



Protektem Pikinini Blong Yu trial to prevent mother-to-child transmission of hepatitis B in Vanuatu

A collaborative research initiative
between the Burnet Institute,
Vanuatu Ministry of Health and the
Doherty Institute





Investigator list

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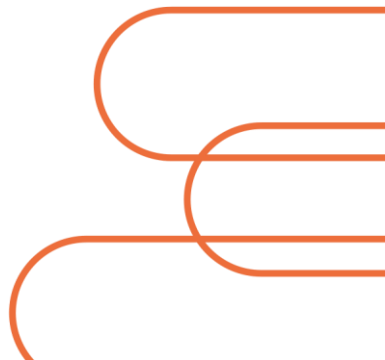
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Background

HEPATITIS B IS ENDEMIC IN MANY PACIFIC ISLAND COUNTRIES

- Most Pacific Island Countries have a high prevalence of hepatitis B
- The prevalence of hepatitis B in Vanuatu is estimated to be ~5% among children and ~9% among adults
- Mother-to-child transmission accounts for around half of new infections globally
- Mother-to-child transmission is associated with worse outcomes including higher likelihood of progression to liver disease and cancer





ANTIVIRAL PROPHYLAXIS TO PREVENT MOTHER-TO-CHILD TRANSMISSION

- WHO recommendations for the use of antiviral prophylaxis in pregnancy to prevent mother-to-child transmission were updated in 2024
- In settings where HBV DNA or HBeAg testing is available, high DNA-driven care is recommended
- In settings where HBV DNA or HBeAg testing is not available, treating all pregnant women with hepatitis B recommended
- This recommendation is conditional, based on low-certainty evidence

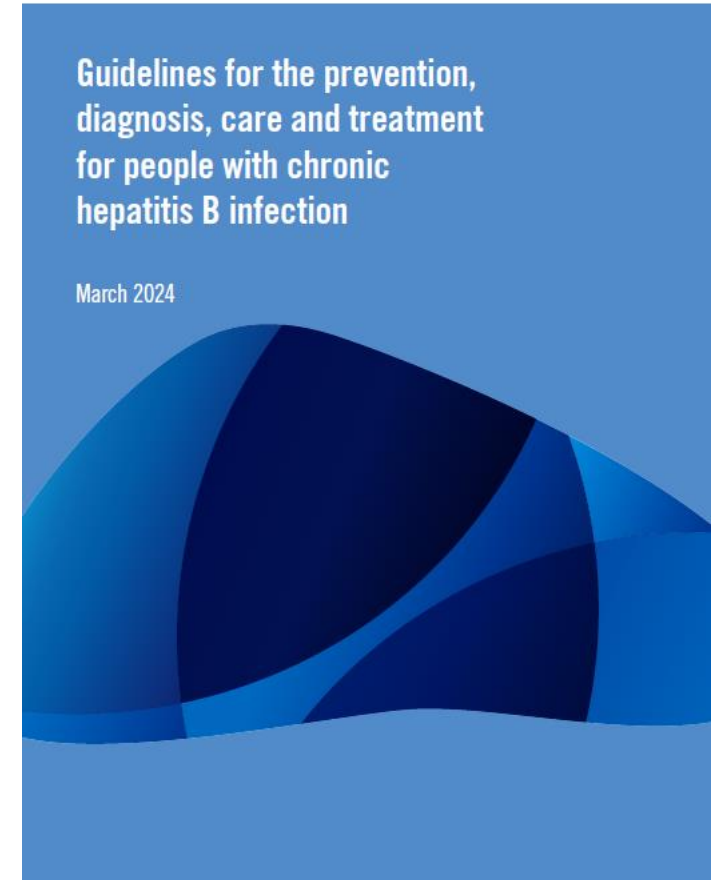
“In settings where HBV DNA or HBeAg testing is available, prophylaxis with tenofovir disoproxil fumarate (TDF) is recommended for all HBV-positive (HBsAg-positive) pregnant women with HBV DNA >200 000 IU/mL or positive HBeAg (preferably from the second trimester of pregnancy until at least delivery or completion of the infant HBV vaccination)”

