are required for providers and clients.

- Contraceptive counselling, including post-abortion contraceptive counselling, needs to be strengthened.
- Knowledge and understanding around the 1996 CTOP Act, including conscientious objection, need to be strengthened.
- Support programmes and incentive schemes, which attract prospective abortion care providers and retain existing providers, need to be developed.

Criminal Law (Sexual and Related Matters) Amendment Act (No. 32 of 2007): Emerging issues for the health sector

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In 1997 a law reform process started to change the existing law on rape. After 10 years of drafting and public consultation, the Criminal Law (Sexual Offences and Related Matters) Amendment Act, No. 32 of 2007 – less formally referred to as the Sexual Offences Act – was finally passed by Parliament and signed by the President on 13 December 2007. The new Act creates a range of new offences (58 in total) and addresses a wide range of issues relating to the management of sexual offences. The Act sets out to afford complainants of sexual offences 'the maximum and least traumatising protection that the law can provide'. To achieve this objective, the legislation repealed certain outdated common law crimes such as rape and indecent assault and replaced them with new, extended statutory offences.

The most salient and positive change brought about by the Act is the re-definition of rape. The old Sexual Offences Act (No. 23 of 1957) provided that only a woman

could be raped and only by a man. The only object with which one could legally be raped was a penis. Forced oral sex did not constitute rape, and neither did the all too common insertion of objects into the victim's vagina or anus. The new Act (of 2007) changes these archaic notions of what constitutes rape. Under the new law, sexual violations of men, women and children by a man or a woman are recognised as an equally devastating injury to the victim's physical, psychological and sexual integrity.

The new definition of rape therefore considers the act of rape to be gender neutral – meaning that both men and women can be raped and commit an act of rape. Rape is now defined as an act of 'sexual penetration' with another person without such person's consent (Section 3 of the Sexual Offences Act). The term sexual penetration replaces the term 'vaginal penetration'. Sexual penetration refers to penetration of the vagina, anus or mouth by a penis *or* the vagina or anus by a penis or other foreign object. This is a necessary and principled shift in our law.

While the element of 'consent' – a contested issue where a rape complainant is required to establish that she *did not* consent to a sexual act – has been retained in the definition, the new Act clearly states that sexual intercourse is not voluntary or without coercion when the sexual act is committed:

- using force or intimidation
- by threats of harm
- by abuse of power or authority inhibiting a person from indicating his or her unwillingness
- under false pretences or by fraudulent means
- with a particular person who is in fact a different person, or such a sexual act is something other than that act; or
- where the person is incapable in law of appreciating the nature of the sexual act because she is
 - asleep
 - unconscious
 - in an altered state of consciousness, including under the influence of any medicine, drug, alcohol or other substance, to the extent that their consciousness or judgement is adversely affected
- a child below the age of 12 years, or
- a person who is mentally disabled.

This explicit list makes it very clear that an accused cannot claim that the victim consented under these circumstances.

The offence of 'indecent assault' has been replaced by the much broader offence of 'sexual assault' (Section 5 of the Sexual Offences Act). Sexual assault is defined as 'sexually violating' another person without such person's consent. Sexual violation covers a very wide range of behaviours, e.g.:

- contact between the genital organs/anus/female breasts of one person and any body part of another person/animal/object
- contact between the mouth of one person and the genital organs/anus/female breasts/mouth of another person
- masturbation of one person by another person (Section 1 of the Sexual Offences Act).

The main distinction between rape and sexual assault is that the latter does not include penetrative forms of sex, except the insertion of an object 'resembling or representing the genital organs of a person or animal' into the *mouth* of another person. It is important for health care professionals to understand the nature of the new offence of 'sexual assault', because outside the legal context sexual assault is often used as a generic term for different types of sexual offences. Medico-legal health care professionals must now be cautious when using this term, particularly when they fill in a J88 form. (A prosecutor or magistrate might interpret the term sexual assault on a J88 form as indicating that there was no penetration.)

