HIV NURSING MATTERS

A publication of the Southern African HIV Clinicians Society

HIV Nursing Matters focuses on Mother and Child care

Cotrimoxazole Prophylaxis Guidelines

Integrated Management of Childhood Illness

Retaining mothers living with HIV and their infants in care

Vertical transmission prevention guidelines

A practical approach to integrated care

PrEP in Pregnancy and Breastfeeding People

NIMART

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OF ANTI-RETROVIRAL THERAPY

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We are excited to present another edition of HIV Nursing Matters. This edition comes just after celebrating World AIDS Day 2023. This World AIDS Day, 1 December, UNAIDS is showing a clear path to end AIDS. At a time when ending vertical prevention seems reachable, it is even more important to focus on the mother and child as a dyad. This edition of HIV Nursing Matters looks specifically at mother and child health.

The first article **"Cotrimoxazole (CTX) Prophylaxis Guidelines for infants exposed to HIV: South Africa (SA) pioneers change"** explores recent evidence showing that CTX prophylaxis in HIV-exposed uninfected (HEU) children does not only fail to reduce mortality and morbidity but indeed can actually cause long-term harm. These harms include selection resistance to CTX, increased resistance to other antibiotics like amoxicillin, as well as increased microbiome dysbiosis leading to several negative long-term effects. This led the South African National Department of Health (DOH) to revise its vertical transmission prevention (VTP) guidelines, despite the WHO failing to do so in 2021, recommending CTX for only HIV-positive children and not for HEU anymore.

The second article **"Integrated Management of Childhood Illness (IMCI): improving access to training through technology"** focuses on the use of an online platform for this training, to alleviate some of the existing training limitations. This revised format includes the use of various styles of learning as well as alleviating the burden on primary health care (PHC) facilities with limited staff and trainers available. Where HIV is concerned, it is encouraged that children have their HIV-status classified at each clinical visit. Although nurses, providing most of PHC services, are the target for IMCI-training, it is beneficial for all health care workers dealing with child health and facility managers to partake in this training.

The third article **"Retaining mothers living with HIV and their infants in care through a differentiated and integrated model of care: postnatal clubs"** focuses on a holistic model of care for all mothers living with HIV and their HIV-exposed infants. This new model of care aims to address the problem of postnatal vertical transmission and disengagement in care. Apart from the clubs providing a peer-led psychological support for these women, the club also includes a one-stop-shop clinical visit that addresses the HIV and non-HIV related needs of mothers and their infants. This pilot was very successful with promising results. However, one size does not fit all and changes to this model are required to make it work in a setting of overcrowded facilities that don't have dedicated club staff. Buy-in and support from the DOH in running these clubs is also needed to move forward.

The fourth article **"South African Vertical Transmission Prevention (VTP) guidelines: a summary"** gives a good overview of the very recently released VTP guidelines focusing on HIV but also syphilis and hepatitis B. Main changes include changes in the definition and management of elevated viral load (VL) in pregnant women to VL >50 copies/ml and how to manage post exposure prophylaxis for the infant. Other changes include the already mentioned removal of CTX for all HEU infants to be given only to HIV- positive infants. The syphilis testing algorithm has also changed to be included at every antenatal visit along with HIV testing. Women who tested positive for hepatitis B should deliver in a facility that has immunoglobulin and monovalent hepatitis B vaccine. The VTP strategy is to prevent HIV transmission to all women of childbearing age and therefore HIV negative pregnant women should be offered PrEP at each ANC visit.

The fifth article **"A practical approach to integrated care"** focuses on the Ideal Clinic Programme (introduced in 2013) and the Integrated Clinical Service Management (ICSM) to build on the strengths of HIV programmes in SA to deliver integrated care to patients with both chronic and or acute diseases who need preventative care. The core components of Ideal Clinic include the Integrated Management of Childhood Illnesses (IMCI) and Adult Primary Care (APC). APC consolidates the practical content from the latest National DOH policies and guidelines into one tool, providing algorithmic approaches to create standardised delivery of care. IMCI is a key part of PHC approach to care of children under 5 years. Limitations of the IMCI led to the creation of the Practical Approach to Care Kit for children (PACK Child) which acts as a clinical tool using similar approaches and layout to that of APC and is both for nurses and other clinicians.

Last but not least is **"PrEP in Pregnancy and Breastfeeding People"**, a necessary intervention on the road to elimination of VT. At least a quarter of new vertical HIV transmissions takes place during pregnancy or breastfeeding. PrEP refers to the use of antiretroviral drugs by HIV-negative individuals who are at substantial risk of acquiring HIV. Pregnant and breastfeeding women, even if they are not classified as high risk for HIV, are all high risks as they are 2-4 times more likely to acquire HIV than non pregnant women. Counseling, HIV prevention intervention - like PrEP-, acute HIV screening; adherence counselling, monitoring , 3-monthly HIV testing and standard antenatal care must be offered to all HIV-negative pregnant and breastfeeding women at risk of HIV transmission. PrEP needs to be integrated into existing service packages and should be offered to all antenatal clients to reduce HIV acquisition and reduce vertical transmission.

Cotrimoxazole Prophylaxis Guidelines for infants exposed to HIV: South Africa pioneers change

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Cotrimoxazole (a fixed-dose combination of trimethoprim-sulfamethoxazole) is a broad-spectrum antibiotic which provides effective prophylaxis against *Pneumocystis carinii* (now *jirovecii*) pneumonia (PCP/PJP) in immunosuppressed adults and children who are infected with HIV.[1-3]

The World Health Organization (WHO) first formulated guidelines in 2000 recommending that all infants born to women living with HIV (WLHIV) should receive daily cotrimoxazole (CTX) prophylaxis until they are tested negative at least 6 weeks following last HIV exposure.[4] These guidelines were reasonable at the time, given that there was no antiretroviral (ARV) prophylaxis for mothers and no available ARV treatment available for infants, resulting in a transmission rate in South Africa of approximately 30%.[5] However, these guidelines became out of date and needed to be revised as HIV diagnosis and treatment options improved.

At the time the original WHO guidelines were drafted, there were no randomised controlled trials (RCTs) testing whether CTX prophylaxis would be effective for all children born to WLWH, the majority of whom were HIV-exposed but uninfected (HEU). The 2013 WHO guideline group meeting made a call for RCTs to evaluate the clinical impact of CTX prophylaxis on children who were HEU.[6] In response to the call, two RCTs were set up in Southern African countries – Botswana[7]

and South Africa.[8] These two countries were chosen as they have a high HIV burden amongst women and relatively good vertical transmission prevention (VTP) programmes, making them 2 of 5 countries with the highest percentage of infants who are HEU. Both RCTs showed conclusively that CTX prophylaxis to children who are HEU does not reduce mortality or morbidity.[7,8]

Additionally, substudies from these two RCTs demonstrated harm with routine CTX prophylaxis in HEU infants. These harms include selection of resistance to CTX[9,10] as well as increased resistance to other antibiotics, notably amoxicillin.[9] This is a concerning finding since amoxicillin is first line treatment for infant pneumonia in many primary healthcare guidelines. *In fact, in the WHO AWaRE antibiotic recommendations, amoxicillin has been assigned an "access" category, requiring countries to ensure its availability and to maintain uninterrupted supply chains because of its safety, efficacy and "lower potential for resistance".*[11] Furthermore, the South African study showed an increase in microbiome dysbiosis in infants receiving prophylaxis. Microbiome dysbiosis has been linked to several immune-mediated, metabolic/cardiovascular and neuropsychiatric diseases or disorders such as obesity, diabetes, asthma, hypertension, inflammatory bowel disease, depression, autism and alzheimers, to name a few.[12]

Despite strong evidence of lack of benefit of CTX prophylaxis, as well as growing evidence of harms associated with routine CTX prophylaxis, the WHO did not make clear changes to their policies in 2021. Their decision was largely influenced by a modelling exercise which favoured retaining CTX prophylaxis. This modelling exercise was presented at a conference13 but has not yet been published in a peer-review journal and has serious flaws. The lack of change in the WHO policy was concerning because, in addition to discounting the evidence of RCTs, this position ignored harms associated with CTX prophylaxis and ignored major improvements in VTP and HIV care and treatment programmes that have occurred over time and which have substantially reduced the numbers of infants who will acquire HIV.[14]

Policy makers in South Africa, however, did not ignore this evidence. In the light of the evidence from these two RCTs showing no benefit for mortality and morbidity of CTX prophylaxis and potential harms, several scientists and paediatricians, both in South Africa and internationally,[14] argued that CTX should no longer be used routinely for prophylaxis among children born to WLWH. The South African Thoracic Society agreed with this position and issued an updated guideline in 2020 recommending discontinuation of routine CTX prophylaxis for infants who are not HIV infected.[15]

In 2021 National Essential Medicines List (EML), CTX prophylaxis guidelines were amended as follows:
'All HIV-exposed or infected infants, to be initiated on CTX prophylaxis starting from 6 weeks of age. If birth and 10 weeks PCR are both negative then CTX prophylaxis should be discontinued'.

Several scientists and paediatricians continued to express concern with this guideline. While 8 weeks of CTX is certainly better than a longer course of approximately 12 months of antibiotics, it is still problematic because of the very large number of infants in South Africa who are affected. Approximately 310 000 [190 000 – 400 000] infants annually in South Africa[16] would receive a drug with no benefit and several potential harms, with obvious costs to the health service.

