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MCHIP Maternal and Child Health Integrated Program

Clinical Observer Training

Facilitator's Guide

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MCHIP is the USAID Bureau for Global Health's flagship maternal, neonatal and child health program. MCHIP supports programming in maternal, newborn and child health; immunization; family planning; malaria; nutrition; and HIV/AIDS, and strongly encourages opportunities for integration. Cross-cutting technical areas include water, sanitation, hygiene, urban health, and health systems strengthening. Visit www.mchip.net to learn more.

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Introduction

The primary purpose of this training is to prepare clinical trainers and other clinicians to be observers and assess the quality of clinical services in an objective and standardized way as part of an observational evaluation study, quality improvement assessment, or other collection activity that involves observing client-provider interactions. To ensure high-quality, reliable data are collected, it is crucial that the observer be able to appropriately observe and determine if clinical steps are performed to standard. After this training, an assessment team of observers will be competent in data collection—including clinical skills observation using structured, standardized observation checklists—and will understand the value of high-quality observational data.

At the point this clinical observer training is taking place, the study protocol and all of the data collection tools and consent forms that facilitators plan to use in the assessment should have been finalized and institutional review board (IRB) approval should have been obtained, if needed.

Clinical Observer Training Syllabus

COURSE DESCRIPTION

The clinical observer 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.

The training will address the following key steps to becoming a competent clinical observer:

1. Understand the purpose, objectives, and plans for assessment and/or study that needs clinical observations.
2. Recognize the value of reliable and high-quality data.
3. Review data collection instruments.
4. Train in the performance of clinical skills observation.
5. Obtain competence in observing clinical skills.
6. Conduct data collection assessments as a clinical observer.

In addition, during this course, participants will use and provide feedback on actual data-collection tools and processes, gain experience completing the data collection tools, and document and discuss findings.

FACILITATOR SELECTION CRITERIA

This course will require multiple facilitators; among these, an overall course leader should be selected. The facilitation team should include

1. an experienced clinician with clinical training and monitoring and evaluation experience, and/or
2. a monitoring and evaluation professional who can lead the facilitation team.

NOTE: It is recommended that there be one facilitator for each eight clinical observer training participants.

PARTICIPANT SELECTION CRITERIA

Participants should be selected from health care professionals, in-service trainers, and pre-service faculty (classroom instructors or preceptors) who

- are interested and available to participate in clinical observation and data collection and documentation,
- are currently practicing clinicians, and
- have been standardized in the latest evidence-based clinical practices that are being assessed (i.e., have been trained in the skills in the last 3 years).

This training could be one of multiple methods as part of a study or program to train participants.

OBJECTIVES

Course Goal

After completing this course, you will be able to competently conduct an assessment in the field using observational data-collection tools both in simulation and in a clinical setting.

Primary Objective

Demonstrate competency in conducting and documenting observations of clinical services, practices, and settings.

Supporting Objectives

- Explain the importance of objective, standardized 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

The learning methods used in this course include the following:

- Small group work and discussions
- Presentations
- Demonstrations and observation
- Observation practice in simulation with anatomic models, role plays, and videos or performances using perfect and flawed simulations as well as in a clinical setting with actual clients and providers

Learning Materials

- Handouts
- Thumbnails
- Videos / performances / role play
- Homework assignments
- Observer checklists
- Self-evaluation
- Quizzes
- Knowledge Assessments

Assessment Criteria

- Course participant is able to demonstrate 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.
- Course participant is able to pass the Final Knowledge Assessment with score of 80% or higher.

Sample Clinical Observer Training Schedule

NOTE TO FACILITATOR: Below is a sample clinical observer training schedule. The length of time required for standardizing skill observations depends on the assessment tool(s). It may take anywhere from 1 extra day to 1 week for complex and detailed assessments where multiple services (e.g., antenatal care, delivery care, sick child care) are being observed. Assessment of each service area will require about 60–90 minutes of practice.

In addition, although clinical observer participants should be clinically up-to-date and practicing clinicians, some may not be familiar with the exact guidelines/checklists that are being used for clinical observations. For example, if World Health Organization (WHO) guidelines are being used for the study but the national guidelines differ, the clinician may not be familiar with the WHO guidelines. Some facilitators have found it necessary to conduct short technical updates in key areas as part of the clinical observer training; this helps standardize all the clinical observers. If you anticipate the need for key clinical updates, build time for them into the schedule.

