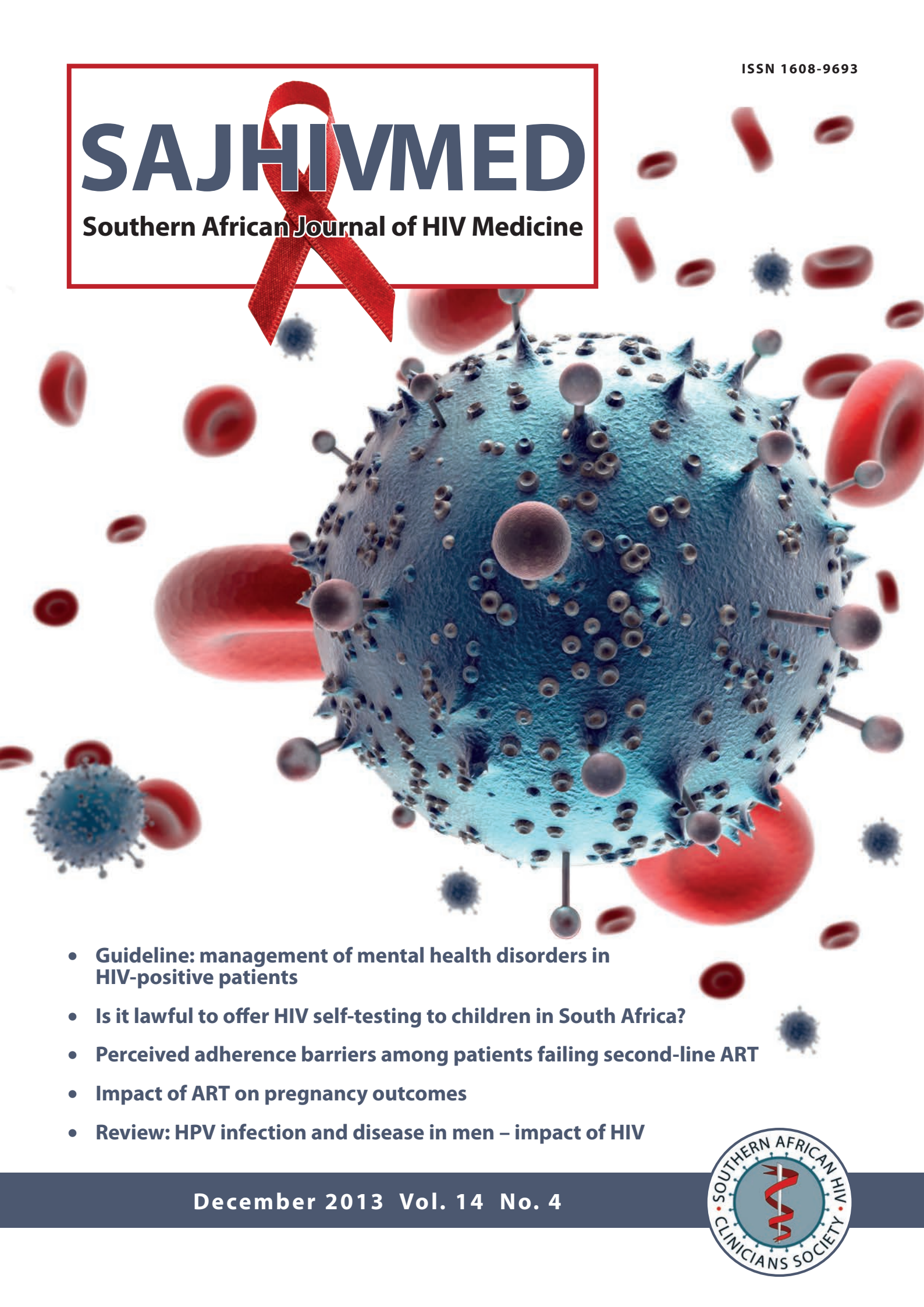


SAJHIVMED

Southern African Journal of HIV Medicine



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- **Is it lawful to offer HIV self-testing to children in South Africa?**
- **Perceived adherence barriers among patients failing second-line ART**
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The SAJHIVMED gratefully acknowledges the generous support of our peer reviewers during the past year, who graciously carved several hours out of busy career and family lives to undertake this important task. We appeal to senior colleagues actively involved in research to serve as peer reviewers and to encourage their juniors to sign up by registering online (www.sajhivmed.org.za) or express their interest via email (publishing@hmpg.co.za).