In 2021/2022, the National Department of Health, Technical Working Group for Prevention of Mother-Child HIV transmission (PMTCT) met to consider policies around PMTCT. Of note is that they agreed to change the name of the PMTCT programme to Vertical Transmission Prevention (VTP) programme to reduce stigmatisation of the mother. The Guideline for Vertical Transmission Prevention of Communicable Infections was published by the South African National Department of Health in June 2023 (find it here: sahivsoc.org/Files/2023 Vertical Transmission Prevention Guideline.pdf). This new guideline recognises the findings from the 2 RCTs which demonstrated that there is no evidence of benefit of CTX to infants who are HEU, and acknowledges that, instead, there are harms due to increased antibiotic resistance and microbiome disruption.

These new guidelines for CTX now clearly state that:

- **Infants who are HIV-exposed are not eligible for routine CTX prophylaxis.**
- **CTX prophylaxis is reserved for infants with confirmed HIV infection to be used in conjunction with suitable antiretroviral regimens.**

The 2023 South African VTP guidelines made these well-considered recommendations related to CTX prophylaxis and also made several other important changes that strengthen HIV care and treatment programmes for adults and children which will in turn reduce vertical transmission even further.

The changes made were the following:

1. Increased emphasis on management of elevated viral loads in pregnant and breastfeeding women. If viral loads are greater than or equal to 50 copies per mL (c/mL), HCWs are encouraged to focus on improved adherence to ART and ensure the mother is on a dolutegravir-containing regimen. This should be a once-daily fixed dose combination regimen unless she is receiving rifampicin-based TB treatment, in which case an additional 50mg DTG is given. DTG-based ART is usually well-tolerated and makes adherence easier.
2. Ensure infant HIV testing is done at birth, 10 weeks and 6 months.
3. All newborn infants should receive dual prophylaxis (zidovudine twice daily and niviripine once daily) until the maternal delivery VL result is known.
4. The definition of an HIV-exposed infant as "higher-risk" should now be considered to be when the maternal VL is greater than or equal to 50 c/mL and no longer 1000 c/mL.
5. HIV-exposed higher-risk (maternal VL greater than or equal to 50 c/mL) breastfed infants should receive 6 weeks of zidovudine and a minimum of 12 weeks of niviripine.

These new changes to the VTP programme increase its robustness thus minimising the risk of HIV infection in infants and maximising access to antiretroviral treatment. These guidelines focus on the root causes of poor outcomes in infants (HIV infection and lack of access to antiretroviral therapy) rather than continuing to provide an ineffective, outdated intervention in case an infant with HIV does not access antiretroviral therapy.

The thoughtful new changes to the South African VTP guidelines also take into account growing awareness of the importance of careful antibiotic stewardship to reduce the dangers of widespread antibiotic resistance. In addition, they recognise the need to take into account some of the more complex effects of antibiotic use during critical developmental time periods on the developing infant microbiome. A sub-study in the South African study[10] showed an increase in gut microbiome dysbiosis at 4 and 6 months of age in infants who received CTX. What is the danger of disturbing the microbiome of infants? Exclusively breastfed infants have a "gold standard" microbiome – predominantly colonised by *Bifidobacteria*, and breastmilk, with its high concentration of oligosaccharides, provides a perfect substrate for *Bifidobacteria*. Evidence shows that when this microbiome is perturbed, especially in the first few months of life, this can result in negative health implications, some of which have lifelong consequences.[17,18]

The lack of change in the WHO guidelines regarding CTX prophylaxis, in addition to discounting the results of two large RCTs and ignoring the unintended adverse outcomes associated with routine CTX prophylaxis, did not take into account major changes in the healthcare context over the last two decades. These include:

1. **Significant improvements in VTP and infant HIV diagnosis** - the last two decades have seen significant reductions in vertical transmission from approximately 30% to below 10% globally and as low as 3.9% at the end of 12 months breastfeeding in South Africa.[16] Infant diagnosis has improved dramatically from ELISA testing to PCR birth testing. With maternal ARV treatment, there is on-going prophylaxis during breastfeeding and more regular maternal viral load testing to ensure an undetectable viral load. This means that far fewer infants are born with HIV infection, they are likely to be diagnosed early, and far fewer infants will acquire HIV during breastfeeding. This translates to millions of infants who are HIV exposed but uninfected (HEU), with South Africa having the highest numbers – estimated to be about 3.5 million.[19]
2. **Significant improvement in health of infants who are HEU over the last 21 years** - new vaccines (hepatitis B,

Approximately 310 000 [190 000 – 400 000] infants annually in South Africa[16] would receive a drug with no benefit and several potential harms, with obvious costs to the health service.

Hemophilus influenza type B, pneumococcus and rotavirus) have resulted in significant reductions in childhood infections, especially pneumonia, in both infants living with HIV as well as those who are HIV negative.[15,20,21] Research has also led to a re-affirmation of the importance of exclusive breastfeeding for improving health and development of children[22] with valuable strides being taken by governments to improve breastfeeding practices. South Africa especially has seen dramatic improvements in rates of exclusive brestfeeding.[23]

Table 1: Summary of healthcare context improvements and disadvantages of cotrimoxazole prophylaxis.

Improvements in Healthcare Context	Disadvantages of Cotrimoxazole Prophylaxis
***Improved vertical transmission rate*: from ±30% to <5%**	*No effect on mortality outcomes in HEU infants*
***Improved VTP*: Birth prophylaxis vs maternal treatment**	No effect on morbidity outcomes in HEU infants
***Improved infant vaccinations*: Hepatitis B, pneumococcus, rotavirus and *Hemophilus influenza* type B**	Increased microbiome dysbiosis, which likely results in long-term adverse health outcomes
Increased support for breastfeeding	Increased resistance to several antibiotics
***Improved infant HIV diagnosis*: ELISA to birth PCR testing**	Confusion for mothers that CTX may act as prophylaxis against HIV

Conclusion

The vertical transmission guideline update incorporates prudent changes including recommendations based on recent evidence from groundbreaking studies. Complete discontinuation of the CTX prophylaxis programme for all those who are HIV negative will free up resources spent on procuring, transporting, storing, and administering CTX which could rather be channelled towards other strategies with proven reduced risk of infectious disease morbidity in HEUs viz: access to early HIV diagnosis of infants, linkage to care for infants and children living with HIV, improved maternal health, and continued support for child health services that are of benefit regardless of HIV status – e.g. immunisations and breastfeeding support. Importantly, it will remove the burden from mothers of daily administration of drugs to the infant.

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Integrated Management of Childhood Illness: improving access to training through technology

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What is IMCI?

The Integrated Management of Childhood Illness (IMCI) strategy was developed by the World Health Organization (WHO) and the United Nations Childrens' Fund (UNICEF) in order to reduce child mortality and morbidity. It recommends the use of an algorithmic approach to classify and manage common childhood illnesses while incorporating preventive interventions into each consultation to decrease child mortality.[1]

In South Africa, IMCI was adopted as the primary strategy for the management of childhood illness in primary health care settings in 1998[2] and the National Department of Health (NDoH) remains committed to improving the uptake and implementation of IMCI across the country. The process of revision and review of the IMCI strategy, with relevant local adaptations, is taken up at 5-year intervals. With each revision all related materials including the IMCI chart booklet, consultation recording forms and training platforms require updating and appropriate dissemination to provinces for implementation.

The traditional IMCI training was conducted over 11 days, placing a significant burden on primary care facilities as staff are away for the full training period. The associated costs (venue hire, accommodation and catering) for the training course were major limitations in the running of the training with the frequency required to reach training targets of more than 80% of nurse practitioners trained in every facility. Additionally, the availability of IMCI trainers in many districts is limited.

Given the advances in technology since the initial roll out of the IMCI strategy and considering resource limitations that impact on printing and dissemination of the relevant job aids, the decision was taken to restructure the IMCI training materials for suitability on an online platform. This will improve access to

pre-service and in-service training for health care workers, facilitate updating of materials in future iterations, and reduce the costs associated with the running the training course.

Revisions to the IMCI training – what is new?

The IMCI training materials have been reviewed and restructured for use on an online platform. The revised format includes the use of text, videos, audio as well as interactive tools to make the learning experience varied and engaging for learners. Regular knowledge checks (formative assessments) are incorporated as learning aids, to ensure that learners have understood the key points being conveyed in each section. In addition to learning the case management strategy for each of the conditions, learners can use the 'Key concepts and facts' section in each module to build their understanding on the importance of the illness in the greater context of child health.

The revised training course can accommodate various styles of learning, including completely independent learning, a facilitated approach using the updated materials or an approach that blends these styles. This should allow IMCI trainers and supervisors to focus on practical training rather than on the delivery of theoretical knowledge.

Those undertaking this training independently can set their own pace and use the interactive tools, audio and video materials in the way best suited to their own learning style. Having the content on an online platform means that learners can learn and revise the content at any time - a notable convenience for busy clinicians.

