

Overview of Clinic Medical Treatments for New Incentives Beneficiaries

1. What is the ARV regimen that women receive prior to delivery? Does the regimen differ by clinic?

- **Summary:** Standard WHO Option B – Triple ARVs starting as early as 14 weeks gestation. Pregnant women who have been on ART prior to their pregnancy maintain the same regimen they have been on. Women who have been on Pre-ART (defined as Cotrim – a drug to prevent opportunistic infections) prior to their pregnancy as well as women who just found out their status are placed on a triple prophylaxis, specifically Tenofovir Lamivudine Efavirenz, irrespective of their CD4 count or WHO staging for the health of the baby.
 - Every woman receives HTC right before delivery at the point of admission. During this session, she is asked whether she has been taking her drugs. If she says no, drugs are given to her at that point. This is easy for the nurses to observe women are in the admission ward for a day or two before they deliver.
- Enrollment into ART or Pre-ART for both pregnant women and the general population is based on WHO Clinical Stages and/or CD4 count. A person on Pre-ART is one who has a high CD4 count and is in Clinical Stages 1 or 2. A person on ART is one who has a low CD4 count and is in Clinical Stages 3 or 4; such a person is placed on drugs (ARVs).
 - A person on Pre ART has a CD4 count above 500 cells/ μ L while a person with a CD4 count below 500 cells/ μ L is on ART.
 - A person on Pre ART does a routine CD4 count test every 3 months while a person who is on ART does a CD4 count test every 6 months.
 - Whether or not a woman is prescribed Cotrim depends on her Clinical Stage (not CD4 count). Women in Stage 2 are prescribed Cotrim.
- The regimen is consistent and does not vary by clinic and is standard in Nigeria.
- Treatment varies by three types of cases. These cases are determined during HTC (HIV Testing and Counseling) during the first ANC visit. The first two types of women are previously known cases; the third is a new case.
- **1) Pregnant women already on ART**
 - This group of women will continue taking the regimen they have been taking before they got pregnant.
 - There are various regimen lines (1st line, 2nd line and salvage regimen) available which depends on the woman's CD4 count, WHO staging and if the virus has developed resistant strains to a previous line of drugs.
 - Zidovudine Lamivudine Nevirapine and Tenofovir Lamivudine Efavirenz are examples of 1st line regimens.
 - Pregnancy does not change a woman's drug regimen. The only reason this would change is if the virus developed a resistant strain due to prolonged use or inconsistent treatment in the past. Ex: If a woman was on first line A and she was not consistently following treatment and starts developing resistance, the clinic would give her drug – i.e., first line B.
- **2) Pregnant women on Pre-ART (not on ARVs but potentially on Cotrim which helps prevent OIs; these are generally women whose CD4 count is high (above 500))**

- The women in this group will be enrolled into ART care and commence ARVs (Tenofovir Lamivudine Efavirenz)
- If she is not in her second trimester she will stop taking Cotrim
- **3) Pregnant women who newly learned their HIV-positive status during their first ANC Visit**
 - Same treatment as women who were on Pre-ART (Cotrim); these women are also prescribed Cotrim in their second trimester
- Every woman is prescribed Cotrimoxazole, known as Cotrim, during the second trimester. No women take Cotrim during their first or third trimesters.
 - Cotrim is not given during the first trimester because that is the stage of organ formation and taking Cotrim at this stage has been shown to cause spina bifida in the infant. By the 2nd trimester, the organs of the baby are well formed and it is safe for the mother to take Cotrim at this point. Cotrim is discontinued during the 3rd trimester because it can cause jaundice in the infant.
 - Cotrim is only given to HIV-positive women
- All types of women will be on triple prophylaxis during the pregnancy. No women take a single dose drug.

2. What ARV do women and infants receive at delivery? Do both the mother and the infant receive a single dose of Nevirapine? Does this differ by clinic?

