PHC & AHL: Obstetrics & Gynaecology
PHC: Family Planning

National Department of Health

Affordable Medicines Directorate
Essential Drugs Program

Primary Healthcare Standard Treatment Guidelines – 2020-4 Review cycle
Adult Hospital level Standard Treatment Guidelines – 2020-4 Review cycle

Evidence

Please access the National Essential Medicines List Committee (NEMLC) report for detailed evidence (including rationale, references and costings) informing decision-making on medicine addition, amendments and deletions:

NHI Website: https://www.health.gov.za/nhi-edp-stgs-eml
Knowledge Hub: www.knowledgehub.health.gov.za/e-library

Disclaimer

This slide set is an implementation tool and should be used alongside the most recently published STG available on the Knowledge Hub. This information does not supersede or replace the STG itself.

Presentation Outline

1	• **Tranexamic Acid** for Postpartum Haemorrhage (PPH) at PHC Level
2	• **Aspirin** for reducing onset of pre-eclampsia in high risk patients at PHC level
3	• **TDF Prophylaxis** for Hepatitis B positive, HIV negative Pregnant Women
4	• **Progesterone** for Pre-term labour *(recap from previous edition)*
5	• **Levonorgestrel intra-uterine device (LNG-IUD)** *(PHC CH7: Family Planning)*

Use of Tranexamic Acid IV for the management of postpartum haemorrhage at PHC level

Background

Tranexamic Acid (IV) reviewed for inclusion in PHC Chapter (2020 review cycle) for management of PPH

NEMLC **DID NOT APPROVE** Tranexamic Acid (IV) for inclusion in the 2020 edition of the PHC STGs or in the 2020-4 review cycle

NEMLC **DID APPROVE** Tranexamic Acid (IV) for inclusion in the Adult Hospital Level STG and EML

Following publication of the updated chapter (2020-4), an appeal with motivation was received for NEMLC **TO RECONSIDER** Tranexamic Acid (IV) for PHC level

Reasons for exclusion:

- "The **composite primary endpoint of death** from all causes or hysterectomy was not reduced with tranexamic acid (534 [5·3%] deaths or hysterectomies in the tranexamic acid group vs 546 [5·5%]in the placebo group, RR 0·97, 95% CI 0·87-1·09; p=0·65)"; **statistically not significant.**
- Generalisability of the results of the WOMANS* Trial to the local primary health care setting was not possible, as the trial was conducted in an emergency hospital setting.
- Referral to higher level of care for appropriate management from primary level may be delayed.
- Price was a major consideration

WOMAN Trial Collaborators. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial. Lancet. 2017 May 27;389(10084):2105-2116. doi: 10.1016/S0140-6736(17)30638-4. Epub 2017 Apr 26. Erratum in: Lancet. 2017 May 27;389(10084):2104. doi: 10.1016/S0140-6736(17)31220-5. PMID: 28456509; PMCID: PMC5446563.

Use of Tranexamic Acid IV for the management of PPH at PHC level

Motivation

In 2023, a motivation to include TXA, IV at PHC level was received arguing that it is reasonable to extrapolate the WOMAN trial findings to the PHC level and that the total price of the TXA, IV in the original review was incorrectly calculated.

NEMLC recommended that:

1. Previous deliberations be revisited
2. PHC/Adult Hospital Level ERC review updated data

The E-MOTIVE (WHO) trial published in May 2023 provides the updated evidence for the use of TXA, IV which can be extrapolated to PHC level.

DETECT AND TREAT POSTPARTUM HAEMORRHAGE EARLY

E

Early detection and trigger criteria

- Calibrated drape for blood loss collection with trigger lines at **300ml and 500ml** for the first hour after birth
- Observations (blood loss, blood flow, uterine tone) every **15 minutes** documented on the blood loss monitoring chart
- Blood pressure and pulse carried out once in the **1st hour** postpartum and documented on the blood loss monitoring chart

Trigger criteria

1 Clinical judgement

2 Blood loss 500ml or more

3 Blood loss 300ml or more plus one abnormal observation

M

Massage of uterus

- Massage until uterus has contracted or for **one minute**

O

Oxytocic drugs

- **10 IU IV oxytocin injection** or diluted in **200-500ml crystalloid** over **10 minutes** plus a maintenance dose for **20 IU IV oxytcin** diluted in **1000ml saline** over **4 hours** (+- misoprostol 800mcg PR/SL if used)

