TRAINING MANUAL

Every Newborn- Birth Indicator Research Tracking in Hospitals (EN-BIRTH) Study

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MODULE 1: INTRODUCTION

1.1 TRAINING SYLLABUS FOR DATA COLLECTORS

Course Description

This data collector training is designed to prepare health professionals or clinical trainers to act as clinical observers, that is, to participate in clinical observation of client-provider interactions. It

includes practice observing in a clinical simulation and practice with clients in a clinical setting (such as the labour and delivery ward or postnatal ward).

Objectives

Primary Objective

To be able to competently conduct facility-based observations and data collection using the study tools (both in simulation and in a clinical setting).

Specifics Objectives

The training will address the following key steps to becoming a competent data collector:

- 1. Understand the purpose, objectives, plans for this study and the value of your role of data
- 2. Recognise the value of reliable and high-quality data.
- 3. Review of data collection tools.
- 4. Learn how to complete the data collection tools completely and accurately
- 5. Gain skills in performing clinical observations/ maternal interviews/ data extraction or verification
- 6. Obtain competency by practising data collection and clinical observation skills.

Data Quality Management

- Explain the importance of objective, standardised observation of clinical service delivery.
- Describe informed consent and why it is important.
- Describe how competency in observation is determined.
- Describe how criteria are used to determine skills performance.
- Describe the process used to develop adequate inter-rater reliability

Learning Methods

- Small group work and discussions
- Presentations
- Demonstrations and observation
- Observation practice in simulation with anatomic models, role plays, and videos or • Self-evaluation performances using perfect and flawed • simulations.

Learning Materials

- Handouts
- Thumbnails
- Videos / performances / role play
- Observer checklists
- Quizzes
- **Knowledge Assessments**

Assessment Criteria & Success Measurement

Ability to demonstrate the clinical observation steps and use of data collection tools

• Course participant demonstrates the steps included in the clinical study tools or observer checklists during observation experiences to at least 80% (preferably higher) when evaluated for inter-rater reliability.

Participants knowledge of the study, observation methods, and related concepts

• Course participant pass the Final Knowledge Assessment with score of 80% or higher.

Week One: Classroom based Course Timetable- generic

Day 1		Corresponding Module & Chapter
09:00-09:45	Presentation:	1.1
45 mins	Overview of Training Syllabus for Data Collectors	1.1
09:45-10:15	Activity A:	
30 mins	Pre-training knowledge quiz	
10:15- 10:45	Presentation:	1.2
30 mins	Introduction to the study	1.2
11:00-11:30	Break	
30 mins	Dicak	
11:30- 12:15	Presentation:	1.3
45 mins	Overview and Structure of Data Collection team	1.5
12:15-13:00	Activity B:	
45 mins	The Data collection team	1.3
45 IIIII13	(30 mins group work + 15 shared discussion)	
13:00- 13:45 45 mins	Lunch	
13:45- 14:00	Presentation:	1.4
45 mins	Why are High Quality Data Important?	1.4
14:00- 15:00	Presentation:	1.5
60 mins	Introduction to the tablets	1.5
15:30-16:00	15:30-16:00 Parel	
30 mins	Break	
16:00- 17:30	Presentation:	1.6
90 mins	Introduction to the data collection application	1.0
Day 2		
09:00- 10:30	Activity C:	1.5 & 1.6
90 mins	Initial practise using the app	1.5 & 1.0
10:30-11:00	Break	
30 mins	break	
11:00- 11:45	Presentation:	1.7
45 mins	Informed Consent for Participants	1.7
11:45-12:30	Activity D:	1.7
45 min	Role play gaining informed consent	1.7
12:30- 13:15	Lunch	
45 mins	Luncii	
12:15 14:00	Presentation:	
13:15- 14:00 45 mins	Procedure for life threatening events where local staff do not	1.8
45 1111115	provide and appropriate response	
14:00- 15:00	Activity E:	
60 mins	SOP Life threatening events	1.8
OU IIIIIIS	30 mins Group work & 30 mins discussion	
15:00-15:30 30 mins	Break	
15:30-16:30	Presentation:	2.1

60 mins	The Role of a Tracking Officer	
16.20 17.20	Activity F:	
16:30- 17:30	Related to role of the Tracking officer	
60 mins	(45 mins + 15min discussion to summarise key points)	
Day 3		
09:00- 09:45	Activity G:	
45 mins	Related to role of the Tracking officer	2.2
	(45 mins + 15min discussion to summarise key points)	
10:00- 11:00	Activity H:	2.2
60 mins	Related to role of the Tracking officer	2.3
44.44.20	(please continue after the coffee break)	
11-11:30 30 mins	Break	
30 1111113	Activity H cont:	
10:00- 11:00	Related to role of the Tracking officer	2.4
60 mins	(45 mins + 15min discussion to summarise key points)	2.4
12:45- 13:30		
45 mins	Lunch	
12:20 14:20	Presentation:	
13:30- 14:30 60 mins	Labour and delivery ward observation: Logistics of data collection	3.1 & 3.2
60 mins	and what to collect	
14:30- 15:15	Activity I:	
45 mins	Review of observation checklist and discussion on key clinical issues	3.2
	(30 mins + 15min discussion to summarise key points)	
15:15-15:45	Break	
30 mins		
15:45- 17:00	Presentation:	3.3
75 mins	Content and flow of L & D app (including essential variables)	
1247.4		
Day 4	Activity I:	
09:00- 11:00	Activity J: Practise inputting observation data using L & D ann	3
09:00- 11:00 120 mins	Practise inputting observation data using L & D app	3
09:00- 11:00 120 mins 11-11:30		3
09:00- 11:00 120 mins 11-11:30 30 mins	Practise inputting observation data using L & D app	
09:00- 11:00 120 mins 11-11:30	Practise inputting observation data using L & D app Break	4.1 & 4.2
09:00- 11:00 120 mins 11-11:30 30 mins 11:30- 12:15 45 mins	Practise inputting observation data using L & D app Break Presentation:	
09:00- 11:00 120 mins 11-11:30 30 mins 11:30- 12:15 45 mins 12:15- 13:00	Practise inputting observation data using L & D app Break Presentation: KMC observation: Logistics of data collection and what to collect	
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09:00- 11:00 120 mins 11-11:30 30 mins 11:30- 12:15 45 mins 12:15- 13:00	Practise inputting observation data using L & D app Break Presentation: KMC observation: Logistics of data collection and what to collect Activity K: Review of observation checklist and discussion on key clinical issues (30 mins + 15min discussion to summarise key points)	4.1 & 4.2
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09:00- 11:00 120 mins 11-11:30 30 mins 11:30- 12:15 45 mins 12:15- 13:00 45 mins 13:00 -13:45 45 mins 13:45-14:00 45 mins 14:00- 16:00 90 mins 16:00- 16:30 30 mins 16:30- 17:30	Practise inputting observation data using L & D app Break Presentation: KMC observation: Logistics of data collection and what to collect Activity K: Review of observation checklist and discussion on key clinical issues (30 mins + 15min discussion to summarise key points) Lunch Presentation: Content and flow of KMC app (including essential variables) Activity L: Practise inputting observation data using KMC app Break Presentation:	4.1 & 4.2 4.2 4.3 & 4.4
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09:00- 11:00 120 mins 11-11:30 30 mins 11:30- 12:15 45 mins 12:15- 13:00 45 mins 13:00 -13:45 45 mins 13:45-14:00 45 mins 14:00- 16:00 90 mins 16:00- 16:30 30 mins 16:30- 17:30 60 mins Day 5	Break Presentation: KMC observation: Logistics of data collection and what to collect Activity K: Review of observation checklist and discussion on key clinical issues (30 mins + 15min discussion to summarise key points) Lunch Presentation: Content and flow of KMC app (including essential variables) Activity L: Practise inputting observation data using KMC app Break Presentation: Data extraction from the registers and Case note Verification IF USING Video observations can insert training here for rest of day 5. Activity M: Practise data extraction from registers using the tools Activity N:	4.1 & 4.2 4.2 4.3 & 4.4 4.3 6.1- 6.3

30 mins		
11:30- 12:00	Presentation:	
30 mins	Interviewing mothers for maternal recall survey	7.1
12:00- 12:30	Activity O:	
30 mins	Mock interviews	7.2
12:30- 13:15	Presentation:	
45 mins	Survey consent, verbal and visual prompts, data to be collected	7.3
13:15- 14:00		
45 mins	Lunch	
14:00- 15:00	Activity P:	
60 mins	Reading the survey	7.4
15:00- 15:30	Presentation:	
30 mins	Introduction to content and flow	7.5
30 mins	Break	
16:00- 17:30	Activity Q:	7.0
90 mins	Variable dictionary	7.6
Day 6		
09:00- 11:00	Activity R:	7.7
120 mins	Role play of survey	7.7
11:00- 11:30	Break	
30 mins	Diedk	
11:30- 12:30	Presentation:	9
60 mins	Bringing it all together and planning for next week	9
12:30- 12:45	Course evaluation	9
15 mins	Course evaluation	3
12:45- 13:30	Lunch	
45 mins		
13:30- 14:30	Activity S: Data collection run through	9.1
60 mins		3.1
14:30-15:00	Knowledge Quiz for data collectors	9.2
30 mins	(to run in parallel with additional supervisor session)	3.2
	SUPERVISORS ONLY TO ATTEND FINAL AFTERNOON	
13:30- 14:15	Presentation:	8
45 mins	Role of the Supervisor & chain of command	_
14:15- 15:00	Presentation:	8
45 mins	Quality assurance mechanisms	
15:00-15:30	Break	
30 mins		
15:30- 16:00	Presentation:	8
30 mins	Schedule of quality checks	
16.00 16.15	Presentation:	
16:00- 16:45	Research team interface with local facility management	8
45 mins	Revision of management in case of life-threating event with no	
16.45 47.45	appropriate response form local staff.	
16:45- 17:15	Presentation:	8
30 mins	How to be a good manager	
17:15- 17:30 15 mins	Question and Answer session	
13 1111112		

Week Two: Facility based Course Timetable- *generic*

Day 1		Corresponding Module & Chapter
am	Facility tour - Meeting with hospital management team	
Am	Facility Orientation 5 days to complete facility orientation checklist (Chapter 18)	
Pm	Split into groups of 4-5. Each with a facilitator Live Practise obtaining Informed Consent	
Day 2	, and the second	
Am	Feedback on previous day Split into groups of 4-5 each with a facilitator and rotate between both KMC & L and D ward Real time walk through of procedure for life threatening events: - Practise responding to a clinical alert within the app	
	 Practise scenarios without a clinical alert Identify and practise calling for help in each clinical setting where you will be observing (Labour, KMC wards, and OT). Do live run through of a scenario and complete all procedures and paper work as per protocol. 	
	Split into two groups and rotate between each ward:	
Pm	Live Observation Practise Using App Rotate through both KMC and L & D ward.	
Day 3		
Am	Feedback on previous day Split into two groups and rotate between each ward: Practise Completing Verification Tools - Find all required documentation for ACS verification tool - Complete ACS verification tool - Find all required documentation for neonatal infection verification tool Complete neonatal infection verification tool	
	Lunch	
pm	Practise Finding & Extracting Data from Ward Registers - Labour and Deliver Register - KMC Register - Neonatal Ward Register	
Day 4		
Am	Feedback on previous day Split into two groups and rotate between each ward:	
	Live Observation Practise Using App	

	Rotate through both KMC and L and D ward.	
	Lunch	
Pm	Split into groups of 4-5 each with a facilitator	
PIII	Live Practise for maternal recall survey	
Day 5		
	Feedback on the week and discussion of possible	
	changes/adaptations to make data collection smoother	
	Optional session:	
Am	a) Participants can identify what they would like to practise again	
	most, a team of facilitators to be available to take small groups	
	of 4-5 to do this.	
	Clinical training update on specific interventions where required	
	Lunch	
Des	Protected time to complete any final parts of the self-directed	
Pm	facility orientation package that participants need to complete.	
Dm	End of Course Test	
Pm	Complete course evaluation	

1.2 INTRODUCTION TO THE STUDY

Background to the study

Every year, 3 million babies are dying in their first month of life, and an additional 2.9 million babies are stillborn. These deaths are often avoidable through quality healthcare and timely provision of routine health interventions, but the lack of data is a major impediment to action.

Country level context1

NATIONAL	BANGLADESH (2015)	NEPAL (2015)	TANZANIA (2015)
POPULATION (000)	160,996	28,514	53,470
TOTAL MATERNAL DEATHS	5,200 ('13)	1,100 ('13)	7,900 ('13)
NMR /1000 LIVE BIRTHS	23	22	19
STILLBIRTH RATE /1000 LIVE BIRTHS	36 ('09)	23 ('09)	26 ('09)

What is the Every Newborn Action Plan (ENAP)?

The Every Newborn Action Plan (ENAP) is based on evidence published in *The Lancet Every Newborn* series and is supported by 197 countries through a World Health Assembly resolution. The ENAP aims to help countries in reaching the Sustainable Development Goal (SDG) **target of fewer than 12 newborn deaths per 1000 live births,** and ENAP target of **fewer than 12 stillbirths per 1,000 total births by 2030**. It is also closely linked to the Ending Preventable Maternal Mortality plan with shared efforts to encourage government leaders, policymakers and program managers to improve quality of care, and end preventable maternal and newborn deaths, and stillbirths.

What is the purpose of the study?

We aim to assess the quality of maternal and newborn health care in order to provide recommendations to national and global health facility monitoring systems. Without this, investors (both governments and partners), program managers and advocates lack the reliable information

¹ http://countdown2030.org/reports-and-articles/2015-final-report

needed to monitor the quality of care, prioritize use of resources, and hold the health system to account.

We expect this study to generate a better understanding of the current practices of care at birth, and for small or sick babies. The results of this study will be used to help reduce maternal and newborn mortality, and preventable stillbirths in Tanzania, Bangladesh and Nepal. These results will also be presented to the World Health Assembly as part of the ENAP, and will inform recommendations to improve the quality of maternal and newborn healthcare across the globe.

How long will the research take?

Facility-based observation and data collection should be completed by March 2018, with findings ready for publication by December 2018.

How will the findings be disseminated?

Results will be widely disseminated at local, national, and international levels. Throughout the research, blogs and news updates will be published on consortium websites and social media. Once analysis is completed, all research findings and tools will be made externally available online, and the data module will be open access and accessible. The results will be published in peer-reviewed journals and presented at national, regional, and international conferences, seminars, and workshops. Briefs, including the study's recommendations and next steps, will also be published linking to policy initiatives and WHA milestones to be disseminated at key UN events and to the public.

Feedback mechanisms to facility and clients

Feedback about the quality of the interventions and recommendations to improve clinical practice and recording of practices will be provided to the facilities and workers, and the results will be published in any relevant local journals. A simple language summary of the findings will be published in the hospital's news board to feedback results to service users and wider participants.

1.3 OVERVIEW AND STRUCTURE OF DATA COLLECTION TEAM

Roles and responsibilities

Throughout this study you will be part of a large and structured data collection team with differing roles and responsibilities. The team is designed so that each person has a clear idea of what they are responsible for whilst also having support from other team members when it is needed. Supervisors will be on hand during every shifts to offer additional help or clarification and will be making sure that all data collection is carried out to a high standard.

The data collection team you are part of, includes team members in the following roles:

- Supervisors
- Tracking officers (TO)
- L&D ward observers
- KMC ward observers
- Register data extractors
- Case note verifiers
- Interviewers
- Video data extractors

Table 4. Roles and Responsibilities of Data Collection Team

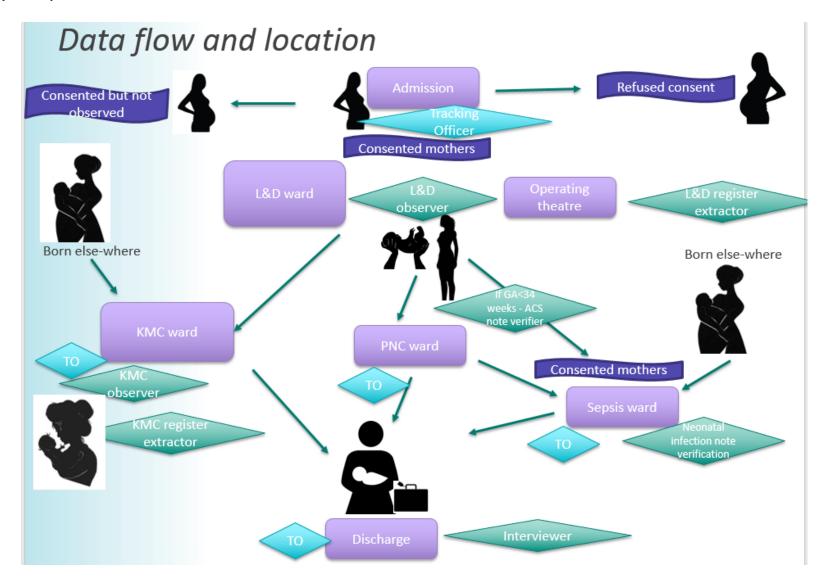
Position	Number	onsibilities of Data Collection Team Key responsibilities	Location in hospital
	in your	,,	
	team		
Supervisors	X	 Ensure all stages of data collection are conducted smoothly and to high quality Carry out data verification of data collected against all data collectors Complete the Data Collector Quality Assurance checklist for each data collector at least once a month Compile a daily report of total participants enrolled at each section versus total admitted, mortality and challenges using a screening and enrolment log and mortality audit form Collect clinical incidence forms from data collectors, compile them and report up to 	All over!
Tracking officers (TO)	X	facility coordinator Enrol eligible mothers/babies at L&D/KMC ward Complete registration forms and take informed consent If consent is refused, ensure no more data is collected on mother or baby Assign consented mothers/babies to L&D/KMC ward observers Once L&D/KMC ward observation is complete, determines next steps of data collection (e.g. L&D/KMC register extraction, ACS note verification, maternal recall survey) and assigns to relevant team members Maintains at all times a general flow of the data collection going on within the facility to ensure staff are positioned correctly and necessary data is being collected Complete the study screening and enrolment log on a daily basis	Admission to L&D ward/OT and admission to KMC ward
L&D ward observers	X	 Identify mothers on the L&D ward who have been assigned for observation by Tracking Officer via the app Ensure well positioned for observation of the relevant parts of the delivery, including observing the birth, and baby once born Have a thorough understanding of the L&D ward observation tool and how to enter data on the app, including how to observe and enter data on mother and baby simultaneously, and how to switch 	L&D ward/operating theatre

		 between mothers if observing two women at similar time Ensure the information on the baby eg resuscitation procedures are observed and the outcome documented in the app. 	
KMC ward observers	X	 Identify mothers/family members assigned for KMC observation by Tracking Officer via the app Ensure well positions for observation of KMC, including observing feeding and any other treatments Have a thorough understanding of the KMC ward observation tool and how to enter data on the app, including how to switch between babies who are being observed at the same time. 	KMC ward
Register data extractors	X	Complete the L&D/KMC extraction form on the app for mothers assigned by the tracking officer	KMC ward and L&D ward
Case note verifiers	X	Complete the ACS/neonatal infection verification form on the app for mothers assigned by the tracking officer	Postnatal ward (for ACS) and sepsis ward (for neonatal infection)
Interviewers	X	 Identify mothers to be interviewed before they are discharged from the hospital in collaboration with the tracking officer Re-consent the mother to be interviewed. If she refuses consent, then stop the interview and ensure no more data is collected. For women who consent- carry out the interview in a polite and gentle manner, ensuring you are aware of sensitive areas (e.g. if she has had a complication during delivery or a stillbirth/neonatal death) Complete the Maternal Recall Survey on the app Ask the mother if she consents for herself and her baby to be followed-up over the coming years, explaining what this will involve 	Postnatal ward KMC ward Neonatal ward/Sepsis ward

Study participant and data flow

As per the table, where you are stationed in the hospital and what data you are collecting will depend on your role. Annex 4 details the flow of the mother and baby through the hospital as well as which data collectors are placed where, you should understand your position in the team and process of data collection in relation to other team members.

Study Participant and Data Flow



GROUP ACTIVITY B: Overview and structure of data collection team

The trainers will now lead you through a group work activity to consolidate what you have learnt in this section 3 of the training.

Objective: To give you the opportunity to understand the flow of mothers/babies and location of data collectors through the health facility.

HANDOUT:

- 1. Title badges for each data collector you have in your team e.g. L&D observer, data extractor, tracking office. NB. Tablets are not needed.
- 2. Place markers- printed sign for each location of data collection, e.g. "Admission", "L&D ward", "KMC ward", "PNC ward", "Sepsis ward"

Time: 45 minute (roughly 30 minutes walking through different scenarios and 15 minutes for questions and discussion)

Instructions:

- Attach to your clothing the badge given to you by the trainer, this will state your job title
- Follow the instructions of the trainer and listen carefully as they walk through the flow of the hospital
- Note down any questions you may have to be asked during the time for questions after the exercise
- NB: This exercise will be revised at the end of the training week but that time you will be expected to lead in narrating what is happening at each step of the process, as the trainer has just done.

1.4 WHY ARE HIGH QUALITY DATA AND CONFIDENTIALITY IMPORTANT?

Data are only valuable if they are high quality; low-quality data are not useful because they do not accurately reflect what is actually happening (for example, on the L&D ward). The quality of data determines the usefulness of the results.

Common Data-Collection Errors

- Misunderstanding the difference between "Didn't happen" or "Don't know"—
 - "Didn't happen" is to be used when you observed that an action was <u>not done</u>, for example you observe that bag and mask ventilation <u>was not used</u> on a baby who was not breathing
 - 2. "Don't know" is to be used when you <u>do not know the answer</u> to the variable, this may be because you were not present or your vision was blocked by a health worker and so you are not sure, for example, whether the baby was dried or not.
- **Missing/unreadable data**—Either data are missing on the app or the data are illegible (only relevant to the paper data collection forms).

- **Data entered incorrectly**—The observer hits the wrong key on an electronic device, or is unfamiliar with the tool.
- Delay in data entry—Time passes between data collection and entry, leading to errors.

Inter-rater reliability

Everyone in the data collection team, regardless of your role, should be taking steps to ensure the reliability of the data you are collecting. In research the term reliability means "repeatability" or "consistency". A measurement is considered reliable if it would give us the same result over and over again.

Inter-rater reliability is the extent to which two or more data collectors agree. Inter-rater reliability is a major consideration in good data quality. People are often inconsistent, easily distracted, tired of doing repetitive tasks, daydreaming misinterpreting and/or biased. In an ideal world two observers/extractors/verifiers/interviewers would be present for each data entry so that their data could be compared and the degree of agreement between the two data sets could be compared. However, for many logistical reasons this is not possible or feasible. Instead, the supervisor in your team will conduct double data entry for at least 10% of cases. Your site coordinator will compare the level of agreement between the two data sets. If there level of agreement is low you may be asked to carry out refresher training. A minimum agreement level of 80% is expected as a cut off for observation. A minimum agreement level of 95% agreement is required for data extraction and case verification.

Confidentiality

Confidentiality refers to the **treatment of information** that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission.

This research study will involve collecting data regarding a mother or baby which may be personal and/or sensitive. All of the data that you collect during the research, along with things you may see whilst in the hospital, read when reviewing notes, or hear when interviewing mothers must be kept confidential and not shared or discussed with anyone else.

Simple steps to endure confidentiality:

- Do not discuss with other data collectors anything about the mother, baby, or family that isn't necessary for data collection. Even without using names people are easily identifiable!
- When discussing with a supervisor or tracking officer a case, using their study ID rather than name, make sure you do it somewhere where you cannot be easily over heard by hospital staff or service users
- In case any relative, friend, or any person you know comes to the health facility or is working in the facility, please alert the supervisor or tracking officer. You should not collect data on someone you know.
- It is also important to ensure the confidentiality of health care workers, do not discuss them or their practise within the hospital or outside the hospital. If there has been an event which you are required to report (as per clinical incidence guidelines) you should make sure this is only shared with your supervisor and not discussed with anyone else on the data collection team.

- If you feel distressed or worried by anything you have seen while on you are working on the study
 and you should wish to discuss it with someone please request a private meeting with your
 supervisor. Your supervisor will be able to offer support.
- Never take pictures/videos or collect any other information unrelated to the study!