Details of the IMCI training course

The IMCI training course comprises 18 modules and a final assessment. The initial modules provide guidance on navigation of the course and overview of the IMCI principles. Thereafter, a case management approach is used for modules 4 to 15. Module 16 provides guidance on feeding young children, while module 17 highlights the promotive care aspects that are part of every IMCI consultation. Finally, common skin conditions are covered in module 18 (see Table 1 for further detail). Once learners have completed

Table 1. IMCI modules

Module	Description
1. Navigating the IMCI course	Detail on the structure and requirements for the course
2. Introduction to IMCI	Background on the IMCI strategy, its benefits and implementation
3. IMCI approach	Discover the IMCI case management principles
4. General danger signs	Description on the principle of triage and signs of severe illness
5. Cough or difficult breathing	The common signs of cough or difficult breathing, wheeze and stridor are explored
6. Diarrhoea	Detail on the classification and management of diarrhoea and its complications
7. Fever	Learn to assess and manage a child with fever
8. Ear problem	Acute and chronic ear problems are discussed
9. Sore throat	Identify which children with sore throat require antibiotic therapy
10. Malnutrition	Learn to accurately assess and manage a child's growth and nutritional status
11. Anaemia	Screen all children for this common co-morbid condition
12. HIV	The principles of HIV testing, exposure and infection in children are presented
13. TB	Assess all children for risk of TB, proceeding with investigation if risk present
14. Sick young infant - bacterial infection & jaundice	The principles of possible serious bacterial illness in the young infant are applied
15. Sick young infant - congenital problems & risk factors	Common congenital problems and other risk factors in young infants are considered
16. Feeding	Understand an approach to feeding at various ages
17. Promotive care	The preventive and promotive aspects of care are explained
18. Skin problems	An approach to common skin problems is offered

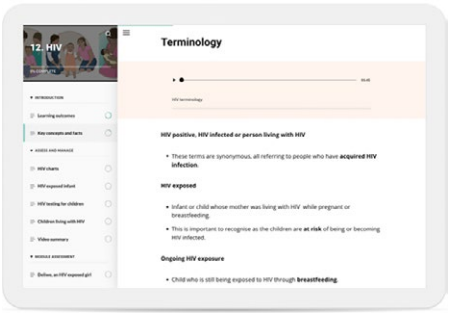
all modules, they may attempt the final assessment. Upon successful completion of the course and assessment, the learner is issued with a Certificate of Achievement. For those doing the course as part of in-service training, a programme of practical training will be required to earn a Certificate of Competence. Detail of this varies by provinces and districts. Where relevant learners should contact their Regional Training Centres for further information.

The IMCI training materials have been reviewed and restructured for use on an online platform.

IMCI and HIV

The IMCI consultation recommends that all children have their HIV status classified at every visit. Marrying the relative complexity of paediatric HIV with the typical IMCI algorithmic approach has proven challenging. As such, a principles-based approach is offered, allowing learners to understand the HIV classifications in children and align them to the recently updated NDoH HIV guidelines. A project to align the IMCI material to the updated HIV guidelines is ongoing.

Image 1. IMCI HIV module



Who is IMCI training for?

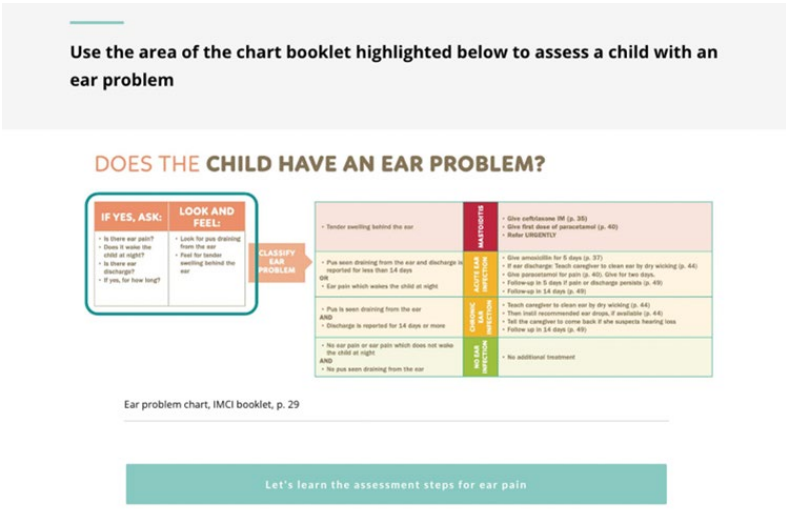
Nurses provide the majority of primary health care services in South Africa and are therefore the primary target group for completion of IMCI training. However, all health care professionals, both qualified and in training, whose work involves the care of children are eligible and would benefit from training in IMCI. This includes doctors, pharmacists, dieticians, physiotherapists and other allied health professionals. In addition, while case management skills would not be essential for facility managers, understanding the principles of IMCI may help in planning of training, staff allocation and rotation. In short, all health professionals at all levels of care who encounter and manage children would benefit from understanding the basics and principles of IMCI.

Image 2. IMCI course registration QR code.

Where can the online training be accessed?

The IMCI training course is available on the NDoH learning management system, the Knowledge Hub. Users can register for the course using the QR code alongside. Access to the course is free for all users. Upon completion of all modules and successfully completing the final assessment, learners will receive a Certificate of Achievement and earn 30 Continuing Professional Development (CPD) points.

Image 3. IMCI chart is presented in each section.



Additional considerations and requirements

Consulting the IMCI Chart Booklet 2022 is essential to build familiarity with the materials as one progresses through the course. This is also available on the Knowledge Hub website and is available as a resource linked to the course.

A reliable internet connection and data are required to access the online training materials. Investigation into the data requirements for the course has suggested that 1GB is required to complete all modules. At the time of writing, the Knowledge Hub had applied for the website to be zero-rated, i.e. no data costs for the user.

Conclusion

The IMCI strategy should be used in all primary care facilities for the management of sick children under the age of 5 years. The benefits of this include the detection and appropriate management of all common childhood illnesses, that all children are screened for HIV, TB and malnutrition, and that other health promotion interventions are included in the consultation. A major limitation in the implementation IMCI is in the accessibility of training.[3] With the restructured training available online and the associated benefits that this offers, we trust that this will facilitate the achievement of IMCI training targets and by extension, improved implementation of this strategy. Until the process of aligning the IMCI HIV chart to the national guidelines is complete, we recommend that users focus on the principles of HIV testing and management and refer to the guidelines for detail as required.

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Retaining mothers living with HIV and their infants in care through a differentiated and integrated model of care: postnatal clubs

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Vertical transmission in South Africa

In South Africa, mother to child HIV transmission (MTCT), now called "vertical transmission" (VT) has drastically decreased in the last ten years from 15% to 3.9% at 18 months of age.[1,2] A variety of factors, including repeat antenatal HIV testing and the successful implementation of "option B+" (pregnant women being started on lifelong antiretroviral therapy-ART-on the same day, regardless of CD4 results) have resulted in substantial decreases in antenatal and intrapartum transmissions of HIV. However, postnatal (or breastfeeding) transmission has not decreased as much over time and is now responsible for over 50% of the national VT.[3,4] As a consequence, the majority of HIV transmissions take place postnatally and are only detected after 10 weeks of age.

Why does postnatal HIV transmission remain a problem?

Studies have shown that postnatal women living with HIV in South Africa are twice more likely to disengage from care than pregnant women.[5,6] Disengagement from care results in poor ART adherence, raised HIV-viral load (VL) and increased chances of VT.[7] Reasons for disengagement in care can be attributed to health

systems related factors as well as patient related factors. Health system related factors include long waiting times at the clinic, high patient volumes, negative experiences with health care workers and the difficult transition from antenatal to postnatal care.[8-10] Patient related factors include travel costs and work pressures, pill fatigue, inadequate knowledge of VT, HIV-related stigma and non-disclosure.[5,11] Furthermore, the added emotional and logistical demands of being a new mother, added to the frequent required under-5 year old clinic visits make clinic attendance for the mother's own health difficult. This is compounded by mother and baby visits being on different days and may result in decreased maternal ART adherence.[12] In South Africa, although the uptake of early infant diagnosis is effective, the uptake of the 6 months and 18 months HIV tests is problematic, resulting in over half of children under two years of age living with HIV not being diagnosed.[13,14] Reasons for this include the those cited in the paragraph above as well as the mobility of children between clinics and health districts, and the lack of digitalisation of the 18 months rapid HIV tests.[13] Of note, integration of PMTCT services with neonatal, maternal and child health has been recommended since 2011 but its implementation has been variable.[15,16]

Description of the initial postnatal club pilot

In 2016, a new differentiated model of care called "postnatal clubs" was designed and piloted in a peri-urban clinic with high HIV antenatal prevalence close to Cape Town, in partnership between MSF, City of Cape Town Health and mothers2mothers (m2m). Postnatal clubs are described as a differentiated and integrated model of care for all mothers living with HIV and their HIV-exposed infants; providing peer-led psychosocial support to this group of women followed by a one stop shop clinical visit addressing the HIV and non-HIV medical needs of the mother and infant.[17] For the infant, this includes offering under-five child health services like vaccinations, growth monitoring and deworming. For the mother, postnatal clubs encourage integration of sexual and reproductive health services by ensuring all women are offered contraception at every visit. The initial pilot showed promising results. Compared to a historical control group, maternal VL completion at 12 months was 1.5 times higher (95% CI: 1.3-1.6) in the club group. Uptake of the children's 9 months and 18 months HIV testing was respectively 1.6 times (95% CI: 1.4-1.9) and 2.0 times higher (95% CI: 1.6-2.6) in clubs compared to historical control group.[18,19] Retention in care was much better for the mother infant pairs (MIP) in the postnatal club. Furthermore, when looking at integration of care, vaccination uptake at 12 months was over 99% for the infants in the club. Duvivier's qualitative study on postnatal clubs' participants and health care workers involved in the clubs showed that mothers enjoyed and learnt from the postnatal clubs as well as created strong peer support in the clubs, helping with disclosure and stigma.[20]

Studies have shown that postnatal women living with HIV in South Africa are twice more likely to disengage from care than pregnant women.[5,6]

Disengagement from care results in poor ART adherence, raised HIV-viral load (VL) and increased chances of VT.[7]

Virtual groups were introduced where there was no space for physical groups to take place or when they were not permitted (during COVID-19).