The Sexual Offences Act also introduces a range of other sexual offences, i.e. compelled rape (forcing one person to rape another), exposure to pornography, and engaging the sexual services of a person. In addition, the Act creates distinctive categories of offences in relation to vulnerable persons, including sexual offences against people with disabilities and sexual offences against children (e.g. exploitation, grooming, exposure to and creation of child pornography). In another positive development, the delayed police reporting of rape can no longer be interpreted as indicating a false complaint and therefore the courts may not draw any negative inference from delayed reporting. Similarly, the lack of a previous consistent statement may not be construed as indicative of a false complaint.

In addition to the new definition of rape, of critical importance to medical practitioners are the Act's provisions relating to:

- post-exposure prophylaxis (PEP) after a sexual offence
- compulsory HIV testing of persons accused of a sexual offence, and

- mandatory reporting of sexual offences against children and persons who are mentally disabled.

This article focuses on the provision of PEP for rape survivors.

Post-exposure prophylaxis for HIV

One of the major limitations of the Act is that it does not provide for a comprehensive package of health care and psychosocial support for victims of sexual violence, despite exhaustive recommendations by legal reformers to include these services in the legislation.² PEP is the only service provided for in the law. Section 28 (1) of the Act sets out that a victim who has been exposed to the risk of being infected with HIV as the result of a sexual offence may receive PEP at a designated public health establishment. The law stipulates: 'If a victim has been exposed to the risk of being infected with HIV as the result of a sexual offence having been committed against him or her, he or she may (a) subject to subsection (2) (i) receive PEP for HIV infection, at a public health establishment designated from time to time by the cabinet member responsible for health [...], at State expense and in accordance with the State's prevailing treatment norms and protocols[...].'³

Section 28 (3) of the Sexual Offences Act stipulates that a medical practitioner or a nurse to whom the sexual offence is reported must provide the following information to the survivor:

- the right to receive PEP for HIV infection in accordance with the State's prevailing norms and protocols
- the importance of obtaining PEP for HIV infection within 72 hours after the alleged commission of the offence
- the right to receive free medical advice on the administration of PEP
- the right to be supplied with a list, containing the names, addresses and contact particulars of accessible public health establishments that provide PEP
- the need to obtain medical advice and assistance with regard to other sexually transmitted infections
- the right to apply for a compulsory HIV test of the alleged offender.

Surely, the provision of some of this information and the service are standard practice and go hand in hand with administering PEP and other medication (while the Act itself does not specify which treatment and medications must be offered to rape survivors, the national Health Directives provide the necessary detail).⁴

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Health professionals should, however, be aware that some of these duties are new (such as compiling a list of accessible public health establishments; and information around compulsory HIV testing) and might require extra resources and training.

It is important to note that coercive or violent forms of rape present a higher risk of HIV transmission than consensual sex, because of the increased risk of injury to the victim. Furthermore, in South Africa a high number of rapes are committed by more than one perpetrator, thereby bearing an increased risk of injury and potentially multiple exposures to HIV.^{5,6} PEP should be taken within a few hours of exposure to HIV. The drugs are most effective when started within *a few hours* of exposure; treatment must be initiated within 72 hours *at the very latest*.⁷ Anecdotal evidence from our work with the police suggests, however, that while rape survivors may have the legal right to PEP their actual access to PEP may be prevented or delayed by misinformation as well as logistic and institutional barriers (e.g. police and health care workers' lack of knowledge of the right to PEP and their responsibilities under the Act). To enable the swift provision of PEP, which will – it is hoped – reduce the likelihood of HIV transmission, it is essential that both health care workers and police officials receive comprehensive training on their duties relating to PEP. Before setting out the duties of health care professionals, some of the limitations of PEP are highlighted below.