1.5 INTRODUCTION TO THE TABLETS

GETTING STARTED

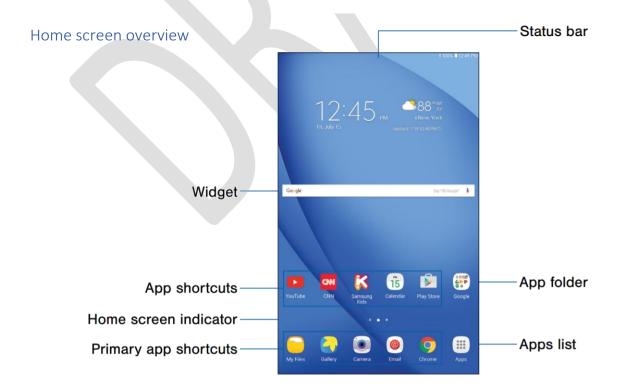
Control buttons overview



- **(A) Front Camera** takes self-portraits/videos of yourself (*will not be used during this project*).
- **(B)** Power/Lock Button turns the device on/off, restarts it, or locks/wakes up the screen.
- **(C) Volume Buttons** adjusts the volume of your device (*will not be used during this project*).
- **(D) Memory Card Slot** optional memory card for removable file storage (*will not be used during this project*).
- **(E) Back Key** Returns to the previous screen, or closes a dialog box, menu, or keyboard.
- **(F) Home Button** Returns to the Home screen.
- **(G) Recent Key** Displays recent apps (*will not be used during this project*).



- **(A) Microphone** records audio and detects voice commands (will not be used during this project).
- (B) USB Charger/Accessory Port connects the USB charger.
- **(C) Headset Jack** connects a headset *(will not be used during this project).*
- **(D) Rear Camera** takes pictures and record videos *(will not be used during this project)*.
- **(E) Flash** illuminates subjects in low-light environments when taking a photo or recording video (will not be used during this project).
- **(F) Speaker** plays music and other sounds *(will not be used during this project).*
- **(G) Speaker** -play music and other sounds *(will not be used during this project).*



Status bar - displays device status icons on the right, and notification icons on the left.

App folder - groups multiple apps into a folder.

Apps list - allows quick access to all of your applications.

Primary app shortcuts - displays these shortcuts on all Home screens.

Home screen indicator - indicates which Home screen is currently visible.

App shortcuts - launches your favourite applications.

Widget - runs as a simple application extension (not a shortcut) on a Home screen.

Status bar overview



The Status bar at the top of the Home screen provides device information (such as network status, battery charge, and time) on the right side and notification alerts on the left.

Turning your device ON and OFF, Flight Mode

To turn on your device, press and hold the **Power key**. To turn off your device, press and hold the **Power key** and select **Power off** \rightarrow OK. When the tablet is ON, press the power button once it is locked and it will be closed. To unlock, first press the power / home button, then the lock / unlock screen will appear on the tablet. Unlocking any side of the screen with the finger pressure will be unlocked. If the screen does not work for some time (5 minutes), the screen will close automatically.

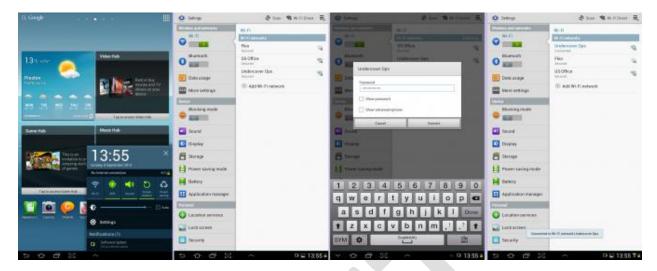
Unlocking the device

When you do not use the device for a specified period, your device turns off the touch screen and automatically locks the touch screen to prevent any unwanted device operations. To manually lock the touch screen, press the Power key. To unlock, turn on the screen by pressing the Power key, tap anywhere on the screen, and then flick your finger in any direction.

Connecting to Wi-Fi

Your device will be configured to use the Wi-Fi or 3/4G connection. In case you have lost connectivity, to connect to Wi-Fi, follow the steps:

- 1. Tap the **Apps** icon in the top right corner of the tablet.
- 2. In the list locate the **Settings** icon (if you can't see it try scrolling left/right).
- 3. Tap on **Wi-Fi** to see the local wireless networks (make sure Wi-Fi is turned on, by sliding the switch at the top on the screen).
- 4. Tap the network you want to connect to and enter the wireless key.



Entering text and numbers

You can enter text and numbers using a keyboard.



Using gestures

To operate the tablet you will rely on touch, using your fingers. Whenever you need to type something, a keyboard will appear onscreen and you can tap keys on that to type them. There is also a kind of special 'language' of gestures that lets you control the tablet in several ways. For example, a double tap will zoom a web page, or holding your finger on the screen might bring up a special menu. There several basic gestures to operate the tablet.



1. Tap

This is simply a quick touch of the screen. It's the simplest gesture there is. It's used to launch apps, select items, and follow web links and so on. It's the equivalent of a left-click on your PC.

2. Tap and hold (and drag)

Touch a part of the screen, and keep your finger in contact with the screen. It's often the equivalent of a right mouse click on your PC, bringing up a context menu. Tap and hold so that the icon appears to 'detach', then drag it to where you want it (will not be used during this project).

3. Scroll

Simply touch a part of the screen that doesn't have a button or link. Keep your finger in contact with the screen and move it up or down, left or right. This is most commonly used for scrolling. If a page is too long to see on the screen, for example, touch any part of the page near the bottom of the screen, then push your finger up the screen, as if you were pushing the page up to reveal the rest of it. This will cause the page to scroll. You can do the same in reverse – or left and right if the page is too wide.

4. Swipe

This is a quick slash across the screen. It can be in whatever direction is needed. It's most commonly used when flipping between pages. The swipe is like flinging the current page aside to reveal the next page. You swipe left or right to switch between them. Swipe can also be used for fast scrolling – you can fling a web page up or down. The velocity of the swipe actually determines how far it scrolls.

5. Pinch-to-zoom

This gesture actually requires more than one finger. Place two fingers (usually the thumb and forefinger, but it doesn't really matter) around a part of the screen you want to enlarge or zoom out of. Then move the two fingers apart to zoom in (enlarge that part of the screen), or pinch them closer together to zoom out. You can think of it like squeezing or expanding the screen. It's often used to zoom in on part of the page that might not be clear (will not be used during this project).

6. Double and triple tap

This gesture involves simply tapping on the screen twice in quick succession. It most often serves a similar function as pinch-to-zoom: double tap on a part of the page you want to zoom in on and double tap again to zoom out.

TABLET MAINTENANCE

Charging the tablet

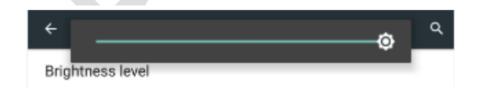
Your device has a built-in battery. To charge the device, connect the USB cable to the USB power adapter, and then plug the end of the USB cable into the multifunction jack. The shape of the USB power adapter may differ depending on your region. Carefully connect to the charger connection. Connected to the charger tab and then connect to the electric line. The batter icon will indicate that the charging is ongoing (). Always try to charge 100% when you can, and then unplug it. Power off the tablet once the work is done, the power of the tablet will be off. The battery charge will last longer and you can work more time.



The batter icon indicates the level of the charge (). When the battery is low, the icon on the right side of the screen will show red colour and show percentage of what percentage is available (). The device will emit a warning tone and display a low battery message. The battery icon will also be empty. If the battery level becomes too low, the device will automatically power off. Recharge your battery to continue using your device. Try not to let the batter reach empty. It could damage it. Also, If possible, don't plug the tab directly into a wall socket. Instead, attach it to a power strip that has a surge protector.

Screen brightness adjustment

When you use your tablet you may find the screen very bright or not bright enough which could strain your eyes. To adjust the brightness of the display open Settings \rightarrow Display \rightarrow Brightness. Drag the slider to adjust the brightness. Remember, the brightness level of the display will affect how quickly the device consumes battery power. The brighter the screen – the faster you will deplete the battery.



Saving energy

Switch the Tab off when you are not working with it. To save energy, unplug the USB power adapter when not in use. Don't leave it attached to the charger constantly. The USB power adapter does not have a power switch, so you must unplug the USB power adapter from the electrical socket when not in use to avoid wasting power. The device should remain close to the electrical socket while charging.

Turning off the sound

Additional sounds during the data collection can be very disturbing and unpleasant. To make sure your device is in the silent mode, adjust the device's volume by pressing the Volume key down. Alternatively, select and drag the sliders to adjust the volume level to the minimum.

Storage

Keep it in the dry place, if possible in Wooden cabinet. Always store the device in the lockable storage to protect it against theft.

Cleaning

Clean the screen with a dry soft cloth only. A clean piece of cotton fabric works well. Never use any chemicals to clean the screen — especially alcohol, ammonia, or solvents.

Physical protection

Use a protective case. The case will protect from breaking by fall. Take care when moving your tablet from place to place. Dropping your tablet on the floor or hitting it against sharp and dull edges will cause physical damage (break or crack the screen or body of the tablet, battery damage), leading to partial or complete malfunctioning of the device, requiring its full replacement. Use Screen protector if possible, and avoid scratching the screen with any sharp objects.

Digital protection

Do not attempt to install any additional software. This can significantly impede the processing power, reduce the storage space, and introduce malicious software, which can lead to unauthorised access to the device, loss of data, and partial or complete malfunctioning of the device. As instructed, do not give your log in details (user name and password) to anyone, including your colleagues. Your login details are person specific and are assigned on individual basis. Passing your login details to third parties is prohibited and can lead to violation of data protection law, as well as loss of data. If you have forgotten your login details, please contact your supervisor. Do not attempt to extract (copy) any data from the tablet. The data is encrypted and cannot be retrieved from the device directly.

Device lost or malfunctioning

If the tablet is lost or stolen, it is your responsibility to notify your manager as soon as possible. If your device is malfunctioning, please notify your manager as soon as possible. Your device might require complete reset and reconfiguration, or replacement. Do not attempt to solve the problem by yourself. You can only attempt to reboot device, by turning it OFF and ON. If possible, do not forget to synchronise the data, otherwise, your data might be partially or completely lost.

TROUBLESHOOTING

Flight mode (ON/OFF)

In **Flight mode**, your connection to all wireless networks is disabled. The **Flight Mode** is usually being activated in areas where wireless devices are prohibited, such as aeroplanes. To synchronise and keep the data up-to-date, your tablet needs to be connected to the network. If your network connection is disabled, your device might be in the **Flight mode**. in the status bar will indicate that your device is in the **Flight Mode**. To activate or deactivate **Flight mode**, go to Settings \rightarrow more settings, and then check the check box next to **Flight mode**.

Device doesn't turn ON

If the battery is completely discharged, you cannot turn on the device, even with the USB power adapter connected. Allow a depleted battery to charge for a few minutes before you try to turn on the device. Always charge the battery only with the original charger provided with the tablet to exclude the possibility of physical damage.

Network or service error message

Your device displays network or service error messages. When you are in areas with weak signals or poor reception, you may lose reception. Move to another area and try again.

1.6 INTRODUCTION TO THE DATA COLLECTION APPLICATION

Introduction

London School of Hygiene & Tropical Medicine (LSHTM) has been implementing a multi-country collaborative study of "Facility-based Maternal and Newborn Quality of Care" in the field sites of Bangladesh, Nepal, and Tanzania. LSHTM is working in collaboration with icddr,b of Bangladesh, Ifakara Health Institute of Tanzania and Nepal Unicef.

Maternal and Child Health Division of icddr,b has given it's technical support to design and develop the Android based application for all sites data collection and project monitoring. The app development team and data management team of icddr,b was composed of different capacity team: a group of program analyst, data management, statistician, epidemiologist, and physicians.

Scope of work

- Develop data capture system for ENAP
- Troubleshooting problems related to data capture system and support study team as required
- Development of ENAP webpage for sharing documents and ENAP Data Entry Software
- Development of Dashboard for monitoring study progress
- Instructions to convert data from SQL to other format

System Overview

Data collection and transmission of reliable data on real-time for monitoring and supporting the project is the key to success for any Project.

London School of Hygiene and Tropical Medicine with the help of Maternal and Child Health Division (MCHD), icddr,b has developed a paperless data collection & management software for collecting data and monitoring the ENAP Study. ENAP Data Entry Software (EDES) is designed to run on android platform (Version 4.1-Jelly Bean or above) and configured base on the health facility of data collectors. Any Smart phone (preferred - Samsung 7/ 10 inches) with internet enabled SIM card can be used for data collection and transmission from different locations. The data can be stored locally in the device first during interview without the internet connectivity and data collectors will be able to manually upload data to the site specific central server through/using the internet at the end of data collection.

Data validation

Data validation is the process of ensuring that a program always operates on clean, correct, consistent and useful data. Maximum validation rules were set in the EDES to prevent errors during data collection. Rules are set to perform the logical and range checks, consistency check, uniqueness check and skipping rules are added for avoiding the collection of undesired information.

Data Upload and Backup

Web service in server end is used for reliable data synchronization via internet. Central server system will backup the ENAP database automatically on a specific schedule. In addition, project team need to maintain a back-up copy of database on a different server/ External Hard Disk

For more safety, the site team should take a backup of the tablet's database at least once a month in a Desktop PC.

System requirements

	Tablet	Central Server
Database	SQLite	SQL Server 2008 R2 (or higher)
Data Collection Software	Android Application:	Web Service: Asp .Net with
	Developed with Java	code behind C# (C Sharp)
Monitoring Tools		Asp .Net (IIS server)

Colour coding

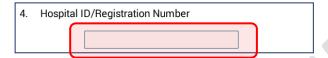
Color	Used in	Description
Green	OB,MRS,DE,ACS,VER	When required action is completed,/Observed-Done
Red	OB,MRS,DE,ACS,VER	When action is incomplete / Observed-Not Done
Orange	Patient	Patient switching button
White	Observation Module	Don't know
Yellow	Observation Module	Selected Tab

Controls used in ENAP Data Entry Software

In the ENAP Data Entry Software some input controls are used for the data collection. These are described below

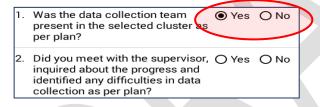
Text Box

- An on-screen rectangular frame allows the user to type text or value
- Text displays on the screen in a simple uniform plain text format
- To type anything (eg Name, Age, Mobile Number) at first select the Text Box then a keyboard will appear (alphbetic / numeric) in the lower part of the screen depending on type of value in Text box. Then s/he can type respective information using that app keyboard.



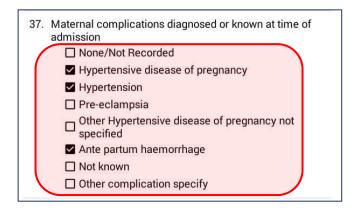
Radio Button

- An element of the graphical user interface which allows a user to select a single item from a
 predefined list of options. Here the data collector need to select one among the multiple
 response
- To select answer s/he have to touch the circle that appears in the left side of the answer



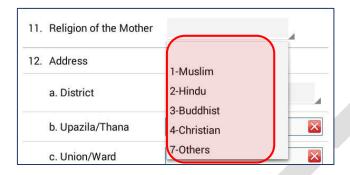
Check Box

- Check boxes allows the data collector in capturing multiple responses
- Specifies the text which are displayed next to it (typically to the right of Check Box)
- This control tool highlights the rectangle when checked. Therefore, if anyone select the box, a tick sign will appear in the box otherwise it will remain empty by default. If the data collector changes her/his mind to remove the tick, s/he needs to touch the check box again.



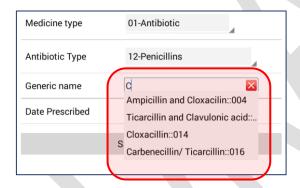
Drop Down List

- Provides multiple choice from a list of mutually exclusive values. However, data collector can be able to **select only the best option**.
- Choices are limited according to the list
- If s/he touch the Drop Down control, a list will be available from where s/he can select the answer/response



Auto-compete

- Enable users to quickly find and select the response from a pre-populated list of values while typing in the text box. Thus, it leverages in searching and filtering the appropriate response
- The widgets provide suggestions while a data collector types into the field



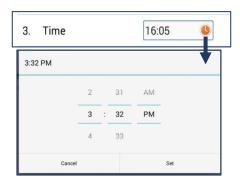
Date Field

- Format will be appear according to DAY/MONTH/YEAR (DD/MM/YYYY)
- One can enter the date value (by scrolling the left display) or can manually select the Day Month and Year from the calender
- By clicking the set button, the real time date will automatically select into the Date Field



Time

- After clicking the clock icon, a digital clock will appear in HOUR MINUTE (HH:MM) and AM/PM format. Data collectors can select time from Time peacker
- By clicking the set button (right behind), the real time will automatically set into the Time field



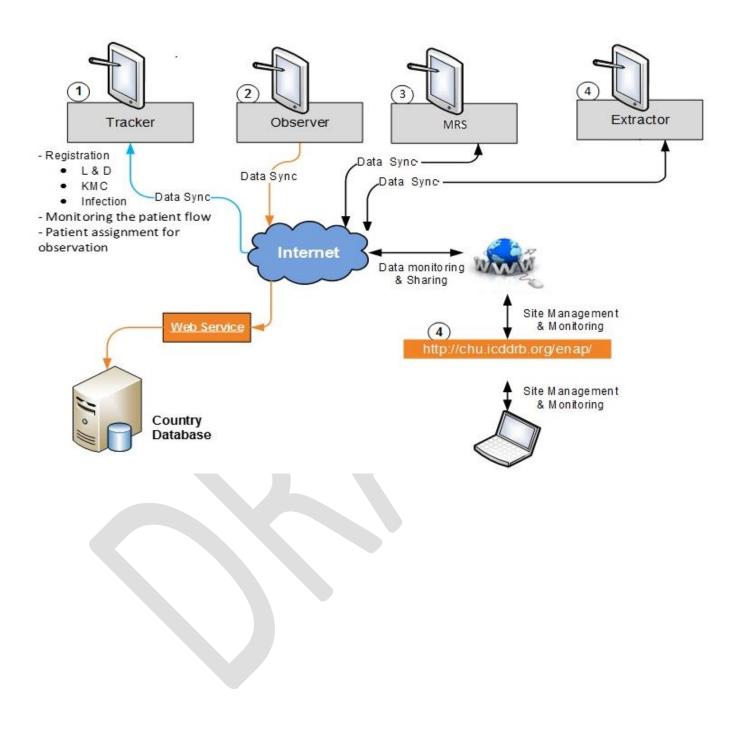
Keypad

Enables user to input data using two types of App keypad.

- Alphbetic
- Numeric



Architecture of ENAP System

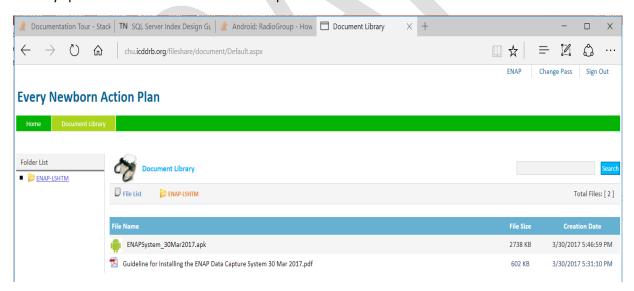


In ENAP system Tracker will be responsible to register the patient, monitor the patient flow, and assign the patient for observation. After registering the patient and sync process, data will be transfer to all the Tabs and the location specific data collector (observer, interviewer or data extractor) will get the options of the system. Data collector will get the access level into the App based on predefined authotization. All the collected information will be stored into the local storage of android device and data will be saved in Database server through the internet using the Data Sync process. After syncronizing data, observer will get a list of patients who have been assigned by the Tracker or other observer. Observer will store the collected information of patients and sync the data into the server. In the same way Data Extractor or Interviewer will extract the information from the Hospital Register books or fill up the MRS accordingly and will save them. Afterward, they will Sync the saved data to the server.

After completion of the data sync process, the monitoring team will get access to monitor the activities of the study using the monitoring web site. There are some pre-formated monitoring report which will run instantly and appear in the App dashboard

Preparing the Device for Data Collection

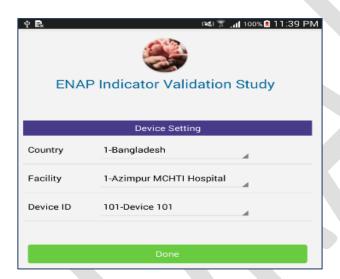
A web site has developed and hosted (http://chu.icddrb.org/fileshare) into the icddr,b, Central Server to share the ENAP Data Entry Software, related documents and user manual. Country Specific apk file and documetns are available into the file sharing web site. By using the URL above or clicking the link above, a login window will appear. In order to login into the system, one needs to select country specific user ID and write down the password.



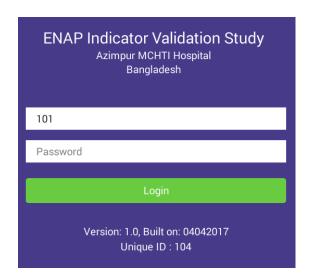
Instruction: Download the "apk" file (ENAPSystem "release date".apk) from web site (Always dowload the latest ENAP apk file as instructed) and install it into the Tab. After dowloading the apk file, touch the apk icon, a dialogue box will appear for confirmation of installation. After touching the install button, ENAP system will start to install the software.



Make sure that the internet conneciton is availabe in to the Tab during the App Set up process. Touching the ENAP icon will appear the Device setting window to appear in screen. Now follow the given instructions to complete the device setting process.



- Select Country, Facility and Device ID from the Drop Down list
- Touch the Done button to start the country specific app set up process
- Please wait untill the completion of the set-up process
- After completing the process, a Login window will appear in the screen



Users

There are four types of user who will in use the App in ENAP system. Each type of user has assigned to do specific activities in collecting data. Each user will be given an User ID (with a password) to log in into the ENAP system.

- -Tracker
- -Observer
- -Interviewer
- -Data Extractor and Verifier

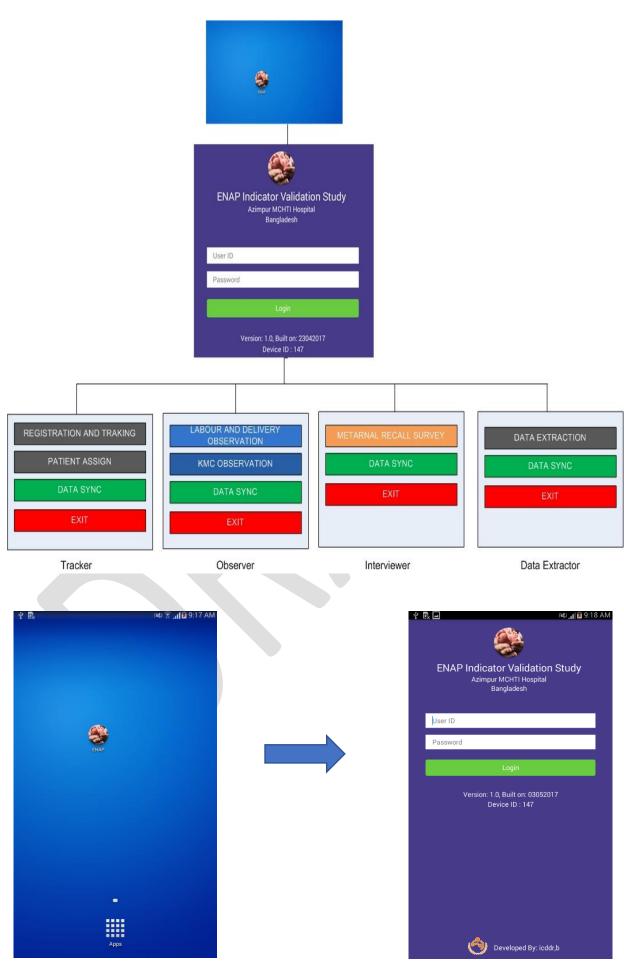


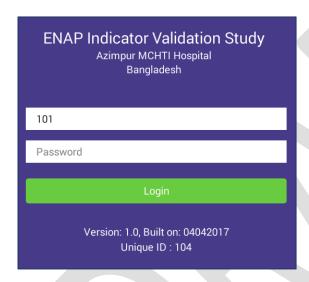
Figure displaying instruction: Touch the ENAP icon and a "Login" screen will appear in the device window, enter valid user ID and password to access the ENAP system. After validating the loging process, Main Menu will appear in the screen based on the type of user.