“Based on a pragmatic approach that weighed up 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”



Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection

March 2024



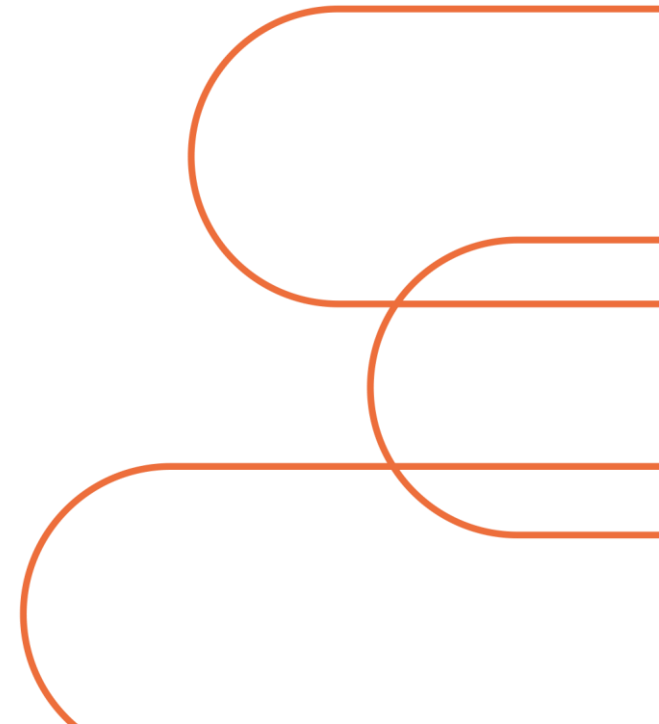


Rationale for the treat-all approach in Vanuatu

RESEARCH GAP

Treating all hepatitis B-infected pregnant women with antiviral prophylaxis to prevent mother-to-child transmission may be a possible alternative in Vanuatu and other Pacific Island Countries to high DNA-driven care, however, the effectiveness of the approach has not been demonstrated.

This field trial will provide evidence to strengthen the updated 2024 WHO prophylaxis recommendations.





Aim and study design

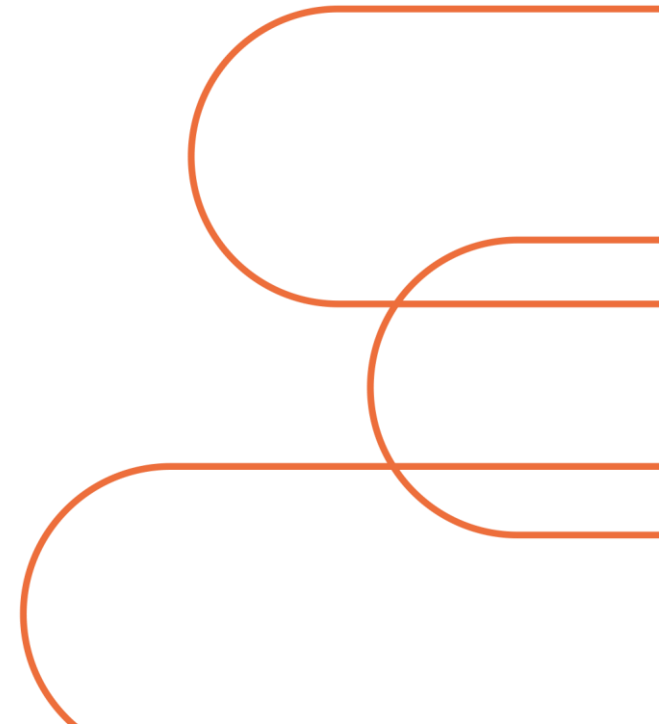
AIMS

The overall goal is to improve maternal and child health in Pacific Island Countries through expanded use of antiviral prophylaxis to prevent mother-to-child transmission of hepatitis B

The primary aim of this study is to evaluate whether a treat-all approach to managing hepatitis B-positive mothers leads to a reduction in hepatitis B-positive infants.