Adaptations to the postnatal club model

Following this pilot, other clinics started implementing postnatal clubs in Cape Town, with the 3rd largest ARV clinic in South Africa starting to implement in 2020. Results are awaited. In 2019, the National Department of Health (DoH) recommended the postnatal clubs as a "best case scenario" which led to a national training and other organisations rolling out the model.[21] Following the national training, postnatal clubs were implemented, including among others, by Anova Health Institute in Johannesburg, Gauteng. While the model was seen as beneficial by staff[22] and was anecdotally shown to lower postnatal vertical transmission in those retained in clubs, changes were needed to ensure implementation was feasible in overcrowded facilities without dedicated postnatal club staff. Emphasis was placed on the provision of integrated care of the MIP, with group or individual support being provided. Virtual groups were introduced where there was no space for physical groups to take place or when they were not permitted (during COVID-19). Unlike the Cape Town implementation, cohorting MIPs into more precise age groups was not possible, mainly due to the lack of dedicated staff at the clinic to support mothers every day of the week. As a result, MIPs were grouped as either under 6 months (exclusively breastfed) or 6 months and older (breast and complementary fed babies). One of the most significant challenges to implementation and threats to sustainability was the lack of involvement of DoH staff in the running of postnatal clubs.[22] Buy in and support from the provincial and district DoH leadership is crucial to successful, long-term implementation of postnatal clubs.

Conclusion

Postnatal clubs showed promising results with improved uptake of infant HIV testing and maternal VL completion compared to a historical cohort. This is a good example of a differentiated model of care for mothers living with HIV and their HIV-exposed babies. However, one size does not fit all, and the model can be adapted to different circumstances, prioritising the integration of maternal and child health. Buy-in and support from the DoH is essential for the model to be implemented further and will hopefully result in reduced postnatal vertical transmission.

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PIMART

PHARMACY INITIATED MANAGEMENT OF ANTI-RETROVIRAL THERAPY

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South African Vertical Transmission Prevention (VTP) guidelines: a summary

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Background to the new national 2023 VTP guidelines

The two main strategies of the vertical transmission prevention strategy is to:

- Ensure that there is maternal viral load suppression. This is achieved by using optimised antiretroviral regimens.
- Provide post-exposure prophylaxis to HIV-exposed infants.

One of the pillars of the vertical transmission prevention strategy is to prevent HIV transmission to women of childbearing age. All HIV-negative pregnant women should be offered pre-exposure prophylaxis (PrEP) and continue to be tested for HIV at the basic antenatal care (BANC) visits (20, 26, 30, 34 and 38 weeks) and at delivery.

For all HIV-positive women, ongoing research has shown that there is no increased risk of neural tube defects if dolutegravir is used pre-conception or any time during pregnancy or lactation. Therefore, Tenofovir/Lamivudine/Dolutegravir (300/300/50mg) (TLD) is the preferred ART regimen during pregnancy.

Baseline assessment

A newly diagnosed HIV-positive pregnant woman will have booking bloods (syphilis RPR, haemoglobin and rhesus) and baseline bloods (creatinine, hepatitis B, CD4 count), and sputum for TB GeneXpert taken. Results should be reviewed within 7 days. HIV testing for the partner should also be offered and PrEP offered if they are HIV-negative.

When TLD is used in pregnancy, the eGFR is not used but rather the actual creatinine value, which needs to be less than 85µmol/L. If the creatinine is greater than 85µmol/L, a repeat creatinine should be taken and if the creatinine is still greater than 85µmol/L, tenofovir (TDF) should be stopped and the patient given instead Abacavir (ABC)/Lamivudine(3TC)/Dolutegravir (DTG).

If the CD4 count<200, cotrimoxazole 960mg daily is initiated.

If CD4 count<100cells/m^3, review the reflex CLAT result. If the CLAT is positive, the patient must be referred for a lumbar puncture to exclude cryptococcal meningitis, irrespective of signs or symptoms of meningitis.

If the hepatitis B is positive and HIV positive, the woman should be commenced on TLD as TDF and 3TC are used to treat chronic Hepatitis B. If the woman is hepatitis B positive and HIV negative, further discussion is needed with a referral centre.

If the TB GeneXpert is positive, sputum for AFBs should be taken and the patient commenced on treatment for tuberculosis. Dolutegravir needs to be boosted when taken with rifampicin. Therefore TLD + DTG 50mg 12 hours apart should be prescribed. Cotrimoxazole should be added irrespective of the CD4 count as TB is a stage 3 clinical disease.

In HIV positive pregnant women, if the TB screening and GeneXpert are both negative, TB prophylactic therapy (TPT) should be prescribed. Rifapentine (3HP) is not recommended for use during pregnancy, so INH 300mg daily and pyridoxine 25 mg daily should be used in pregnancy.

Supplements

Calcium and iron supplements when taken with DTG on an empty stomach result in reduced DTG levels, so calcium and iron need to be taken with DTG with food. However, calcium and iron should be taken at least 4 hours apart. DTG also interacts with other cations (e.g. magnesium and aluminium) which are frequently found in antacids. Antacids should be taken at least 6 hours before or 2 hours after taking DTG.

Case: A 29-year-old G1P0 presents to your clinic with nausea and vomiting. Her last menstrual period was 3 months ago. Her pregnancy test is positive, RPR rapid negative, Hb 11,5g/dL and HIV positive. She is counselled and ART discussed. Baseline bloods and sputum for GeneXpert are taken. TLD is prescribed which she wants to take in the morning. She will also take her calcium supplements in the morning with breakfast. She is advised to take the iron supplements at supper. She returns after 4 days for her results. The CD4 count is 90cells/mm^3, CLAT negative, creatinine 100µmol/L and hepatitis B negative.

Result	Action	Comment
CD4 count 90cells/mm^3	Remember to check the reflex CLAT result. Start cotrimoxazole.	Cotrimoxazole is prescribed if CD4 count < 200 cells/mm^3
CLAT negative	No further action.	If CLAT positive, refer for lumbar puncture irrespective of symptoms.
Creatinine 100µmol/L	Repeat blood for creatinine since she had been complaining of nausea and vomiting.	Creatinine needs to be less 85µmol/L to continue to use TLD. If the repeat creatinine remains over 85µmol/L, she will need to be changed to ABC/3TC/DTG.

For all HIV-positive women, ongoing research has shown that there is no increased risk of neural tube defects if dolutegravir is used pre-conception or any time during pregnancy or lactation.

Ongoing monitoring

If the woman is a known HIV positive client, blood for viral load (VL) should be taken at the booking visit (use electronic gate keeping code C#PMTCT). These results should be reviewed within 1 week. If the VL<50, repeat it at delivery (C#DELIVERY).

If the woman is newly diagnosed HIV positive at booking, start TLD. Repeat blood for creatinine and VL at 3 months. If the VL <50, repeat the VL at delivery.

If the VL>50 during pregnancy or lactation, then consider A-B-C-D (adherence, "bugs" or opportunistic infections, correct dose, drug interaction) and repeat the VL after 4-6 weeks (fit the date into BANC visits).