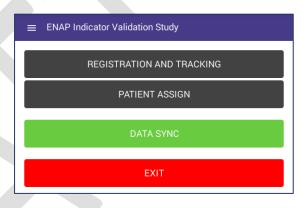
1.0 Tracker

Registration process is the first entry point to enroll a patient into the system. Trackers are responsible for initiating the registration process and their responsibilities are:

- Register a patient
- Monitor the patient flow
- Patient assignment for observation and
- Patient reassignment for another observer

Tracker is not allowed to see the information of observation/recall survey/data extraction/data verification/maternal interview.





Tracker menu in the TAB has the following options:

- 1.1. Registration and Tracking
- 1.2. Patient Assign
- 1.3. Data Sync
- 1.4. Exit

1.1. Registration and Tracking

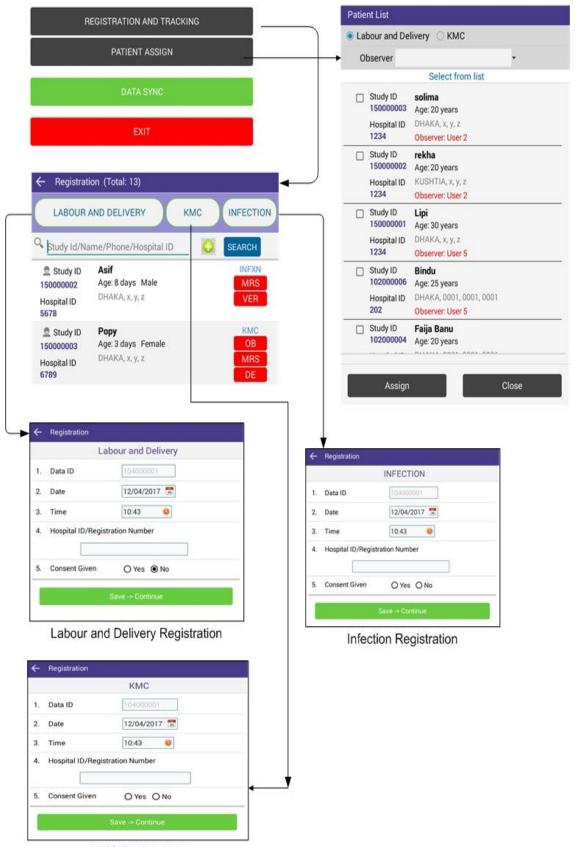
Touch "Registration and Tracking" button from the main menu and the following window will appear in screen. Tracker can register patient for Labour and delivery, KMC and Infection. by clicking the button of same name



- 1. Labour and Delivery Registration,
- 2. KMC Registration
- 3. Infection Registration.

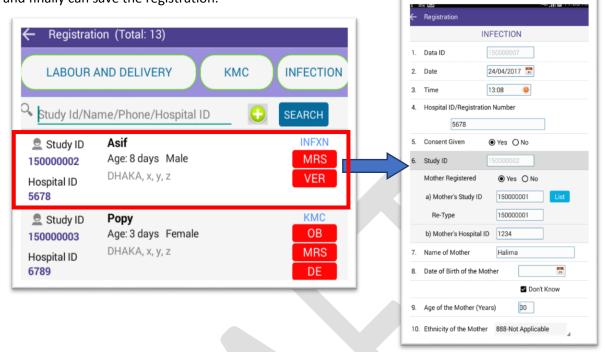
For example, by touching "LABOUR AND DELIVERY" button (red circle), "KMC" button (black circle), and "INFECTION" button (green circle), tracker can be able to register the labour and delivery patient, KMC patient and infection patient, accordingly.

After registration, s/he can see the registered patients information on the dash board of the TAB and only the tracker can be able to edit any information of the registered patient by touching the respective patient ID or the patient information presenting row. Trackers can switch any of the three registration options by clicking the respective button. But the trackers are not allowed to access in Observation (OB), Maternal Recall Survey (MRS), Data Extraction (DE) Section and verification (ACS & VER).

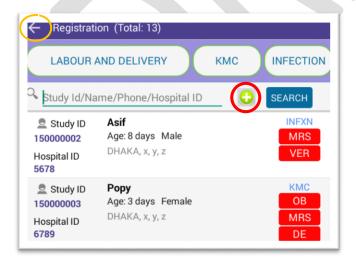


KMC Registration

Figure display: After touching or clicking on the respective row or id, s/he(tracker) can see detail information of a specific patient and then tracker can edit any information of the respective patient and finally can save the registration.



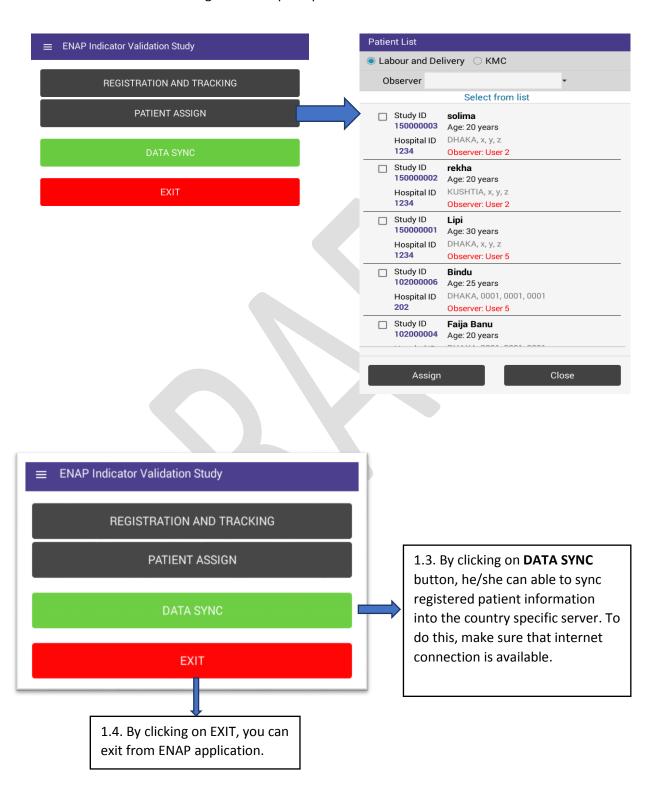
By clicking on Plus button (red circle), a search option will appear which will allow to search or filter a particular patient's information from the registered patient list. After completing necessary work/entry, tracker need to select the "save-> continue" button to save the collected information. Afterward, the system will automatically redirect him/her to the registered patient list. However, by pressing the BACK () button (yellow circle) s/he can get back to the patient list without saving the information.





1.2. Patient Assign: By pressing the "Patient Assign" button, a tracker can assign a registered patient to a particular observer from the patient list who are under incomplete observation status. (An incomplete patient pop-up list will be available by clicking the patient assign button).

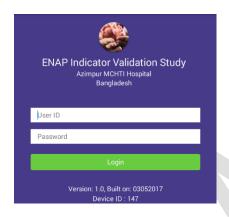
Tracker can be able to re-assign an incomplete patient's observation to another observer.

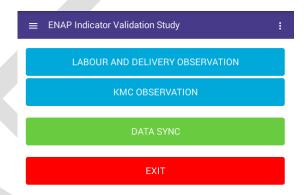


2.0 Observer:

After completing the above mentioned steps of the tracker and data sync process, data will be transferred to the server. Also, patient information will be availabe in all the Tabs when the user will process the data sync. Regarding the assignment of the patients, observer will be able to get the list of all assigned patients which need to be observered by him/her. An observer will do the following:

- 1. Look at the list of registered patients that has already been assigned by Tracker/another observer
- 2. Observe single or multiple patients
- 3. Observer can re-assign any patient to another observer at the end of his/her shift



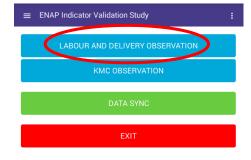


Role or responsibilities of an Observer:

- Observation based on assignment
- Patient switching
- Final Outcome
- Pause observation
- Complete observation
- Observation handover/Shift change

After Successful login (by entering the user ID and password), an observer will find the Observation menu. Observation menus have following four options:

- 2.1. Labour and Delivery observation,
- 2.2. KMC Observation
- 2.3. Data Sync
- 2.4. Exit

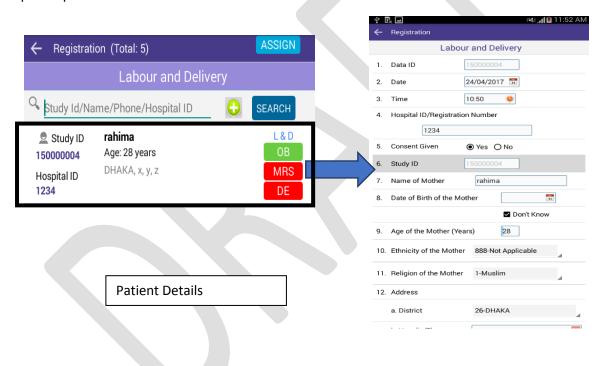


2.1. Labour and Delivery observation

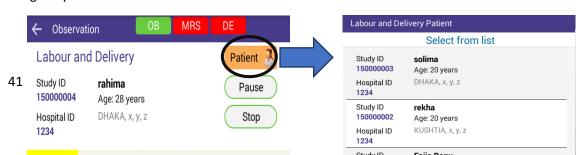
By clicking on "Labour and Delivery Observation" button s/he (Observer) can enter labour and delivery observation module/menu. By using the search panels he can select patients for observation and also s/he can scroll the patient list to select from the list. Observer can enter into the

observation process by clicking on "OB" button. A list of observation tools will be available when s/he selects a patient for observing a particular section of observation. An observer has no access to modify on MRS or DE Sections but s/he can see the patient status of MRS or DE.

After clicking on the respective patient row or id, the observer can see detailed information of a specific patient.



S/he (observer) can switch between patients by pressing the "Patient" button and can select the assigned patient from the list.

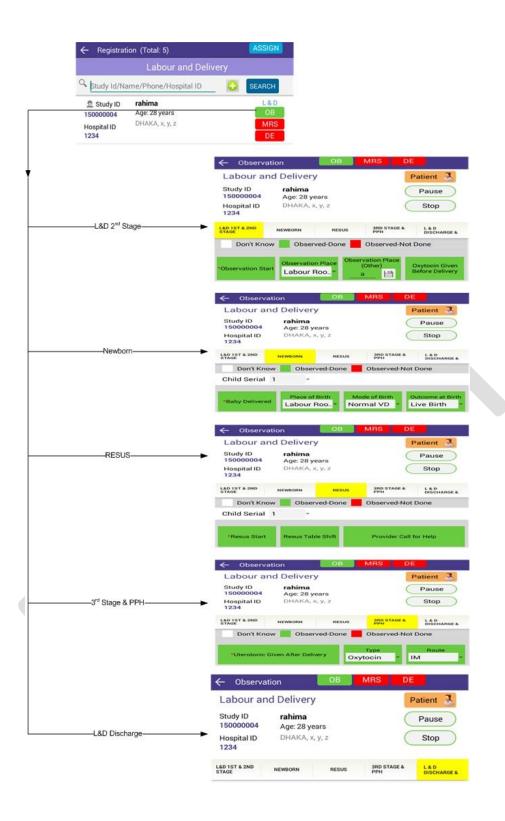


By clicking "OB" button (blue circle), observer can observe the following 5 observation parts:

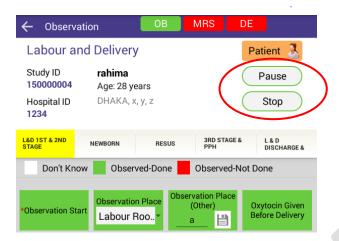
- 2.1.1. L&D 1st & 2nd Stage
- 2.1.2. Newborn
- 2.1.3. RESUS
- 2.1.4. 3rd Stage and PPH
- 2.1.5. L&D Discharge & Outcome.







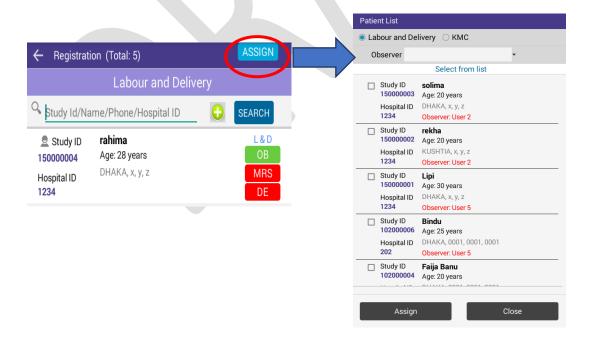
There are another two buttons (behind the Patient Button) in the Labour and Delivery observation window:



PAUSE BUTTON: An observer can pause the observation at any stage of observation by clicking the PAUSE button. Clicking on pause, a pop up window will appear for confirmation. By selecting "Yes", the observation will go on the "Resume" status. Afterward, s/he can RESUME the PAUSED observation by clicking the RESUME button.

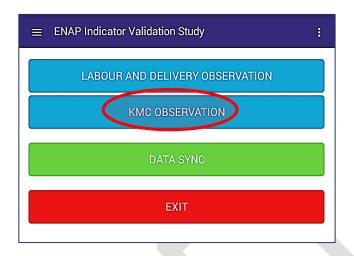
STOP BUTTON: Due to some unavoidable circumstances, an observer can STOP the observation at any stage of observation by clicking the STOP button. When an observer clicks the STOP button, a pop-up window will appear with the incomplete forced variables list. By pressing STOP button, the system will automatically redirect the observer to the 5th TAB (L&D Discharge & Outcome). By filling-up the 5th TAB information, an observer can pre-maturely end the observation.

S/he (observer) can reassign a patient to another observer by pressing the "Assign" button.



2.2. KMC Observation:

By clicking "KMC OBSERVATION" button (red circle), s/he(observer) can observe the following five KMC observation parts:

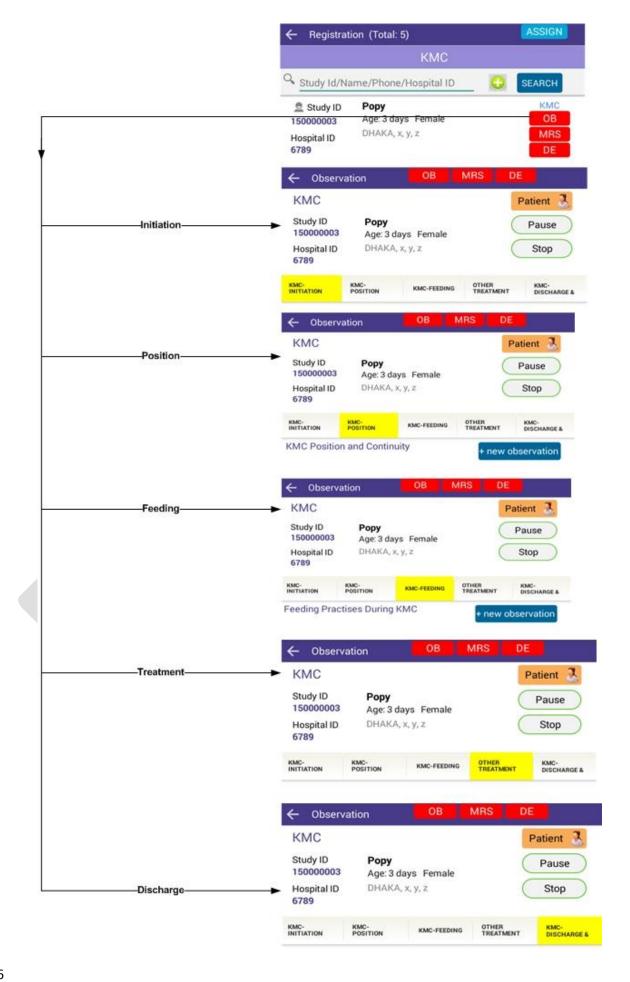


- 2.2.1. KMC Initiation
- 2.2.2. KMC Position
- 2.2.3. KMC Feeding
- 2.2.4. Other Treatment
- 2.2.5. KMC Discharge and Outcome

By clicking on "KMC Observation" button observer can enter KMC observation module. Alternatively, by using the search panel s/he can search and select any patient for observation by clicking on OB button. A list of observation tools will be available when s/he selects a patient for observation of a particular section of KMC observation. S/he (observer) can switch patient to another observer by pressing the "Patient" button and observe the list. An observer has no access to edit on MRS or DE Section but s/he can see the status of MRS or DE.







There are another two buttons (avaiable on top of screen) in the KMC observation check list:

PAUSE BUTTON: An observer can PAUSE the observation at any stage of observation by clicking the PAUSE button. Clicking on pause, a pop up window will appear for confirmation. By selecting "Yes", the observation will go on the "Resume" status. Afterward, s/he can RESUME the PAUSED observation by clicking the RESUME button.

STOP BUTTON: Due to some unavoidable justified situation, an observer can STOP the KMC observation at any stage of observation by clicking the STOP button. By pressing STOP button, the system will automatically redirect the observer to the 5th TAB (KMC Discharge & Outcome). By filling-up the required 5th TAB information, an observer can pre-maturely end the observation.

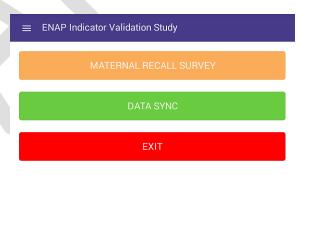
3.0 Interviewer:

Third user role in ENAP system is Interviewer's role with the below stated responsibility:.

• Interviewer can interview the mother (only when observation/note verification is completed for that particular mother).

Like a Tracker, a group of IDs (with password) are assigned to the Interviewer. Login with this ID, an interviewer can perform their task as defined in the observer role.





After Successful login (using user ID and password), s/he will be able to enter into the Maternal Recall Survey (MRS) menu. MRS menu has the following three options:

- 3.1. Maternal Recall Survey,
- 3.2. Data Sync,
- 3.3 . Exit
- 3.1. By clicking on "Maternal Recall Survey" button, intervisively module. By using the search panel, s/he can search

ENAP Indicator Validation Study

MATERNAL RECALL SURVEY

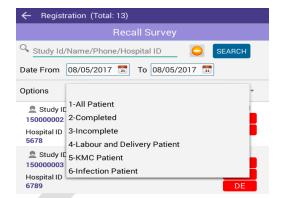
DATA SYNC

EXIT

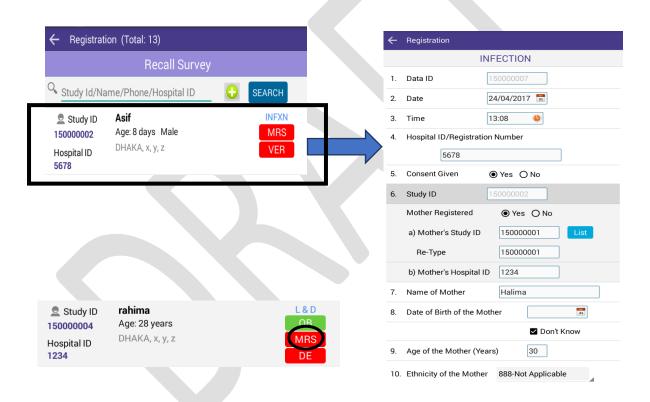
by clicking on MRS Button. A list of MRS tools will be available when s/ne selects a patient for

interview of a particular section of MRS. An Interviewer has no access to edit on OB or DE Sections but s/he can see the status of OB or DE.



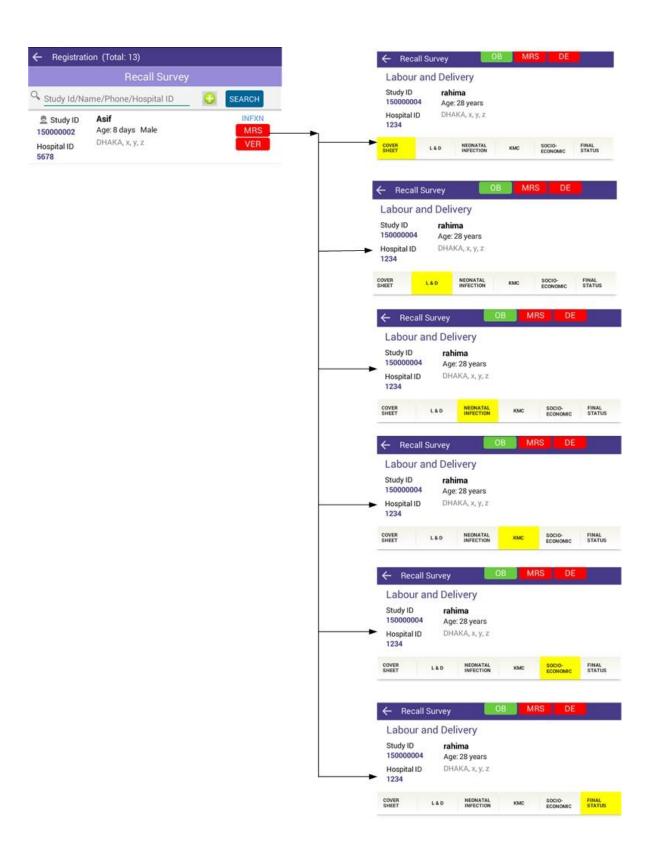


After clicking on the respective row or patient id, interviewers can see detailed information of a specific patient.



By clicking "MRS" button (Black circle), S/he can have the following six interview check list TABs:

- 3.1.1 Cover Sheet,
- 3.1.2. L&D,
- 3.1.3. Neonatal Infection,
- 3.1.4. KMC,
- 3.1.5. Socio-Economic, &
- 3.1.6. Final Status

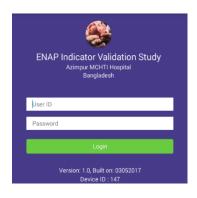


4.0 Data Extractor (DE):

Fourth role of the ENAP system is played by the Data Extractor. Data extractor has following responsibilities:

Extract information for a particular section of a patient from hospital register

Like the Tracker, a set of IDs are assigned to the DE. Using the ID and password, DE can be able to Login to perform their task as defined in the DE role.





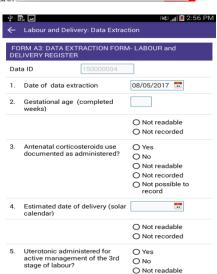
After Successful login s/he will be able to access the Data Extraction menu.

- 4.1 Data Extraction
- 4.2 Data Sync
- 4.3 Exit
- 4.1. By clicking on "Data extraction" button Data Extractor can enter Data extraction module. By using the search panel s/he (DE) can search and select the specific patient for Data extraction. By selecting a patient and then clicking on DE Button, data extractor can extract the data related to L & D and KMC patients from the hospital register books.









Instructions related to Maintainance of Tablet/tab

- Switch the Tab off when you are not collecting data
- Keep it in the dry place, if possible in Wooden cabinet
- Always try to charge the Tab to full battery, and then unplug it.
- Don't leave the tab attached to the charger constantly.
- Don't let the battery reach empty. It could damage the battery life of tab
- If your battery can't hold charge when turned off, or seems to drain out its power much quicker than the usual time. Call and contact with Vendor
- If possible, don't plug the tab directly into a wall socket. Instead, attach it to a power strip that has a surge protector.
- If a charger starts to get very hot druing charging the tab, unplug it and consult with Vendor
- Use a protective case. The case may protect the tab from damage due to unintertional fall
- Take care of the tab druing handling or moving from place to place.
- Clean the screen with a dry soft cloth. Normally, a clean piece of cotton fabric works well.
 Never use any chemicals to clean the screen especially alcohol, ammonia, or solvents.
- Use Screen protector for the tabs
- Don't try to scratch at the time of selecting a button for data collection
- Don't use a pen or other sharp implement on your tablet, even a stylus
- Don't install any unnecessary softwrare or game. It will make the make the memory full and let the Tab to run slow.