STUDY DESIGN

This study is a prospective, single-arm field trial, assessing the effectiveness of treating all hepatitis B-positive pregnant women compared to a real-world external control group.





Project location and scope

LOCATION

Intervention sites

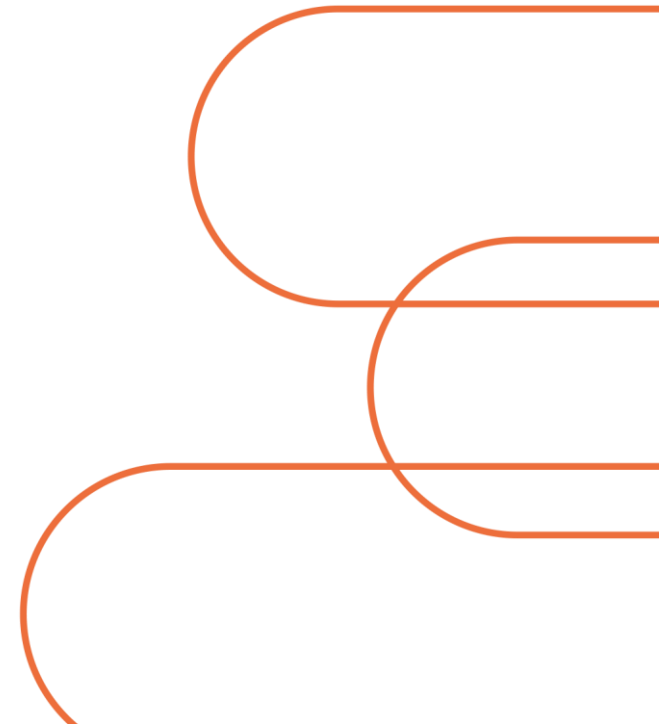
- Shefa Province

Control sites:

