THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

Affordability of HBV Testing in an Antenatal Setting vs SOC: A Perspective from Uganda.

Disclosure:

This presentation is made on behalf of Cepheid.

Background:

A study was done in Uganda to describe the operational characteristics and ease of use of the assays and cost of utilizing GeneXpert® machines for hepatitis B viral load testing in comparison to the centralized conventional testing

Presently, all viral load testing for Hepatitis B done as centralized using plasma.

Presentation Outline

- Study Objectives
- Study Overview
- Comparison of Xpert® platform with Cobas Taqman
- Key Findings from Phase I and II
- Lessons & Conclusion

Specific Objectives

Phase I of the study:

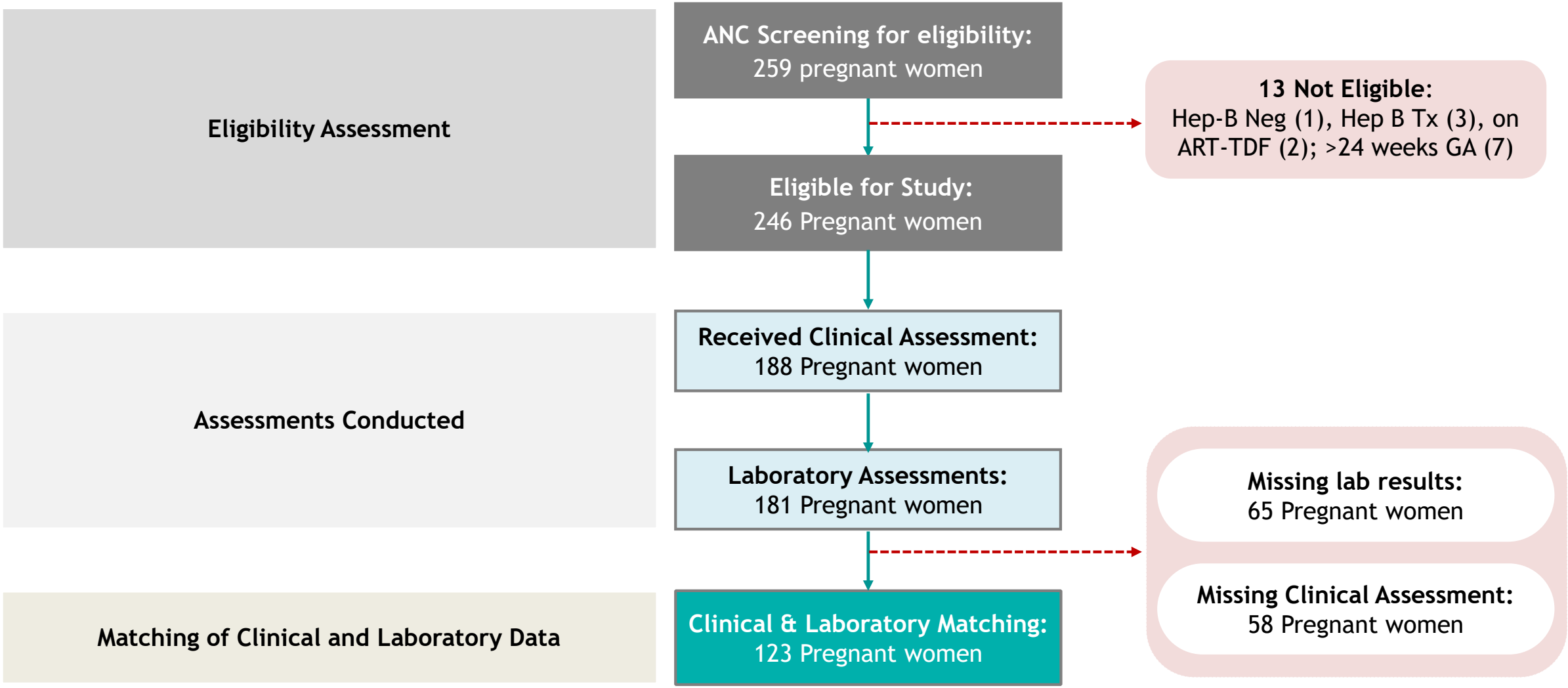
1. To verify the diagnostic accuracy of the Cepheid Xpert® Hepatitis B viral load platform with the TaqMan HBV test Roche platforms at CPHL.

Phase II of the study:

1. To describe the operational characteristics and ease of use of the assays and their suitability for Uganda among laboratory technicians at selected health facilities in Uganda.