T

Tranexamic acid

- **1g IV injection of tranexamic acid** or diluted in **200ml crystalloid** over **10 minutes**

IV

IV fluids

- IV fluids in addition to the infusion should be given if clinically indicated for resuscitation and will require a **2nd IV access**

E

Examination and escalation

- Ensure bladder is empty, evacuate clots, check for tears with an internal examination and placenta for completeness
- Escalate if bleeding does not stop after first response or you are unable to identify or manage cause of bleeding

Implementation strategies

Audit newsletters: sharing with all staff monthly detection and bundle use rates along with PPH, severe PPH, blood transfusion, laparotomy and death from PPH rates and given feedback at monthly departmental meetings

Champions: midwife and doctor to oversee change, troubleshoot, give feedback on audit newsletters, connect with other champions through chats, meeting and websites for sharing knowledge and lessons learnt

Trolley and/or carry case: including all medicines and devices required for the treatment of PPH restocked after every use and complete a stocking checklist at the start of every shift

Training: on-site, simulation-based, and peer-assisted training of 90 minutes to a whole day facilitated by the use of provider guides, flipcharts and job aids displayed in labour wards

World Health Organization

human reproduction programme hrp research for impact

E-MOTIVE Trial Summary

The E-MOTIVE (WHO) trial published in May 2023 provides the updated evidence for the use of TXA, IV which can be extrapolated to PHC level.

E-MOTIVE trial has shown that a bundle of care that includes TXA given by midwives at district hospital level reduces postpartum haemorrhage (PPH) by 60%.

E-MOTIVE
First response to PPH

The E-MOTIVE trial was the Early detection of Postpartum Haemorrhage and treatment using the WHO MOTIVE 'first response' bundle: a parallel cluster-randomized trial that included a baseline control phase, along with mixed-methods evaluation in 210 132 low risk women undergoing vaginal delivery.

Results of the study can be extrapolated to community health center/midwifery obstetrics unit level, as all the interventions in the trial were given by midwives without intervention from a doctor. All women with a significant bleed will be urgently transferred to the next level of care, so further management will be under doctor or specialist care.

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Reference: Gallos I, Devall A, Martin J, Middleton L, Beeson L, Galadanci H, et al. Randomized Trial of Early Detection and Treatment of Postpartum Hemorrhage. New England Journal of Medicine. 2023 May 9;0(0).

2030 NDP

30 YEARS OF FREEDOM
South Africa 1994 - 2024

Use of Tranexamic Acid IV for the management of PPH at PHC level

NEMLC Recommendation

NEMLC supports the use of tranexamic acid (TXA) 1g IV (by slow injection or infusion in 200mls of N Saline over 10 minutes) for PPH for all levels of care, which may be initiated by a nurse, but only with prior approval of a medical practitioner.

Use of Tranexamic Acid IV for the management of PPH at PHC level

Changes to the STG

MEDICINE TREATMENT

Replace fluids:

Sodium chloride 0.9%, IV, infused as fast as possible in one IV line.

AND

Oxytocin, IV 20 units in 1 000 mL sodium chloride 0.9% infused at 250 mL/hour in 2nd IV line.

AND

Tranexamic acid, IV, 1g in 200 mL sodium chloride 0.9% over 10 minutes, or 1g by slow IV injection, which may be initiated by a nurse, but only with prior approval of a medical practitioner

Aspirin for reducing onset of Pre-eclampsia in high risk patients at PHC level

Background

1. Historically, NEMLC retained Aspirin for secondary level initiation in all women with chronic hypertension, who are pregnant as the patient would require referral to the secondary level of care for evaluation and management.

2. NEMLC highlighted that pregnant women with chronic hypertension may have been on complex and teratogenic antihypertensive medication and ultrasound scanning to evaluate the foetus for abnormalities, and/or switching to safer medication would be appropriate for secondary level.

3. Therefore, initiation of prophylactic aspirin for pre-eclampsia would also only be appropriate for secondary level of care.

4. However, patients with historical risk factors (e.g. previous history of pre-eclampsia) might not be referred immediately to secondary care, but only at a scheduled appointment, which may be a few weeks later. These patients will then potentially miss out on the benefit of early initiation of aspirin prophylaxis.

