



Point of Care HIV Viral Load at Delivery to Facilitate Infant HIV Diagnosis and Maternal ART Adherence in Uganda: a randomized trial



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Vertical Transmission Elimination in Uganda



- Coverage of pregnant women who receive ART for PMTCT – >98%
- Early infant diagnosis coverage – 66% (59%–82%)
 - <55% of HEI receive a virological test within 2 months of birth
 - 28% receive final rapid test at 18 months
- Vertical transmission rate – 2.8% (95% CI: 2.0–3.9%)
 - Seroconversion during pregnancy or breastfeeding
 - ART discontinuation post-delivery
 - Missed infant nevirapine prophylaxis

Rationale for POC VL at Delivery

- PMTCT optimization
 - Pregnant women already at clinic
 - Discharged 8–24 hours after delivery
 - POC VL results available within 90 min
 - Motivate post-partum ART continuation
- Addresses a significant gap in early infant diagnosis (EID)
 - Same day results increase EID coverage
 - Motivates ART adherence during breast feeding for HIV free baby



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Kingasa Study Rationale

- Limited data on whether POC VL testing improves viral suppression among pregnant women with HIV
- To evaluate if POC viral load testing with same day ART adherence support improves viral suppression among pregnant and post-partum women with HIV compared to standard of care (SOC) lab-based HIV VL testing



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Population and Procedures

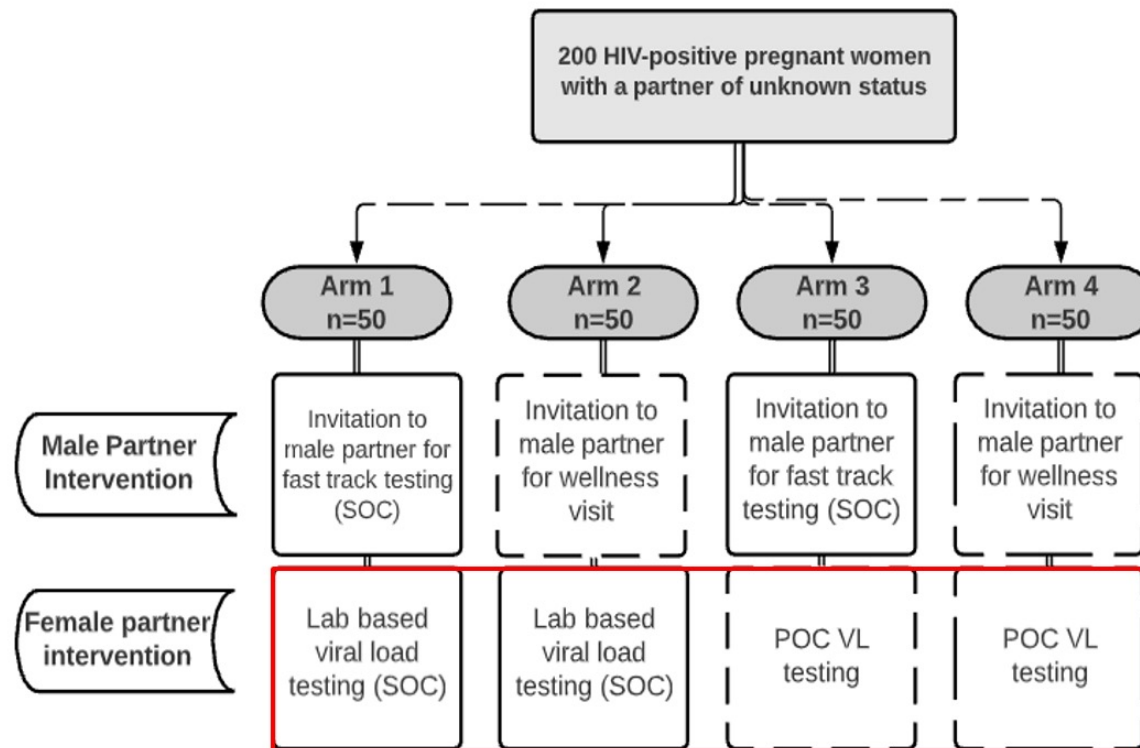
- Study duration: Feb 2021 – July 2022
- Pregnant women with HIV
 - ≥ 18 years of age
 - Male partners of unknown HIV status
 - Attending ANC at Kitebi Health Center III
 - Randomized 1:1:1:1 to four groups using a factorial design
 - Followed every 3 months until 3 months postpartum
 - Blood samples drawn by research midwives
 - Testing conducted by lab tech at clinic lab
 - All POC VL testing was performed using the Cepheid Xpert HIV-1 Viral Load test on the GeneXpert® System