Sincerely,
Landon Myer



MESSAGE From the Editor

is issue features a diverse sampling of HIV medicine from across South Africa (SA). Several contributions provide a glimpse into the future of the HIV epidemic in the country, and in turn, our responses.

In the area of the prevention of mother-to-child transmission (PMTCT) of HIV, the use of triple-drug antiretroviral therapy (ART) regimens in HIV-infected pregnant women is becoming standard of care – whether as short-term prophylaxis against mother-to-child transmission or as lifelong treatment. In Europe and North America, the use of ART in pregnancy has raised concerns around potential toxicities in HIV-exposed pregnancies and infants. It is important to remember that almost any such toxicity is likely to be uncommon in comparison to the risk of vertical HIV transmission. Still, with more than 200 000 pregnant women exposed to ART each year across SA, the possibility that *in utero* ART exposure may contribute to adverse pregnancy or child health outcomes requires consideration. Aniji *et al.*^[1] report the outcomes of a small cohort of HIV-exposed pregnancies from Limpopo Province. While the sample is small and there are limitations to the design, the findings for no association between early *in utero* ART exposure and either prematurity or low birthweight appear somewhat reassuring. There are a number of major, ongoing studies across the country investigating these issues, and with the 2013 revisions to the PMTCT guidelines in full implementation, additional evidence is eagerly anticipated.

In thinking about health systems, we know that nurse-driven services form the basis of primary healthcare across SA, and most HIV-positive individuals are managed through nurse-initiated management of antiretroviral therapy (NIMART) services. One of the core challenges to NIMART services is providing appropriate clinical support to nurse practitioners. In this regard, the National HIV & TB Health Care Worker Hotline serves as a valuable resource. Swart *et al.*^[2] present a descriptive analysis of the queries that the hotline has received recently from nurses. Their report provides readers with valuable insight into the types of questions that arise in primary care, and with this, a valuable basis for future training interventions.

There is considerable excitement in public health circles about human papillomavirus (HPV) vaccination across SA and its eventual impact on cervical cancer epidemiology, particularly in HIV-positive women. However, the manifestations of HPV in men have been largely neglected. Delany-Moretlwe *et al.*^[3] review the epidemiology and natural history of HPV in men, emphasising the role of circumcision and vaccination in future prevention efforts. In addition, self-testing for HIV infection has been controversial, both locally and internationally, as a strategy to increase awareness of individual HIV status. Strode *et al.*^[4] comment on the ethico-legal aspects of HIV self-testing in adolescents, and raise important questions about the risks v. benefits of allowing self-testing in young people – clearly a double-edged sword.

Inevitably, the number of patients initiating second-line ART regimens is growing in most parts of the region, and following

from this, a small but increasing number of patients are found to be failing second-line regimens. Failure of a second-line regimen is considered grounds for specialist referral in many settings, but this is certainly not always possible. This issue features two contributions regarding the management of patients on second-line regimens in primary care settings in Cape Town. First, in a group of 69 patients with sustained viraemia on a second-line regimen, Garone and colleagues^[5] report that a substantial proportion appeared to re-suppress with targeted adherence support. In parallel with this, Barnett *et al.*^[6] present a qualitative study using a unique photo-based methodology to suggest that the barriers to adherence in this group of patients vary notably between patients and providers, underscoring the complexity of supporting patient adherence. This research is from small, local studies, but is surely a harbinger of the kinds of issues that the national ART rollout will face in the years to come.

Finally, few among us would question the role of mental health as part of long-term health outcomes in HIV-positive patients, including the interplay of mental disorders and treatment adherence, as well as the neurocognitive effects of HIV disease. However, many providers struggle with practical steps to support the mental health of their patients. To help fill this gap, the Southern African HIV Clinicians Society has produced a valuable guideline^[7] on the management of different types of mental health disorders in HIV-positive patients. The guideline is at once comprehensive but accessible – an impressive feat given the breadth and complexity of mental disorders – and hopefully readers will be able to put it to good use in practice.