Use of Aspirin at PHC level

Evidence

Level of Evidence: Systematic Reviews, Randomised Control Trials & Guidelines

SAFETY	Low-dose aspirin has been widely regarded as safe in pregnancy, although there are small increases in bleeding risk; mostly intrapartum and postpartum bleeding and a small (0.06%) increase in neonatal intracranial bleeds. Most of these risks can be mitigated by discontinuing aspirin by 36 weeks, based on the lack of effectiveness for prevention of term pre-eclampsia.
AVAILABILITY	Aspirin is widely available, inexpensive and has a favourable fetal and maternal safety profile and research shows that aspirin prophylaxis for women at risk of hypertensive related diseases of pregnancy particularly in low- and middle-income countries results in reduction in the risk of early onset preeclampsia
GUIDELINE ALIGNMENT	In line with local National Maternity Care Guideline and the International Society for the Study of Hypertension in Pregnancy the aspirin dosing is recommended at bedtime to prevent gastric irritation and initiated from 6 weeks of gestation (but preferably before 16 weeks) until 36 weeks.
RECOMMENDATION	Aspirin, 150mg, oral for reduction in the risk of early onset pre-eclampsia in pregnancy at PHC level for nurse initiation, in alignment with NDOH maternity and hypertension in pregnancy guidelines.

References:

1. Ngene NC, Moodley J. Preventing maternal morbidity and mortality from preeclampsia and eclampsia particularly in low- and middle-income countries. Best Pract Res Clin Obstet Gynaecol. 2024 Feb 15;94:102473. doi: 10.1016/j.bpobgyn.2024.102473. Epub ahead of print. PMID: 38513504.

2. NDOH. National Maternity Care Guidelines. Updated 2024.

3. Magee LA, Brown MA, Hall DR, Gupte S, Hennessy A, Karumanchi SA, Kenny LC, McCarthy F, Myers J, Poon LC, Rana S, Saito S, Staff AC, Tsigas E, von Dadelszen P. The 2021 International Society for the Study of Hypertension in Pregnancy classification, diagnosis & management recommendations for international practice. Pregnancy Hypertens. 2022 Mar;27:148-169. doi: 10.1016/j.preghy.2021.09.008. Epub 2021 Oct 9. PMID: 35066406.

Use of Aspirin at PHC level

NEMLC Recommendation

NEMLC supports the use of aspirin 150mg oral, until 36 weeks of pregnancy, for prevention of pre-eclampsia for all levels of care.

Use of Aspirin at PHC level

Changes to the STG

From confirmation of pregnancy (all women with risk factors. including: pre-eclampsia in a previous pregnancy, chronic hypertension, diabetes, antiphospholipid syndrome, or systemic lupus erythematosus (SLE)):

- Aspirin, oral, 150 mg, taken at bedtime, preferably not on an empty stomach, until 36 weeks
  - Start at 6 weeks of gestation but preferably before 16 weeks
  - Stop at 36 weeks to reduce risk of bleeding during labour
  - Administration at bedtime reduces the risk of gastric irritation
- Refer to the next level of care as appropriate for the condition (see below). Women with a prior history of pre-eclampsia, but otherwise well, can be referred for the next available appointment, preferably around 20 weeks.

Tenofovir Prophylaxis for Hepatitis B positive women, HIV negative pregnant women – AHL

Background

The World Health Organisation Guidelines[1,2] have been updated as reflected below:

[1]Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection. Geneva: World Health Organization; 2024. Available at: https://www.who.int/publications/i/item/9789240090903, Accessed 11 July 2024).

[2] Prevention of mother-to-child transmission of hepatitis B virus: guidelines on antiviral prophylaxis in pregnancy. Geneva: World Health Organization; 2020. Available at (https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hepatitis/prevention/mother-to-child-transmission-of-hepatitis-b, Accessed 11 July 2024

7.4.2 New recommendation – TDF prophylaxis for all HBsAg-positive pregnant women (where there is no access to HBV DNA testing)

In many settings, HBV DNA or HBeAg testing is not available to enable targeted TDF prophylaxis for pregnant women with high HBV DNA levels at high risk of MTCT. In such settings, universal TDF prophylaxis could be a strategy to reduce the risk of MTCT of HBV infection, alongside HepB3 and birth-dose immunization. However, no study has compared directly the effectiveness among hBsAg positive pregnant women of universal TDF prophylaxis versus no or targeted prophylaxis. In addition, low- and middle-income countries with high prevalence of HBsAg positivity among pregnant women often overlap with those with low or no uptake of hepatitis B birth-dose vaccination.