2. Estimate the cost of utilizing GeneXpert machines for Xpert Hepatitis B viral load testing in comparison to the centralized conventional hepatitis B testing conducted by CPHL.

Phase II: Consort diagram on participants' enrolment and data management



Overview: Performance Evaluation of Xpert® HBV Viral Load as a PoC assay in Uganda

PICO Question:	**Is the Xpert® HBV PoC test as accurate and equally easy to use for diagnosing Hepatitis B in pregnant women in Uganda?**

Intervention Characteristics

- **Phase I:** Lab-based-compared Xpert and COBAS TaqMan
- **Phase 2:** Field-based- assessed operational feasibility, care linkage

Phase I: Xpert® HBV PoC performed comparably with other platforms

- **Accuracy:** Perfect agreement with COBAS TaqMan reference test
- **Sensitivity:** 100% (95% CI: 90%-100%)
- **Specificity:** 100% (95% CI: 78.2%-100%)
- **Correlation:** Strong correlation (R=0.99) Xpert® vs Cobas Taqman

Study phase II and Participant characteristics

Participant Characteristics

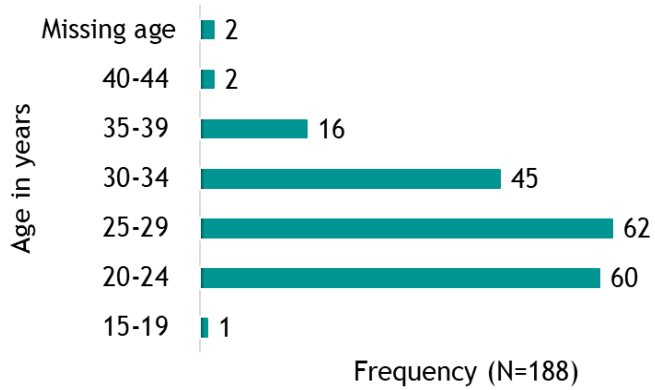
- **Phase 2:** Involved Pw at ≥24 WoA
- Only those who provided informed consent were included in the pilot study
- Pw who did not provide consent received the conventional care for HBV PMTCT

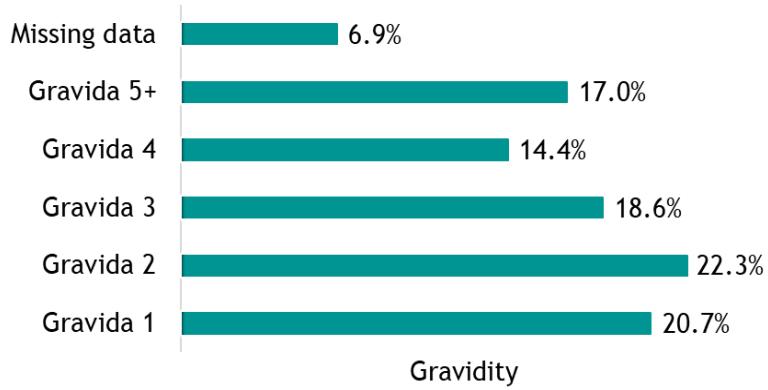
Intervention Settings

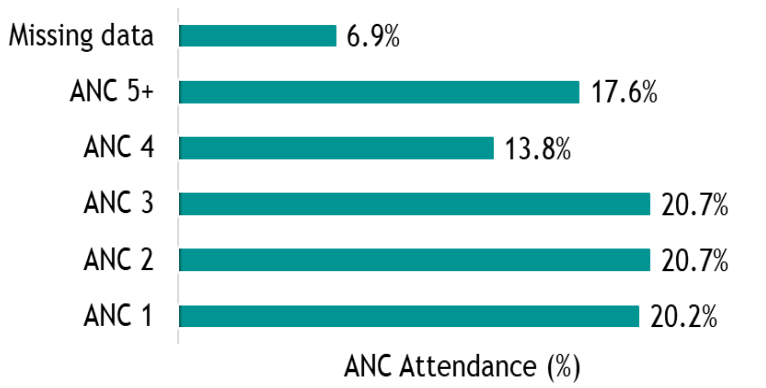
- **Phase 2:** Conducted in **10 high-volume hospitals** in Uganda
- Data collection was undertaken by trained midwives and laboratory personnel

Intervention Process

- Pw screened for HBV at ANC alongside HIV and syphilis screening
- HBsAg+ Pw blood samples sent for PoC Xpert® testing
- Pw with VL>200,000 linked for TDF prophylaxis & follow up