GROUP ACTIVITY C: Initial practise using the tablet and app

Objective: to ensure data collectors understand how to use the tablet and app for data collection.

Time: 90 mins total

Handouts / Materials: fully charged tablets with the ENAP app installed

Instructions:

The trainer will now lead you through excercises that allow you to practise using the tablets and app, these excercises may not reflect the roles you will go on to do but they provide practise in app use.

Exercise 1 (30 minutes): practicing tablet and app basics

Exercise 2 (20 minutes): role playing as a tracking officer and a mother

Exercise 2 (20 minutes): data entry as an observer on the LD ward

Questions and discussion session (20 minutes)

1.7 INFORMED CONSENT FOR PARTICIPANTS

Procedure for obtaining informed consent from participants

Who can give consent?

- All adult research participants (aged 18 years and above) must personally give informed consent.
- If the mother is under 18 years, an assent should be signed by the mother and consent obtained from the next of kin
- If the mother can't read or write, an impartial witness should sign the consent form, and thumb print obtained from the mother
- Mothers should provide informed consent on behalf of participating infants.
- If the mother is unable to give informed consent in an emergency, consent may be obtained from her next of kin however, the mothers' consent should be obtained at nearest opportunity and takes precedence

Who can take consent?

Trained data collectors only.

How is consent obtained?

- 1. Written informed consent must be obtained using the official study consent forms (those that were agreed by the institutional review board (IRB) for this study).
- 2. Consent forms will be paper.
- 3. Consent forms should be in the local language
- 4. Read all parts of the consent form aloud to the participant
- 5. Allow sufficient time to provide additional information and answer any questions
- 6. Do not illicit consent using any duress or incentive
- 7. Ensure participant marks their response on form / tablet as indicated.

GROUP ACTIVITY D

Handouts: sample written consent form for study participants (annex 1)

Objective: To give you the opportunity to practice obtaining <u>informed</u> consent.

Time: 45 minutes

Instructions:

- Break into teams of three.
- Identify one person to be the person obtaining informed consent, one to be the potential research subject, and one person to observer the process and offer feedback. Each participant will have the opportunity to play each of the three roles.
- Conduct a role play using the consent forms and obtaining informed consent.
- The person who was observing the process should give feedback on the role play and the process in which informed consent was

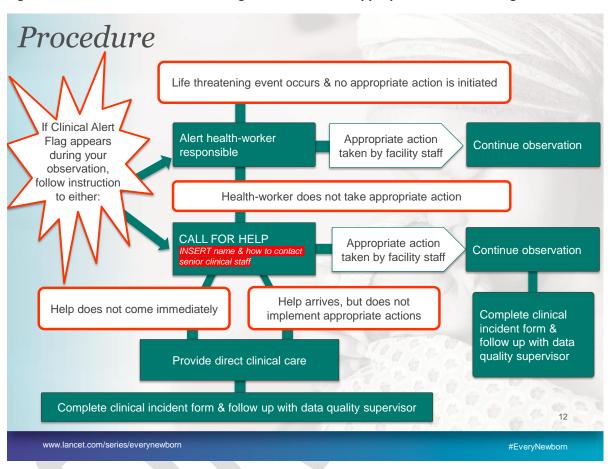
If time allows, hold group discussion:

- What was the experience of obtaining informed consent like?
- What was difficult?
- What was easy?

• Questions/comments on the language used in the consent procedure?

1.8 PROCEDURE FOR LIFE THREATENING EVENTS WITHOUT AN APPROPRIATE RESPONSE

Figure 1. Procedure for life-threatening events where no appropriate action is being taken



Since this research is being conducted in hospital settings where clinical care is being delivered, we expect that clinical observers will collect data during life-threatening situations. There is a risk that clinical observers may observe a life-threatening situation where appropriate action has not been initiated / implemented by facility healthcare staff. In the event the safety (or life) of a patient is deemed to be endangered, action should be taken in line with Figure 1.

All selected facilities will identify a senior healthcare provider (physician or midwife depending on the facility level) who must be present in the facility (or immediately reachable and available) at all times during data collection. A rota with clear on-call system can be utilised. This requirement will be agreed with the in country senior PI, the MOH and every facility manager where we are working.

In addition, all clinical observers are expected to have completed training updates on the interventions of study within the last three years. A brief update on each intervention of interest will also be provided as part of standard observer training and observers will need to pass knowledge testing before commencing work in a clinical site.

Follow up:

Observers should complete the clinical incident form with their research supervisor. Each health facility should identify a named person responsible from hospital management to be contacted in all

cases where observers need to implement the SOP in accordance with Figure 1. The named person responsible from hospital management will work with the research team following clinical incidents and should receive a copy of the clinical incident form. Clinical incident forms should be collated and reviews at facility, country and LSHTM level and are the basis for monthly (can be more frequent at facility level if required) case review and updates.

GROUP ACTIVITY E

Objective: To give trainees the opportunity to practice using the procedure algorithm / clinical

incident forms. **Time:** 30 minutes

Materials: critical incident forms

Instructions:

1. Break into teams of three.

- 2. Identify one person to be the data collector, one to be the consented mother, and one person to watch. Each participant will have the opportunity to play each of the three roles: data collector, research subject, watching.
- 3. Conduct a role play using the algorithm and testing different clinical scenarios you have experienced in your own practise.
- 4. Work together to identify any clinical or ethical challenges you may face and potential solutions.



MODULE 2: REGISTRATION Role of the Tracking Officer

The tracking officer is a vital part of the team and central to ensuring that the rest of the data collection team is able to collect the necessary information on mothers/babies across different locations of the hospital.

General roles and responsibilities:

- To identify eligible mothers/family members for enrolment
- Collect basic information on all eligible mothers/family members
- Carry out informed consent
- Assign mother/family members/babies to appropriate data collectors
- Ensure all relevant data is collected on ach enrolled person as they pass through the health facility

Logistics of being a tracking officer

Position in the health facility: The tracking officer will be stationed between the flowing locations in the health facility:

- Admission desk for L&D
- KMC ward
- Neonatal ward
- Post-natal ward
- Sepsis ward

The tracking officer will likely be positioned at the L&D ward for the majority of time, moving to the other specified locations regularly to check for admissions that meet the criteria for data collection or for mothers/family members who are soon to be discharged.

Interaction with mothers/family member: The tracking officer, unlike other data collectors, is able to talk to the mother/family member and review the ANC/partograph which may be available in order to collect the required information. Ensure you are always patient and respectful to mother/family member as they may have experienced a distressing event during their time in the health facility. The tracking officer will be required to speak to the mother/family member in order to achieve the following:

- Collect minimum data on the mother/family member
- Collect informed consent
- Collect information on previous obstetric history and current pregnancy (for women being observed on the L&D ward/operating theatre)

Key tasks of a tracking officer

The key steps to be followed by the tracking officer differ between location in the health-facility, if a baby was in-born or out-born. Key steps and tasks in each location are as follows.

Labour and delivery ward

1. Identify all pregnant women at admission to the L&D ward/ antenatal wards

- Collect and enter the mother's basic data in to the app (see variable dictionary, basic data includes: name, DOB, age, ethnicity, religion, years of education)
 NB. This basic data should be collected for all women before obtaining consent.
- 3. Carry out the informed consent procedure with the woman using the paper based
- information sheet and consent form (Annex 1)
 4. If the woman does not consent- make sure no more data is collected on her (this includes no observation, extraction, verification or interview data)
- 5. <u>If the woman does consent-</u> proceed to collect information on her obstetric history and current pregnancy.
 - **NB.** If a mother has a gestational age at admission of ≤34 weeks you should make a note of her study ID as she will need to be flagged to a data extractor/verifier for ACS note verification.
- 6. Assess whether there are enough observers on shift to observe the mother on the L&D ward or in the operating theatre
- 7. Assign the mother to the observer you think is best able to observe her. This decision should take in to account the number of other women the observer may have to observe at the same time (if any) as well as the stage of labour of the women, and whether they are primips or mulitps. In summary, aim to assign women to observers who will be able to observe and collect all necessary data, if there is only one woman per observer this is easy, when observers are observing multiple women at the same time this will need more thought.

Recommendation: No observer should be assigned more than <u>three women</u> to observe at any one time.

KMC ward

Inborn babies

- Make sure you are aware of babies who were observed on the L&D ward/operating theatre and have been transferred to the KMC ward. To do this:
 - You can ask the mother if she has been registered previously for L&D observation. If the mother is already registered you can enter the "patient assign" section of the app and identify the mother by her ID, names, age and date of birth to match in the App.
 - Additionally, you can ask L&D observers to inform you when this happens to a baby they were observing.
- Ensure there is a suitable observer on the KMC ward to observe this baby.
- Using the app to assign the observation to the suitable observer on the KMC ward.

Out born babies

- 1. Identify babies who were born elsewhere and are being admitted to the KMC ward, this will require frequent visits to the KMC ward to check for recent admissions
- 2. Collect and enter the mother/family member's basic data in to the app (see variable dictionary, basic data includes: name, DOB, age, ethnicity, religion, years of education) NB. This basic data should be collected for all women before obtaining consent.
- 3. Carry out the informed consent procedure with the mother/family member who is with the baby
- 4. <u>If consent is refused</u>- make sure no more data is collected on the baby or mother/family member

5. <u>If consent is given</u>- register and assign the baby to an observer who is on shift and able to observe the baby

Neonatal ward

In-born babies

- 1. Make sure you are aware of in-born babies who were observed on the L&D ward/operating theatre and have been transferred to the neonatal/sepsis ward for possible cases of severe bacterial infection. You can ask L&D observers to inform you when this happens to a baby they were observing.
- 2. Visit the neonatal ward regularly to check for babies who may not have been delivered in the facility/their delivery may not have been observed as part of the study, but who meet the following criteria:

Inclusion criteria:

- Baby on neonatal ward, recorded in register and main diagnosis is infection (sepsis/meningitis)
- Baby's age <28 days at time of admission

Exclusion criteria:

- Baby with congenital abnormality
- Neonatal encephalopathy/ severe asphyxia
- Preterm <34 weeks
- Weight at admission <2000 grams
- 3. Ensure that the case notes of the baby are verified by the study team (data extractors/verifiers)

Out-born babies

- Identify babies who were born elsewhere and are being admitted to the neonatal ward and meet the above inclusion and exclusion criteria
- Collect and enter the mother/family member's basic data in to the app (see Variable
 Dictionary, basic data includes: name, DOB, age, ethnicity, religion, years of education)
 NB. This basic data should be collected for the mothers/family members of all eligible
 babies before obtaining consent.
- Carry out the informed consent procedure with the mother/family member
- If consent is refused, make sure no more data is collected on the baby or mother/family member
- If consent is given, register and assign the baby to data extractor/verifier who is on shift and able to verify the case notes

Maternal Recall Survey

1. Ensure you are aware of the approximate timeline for discharge of all mothers/family members who consented and had data collected on themselves or their babies as part of the study.

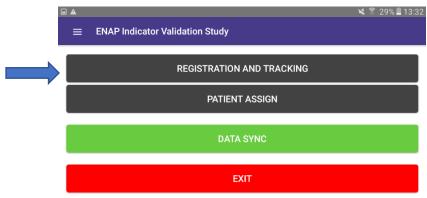
- 2. As a tracker it is your role to alert an available interviewer of a mother who is soon to be discharged and assign the interview to them on your tablet. The interview takes approximately an hour so if possible to alert the interviewer while the mother is waiting to be discharged that would be the most time efficient approach.
- 3. When you assign a mother/family member to an interviewer on the app it is important you hand over to the interviewer the current conditions of the baby; alive, fresh stillbirth, macerated stillbirth, stillbirth- condition unknown. This information should be given to the interviewer before they start the interview so that they can adjust their manner as necessary.

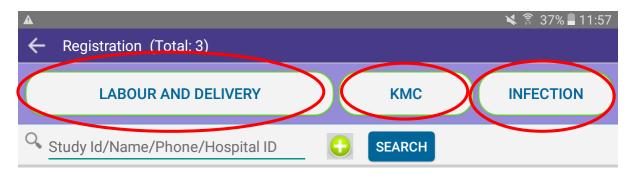


Using the data collection app

Registration

The top section available to you once you have logged in to the app is the "Registration and tracking" section. In this section you can register new study participants as well being able to see those you have previously registered.





At the top of the screen there are three buttons for three different types of registration, "Labour and Delivery", "KMC" and "Infection". The table below shows you which form/section of the app to use in which situation.

Situation	Form to be used
Pregnant woman at admission	L&D registration form
Inborn baby referred to KMC	KMC registration form
Out born baby admitted to the KMC ward	KMC registration form
Baby admitted to sepsis ward with neonatal infection	Infection registration form

Basic data: Once you have selected the correct registration form the app will then take you through the process of collecting basic data on the mother and obtaining consent. Basic data (including name, DOB, age, ethnicity, religion, years of education - see variable dictionary) are to be collected on all women before you ask for consent. This means that you will register every mother who is admitted at L & D, KMC and neonatal sepsis ward.

Obtaining consent: For all three types of registration- follow the steps and procedures taught in Module 1 to obtain informed consent. Or if consent is refused thank the mother for her time and stop data collection there, entering in to the app that consent was refused- this will block the rest of the questions and you will not be able to enter any more data on this participant.

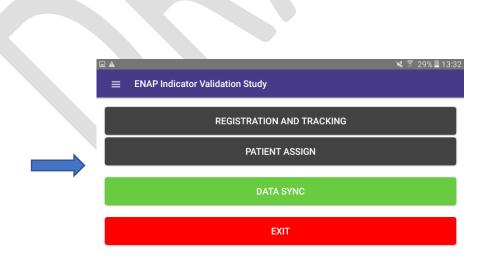
For mothers on the L&D ward who consent to you will then collect more information on obstetric history and current pregnancy. Follow the questions listed on the app and either ask the mother or obtain the information from her ANC card.

When all of the registration information is complete and you have pressed "save and continue" you can then return to the main menu.

Patient Assign

Once you have consented and registered a mother/family member for data collection you need to assign them to an appropriate data collector.

On the main menu click on "Patient assign" button to allocate the patient to an observer who is able to observe the mother on L&D ward or the baby and mother/caregiver on KMC ward.



When you press "Patient Assign", a patient list will appear of mothers/family members/babies who have been consented and registered and who you are able to assign to a data collector. If, for example, you wish to assign a mother who you have just registered on the L&D ward to an observer on the L&D ward you should make sure at the top of the patient list you have selected "Labour and Deliver". If you were assigning a baby for observation on the KMC ward make sure "KMC" is selected.

You then select the mother/family member/baby from the list of patients so that their information turns green in the app, then select the observer you wish to assign them to from the drop down list of observers. Make sure to take in to account the instructions given above when choosing an observer on the L&D ward. Once you have selected the observer and patient then press "Assign". This will then mean the data collector you have chosen will have access and can collect data on this person/baby.



GROUP ACTIVITY F: Review of data flow and location of tracking officer

Objective: To allow tracking officers to review the data flow including movement of mothers and babies and locations of tracking officers

Time: 60 minutes

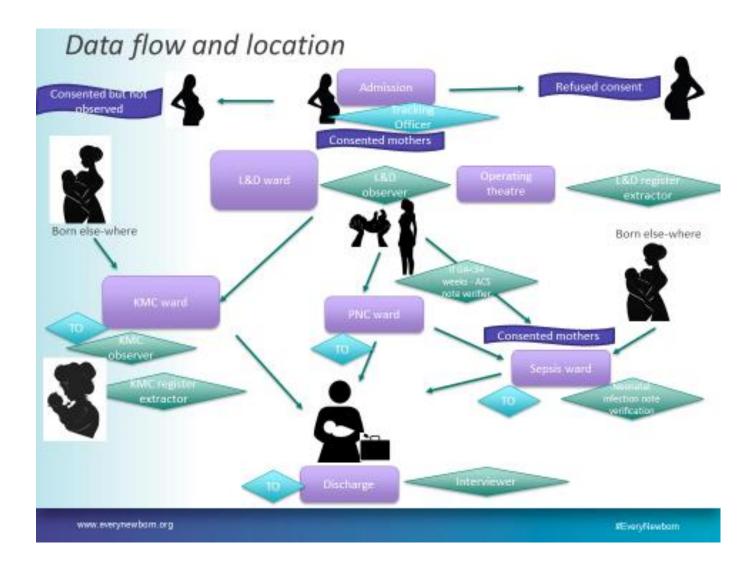
Handout:

• A print out of Annex 4 for each trainee

Instructions:

Review Annex 4 and discuss as a group:

- Areas you do not understand
- Areas where you foresee issues/challenges



GROUP ACTIVITY G: Review of Registration Forms

Objective: To allow tracking officers to review the registration forms in the app and identify and discuss any sections that may not be understood clearly.

Time: 45 minutes

Handouts:

- 1. Variable Dictionary sections (print out):
 - L&D registration
 - KMC registration
 - Neonatal infection verification registration
- 2. Tablet logged in as Tracking officer

Instructions:

- 1. The trainer will split you in to smaller groups for review of the variable dictionary and app
- 2. In your smaller group work your way through the variable dictionary and relevant sections of the app
- 3. Make notes of any questions relevant to wider group to be shared during designated time at the end of the exercise.

GROUP ACTIVITY H: Role play

Objective: To give tracking officers the opportunity to practice completing the L&D, KMC and neonatal infection verification registration forms on the tablets, including obtaining informed consent and then assigning cases to data collectors.

Time: 120 minutes

Handouts:

- Tablets logged in as tracking officer
- Paper information and consent forms

Instructions:

- The trainer will divide you up in to small groups and explain the exercise
- You should repeat the role plays as the trainer describes, rotating team members between roles and using the different registration forms
- At the end you will discuss as a group the following questions so make sure to think of them while you do the role plays:
 - What was the experience of registering and consenting mothers?
 - What was the experience of using the tablet to collect data?
 - What was difficult?
 - What was easy?
 - What would you do differently next time?

MODULE 3: OBSERVATION- LABOUR AND DELIVERY

Logistics of data collection on L&D ward

Position in the health facility: While the labour and delivery wards of all facilities are different, they are likely to be crowded with people and equipment, especially at the time of birth. It is vital that, whilst ensuring you are able to observe the delivery and clearly see the mother and baby, you are not obstructing the health care workers in their work or intimidating the mother. This will require judgement on your behalf and you may well be required to change position numerous times throughout the observation. Please always be aware of your positioning both in relation to the health care workers and the mother ensuring you will not obstruct care.

Interaction with mothers/health care workers: All of the data you are to be collecting must come from observation alone i.e. you should not collect any information via asking questions of the mother/family/health care workers and you should not refer to any records (registers, patient notes, ANC cards etc.). If you cannot collect the information via observation then you must enter "Don't know" on the app.

Golden Rules:

- 1. Do not talk to or ask questions of the mother/ family members/ health care workers attending the mother
- 2. If you did not observe the information then enter "don't know" in to the app, DO NOT try and collect it from elsewhere (e.g. looking at the notes/register or asking the mother/health care worker
- 3. If a mother/family member/ health care worker tries to talk to you about anything to do with the study you should reply with "I am sorry I am not able to discuss any further" and refer them to your supervisor for further details.

The L&D ward

Add facility specific L&D ward information. For example:

- Number of beds
- Average number of deliveries per day
- Average number of midwives/doctors working per shift

If available- add a sketch/map of the L&D ward with its rough layout.

Data to be collected

As an observer on the labour and delivery ward you will be collecting data through labour, birth, and the immediate postpartum period. Your observation will commence from admission to labour and delivery ward/operating theatre and conclude when mother and baby are discharged to a different ward. While it is important to make sure you are present and observing the mother at various stages throughout the labour and birth, you do not need to be present the entire first stage. It is good practise to check in on the mother every 15 minutes to ensure you are aware of the stage of progression of the labour and do not miss any periods during which you should be collecting data. If you are observing more than one woman at a time it is important that you are aware of the progression of each woman's labour, ensuring that you are present to collect the following data:

1. L&D 1st & 2nd stage

- Date
- Time
- Place or observation
- Checking and recording of fetal heart sound
- Checking of liquor
- Augmentation of labour with oxytocin

- Place
- Date
- Time
- Mode of birth
- Number of babies (singleton/multiple)
- Use of partograph

2. Newborn

- Condition of baby at birth
- Sex of baby
- Whether or not the baby is crying
- Whether or not the baby is breathing
- Heart rate checked
- Cord clamped/tied
- Cord cut

- Anything applied to cord, if so- what?
- Baby dried
- Baby placed skin to skin
- Baby wrapped, if so- what in?
- Breastfeeding initiated
- Birth weight
- Type of scales used for birth weight

3. Resuscitation

- Whether or not resus required
- Baby moved to the resus table
- HW calls for help
- Stimulation administered
- Stimulation outcome
- Mouth, throat, noses checked for secretion?
- Suction used and type of suction
- Bag and mask ventilation
- Correct mask position for ventilation?
- Correct mask size for ventilation?
- Appropriate head position
- Time of bag and mask inflation starts

- Time of bag and mask inflation ends
- Inflations of bag and mask per 30 seconds
- Oxygen given
- Endotracheal Intubation
- Chest compressions
- Drug (???)
- Additional resus actions
- Time resus stops
- Mother/family counselled
- Number of health workers involved in resus
- Outcome of resus

4. 3rd stage and PPH

- Uterotonic is given- type and route
- Time of administration of uterotonic
- Time placenta delivered
- Placenta checked
- PPH blood loss
- HW counsels mother
- HW counsels family
- Vital signs monitored
- Input-output monitor
- Catheter before PPH
- Catheter after PPH
- IV channel established before PPH
- IV channel established after PPH
- Blood grouping and cross matching done

- Blood sent for grouping and cross matching
- Blood transfusion
- Uterotonic for PPH type, route
- Antibiotic given
- Analgesia type and route
- Manual removal of placenta
- Hand washing for MRP
- Sterile gloves for MRP
- Bimanual compression
- Balloon tamponade
- Non Pneumatic Anti-Shock Garment (NASG)
- Time PPH management stops
- Number of health workers involved
- PPH management outcome

5. Discharge and outcome from L&D

- Date of discharge
- Time of discharge
- Mother's condition at discharge
- Mother discharged to
- Baby condition at discharge
- Baby discharged/transferred to
- Status of the observation
- If partially completed, why
- Any incidents to report

GROUP ACTIVITY I: Review of observation checklist and discussion on key clinical issues

Handout: Variable Dictionary (in App or print out)

Objective: To allow L&D observers to review the variable dictionary and identify and discuss any clinical procedures that are different from their current routine practise.

Time: 45 minutes

Instructions:

Please split into groups of 3-4 people and review the Variable Dictionary. Please identify and discuss:

- 4. Any areas of practise that differ from your own
- 5. Any questions
- 6. Any clinical content you are unsure of
- 7. Possible solutions for any issues you think may arise

Content and flow of L&D app

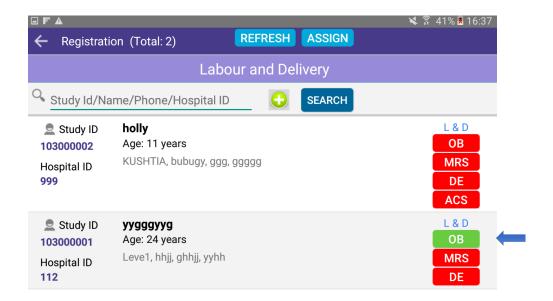
When you are signed into the app and click on the "Labour & Delivery Observation" button, you will see a list of the women on the ward who are assigned to you for observation. It is your responsibility to ensure you monitor the progress of women sufficiently to ensure you are present during events requiring your observation.

Identifying the woman for observation

When it is time for you to observe a delivery you should click on the study ID of the woman from the list of women you are allocated for observation. This will take you to the L&D checklist to be completed for this woman as per instructions below.