Happy reading.

Landon Myer

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MESSAGE

From the Executive

I have spoken before about where we are in the HIV epidemic in South Africa (SA) today. The heady days when there were scientific breakthroughs every few months are over. The excitement surrounding increased treatment access, improved antiretroviral therapy (ART) regimens and nurse-initiated management of antiretroviral therapy (NIMART) have settled; HIV no longer makes the news every other day. What we have achieved is truly remarkable: SA has the largest antiretroviral (ARV) programme in the world, with estimates of as many as 2.4 million people receiving ART. HIV healthcare workers can be proud of the contributions they have made – and continue to make – to lessen the burden of this disease.

Now that the excitement has passed, it is time to get on with the slog of rolling out and sustaining a massive treatment programme. What we are finding is that this may actually be our greatest challenge yet. In this issue of *SAJHIVMED* you will find an insert highlighting key points from a national survey conducted by the Stop Stock Outs Project assessing ARV and tuberculosis drug stockouts at the facility level. As you will see, the report found that the problem is far beyond previous estimates, and affects most provinces. The telephone survey, which took place during September and October 2013, obtained information from over 2 000 health facilities. Around one in every five facilities in SA reported a stockout or shortage during the 90-day period covered in the survey. Free State, Limpopo and Mpumalanga provinces were the worst affected,

with 54%, 41% and 26% of facilities affected, respectively. In 20% of facilities facing stockouts, patients were sent away with no medicine.

To some of you these results won't be surprising at all, as you are negotiating medicine shortages and stockouts on a daily basis. What the report makes clear is that stockouts are so common, that they represent a credible threat to the success of the national ARV programme.

The report is also a reminder that although the fight may be over, the battle is far from won. As we begin 2014 and prepare to mark ten years of ART in the public sector, we must celebrate what we have achieved, but not become complacent about where we need to be. As healthcare workers we must redouble our efforts and contribute our part to strengthening the health system, whether it's reporting medicine stockouts, corruption or inefficiencies within the system. What we have accomplished in ten years is no less than remarkable; what is possible for us to achieve in the next ten is truly inspiring.

Francesca Conradie

President

Southern African HIV

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Call for submissions

A decade of antiretroviral therapy in the public sector

As 2014 marks the 10-year anniversary of the public sector rollout of antiretroviral therapy (ART) services in South Africa, *SAJHIVMED* is planning a special edition to reflect on the lessons learned and celebrate the achievements during this time.

As part of this, *SAJHIVMED* is calling for submissions from healthcare workers, policy makers and researchers towards this special edition. Contributions of all shapes and sizes are welcome. We are particularly interested in 'reflections' from clinicians on the ground – providing insight into the realities of delivering ART to increasing numbers of patients, often under difficult circumstances.

These submissions can take the form of editorials of 500 - 1 000 words or longer, commenting on individual experiences of providing HIV care and treatment services at all levels of care. If you are interested, please submit these pieces by 15 January 2014 via the journal website (<http://www.sajhivmed.org.za>) or email the Editor directly (landon.myer@uct.ac.za).



FORUM

Is it lawful to offer HIV self-testing to children in South Africa?

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Health-facility-based HIV counselling and testing does not capture all children and adolescents who are at risk of HIV infection. Self-testing involves conducting an HIV test at home or in any other convenient space without the involvement of a third party. It is increasingly being argued that it should be incorporated into national HIV-prevention programmes as one of a range of HIV counselling and testing approaches. Although this model of HIV testing is being seen as a new way of reaching under-tested populations, no studies have been conducted on offering it to children. HIV self-tests are now available in South Africa and are sold without the purchaser having to be a certain age. Nevertheless, all HIV testing in children must comply with the norms set out in the Children's Act (2005). Here we explore whether offering self-testing to children would be lawful, by outlining the four legal norms that must be met and applying them to self-HIV testing. We conclude that, although children above the age of 12 years could consent to such a test, there would be two potential obstacles. Firstly, it would have to be shown that using the test is in their best interests. This may be difficult given the potential negative consequences that could flow from testing without support and the availability of other testing services. Secondly, there would need to be a way for children to access pre- and post-test counselling or they would have to be advised that they will have expressly to waive this right. The tests are more likely to be lawful for a small sub-set of older children if: (i) it assists them with HIV-prevention strategies; (ii) they will be able to access treatment, care and support, even though they have tested outside of a health facility; and (iii) psychosocial support services are made available to them via the internet or cell phones.