- Infants receive a single-dose of Nevirapine oral suspension within 48 hours after delivery. They continue to receive a dose everyday for six weeks. This is irrespective of the infant feeding method.
- Women are no longer given Nevirapine during delivery. This practice was used during the inception of PMTCT; however, the triple prophylaxis that women are initiated on during pregnancy is active enough to prevent transmission during delivery. Furthermore, Nevirapine was found not to be suitable to certain women such as co-infected women, meaning women who have both TB and HIV.
 - Every woman receives HTC right before delivery at the point of admission. During this session, she is asked whether she has been taking her drugs. If she says no, drugs are given to her at that point. This is easy for the nurses to observe women are in the admission ward for a day or two before they deliver.
- A few women are on a regimen that contains Nevirapine (for example, Zidovudine Lamivudine Nevirapine). These women are all previously known cases and were not placed on that regimen specifically for their pregnancy.

3. Do infants and mothers receive follow-up drugs at the clinic, for the weeks after delivery?

- The mother is given ARVs to last her for 2 months after delivery.
- The baby is given Nevirapine suspension to last for 6 weeks. The baby is supposed to be given approximately 1.5 ml everyday, sometimes a bit more for larger babies.
- After the 6-Week Check-Up, Nevirapine is discontinued and the baby is started on Cotrim. The mother is also restarted on Cotrim at 6 weeks so from 6 weeks on the mother takes her ARVs + Cotrim.

- An exception to this is if the mother refuses to continue taking ARVs or says she has not been taking them. Then the baby will continue taking Nevirapine at higher dosages throughout the breastfeeding period.
- Photo of treatment that only applies to positive women who are breastfeeding but are not on ARVs:

EXTENDED SIMPLIFIED INFANT NVP DOSING RECOMMENDATIONS

S/NO	AGE	DOSE	Volume with respect to Nevirapine suspension 50mg/5ml
1.	Birth** to 6 weeks		
A	Birth weight – 2kg – 2.499kg	10 mg once daily	1ml
B	Birth weight - >= 2.5kg	15 mg once daily	1.5ml
2	>6 weeks to 6 months	20 mg once daily	2ml
3	>6 months to 9 months	30 mg once daily	2.5ml
4	>9 month to end of Breast feeding	40 mg once daily	4ml

HOWARD UNIVERSITY
the

- At the start of ANC, women are told they should continue taking ARVs until at least six weeks after the cessation of breastfeeding and that they can stop taking drugs if their CD4 count is high. However, every woman is advised that once they start taking ARVs they should continue because over time their immune system is less able to deal with the virus in the absence of ARVs.
 - If their CD4 count is low, they are advised to keep taking ARVs.
 - Most nurses advise the mothers to continue taking ARVs throughout their lifetime irrespective of their CD4 count.
 - Mothers are advised to practice exclusive breastfeeding or only use formula (not mixed feeding). It is believed that mixed feeding in the first six months carries a greater risk of transmission because the other liquids and foods given to the baby alongside the breastmilk can damage the already delicate and permeable gut wall of the small infant and allow the virus to be transmitted more easily. Mixed feeding also poses the same risks of contamination and diarrhea as artificial feeding, diminishing the chances of survival.
 - Most women breastfeed for at least 6 months and up to two years.
 - Working class women breastfeed for a shorter length of time because they have to return to work.

4. Are HIV+ women who enroll in the ARP program handled in the same way as PMTCT enrollees?

- From the hospital: Yes, they are both enrolled into ART and receive the full complement of PMTCT services.
- From the ARP program: Enrollment is the same, but they do receive different reminder text messages.
 - The cash transfer for the EID test was phased out to have a streamlined/scalable ARP model and avoid data collection issues.
 - We have not yet introduced the EID transfer in the ARP Program and do not plan to do so in the near future. We have a few open questions about the EID transfer in the ARP setup and would like to learn more from the RCT. To summarize the main factors that led to this decision: we are currently capacity constrained and want to focus as much effort as possible on scale-up since delivery has higher impact on mortality. This coupled with delays in processing EID test results and concerns about whether women collect these results to know if their newborn needs follow-up care have been the primary factors influencing our thinking about this.