The Guidelines Development Group recognized the lack of direct empirical evidence to directly support the effectiveness, cost–effectiveness and feasibility of a universal prophylaxis approach. In settings without access to HBV DNA assays, a conditional recommendation to expand TDF prophylaxis to all HBsAg-positive pregnant women was therefore based on an overall pragmatic approach. This includes addressing the challenge of ongoing MTCT in settings without access to HBV DNA assays, the overall significant balance towards benefits versus harms of this approach, as well as low-certainty evidence based on data from cost–effectiveness modelling. This modelling analysis across 110 countries representing all WHO regions suggested that prophylaxis for all HBsAg-positive pregnant women would have great impact on PMTCT of HBV, with about 4.9 million (95% CI: 4.7 million–5.1 million) neonatal infections averted. The relative cost–effectiveness of the universal and HBV DNA–driven strategies (each compared with a sole hepatitis B birth-dose strategy) was highly dependent on the relative costs of treatment and diagnostic tests *(18)*.

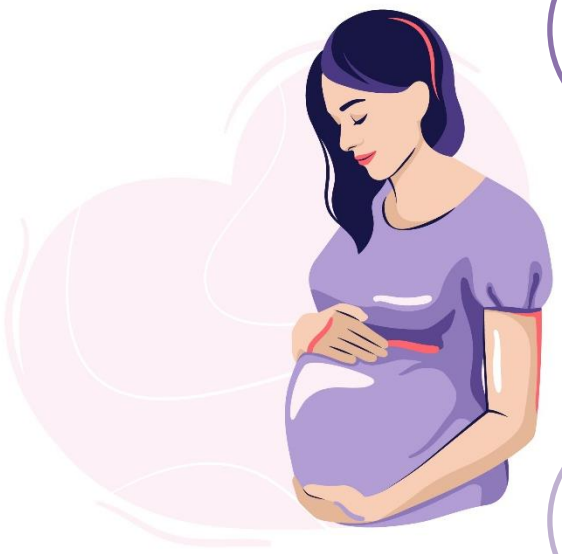
More recent data based on timing of antiviral prophylaxis from the previous systematic review *(11)* showed that antiviral therapy at least four weeks before delivery reduces HBV DNA levels at delivery *(19)* and may reduce the risk of MTCT among babies who do not receive a timely hepatitis B birth dose, hepatitis B immune globulin or complete HBV immunization, a common concern in endemic countries.

Other key considerations include the following.

1. HBV perinatal transmission continues to be the dominant mode of ongoing HBV transmission worldwide *(21)*, and especially in sub-Saharan Africa, which continues to have low uptake of hepatitis B birth-dose vaccination. Data also indicate a significant residual risk (>10%) of HBV MTCT among highly viraemic (≥200 000 IU/mL) pregnant women despite receiving a timely hepatitis B birth dose *(10,22)*.

Tenofovir Prophylaxis for Hepatitis B positive women, HIV negative pregnant women - AHL

Recommendation



- Tenofovir monotherapy for the prevention of vertical transmission of Hepatitis B in HIV Negative pregnant women with chronic active Hepatitis B infection who are HBeAG positive.
- Maternal TDF prophylaxis be pragmatically offered to all HBsAg positive pregnant woman even if the HBeAg or viral load result is unavailable
- Consider Tenofovir Alafenamide (TAF) for people (including pregnant women) with impaired kidney function (eGFR 15-50mL/min) and/or osteoporosis noting that TAF is not recommended if eGFR is <15 ml/min)

Referral for Tenofovir Alafenamide (TAF)

Considerations in renal impairment

MATERNITY CARE GUIDELINES

- Women with known renal disease should be referred to a specialist to evaluate for the presence and severity of renal impairment, proteinuria and/or hypertension.
- Women with hypertension and proteinuria prior to 20 weeks gestation should be referred for tertiary care for further work-up.
- Pregnancy is contra-indicated in women with stage 4-5 chronic kidney disease. (Glomerular filtration rate < 30 mL/minute and serum creatinine > 250 umol/L)

Tenofovir Prophylaxis for Hepatitis B positive women, HIV negative pregnant women - AHL

Changes to the STG

Prevention of perinatal transmission

» Caesarean delivery is reserved for obstetric indications only.
» Delivery should take place in a facility that can offer Hepatitis B vaccination to the baby at birth.
» Administration of ARVs active against HBV from 28 weeks of pregnancy will further reduce risk of vertical transmission.