S Afr J HIV Med 2013;14(4):151-154. DOI:10.7196/SAJHIVMED.987



Globally, in 2010, 3.4 million children aged <15 years were HIV-positive, 90% of whom were living in sub-Saharan Africa.^[1] In 2011, UNAIDS estimated that in South Africa (SA) alone there were about 460 000 children aged 0 - 14 years living with HIV. Health-facility-based HIV counselling and testing (HCT) does not capture all children and adolescents who are at risk of HIV infection.^[2-5] The large number of children not treated suggests that there are still relatively low rates of testing among children.^[6] Children are either being missed by the prevention of mother-to-child transmission of HIV (PMTCT) services, are surviving past two years of age without being tested, or are infected a *ter* birth through child abuse or health-service-acquired infection. In addition, children aged >12 years may be at increased risk because of their own sexual activity.^[7-9] Similarly, rates of testing among adolescents are particularly low, especially among young males, despite this being an at-risk population.^[9] This highlights the need for new, targeted, innovative, age-appropriate counselling and testing services for children and adolescents.^[10]

Low uptake of HIV testing is attributed to both supply and demand factors. On the supply side, key factors include inconvenient clinic hours, the inaccessibility of health facilities and the high cost of travelling to clinics.^[11] In terms of demand, even if testing services are available, these do not always translate into willingness to test.^[12] Research has shown that

deep-seated concerns regarding stigma, discrimination and the fear of positive results act as barriers to increased uptake of HIV-testing services in high HIV prevalence settings.^[13]

HIV self-testing (HST) refers to the performance of a simple saliva or blood-based test similar to a pregnancy test in the privacy of a home or in any other convenient space without the involvement of a third party.^[14,15] Richter *et al.*^[16] point to four potential benefits of such testing; it could: encourage regular HIV testing, allay fears of stigma and possible breaches of confidentiality, decrease the overall costs of HIV testing through removing the need for face-to-face counselling, and facilitate earlier diagnosis and access to treatment. Based on increasing evidence from feasibility and acceptability studies, activists and public health policy-makers have argued that HST should be incorporated into national HIV-prevention programmes as one of a range of community-based HCT approaches.^[17,18] Community-based HCT models such as home-based and mobile testing have significantly improved testing uptake and have reached higher rates of first-time testers in sub-Saharan Africa.^[19-23]

HIV self-tests are now available in SA. They sell for approximately R100 at pharmacies and have a shelf-life of two years. They can also be ordered via the internet.^[24] Detailed instructions are in the packaging and they generally require the user to place a drop of blood on a test strip; if a dark line develops on the strip, it indicates that the person is HIV-

positive.^[24] Highly accurate oral self-test kits exist with a sensitivity of 92% and a specificity of 99.9%.^[17,24] While some HIV self-tests are available in SA, the distribution and use of these tests is largely unregulated as the country's legal and policy frameworks do not specifically allow for their dissemination.^[16] This means that there are no specific regulatory restrictions on the sale of such products to persons aged <18 years. Nevertheless, all HIV testing in children must comply with the norms set out in the Children's Act (2005), and accordingly, regardless of the model of testing, must meet these minimum standards.^[25]

Although this innovative model of HIV testing is being seen as a new way of reaching under-tested populations, no studies have been conducted on offering HST to children. There has also not been any conceptual work exploring: (i) whether this is an appropriate model of testing to offer to children; and (ii) if it was found to be acceptable, whether there would be country-specific legal barriers to providing it to them. Here we explore whether offering self-testing to children would be lawful in terms of the Children's Act, by outlining the four legal norms that must be met and by applying them to HST.

The legal framework

The Children's Act (2005) describes the rights of children to consent independently to a number of health interventions.^[26] It provides expressly for *when* and *how* HIV testing may be done with children.