Limitations of PEP

While it is a positive development that the law introduces the survivor's right to PEP, there are several limitations to this right. First, PEP will only be provided at State expense at 'designated health facilities' (Section 28 (1) of the Act). Accordingly, *not all* public health facilities offer PEP free of charge. While some provinces decided to designate health care facilities for the provision of PEP, others offer PEP at all hospitals. The second limitation is addressed in Section 28 (2) of the Act, which sets out that a rape survivor will only be provided with PEP at State expense if he or she lays a criminal charge with the police or reports to a designated health establishment. *It is critical for health care practitioners to understand that a criminal charge does not have to be laid for PEP. Instead, a 'report' of rape to a health care facility is sufficient to warrant the administration of PEP.* The third limitation lies in the nature of PEP. Because the drugs' effectiveness declines rapidly over time, the victim needs to present at the designated health establishment within 72 hours of the commission of the offence (Section 28 (2) of the Act).

Health care workers' duties pertaining to PEP

The 2009 Directives by the Department of Health⁴ (Health Directives) aim to guide health care professionals in implementing the new legislation. Despite the fact that the Directives are incomprehensive and poorly drafted, they do provide *some* guidance on post-rape health care services. (Instead of providing complete guidelines, the Directives request that they be read with the Department of Health's National Sexual Assault Policy and the National Management Guidelines for Sexual Assault Care, which provide much more detailed information on post-rape health care services. The drafting of the Health Directives is poor in terms of structure and language.) The following section briefly outlines certain aspects relating to the administration of PEP under the Directives.

PEP can only be given to rape survivors who are HIV negative. The Directives therefore request that the survivor be tested for HIV before he/she can be given PEP.⁸ The Directives stipulate, however, that 'a 3-day starter pack must be offered to those patients who prefer not to test immediately, those who are not ready to receive results immediately or those who are unable to consent immediately due to severity of injuries or traumatising'.⁹ This provision acknowledges that the treatment needs to be started as soon as possible and that starting the treatment is more important than testing the survivor.

If the rape survivor agrees to be tested and tests HIV negative, he/she is given a week's supply of PEP. At the first follow-up appointment after a week the survivor receives the remainder of the drugs. However, the Directives accept that this kind of drug administration may sometimes be impractical and therefore stipulate that '[f]or those patients who cannot return for their one-week assessment due to logistical or economic reasons, a 28-day treatment supply with an appointment date must be given'.¹⁰ Unfortunately, the Directives lack provisions on what to do if a rape survivor does not want to test for HIV immediately *and* is unable to return for the collection of the remainder of the drugs at the 1-week assessment. It is therefore unclear what health care professionals should do in this instance.

The administration of PEP goes hand-in-hand with the provision of comprehensive information. First, the HIV test requires the health care worker to undertake pre- and post-test counselling. Second, the health care worker should advise the survivor that it is necessary to use condoms while on PEP and until the 3-month follow-up visit. Third, it is necessary to provide in-

depth adherence counselling. In addition, the health care worker should improve adherence by:

- explaining
 - how to identify each tablet
 - when to take them
 - expected side-effects and management options for side-effects
- *always* providing an anti-emetic with the treatment
- offering home visits and follow-up phone calls
- advising the survivor to keep a pill diary
- providing referrals to NGOs and support groups.¹¹

Understandably, the provision of comprehensive health care services, including PEP, may be overwhelming in the light of the current shortage of health care workers and resource constraints at public health facilities. Yet, it is necessary that health care workers understand their duties and responsibilities in order to minimise negative health consequences for rape survivors.

Conclusion

The new sexual offences legislation introduces necessary and long overdue changes to the previous law on sexual offences. The creation of a right to PEP is a first step, but does certainly in itself not achieve affording victims the 'maximum and least traumatising protection that the law can provide'. For the somewhat limited right to have any positive impact at all, it is essential that government departments, such as health, and the SAPS equip their staff to put this right into practice.

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Contraception and HIV/AIDS

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When the words contraception and HIV appear in the same sentence they usually elicit a one-word response – condoms – seldom with any reference to other more effective forms of contraception.