This schedule can be adapted to your specific training needs, allowing more or less time for some sessions or even eliminating sessions if time is very limited. For further guidance, please see Appendix E for a longer sample training schedule focused on maternal and newborn care.

Time	Item	Facilitator
Day One		
15 min	Registration	
optional, 30 min	Session 0: Optional Pre-Quiz	
45 min	Session 1: Clinical Observer Training: Course overview	
30 min	Session 2: Clinical Observer Training: Why are high-quality data important?	
BREAK		
60 min	Session 3: Clinical Observer Training: How do I collect good-quality data?	
LUNCH		
60–120 min	Session 4: Clinical Observer Training: What's the plan?	
BREAK		
45 min	Session 5: Clinical Observer Training: How do I obtain informed consent?	
15 min	Take-home messages Homework assignment Closing	
Day Two		
15 min	Review of homework assignment	
60 min	Session 6: Clinical Observer Training: Which tool do I use and how?	
BREAK		
90 min	Session 7: Clinical Observer Training: How do I standardize my skills observations?	
LUNCH		

Time	Item	Facilitator
120 min	Session 7 (continued)	
60 min	Final knowledge assessment Plan logistics for Session 8: Time to practice! clinical observations	
BREAK		
Day Three		
60 min	Pre-clinical meeting	
To be determined	Session 8: Clinical Observer Training: Time to practice! Clinical observations / data collection	
15 min	Pre-lunch check-in	
LUNCH		
To be determined	Clinical observations / data collection Evaluations	
60 min	Post-clinical meeting	

Facilitator's Guide

Facilitator Checklist and Preparatory Activities

FACILITATOR PREPARATION

(to be completed by lead facilitator prior to start of the course)

Logistics

Complete at least 1 to 2 months prior to training:

- Ensure the training venues have been appropriately selected (classroom and clinical observation sites) and are adequate to create a positive learning climate, conduct planned activities, and meet the course objectives.
- Confirm clinical observation pre-test/practice health facilities and their capacity, hours of operation, and daily expected caseload of services of interest.
- Meet with clinical staff and management.
- Ensure that client scheduling is arranged with clinic staff or management as needed.
- Ensure participants have been invited (include information on travel reimbursement, per diem provided, lodging facilities, etc.).
- Ensure any consultants needed are arranged for (scope of work, contracts, etc.).
- Ensure logistics are being managed (include dietary needs, travel and transportation, lodging, and per diem).
- Ensure transportation to clinical observation site is arranged (if needed).

Materials

- Gather and be very familiar with necessary study documents:
  - Study or assessment operations manual
  - Study protocol
  - Schedule of full study, including data collection, data analysis, and report preparation
  - Informed consent forms
  - Relevant study data-collection tools
  - Fieldwork manual
- Shortly before training:
  - Determine which clinical scenario(s) will be used for Session 7 (see Appendices C and D) and gather necessary materials
  - Develop necessary materials based on which clinical scenarios will be used
  - Develop Handout: Study Plan Overview Template for Session 4
  - Develop slides for Session 4 PowerPoint, "What's the plan?"
  - Develop quiz for beginning of Day 2 to evaluate homework assignment from end of Day 1
  - Determine facilitators and practice Session 7 scenarios with co-facilitators if NOT using videos (see Appendix D)

- One week prior to training, gather/prepare necessary materials:
  - Clinical Observer Training Learner's Guide (1 copy for each participant)
  - Final Knowledge Assessment (1 copy for each participant)
  - Download videos if necessary
  - Informed consent forms (1 copy of each form for each participant or use Handout: Sample Written Consent Form for Study Participants from Session 5)
    - Note: If the study has been approved by the institutional review board (IRB), it will bear a stamp on the approved consent forms; it is important to use these versions of the consent forms during data collection
  - Hard copies of relevant study data-collection tools (2 copies of each tool for each participant—one for the classroom and one for practice with the tools at a health facility) or mobile devices and final data-collection applications if data collection will be done using mobile phones or tablets
  - Handout: Study Plan Overview Template for Session 4
  - Quiz for beginning of Day 2 to evaluate homework assignment from end of Day 1 (1 copy for each participant)
  - Visit classroom and arrange; check supplies and equipment:
    - Flip charts and markers
    - Notebooks and pens for participants
    - Laptop, projector, and screen
    - Football or ball for icebreaker
    - Prizes for Optional Pre-Quiz
    - Printer
    - Computer with speakers and Internet access to play YouTube videos OR flash drive with videos OR scripts and relevant clinical materials to present perfect and flawed performances
    - Clinical equipment related to Session 7 if using scripted or spontaneous performances (see Materials Needed lists in relevant Appendix D scripts)
- Prepare certificates for statements of qualification or participation (see Appendix F)