To identify the mother and make sure you select the correct mother from the list for observation you should match the mother and the entry on the app by the following information:

- Mother's name (3 names)
- Mothers address
- Mother's date of birth (Age)

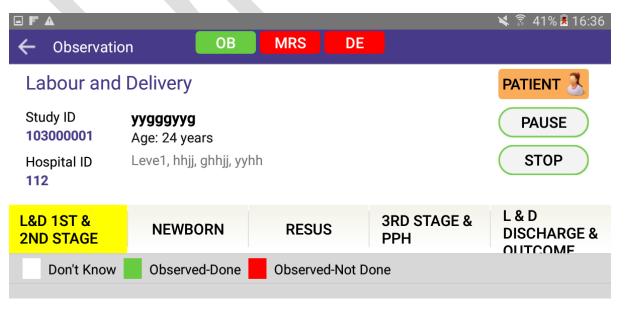


Entering data

The app is structured in a sequence that reflects the expected order of events during labour and delivery, of course the delivery may not proceed exactly as expected and you will likely need to switch between screens using the tabs and enter data in a different order than it is presented in the app. The app is set up so that you can do this easily. There are four tabs for data entry and they occur in the following order:

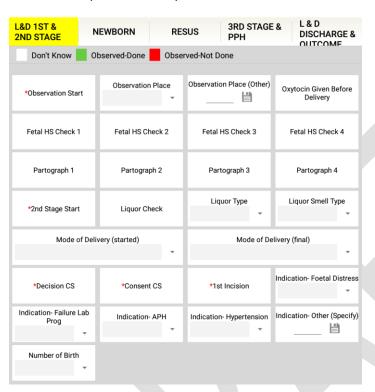
- 1. L&D 1st & 2nd stage
- 2. Newborn
- 3. Resus
- 4. 3rd stage & PPH
- 5. L&D discharge & outcome

You can easily switch between tabs at any time.

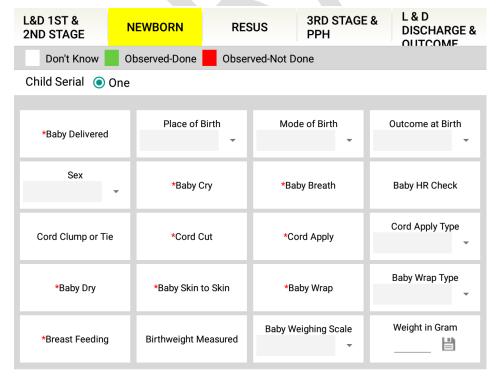


Tab 1: "L&D 1st & 2nd Stage"

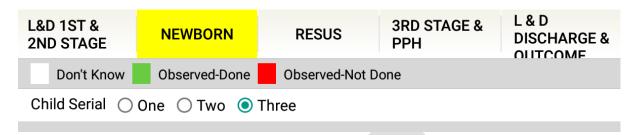
In to this tab you will enter the data relevant to the first and second stages of labour, up until and including the delivery of the baby. The order of the variables is to reflect the usual order of events during the first stage of labour, but of course not all deliveries will follow this order and so you can enter information in a different order. Try and enter information immediately as the event is observed or as soon as possible after you have observed the event.



Tab 2: "Newborn"



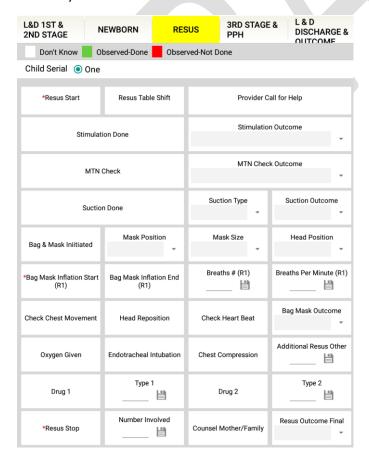
Each Newborn tab should contain information on one baby only. If on the "L&D 1st & 2nd Stage" tab you have entered that there has been more than one baby born then on the "Newborn" tab you will see at the top the option to select baby number 1, 2, or 3, this enables you to complete the "Newborn" tab two/three times- once for each baby. It does not matter how you decide which is baby 1, 2 or 3 as long as you know which baby is which and enter the data separately. If the baby or one of the babies is not breathing you next proceed to the tab 3, "Resus" and enter the information for that baby.



N.B. If there was only one baby born and you entered on the L&D 1st & 2nd Stage tab that "number f Birth" was 1 then this option to enter the serial number for the baby will not appear.

Tab 3: "Resus"

This tab is only to be completed for babies which you have stated on the "Newborn" tab are not crying/breathing. If the baby is crying/breathing and you have entered this data on that tab then the questions on the "Resus" tab will not be available to you as you do not need to collect this information. If on the "Newborn" tab you have entered for a baby that it is not crying/breathing then you will come straight to the "Resus" tab and enter the information on that baby and the resuscitation process for that baby.



If bag and mask is used on the baby you are required to enter information on the timing and number of inflations of the bag and mask for the first cycle for bag and mask inflations. See the variable dictionary for the variables and their order. Once you have selected the "Bag Mask Inflation Start" variable the app will automatically start timing until you enter the variable "Bag Mask Inflation End of Timed Cycle". During this first cycle you need to count the number of inflations of bag and mask that you observe and then enter this number in to the text box "Inflations of Bag & Mask #". The app will then calculate the rate of bag and mask inflation over the period and it will automatically calculate and complete the variable "Inflations Of Bag & Mask Per Minute".

One of the last variables on this tab is the variable "Number involved", this variable asks you to enter the number of health care workers involved in the resuscitation of the baby. This requires you to make a judgement, for example if there are four medical students observing the resuscitation but not actively involved you should not count them.

Once your observation of the resuscitation is complete please ensure that you return to the "Newborn" tab to enter any remaining information such as birthweight etc.

Tab 4: "3rd stage and PPH"

This tab provides space to enter data on the 3rd stage of labour. This first variables (placenta delivered, placenta checked, and bleeding after delivery) are to be completed for <u>all deliveries</u>. If you enter that the mother experienced normal bleeding then you do not need to enter any further data on this tab for PPH and the rest of the variables on the tab will be blocked. You can then move on to tab 5, "L&D Outcome & discharge".

One of the last variables on this tab is the variable "Number involved", this variable asks you to enter the number of health care workers involved in the management of a maternal PPH/retained placenta. This requires you to make a judgement, for example if there are four medical students observing the resuscitation but not actively involved you should not count them.

If the mother does experience either PPH or retained/partially retained placenta then you should continue to enter data for the PPH/retained placenta variables on the tab. See variable dictionary for an explanation of each of these.



Tab 5: "L&D Outcome & discharge"

Once the labour and delivery is over and the mother and baby are leaving the L&D ward you complete tab 5 with the necessary information.

Observing simultaneously occurring events

It is possible that two events which you should observe occur at the same time making it hard to observe them both. This will be made even harder if the two events are happening in different places e.g. a mother experiencing a PPH while her baby is being resuscitated. While cases like these will be rare it is important you react quickly to ensure not too much data is missed. You should alert your supervisor to the situation and ask them to help you with the observation- for example they can observe the resuscitation while you continue to observe the mother during PPH, or vice-versa. If the supervisor is not available for the observation they will ask the tracking officer to assign another observer to the patient. You and the second person for the observation should then coordinate between you to ensure that as much of the required observation is carried out.

If you are unable to get another team member to help you with the observation and so the observation is partially incomplete you can enter this information on tab 5 "L&D Outcome & Discharge"; where it asks "What is the status of the observation" and you can provide more information in the following variables, see data dictionary.

Clinical Incidence reporting

Final status of this observation		
6.	What is the status of the observation?	CompletePartially incompleteTotally incomplete
8.	Do you want to report any incident?	
	If yes, then what is the incident?	
9.	Write down the serial number of t incident form.	he
SAVE -> CONTINUE		

If you have to stop/pause the observation due to observing a life threatening event without appropriate response you should report the incidence on this tab. You will be asked to enter a short description of the incident and then to enter the ID number that is printed on the top of the paper "Clinical incidence form". Enter this ID number and then complete the form (see Annex 2) and submit directly to your supervisor.

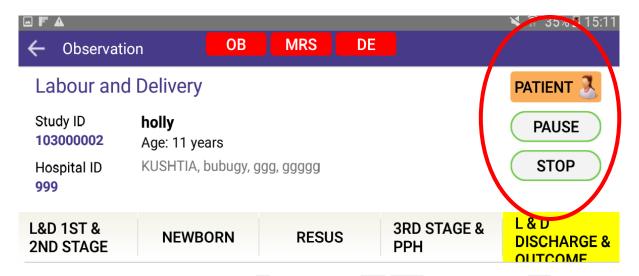
"STOP" and "PAUSE" buttons

Pause button: you should use this button if you want to pause the observation for a period of time and restart it later. This may be due to needing a washroom break, the mother's labour not progressing as fast as you had anticipated or many other reasons.

Stop button: the stop button is to be pressed when you have to stop an observation before it has ended and you will not be restarting it later. There will be a pop up box that appears when you press this button and you will be asked for more information as to why the observation has to be prematurely stopped.

"PATIENT" button

If you are observing more than one mother at a time and you need to switch between mothers you can use the "patient button" at the top right hand corner of the screen. When you press this button you will be shown a list of other mothers who are assigned to you and you can select one from this list to start observing a different mother.



Essential variables

You should be making every effort to collect information for every variable in the L&D checklist, the aim is to have as few "Don't know" answers as possible. However sometimes you will have missed an event and so have missing data that will be entered as "Don't know". It is important to note that on each tab there is one variable for which you must enter data, i.e. the app won't let you leave it as "don't know" for this variable. This means you must have observed whether or not the event took place and you must enter "didn't happen" or "observed". If you try to save and close the L&D ward checklist for a women but you haven't entered information for each of the essential variables, a warning box will pop up informing you which essential variables are missing and you will have to go back and enter the data for those variables. You are able to move between tabs in the L&D checklist without this warning box appearing, it is only when you leave the entire checklist that this box will appear.

The essential variables on each tab are:

- L&D 1st & 2nd stage tab: delivery type
- Newborn tab: baby condition
- Resus tab: bag and mask ventilation initiated
- 3rd stage and PPH tab: uterotonic after delivery
- L&D discharge and outcome: baby discharged to

Recap on response to life threatening events

• When should I intervene?

During any life-threatening scenario where local staff are not taking the appropriate action, or when instructed by a clinical alert.

What should I do?

You should follow the procedure algorithm for these events (chapter 8), instructions provided by a clinical alert will direct you to the correct part of the algorithm.

What is a clinical incident form?

This is a mandatory form that should be completed with support from your supervisor and in all cases indicated by the procedure algorithm.

• What next?

Your supervisor will contact the named responsible from hospital management team and ensure they have a copy of the clinical incident form. This form will also be used as part of incident review management at facility, country and international level.

GROUP ACTIVITY J: Practise with simulation/video

Handout: Tablets with the L&D checklist open

Objective: To give trainees the opportunity to practice completing the L&D checklist on the tablet using observation of either a simulation or video of a birth.

Time: 120 minutes

Trainee Materials: Stop watch and tablet with the L&D checklist open

Instructions:

Using the L&D checklist on the tablet enter the relevant data from the video/simulation of a birth

After a group discussion shall be help on:

- What was the experience of observing labour and delivery?
- What was the experience of using the tablet to collect data on labour and delivery?
- What was difficult?
- What was easy?
- What would you do differently next time?

MODULE 4: OBSERVATION – RESUSCITATION VIDEO (NEPAL) VIDEO OBSERVATIONS

Background

Video filming helps in continuous monitoring of resuscitation procedure. Several studies¹ in high-income settings have used video filming as a gold standard measure to evaluate the change in the health workers' competency and performance on neonatal resuscitation. In Nepal, a hospital-based study was conducted to evaluate the change in health workers' performance both in simulated and clinical settings as well as perinatal outcome after implementation of Helping Babies Breathe Quality Improvement Cycle (HBB QIC). Video filming of the neonatal resuscitation was done to evaluate the change in the health workers' performance after the introduction of HBB QIC.

Objective of the session

After the completion of the session, the participants will be able to:

- explain the functions of CCTV camera
- understand the process and be able to extra observation data from filmed clinical events
- ensure the overall functioning of CCTV video recording

Teaching Methods

- Presentation and discussion
- Demonstration (one video)??
- simulation exercise (5 Cases)
- data entry exercise (5 Cases)

Participants

Video Record Observer (VRO) with qualification of Diploma in IT-2

Part 1- What is CCTV camera?

Duration: 30 min

Closed-Circuit television (CCTV) is also known as video surveillance, is the use of video cameras to transmit a signal to a specific place, on a limited set of monitors.

CCTV surveillance of the resuscitation table should be installed to closely monitor the condition of the newborn and evaluate the procedures done by health service providers to help newborns breathe before it is too late.

Materials required in CCTV Cameras installation

- CCTV Cameras
- Monitor
- Wire
- Recorder
- Hard drive
- Mouse

Part 2-How does the CCTV camera function?

Duration: 2 hour 30 min

Neonatal resuscitation is recorded using a CCTV camera for video monitoring, consisting of 1 fixed camera installed in the overhead radiant warmer in all the delivery units. The video recorder is permanently mounted 1 meter above the resuscitation table and zoomed so as to provide a field of view that includes the entire table with hands of the resuscitation team. The obstetric procedures and faces of the resuscitation team should not be visible. The camera should provide a 24-hour recording without audio and should be switched on automatically to record the procedure with any movement in the table. The video recorder should display a continuous date and time of the recorded resuscitation image-allowing timing of performed procedures to the nearest second. All the recorded videos should be stored in a hard drive with a monitor.

To record the resuscitation procedure, an observation sheet has been developed which consists of time of delivery; time when the baby was brought to the table; whether the baby was crying or not; duration of suction, stimulation, bag-and-mask ventilation and any other procedure was done.

Part 3- Ensure the overall functioning of CCTV video recording

Duration: 30 min

- Check the quality of video whether the video is clear or not.
- Ensure the video is being recorded
- Keep the back up by extracting the record everyday in the hard drive safely.
- Clean the lens time to time for better quality of video.
- Be sure to keep video records safely and maintain confidentiality
- Share the video records only to authorized person in team

Definition of Procedures to be monitored via film observation

While observing the neonatal resuscitation videos you need to be familiar with a few key interventions that you are likely to observe while watching the videos. Definitions of these interventions can be found in the Variable Dictionary. These variables are:

- Stimulation by rubbing the back vigorously
- Suctioning nose/mouth
- Bag and Mask ventilation
- Oxygen Supply
- Endotracheal Intubation
- Chest compression
- Gasping

MODULE 5: OBSERVATION- KMC

1. Logistics of data collection

Position on the KMC ward: It is important that you observe the mothers/caregivers and baby closely enough that you can collect the required information, while at the same time ensuring maximum level of comfort and ease for mothers/caregivers and baby, i.e. not crowding them. Please also ensure that you are not obstructing the health care workers during a consultation or treatment at any stage of observation.

Interaction with mother/health care workers: All of the data you are going to be collecting must come from observation alone i.e. you should not collect any information via asking questions of the mother/family/health care workers and you should not refer to any records (registers, patient notes, ANC cards etc.). If you cannot collect the information via observation then you must enter "Don't know" on the app.

Golden Rules:

- 4. Do not talk to or ask questions of the mother/ family members/ health care workers on the KMC ward
- 5. If you did not observe the information then enter "don't know" in to the app, DO NOT try and collect it from elsewhere (e.g. looking at the notes/register or asking the mother/health care worker)
- 6. If a mother/family member/ health care worker tries to talk to you about anything to do with the study you should reply with "I am sorry I am not able to discuss any further" and refer them to your supervisor for further details

NB. The only exception to these rules is that you may ask the health worker for the name and date of birth of the baby in order to match he baby to the correct baby in the app. More details are given below.

KMC ward:

Add facility specific KMC ward information. For example:

- Number of beds
- Average number of KMC cases received per day
- Average duration of stay on KMC ward
- Maximum length of stay on the KMC ward
- Average number of midwives/doctors working per shift on KMC ward

If available- add a sketch/map of the L&D ward with its rough layout.

2. Data to be collected

It is important that you are present on the KMC ward during the mother/family member and baby's first hour on the ward as you will be observing <u>initiation of KMC</u>, after observing this you will need to check in on the baby **every hour** to observe and enter in to the app information on <u>KMC position</u> and

<u>feeding practises</u>. The <u>other treatment</u> section will only be applicable to sick babies receiving additional treatment in the KMC ward. When it is time for the baby to leave the KMC ward and they are being discharged you will then enter information on the <u>KMC discharge outcomes</u>. The tabs in the app are designed to mirror this sequence of events, of course you will need to move between the tabs depending on the type of information you have to enter and the sequence of events.

The five tabs in the KMC app are as follows, with the following variables present on each tab:

1. KMC initiation

- KMC initiation started
- Date of KM initiation
- Time of KM initiation
- Conversation about KMC
- Baby in KMC position
- Baby wearing hat
- Baby vertical

2. KMC Position

- Date of observation
- Time of observation
- Baby in KMC position
- KMC done by
- Baby vertical
- Baby in skin to skin contact
- Legs flexed in frog position

3. KMC Feeding

- Date of observation
- Time of observation
- Baby being cup fed
- If cup fed- by who and how much

4. "Other Treatment"

- Other supportive care being given
- Antibiotics being given
- If yes- name antibiotics

5. Discharge Outcome

- Baby's condition at discharge
- Date of discharge from KMC ward
- Time of discharge from KMC ward
- Baby's weight at discharge
- Baby discharged/transferred to
- Mother's condition at discharge from KMC ward
- Mother discharged to
- Status of observation
- Incidents to report

- Baby in skin to skin contact
- Legs flexed in frog position
- Cheek of baby in contact with mother's chest
- Baby wearing a nappy/diaper
- Baby fixed with cloth/special wrap/other
- Cheek of baby in contact with mother's chest
- Baby fixed to chest of mother
- Baby wearing a nappy/diaper
- Baby wearing a cap/bonnet
- Baby is wearing socks
- Baby being nasogastric fed
- If nasogastric fed- by who and how much
- Baby sucking at breast
 - Other treatments being given
 - If yes- name treatment
- Oxygen being given
- If yes- describe the incident and note incident form number

ACTIVITY K: Review of variable dictionary and clinical summary

Objective: To allow the group to review the variable dictionary and identify and discuss any clinical procedures that are different from their current routine practise.

Time: 45 minutes Instructions:

Please split into groups of 3-4 people and review the KMC sections of the Variable Dictionary. Please identify and discuss:

- 8. Any areas of practise that differ from your own
- 9. Any questions
- 10. Any clinical content you are unsure of
- 11. Possible solutions for any issues you think may arise

3. Content and flow of checklist

Sign in to the app with your user name and password. Click on the blue "KMC observation" button to get to a list of patients on the KMC ward.

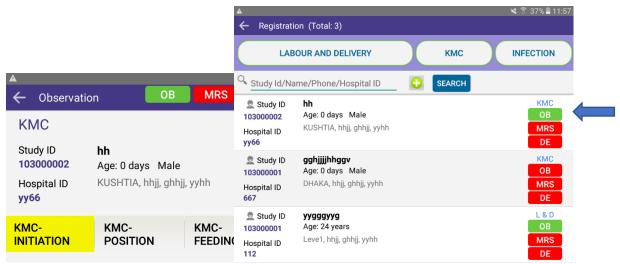
Identifying the woman for observation

When it is time for you to observe a baby in KMC you should identify the correct baby for observation from the list available to you on your app.

To identify the baby and make sure you select the correct baby from the list for observation you should match the baby and the entry on the app by the following information:

- Baby's name
- Baby's date of birth

You can get this information on the baby by asking the health worker present on the KMC ward. Once you have selected the mother/family member and baby for KMC observation click on the button "OB" to begin the observation of KMC. This will take you to the KMC checklist to be completed for this baby as per instructions below.



While observing the mother/caregiver and baby during their first hour on the KMC ward you should observe the initiation of KMC and enter this information on the first tab, "KMC initiation".

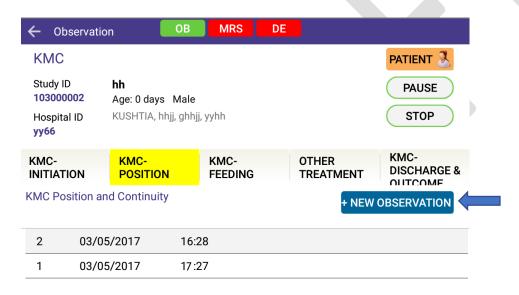
Tab 1 "KMC initiation"

For KMC initiation, the tablet application will automatically record the date and time of initiation. For observation of initiation on the initiation tab, variables 4-11 requires you to check whether each of the requirements for an appropriate initiation are being fulfilled. For details on the variables please refer to the variable dictionary. For observation point 12, you are required to observe the material being used for to fix the baby in KMC position and touch the appropriate answer options, only one answer can be selected. If you touch "Others", please type the material that is being used in the text box that will appear. When complete, touch the save and continue button at the bottom of the screen.

Tab 2: "KMC Position"

You should be observing the position of the baby in KMC <u>each hour during your shift</u>. Use your stop watch to keep track of the time and make sure that you complete a new observation each hour. When it is time to make an observation on KMC position click the "new observation" button. This will take you to a new record for observation of KMC position. If the baby is in KMC at the time of observation, touch yes and record the person who is providing the KMC. The next stage records the baby's position at the time of observation. Check the boxes only if you can observe and agree to each of the variables mentioned from 5(a) to 5(h). For detailed explanation of the observation checklist refer to the variable dictionary. Touch the save and continue button when complete.

If the baby is not in KMC, check no and then touch the "save and continue" button.



In order to observe and record feeding practices, touch the KMC-feeding tab and touch the new observation button. Similar to observation of KMC position, there will be <a href="https://hourly.com/hourly-observation-com/hourly-obs

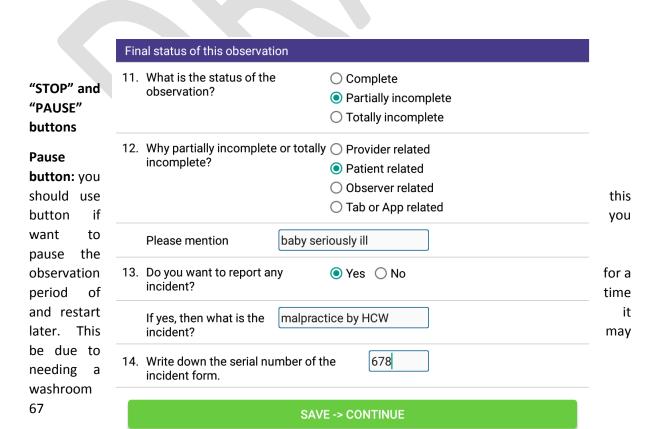
Tab 4: "Other treatments"

For sick babies receiving any other treatment at the KMC ward, you need to complete the other treatments tab of the observation application. If the baby is not receiving any supportive care, select no and then "save and continue". If the baby is receiving other supportive care you will need to observe the drug names and select the appropriate answers from the list provided in the drop down menus or enter the information in to the text boxes.

Tab 5 "KMC discharge & outcome"

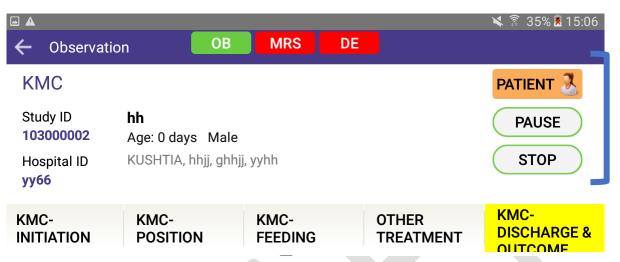
The final tab of the app contains information on discharge and outcome. Observe the condition of the mother and baby at discharge and select the appropriate options. If the baby has died you should select a "neonatal death", the questions asking for information on the baby at discharge will then disappear. If the baby is alive at discharge enter the date and time of discharge, baby's weight at discharge and where they are discharged/transferred to.

On this tab is where you should also note the final status of the observation- whether or not it is complete, partially complete or totally incomplete. If the observation is not complete you will be asked to select the reason for the incomplete observation from the options; provider/patient/observer/tab or app related. You can also record on this tab whether or not you have an incident to report, if so you are asked to enter a short description of the incident and the ID number of the paper-based incident form. You should then complete the incidence form and hand it to the shift supervisor.



break or many other reasons. When you return to the observation you should press the "Resume" button which you will see has appeared.