Phase II: Xpert® HBV PoC testing improved all aspects of turn-around-time

Duration (Days)	Turn-around Time Categories									
	Sample collection Vs sample dispatch to Lab		Sample reception Vs results dispatch from Lab		Results dispatch Vs Receipt by provider		Results receipt by provider Vs Receipt by Mother		Sample Collection Vs Results Receipt by mother	
	N	%	N	%	N	%	N	%	N	%
Same day	175	96.7	180	99	140	77	167	92	111	61
1 to 2	2	1.1		0	34	19	9	5	49	27
3 to 4	1	0.6	1	1	3	2	2	1	12	7
5 to 6	1	0.6		0	2	1	1	1	5	3
7 to 8	1	0.6		0	1	1	1	1	2	1
11 to 12	0	0.0	0	0	1	1	1	1	1	1
>14	1	0.6	0	0	0	0	0	0	1	1
Grand Total	181	100	181	100	181	100	181	100	181	100

High-Level Findings:

- **Fast Lab Processing:** **96.7%** of samples were dispatched to the lab, and **99%** of results were processed on the same day.
- **Provider Delays:** Only **77%** of providers received results immediately after dispatch
- **Patient Receipt Issues:** Only **61%** of mothers received results the same day; **27%** waited 1–2 days

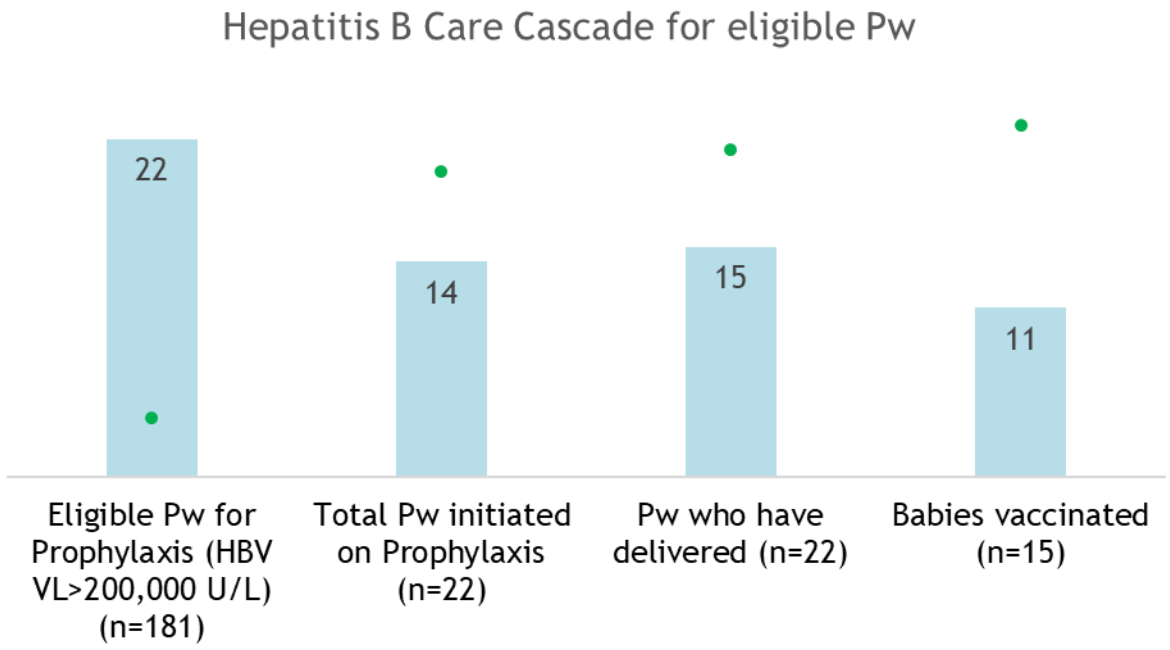
Key Bottleneck: Delays in result transmission from lab → provider → mother, affecting timely treatment