Keys to Success for Facilitators

1. Recruit participants who meet the selection criteria (see Clinical Observer Training Syllabus).
2. Ensure class size is small enough for effective training and for each participant to gain enough practical experience to become competent.
3. Schedule enough time for the knowledge components as well as practical activities.
4. Meet with the co-facilitators to prepare for the training:
    - Review the learning resource package in detail and prepare items on the Facilitator Checklist and Preparatory Activities.
    - Review study goals, objectives, and key indicators prior to the start of the course. Select key outcomes/items that need to be measured and/or completed.
    - Ensure that tools have all necessary—but no extraneous—items. Remember, less can be more. With shorter tools, more attention is focused on the key outcomes/items. Work with the team to revise tools if necessary.
    - Review all relevant tools prior to the start of the course so that all facilitators are in agreement.
    - Ensure that the practical/pre-test sites to be used in Session 8 are aware that the participants will be visiting. Where possible, ensure that the practical sites have sufficient volume of patients / learning opportunities for course participants to be able to observe and use tools during their practical experience.
    - Review Facilitator Directions: Calculating Inter-Rater Reliability of Participants for Sessions 7 and 8, Appendix A, and Appendix B.
5. When reviewing the tools in Session 6 and Session 8, emphasize the following:
    - Definitions—Discuss the relevant definitions and terminology so that participants clearly understand the tools prior to data collection.
    - Skip patterns—Review the skip patterns of tools adequately. Participants should be able to skip appropriate sections as needed depending on the clinical situations.
    - Response choices—Review response choices "Yes," "No," "Not applicable," and "Don't know." Explain when to use "Not applicable" and "Don't know" and when not to, if relevant, giving examples of each.
    - Comments—Review the importance of comments and when to use them to explain the context of the clinical observation.

Session 0: Optional Pre-Quiz

SESSION PLAN

<table>
<tr><th>Date:</th><th>Venue:</th><th>Session Number: 0</th><th>Duration: Optional, 30 Minutes</th></tr>
<tr><td colspan="4">Step 1: Understand the purpose, objectives, and plans for assessment and/or study that needs clinical observations. Recognize the value of reliable and high-quality data.

Session Title: Optional Pre-Quiz</td></tr>
<tr><td colspan="4">Session Objective:
At the end of the session, participants should be able to describe specific monitoring and evaluation terminology.</td></tr>
<tr><th colspan="3">Methods and Activities</th><th>Materials/Resources</th></tr>
<tr><td colspan="3">Format:
Quiz
Large group discussion

Content:
None

Activity:
1. Ask participants to turn to Handout: Review Quiz.
2. Tell participants that they will have 15 minutes to finish the quiz.
3. Review quiz answers in the large group.
4. Give prizes to participants for correct answers.
5. Through discussion, reinforce the following reasons to invest in and improve data collection and reporting:
- What gets measured, gets done.
- If you don’t measure results, you can’t tell success from failure and you can’t identify gaps and find solutions.
- If you can’t see success, you can’t learn from it and share it.
- If you can’t see success, you can’t reward it.
- If you can’t reward success, you probably are rewarding failure.
- If you can’t recognize failure, you can’t correct it.
- If you can demonstrate cost-effective results, you can scale up.
6. Ask participants if they have any questions prior to moving on to the next session.

Summary:
Reinforce why data collection is important and link its importance to the larger purpose of this training.</td><td>• Handout: Review Quiz
• Prizes for correct answers</td></tr>
</table>

HANDOUT: REVIEW QUIZ

1. Name three methods for collecting data.

   a.

   b.

   c.

