Surveillance, Recruitment, Pre-Screening, Screening, and Enrollment Process

<table>
<tr><td></td><td colspan="4">STEP 1: RECRUITMENT</td></tr>
<tr><td>Pregnancy Surveillance</td><td colspan="4">Conduct routine surveillance via health and demographic surveillance systems (HDSS) or facility-based pregnancy surveillance to identify women of reproductive age (WRA).</td></tr>
<tr><td rowspan="4">MNH00: Pre-Screening Form</td><td colspan="4">STEP 2: PRE-SCREENING
For all women in pregnancy surveillance complete MNH01 to pre-screened PRiSMA MNH study based on the following criteria:
(1) clinical signs of pregnancy, (2) estimated gestational age <25 weeks, (3) required age per local standard, and (4) lives in the catchment area with no plans to relocate.</td></tr>
<tr><td colspan="2">If they meet all 4 presceening criteria
Continue on to consent process
⇩</td><td>If they are pregnant, but do not meet other prescreening criteria. they are not eligible for the PRISMA MNH studyongoing surveillance. Do not screen again until after pregnancy end.
⊗</td><td>If they do not have clinical signs of pregnancy, they are not eligible for the PRISMA MNH studyongoing surveillance. Return in 2-4 months to continue pregnancy surveillance.
⊗</td></tr>
<tr><td colspan="2">STEP 3: PRISMA MNH CONSENT
Complete Informed Consent for PRISMA MNH Study</td><td colspan="2" rowspan="2"></td></tr>
<tr><td>Participant consents
⇩</td><td>Participant does not consent
⊗</td></tr>
<tr><td>MNH01: Ultrasound Exam Form</td><td colspan="2">STEP 4: ULTRASOUND
Complete ultrasound for pregnancy confirmation and gestational age dating.</td><td colspan="2" rowspan="2"></td></tr>
<tr><td>MNH02: Enrollment Form</td><td>Women with verified gestation <20 weeks will confirm eligibility and be invited to enroll in PRiSMA MNH.
✓</td><td>Women with verified gestation >=20 weeks are not eligible for PRISMA MNH Study.
⊗</td></tr>
<tr><td>Complete Enrollment ANC Visit</td><td colspan="4">MNH03: Social and Demographic Information
MNH04: Clinical status
MNH05: Anthropometrcis
MNH06: Point-of-care diagnostics
MNH07: Speciment collection</td></tr>
</table>

Table 1: Target windows for antenatal and postnatal care visits

Period	Visit	Accepted Visit Windows	
		On Time	Late
Antenatal care	Enrollment	<20 weeks	Ineligible if ≥20 weeks. If enrolled ≤17 weeks, schedule a separate ANC-20 visit. If enrolled ≥18 weeks, combine the visit with ANC-20.
	ANC-20	18 to 22 weeks	23 to 25 weeks
	ANC-28	26 to 30 weeks	None (skip visit if missed on-time window)
	ANC-32	31 to 33 weeks	34 weeks to delivery (overlapping with ANC-36 visit because ultrasound and labs are required for this visit)
	ANC-36	34 to 38 weeks	38 weeks to delivery
Delivery	IPC	Delivery to 72 hours	Can be collected at the first PNC visit if on-time visit window missed.
Postnatal care	PNC-0	3 to 5 days	None (skip visit if missed on-time window)
	PNC-1	7 to 14 days	None (skip visit if missed on-time window)
	PNC-4	28 to 35 days	None (skip visit if missed on-time window)

	PNC-6	**6 to 7 weeks**	**8 to 12 weeks (skip visit if missed late window)**
	PNC-26	**26 to 28 weeks**	**29 to 39 weeks (skip visit if missed late window)**
	PNC-52	**52 to 54 weeks**	**55 to 64 weeks (or until confirmed lost to follow up)**

Table 2. Schedule of study visits and CRF use

Data Captured		Study Visits												
		[Home (H), Facility (F)]												
		[X (required), O (optional), * (as indicated)]												
		ANC					IPC	PNC						
		<20 wk	20 wk	28 wk	32 wk	36 wk	Birth	72 hr	1 wk	4 wk	6 wk	6 mos	1 yr	Ad Hoc
		F	F	F	F	F	H/F	H/F	H	H/F	F	H/F	H/F	F
Entry	00: Pre-screening (H)	X												
	01: Ultrasound (F)	X	O	O	X	O								
	02: Enrollment Status (F)	X												
Mother	03: Sociodemographic (H)	X												
	04: ANC Clinical Status(F)	X	X	X	X	X								
	05: Anthropometrics (F)	X	X	X	X	X	X				X	X	X	
	06: POC Diagnostics (F)	X	X	X	X	X	O	X	X	X	X	X	X	
	MHF: Medical History (F)	X	O	X	X	O				X				
	07: Specimen Collection(F)	X	O	X	X	X	O				X	X		
	Lab request form (F)	X	O	X	X	X	O				X	X		
	08: Lab Results (Office)	X	O	X	X	X					X	X		
	25: Depression (H)		X		X						X			
	12: PNC Clinical Status							X	X	X	X	X	X	
Birth	09: L&D Outcome						X							
	10: Maternal Post-delivery Outcome						X							
	11: Newborn Birth Outcome						X							
Infant	13: Clinical Status							X	X	X	X	X	X	
	14: POC Diagnostics							X	X	X	X	X	X	