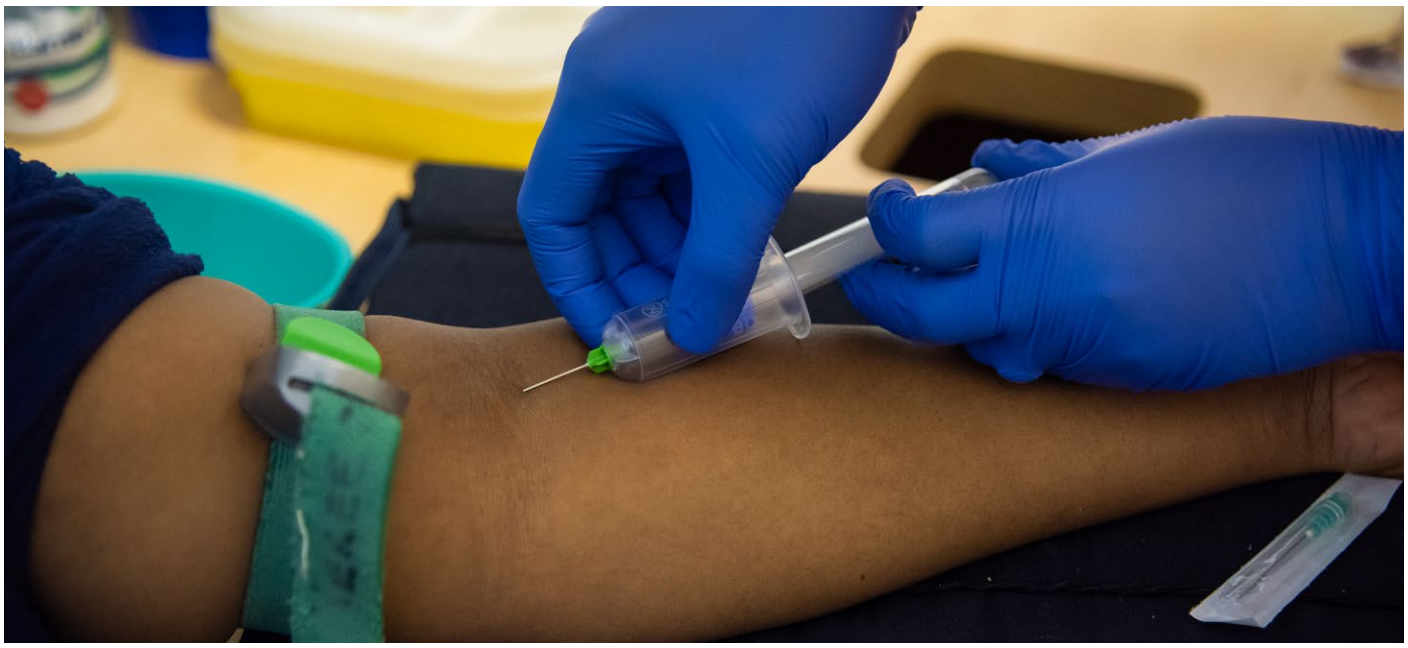
	Known HIV positive on ART	Newly diagnosed HIV positive and pregnancy positive
Medication	Ensure patient is on DTG-based regimen	Start on TLD
Baseline bloods	CD4 count, Cr, VL, Hep B	CD4 count, Cr, Hep B
Monitoring	VL, Cr at booking. If VL<50, repeat VL at delivery.	Cr and VL after 3 months. If VL <50, repeat VL at delivery.
	If VL>50, do A-B-C-D assessment. Repeat VL 4-6 weeks (at appropriate BANC visit, using C#PMTCT code).	If VL>50, do A-B-C-D assessment. Repeat VL 4-6 weeks (at appropriate BANC visit, using C#PMTCT code).
Delivery	Do VL (C#Delivery code).	Do VL (C#Delivery code).
Postpartum monitoring	Lactation: If delivery VL<50, repeat VL at 6 months.	Lactation: If delivery VL<50, repeat VL at 6 months.
	Lactation: If delivery VL>50, do A-B-C-D. Repeat VL after 4-6 weeks (fit into EPI visits) – C#PMTCT code	Lactation: If delivery VL>50, do A-B-C-D. Repeat VL after 4-6 weeks (fit into EPI visits) – C#PMTCT code

Case: An 18-year-old G1P0 is newly diagnosed with HIV at her booking visit at 20 weeks. She reports that her boyfriend has left her, and she doesn't have a new boyfriend. Her booking bloods are as follows: Hb 12, RPR non-reactive, Rh pos. Baseline bloods are taken, and she is started on TLD. She returns a week later for the results which show: Cr 75, Hep B negative and CD4 count 470. Her antenatal care continues uneventfully. She returns at 3 months for bloods: Cr and VL. A week later her bloods are reviewed: Cr 80, VL 20 000. The A-B-C-D approach is taken. She has attended all her ANC visit dates. She has forgotten to bring her tablets, so a pill count hasn't been done. She reluctantly discloses that she now has a new boyfriend who she has not yet disclosed her status to. Upon further probing she admits that she has not been taking her TLD regularly – she misses frequently when she is visiting her boyfriend. She is counselled and agrees to bring her boyfriend the following week and they will both test for HIV together. A date is given for a repeat VL in a month. The boyfriend comes the following week, and they test for HIV together. They both test HIV positive. The boyfriend is very accepting of being HIV positive and agrees to being started on TLD. He says he will support his girlfriend and understands the importance of having a suppressed VL for reducing vertical transmission to the infant. A month later the VL is repeated. The results showed VL<50. She is congratulated and is very happy. Her next VL will be taken at delivery (C#DELIVERY).

Optimising care for the HIV exposed infant to minimize vertical transmission

There are three changes in the new VTP guidelines for minimising vertical transmission to HIV-exposed infants.

1. The definition of "high risk" has been changed from a maternal VL>1000 to a VL>50.
2. All HIV-exposed infants will now be discharged on dual prophylaxis, namely zidovudine (AZT) and nevirapine (NVP). At the postpartum 6 day follow up visit, the maternal delivery VL will be reviewed. If the delivery VL<50, the zidovudine can be stopped, and the infant continued on NVP for 6 weeks. However, if the maternal delivery VL>50, or the delivery VL is



not found, then the infant should continue AZT until 6 weeks and NVP for a minimum of 12 weeks.

3. Cotrimoxazole will now only be prescribed to confirmed HIV positive infants and not all HIV-exposed infants, irrespective of breastfeeding status.

HIV testing should be done using the PCR test when the infant is under 18 months of age. PCR testing should occur at birth, 10 weeks and 6 months of age, and 6 weeks after cessation of breastfeeding, or at any time that the infant appears unwell. All infants (HIV-exposed and unexposed) should be HIV tested at 18 months using a HIV rapid test. If the rapid test is positive, a confirmatory PCR should be done.

Re-engagement into care

If a woman has disengaged from care and now returns pregnant, there are two things to consider: the clinical condition of the woman, and the duration of not being on ART.

If the pregnant woman has disengaged from care for less than 28 days and is well (no clinical complaints), she can be re-engaged into routine care.

However, if the patient presents clinically unwell or returns to care after 28 days, she will need to be assessed by a clinician.

If she returns after more than 90 days, blood for CD4 count needs to be taken and the results reviewed within 7 days. She should be restarted on TLD and VL repeated after 3 months.

Clinical condition	Disengaged care for less 28 days	Disengaged care for 29-90 days	Disengaged care for >90 days
Clinically well	Give TLD and BANC date	Clinical assessment Give TLD and BANC date	Clinical assessment Give TLD Take blood for CD4 count. Review result within 7 days. Repeat VL after 3 months
Clinically unwell/on TB treatment	Clinical assessment by clinician	Clinical assessment by clinician	Clinical assessment by clinician. Blood for CD4 count.

Syphilis

South Africa has seen a 30% increase in syphilis cases from 2015 to 2019. The new VTP guidelines have the following changes:

- Syphilis testing will be done using a rapid syphilis kit so the result can immediately be acted upon. However, the rapid syphilis test remains positive for life, so if the rapid test is positive, a follow up confirmatory blood test is needed.
- Syphilis testing will be conducted at the booking visit. If negative, retesting will be done at BANC visits 20, 26, 30, 34, 38 weeks, and at delivery.

There is now a dual HIV/syphilis testing kit available, which can be used if the HIV and syphilis status are negative or unknown. However, if the woman is known HIV positive, the rapid syphilis kit should be used for ongoing testing during her pregnancy. Likewise, if a woman is known syphilis positive but HIV negative, the rapid HIV testing kit should be used.

If the rapid syphilis test is positive, blood should be taken and RPR and specific syphilis test requested on the laboratory form. To monitor the response to treatment, blood for RPR should be taken and a decrease in titre observed for. A 4-fold titre decrease indicates treatment success.

Syphilis is treated with benzathine penicillin 2,4 MU IMI x3 doses, given weekly. It is acceptable to receive the injections up to 14 days between injections. However, if the injections are received more than 14 days apart, the syphilis is considered to be incompletely treated.

If a fresh stillbirth (FSB) or macerated stillbirth (MSB) has been delivered, the placenta needs to be sent away for histology to exclude syphilis.

Hepatitis B

Women who are hepatitis B positive should ideally deliver in a facility that stocks immunoglobulin (HBIG) and the monovalent hepatitis B vaccine. Following delivery, the infant should be given hepatitis B immunoglobulin (HBIG) 200IU IMI and hepatitis B vaccine 0,5ml IMI as soon after delivery as possible (preferably within 24 hours). Routine hepatitis B immunisations should be given at 6, 10, 14 weeks and 18 months. At 9 months the infant should be followed up and blood taken for hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (HBsAb).

Resources

- Guideline for Vertical Transmission Prevention of Communicable Infections. South African National Department of Health. August 2023. Available at: 2023 Vertical Transmission Prevention Guideline.pdf (sahivsoc.org)
- Adult Primary Care (APC) Clinical Tool (2023). Available at: https://knowledgehub.health.gov.za/elibrary/adult-primary-care-apc-clinical-tool-2023.

A practical approach to integrated care

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It's 04h30am and Lesedi needs to wake her 7-year-old, Lethabo. He's been awake several times in the night, coughing and wheezing, and she longs to let him sleep but if they are to make their appointment at the clinic today, they need to get moving. Lesedi is starting to feel desperate. This is the third time this month that she has had to ask her boss for a day off to take Lethabo to the clinic. He was seen for his routine HIV check-up, but they had to go back another day for his cough, to be seen by the child health nurse. At that visit, they sent off TB tests and gave him antibiotics and an inhaler for 5 days. These seem to help initially, but the cough and wheeze always return. Lesedi is returning for the TB results today. Lesedi doesn't think it's TB. Lethabo has been struggling with this nighttime cough and recurrent wheezing since he was young. She has taken Lethabo to the clinic many times for this but each time, they see someone new, and he seems to get the same treatment. He also never receives any treatment for his itchy eyes and runny, blocked nose and ongoing sneezing. However, these symptoms, together with his nighttime cough affect his sleep. Because of this he seems to be struggling at school, and she wonders if he is growing as he should be, as routine checks like this no longer seems happen after the age of five. She worries too because her own HIV check-up is coming up and she is going to need to take more time off work – at least she knows that she can get her family planning and yearly Pap smear done at the same time. She silently wishes that Lethabo's clinic visits could be a bit more like this, where she can get many things sorted out at once.