2. Name three reasons we collect data.

   a.

   b.

   c.

3. Match the term in column 1 with the correct definition in column 2. Each item is only used once.

Term	Definition
1. Quantitative data	a. The financial, human, and material resources used in a program/intervention.
2. Qualitative data	b. The extent to which a measurement test accurately measures what is intended to be measured.
3. Validity	c. A quantitative or qualitative variable that provides a valid and reliable way to measure achievement, assess performance, or reflect changes connected to an intervention.
4. Formative evaluation	d. The results of a program/intervention; the direct products or deliverables of programs/interventions.
5. Indicator	e. Data measured on a numerical scale that can be analyzed using statistical methods.
6. Effectiveness	f. A type of evaluation intended to improve the performance of a program/intervention and designed to be undertaken during the intervention/program.
7. Inputs	g. The extent to which a program has achieved its objectives under normal conditions in real-life settings
8. Outputs	h. Data collected using interviews, focus groups, and key informants. Provide understanding of social situations and interactions.
9. Reliability	i. Consistency or dependability of data collected, as established through the repeated use of a scientific instrument or data collection procedure.

ANSWER KEY FOR REVIEW QUIZ

1. Surveys, focus groups, observations, structured interviews, chart reviews, etc.
2. Various answers that can include: to inform decision-making, determine funding priorities, improve quality of services, evaluate pilot programs, etc.
3. Matching key:
   Term 1: Definition e
   Term 2: Definition h
   Term 3: Definition b
   Term 4: Definition f
   Term 5: Definition c
   Term 6: Definition g
   Term 7: Definition a
   Term 8: Definition d
   Term 9: Definition i

Session 1: Clinical Observer Training: Course Overview

SESSION PLAN

Date:	Venue:	Session Number: 1	Duration: 45 Minutes

Step 1: Understand the purpose, objectives, and plans for assessment and/or study that needs clinical observations. Recognize the value of reliable and high-quality data.

Session Title: Clinical Observer Training: Course Overview

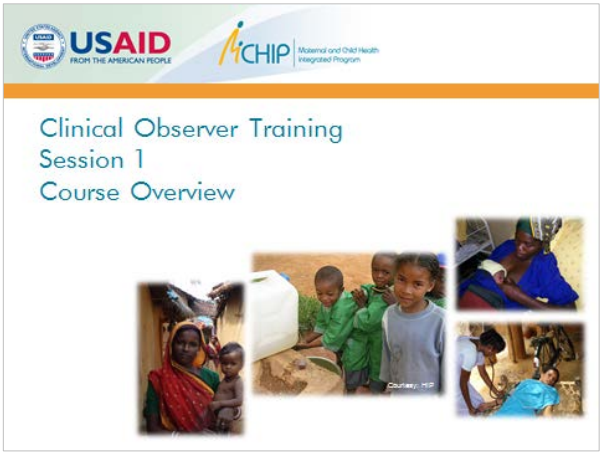
Session Objective:
At the end of the session, participants should be able to

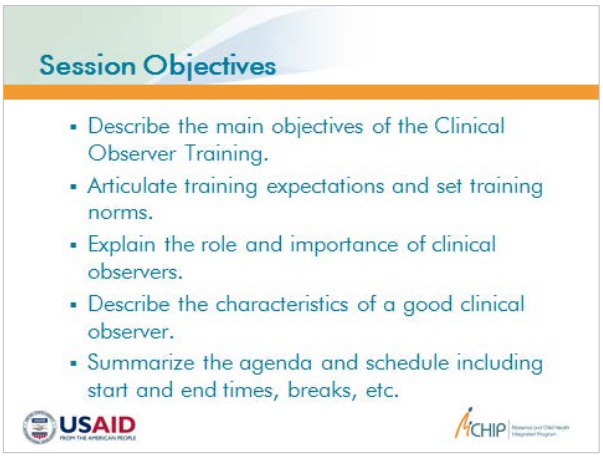
- describe the main objectives of the Clinical Observer Training,
- articulate training expectations and set training norms, and
- summarize the agenda and schedule including start and end times, breaks, etc.