Dual protection

Male and female condoms are the only contraceptives that afford dual protection, i.e. simultaneously prevent both pregnancy and STI/HIV infection. Condoms are effective when used correctly and consistently, with failure rates of 2% and 5% for male and female condoms respectively. In typical use, failure rates are 15% for male condoms and 21% for female condoms.¹

Recently I have seen a number of women, often requesting termination of pregnancy, reporting that 'We were using condoms and don't know how this (pregnancy) happened'. Many had previously used pills or injections, but switched to condoms, in response to messages promoting condoms for HIV prevention. Some HIV-infected women said lay counsellors actively discouraged use of other contraceptives. Emergency contraception in the event of a condom accident was seldom mentioned during counselling, and advance provision of emergency contraception pills was rare.

Whether this is the true counselling message, or merely the client's interpretation, is open to question. Whatever the case, it is an extremely worrying situation.

Dual method use

Clearly, we need to review communication with regard to behavioural change to include the benefits of dual method use. This entails using highly effective contraception, of the client's choice, to prevent pregnancy, in addition to correct and consistent use of male or female

condoms to protect against STI/HIV infection or reinfection. It requires a clear explanation about the limitations of a single method and supportive counselling, as some research suggests that HIV-infected women using effective contraception are less likely to use condoms, even with an uninfected partner.²

Reproductive rights

Reproductive rights, choices and access to sexual and reproductive health services for individuals and couples living with HIV should be similar to those for uninfected men and women. Availability of accurate information, counselling and access to a wide range of contraceptive methods allow women and couples with HIV to consider their reproductive choices and plan for the future, avoiding unintended pregnancies and intended pregnancy when HIV transmission risk is at its lowest. Use of effective contraception further allows safe use of certain antiretrovirals that are teratogenic (e.g. efavirenz).

Contraceptive choices for women with HIV/AIDS

The World Health Organization (WHO) has developed guidance in the form of *Medical Eligibility Criteria for Contraceptive Use* (MEC) based on expert review and consensus of all available scientific evidence. The following summary of contraceptives, available in South Africa and suitable for use by women with HIV/AIDS, is based on the most recent WHO MEC recommendations.³

Barrier methods

Male and female condoms play an essential role in dual protection, as described above, but other contraceptives may provide better pregnancy prevention.

Hormonal contraception

Not much data are available about HIV/AIDS and hormonal methods other than combined oral contraceptive pills (COCs) and the progestin injection, depot medroxyprogesterone acetate. It is likely that hormones administered by other routes, e.g. transdermal patches and subdermal implants, will have similar outcomes.

Theoretical concerns have been raised about the role of hormonal contraceptives in increasing a woman's risk of acquiring HIV by promoting genital shedding of the virus, thus increasing risk of transmission and/or accelerating disease progression. Based on existing evidence, the WHO does not recommend changes to current prescribing practices; however, these may be revised as new evidence becomes available.

In addition, drug interactions with some antiretrovirals decrease serum hormone levels through enzyme induction, potentially reducing contraceptive efficacy. Other antiretrovirals increase hormone levels, perhaps exacerbating adverse effects. It is possible that hormone use may affect antiretroviral therapy. Our knowledge in this area is limited, based purely on serum hormone levels, not on pregnancy outcomes or ovulation indicators. Further research is needed to clarify these important issues.

Combined oral contraceptives

In the absence of other medical conditions, women with HIV or AIDS, including those using antiretrovirals (with the exception of ritonavir-boosted protease inhibitors), can safely use 30 µg COCs if taken regularly.

Progestin injections

No significant drug interactions were found between antiretrovirals and medroxyprogesterone acetate, which are safe to use at normal intervals. Clients should be encouraged to receive injections on time. (Data are lacking on norethisterone enanthate.)

Emergency contraceptive pills

Emergency contraceptive pills may be used without increasing the dosage.