Kingasa Pilot RCT Design

Factorial design evaluating two interventions to:

- 1) Increase HIV testing and engagement in care among male partners of pregnant women
- 2) Improve ART continuation and adherence among pregnant women with HIV



← Focus of this talk



Data Analysis

- Intent to treat comparison of proportion of women virally suppressed at 3-months postpartum by randomization arm: Arms 1 + 2 vs Arms 3 + 4
- Multivariate log binomial regression models with robust standard errors to estimate prevalence ratio of achieving viral suppression



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Characteristic N (%) or median (IQR)	POC VL (N=77)	SOC (N=74)	Total (N=151)
Age (years)	28 (25-32)	27 (24-31)	28 (24-32)
Education (<13 years)	68 (88%)	57 (77%)	125 (83%)
Currently married	70 (91%)	69 (93%)	139 (92%)
Partnership duration (years)	4 (2-6)	3 (1-6)	3 (2-6)
Polygamous partnership	28 (36%)	23 (31%)	51 (34%)
Partner age difference	5 (2-9)	6 (2-10)	6 (2-9)
Partner tested for HIV	20 (26%)	18 (24%)	38 (25%)
Number of prior live births			
0	12 (20%)	13 (25%)	25 (23%)
≥1	65 (80%)	61 (75%)	126 (77%)
ART use at enrollment	75 (99%)	72 (97%)	147 (98%)
Plasma viral load (<50c/ml)			
Undetectable	59 (86%)	56 (80%)	115 (83%)
Detectable	10 (13%)	13 (21%)	23 (17%)
Detectable viral load (c/ml)	5,410 (363-21,500)	116 (70-200)	225 (82-15,700)
Disclosed HIV status to partner			
Yes	35 (45%)	25 (34%)	60 (40%)
No	40 (55%)	46 (66%)	86 (60%)



Pregnancy Outcomes	POV VL	SOC
Birth outcome		
Liveborn	64 (91%)	61 (95%)
Neonatal death/stillborn/abortion	6 (9%)	3 (5%)
Type of delivery		
Vaginal	68 (92%)	55 (85%)
Caesarean section	6 (9%)	10 (15%)
Baby HIV status		
Negative	46 (68%)	42 (69%)
Not tested	22 (32%)	19 (31%)
Time from delivery to baby HIV test (days)	0 (0-4)	97 (47-105)
ART Outcomes		
On ART at postpartum visit	75 (99%)	72 (97%)
Post-partum viral suppression (<50 c/ml)	89%	82%
Post-partum viral load (median, IQR)	237 (92-664)	840 (109-23,760)
Separated with partner (postpartum visit)	4 (6%)	8 (12%)

Primary outcome

- Prevalence of viral suppression at 3 months postpartum
 - 89% vs 82% for POC VL vs. SOC
- Prevalence ratio 0.59; 95% CI: 0.17–2.02; $p=0.41$
- Women randomized to POC VL testing as likely to have undetectable viral load as women randomized to SOC



Qualitative Methods

- In-depth interviews with 30 women and men, and 15 healthcare providers
- Women receiving POC VL testing (N=22) were purposefully sampled
- Interviews conducted by trained Ugandan social scientists in Luganda using a semi-structured interview guide with open-ended questions and probes
- Interviews audio-recorded and transcribed into English
- Inductive content analysis approach to data analysis



POC VL Implementation Challenges

- 48% of mothers in the qualitative sample delivered at another health facility
 - COVID-19 restrictions presented challenges for mothers and implementing staff
- Implementers made home visits to collect blood samples for POC VL testing at delivery
 - Sample collection occurred a few days after, rather than immediately after, the birth
- Research staff called the mother for permission to conduct home visit and to fix a time
 - Mother informed a technician would travel to her home for the procedure
 - Staff contacted the lab to inform them of home visit
 - Technician called mother to introduce himself, confirm agreement, and get directions