Phase II: Xpert® Costing POC Vs Conventional

Category	COBAS Platform	Unit Cost (USD)	GeneXpert Platform	Unit Cost (USD)
Main Assay Kit	KIT COBAS 5800 HBV 192T IVD	8.78	Xpert® HBV Viral Load (10 tests)	14.90
Controls	HBV/HCV/HIV-1 CONTROL CE-IVD (8 x 0.65 mL)	1.85	Built-in Internal Control	-
Negative Control	NHP NEG RMC IVD (16 x 1 mL)	0.25	Included	-
Processing Plates	COBAS OMNI PROCESSING PLATE	0.07	Not required	-
Amplification Plates	COBAS OMNI AMPLIFICATION PLATE	0.19	Not required	-
Wash Reagent	COBAS WASH Reagent IVD (4.2 L)	0.02	Included in the cartridge	-
Specimen Diluent	SPEC DIL REAGENT IVD (4 x 875 mL)	0.42	Included in the cartridge	-
Lysis Reagent	LYS REAGENT IVD (4 x 875 mL)	0.34	Included in the cartridge	-
Magnetic Particles	MGP IVD	0.05	Included in the cartridge	-
Pipette Tips	OMNI PIPETTE TIPS	0.36	Not required	-
Waste Bags	Solid Waste Bag Set of 20	0.16	Cartridge Disposal	unknown
Secondary Tubes	Secondary tubes (Box of 1000)	0.29	Basic pipette only	unknown
Total Assay-Cost		12.79		14.90
Phlebotomy Supplies	Blood Collection Tube (K2-EDTA + PPT)	0.15	Same	0.15
	Needle & Tube Holder (21G, 1.25 in)	0.27	Same	0.27
	Gloves	0.05	Same	0.05
Total Phlebotomy Cost		0.47		0.47
Sample Transportation	**Cost per sample**	**2.0**	Test done onsite	
The overall cost per test		**15.26**		**15.37**

Costing for POV and Conventional comparable: however this does not take into consideration patient costs for returning to pick results for conventional (several times) other costs such as personnel, water, waste management electricity, etc not included. **Need to take advantage of economies of scale if to be scaled up to large extent!**

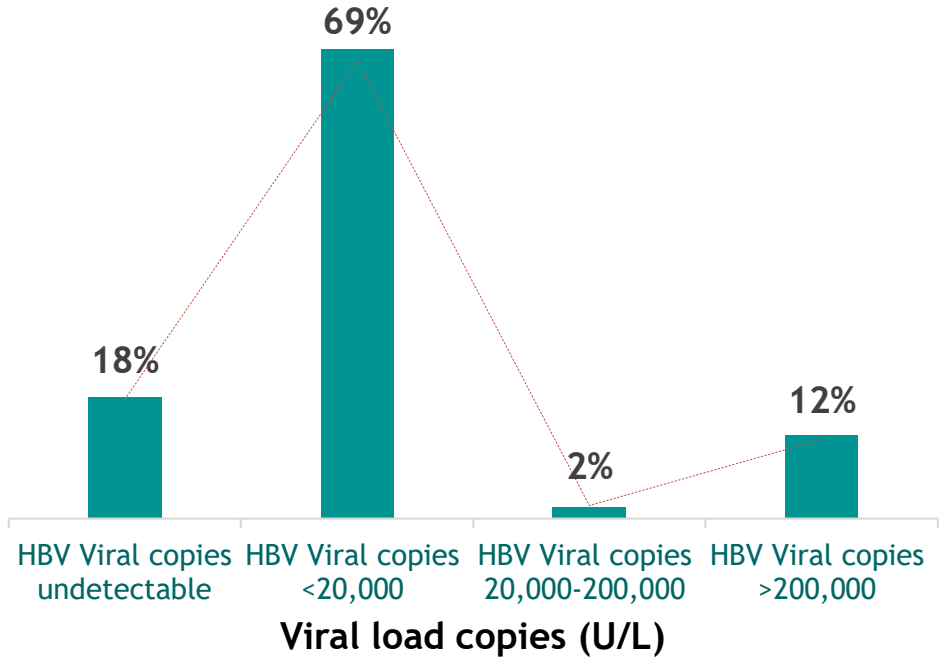
Phase II: Xpert® Linkage to Treatment



- Of the mothers provided hepatitis B (HBV) prophylaxis, 12 were still in care at the end of the study. Three were documented as lost to follow-up, and the rest had no facility records available
- One mother had HIV, syphilis and HBV, but could not be traced as had been a referral from a lower-level health facility

- *"Eligible pregnant women received the point-of-care test and the results in one to two hours." Midwife*
- *"It helped in clinical judgment... because some patients may not have clear symptoms, but the viral load could be very high." Clinician*

Majority of HBV patients had low viral load, but high-risk cases existed



Key Findings from HBV GeneXpert Testing

- **87%** of patients had **low or undetectable HBV viral loads**
- **18%** had undetectable viral copies
- **69%** had viral copies **<20,000 U/L**, considered low risk

High-Risk Cases Identified

- **2%** had viral copies between **20,000-200,000 U/L**
- **12%** had viral copies **>200,000 U/L**, indicating a high risk of mother-to-child transmission

Healthcare providers highlighted positive experiences on benefits, ease of use and feasibility of the Xpert® platform

Qualitative Approach: Principal investigators scheduled frequent virtual check-ins and held a detailed feedback session at the end of the study with healthcare providers from the 10 participating health facilities. These sessions provided valuable insights into the Xpert® platform, contributing to the qualitative components of the evaluation

Ease of Use

Most facilities found the GeneXpert platform easy to operate, requiring minimal training for healthcare workers.