- Sanma province
- Malampa province

TIMELINE

- Recruitment 2024 - current
- Follow up of infants 6 months after birth



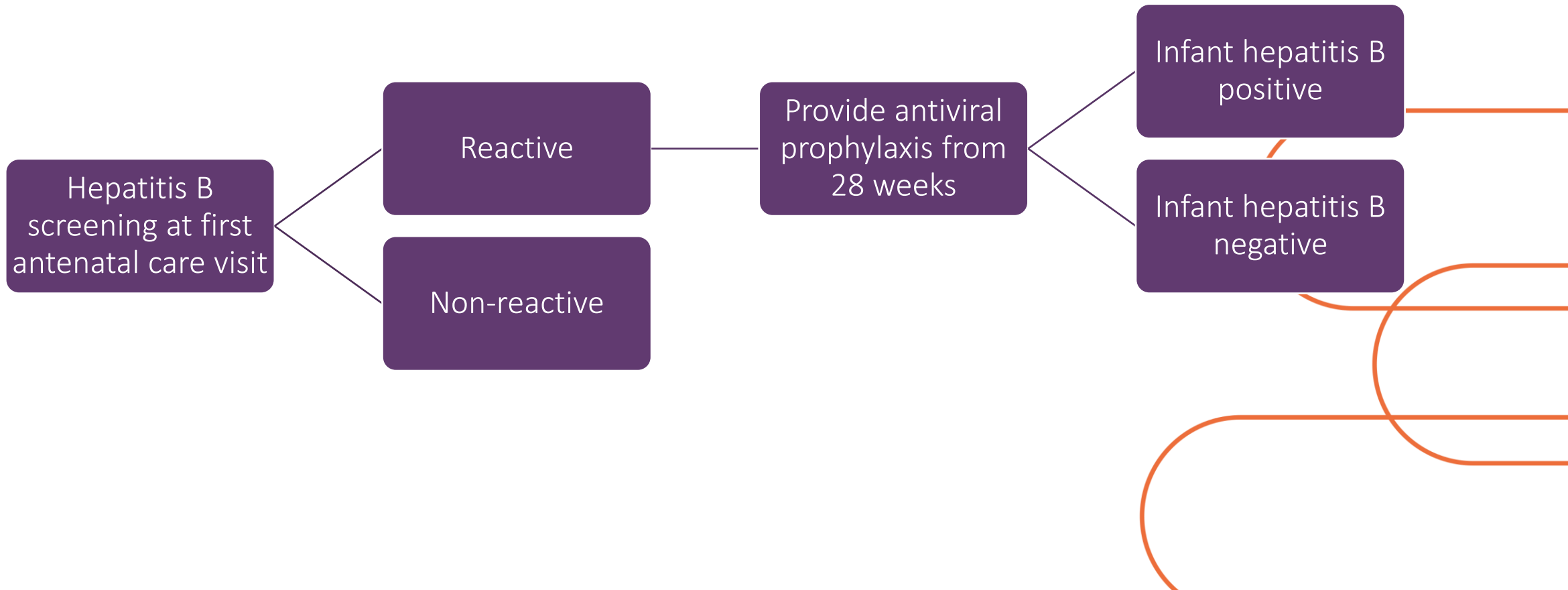


Participant eligibility and recruitment

- Eligibility criteria:
 - The eligible population is pregnant women diagnosed with hepatitis B in their first antenatal care appointment
 - Pregnant women who present for their first ANC appointment in third trimester or who have not had a negative HIV test are ineligible
- Recruitment:
 - A research nurse and research laboratory officer are located at main recruitment sites
 - Research team reviews records in other sites and refers eligible women
 - The research nurse will discuss the project with the pregnant women and go through the detailed Participant Information and Consent Form and video
 - All participants from the same clinic will be recruited to the same treatment arm (intervention or control)