What Lesedi is longing for is a comprehensive, integrated care approach where she and her son can be seen together, and have multiple problems addressed at once. Integrated health services are designed to be delivered so that adult and child patients receive a continuum of health promotion, disease prevention,

diagnosis, treatment, disease-management, rehabilitation, and palliative care services, according to their needs throughout the life course. These services are typically co-ordinated across levels of care, with streamlined referrals between primary care level and hospital-level or primary care level and community level. Evidence shows that health systems oriented around the needs of people and communities are more effective, cost less, improve health literacy and patient engagement, and are better prepared to respond to health crises.[1]

How is Integrated Health Care implemented in South Africa's Public Health sector?

South Africa launched 'The Ideal Clinic Programme' in 2013, as a way of systemically improving the quality of care provided in Primary Health Care (PHC) facilities, with roll out in all 9 Provinces starting in 2015.[2] The programme defines an 'ideal clinic' as a clinic with good infrastructure, adequate staff, adequate medicine and supplies, good administrative processes, and sufficient supplies.[3] A key focus within the Ideal Clinic is Integrated Clinical Service Management (ICSM), a health-system strengthening model that builds on the strengths of South Africa's HIV programme, to deliver integrated care to patients with chronic and/or acute diseases who require preventative services.[4,5] Both of these programmes use relevant clinical policies, protocols, and guidelines, and harness partner and stakeholder support to implement these. Standardised clinical guidelines assist healthcare professionals in diagnosing, treating, and preventing both adult and childhood conditions, while also promoting early intervention, continuity of care, and family-centered approaches. They also aim to reduce medical errors and enhance patient safety, ultimately improving quality of care.

> Integrated health services are designed to be delivered so that adult and child patients receive a continuum of health promotion, disease prevention, diagnosis, treatment, disease-management, rehabilitation, and palliative care services, according to their needs throughout the life course.

The core clinical components of the Ideal Clinic Initiative, used widely throughout South Africa (SA) to deliver integrated clinical services, are the

Integrated Management of Childhood Illnesses (IMCI),[6] and the Adult Primary Care (APC) clinical tool.[7]

Adult Primary Care (APC)

The APC clinical tool was also introduced back in 2013. It is a comprehensive, integrated clinical tool, designed to support a clinician's decision making during a primary care consultation. The APC clinical tool consolidates practical content from the latest National Department of Health policies and guidelines from the vertical clinical programmes (like TB, HIV, non-communicable diseases, maternal health, palliative care) into just one tool, providing algorithmic approaches to over 500 symptoms, syndromes, diagnoses, and conditions. It aligns closely with the South African Standard Treatment Guidelines and Essential Medicines List (STG/EML) and uses colour-coding to clarify user scope of practice and facilitate task-sharing between cadres of staff. It uses consistent layout and design features to promote a standardised delivery of care. A case-based training package, which blends face-to-face training methods with online self-supported training, supports its implementation and embeds its use in everyday practice.

Integrated Management of Childhood Illnesses (IMCI)

IMCI was introduced in SA in 1996 and adopted two years later as a key part of the PHC strategy to deliver care to children under the age of five years.[8] The original intention of IMCI was to address common causes of childhood mortality and this has determined the limited selection of conditions included in IMCI. Even with some adaptation of the IMCI package to include child-health challenges encountered in this country, like HIV and TB, evolving disease burdens like chronic diseases such as asthma, allergy, obesity, behaviour disorders and older child health needs highlight its limitations.

A co-ordinated, integrated approach that expands on IMCI content and focuses on long-term health conditions in children, care for children older than 5 years and incorporates a renewed focus on comprehensive well-child care, is needed. Child health care responsibilities also need to be expanded and active involvement from a wider range of primary health care clinicians, like clinical nurse practitioners and primary care doctors, needs to be encouraged and supported. Recently, a clinical tool that uses approaches and layout similar to APC, has been developed in response to these growing needs – this tool is known as PACK Child - the 'Practical Approach to Care Kit' for children.[9]

PACK Child

Like APC, the PACK Child clinical tool provides an expanded, comprehensive content-set in terms of emergencies (like burns and poisoning), and symptom-based approaches (like the child with limp, or skin rash). It also covers priority long-term conditions including: nutrition problems (both underweight and overweight issues), TB and HIV (prevention and treatment), allergy, mental health issues (like behavioural problems, emotional distress, school problems, sleep problems), special needs (like down syndrome and cerebral palsy) as well as an approach to palliative care needs. It allows for providing integrated care at every visit, attending to both acute and chronic problems but also the routine 'well-child' care like HIV and TB screening, growth monitoring, immunisation status, deworming and psycho-social risk assessments including caregiver health. A large focus is on risk minimisation over time, rather than just on the day. It is designed to be a resource to support IMCI-trained nurses, clinical nurse practitioners and primary care doctors. It supports task-sharing and seeks to

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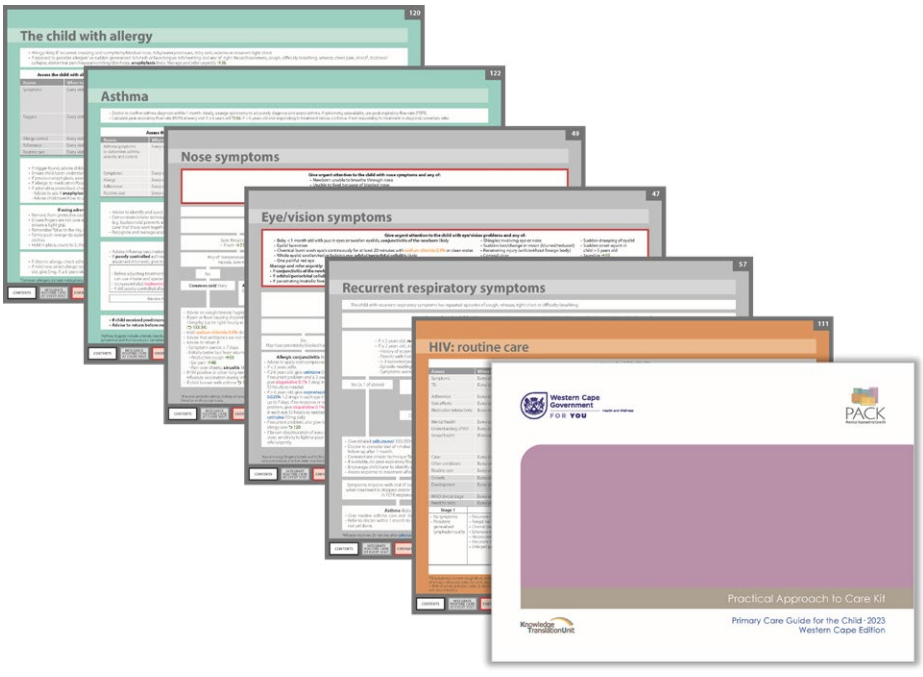

shift the mentality that primary health childcare is solely the responsibility of the IMCI-trained nurse.

This tool was developed by the Knowledge Translation Unit, in close collaboration with nurses, doctors both generalists and specialists, working with children at different levels of care, as well as many policymakers. Over the last 7 years, the tool has been developed,[10] piloted and evaluated[11,12,] and further refined. Finally, the content has been updated to reflect latest policies and guidelines from 2023 and is being launched and scaled up in the Western Cape. An introductory online training course accompanies the launch, aimed at orientating users to how the clinical tool works. It covers the fundamental principles like integrating routine well-child care into every visit, and places emphasis on getting the basics, like growth monitoring, right.

PACK Child may have supported a more integrated, person-centred experience for Lethabo and his mother. During his HIV check-up visit, his recurrent respiratory symptoms may have prompted a likely diagnosis of asthma, and this may in turn have prompted identification of common co-morbidities like allergic rhinitis and conjunctivitis which, when treated adequately, would allow him to sleep peacefully and attain his full potential at school. His routine 'well child' care would have also been prompted and his growth measured, plotted, interpreted, and acted upon. Ideally, Lethabo and his mother should be able to access care and receive treatment from one clinician together.

Integrated clinical tools, like APC and PACK Child, that focus on the identification and management of long-term health conditions, have an untapped potential to improve health care and help the people of South Africa to thrive, not just survive.

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Pre-Exposure Prophylaxis in Pregnancy and Breastfeeding People

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Introduction

Women in sub-Saharan Africa face a high risk of HIV acquisition during pregnancy and breastfeeding[1] and the risk of acquiring HIV more than doubles during this period.[2] While the elimination of vertical transmission services has expanded rapidly in the region, few primary prevention interventions exist for HIV-negative pregnant women in antenatal care.[3,4] This is a missed opportunity that has implications for women and their unborn babies. HIV, syphilis, TB, hepatitis B, malaria, and more recently, listeriosis, are all infections with significant impact on maternal and child health outcomes in South Africa. Although all these infections are important, this article will focus on preventing HIV acquisition during pregnancy and breastfeeding.