Intrauterine contraception

Hormone-releasing intrauterine systems and copper IUDs may be used by appropriately screened women with HIV or AIDS, provided those with AIDS are clinically well on antiretrovirals. Studies have shown no increase in HIV acquisition in IUD users, and no significant increase in complications in HIV-infected IUD users compared with uninfected users.⁴ IUD use does not increase genital shedding of HIV.⁵

Surgical sterilisation

This is a good option for either males or females who do not want more children. Careful counselling is essential as the procedure is considered permanent and irreversible. HIV-infected women may be vulnerable to coercion by society, family and/or health care providers.

With limited exceptions, almost any method of contraception can be used by women with HIV/AIDS. Use of condoms for dual protection should be encouraged in addition to the chosen contraceptive method.

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Compulsory HIV testing of alleged sexual offenders: Role of the health care professional

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In December 2007 the Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007, commonly referred to as the Sexual Offences Act, was signed into law. The legislation repealed outdated common law crimes, created new statutory offences and amended criminal procedural law in order to afford victims 'the maximum and least traumatising protection that the law can provide' (Section 2 of the Sexual Offences Act). The new Act also created two distinct health-related services for victims of sexual offences: (i) the administration of post-exposure prophylaxis (PEP); and (ii) the compulsory HIV testing of alleged offenders. These services will only have an impact if health care professionals understand their duties and role in the implementation process. While another article in this issue of CME sets out the implications of the right to PEP,¹ this article discusses the provisions for compulsory HIV testing of alleged offenders and their implications for health care professionals.

Overview of the compulsory HIV testing process

Under the Sexual Offences Act, alleged offenders (the terms 'alleged offender' and 'accused' are used interchangeably) can be tested on application by the victim of the sexual offence or on application by the police. While the legal requirements for an application by the victim differ from

those for an application by the police, the process is the same once an application has been granted. This article focuses on victim-initiated applications.

Application and court process

It is important to understand that the compulsory HIV testing proceedings are completely separate from the criminal trial. Both male and female victims of sexual offences may apply for a compulsory HIV test of the perpetrator before the criminal trial. To make such an application for a compulsory HIV test of the accused, the victim must first lay a criminal charge with the South African Police Service (SAPS) (Section 30 (3) of the Sexual Offences Act). The charge (and application) can also be brought by an interested person acting on behalf of the victim. According to Section 27 of the Sexual Offences Act, a number of people can act as an interested party on behalf of the victim, including:

- the parents, caregiver or guardian of the victim
- the victim's medical practitioner or health care provider
- the victim's partner
- a social worker.

The application can only be brought *within 90 days* of the alleged commission of the sexual offence (Section 30 (1) of the Sexual Offences Act). This time period was chosen because during the 90 days after the sexual offence the victim is unable to find out conclusively whether he or she has been infected with HIV through the offence.² A negative test result at this stage would be unreliable owing to the window period. Due to this unreliability, the lawmaker thought it justifiable to force the alleged offender to be tested.

Once the victim or interested person has submitted the application, the investigating officer must forward the application to the relevant magistrate's court within two working days (Section 30 (4) of the Sexual Offences Act; Section 3 (2) (b) of the Criminal Law (Sexual Offences and Related Matters) Amendment Act Regulations).³ The magistrate must scrutinise whether there is prima facie evidence for the following (generally, prima facie evidence means that if the magistrate or judge were to believe the facts presented, he or she would find in favour of the applicant):

- a sexual offence has been committed against the victim by the alleged offender
- the victim may have been exposed to the body fluids of the alleged offender
- no more than 90 calendar days have

lapsed since the commission of the alleged offence (Section 31 (3) of the Sexual Offences Act).