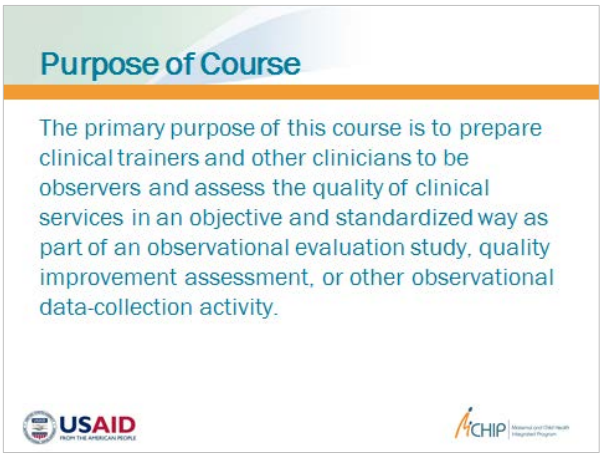
Methods and Activities	Materials/Resources
Format: Large group discussion **Activity**: Icebreaker—Football **Trainer Note**: This activity is designed so that each participant speaks out loud to the group within the first few minutes of the beginning of the training. This will reinforce the important expectations that participants speak up, ask questions, and participate actively in the workshop. It also allows participants to learn each other's names and begins to develop a trusting learning environment. Ask participants to form a circle. Hold the football and introduce yourself (name, your facility name, and title) and state one expectation you have for the training (have someone note expectations on a flip chart). Toss the football to another participant who repeats the name of the person he received the ball from, then states his own name, his facility's name, his title, an activity he likes to do in his free time, and one expectation for the workshop. This should take just a few minutes. **Content**: 1. Introduce yourself. 2. Welcome and thank all participants for attending the XX-day Clinical Observer Training. 3. Acknowledge the host and other key stakeholders. 4. Explain the importance of this workshop, mention how the participants were selected, and share that this workshop will allow participants to competently conduct an evaluation in the field using data collection tools both in simulation and in a clinical setting. 5. Present the Session 1 PowerPoint, "Course Overview," emphasizing the Purpose of Course and objective slides, and review the course syllabus. 6. Review the 1-day agenda, emphasizing that a lot will be covered in a very short time so it is important that everyone is back on time from breaks and lunch. 7. Review the participants' packet of materials.	▪ Flip chart on easel with workshop title, dates of training, and sponsor ▪ Session 1 PowerPoint (including introductions, objectives, agenda) ▪ Name tents and markers ▪ Participant packets (packet containing Learner's Guide, notebook, and pen should be on each participant's table/desk prior to beginning of training) ▪ Football

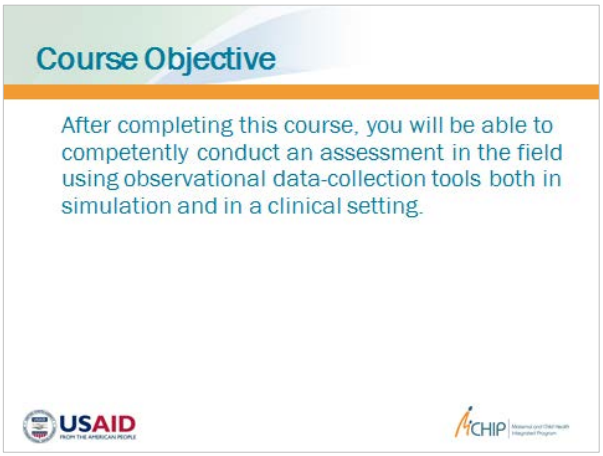
8. Tell participants that this will be a participatory and interactive workshop, meaning all contributions are welcome and they should feel free to ask questions, provide answers to questions posed by other participants, and speak up if they don't understand something. 9. Ask the group to brainstorm "norms" for the workshop. Make sure final list includes: - all cell phones should be turned off or switched to vibrate, - respect people's contribution, and - respect time. 10. Ask if there are any questions before transitioning to the next activity. **Summary**: Summarize the norms and expectations for the workshops. Reinforce that the course will require active participation and that there is a lot of content. It is important that participants attend the whole course and arrive on time.	