According to epidemiologic estimates by UNAIDS for the year 2020, the cause of a quarter of new vertical HIV transmissions was due to a person acquiring HIV during pregnancy or breastfeeding. It will be impossible to eliminate vertical transmission of HIV without expanding access to HIV prevention strategies, such as pre-exposure prophylaxis (PrEP), for pregnant and breastfeeding people (PBFP).[5] According to recent mathematical modelling in South Africa it has been demonstrated that if 80% of all HIV-negative women use PrEP in pregnancy and breastfeeding, perinatal HIV could be reduced by 40%.[6,7]

PrEP is defined by the World Health Organization (WHO) as the use of antiretroviral drugs by HIV-negative individuals who are at substantial risk of acquiring HIV, to prevent HIV acquisition. Given evidence that oral PrEP is a safe and appropriate strategy for preventing HIV in PBFP, increased vulnerability during these periods, and implications for potential transmission to infants, it is important to include and prioritise these populations in PrEP delivery.[8,9]

PrEP, PEP and ART

PrEP is antiretroviral medication taken by HIV-negative people to prevent HIV infection. PEP (post-exposure prophylaxis) is antiretroviral medication taken within 72 hours after an exposure to HIV and continued for 28 days after the exposure to prevent acquisition of HIV. ART is lifelong therapy for HIV-positive individuals.

The guidance below is taken from the National Department of Health, Updated guidelines for the provision of oral PrEP to persons at substantial risk of HIV infection 2021.[10]

PrEP as part of a comprehensive package of services

All people of reproductive age need access to comprehensive information, as well as non-judgemental, confidential, and (as necessary), youth friendly sexual and reproductive health services. HIV-negative pregnant and breastfeeding women at risk of contracting HIV, must be counselled and offered HIV prevention interventions, including PrEP, together with acute HIV screening, adherence counselling, safety monitoring and three-monthly HIV testing, and antenatal care.

PrEP must be integrated into existing services and all PBFP should be offered a comprehensive package of services which includes HIV testing, risk reduction counselling, ART initiation for those diagnosed with HIV and PrEP initiation for those who are HIV-negative and at risk for HIV, syndromic STI diagnosis and treatment, condoms and lubricants, counselling for mental health and TB screening. Partners should be offered voluntary male medical circumcision, HIV testing and treatment and syndromic management of any STI's.

How to start your PBFP clients on PrEP

Figure 1 details how to start a pregnant client on oral PrEP .

Screening for PrEP

Any PBFP requesting PrEP should be offered PrEP even if the client is not considered high risk by the health care provider. The provider should also be cognisant of factors that correlate with increased risk for HIV like condomless sex, multiple partners, a partner/s whose HIV status is unknown, an HIV-positive partner not on treatment, a recent diagnosis of an STI and sex under the influence of alcohol or drugs. Providers should consider offering PrEP to any PBFP who have had multiple courses of PEP or who have ongoing risk for HIV after a course of PEP.

PrEP is defined by the World Health Organization (WHO) as the use of antiretroviral drugs by HIV-negative individuals who are at substantial risk of acquiring HIV, to prevent HIV acquisition.

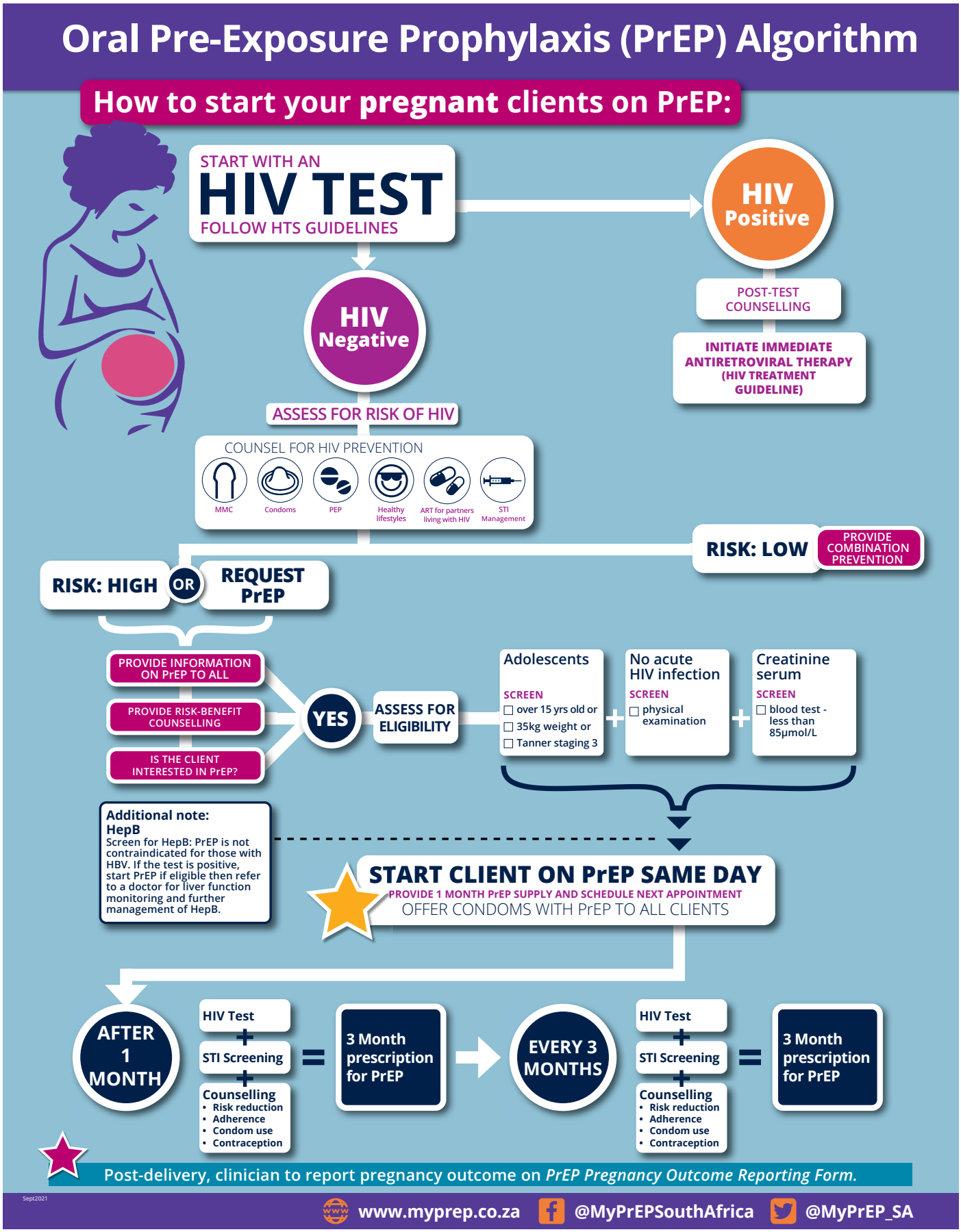
Eligibility for PrEP

PBFP who are HIV-negative, weigh over 35kgs, do not have any contraindications to taking PrEP and who are not acutely infected with HIV (in the window period) should be offered PrEP. It is important for the provider to ensure that there are no signs of acute HIV infection including flu like symptoms or a rash. PrEP should be delayed until symptoms have subsided, and a repeat HIV test is negative. A serum creatinine greater than 85 µmol/L in a pregnant woman and a creatinine clearance less than 50 mL/min/1.73m^2 during breastfeeding is a contraindication for PrEP.

Investigations

Following a negative HIV test, the PBFP should be started on PrEP on the same day - there is no need to wait for results of the baseline investigations. Blood should be sent for creatinine testing and HepBsAg. If the HBV test is positive, refer the client for liver function monitoring. Creatinine should be repeated during pregnancy at three- and 6-months post initiation.

Figure 1. Job Aid for Clinicians: PrEP Algorithm for Pregnant Women



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Prescription of drugs

The recommended oral PrEP regimen for PBFP is TDF/FTC one tablet by mouth daily. This tablet can be taken anytime of the day, with or without food, and can be stored at room temperature. PrEP is initially prescribed for one month. At the month 1 visit the HIV test is repeated and then PrEP can be prescribed for 3 months. The HIV test is then repeated every 3 months with a repeat prescription and an STI screen.

Counselling

The choice to start, continue or discontinue PrEP when a woman becomes pregnant should be made by the woman, following discussion of the risks and benefits with her healthcare provider. All PBFP should receive education and counselling about PrEP (Table1).

Table 1. Key counselling messages before PrEP initiation and during follow-up visits.