If the magistrate is satisfied with the evidence, he/she must make an order for the alleged sexual offender to be tested for HIV. The magistrate will then notify the police of the outcome of the application (Section 31 (4) of the Sexual Offences Act). The police, in turn, must inform the applicant (i.e. the victim or interested person) and, if the application was successful, make the accused available for the HIV test (Section 31 (5) of the Sexual Offences Act). The accused cannot refuse to have the HIV test or challenge the magistrate's decision. The refusal to have the test constitutes an offence (Section 38 (2) of the Sexual Offences Act).

Testing the accused at the health facility

If an order for a compulsory HIV test was granted, the police will ask a health care professional at a designated health facility to take two body specimens (i.e. blood samples) from the accused. While any 'medical practitioner or nurse' can take the specimens, only the head of the designated health care facility or a person designated by him/her may 'perform one or more HIV tests on the body specimens of the alleged offender as are reasonably necessary to determine the presence or absence of HIV infection in the alleged offender' (Section 33 (1) (c), (d) of the Sexual Offences Act). The Directives issued by the Department of Health (hereafter: Health Directives) stipulate that an enzyme-linked immunosorbent assay (ELISA) must be used for the HIV test (Directive 2, No. 16 (a) of the Health Directives).⁴

Once the test result is obtained, the health care professional who carried out the test must 'record the results of the HIV test in the prescribed manner' (Section 33 of the Sexual Offences Act). The test result must be recorded 'in triplicate' and must be put into three separate envelopes (Section 8 of the Criminal Law (Sexual Offences and Related Matters) Amendment Act Regulations). The envelopes must be marked 'confidential with: the case number, name and rank of the investigating officer, name of the survivor (i.e. the victim), and name of the alleged offender' (Directive 3, No. 17 (e) of the Health Directives).

One sealed record of the test results must be retained at the health care facility and duplicate *sealed* and *separate* records have to be forwarded to the investigating officer (Section 33 (1) (d) of the Sexual Offences Act). The investigating officer will then inform the victim/interested person and

the alleged offender of the outcome of the HIV test by handing each of them a sealed envelope containing the test result and written information on how to deal with the test result (Section 33 (1) (e) of the Sexual Offences Act). The sealed record retained by the health care facility may be requested by the police at a later date if: (i) the original application was made by or on behalf of the victim and the police or the prosecutor subsequently applies to see the existing test result; or (ii) the original application was made by the police and the victim subsequently applies to see the existing test result.

Confidentiality and disclosure of the test result

The health care professional will hand duplicate *sealed* envelopes to the police. The police, in turn, must communicate the test result to the accused and applicant by handing each of them a *sealed* envelope. Accordingly, only the applicant (i.e. the victim or, if the police applied, the relevant police officer) and the accused will be informed of the outcome of the test in order to protect the confidentiality of the accused.

If an application was brought by or on behalf of the victim, only the victim and the alleged offender will be informed of the test result – the police will *not* be informed. Similarly, a victim will *not* be informed of the test result if the application for the test was made by the police. If a test has been carried out on application by one party (e.g. the victim) and the other party (e.g. the police) wants to get access to the test result at a later stage, it has to make an application to obtain the existing test result. If the court grants the application the applicant will be informed of the existing test result; the alleged offender will not be retested.

Withdrawal of sexual offence charge

Sometimes, the sexual offence charge is withdrawn during the investigation process. If a charge is withdrawn at the request of the victim while a compulsory HIV testing process on his/her behalf is underway, the court order for the HIV test lapses (Section 33 (2) (a) of the Sexual Offences Act). As a result, the test may not be carried out or, if the accused has already been tested, the specimens taken or results obtained before the lapsing of the order must be destroyed (Section 33 (2) (b) of the Sexual Offences Act). Unfortunately, the Health Directives do not provide any guidance on the issue of notification of the accused. It therefore remains unclear whether an alleged offender who has already been tested should still be notified of the test result.