Stop button: the stop button is to be pressed when you have to stop an observation before it has ended and you will not be restarting it later. There will be a pop up box that appears when you press this button and you will be asked for more information as to why the observation has to be prematurely stopped.



"PATIENT" button

If you are observing more than one baby on the KMC ward at the same time and you need to switch between babies you can use the patient button at the top right hand corner of the screen. When you press this button you will be shown a list of other babies who are assigned to you and you can select one from this list to start an observation on another baby.

4. Recap on response to life threatening events

When should I intervene?

During any life-threatening scenario where local staff are not taking the appropriate action, or when instructed by a clinical alert.

What should I do?

You should follow the procedure algorithm for these events (chapter 8), instructions provided by a clinical alert will direct you to the correct part of the algorithm.

• What is a clinical incident form?

This is a mandatory form that should be completed with support from your supervisor and in all cases indicated by the procedure algorithm.

What next?

Your supervisor will contact the named responsible from hospital management team and ensure they have a copy of the clinical incident form. This form will also be used as part of incident review management at facility, country and international level.

ACTIVITY I: PRACTISE WITH SIMULATION

Handout: Tablet with KMC section open

Objective: To give trainees the opportunity to practice completing the KMC checklist on the tablet using a simulation of a baby and mother carrying out KMC.

Time: 90 minutes

Materials: a NeoNatalie, someone to play the mother, a cloth to wrap the baby in KMC positions, feeding cap or nasogastric tube if stimulation does not involve breast feeding.

Instructions:

Using the KMC checklist on the tablet enter the relevant data from the simulation of a mother and baby in the KMC ward

Hold group discussion:

- What was the experience of observing KMC?
- What was the experience of using the tablet to collect data on KMC?
- What was difficult?
- What was easy?
- What would you do differently next time?

MODULE 6: DATA EXTRACTION AND VERIFICATION

REGISTER DATA EXTRACTION AND RECORD VERIFICATION

1. Introduction and General Instruction:

Data collectors in the role of register data extractors and case note verifiers have the following two broad objectives:

- Register data extraction: you are responsible for extraction of the required data from the registers
 (and no other source) and recording the information that is available in the relevant extraction
 form in the app in both the L&D ward and KMC ward
- Case note verification: following the separate case definitions for ACS and neonatal infection (see below) collect the relevant data available from patient records, lab reports and other sources and enter in to the relevant verification form in the app

General rules to follow when extracting data from registers or verifying case notes:

- In case you are unable to read what is written on the register or the forms, call for a second review by your supervisor
- If both of you fail to read the information then check the button on the app "Not Readable"
- If the required data is not in the document you are reviewing then check the button on the app "Not Recorded", do not leave the variable blank/record zero/guess the variable.

2. Extraction of Data from LD and/or KMC Registers

Steps to follow for Data Extraction:

- Each day check your tablet for a list of women/newborns who have been observed either in L&D ward or KMC ward, or both
- Identify the mother/baby ID and place of observation to know which register is to be reviewed, (for example, if the mother was observed in the L&D ward/operating theatre then you need to find and review the L&D ward register, if the baby was observed on the KMC ward then you need to go and review the KMC register).
- Match each observation case with study ID/admission number in the respective registers to find the entry in the L&D/KMC register from which you are to extract the data
- Using this entry in the register complete the extraction form on your tablet with all of the
 information that is available in the register and abiding by the general rules listed above. Do
 not consult any other data sources, you should only extract data from the register
- The sequence of variable will not always be exactly the same as your available registers. Be careful you are entering the correct variable information in the correct section of the tablet.
- If information is not available in the register you are reviewing do not ask health workers or anyone else what the information is or where it may be recorded. Enter the information in to the tablet as "not recorded".

3. ACS and Neonatal Infection Case Note Verification

General instructions

• Strictly limit collection of information to what is written in the following records:

- Patient chart
- Drug chart
- Lab report
- Nursing report
- Case record form
- EMOC register
- If the required information is not available in one of the above data sources, do not refer to any other mean for e.g. consultation with the patient/attendants/health workers for information

Verification of ACS

• **Selection criteria:** Each day check your tablet and the list of women who were observed during L&D to identify those women who meet the following criteria:

Inclusion criteria:

Mother consented to data collection and birth was observed

AND, at minimum one, of the following:

- Mother admitted with gestational age ≤ 34 completed weeks
- Previous history of threatened preterm labour during this pregnancy
- Using the ID/admission number/IP registration number for this women, find her relevant notes to be reviewed as part of data verification
- Review patient chart, drug chart, nursing report, case record form/EMOC register (Bangladesh) to verify diagnosis and treatment of preterm pregnancy with ACS
- Enter the information that is available in to the verification form on the tablet

Verification of neonatal infection notes

• **Selection criteria:** Each day visit the inpatient paediatric/neonatal ward and review the register for newly admitted patients who meet the following criteria:

Inclusion criteria:

- Baby on neonatal ward, recorded in register and main diagnosis is infection (sepsis/meningitis)
- Baby's age <28 days at time of admission

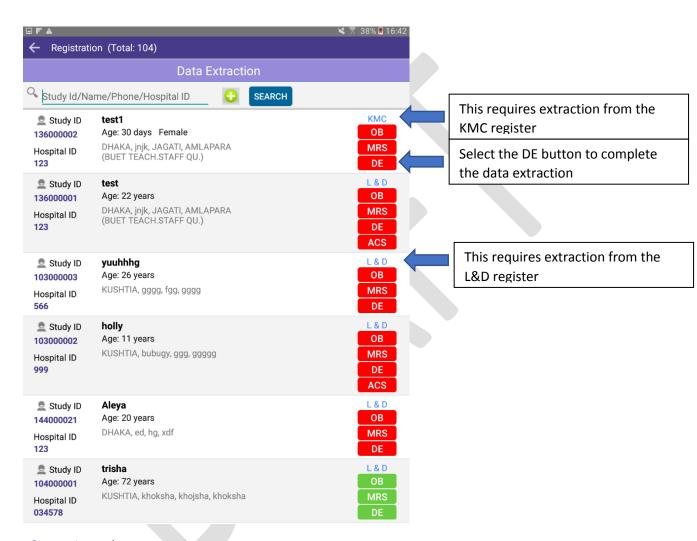
Exclusion criteria:

- Baby with congenital abnormality
- Neonatal encephalopathy/ severe asphyxia
- Preterm <34 weeks
- Weight at admission <2000 grams
- Identify the relevant documents for this patient: patient chart, drug chart, lab report, nursing report
- Complete the verification form on the app with the information available, following the general rules laid out above

4. Content and flow of the data extraction app

Open the app and log in with your log in details. Select the data extraction button, this will take you to a list of the different mothers/babies for which data extraction is required. You will be able to see from the right side of this list whether it is data extraction from the L&D or KMC register which is required. Identify the women/baby from the list as per instructions above and go to the data extraction for by pressing the "DE" button.





L&D register data extraction

When in the L&D register data extraction form you should proceed through all of the questions either entering the information that is recorded in the register, or recording "not readable" or "not recorded" as per the instructions above.

Question 6 ask about the "Number of Birth", if you enter One then questions on "Child 1" will appear to be completed from the register with the information on the baby. If you enter that the number of birth was Two you will see that the same questions are repeated- for "Child 1" and "Child 2", and likewise if you select Three- the questions will be duplicated for the three children.

6.	Number of Birth	○ One ● Two ○ Three
7. 0	Child 1	
	a. Mode of birth/ delivery	 Normal vaginal delivery Vaginal breech/ Vacuum Extraction/ Forceps (any) Elective /Emergency caesarean section Not readable Not recorded
	b. Date of Delivery	○ Not readable ○ Not recorded

Once you have completed all of the information and reached the end of the extraction form the final questions ask whether the extraction is complete, in the case that it is not complete you should enter the reason for this, adding more detail in the text box provided. Then press "Save and Continue" to return to the list of participants for data extraction.

12.	What is the final status of the data extraction for this patient	CompletePartially IncompleteTotally incomplete/Record not found	
13.	Why partially incomplete or totally incomplete?	Provider related Patient related Observer related Tab or App related	
14.	Please mention		
	SAVE -> CONTINUE		

KMC register data extraction

When in the KMC register data extraction form you should proceed through all of the questions either entering the information that is recorded in the register, or recording "not readable" or "not recorded" as per the instructions above.

Once you have completed all of the information and reached the end of the extraction form the final questions ask whether the extraction is complete, in the case that it is not complete you should enter the reason for this, adding more detail in the text box provided. Then press "Save and Continue" to return to the list of participants for data extraction.

GROUP ACTIVITY M: Practise data extraction from the registers

Objective: To give trainees the opportunity to practise using the data extraction forms, the app, and to familiarise themselves with the facility registers.

Time: 45 minutes

Handout / Materials: Tablets with app based data extraction tool installed (minimum 1 between 2), extracts from all the local relevant registers that data extractors will be expected to work from

Instructions:

Using the app based data extraction tool, please review the different register extracts and input the required data into the tablet.

Facilitators (and a member of the technical app support team) should be on hand to answer questions and support participants (suggest at least 1 facilitator to every 8 participants).

If time allows, hold group discussion:

- What was the experience of extracting data?
- What was the experience of using the tablet to collect the data?
- What was difficult?
- What was easy?
- What would you do differently next time?

GROUP ACTIVITY N: Practise using data verification tools for ACS & Newborn sepsis

Objective: To give trainees the opportunity to practise using the data verification tools for ACS and newborn sepsis, the app, and to familiarise themselves with the local patent records and registers.

Time: 45 minutes

Handout / Materials: Tablets with both app-based verification tools installed (minimum 1 between 2), sample patient records and register details (from individuals who have received ACS and or antibiotics treatment of newborn sepsis).

Instructions:

Using the app-based verification tool, please review the different patient records and input the required data into the tablet.

Facilitators (and a member of the technical app support team) should be on hand to answer questions and support participants (suggest at least 1 facilitator to every 8 participants).

If time allows, hold group discussion:

- What was the experience of verifying data?
- What was the experience of using the tablet to collect the data?
- What was difficult?
- What was easy?
- What would you do differently next time?

MODULE 7: MATERNAL RECALL SURVEY INTERVIEWING MOTHERS FOR MATERNAL RECALL SURVEY

Introduction to tool and purpose

The Maternal Pre-discharge Recall Survey is a data collection questinnaire that will be administered before women are discharged from the health facility. The **main aim of the MRS** is to determine the accuracy of a mother's recall of the practice and need to provide information about possible use in future surveys. Specifically, the survey will determine if mothers at discharge can accurately recall coverage and content of care of the interventions received.

The Survey will be administered to all women who consented to the study that were observed and/or whose notes were verified and whose newborn received at least one of the following newborn interventions: ACS, resuscitation, kangaroo mother care and neonatal infection. The Tracking Officer will assign women to you to interview through the tablet app before discharge.

The survey will take about 45-55 minutes to administer and consists of the following five sections and sub-sections:

Section	Title	Sub-sections Sub-sections
Section I	Cover sheet and maternal information	 Interviewer Details Maternal Details Current pregnancy history Perinatal data
Section II	L & D Recall survey	 ACS Uterotonics Essential newborn care (ENC) practices Newborn resuscitation Cord care and chlorhexidine cord cleansing
Section III	Treatment of neonatal infection	
Section IV	KMC	
Section V	Socio-economic status (SES)	
Section VI	Final status	

It is important to note that the interviewer will ask questions about **ALL** of the study interventions, in addition to maternal information, birth registration and socioeconomic status. Some questions ask about the specific intervention while other questions address aspects of quality of care, such as did a health worker explain to the woman what happened to her baby during resuscitation. The questionnaire has been developed so if a woman or her newborn did not receive an intervention the specific questions will not be asked.

Survey logistics

Location

The Maternal Recall Pre-discharge Survey is administered to mothers **PRIOR** to discharge in one of three locations:

Post-natal care ward

- KMC ward
- Neonatal/sepsis ward

It is recommended, if possible, to find a quieter private space with seating for both yourself and the mother to administer the interview. This will aim to ensure the maximum level of comfort with the mothers and that you are not interfering with the health care workers during a consultation or treatment or with the discharge process. Be sure to review specific layout diagrams of each hospital site with the supervisor so you are aware of the space available in each ward to administer the interview.

Timing

This survey is administered <u>PRIOR</u> to a woman's discharge from the facility and should allow enough of time for the mother to respond to all of the questions well before she leaves the hospital. The survey will take about 45-55 minutes so it is important that you liaise with the supervisor and tracking officer regarding the timing of the survey so the best time is planned and coordinated with each ward.

Role of interviewer

The interviewer occupies the central position in the survey because he/she collects information from respondents. Therefore, the success of the survey depends on the quality of each interviewer's work.

In general, the responsibilities of an interviewer include the following:

- Locating the women to be interviewed as assigned by the Tracking Officer
- Find a private area to conduct the survey
- Confirming re-consent to the survey and seeking consent to the Follow Up Study
- Interviewing all allocated women using the version of the Maternal Recall pre-discharge survey loaded on your tablet
- Checking completed interviews to be sure that all questions were asked and the comments section is completed as appropriate
- Follow the comments and prompts in the app and ensure all questions have a response
- Upon completion of the survey, thank the woman for her time and complete the newborn's head circumference measurement if mother consented to Follow Up Study (as applicable per site)

These tasks will be described in detail throughout this section of the manual.

Tracking Officers will assign questionnaires using the mobile app and handover information about the respondents to each interviewer verbally. After logging in, interviewers will be able to access the survey for the respondents who have been assigned.

The questionnaire in the mobile app is synchronised using available internet connection (3G, etc.). Questionnaires can be collected off-line. Interviewers don't need internet connection to collect the data if they have already downloaded the questionnaires assigned by the supervisors. Once interviewers have an opportunity to connect to the internet, they should synchronize their data. The completed questionnaire will be sent automatically to the supervisors.

Training of interviewers

Although some people are more adept at interviewing than others, one can become a good interviewer through experience. The training will consist of a combination of the classroom training and practical experience. Before each training session, the interviewers should study this manual carefully along with the questionnaires, writing down any questions they have. Ask questions at any time to avoid mistakes during actual interviews. Interviewers can learn a lot from each other by asking questions and talking about situations encountered in practice and actual interview situations.

Each interviewer will receive a package with the following materials.

- Maternal Pre-discharge Recall Survey Questionnaire. This is the paper version of the survey programmed on the mobile tablet app.
- Kit bag with Follow up consent folder, visual prompt picture packet and objects
- Training Manual, with this module section and related annexes
- Tablet with the MRS data collection app

The interviewers will have these materials at the health facility during fieldwork.

During this training, the questionnaire sections, questions, and instructions will be discussed in detail. The interviewer will see and hear demonstration interviews conducted in front of the class as examples of the interviewing process. The interviewers will practice reading the questionnaire aloud to another person several times so that they may become comfortable with reading the questions aloud. The interviewers will also be asked to take part in role playing in which they practice by interviewing another trainee. The interviewers will be instructed how to enter the responses into an app in a mobile tablet.

The training will also include practice interviewing in which they will actually interview respondents in the health facility. The interviewers will be required to enter the data on the mobile tablet and perform checks just as they will do during the actual study. The app has been programmed to highlight missing fields. The interviewer must enter data for ALL fields in the maternal recall pre-discharge survey.

The training you receive as an interviewer does not end when the formal training period is completed. Each time a supervisor meets with you to discuss your work, your training is being continued. This is particularly important during the first few days of fieldwork. As you run into situations you did not cover in training, it will be helpful to discuss them with your supervisor. Other interviewers may be running into similar problems, so you can all benefit from each other's experiences.

Supervision of Interviewers

Training is a continuous process. Observation and supervision throughout the fieldwork are a part of the training and data collection process. Your team supervisor will play very important roles in continuing your training and in ensuring the quality of the data collected. They will:

- Spot-check some of the women selected for interviewing to be sure that you interviewed the correct women
- Review each questionnaire to be sure it is complete and consistent
- Observe some of your interviews to ensure that you are asking the questions in the right manner and recording the answers correctly
- Meet with you on a weekly basis to discuss performance
- Help you resolve any problems that you might have with finding the assigned women, understanding the questionnaire, or dealing with difficult respondents.

Conducting an interview

Successful interviewing is an art and should not be treated as a mechanical process. Each interview is a new source of information, so make it interesting and pleasant. The art of interviewing develops with practice but there are certain basic principles that are followed by every successful interviewer. In this section you will find a number of general guidelines on how to build rapport with a respondent and conduct a successful interview.

Building Rapport with the Respondent

The Tracking Officer will assign an interviewer to each woman for the Maternal Recall Pre-discharge survey.

As an interviewer, your first responsibility is to establish a good rapport with a respondent. At the beginning of an interview, you and the respondent are strangers to each other. The respondent's first impression of you will influence their willingness to cooperate with the survey. Be sure that your manner is friendly as you introduce yourself. Before you start to administer interviews in a ward, your supervisor will have informed the healthcare workers, who will in turn inform selected women on the ward that you will be coming to interview them. You will also be given an identification badge that states that you are working with ENAP Metrics facility-based study.

1. Make a good first impression

When you arrive at the ward, do your best to make the respondent feel at ease. With a few well-chosen words, you can put the respondent in the right frame of mind for the interview. Open the interview with a smile and greeting such as "good afternoon" and then proceed with your introduction.

2. Reconfirm the respondent(s) consent to be interviewed

You must reconfirm the respondent's informed consent for participation in the survey before you begin an interview. A special statement is included at the beginning of the Questionnaire. The statements explains that the woman previously gave informed consent to take part in this survey about her delivery experience before being discharged and asks if she still consents to taking part in this survey. You must ask this question and indicate accordingly before continuing the survey.

3. Always have a positive approach

Never adopt an apologetic manner, and do not use words such as "Are you too busy?" Such questions invite refusal before you start. Rather, tell the respondent, "I would like to ask you a few questions" or "I would like to talk with you for a few moments."

4. Assure confidentiality of responses

If the respondent is hesitant about responding to the interview or asks what the data will be used for, explain that the information you collect will remain confidential, no individual names will be used for any purpose, and all information will be grouped together to write a report.

Also, you should never mention other interviews or show completed questionnaires to the supervisor or field editor in front of a respondent or any other person.

5. Answer any questions from the respondent frankly

Before agreeing to be interviewed, the respondent may ask you some questions about the survey or how he or she was selected to be interviewed. Be direct and pleasant when you answer.

The respondent may also be concerned about the length of the interview. If they ask, tell respondents that the interview usually takes about 45-55 minutes. Indicate your willingness to return at another time if it is inconvenient for the respondent to answer questions then.

Respondents may ask questions or want to talk further about the topics you bring up during the interview, e.g. about specific occurrences that occurred during their hospital stay. It is important not

to interrupt the flow of the interview so tell them that you will be happy to answer their questions or to talk further after the interview.

If a respondent becomes distressed during an interview, please refer to the protocol for managing distress during a maternal interview, in Annex 21. For example, a woman might get emotional crying while answering certain questions, especially if a stillbirth or neonatal death, or might become angry about the care she received whilst at the hospital.

6. Interview the respondent alone

The presence of a third person during an interview can prevent you from getting frank, honest answers from a respondent. It is, therefore, very important that the individual interview be conducted privately and that all questions be answered by the respondent.

If other people are present, explain to the respondent that some of the questions are private and ask to interview the person in the best place for talking alone. Sometimes asking for privacy will make others more curious, so they will want to listen; you will have to be creative. Establishing privacy from the beginning will allow the respondent to be more attentive to your questions.

If it is impossible to get privacy, you may have to carry out the interview with the other people present. However, in such circumstances, it is important that you remember that:

- If there is more than one woman selected on the ward to be interviewed, you must not interview one in the presence of the other
- Extra effort should be made to gain privacy if the other person is of the opposite sex, particularly the husband.

In all cases where other individuals are present, separate yourself and the respondent from the others as much as possible.

Tips for Conducting the Interview

1. Be neutral throughout the interview.

Most people are polite and will tend to give answers that they think you want to hear. It is therefore very important that you remain absolutely neutral as you ask the questions. Never, either by the expression on your face or by the tone of your voice, allow the respondent to think that she has given the "right" or "wrong" answer to the question. Never appear to approve or disapprove of any of the respondent's replies.

The questions are all carefully worded to be neutral. They do not suggest that one answer is more likely or preferable to another answer. If you fail to read the complete question, you may destroy that neutrality. For example, if you only ask part of a question, the woman might be more likely to answer with a "YES." This would be what we call "leading question," which is why it is important to read the whole question as it is written.

If the respondent gives an ambiguous answer, try to probe in a neutral way, asking questions such as the following:

"Can you explain a little more?"

"I did not quite hear you; could you please tell me again?"

"There is no hurry. Take a moment to think about it."

2. Never suggest answers to the respondent and only record what the woman says.

If a respondent's answer is not relevant to a question, do not prompt him/her by saying something like "I suppose you mean that... Is that right?" In many cases, she will agree with your interpretation of her answer, even when that is not what she meant. Rather, you should probe in such a manner that the respondent herself comes up with the relevant answer. Only read out the list of coded answers to the respondent when indicated by the prompt "READ ANSWER CHOICES." For other questions do not read out the coded answers, even if she has trouble answering.

3. Do not change the wording or sequence of questions.

The wording of the questions and their sequence in the questionnaire must be maintained. If the respondent has not understood the question, you should repeat the question slowly and clearly. If there is still a problem, you may reword the question, being careful not to alter the meaning of the original question. Provide only the minimum information required to get an appropriate response.

4. Handle hesitant respondents tactfully.

There will be situations where the respondent simply says, "I don't know," gives an irrelevant answer, acts very bored or detached, or contradicts something they have already said. In these cases, you must try to re-interest them in the conversation. For example, if you sense that they are shy or afraid, try to remove their shyness or fear before asking the next question. Spend a few moments talking about things unrelated to the interview (for example, their town or village, the weather, their daily activities, etc.).

If the respondent is giving irrelevant or elaborate answers, do not stop them abruptly or rudely, but listen to what they have to say. Then try to steer them gently back to the original question. A good atmosphere must be maintained throughout the interview. The best atmosphere for an interview is one in which the respondent sees the interviewer as a friendly, sympathetic, and responsive person who does not intimidate them and to whom they can say anything without feeling shy or embarrassed. As indicated earlier, a major problem in gaining the respondent's confidence may be one of privacy. This problem can be prevented if you are able to obtain a private area in which to conduct the interview.

If the respondent is reluctant or unwilling to answer a question, explain once again that the same question is being asked of women in the facility who are part of the study and that the answers will all be merged together. If the respondent is still reluctant, simply note DON'T KNOW/DON'T REMEMBER and proceed as if nothing had happened. Remember, the respondent cannot be forced to give an answer and you can mark later in the notes that the respondent refused.

5. Do not form expectations.

You must not form expectations of the ability and knowledge of the respondent. For example, do not assume women who are less educated or illiterate do not know about their care at the facility.

6. Do not hurry the interview.

Ask the questions slowly to ensure the respondent understands what is being asked. After you have asked a question, pause and give the respondent time to think. If the respondent feels hurried or is not allowed to formulate their own opinion, they may respond with "I don't know" or give an inaccurate answer. If you feel the respondent is answering without thinking just to speed up the interview, say to the respondent, "There is no hurry. Your opinion is very important, so consider your answers carefully."

Language of the Interview

Local language will be used for all women to be interviewed. The questionnaires for Bangladesh, Nepal and Tanzania have been translated into Bengali, Nepali and Swahili respectively. The questionnaire is also available in English for all three countries.

There might be few cases in which respondents do not speak your language or English. In such cases the interview cannot be started. Indicate thank you to the woman, stop on app as indicated, record in interviewer's comments and notify your supervisor.

We will be practicing interviews in the agreed local language during training. However, there may be times when you will have to modify the wording of the questions to fit local dialects and culture. It is very important not to change the meaning of the question when you rephrase it or interpret it into another language.

GROUP ACTIVITY O: Mock interviews

ACTIVITY 0: Mock interviews

Objective: To have the opportunity to observe mock interviews to become more familiar with interview skills and building rapport with respondents

Time: 30 minutes

Trainee Materials: Paper version of the Maternal pre-discharge recall survey

Instructions:

PART 1

Trainers will complete mock interview for Survey section 1 (15 minutes) and section 5 (5 minutes).