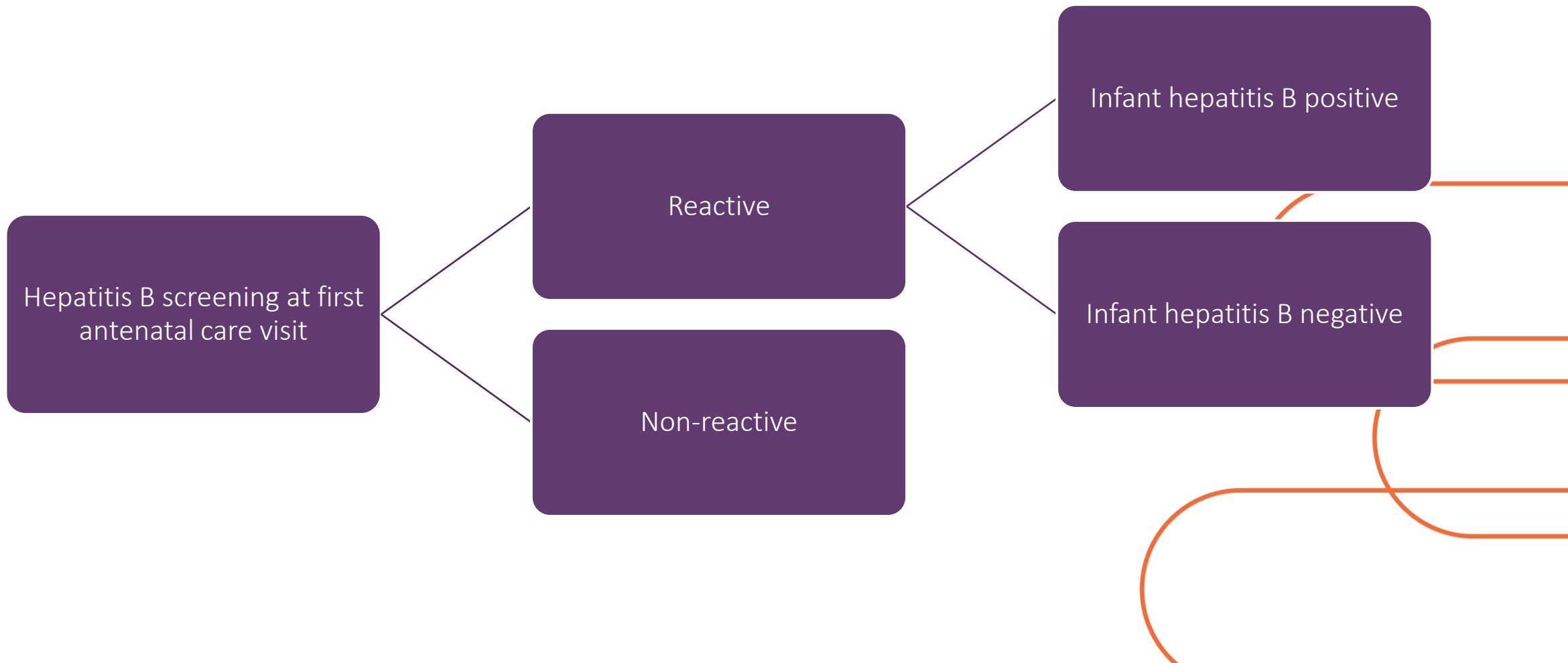


Intervention group: Treat-all hepatitis B-infected pregnant women






















Control group: Standard care





Data collection timepoints

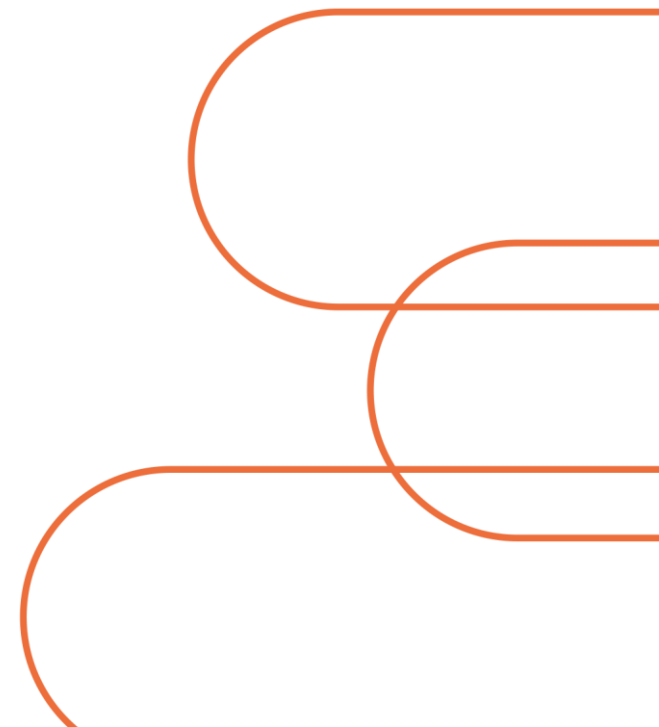
	Pregnancy			Infancy					
	Weeks 0-12	Weeks 12-28	Weeks 28-delivery	<24 hours	6 weeks	10 weeks	14 weeks	6 months	12 months
HBsAg test	 								
If positive: 									
Recruitment and consent	 								
HBV viral load test	 								
Tenofovir prophylaxis			 						
Monitoring			 						
Hepatitis B vaccination				 					
Recruitment and consent					 				
HBsAg test								 	