Pregnant women who are HBsAg/ HBeAg positive and HIV negative

» All HIV negative pregnant women are eligible for HIV Pre-exposure prophylaxis (PrEP) (see PHC STGs and EML, section 11.11: Pre-exposure prophylaxis (PrEP)). TDF, which is included in the oral PrEP regimen, has anti-HBV activity, and will reduce the risk of vertical transmission of HBV.
» Women who are HIV negative and HBsAg positive who decline PrEP must be counselled that TDF will reduce risk of vertical transmission of Hepatitis B to the baby, particularly if HBeAg is positive or HBV viral load is high.
» TDF 300 mg daily should be administered from 28 weeks of pregnancy until birth to women with a high hepatitis viral load (≥200 000 IU/mL), or positive HBeAg, or where HBeAg/viral load result is unavailable at 28 weeks.
» For care of babies born to: (1) mothers with acute hepatitis B infection at the time of delivery, (2) mothers who are HBsAg-positive, or (3) mothers who are HBeAg-positive, see Primary Health Care STGs and EML, section 6.6.5: Hepatitis B exposed infant.
» Obtain infectious disease specialist or internal medicine physician opinion before stopping TDF as there is a risk for postpartum hepatitis flare.
» Consider continued treatment for HBV after delivery where indicated (see section 1.2.4.2 Hepatitis B, chronic (non-HIV coinfection)).

REFERRAL

» Cirrhosis.
» Liver failure.
» Renal dysfunction (TDF is contraindicated in renal impairment. Tenofovir alafenamide (TAF) should be prescribed in place of TDF).
» Refer all infected babies to a specialist paediatrician for further management.

Progesterone for Pre-term labour AHL (Recap from previous edition)

Background and Evidence

A medicine review on progesterone to prevent preterm labour was completed. The key findings of the review are highlighted below:

Objective

To **review the evidence** for the use of **vaginal progesterone** for use in women at high risk for preterm birth (based on previous history) if they are found to have a shortened cervix under 24 weeks gestation.

Population

For women with **mid-trimester cervical shortening** and no prior spontaneous singleton preterm birth**, daily vaginal progesterone treatment** through 34 weeks of gestation be offered.

Population

For women with a **singleton pregnancy** who have had a **previous spontaneous singleton preterm birth**, **progesterone treatment** is a reasonable option

Guidelines

The **NICE guideline recommends** that cervical cerclage be considered in women with a **cervix length ≤25mm** with previous history of cervical trauma or previous preterm pre-labour rupture of membranes.

Safety

For women who choose to take **progesterone for preterm birth** prevention, it appears to be **safe with no major adverse events** noted in follow-up studies up to two years.

Formulation

The studies show that **reasonable options include a vaginal suppository** (100 or 200 mg), **gel** (90 mg), or **tablet** (100 mg micronized progesterone).

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

For the full medicine review:
[Hospital Level (Adults) Medicine Reviews, Costing and NEMLC Reports 2017 - 2019 | Department of Health Knowledge Hub]

2030 NDP

30 YEARS OF FREEDOM
South Africa 1994 - 2024

Progesterone for Pre-term labour AHL (Recap from previous edition)

NEMLC Recommendation

NEMLC recommended daily vaginal progesterone treatment through to 34 weeks of gestation in:

RECOMMENDED

1. **Mid-trimester cervical shortening (defined as ≤25 mm before 24 weeks gestation) with no prior spontaneous singleton preterm birth**

2. **Women with a history of spontaneous preterm birth or mid-trimester loss.**

NB: In the South African setting, routine cervical screening is not practiced in low-risk women as it is considered to be unpractical and unaffordable - sonography (ultrasound imaging) is not readily available at all facilities.

Progesterone for Pre-term labour AHL (Recap from previous edition)

Rationale for Recommendation

1. Guidance **aligned with NICE Guideline** recommendations that were informed by systematic review and meta-analysis that included the **OPPTIMUM study** which showed conflicting results of no benefit of vaginal progesterone in preventing preterm labour.

2. **Subgroup analysis** and individual **participant data** meta-analysis of low to moderate quality evidence showed that for women with a history of spontaneous preterm birth, or women with a short cervix (≤25mm), **vaginal progesterone decreases the number of preterm births (at <34 weeks' gestation) compared to placebo.**

3. Furthermore, pharmacological management with **vaginal progesterone** is **non-invasive and less costly** compared to cerclage.