Duties of health care professionals

Health care professionals may deal with compulsory HIV testing in three ways. First, the law requires them to inform victims of their right to apply for a compulsory HIV test. Second, the health care professional may be asked to apply for an HIV test on behalf of the patient as part of the aforementioned ‘interested person’ provision (Section 27 of the Sexual Offences Act). Third, a health care professional may have to carry out a compulsory HIV test on an alleged sexual or, if the police applies, other offender where a court made an order for such a test.

Provision of information

Section 28 (3) (a) of the Sexual Offences Act sets out that ‘when or immediately after laying a charge’, the victim must ‘be informed [...] by a medical practitioner or a nurse to whom the incident is reported [...] of the services referred to in subsection (1)’, which includes compulsory HIV testing of the accused. The law defines ‘medical practitioner’ and ‘nurse’ as a person registered as such under the relevant legislation (the term medical practitioner means a person registered as a medical practitioner in terms of the Health Professions Act, 1974 (Section 27 of the Sexual Offences Act)).

While the law created a clear obligation for health care professionals, the Health Directives lack provisions that clarify this duty. It is recommended, however, that the health care professional address the benefits and limitations of compulsory HIV testing when informing victims of the right to apply for such a test.

So what are the limitations of compulsory HIV testing? Compulsory HIV testing is meant to inform the victim whether the alleged offender is infected with HIV ‘with the view to – reducing secondary trauma and empowering the victim to make informed medical, lifestyle and other personal decisions; or using the test results as evidence in any ensuing civil proceedings’ (Section 34 (a) of the Sexual Offences Act). The purpose of the testing can therefore be summarised to help the victim to make decisions about: (i) (continuing or stopping) PEP; (ii) practising safer sex with the consensual sexual partner; and (iii) reproductive health.

It has been argued that testing the alleged offender fails to achieve any of these purposes, because the test result is not necessarily reliable or indicative of the risk for the victim.⁵ If the alleged offender is tested during the window period, the test result might be HIV negative, although his/her HIV status is actually positive.

The test result may therefore create a false sense of security in the victim and may, as a result, lead the victim to stop PEP and/or practising safer sex with the consensual sexual partner. Such decisions may lead to HIV infection in the victim and his/her consensual sexual partner. An HIV-positive test result, on the other hand, may be misinterpreted by the victim to mean that HIV was transmitted during the sexual offence. Whether HIV was transmitted during the sexual offence depends on numerous factors, such as the viral load of the accused at the time of the offence; prevalence of other sexually transmitted diseases in either the accused or the victim; injuries during the rape; etc. Health care decisions should therefore not merely be based on the test result.

To prevent ill-informed decisions by the victim, the health care professional should explain the limited utility of compulsory HIV testing when he/she informs the victim of the option of applying for a compulsory HIV test. It should be stressed that the test is unable to determine the risk of transmission and that the status of the accused does not necessarily reflect the victim’s HIV status. Furthermore, the limited reliability of an HIV-negative test result should be emphasised. The provision of this information by the health care professional is of particular importance, given that the victim will not come into contact with any medical personnel during the application process for the compulsory HIV test.

Filing an application

Another way health care professionals may deal with compulsory HIV testing is by filing an application. A health care professional qualifies as an interested person under Section 27 of the Sexual Offences Act and can therefore bring an application on behalf of a patient (i.e. the victim). There are currently no guidelines under which circumstances a health care professional should make an application on behalf of his/her patient. The law only stipulates that a health care professional may make the application for the victim. In this case, the health care professional would have to go to the police station to file an application.

The application on behalf of the victim generally needs to be brought with the written consent of the victim, unless the victim is:

- under the age of 14 years
- mentally disabled
- unconscious
- a person in respect of whom a curator has been appointed, or

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- a person whom the magistrate regards as unable to provide consent (Section 30 (1) (b) of the Sexual Offences Act).

The application process is not different from when a victim applies. If the order is granted and the test performed, the investigating officer will hand the sealed envelope with the test result to the health care professional and the latter would then need to inform the victim.