PART 2

Discussion in plenary (10 minutes)

- How was the rapport between the interviewer and interviewee?
- What did you find worked well with the interview?
- What did you find didn't work about the interview?
- What do you think might be challenging in the health facility setting?
- What are your views about stillbirths and neonatal deaths?

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CONSENT, PROMPTS AND DATA TO BE COLLECTED

Survey informed re-consent

When women were admitted to the hospital, they consented to overall study, including the maternal recall pre-discharge survey. You must reconfirm the respondent's informed consent for participation in the survey before you begin an interview.

A special statement is included at the beginning of the Questionnaire. The statement explains that the woman previously gave informed consent to take part in this survey about her delivery experience before being discharged and asks if she still consents to taking part in this survey. You also can show her the Study's Admission Information form to remind her of the details. As indicated on the admission information and consent forms, you can assure the woman that her participation in the survey is

completely voluntary and that it is their right to refuse to answer any questions or stop the interview at any point.

You must obtain a woman's re-consent before she participates in the interview and indicate YES or NO accordingly before continuing the survey. If a woman refuses re-consent, stop the survey and thank her for her participation in the study.

ENAP Metrics Follow up information and informed consent forms

What is the ENAP metrics Follow Up study?

The ENAP metrics facility based Follow Up study is a follow-on study from this observational study where a cohort (group) of consenting mothers and their newborns will be followed up for a minimum of 2-years. The main aim of the Follow Up Study is to determine the developmental outcomes of infants at 2 years of age who received at least one of the following newborn interventions: antenatal corticosteroids, newborn resuscitation, kangaroo mother care and treatment for neonatal infection.

If IRB has been approved for the Follow Up study, read the Follow Up information and consent form and ask the woman to sign/thumb print the form if she consents for the Follow Up Study. All women who consent will be contacted on a monthly basis using the mobile number provided for brief call check ins. Screenings and assessments for the newborn will be administered at set intervals, with the first screening projected to take place at six months. Transport costs will be provided to the facility for the appointments.

If she consents, the newborn's head circumference measurement will be completed using a specific standard operating procedure and recording the mesaurement in the study's follow up app module following the end of the survey. See Annex 22 for Standard Operating Procedure for measuring a newborn's head circumference. All interviewers should be familiar with this SOP and be comfortable measuring a newborn's head circumference. All other necessary information will have already been gathered on the other data collection tools.

Who can give consent?

- All adult research participants (aged 18 years and above) must personally give informed consent.
- If the mother is under 18 years, an assent should be signed by the mother and consent obtained from the next of kin
- If the mother can't read or write, an impartial witness should sign the consent form and thumb print obtained from the mother
- Mothers should provide informed consent on behalf of participating infants.
- If the mother is unable to give informed consent in an emergency, consent may be obtained from her next of kin however, the mothers' consent should be obtained at nearest opportunity and takes precedence
- Mothers whose infants are residing around the study area and will be able to bring their children for follow up

Who can take consent?

Trained data collectors only.

How is consent obtained?

- 1. Written informed consent must be obtained using the official study consent forms (those that were agreed by the institutional review board (IRB) for this study).
- 2. Consent forms will be paper / electronic based in the tablet.

- 3. Consent forms should be in the local language together with the English translation
- 4. Read all parts of the consent form aloud to the participant
- 5. Allow sufficient time to provide additional information and answer any questions
- 6. Do not illicit consent using any duress or incentive
- 7. Ensure participant marks their response on form.
- 8. Ensure you indicate the participant's response on the tablet Follow Up question as indicated.

What do I do with the form after consent is given/not given?

Put the paper consent form once signed/thumb printed or not signed/thumb printed in the Follow Up study folder in your kit bag. When you return your kit bag at the end of every day, give the consent form folder to the supervisor. These forms will then be filed in paper form and a secured in locked cabinets.

In cases of stillbirth or neonatal death

You might interview a woman who had a stillbirth or neonatal death. This is a sensitive topic so it is very important to be aware of the condition of the baby prior to the interview. The Tracking Officer will handover the condition of the newborn when giving you the details of the mother to be interviewed.

The interview will only take about 10 minutes of the woman's time if the baby is dead as the woman will only answer a subset of the survey questions. This is indicated with pre-programmed skip patterns in the survey. You will familiarise yourself with this skip pattern during the training.

Please note the sympathetic introductory text on the mobile app if the baby is dead. This should be read aloud prior to administering the interview to the woman.

IF BABY IS DEAD, sympathetic introductory text: I am sorry about the loss of your baby and I understand that it is not easy to talk about this loss. Thank you for agreeing to take part in this survey. I will ask a few questions about your delivery experience. At any point if you need to take a break please let me know and you can also leave the interview at any time. These questions should take no more than 10 minutes of your time.

In cases of multiple births

In the case of multiple births, the survey will only refer to the first birth. The current condition of baby for the first birth should only be recorded and read the introductory text specific for multiple births:

IF MULTIPLE BIRTHS: I will ask you questions about the birth of your first baby only.

Verbal and visual prompts

Verbal prompts

Throughout the survey, you will see prompt text indicated in UPPER CASE for you to read silently to yourself and the actual text in lowercase to read aloud to the woman. This text has been agreed and helps to remind, cue or aid the woman's understanding of the question, such as rephrasing the question or explaining what is meant by specific terminology, such as "caesarean section."

You should note the text in UPPER CASE however do not read this text out loud. This text is meant to be read only by you silently to yourself to remind you either how to record the answer choice, if you need to read the answer choices or to use prompt text if needed etc.

See example from below for verbal prompts about the type of birth:

Section 1.4 Q27: Was the baby born by vaginal delivery, forceps, vacuum, assisted breech or caesarean section?

PROMPT FOR FORCEPS: that is, an instrument to help pull the baby out PROMPT FOR VACUUM: that is, suction to help pull the baby out? PROMPT FOR C SECTION: that is, did they cut your belly open to take the baby out? USE VISUAL PROMPTS AS NEEDED FOR FORCEPS AND VACUUM EXTRACTION

See examples from Mother's information section and Essential Newborn Care section about how to record the answer:

Section I.4 Q 39: When are you planning to get your birth certificate?

DEPENDING ON MOTHER'S ANSWER, WRITE ANSWER IN EITHER WEEKS OR MONTHS

Section II.3 Q 16a: How long after birth did you first put your baby to your breast? IF LESS THAN 1 HOUR, RECORD '01' HOURS; IF LESS THAN 24 HOURS, RECORD HOURS; OTHERWISE, RECORD DAYS

Verbal probes

There are three instances where a probe might be necessary. A probe is text that should be read aloud as necessary to facilitate the woman's understanding of the question to encourage her to say more in response to a question. This text has also been agreed so must only be used as stated.

See example below from Resuscitation section:

Section II.4 Q 20a: Was anything done to help your baby breathe? PROBE IF NECESSARY: that is, did anyone try to help your baby to breathe?

Visual prompts

Throughout the survey, if a question requires a visual prompt the text is noted in UPPER CASE. This typically refers to a picture however there are a few questions that ask for you to show the actual object, such as a device or medicine or form.

See examples below:

Visual prompt to show picture of bag and mask

Section II.4 Q 22: Did anyone use a plastic device to help your baby breathe?

PROMPT: SHOW PICTURE OF BAG AND MASK

Visual prompt to show tube of medicine (NOTE: Bangladesh and Nepal ONLY)

Q 28: What was applied to the cord? (Show tube)?

PROBE: Anything else?

INSTRUCTIONS: SHOW A TUBE OF CHLORHEXIDINE TO THE MOTHER

Visual prompt to show birth notification form

Section I.4 Q33: In addition to this notification, a baby should also receive birth certification. Did you receive this form? SHOW FORM

Kit bag

When you arrive to the facility, you will need to pick up a kit bag with a folder for Follow Up study informed consent forms and both the visual prompt picture booklet and the objects to use during every interview. The booklet of visual prompt pictures has been agreed to be used at the facility. The visual prompt objects, such as devices, medicines and birth registration and certificate forms, will be in your kit bag. The devices and medicine cannot be taken outside the facility so you will need to return/hand in the bag after every shift. This way it also will be available for another interviewer.

You need to check your kit bag at the beginning and end of every shift. The kit bag checklist is included in Annex 19 of this manual. If something is missing, inform your supervisor so it can be replaced. This is important so the survey is administered to every woman in a similar way.

Section	Sub-sections	Visual prompt pictures	Visual prompt devices, medicines or forms	
Section I: Cover sheet and	Interviewer Details	-		
maternal information	Maternal Details			
	Current pregnancy history	Q18: GA measurement for 1) last menstrual period 2) fundal height 3) ultrasound	Q22: stethoscope, fetoscope or pinard	
	Perinatal data	Q22: Listening to baby's heart rate with 1) doppler or other machine to hear fetal heart rate 2) any device where midwife listens with device such as stethoscope, fetoscope or pinard Q27: Mode of delivery 1) baby born using forceps 2) baby born using vacuum extraction Q31: Type of weighing scale 1) analogue scale 2) electronic digital scale	Q36: Birth notification form Q37: Birth certification form	
Section II: L & D Recall	ACS		Q04: Samples of ACS medicines	
survey	Uterotonics			
	Essential newborn care (ENC) practices	Q13: Skin to skin		
	Newborn resuscitation	Q22: Bag and mask		
	Cord care and chlorhexidine cord cleansing		Q28a: Tube of chlorhexidine (only Nepal and Bangladesh)	
Section III: Treatment of neonatal infection	Z=1, ===, 1===1, ====	* IF A WOMAN does not know the answ after given a prompt or probe indicate answer as usual as "Don't know/don		
Section IV: KMC			remember" and move onto the next	
Section V: Socio-economic status (SES)	-		question*	

Data to be collected

As an interviewer, you will be collecting data from women who consent **PRIOR** to their discharge from the facility. The survey asks questions about the woman's recall about her pregnancy history, her delivery experience and care for her newborn during her stay at the facility. It also asks information about other key areas included in the study, such as birth registration and socioeconomic questions.

Data to be collected through the interview includes the information as listed below in the following 6 sections and sub-sections. Also refer to Annex 23 for the paper version of the questionnaire and Annex 24 for the variable dictionary and explanations.

Section I: Cover sheet and maternal information

Interviewer to remind the woman that she consented to the survey and seek re-consent for the survey and consent to the ENAP metrics follow up study.

- 1. Interviewer Details
- Date of the interview
- Time of the interview
- Language used

Current condition of the baby (only first born if multiple births)

- 2. Maternal Details
- Woman's re-consent to the survey
- Woman's birth date and age
- Woman's address
- Woman's mobile number
- 3. Current pregnancy history
- Baby's due date
- Gestational age methods
- When she received her first antenatal care (in weeks or months)
- 4. Perinatal data
- Method for listening to the baby's heart rate during labour
- Condition of baby during labour
- Place, date and time of delivery
- Type of birth (vaginal delivery, forceps, vacuum, assisted breech or caesarean section)
- C-section time and reason (as appropriate)
- Baby's weight at birth
- Method of birth weight measurement
- Sex of baby

- Her husband or family member's mobile number
- Confirmation of the best way to contact her (Note: VERY important for follow up study)
- How many antenatal check-ups she received during her pregnancy
- Gestational age at time of birth
- Perceived size of baby (very large, larger than average, average, smaller than average, or very small)
- Birth complications
- Number of nights in hospital
- If birth notification and/or birth certificate form was received
- Woman's knowledge about how to get a birth certificate for her baby
- When she plans to get birth certificate
- Her concerns about getting a birth certificate

Section II: L & D Recall survey

- 1. ACS
- If her baby was born too soon or early
- If the woman was at risk of or in threatened preterm or premature labour
- If any medicine was given because baby was at risk of being born too early
- 2. Uterotonics
- If medicine was given immediately after delivery of baby
- Route and timing of medicine
- If health worker informed mother about medicine
- 3. Essential newborn care (ENC) practices

- If the woman was told the reason for the medicine
- Name of medicine
- Route and number of doses of the medicine
- When last dose was received before baby was born
- Name of medicine
- If the woman was told the reason for the medicine
- What was the reason for medicine

- If her baby was dried or wiped immediately after birth
- If her baby was placed on chest, naked against her skin
- Timing of skin to skin
- Where the baby was placed if not skin to skin
- 4. Newborn resuscitation
- If her baby cried after birth
- If her baby had trouble breathing after birth
- If her baby received help to breathe
- If her baby's back was rubbed or any other stimulation provided
- If bag and mask was used and for how long
- If a suction was used to clean her baby's airways
- 5. Cord care and chlorhexidine cord cleansing
- If anything was applied to stump of cord after it was cut
- What was applied to the cord
- Timing chlorhexidine was first applied and who applied it

- Timing of first bath
- If the mother breastfed
- Timing of and assistance with breastfeeding
- Alternative drinks other than breastmilk
- If other actions were taken to help the baby breathe
- If the baby was admitted to the neonatal ward
- If a health worker explained what happened to the baby
- What was the explanation of what happened
- Reason why treatment was applied to the stump
- If given medicine to take home

Section III: Treatment of neonatal infection

- If her baby was admitted to neonatal ward
- If she knows the baby's diagnosis and what it is
- Baby's type of infection
- Baby's weight at time of admission to unit
- If her baby had seizures and for how many days
- If her baby received injection/antibiotics, the name of medicine and how many days

- If she as antibiotics to take home
- If the baby received oxygen
- If diagnostics tests were completed and which ones
- If her baby received feeding support
- If her baby received phototherapy
- How long her baby was admitted to inpatient care
- If her baby was referred to another place or health facility
- Baby's weight at time of discharge

Section IV: KMC

- If baby born before the expected date of delivery or born too soon or too small and had extra care and help to stay warm and be able to feed
- Baby's weight at time of admission to unit
- If she was told about ways to help her baby

- If a health worker told her about KMC
- If her baby received KMC
- Who performed KMC
- Reasons for KMC
- KMC positioning
- KMC education
- Time baby in KMC position for last 24hours
- Reasons why baby was not in KMC position
- Feeding methods in last 24 hours
- Section V: Socio-economic status (SES)
 - Household items, specifying number of TVs owned
 - Type of fuel household uses for cooking
 - Main material of the floor
 - Main material of the walls
 - Main material of the roof
 - Number of rooms in household used for sleeping
 - Modes of transport owned
 - If member of household has a bank/cooperative or other savings account

- If she was told by health worker how to recognise if her baby was unwell
- What signs of the baby being unwell were discussed
- If she received pre-discharged counselling
- What was discussed in pre-discharge counselling
- Length of stay in the KMC section
- Baby's weight at time of discharge

Section VI: Final status

- Status of the observation
- Explanation if partially complete or incomplete

GROUP ACTIVITY P: Reading the survey

ACTIVITY P: Reading the survey

Objective: To provide the opportunity to practice reading the maternal recall pre-discharge survey to become familiar with the content and terminology

Time: 1 hour

Trainee Materials: Paper version of the Maternal recall pre-discharge survey, stop watch

Instructions:

PART 1

In groups of 2 people, take turns reading aloud the paper version of the survey for 25 minutes each. Practice reading each question accurately and slowly so your partner can understand. Remember to follow the verbal prompts! This part of the activity should take about 50 minutes to complete.

Discuss with your partner:

- What did you find easy about reading the survey?
- What felt more challenging about reading the survey?
- Do you understand the overall survey?
- Are there any questions that you don't understand?
- Are there any words that you are not able to pronounce?

PART 2

Share your answers and discuss in plenary as large group for 10 minutes

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CONTENT AND FLOW

Introduction to content and flow of survey

Maternal recall survey (MRS)

The survey is structured on the app in a sequence that reflects the order of events during a woman's stay at the facility followed by the socio-economic status section. It will be very important for you to review the survey to be familiar with the different sections, introductory text, skip patterns and verbal and visual prompts in the tablet app.

As mentioned in sections above, throughout the survey you will need to read aloud questions and prompt text in lower case. You should note the text in upper case however do not read this text out loud. You also will need your kit bag with you for the Follow up Study consent form folder, visual prompt pictures and actual devices/medicines/forms.

In the application installed in your tablets, when you login and touch "MATERNAL RECALL SURVEY" the list of women admitted to study will appear who need to be interviewed. The Tracking Officer will allocate



women to each interviewer who need to be interviewed on one of three wards: Post-natal care ward, KMC ward, and Neonatal ward/Sepsis ward.

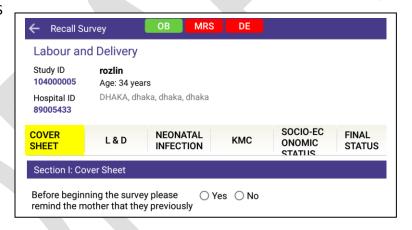
The "MRS" button will be red for each woman who needs to complete the maternal recall survey. The "MRS" button will be green if a woman has already received the MRS. The ward will be indicated in all capital blue text at the top right corner of each woman's data list

Once you have located the woman on the ward for the survey and confirmed a convenient time for survey, select the "MRS" red button to the right hand side of her name to start administering the survey when ready.



You will see the woman's name with hospital details at the top and below you will see the following 6 horizontal tabs:

- 1. COVERSHEET
- 2. L&D MATERNAL RECALL
- 3. INFXN
- 4. KMC
- 5. SES
- 6. FINAL STATUS



For each survey section and a few of the survey sub-sections, there is **introductory text** that should be read prior to starting the survey and before asking the questions in specific sections.

The survey has been structured so the **sequence of the questions** reflects the order of events during a woman's stay at the facility. If a question has a follow up related question, it typically will precede that question indicated as a sub-question. Typically, the sub-question becomes visible or stays hidden depending on the answer selected.

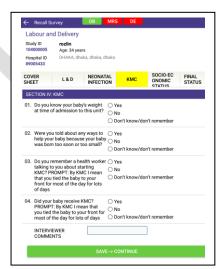
The answer selection options throughout the survey will vary. Some answer fields will be straightforward to select such as "Yes" "No" or "Don't know/don't remember" with one answer selection only and the drop-down calendar for dates. Other answer fields will will be alpha or numeric text boxes. This might require you to fill in the answers using numbers only, such as mobile numbers, or only with double digit numbers, such as weeks/months, while other answer fields will limit to alphabet text only or a combination of alphabet text and numbers. Some questions will allow for selection of multiple answers options, and for all answers if "Specify, other" is selected, please type the exact answer that was provided by the woman. The survey answer fields have a type character limit of 100 – this should be enough space to enter the woman's answer. REMEMBER YOU MUST SELECT AN ANSWER OPTION FOR EVERY QUESTION.

There are **skip patterns** built into the survey app depending on certain answers selected. This ensures that each woman answers the survey sections that are most applicable to her stay in the facility.

At the end of each survey section, there are free text boxes to enter **interviewer comments**. Interviewer comments could include observations about the woman's answers or behaviour, if the interview was interrupted or any issues that needs to be followed up with the supervisor.

Closely review the maternal recall pre-discharge survey variable dictionary so you are familiar with each question, the order, the answer selection options, related skip patterns and the associated visual and verbal prompts.

NOTE: The mothers might not be able to answer all of the questions. It is important that you only ask the question and use the prompts as indicated, and only record the answer the mother provides. DO NOT provide additional information or help. This is very important to ensure data collected the same way from all the mothers.

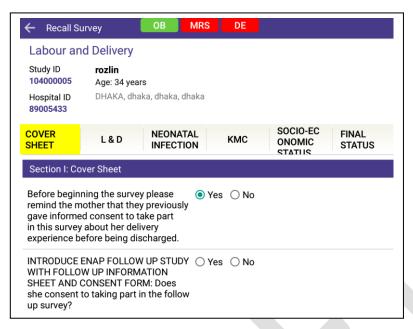


SECTION I: COVERSHEET

Before beginning the survey you need to remind the woman that she previously gave informed consent to take part in the survey about her delivery experience and confirm that you have done this by selecting "YES".

You also need to introduce the ENAP Follow up study with the Follow up information sheet and consent form. Follow the prompts on the app to read aloud the information sheet and ask the woman

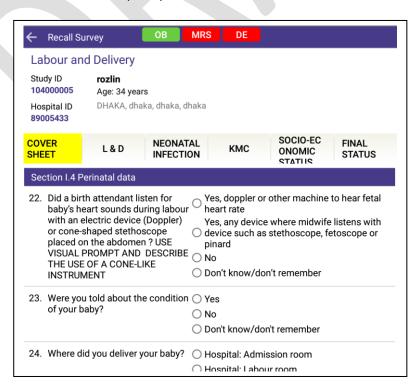
to sign/thumb print the consent form. If she consents, select "YES" on the app and ensure you keep the paper form to give to the supervisor.



Section I has the following four sub-sections:

- 1. Interviewer details
- 2. Maternal details
- 3. Current pregnancy history
- 4. Perinatal data

For each sub-section, closely review the variable dictionary with the app so you are familiar with the introductory text, each question, the order, the answer selection options, related skip patterns and the associated visual and verbal prompts.



For example, in the interviewer details section, you will enter your information and the information handed over from the Tracking Officer.

When you begin the survey, you will need to read the introductory text:

GENERAL INTRODUCTORY TEXT: Thank you for agreeing to answer a few questions about your delivery experience. These questions should take no more than 45-50 minutes of your time.

IF MULTIPLE BIRTHS: I will ask you questions about the birth of your first baby only.

IF BABY IS DEAD, USE SYMPATHETIC INTRODUCTORY TEXT: I am sorry about the loss of your baby and I understand that it is not easy to talk about this loss. Thank you for agreeing to take part in this survey. I will ask a few questions about your delivery experience. At any point if you need to take a break please let me know and you can also leave the interview at any time. These questions should take no more than 10 minutes of your time.

If the baby's outcome is dead, the survey on the app is pre-programmed to Q36 and then will skip to Section II.1 only.

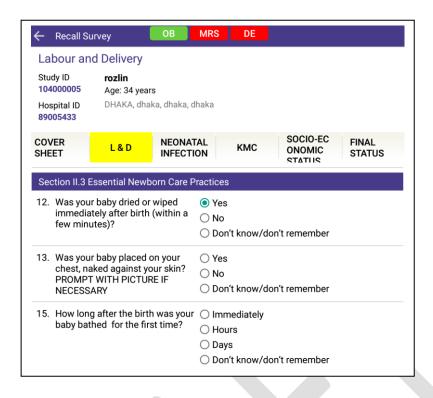
When complete, enter any comments in the interviewer comments box and then touch the save and continue button at the end.

SECTION II: L&D MATERNAL RECALL

This section has the following five sub-sections:

- 1. ACS
- 2. Uterotonics
- 3. Essential newborn care practices
- 4. Newborn resuscitation
- 5. Cord care and chlorhexidine cord cleansing

For each sub-section, closely review the variable dictionary with the app so you are familiar with the introductory text, each question, the order, the answer selection options, related skip patterns and the associated visual and verbal prompts.

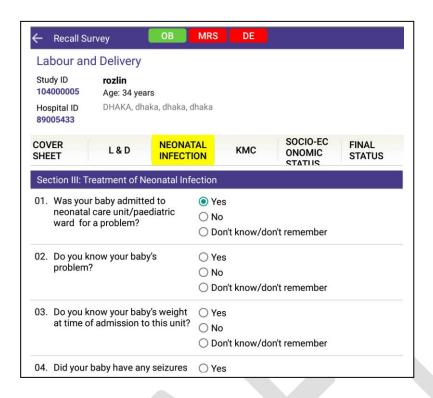


If the baby's outcome is dead, the survey on the app is pre-programmed to complete only section II.1 ACS questions only and then will skip to the end.

When complete, enter any comments in the interviewer comments box and then touch the save and continue button at the end.

SECTION III: INFXN

Closely review the variable dictionary for this section with the app so you are familiar with the introductory text, each question, the order, the answer selection options, related skip patterns and the associated visual and verbal prompts.



When complete, enter any comments in the interviewer comments box and then touch the save and continue button at the end.

SETION IV: KMC

Closely review the variable dictionary for this section with the app so you are familiar with the introductory text, each question, the order, the answer selection options, related skip patterns and the associated visual and verbal prompts.