Norman JE, Marlow N, Messow CM, Shennan A, Bennett PR, Thornton S, Robson SC, McConnachie A, Petrou S, Sebire NJ, Lavender T, Whyte S, Norrie J; OPPTIMUM study group. Vaginal progesterone prophylaxis for preterm birth (the OPPTIMUM study): a multicentre, randomised, double-blind trial. Lancet. 2016 May 21;387(10033):2106-2116. doi: 10.1016/S0140-6736(16)00350-0. Epub 2016 Feb 24. Erratum in: Lancet. 2019 Jan 19;393(10168):228. doi: 10.1016/S0140-6736(18)32625-4. Erratum in: Lancet. 2019 Apr 20;393(10181):1596. doi: 10.1016/S0140-6736(19)30860-8. PMID: 26921136; PMCID: PMC5406617.

Progesterone for Pre-term labour AHL (Recap from previous edition)

New STGs Added

Medicine treatment
Women should be counselled that 20 cerclage procedures will prevent one preterm delivery (NNT 17 to 20) and that progesterone is successful in
1 out of every 8 cases (NNT 6 to 8), to assist them in making an informed decision.

Consider prophylactic vaginal progesterone ***or*** cervical cerclage (MacDonald suture) for women with:
» history of spontaneous preterm birth (27-34 weeks) or midtrimester loss (16-24 weeks), ***and/or***
» cervical length ≤ 25 mm confirmed on ultrasound (16-24 weeks).
Progesterone, PV, 200 mg daily.
- Stop treatment at 34 weeks and refer to antenatal services at primary level of care for further management.

(**Note**: Vaginal progesterone may be considered in high-risk women with a normal cervix length confirmed on ultrasound).

Consider prophylactic cervical cerclage (MacDonald suture) ***only*** for women with:
» cervical length ≤ 25 mm confirmed on ultrasound (16-24 weeks),
AND
» history of preterm prelabour rupture of membranes (PPROM), ***or***
» history of cervical trauma.

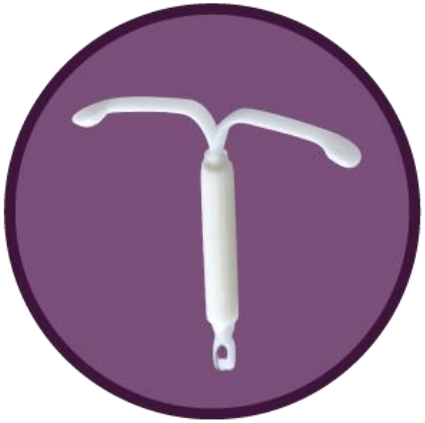
Rescue cerclage:
» If the cervix is already open and the membranes exposed, but unruptured, consider a rescue cervical cerclage (16-27 weeks).
» Do not insert a rescue cerclage if there are contractions, active vaginal bleeding or signs of infection.
Cerclage should be removed at 36 weeks, and thereafter the patient can be referred to antenatal services at primary level of care.

Referral
Women with recurrent losses and previous cerclage that torn out (severe cervical trauma), as they may require an abdominal cerclage.

Levonorgestrel Intra-uterine Device (LNG-IUD) for PHC use *(PHC CH 7:Family Planning)*

What is Mirena?

A small T-shaped hormone releasing device that is inserted (by healthcare professional) into the uterus to prevent pregnancy



How does it Work?

Levonorgesterol, released by the device thickens the cervical mucus to prevent sperm from reaching or fertilizing the egg

Pros:
Highly Effective
Does not require daily/monthly monitoring

Cons:
High Cost

Previous NEMLC Standing on Mirena

On 27 April 2015, NEMLC had recommended that standard-dose LNG-IUD, 52mg not be recommended for contraception, as despite comparable effectiveness and safety with copper IUD, standard-dose LNG-IUD, 52mg is not affordable for contraception

Following a health economic analysis, on 27 September 2018 NEMLC recommended standard-dose LNG-IUD, 52mg for refractory abnormal uterine bleeding as third-line treatment option at Tertiary and Quaternary Level of Care

More recently, on 17 September 2020 NEMLC recommended that the low-dose LNG-IUD, 19.5mg not be included on the PHC EML, as it is expensive relative to other contraceptive agents currently included on the EML

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

30 YEARS OF FREEDOM
South Africa 1994 - 2024

Levonorgestrel Intra-uterine Device (LNG-IUD) for PHC use *(PHC CH 7:Family Planning)*