A health care professional who applies for an HIV test on behalf of the victim should counsel the victim thoroughly on the limited utility of the test result and should advise the victim to his/her best knowledge on any health decisions that need to be made.

Execution of testing order

Finally, health care professionals may be required to carry out the compulsory HIV testing order. In this case, the health care professional must, before collecting the body specimens from the alleged offender, ensure that the test was requested within 90 days of the alleged commission of the offence (Directive 2, No. 15 (a) of the Health Directives). This obligation is, however, ambiguous, because (i) the magistrate will only have ordered the test if the application was made within the 90-day limit; and (ii) once an order has been made, the health care professional is not in a position to overrule the court order. In addition, the health care professional must offer the accused pre-test counselling or ensure that such counselling has been offered before conducting the test (Directive 2, No. 15 (b) of the Health Directives). The Health Directives also stipulate that the health care professional has to provide all relevant information on HIV/AIDS to the alleged offender (Directive 2, No. 15 (c) of the Health Directives).

Accordingly, the alleged offender receives some HIV-related information before the HIV test. After the test, however, post-test counselling is not provided because the alleged offender is informed of the test result by the investigating officer rather than the health care professional. The alleged offender receives the test result in a sealed envelope with a notice explaining the test results. While this way of informing alleged offenders gives them the opportunity to expose themselves to the test results when they feel ready to do so, it also means that they may lack information and support generally provided through post-test counselling.⁶

It should be noted that while the alleged offender receives at least some counselling before the test, the victim might not receive any counselling. As noted earlier, such counselling would be important in the light of possible misinterpretation of the test result. The victim may be unaware of the window period and/or may think that the test result reflects his/her own HIV status. Yet, since the police hands the test result to the victim, counselling of the victim is not foreseen. The Sexual Offences Act and the National Instructions' for the SAPS do not address counselling of the victim. The Health Directives, however, require the police to ensure that the victim has been counselled before receiving the test result, but the Directives lack details on who should provide this counselling and at what time (Directive 3, No. 17 (g) of the Health Directives). Health care professionals are therefore strongly advised to use the opportunity when they are providing sexual offence-related health care services to counsel victims on compulsory HIV testing and its limitations.

Ethical and human rights concerns

Testing persons for HIV against their will and disclosing the test result to others raise clear ethical concerns. While it is beyond the scope of this article to discuss these concerns comprehensively, health care professionals should be aware that the law does not make provision for a health care professional to refuse to carry out the coerced medical procedure. This may put health care professionals in a difficult position because of their ethical code of conduct.

The forced HIV test also infringes the alleged offender's human rights (such as privacy, dignity, and bodily integrity). The lawmaker argues that if there is prima facie evidence for a sexual offence, the victim's human rights (dignity; bodily and psychological integrity) outweigh the alleged offender's rights.⁸ Despite good intentions, however, compulsory HIV testing may actually do more harm than good,⁹ as has been noted above.

In order to keep the human rights impact to a minimum, the law requires that test results be kept confidential and only allows their disclosure to a limited number of people (Section 37 of the Sexual Offences Act). As noted earlier, health care professionals may therefore only communicate the test result to the investigating officer and must do so by means of a sealed envelope. In addition, 'all test results of alleged offenders must

be kept in a locked cabinet/cupboard with access restricted only to the head of the health establishment or unit' (Directive 3, No. 17 (c) of the Health Directives).

Conclusion

The involvement of health care professionals in the execution of compulsory HIV testing orders is mostly limited to routine clinical practice such as HIV counselling and testing. Yet, due to the construction of the testing process by the lawmaker, health care professionals cannot render post-test counselling services, which might be detrimental for both the alleged offender and the victim. While the accused will at least be given some information before the test, the relevant policies fail to appropriately address counselling of the victim. In order to protect victims from misinformed decisions, and possibly HIV infection, health care professionals are advised to mitigate the legal ambiguity by providing comprehensive information to victims when they present for post-rape health services.

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