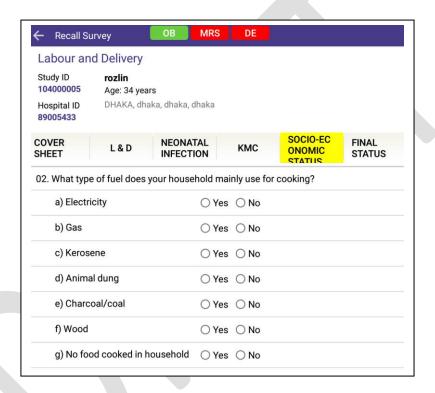


When complete, enter any comments in the interviewer comments box and then touch the save and continue button at the end.

SECTION V: SES

The final section of the MRS contains socio-economic status questions which are explained in the **introductory text** "I will now ask you some questions about your household and items you might own." This information will help to provide extra information about woman and her home environment that is important for the study.

Closely review the variable dictionary for this section with the app so you are familiar with the introductory text, each question, the order, the answer selection options, related skip patterns and the associated visual and verbal prompts



When complete, enter any comments in the interviewer comments box and then touch the save and continue button at the end.

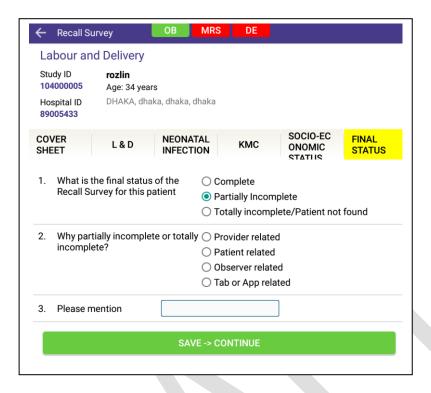
When the survey ends, thank the woman for her participation as indicated in the Thank you text in the app and complete the section with open text for "Interviewers comments." Remember to record any observations of the woman's behaviour, the interview setting and environment, if a question was refused etc. in this section.

Once completed, hit "Save and exit" and go the next section.

SECTION VI: FINAL STATUS

This section indicates the final status of the respondent's maternal recall survey. You will need to indicate if the survey is complete, partially complete or incomplete and indicate the reason along with other relevant notes.

Closely review the variable dictionary for this section with the app so you are familiar with the questions and the answer selection options.



When complete, touch the save and continue button at the end and complete the **Follow up module** for measuring head circumference if the mother consented.

Follow Up Module Discharge module

This module is the first section in the Follow up module for measuring head circumference. The identifying information about the mother and newborn will already be autocompleted in the app.

The newborns head circumference measurement will be entered in the text box. Closely review the variable dictionary for this section with the app so you are familiar with the questions and the answer selection options, and the SOP in Annex 22 for the procedure.

When complete, touch the save and continue button at the end.

GROUP ACTIVITY Q: Variable dictionary

ACTIVITY Q: Variable dictionary

Objective: To become more familiar with the content and flow of the survey through detailed review of the variable dictionary

Time: 1.5 hour

Trainee Materials: Maternal recall survey section of the variable dictionary, kit bag

Instructions:

PART 1

In groups of 4 people, review the Maternal recall survey section of the variable dictionary. Aim to review each section so you are familiar with the introductory text, each question, the order, the answer selection options, related skip patterns and the associated visual and verbal prompts. This part of the activity should take about 75 minutes to complete.

Discuss with your group:

- What did you find easy about reviewing the survey?
- What felt more challenging about reviewing the survey?
- Do you understand the skip patterns?
- Are there any parts of the survey that you don't understand?

PART 2

Share your answers and discuss in plenary as large group for 15 minutes

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GROUP ACTIVITY R: ROLE PLAY OF SURVEY

ACTIVITY R: Role play of survey

Objective: To practice administering the full maternal recall pre-discharge survey using the app on tablets and kit bag

Time: 2 hours

Trainee Materials: Tablet with mobile app, stop watch, Kit bag

Instructions:

PART 1

In groups of 2 people, complete role play activity in which you practice by interviewing another trainee using the tablet. This part of the activity should roughly take about 1.5hours. One person should be the interviewer, and one person would be the interviewee. Be sure to have your kit bag so you can fully administer the survey. Time the interviews and record this information.

Discuss with your partner:

- How long did the interview take you? Was this longer or shorter than you expected? Why?
- What did you find easy about administering the survey?
- What felt more challenging about administering the survey?
- Are there parts of the survey that you don't understand?
- Are there parts of the app that you don't understand?

PART 2

Share your answers and discuss in plenary as large group for 30 minutes

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MODULE 8: SUPERVISION

1. Introduction

As covered in module 1, the ENAP metrics observational study of facility-based maternal and newborn quality of care, aims to assess the quality of maternal and newborn health care in order to provide recommendations to national and global health facility monitoring systems. Without this, investors (both governments and partners), program managers and advocates lack the reliable information needed to monitor the quality of care, prioritize use of resources, and hold the health system to account.

Supervisors play a highly important role within this study and the data collection team. They are the primary links between the senior study staff and the data collectors. As such, they are responsible for ensuring both the smooth progression of data collection as well as the quality of data collected.

This training builds on the content you have learnt this week. Having attended the training of all cadres of data collectors, you will have a good understanding of roles and responsibilities within the team (as well as how the data being collected fit together to form the "bigger picture" of the larger study). This additional module specifically for supervisors provides training on the steps to be taken to ensure the data collection team are working well together and collecting high quality data. This training module also gives guidance on how to work well with the study site coordinator.

Roles & responsibilities

The site supervisors are the most senior members of the facility-based data collection team. He/she is responsible for the well-being and safety of team members, making sure the team is functioning efficiently while also ensuring the completion of the assigned workload and the maintenance of data quality.

The specific responsibilities of supervisors include:

- Maintaining regular communication with the study site coordinator, in order to receive daily instructions and assignments and report back on progress and challenges
- Managing the data collection team on shift, ensuring everyone feels confident and equipped to carry out their job
- Organising and leading weekly check-ins with each data collector to discuss and resolve any issues
- Conducting periodic inter-rater reliability checks on data collectors
- Completing the Data Collector Quality Assurance checklist for each data collector at least once a month
- Compiling a weekly report of data quality to hand over to the study site coordinator
- Collecting clinical incidence forms from data collectors, compile them and report the summary information to the study site coordinator

Logistics of being a supervisor Activities

Location in the health facility

As a supervisor you will be provided with a room in the health facility which you can use as an office. This room may be shared with the site coordinator or other members of the study team and so should be shared respectfully. The room will have space for you to store the documents and materials you need to conduct your tasks as supervisor.

The roles of a supervisor span all data collection activities and therefore also different locations within the health facility. While the office room can be considered a base from which you work you will be expected to be moving between the following locations during your shift, as and when needed:

- Labour & delivery admission desk
- Labour & delivery ward
- Operating theatre
- Post-natal care ward

- KMC ward
- Neonatal ward
- Sepsis ward

Materials

The following are some of the materials that you may find useful to use to enable you to manage your responsibilities as a supervisor:

- Staff rota- who is working when and where
- Human resources log book: to keep a track of any team absences, sickness etc.
- Clinical incident without appropriate response summary list: to monitor frequency and type of incidence
- Complaint log book- to record summary information on any complaints that may be made against study staff or similar.

Interaction with mother/health care workers

The extent to which data collectors can interact with mothers/health care workers differs by the cadre of data collectors, e.g. observers should have very minimal interaction with mothers and/or health care workers, whereas interviewers will be interacting with mothers for a large part of their day as they conduct the interviews.

As supervisors you will be the team member to whom data collectors come when there has been an incident experienced by a member of the data collection team which they need help with. You are therefore likely to have to interact with healthcare workers, mothers, and family members on numerous occasions. The following section details the processes to be taken in each of these possible events and the box below outlines the manner in which you should conduct yourself during each of these interactions.

Communication guidance

- 1. During interactions with the mother or family members be sensitive and respectful, remember that they may have recently experienced distressing events such as a birth complication or even a stillbirth or neonatal death.
- 2. If you need to have discussions with any of the healthcare workers in the health facility you should be respectful of their time and ensure you are not disturbing of keeping them from their work.

2. Procedures for response to incidents

During all stages of data collection and across all cadre of data collection staff, there is potential for things to go wrong, not go to plan, or to be difficult in some way or another. As the supervisor and the manager of the data collection team you will often be the person that data collectors come to when they experience problems. The table below gives examples of some incidents which you may be faced with and details the steps to be taken in each case.

Incident	Steps to be taken
An observer reports having witnessed a life threatening event without appropriate response An observer is unable to observe multiple events taking place concurrently and so they call the supervisor to help with data collection	 Steps to be taken Collect the clinical incidence form from the data collector (you may need to help them complete this form). Alert the local clinical manager, and share any information they require to manage the incident from their side Collate the form with the other forms for that month and add the incident to the monthly summary list. All forms are to be passed to the study site coordinator at the end of each week. Determine whether the observer is distressed by what they have witnessed and requires further discussion or comforting. In the case that a data collector is distressed by what they have observed make the study site coordinator aware of this as they may need time off work or rotation to a different area/form of data collection. If there is a tracking officer who is available and who has received the relevant training (on the L&D ward observation or KMC ward observation for example) you should ask them to help the observer to carry out the observation. If a tracking officer is not available or has not received the required training and you are available to help, do so. Go with the data collector to the site of data collection. Ensure your tablet is logged in as the relevant cadre of data collector, access the study participants record The observer should inform you of what they need help in observing, e.g. whether it is the baby during resus or the mother experiencing PPH Carry out the observation as per the observer training,
	 Carry out the observation as per the observer training, entering the information in to the tablet When the aspect of the observation you are helping with is complete, save and close the relevant section of the app and return to your normal duties.

A data extractor/verifier is unable to read information in the register/case notes	- Inspect the register/case notes, if you can read the
	information in question inform the data collector what is
	says so that they can enter it in to the app
	- If you are unable to read the information, the data
	collector should enter "Not Readable" in to the app
There are problems with an app or	- Referring to the app and tablet training modules, try and
	resolve the issue
	- If you are unable to resolve the issue give the data
tablet	collector another tablet to use in the meantime and pass
	the tablet that isn't working to the study site coordinator
	who will proceed with getting it fixed.
	- Take the complainant to your office or somewhere else
	where you can have a private conversation
	- Listen to the complaint and record the information as well
	as the name and contact number of the complainant, if
	they are happy to give it.
	- If it is a complaint you feel comfortable addressing e.g. a
	member of the data collection team has been rude or
	disruptive, inform the complainant of the action you will
A health worker/mother/family	take to address the problem
member comes to you with a complaint	- If the complaint is more serious and you are not sure how
about a data collector	to address it inform the complainant that you will pass the
	information on to the study site coordinator so that they
	can take action. The study site coordinator will then be in
	touch with the complainant to inform them of the action
	taken.
	- Thank the HW/mother/family member for coming to you
	and encourage them to let you know if any other issues
	arise.
	alise.

3. Management of the data collection team

In order to ensure that data collection is conducted smoothly and to a high quality you will be required to efficiently manage the data collection team, ensuring everyone on shift is able to conduct the tasks required of them.

How to be a good supervisor

The 10 main qualities required to be a good supervisor are:

- 1. **Great communication skills**: As a supervisor one must communicate clearly and correctly to avoid misunderstandings and frustrations. When receiving information from a team member, be should be sure to receive it correctly there is no harm in asking again if necessary.
- 2. Adapt to the changes: The study is likely to go through different stages as data collection gets underway, you will need to be flexible to these changes and adapt to what is required of a supervisor throughout the different stages of the study.

- 3. **Value the employees**: The people are any supervisor's real asset. They are ones running the study and doing the work. A good supervisor understands their worth and treats them accordingly.
- 4. A coacher/mentor: Share your experience. A good supervisor shares their wisdom, knowledge and experience with the employees. They help them perform better. This also strengthens the bond and the trust between them.
- 5. **Disciplined**: A supervisor can only expect team member to be disciplined is they also display discipline. The supervisor is an example Come on time, meet the time-lines, be polite and respectful.
- 6. **Feedback**: Feedback should be constructive, fair and honest. It is important to tell people what they need to improve, how they can improve it and also what they are doing well! Remember to thank people where they deserve it.
- 7. **Be an example:** Be hands on Do not just always delegate. At times the supervisor should take on projects too. They may try picking up something less attractive or uninteresting and complete it wonderfully. This sets an example to all the team about taking up challenges and about how any work is important.
- 8. **Be approachable**: The team members should not hesitate in approaching the supervisor with their concerns and problems. An efficient supervisor will make sure that there is enough trust and openness between them and the employees for the latter to come to the supervisor with their grievances.
- 9. Be considerate: People are not just employees. They have families, friends and a life beyond work. Unless there is something urgent, do not make them work beyond the usual hours. Let them have their weekends and vacations. Be practical when setting the time-lines. This all will in turn improve the efficiency and the productivity of the employees.
- 10. **Positive attitude**: Be polite. Wish team members good mornings and be generous in thanking them. Inquire after their families and other non-work issues where appropriate.
- 11. **Criticise constructively**: When mistakes happen a good supervisor tries to understand the reasons behind the mistake. Feedback to the team member in a constructive way that is in proportion to the mistake. Do not scream, shout or scold. Give constructive feedback; show them the right way to do things.

A supervisor ought not to take the power for granted but should continually work on the qualities required to become a great supervisor.

Daily managerial activities

The following steps lay out good practise for management of the team and should be <u>conducted each</u> day:

1. Beginning of shift team meeting

- Lead the group in discussion of any questions or concerns
- Check that each member of the team has the equipment and tools needed for the upcoming shift

2. Daily check in with each cadre of data collector

- Ensure you meet with each cadre of data collector at least once a day, you can meet with them as a group or however many are available at any one time; it may be

- appropriate to see staff while they are performing their duties rather than remove them from the clinical environment (especially if they are observers).
- Ensure the data collectors have the equipment needed for data collection- e.g. charged and working tablets, kit bag (for interviewers). A charging station with additional tablets should be set up in the office.
- Check whether there are any points of confusion or misunderstanding and if so take steps to resolve them.

3. End of shift team meeting

- Congratulate the team on things that were done especially well that day
- Lead a group discussion on things that did not go to plan and how this may be improved on the next shift.

Weekly managerial activities

One-to-one meeting with data collectors

Each week you should meet with each data collector on a one-to-one basis. Try to meet in a private area where you can have a quiet conversation, it should be an informal chat but you need to provide the privacy for data collectors to disclose information or troubles they may be experiencing.

Points for discussion will differ with data collectors but as a rough guide:

Things to ask the data collector:

- Things the data collector has found to have gone smoothly /things they are pleased with
- Things that have been troublesome for the data collector
- Any ideas or suggestions the data collector may have for improvements to data collection
- Any issues within the data collection team
- The general wellbeing of the data collector: are there personal things going on which are affecting the data collector at work? Has the data collector been distressed by anything they have experienced/witnessed while at work?
- Does the data collector have any feedback or requests of you as a supervisor?

Things to tell the data collector:

- Feedback on their attendance at work
- Feedback on their general manner at work- clothing, communication skills, team work skills etc.
- Feedback on data quality assurance: present to the data collector their individualised data on capture and completeness of key variables, as detailed below.

Whole team meeting

Once a week the whole data collection team should meet for a more detailed discussion of progress and facilitators and barriers to data collection as well as a more informal team catch up. These meetings will be important to share information relevant to the whole team as well as providing encouragement and support to the team. It should be a useful update and planning meeting as well as a relaxed time for team members to see each other away from the daily activities of data collection.

Throughout the week, as things come up which seem relevant to the team meeting you can make a note to add them to the agenda. As a guide the below is a generic agenda to be adapted.

Weekly Team Meeting – Generic Standing Agenda

- 1. Introduction from the supervisor- summary of the week and words for praise
- 2. Summary of data quality monitoring statistics- over all capture and completeness
- 3. Team structure/management updates
- 4. Messages/notes for the coming weeks
- 5. Question and discussion round lead by data collectors: what has been easy/hard this week? What could be improved and how?
- 6. Any other business

4. Working with the study site coordinator

The study site coordinator is your line-manager and the member of the team to whom you must both take instructions and report back information. The study site coordinator is responsible for reporting overall study progress, and information on challenges; you they will require regular updates from you on this information. The study coordinator will be available to provide support to you on anything you may struggle with, (from management of the data collection team, to monitoring of data quality assurance).

It will be up to the study site coordinator to inform you of when and how to meet, and how best you will work together. As a guidance:

1. Daily catch up meeting

- Present to the study site coordinator the summary statistics for the day
- Make the supervisor aware of any human resource issues for the following day-holidays, sick leave etc.
- Hand over to the study site coordinator any materials that may be needed for the next shift- log books etc.

2. Weekly in-depth meeting

- Present the capture cascade and completeness data for the week, both for the health facility as a whole and filtered by data collector
- Highlight to the study site coordinator particular issues for data quality assurance and discuss how they may be improved or resolved
- Hand over the weekly clinical incidents forms along with the total tally sheet. If necessary to discuss any incidents in particular flag these to the study site coordinator.
- Discuss management of the data collection team and any human resource issues (staff who are routinely late, staff who are ill, staff who are struggling with the role etc.)
- Discuss any areas you may be struggling with as a supervisor and how the study site coordinator may be able to help

GROUP ACTIVITY T: Scenarios for Supervisors

Objective: To have the opportunity to discuss as a team your response to certain scenarios

Time: 30 minutes

Instructions:

Part I (20 mins)

- The trainer will split you up in to smaller groups and will present you with a number of different scenarios which may arise while you are working as a supervisor
- As a group discuss how you would respond to each of the scenarios

Part II (10 minutes)

 Whole group discussion of the scenarios and points of dis/agreement that came up during the group work

5. Monitoring & Supervision for Data Quality Assurance

Inter-rater reliability

Everyone in the data collection team should be taking steps to ensure the reliability of the data they are collecting. In research the term reliability means "repeatability" or "consistency". A measurement is considered reliable if it would give us the same result over and over again.

Inter-rater reliability is the extent to which two or more data collectors agree. Inter-rater reliability is a major consideration in good data quality. As the supervisor it is your responsibility to conduct <u>double data entry for at least 10% of data entry cases</u>. Supervisors and study site coordinators will together compare the level of agreement between the two data sets. If the level of agreement is low, the data collector may be asked to carry out refresher training. For example, both the supervisor and KMC observer would complete the KMC observation app on the same clinical scenario and at the same time. Once the observation is complete, the two data sets should be compared (see Figure 1). A minimum agreement level of 80% is expected as a cut off for observation data. A minimum agreement level of 95% agreement is required for data extraction and case verification data.

Figure 1- Calculation for level of agreement between two data sets

Number of variables found to be different

Total number of variables in that observation

X 100

Monitoring Data Quality

Three tiers of Monitoring and Supervision should be carried out for the smooth operation of the ENAP project.

- 1. Facility Specific Monitoring
- 2. Country Specific Monitoring
- 3. Global Monitoring

As supervisors you have an important role to play in the monitoring of data quality at the first level-facility specific monitoring. The monitoring of data quality at this levels fits in to two categories; participant capture cascade, and indicator completeness, each are detailed below.

Participant capture cascade

The % of study participants progressing through each stage of data collection. It is to be expected that not all study data will be collected on all eligible mothers, family members and babies attending the health facility. In other words we are expecting a drop off between the stages of – taking of basic data, consent, data collection started, and data collection completed. Figure XX shows the stages where there is the potential for a drop in capture and gives some examples of possible reasons for these drops.

The role of the supervisor is to monitor the capture cascade and the % loss at each stage, in total and for each data collector. Some loss is expected but it is important to monitor the levels to ensure that it does not fall below the bench marked levels laid out in figures 2-4.

Steps for monitoring and evaluating data capture:

- Monitor the % of study participants progressing through stages of data collection to ensure it is the same/above the bench marked levels.
- Filter participant capture by each data collector to identify data collectors who may be losing more participants than benchmarked amounts. If this is the case discuss with the data collector why this may be happening and how it may be improved.



Capture Cascade: L&D observation

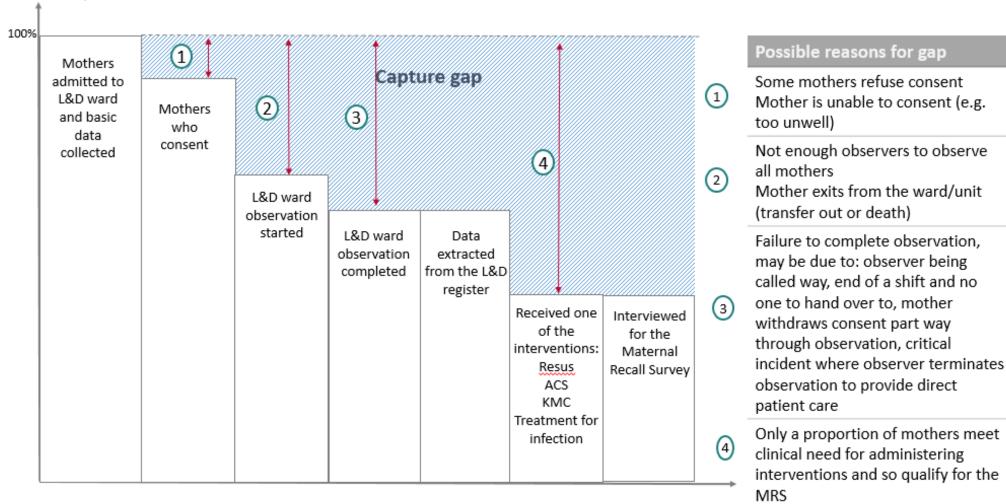


Figure 2- Capture cascade for L&D observation

Capture Cascade: KMC observation 100% Babies 1 Capture gap admitted to KMC ward Mothers/ 1 KMC ward KMC ward Data Interviewed family observation observation for the extracted members completed from the started Maternal who give KMC register Recall Survey consent on KMC ward

Possible reasons for gap

Some mothers refuse consent Transferred to a different ward/facility/unit

Figure 3- Capture cascade for KMC observation

Capture Cascade: Neonatal Infection Verification 100% Capture gap Babies on sepsis/neonatal Interviewed ward meeting Mothers/ Neonatal for the eligibility criteria family infection Maternal members case notes Recall Survey who give reviewed consent

Possible reasons for gap

Some mothers refuse consent

Transferred to a different

ward/facility/unit

Figure 4- Capture cascade for neonatal infection verification

Indicator completeness

The % of completeness of data for a few specific variables. This element of the data cascade assesses how much of the required data the data collectors have been able to collect. Data collectors are trained to try and collect all of the necessary information, however, it is understood that sometimes that may not be feasible and for some variables the data collectors may not have enter the required information. Supervisors will check on the summary statistics of completeness of a few specific variables and monitor these levels to ensure they do not fall below levels benchmarked as acceptable. Steps for monitoring and evaluating data completeness:

- Review completeness for each key variable filtered by data collector to identify data collectors who may have more missing data than the benchmarked levels. If this is the case discuss with the data collector why this may be happening and how it may be improved.
- Present this feedback per data collector and in total at the end of each shift, or during the team meeting

The table below lists the variables for each of L&D, KMC and infection management data collection. These are the variables which you will analyse the % completeness of, i.e. for what proportion of the study population was information on these variables collected?

Dashboard	Indicator
L&D Data Collection	■ % of Suspected Premature Labour Registered
	% of Vaginal Delivery and C-Section Observed
	■ % of Live Birth Observed
	% of Low Birth Weight Observed
	■ % of Resus Observed
	% of Uterotonic Given after Delivery Observed
	■ % of PPH Observed
	% of MRS Module ACS, Uterotonic, Newborn, Resus and
	ENC Completed
KMC Data Collection	• % of KMC Initiation Observed
	% of KMC Positioning & Continuity Observed
	% of KMC Feeding Practices Observed
Infection Management	% of Antibiotic Given

GROUP ACTIVITY U: Data Quality Monitoring Practise

Objective: To have the opportunity to review the tools and mechanisms for data quality monitoring **Time:** 60 minutes

Handouts: tablet or laptops to view the data dashboards. Print out copies of variables for completeness monitoring and capture cascade.

Instructions:

The trainer will lead you through the following:

- Review the data dashboards to make sure you understand the data presented
- Carry out practise calculations to assess level of inter-rater reliability
- Discuss steps to be taken in the case of poor data quality