Turnaround Time

Several sites highlighted that point-of-care testing significantly reduced the time to receive HBV viral load results, from months to just a few hours

Integration with other services

Some sites e.g., Jinja reported integrated the testing results into existing Hepatitis B clinics, allowing seamless linkage between testing, counseling, and treatment initiation in a single visit

However, facilities noted the need to balance testing HBV viral load with TB, HIV, and COVID-19 on the GeneXpert platform

Patient Satisfaction

The faster results reduced unnecessary follow-up visits, transportation costs and inconvenience for mothers, ultimately improving their experience

Model provider responses on Xpert® platform: Positive Experiences

Xpert® was found to be easy to use for HBV viral load measurement: *The machine is very easy to use when we're running those tests, and most of the time we are within the turnaround time. The main challenge we have is interpreting the results, especially when they come in log values or when we get error messages. We could benefit from additional training on this.*

Xpert® reduced turnaround time: *Before it was really challenging, in that, when you took off the samples of the patients and you were forced to tell the patient the results would be back maybe by two or three months, and still a patient may return and may not see the results. But with the point-of-care test, we now receive results within one to two hours, and if there is a delay, then a maximum of three hours.*

Xpert® was easy to integrate with other services:
"We have an integrated clinic which manages both hepatitis B and HIV…So, when point-of-care testing was introduced, it became easier to streamline HBV care within our existing system, ensuring that mothers who tested positive were immediately assessed and linked to treatment without delays".

"We had to balance the use of the GeneXpert platform for TB, HIV, and now HBV. In some instances, when the machine was fully loaded with TB and HIV samples, we had to wait for an available slot to run HBV tests"

Xpert® was linked to increased provider and patient satisfaction: *Mothers appreciated getting their results the same day. They no longer had to wait for months or make multiple visits just to get their viral load results. This has made them more willing to engage with care and follow through with the treatment plan.*

Challenges in Implementing HBV Point-of-Care Testing

Category	Key Challenge	Verbatim Response
Operational	Cartridge Issues	*At first, the machine rejected the cartridge, and we had to call Cepheid. I sent the serial number of the GeneXpert, and they were able to rectify that configuration online*
	System Configuration	*When you scan it doesn't work, but when you enter the code manually, it could allow. We found a way around it, but it slowed down our testing process*
	Commodity Stockouts	*We had stockouts of hepatitis B test kits, which meant that for some time, we couldn't conduct any tests. This delayed our ability to assess patients*
Data Management	Result Interpretation Challenges	*The machine is very easy to use when running those tests, but the challenge is interpreting the results, especially when they come in log values. We also get errors that we don't fully understand*
Workforce & Prioritization	Workforce Limitations	*The workload in the lab is high, and at times, there is no one to notify clinicians that results are ready. This delays patient care*

Conclusions: Xpert® HBV PoC enhances linkage to care but barriers need to be addressed for a national scale-up

+ MCH Team Dynamics

- Positive attitudes among ANC teams enabled the successful integration of services, linking HBV-positive women to care
- High levels of motivation and cooperation among teams were key to effective service delivery

Costing Saving

- Costs of conventional and POC are comparable
- This when taken in context of mothers being linked to care and treatment immediately and avoidance of having to return for results means POC is ultimately more cost effective
- Planned roll out will need to take advantage of economies of scale if many other countries roll out

ANC Services Integration+

- Integration of hepatitis clinics within maternal care points facilitated comprehensive care for Pw
- Sites with co-location of hepatitis services with ANC /MCH service points me client needs more effectively

Follow up and Community engagement

- Community outreach initiatives need to be integrated HBV and syphilis testing, to ensure all mothers were reached and linked to care
- Utilizing all health fora to access mothers significantly expanded the reach of services
- Targeted retesting of pregnant women at 24 weeks, beyond initial ANC1 screening, identified previously missed cases
- Dedicated follow-up efforts ensured that clients were linked to care and supported through the continuum of services

Thank you for listening

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