Considerations for inclusion

Consideration	Rationale
Supply Challenges	With contraceptive supply challenges, new agent would be considered
Choice	Patients concerned have a right to choose whether to use contraceptives and also which method to use.
Uptake of contraceptives	Uptake of contraceptives has not increased substantially since 2013. Increasing the contraception options would provide a broader base to choose from.
Advantages over Copper IUCD	Different mechanism of action Decreases menstrual blood after 3 months of use with amenorrhea in about 20% of women Decreases menstrual pain and the risk of pelvic infection and endometrial cancer
Cost	Administering LNG-IUD 52mg instead of a Copper IUCD (most relevant comparator) will result in a R560.78 increase in cost per patient over a five-year time horizon.
Drug Interactions	LNG-IUD is an acceptable option for women living with HIV, as apart from the contraceptive benefits, there is a decreased risk for HIV transmission LNG-IUD is not a contra-indication in patients with veno-thromboembolism on chronic anticoagulants from the STG.

National Department of Health: Affordable Medicines, EDP- Primary Healthcare level. Medicine Review: Levonorgestrel-releasing intrauterine system for contraception, April 2013. https://www.knowledgehub.org.za/e-library
National Department of Health: Affordable Medicines, EDP- Primary Healthcare level. Medicine Review: Low-dose levonorgestrel-releasing intrauterine system for contraception, August 2020. https://www.knowledgehub.org.za/e-library

Levonorgestrel Intra-uterine Device (LNG-IUD) for PHC use *(PHC CH 7:Family Planning)*

NEMLC Recommendation

NEMLC recommended that **LNG-IUD 52 mg** be included in the PHC STG and EML at the reduced proposed price of R720.36 as a contraceptive option.

Low-dose LNG IUD 19 mg was recommended for inclusion to the **therapeutic interchange database** as an alternative option of a progestin-containing IUD.

NEMLC also recommended the monitoring of discontinuation rates (by Provinces) and implementation with adequate training (by the NDoH Programme).

Levonorgestrel Intra-uterine Device (LNG-IUD) for PHC use *(PHC CH 7:Family Planning)*

Addition to the STGs

7.2.2 Levonorgestrel intra-uterine system (LNG-IUD)

Z30.0/Z30.4/Z30.8

Dual protection with barrier methods is recommended to reduce the risk of STIs including HIV.

The LNG-IUD is an effective, safe, reversible long-term contraceptive method requiring no patient effort to adhere to the method, has minimal hormonal adverse effects and is not prone to drug interactions.

- Progestin-only intrauterine device, e.g.:
- Levonorgestrel, intrauterine device, 52 mg.

HIV infection is NOT a contra-indication to the use of an LNG-IUD.

The LNG-IUD is a T-shaped plastic device that steadily releases a small amount of levonorgestrel every day. It has the added benefit of reducing menstrual cramping and heavy menstrual bleeding. It can be inserted by specially trained heath care professionals, any time during the menstrual cycle once pregnancy has been excluded (by clinical history or with a pregnancy test if required). Insertion at menstruation may be easier for the patient resulting in less discomfort and spotting. For use by women of any age, regardless if they had children before.

LNG-IUD may be inserted immediately postpartum or post miscarriage (within 48 hours) providing that no contra-indications are present (chorioamnionitis, ruptured membranes for more than 18 hours or postpartum haemorrhage). A provider requires specific training in postpartum insertion by hand or using a ring forceps.

Counsel women to return if they experience complications (excessive bleeding, excessive pain, fever or foul smelling discharge).

LNG-IUD may also be inserted at 4 or more weeks postpartum.

Advise the patient when to return:

- Expulsion of LNG-IUD or if strings of the LNG-IUD protrude.
- Complications (see below).
- Routine follow-up after 3–6 weeks.

LNG-IUD is not recommended for women with acute venous thromboembolism, severe liver cirrhosis, active pelvic inflammatory disease (PID), purulent cervicitis, unexplained uterine bleeding, cervical- breast- ovarian- or endometrial cancers or other uterine abnormalities.

<u>For mild pain and discomfort after insertion:</u>

- Ibuprofen, oral, 400 mg 8 hourly with or after a meal as needed for up to 3 days.

REFERRAL

- Excessive pain or bleeding after insertion.
- Signs of infection within 7 days of insertion (e.g. fever, abdominal pain and/or foul-smelling discharge).

Abnormal bleeding for > 3 months.

Thank you