COURSE OVERVIEW: NARRATION NOTES








Course Objective
After completing this course, you will be able to competently conduct an assessment in the field using observational data-collection tools both in simulation and in a clinical setting.
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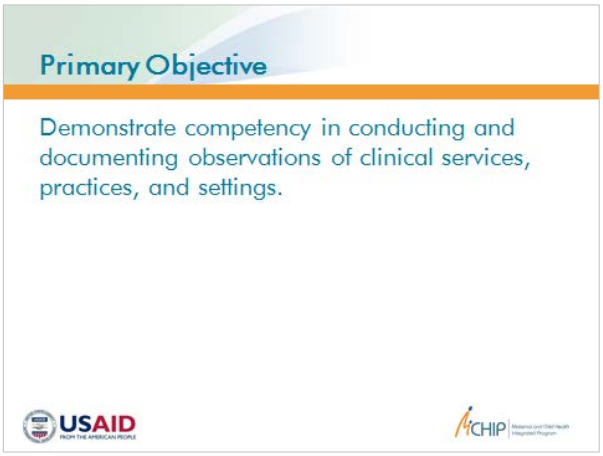
Primary Objective
Demonstrate competency in conducting and documenting observations of clinical services, practices, and settings.
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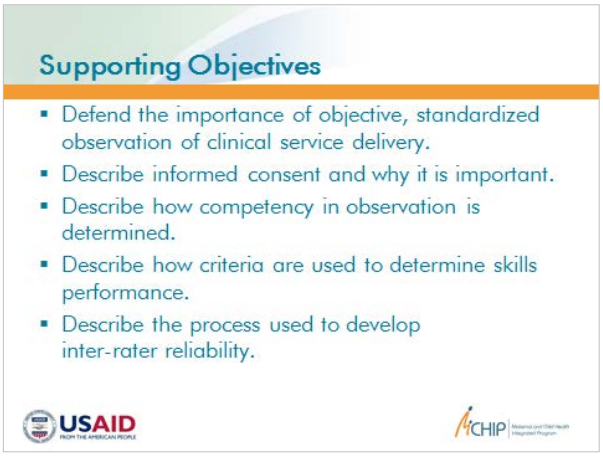
Supporting Objectives
Defend the importance of objective, standardized observation of clinical service delivery.
Describe informed consent and why it is important.
Describe how competency in observation is determined.
Describe how criteria are used to determine skills performance.
Describe the process used to develop inter-rater reliability.
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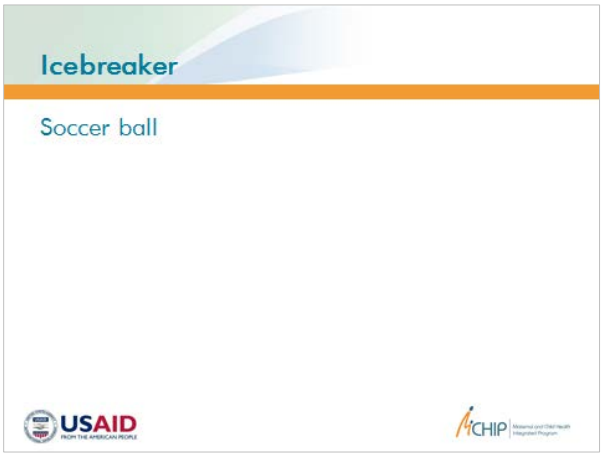
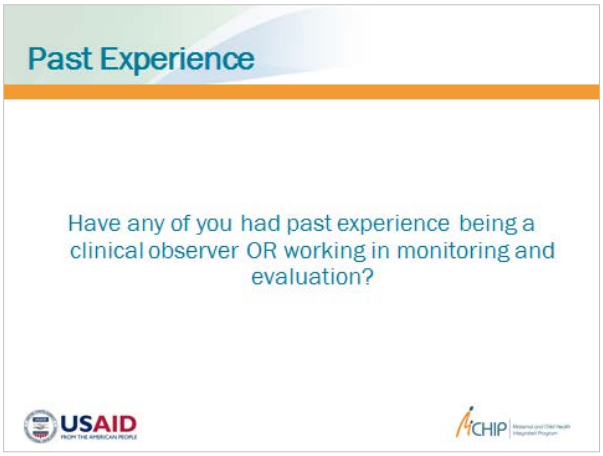
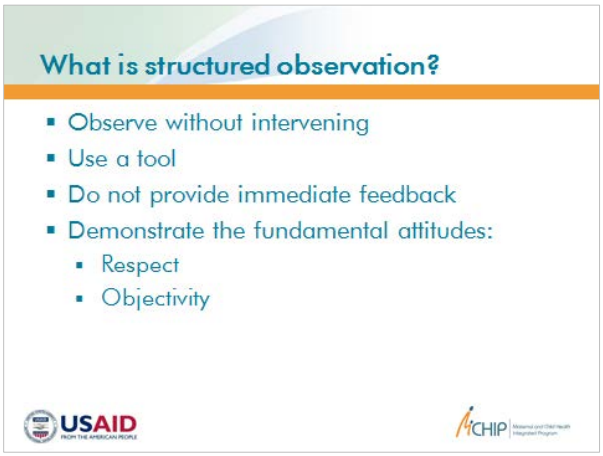