	DATA CAPTURED	ANC					IPC	PNC						
		<20 wk	20 wk	28 wk	32 wk	36 wk	Birth	72 hr	1 wk	4 wk	6 wk	6 mos	1 yr	Ad Hoc
		F	F	F	F	F	H/F	H/F	H	H/F	F	H/F	H/F	F
	15: Vaccination							X	X	X	X	X	X	
Services	16: ANC Exit Interview					O								
	17: IPC Exit Interview						O							
	18: PNC Exit Interview												O	
Other	19: Mat Hospitalization													X
	20: Infant Hospitalization													X
	21: Adverse Events													X
	22: Protocol Deviation													X
	23: Maternal Close-out												X	
	24: Infant Close-out												X	
	Verbal Autopsy													X

Procedures in Event of Fetal Loss Identified During ANC Period

If any fetal loss (spontaneous or induced abortion, stillbirth) is identified during the ANC period, it should be recorded on CRF MNH04 (ANC Clinical Status Form). The following forms should be completed at the time the pregnancy outcome is identified: CRFs MNH09 (Maternal Labor and Delivery Outcome), MNH10 (Maternal Post Delivery Outcome), and MNH11 (Newborn Birth Outcome).

The woman should then be followed using CRF MNH12 (Maternal PNC Clinical Status) for 42 days (PNC-0 through PNC-6) in the event of an abortion (pregnancy end <20 weeks gestation) and for one year (PNC-0 through PNC-52) in the event of a stillbirth.

Table3. Schedule of study maternal laboratory and clinical assessments at ANC visits

Category	Assessment	Timing				
		Enrollment	ANC-20	ANC-28	ANC-32	ANC-36
Clinical status	Ultrasound exam	X			X	
	Maternal height	X				
	Maternal weight	X	X	X	X	X
	Mid-upper-arm circumference (MUAC)	X	X	X	X	X
	Blood pressure	X	X	X	X	X
	Fetal heart rate (ultrasound)	X			X	
	Fetal heart rate (fetoscope or doppler)		X	X		X
Micronutrients	Vitamin B12 (Holotranscobalamin)	X			X	
	Vitamin B12 (Total cobalamin / serum B12)	X			X	
	Folate	X			X	
	Vitamin A (retinol binding protein)	X			X	
	Iodine (thyroglobulin)	X			X	

	Ferritin (+ CRP, AGP)	**X**			**X**	
Inflammation	C-reactive protein (CRP)	**X**			**X**	
	Alpha 1-acid glycoprotein (AGP)	**X**			**X**	
Communicable diseases	HIV (**Repeat test at ANC-36 if clinically indicated or locally recommended)*	**X**				*
	Tuberculosis (**GeneXpert test only if screened positive for symptoms on W4SS. Repeat test at ANC-36 if clinically indicated or locally recommended).*	*				*
	Malaria RDT (**Repeat test at ANC-36 if clinically indicated or locally recommended)*	**X**				*
	Syphilis (**Repeat test at ANC-36 if clinically indicated or locally recommended)*	**X**				*
	Hepatitis B	**X**				
	Hepatitis C	**X**				
Non-communicable diseases	Full blood count	**X**				
	Hemoglobin assessment[1]	**X**	**X**	**X**	**X**	**X**
	Liver function test[2]	**X**			**X**	
	Kidney (renal) test[3]	**X**			**X**	
	Blood group / Rh factor	**X**				
	Urinalysis (dipstick)[4]	**X**	**X**	**X**	**X**	**X**
	Blood glucose (2 hour 75g oral glucose-tolerance test recommended per WHO guidance)			**X**		
	Hemoglobin A1c	**X**				

	Thyroid function test (TSH, Free T4, Free T3)	**X**			**X**	

Table 4: Schedule of study neonatal/infant laboratory and clinical assessments at PNC visits

Category	**Assessment**	**Timing**					
		PNC-0	**PNC-1 1 week**	**PNC-4 4 weeks**	**PNC-6 6 weeks**	**PNC-26 6 months**	**PNC-52 1 year**
Clinical status	Anthropometry	**X**	**X**	**X**	**X**	**X**	**X**
Point-of-care	Hemoglobin				**X**	**X**	**X**
	Bilirubin	**X**	**X**				
	Malaria					**X**	**X**
Tests only as indicated	HIV *(*in the case of maternal infection)*				*	*	*
	Lactate *(*in the case of suspected birth asphyxia)*	*					
	Hepatitis B *(*in the case of maternal infection)*						*

Table 6: Schedule of study maternal laboratory and clinical assessments at PNC visits

Category	Assessment	Timing					
		PNC-0	PNC-1	PNC-4	PNC-6	PNC-26	PNC-52
Clinical status	Maternal weight				X	X	X
	Mid-upper-arm circumference (MUAC)				X	X	X
	Blood pressure	X	X	X	X	X	X
Micronutrients	Vitamin B12 (Holotranscobalamin)				X		
	Vitamin B12 (Total cobalamin / serum B12)				X		
	Vitamin A (retinol binding protein)				X		
	Folate				X		
	Iodine (thyroglobulin)				X		
	Ferritin (+ CRP, AGP)				X		
Inflammation	C-reactive protein (CRP)				X		
	Alpha 1-acid glycoprotein (AGP)				X		

Non-communicable diseases	Hemoglobin assessment[1]	**X**	**X**	**X**	**X**	**X**	**X**
	Urinalysis (dipstick)				**X**		