The drafters of the Act considered HIV testing to be an area in which children's rights were being abused and special protection was needed. Accordingly, sections (s) 130 - 133 of the Children's Act create four norms regulating HIV testing. These are that a child: (i) may only be tested for HIV in specific circumstances (s 130(1)(a) - (b)); (ii) must be counselled before and after the HIV test (s 130(1)(a) and 132); (iii) can consent independently to an HIV test from the age of 12 years (s 130(2)); and (iv) has a right to privacy regarding their HIV status (s 133).

The circumstances in which a child may be tested for HIV

Parliament has expressly limited the circumstances in which HIV testing may be undertaken with children.^[25] The Act provides that, other than in exceptional circumstances, HIV testing in children will only be lawful if it is in the best interests of the child and is undertaken with consent.^[25] This means that, unlike most other health interventions where children of a certain age or with a particular level of capacity can autonomously choose the intervention, with HIV testing it must be demonstrated that taking the test is in their best interests.^[26]

Our courts have generally held that in determining the best interests of the child, an effort must be made to establish if a decision will promote a child's physical, moral, emotional and spiritual welfare.^[27] Furthermore, it should be seen as a flexible standard which is applied with due consideration to the individual circumstances of the child.^[28] The Children's Act gives substance to this assessment by listing a number of factors that should be used in such an analysis. These include: the effect that the decision will have on the child's circumstances, its impact on their physical and emotional security, as well as the need to protect the child from physical or psychological harm.^[25]

If we apply these principles to HIV testing generally, we would argue that testing undertaken for prevention or treatment purposes would be in the best interests of the child as it promotes their right to basic healthcare services in terms of s 28 of the Constitution.^[29] However, HIV testing aimed at discovering a child's HIV status and using this

information to discriminate against the child, by e.g. withholding a bursary for tertiary education, would be contrary to the child's best interests.

If we apply these principles to HST specifically, we submit that the following factors would need to be taken into account in establishing whether it could be in the child's best interests: (i) the emotional impact of a child discovering their HIV status on their own, and potentially without support; (ii) the possibility that adults could use self-testing to coerce children to be tested for HIV; (iii) the confidential nature of such testing, which may meet the needs of some adolescents with privacy concerns; (iv) the availability and accessibility of other forms of HIV testing; (v) the child's age, level of maturity and ability to cope with this particular form of testing; (vi) the views of the individual child on HST; and (vii) the capacity of the child to consent to the HIV test.

If we weigh and balance the above factors, we would argue that HST could not be considered to be in the 'best interests' of all children. Our reasons are: Firstly, several authors have suggested that many would be too young to cope with the impact of receiving an HIV test result on their own. Secondly, others have suggested that in the absence of pre- and post-counselling there is potentially a risk of suicide for an individual who might be distressed.^[30] Thirdly, a study conducted in Kenya^[31] revealed that the main challenge of a self-testing programme was providing links to support services. Napierala Mavedzenge *et al.*^[32] highlight how HST delinks testing and counselling, potentially depriving individuals of access to a range of critical services.^[32] Furthermore, if other testing services are accessible and available, it would seem more appropriate that young children use such services where they can be assured of both support and access to treatment. Fourthly, there are some concerns in the literature that self-testing may not be in the best interests of children in that it could be used in a coercive way in the home environment and could possibly result in an abuse of individual rights. It appears that the authors are alluding to the possibility of the test being used by adults to test children at home as, e.g., 'punishment' for being sexually active. Given that the test is done in private, it would always be difficult to ensure that it is not being undertaken for the benefit of third parties. However, there are no data available to support this potential risk.^[32,33]

Nevertheless, it is possible that for certain older children (aged 16 years) who are at high risk of HIV infection, this may be a testing model that appeals. We base this on the emerging evidence on self-testing for adults. Several studies have documented high acceptability, uptake and accuracy of oral self-testing.^[20,34] Furthermore, adult users of HIV self-tests have found them easy to use, the instructions comprehensible,^[35] and that they have a high level of accuracy (99.2%).^[20] This model of testing offers high levels of personal control to children with the capacity to consent to testing and privacy for those who wish to establish their HIV status without the involvement of a third party. If accompanied by alternative forms of support such as telephone counselling or internet-based advice, children may not necessarily be lost to care.