Topic	Key Messages
What is PrEP?	• PrEP is ARV medication that can be taken by HIV-negative persons before exposure to HIV to prevent an HIV infection. • PrEP is an additional HIV prevention option and, where possible, should be used in combination with other interventions such as condoms. • PrEP does not protect against other STIs or prevent pregnancy.
PrEP is not for life	• PrEP is taken for as long as the individual is at risk for HIV infection. • PrEP can be discontinued if the individual is no longer at risk.
PrEP works if taken	• For PrEP to be effective, it must be taken every day. • Consistent use requires that PrEP be included in the daily routine. • If a dosage is missed, the client must take the PrEP drug as soon as he or she remembers and continue to take daily as before. It can be taken with or without food and at any time of the day.
Side effects	• PrEP is safe, with no side effects in most of the users. • Some individuals may report minor side effects in the first month of PrEP use, such as diarrhea, headache, abdominal pain and nausea. • Major side effects associated with PrEP are very rare.*
Drug interactions	• Taking alcohol will not reduce the effectiveness of PrEP. • PrEP can be taken with any kind of contraception and sex hormones.
Starting and stopping PrEP	• 7 consecutive days of PrEP are needed before achieving full protection from HIV infection. • PrEP should be continued for 28 days after the last potential HIV exposure in those wanting to cycle off PrEP. • The client should notify the provider if he or she decides to stop taking PrEP.
Pregnancy and breastfeeding	• WHO recommends that PrEP is safe for use in pregnant or breastfeeding women at substantial risk of HIV infection.
Safer conception	• In serodiscordant relationships, PrEP can be safely used by the HIV negative partner for safe conception.
Visit schedule	• The client must return for a month one and thereafter 3-monthly for follow-up HIV testing, counselling and safety monitoring visits.

**Major side effects are extremely rare and may include renal toxicity and metabolic complications decreased bone mineral density (which is reversible), extremely small risk of lactic acidosis and hepatic steatosis or steatohepatitis*

In addition to routine counselling PBFP should be advised of the safety, benefits, and side effects of taking PrEP during pregnancy and breastfeeding as outlined in Table 2. The key message for risk benefit counselling is that the benefits of taking PrEP during pregnancy and when breastfeeding for an HIV-negative woman, far outweigh the risk of any possible harm to the mother and baby.

Table 1. Key counselling messages before PrEP initiation and during follow-up visits.

What is the risk of contracting HIV during pregnancy for the mother and baby?	What are the risks of PrEP drugs to the baby?	What are the benefits of taking PrEP during pregnancy and breastfeeding?
• Biological and behavioural changes during pregnancy increase the likelihood of women contracting HIV. • The likelihood of a women contracting HIV is 2-3 x more than a non-pregnant woman. • Women recently infected with HIV have a much higher chance of passing on HIV to their unborn baby because of the high levels of the virus in the body during the time of acute (new) infection and not yet being on ART.	• Very low concentrations of PrEP drugs are secreted in the breastmilk. • PrEP use in HIV negative pregnant women has been shown to be safe for the mother and baby. • There has been extensive use of TDF/FTC (PrEP drugs) over many years by pregnant women as part of HIV treatment, and there is no indication of any harmful effects for the baby.	• An HIV-negative pregnant or breastfeeding woman taking PrEP can protect herself from contracting HIV thereby reducing the risk of passing HIV to her unborn or breastfed baby. • PrEP is easy to take as it only requires one pill a day. • PrEP can be taken by the woman without anybody else knowing if she wants to keep it to herself. • PrEP can be used when a woman and her partner want to conceive safely if she is HIV-negative and her partner is HIV-positive. • PrEP can also be used by couples when one partner is HIV-positive (and not on ART or virally suppressed) and the other is HIV negative.

Discontinuation of PrEP

PrEP should be discontinued in the event of a positive HIV test and ART initiated as soon as possible. Resistance is unlikely but is a possibility and expert opinion should be obtained if there are resistance concerns. All persons on PrEP that have seroconverted must be reported.

Key take home points

- Women are at increased risk of HIV acquisition during pregnancy and breastfeeding.
- PrEP is safe and should be offered to all pregnant and breastfeeding people who are at high risk for HIV.
- PrEP should be offered as a component of a comprehensive sexual and reproductive health service.
- A negative HIV test is a pre-requisite for PrEP initiation and should be repeated one month after initiation and then every 3 months whilst on PrEP.
- Remember to screen for other STIs, including syphilis and hepatitis B.

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Clinical tips

1. When initiating DTG a slight raise in creatinine may occur, this is not renal dysfunction.
2. DTG absorption is significantly decreased by polyvalent cations (calcium and iron supplements, antacids, laxatives, buffers). Always check other medications.
3. A suppressed VL can prevent sexual transmission of HIV. Remember U=U.
4. All women with HIV must have a VL test done at the time of delivery.
5. TPT should be given to all pregnant women with HIV, regardless of their CD4 count.
6. Ensure stable patients on ART are provided with multi-month dispensing.
7. Always ask at every visit about TB contacts and TB symptoms in all children and their caregivers.
8. With access to new DTG dispersible formulations, most children >3kg and >1 mth of age can be on a DTG-based regimen.
9. TLD is preferred first-line ART for all children ≥ 30 kg and ≥ 10 years.
10. The preferred first-line regimen from birth to 4 weeks of age is AZT+3TC+NVP.
11. All HIV-exposed infants must be given dual prophylaxis AZT+NVP until the mother's delivery VL is known.
12. Counselling and education are vital for successful treatment and care of children living with HIV and their families.
13. Initiating TLD or DTG in pregnant women carries no risk of neural tube defect. Counsel the patient about this safety information and allow her to make an informed choice.
14. Adolescents are at a higher risk for poor adherence and poor viral suppression and require more intensive support.
15. If the patient is on rifampicin, DTG needs to be given 12-hourly rather than daily. If on fixed-dose combination TLD tablet, add an additional DTG 50mg 12 hourly.
16. Pregnancy does not preclude screening for cervical cancer, and can be performed up to 20 weeks.
17. After delivery, provide stable women on ART with 2 months of ART at discharge.
18. Any infant with a positive birth HIV PCR requires immediate ART initiation.
19. Do an age-appropriate HIV test at six weeks post cessation of breastfeeding.
20. HIV-negative pregnant and breastfeeding women are at increased risk of acquiring HIV and should be offered PrEP.

DTG - dolutegravir; VL - viral load; U=U - undetectable = untransmittable; TB - tuberculosis; TLD - tenofovir/lamivudine/dolutegravir; AZT - zidovudine; 3TC - lamivudine; NVP - nevirapine; ART; antiretroviral therapy; PCR - polymerase chain reaction; PrEP - pre-exposure prophylaxis.

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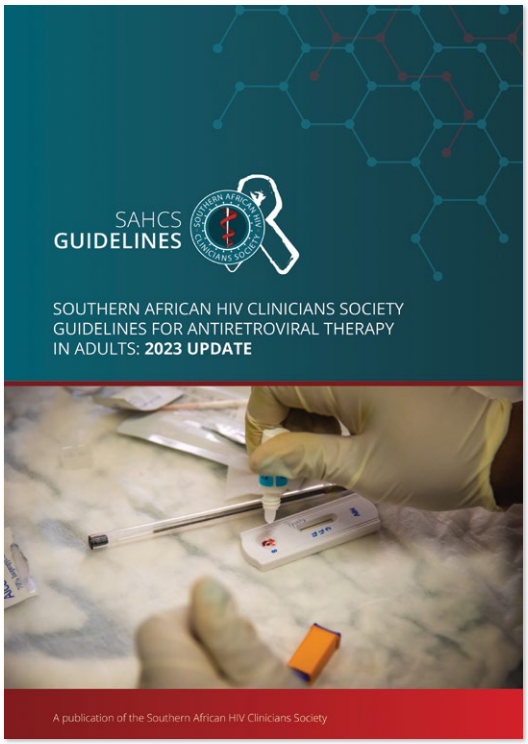

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The National HIV & TB Health Care Worker Hotline provides information on queries relating to:

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- HIV testing
- Management of HIV in pregnancy
- PMTCT
- Drug interactions
- Treatment/prophylaxis of opportunistic infections
- Drug availability
- Adherence support
- Management of DS and DR tuberculosis
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WE ARE A COMMUNITY OF HEALTHCARE PROVIDERS DEDICATED TO DELIVERING EVIDENCE-BASED, HIGH-QUALITY HIV CARE

The Southern African HIV Clinicians Society (SAHCS) is a community of healthcare professionals that work in a variety of spaces, including public, private, and allied healthcare organisations. Our commitment lies in empowering our community to deliver evidence-based, up-to-date, and patient-centred HIV healthcare of the highest quality.

We strive to support and strengthen the capacity of our members. We achieve this through the development of our clinical guidelines and job aids, offering training courses and conferences, publishing the SAJHIVMED scientific journal and the HIV Nursing Matters publication, organizing regular Continuous Medical Education meetings and webinars. We are dedicated to fostering collaboration across cadres and borders to improve the lives of all those affected by HIV.

As a member of SAHCS, you will have access to trusted clinical knowledge, enabling you to enhance your clinical practice and provide high quality HIV prevention, treatment, and care.

SAHCS MEMBERSHIP BENEFITS INCLUDE:

- Free access to CME meetings and webinars
- CPD certificates for courses and webinars completed
- Free access to previous webinars to enable you to learn when it suits you
- Preferential registration to SAHCS workshops
- The opportunity to network and collaborate with other healthcare providers who have an interest in HIV
- Free access to:
  - the DHET PubMed® accredited Southern African Journal of HIV Medicine (SAJHIVMED)
  - SAHCS HIV Nursing Matters Publication
  - HIV and related diseases clinical updates and articles
  - Evidence-based SAHCS and NDoH clinical guidelines

CLICK HERE TO JOIN THE SAHCS COMMUNITY FOR FREE!

Or send an email to mirriam@sahivcs.org

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UNITING HEALTHCARE WORKERS IN HIV CLINICAL EXCELLENCE