Implementation Challenges

- Home visits for mothers who had not disclosed HIV status required creativity to maintain confidentiality

“When I got there they welcomed me, the husband gave me a seat and we started conversing. I spent almost three hours because the man had a lot of questions. ... I told him, ‘when these mothers come to us at the facility we always encourage them to come with you [partner] ... but you did not come. So allow me to explain to you why we are following [your wife]’. But I did not disclose to him that she is HIV positive. I just created my own story. I told him that we followed her home because she did not deliver from [Kitebi Clinic] ... and she was discharged without us knowing what packages were given to her and how she was faring. So that is why I am here.... Fortunately, he accepted and I took off both samples from the mother and child.” Lab Technologist



Implementation Challenges

- Disadvantages of POC VL Testing Before Birth
 - Capturing the attention of a laboring mother to draw blood and report results was challenging
 - Timing blood draws to take place early in the labor process was seen as ideal

“...it is good to start your procedures, maybe when the mother has just started labor. ...When mothers are delivering, at times they introduce an IV line. So, during that process, if the midwife knows [about the planned blood draw] maybe she can do it at that time.” Research Nurse.



Implementation Experiences

- Advantages of POC VL Testing After Birth
 - After birth, blood draws from mother and infant for POC VL testing were completed in a single interaction. However, the timing had to be precise – not too soon after delivery, to allow the mother to recuperate and visitors to come and go, but not so long after that the mother has already left for home.

“[The mothers] have been through a lot of struggling, ... and we want to do the test when the mother is fine. Some mothers have post bleeding, some are new mothers and are just learning how to breastfeed the baby. The babies are also crying. There is a lot that happens after delivering, so the mother should be given some time to rest. 30-60 minutes will be a good time to take the mother for POC VL testing.” Research Nurse



Qualitative Findings – Pregnant Women

- Category 1 – POC VL testing encouraged and improved maternal ART adherence
- Category 2 – POC VL testing helped mothers protect their babies from acquiring HIV
- Category 3 – POC VL testing improved maternal emotional wellbeing





Category 1: POC VL testing encouraged and improved maternal ART adherence

POC VL testing encouraged and improved maternal ART adherence

- POC VL testing viewed as “lifesaving” because it encouraged ART adherence (*‘I prefer same day results because I can base on the results to save my life’*).

“I decided to take ART like no man’s business, because I got scared that if I continue being careless, I may die soon. When you are told that your virus is not suppressed, you know what to do when you go back home. If you have not been adhering well to your drugs, you have to change immediately. This is not the case when you leave hospital without knowing your results. You cannot know if you are not adhering well to your drugs until when you go back to your next visit”.



POC VL testing encouraged and improved maternal ART adherence

- Viral suppression was viewed as positive reinforcement, confirming to women how well they had been taking their ART, and motivating them to continue.

“I felt good and happy because it felt like as if I had cured [myself] of HIV (she laughs). I was strong because I knew that I was adhering well to my drugs and there was no way the results would show otherwise. I did not have any fears at all. If they say that whoever has been adhering well to their drugs will be cured from HIV, I will definitely be among those ones. I take my drugs very well”.



POC VL testing encouraged and improved maternal ART adherence

- POC VL testing enabled health workers to act immediately to improve women's health.

“The viral load test is very important because it helps you to know whether you are adhering well to your drugs or not. It also helps the health workers to know if the drugs they are giving you are working well. For example, when I did my third viral load test, I was told that my virus was not suppressed, and the health worker decided to change the regimen for me. If the test was not done, the health worker would not have known that the drugs are no longer working well for me”.





Category 2: POC VL testing helped mothers protect their babies from acquiring HIV

POC VL testing helped mothers protect their babies from acquiring HIV

- POC VL results served as a reminder and catalyst for mothers to fight towards achieving viral suppression prior to delivery.