Dosing schedule

INTERVENTION ARM

- TDF (antiviral prophylaxis)
- One 300mg tablet, once per day
- From as early as possible in second trimester until completion of hepatitis B vaccination series (~40 weeks maximum)
- Monthly dosing by research team, plus weekly compliance and monitoring checks





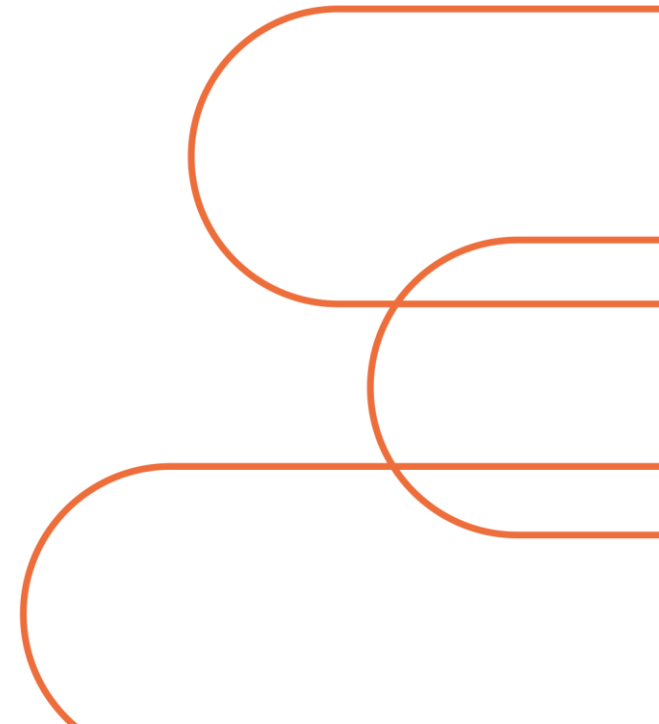
Ethical review and trial registration

CONSENT PROCESS

- All participants will be provided with information about the study and what participation involves before they decide whether to consent or not
- Written and verbal information will be provided in Bislama, or English or French if preferred
- Written consent from the mother will be required
- After birth, we will request consent to include the infant also
- Participants can withdraw at any time

AUSTRALIA

- Application has received approval from the Vanuatu MOH Ethics Committee and the Alfred Hospital Human Research Ethics Committee, which is registered and certified with the Australian National Health and Medical Research Council
- Trial has been registered with the Australian New Zealand Clinical Trials Registry



Recruitment to date: Eligibility and participation rates

- As of 22 July 2025: 56 participants
- 46 intervention arm
- 10 in control arm

- 12 ineligible:
 - Late presentations (3rd trimester)
 - HIV test refusal
 - HIV test not offered

Title	Antenatal HIV, syphilis and hepatitis B screening and positivity in selected sites in Vanuatu, 2024
Paper Status	Abstract Accepted - 15-Minute Oral Presentation
Session Details	Concurrent Session 3B: Abstract Session - Closing the Gap: Perinatal Care as a Pillar of Viral Hepatitis Elimination Thursday, Aug 7, 2025 14:30 - 15:30 Ballroom 2
Presentation Time	14:35 - 14:50

And

Title	Understanding perceptions on feasibility of midwife-delivered care for hepatitis B during pregnancy in Vanuatu: Interviews with stakeholders
Paper Status	Abstract Upgraded - Plenary Oral
Session Details	Plenary Session 3: Innovating Ethically – Ethical Considerations in Finding the ‘Missing Thousands’ and Sustainable Hepatitis C elimination Friday, Aug 8, 2025 09:30 - 11:00 Ballroom 2&3
Presentation Time	10:45 - 11:00



Next steps

- Investigate reasons for ineligibility
 - HIV refresher training for nurses
 - Barriers to testing among pregnant women
- Expansion to another control sites
- Recruitment is expected to be complete by mid-2025 and infant follow-up complete by end of 2025
- Final results expected early 2026



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