Consent

The Children's Act states that children aged >12 years can consent independently to an HIV test.^[26] Given that there is no express capacity requirement for HIV testing, it is presumed that all children aged >12 years can make this decision.^[27]

If we apply these principles to HST, it means that children as young as 12 years could theoretically consent without assistance to an HIV self-test, provided that the other obligations in the Children's Act relating to

the best interests of the child and counselling are met. One issue raised in the literature is the possibility of such consent being coerced.^[33] Accordingly, it has been submitted that to avoid this possibility, laws and policies should be put in place to ensure that vulnerable groups such as children are not tested against their will.^[36]

Pre- and post-test counselling

The Children's Act (s 132) requires pre- and post-test counselling by an appropriately trained person. The Act does not describe the manner in which the counselling should be provided or the information that must be given to children during the counselling processes. McQuoid-Mason^[37] submits that this provision simply means that 'during pre-test counselling the benefits, risks and social implications of an HIV test must be explained to the child, while during post-test counselling the implications of the results must be explained.'

The lack of accompanying counselling is a key concern in the literature on self-testing.^[36] It has been argued that pre-test counselling provides an opportunity to make informed decisions on whether to test or not, while post-test counselling informs individuals of their HIV status, provides information on HIV prevention, encourages them to test regularly, reduces the risk of HIV transmission to others, and offers psychosocial or referral support to HIV-positive clients.^[36]

Counselling is a mandatory requirement in the Children's Act, which means that testing without counselling is unlawful unless a child waives their right to this service. This therefore serves as an obstacle to self-testing by SA children. The Act does not specify the nature of the counselling; thus, it is possible that, e.g., telephone counselling could suffice. The National HIV Counselling and Testing Policy also does not specify that counselling must be face to face. Instead, it provides a list of the minimum information that should be provided in pre- and post-test counselling sessions.^[38]

Confidentiality

The Children's Act (s 133) provides that children have the right to confidentiality regarding their HIV status.^[26] Furthermore, information on a child's HIV-positive status may only be disclosed with the consent of that child if they are aged >12 years.^[37]

A key strength of the self-testing approach is that it ensures that confidentiality is maintained. A study conducted in Singapore^[39] found that confidentiality was a key reason why people preferred to buy over-the-counter HIV test kits. The right to confidentiality in the Children's Act is therefore not a barrier to self-testing.

Conclusion

There is some preliminary evidence that HST could be a valuable new HIV-prevention strategy in that it gives persons at risk of HIV infection another way of discovering their HIV status. Although no research has been undertaken on whether this model is suitable for children, we argue that this work needs to be done as a matter of urgency, as they are a group at high risk of HIV infection.

This review of the SA legal framework has shown that the law does not expressly prohibit or regulate the offering of self-tests to children. Nevertheless, the way in which self-testing was offered would have to comply with the Children's Act. This means that only children aged >12 years could use an HIV self-test on their own, as below this age they do not have the capacity to consent. Furthermore, there would be two potential legal obstacles. Firstly, it would have to be shown that using an HIV self-test is in their best interests. This standard may be

hard to meet, given the potential negative consequences that could flow from testing without support and the availability of other forms of HIV testing. Secondly, there would need to be a way for children to access pre- and post-test counselling or for children to be advised that they will expressly have to waive this right. Thus, simply offering self-HIV tests to all children aged >12 years would not be lawful, unless it could be shown that it was in their best interests and that counselling was provided.

Given these legal obstacles, we would suggest that it is only a small sub-set of children for whom such testing would be considered lawful. We argue that for older children (aged >16 years) self-testing may be in their best interests if: (i) it assists them with HIV-prevention strategies; (ii) they will be able to access treatment, care and support even though they have tested outside of a health facility; and (iii) psychosocial support services are made available to them via the internet or cell phones.

It is submitted that although self-testing in children is an under-explored issue, it requires further debate and discussion. Policy guidance is needed on when a self-test would be in a child's best interests and how children who choose such a testing model can receive counselling and appropriate referral to services, if required.

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