“I got to know about my high viral load results four months before delivery and I fought to suppress it. If I had taken the other one [SOC testing], I would have got results when it is one month for me to deliver so I would have delivered with a high viral load which puts the baby on high risk of getting HIV. I wouldn't have known, and I wouldn't have reacted the way I reacted. The other thing is the joy of having an HIV negative child. I was scared to miss that joy because I brought my first baby on earth when is negative and I was happy so I thought about that joy, and I said I should take ART to avoid transmitting HIV to my unborn baby”.



POC VL testing helped mothers protect their babies from acquiring HIV

- POC VL results gave women the knowledge and information necessary to make rapid decisions that could impact their babies' health.

"...learning the results on the same day is best for me because I get to know if I can infect the child or not when I am pregnant".



POC VL testing helped mothers protect their babies from acquiring HIV

- POC VL results directly influenced mothers' decision on whether they felt it was safe enough to breastfeed their babies immediately following birth.

“Once you have the results then you can decide whether to breastfeed the child or not. It was the reason why I asked to have my viral load tested immediately I gave birth. There was no way I could put my child at a risk of breastfeeding when I know my viral load is high. The chance of the baby getting HIV would be high but now I started breastfeeding when I am comfortable that my baby will not get HIV from me since my viral load was suppressed. At that time, I was thinking about protecting my baby and that is why I asked for viral load test so that I decide well”.





Category 3: POC VL testing improved maternal emotional wellbeing

POC VL testing improved maternal emotional wellbeing

- Women perceived that POC VL testing improved emotional wellbeing, by alleviating anxiety and agony [resulting] from waiting until their next clinical visit to receive viral load results.

“[I prefer receiving my results] that same day. When you go to hospital while sick, you expect to be told what is disturbing you. When you go back without knowing, it stresses you a lot and you cannot settle without knowing what is disturbing you. It is important for one to know because it helps you to know what to do next. When you are not told whether your viral load is suppressed or not, you keep wondering what the results will be whereas if you know the results, you go back home knowing whether to continue adhering well or improve adherence if you have not been adhering well to your drugs”.



POC VL testing improved maternal emotional wellbeing

- Women acknowledged that waiting for viral load results caused uncertainty, stress and frustration.

“I prefer the one where I get my results immediately because it soothes your heart. The viral load test where you have to get the results on your next visit is not good because you are always worried about the results that you will be given. You always wonder what the health workers will tell you when the viral load is not suppressed. You are always looking at the phone to see if maybe a health worker will call you and when he/she calls, you still wonder what the health worker will tell you. Living in fear is not good at all. I would rather get my results immediately than wait”.



POC VL testing improved maternal emotional wellbeing

- Women also described the detrimental toll that waiting for their results had on their health (you even get high blood pressure!) and felt that this stress would negatively impact them (*you will be worried all the time and even fail to take your pills well*). It made women feel “happy” by eliminating this stress through POC VL testing.

“[POC VL testing] makes me happy because I do not worry about that all the time...for the standard VL test, I could spend much time worried thinking: ‘I wonder what the results will be like? I wonder what the VL is?’ and yet remember that the more you worry, the more your CD4 count lowers. Yet, for the quick test when you learn your results early, it makes you happy”.



Qualitative Summary – Pregnant Women

- 1) Women overwhelmingly preferred POC VL testing over SOC VL testing
- 2) Women understood purpose of viral load testing and role of ART adherence in achieving viral suppression
- 3) Receiving viral load results motivated women to continue adhering well to ART
- 4) Women valued receiving POC VL testing during pregnancy, at delivery, and during breastfeeding, to protect their babies from HIV



Quant and Qual Data Summary

- Pilot RCT of 151 women
 - 86% had post partum viral suppression with no difference by randomization arm
 - Median detectable VL 225 c/ml
 - 48% of women had not disclosed HIV status to partner by exit
- POV VL eliminated waiting time for results, encouraged maternal ART adherence, reduced stress and provided an opportunity to immediately alter infant feeding practices.
- Operationalizing POC VL at delivery benefits from a flexible approach that respects patient preferences.



Implications for Implementation

- POC EID complements centralized lab testing
- Integration of POC EID in national diagnostic testing network
 - Hard-to-reach areas
 - Underserved populations
 - Task shifting in support of DSD
- POV VL facilitates quicker diagnosis and treatment of infants with HIV
 - Decreased morbidity and mortality



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*CE-IVD. In Vitro Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Thank You