5. For the ARP program, does New Incentives believe that the clinics are able to provide what is needed to reduce risks associated with at-risk pregnancies? Why does New Incentives believe this? [the below responses are from Mrs Okodi - PMTCT focal person at GH Ikot Ekpene and Dr. GP Udo - Resident Doctor at GH Ituk Mbang]

- **Overview of At-Risk Factors:**
 - **Age: under 20 years old**
 - **Age: over 35 years old**
 - **Anemia**
 - **Hepatitis**
 - **HIV-Positive**
 - **Preeclampsia**
 - **Protein in urine**
 - **Tuberculosis**
 - **History of postpartum hemorrhages**
 - **Previous miscarriage**
 - **Previous stillbirth**
 - **2 or more previous C-sections**
 - **Previous church delivery**
 - **Previous home delivery**
 - **Previous TBA delivery**
- **Anemia:** anemic women are given routine haematinics, Vitamin C and B and folic acid. The woman's PCV/Hb level is determined 3 to 4 times during the pregnancy. This is to

help monitor the blood level during the pregnancy. In a case where the blood build up is not significant, a blood transfusion is done.

- **Hepatitis:** If infected, a series of tests are carried out to ensure the woman's liver is not affected and she is placed on drugs. The baby is injected 24-48 hours after birth with immunoglobulin to prevent transmission of the virus from the mother; the child is vaccinated against Hepatitis 24 hours after birth. Note that the hospital does not provide this injection so the mother is informed ahead of time to make provision for purchasing the injection at a pharmacy (in most cases, a pharmacy that partners with the clinic).
- **Pre-eclampsia:** the woman is placed on magnesiumsulfat. If her gestational age is below 28 weeks the pregnancy will be aborted but if pregnancy is above 28 weeks and close to 32 weeks the baby will be delivered since at this time the baby can survive outside the uterus.
- **Protein in urine:** the woman is placed on drugs and urinalysis is conducted a minimum of 4 times before delivery.
- **Tuberculosis:** the woman receives TB drugs.
- **History of postpartum hemorrhage:** there is always a high chance of re-occurrence of postpartum hemorrhages in women who have experienced them in previous pregnancies. Such women are placed on haematinics to build up their blood level; PCV/Hb is done about 2 times during pregnancy to determine their blood level. Immediately after delivery 10 IU of Oxytocin is administered intramuscularly to the woman and in the absence of that 0.5mg Ergometrine may be administered intramuscularly. After that the uterus is massaged to enable it to contract by a process called 'rubbing-up contraction' and afterwards the placenta is delivered by a method called controlled cord traction (CCT). During this process the woman loses some blood and at this point 1 liter of IV fluid plus 40 IU of Oxytocin is administered to her intravenously to control the bleeding.
- **2 or more previous C-sections:** a woman has an approximately 25% chance of delivering via CS especially if her last delivery was before 15 months before conception. Such women are watched closely and an ultrasound scan is done more often to ensure the baby is well positioned and the size of the baby is normal.
- **History of miscarriage(s):** the most common cause of this is cervical incompetence so for women who have this history, at about 12 weeks of pregnancy cervical cycling is done for such a woman to tighten the cervixes. The woman is placed under close watch during the pregnancy especially during the last trimester she undergoes series of counselling because it is believed that this occurrence could have affected her psychologically.
- **History of stillbirth(s):** these women are closely monitored during the period of the pregnancy. They also undergo a series of counselling during which the health worker tries to identify any behavior which may pose a threat to the pregnancy. In addition, the doctor/health worker takes a closer look at her medical history to determine if she might have had a preexisting condition during her previous pregnancy such as hypertension, and if she had any of those conditions in the past, a series of test will be carried out to determine if such conditions are present in the current pregnancy, and treatment will be started immediately.

Supply Side

New Incentives conducts supply side assessments at its clinics to have a basic understanding of the clinic's ANC and delivery ward capacity. The assessments build on international protocols and inputs from a MD and are coded in the doForms survey app.

CS

New Incentives either operates at General Hospitals that are able to handle CS deliveries or at smaller clinics, mostly Primary Health Centres, that refer women to larger hospitals participating in the cash transfer program.

Fraud Protection

To prevent fraud by nurses, the less verifiable at-risk conditions are not openly shared with clinic staff. This includes age or location of previous delivery (e.g. church delivery). As New Incentives staff review the patient registers and only enroll a randomized subset of all women, the likelihood of gaming the system is lower. Moreover, New Incentives conducts Call Audits among beneficiaries which include questions on fraud by nurses.