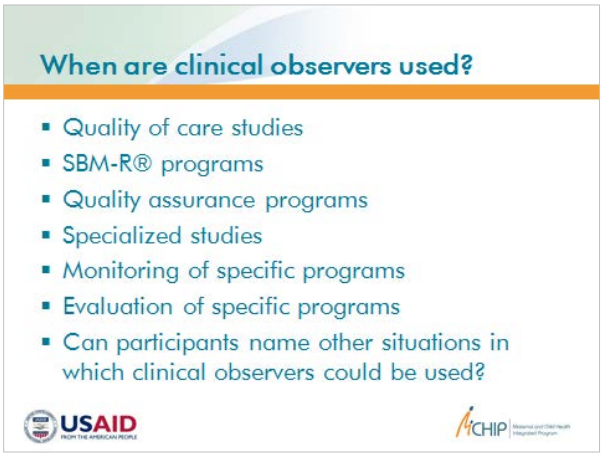
Ask participants if they have had experience being a clinical observer or working in monitoring and evaluation. If yes, what was the experience like? What did they do?

A clinical observer is a person who is sent to observe—but not participate in—an activity. The goal of the observer is to simply watch a process unfold. The process should unfold the same way whether or not the observer is there to watch. Clinical observers accurately document their observations.

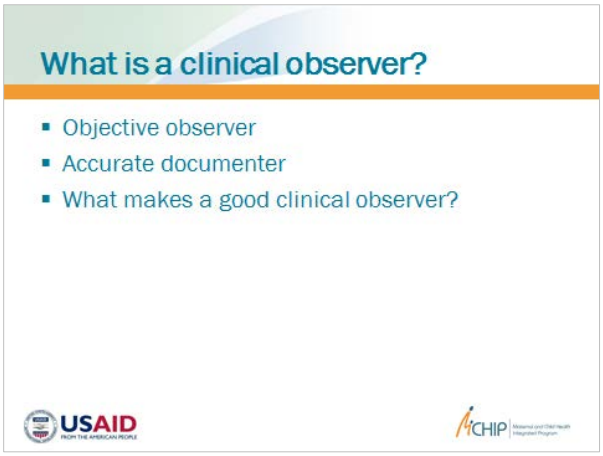


To systematically observe an act or an element of service delivery without intervening

A tool is used to observe the elements and stages of a process or service delivery in an organized fashion



Standards-based management and recognition (SBM-R) is a practical management approach for improving the performance and quality of health services. The approach uses defined standards and accompanying verification criteria that outline the desired level of performance to meet the standard. By implementing the SBM-R process, gaps are identified and resolved over time, achieving improved quality in specific health service areas.



The goal of the observer is to simply watch the process unfold, which it should do in the same way whether or not the observer is there to watch.

Clinical observers accurately document their observations.

The most valid measure of quality of care comes from observation of practice, but this is challenging to do (e.g., provider/client interaction/communication; use of infection prevention practices; use of the partograph; use of active management of the third stage of labor).

Calibration with other observers means the facilitator will look at inconsistencies across observers and address them until the observers can observe in the same, standardized way.

The course aims to address all the components to develop participants into competent clinical observers. The goal is to have each participant become a competent observer by the end of the course.

Session 2: Clinical Observer Training: Why are high-quality data important?

SESSION PLAN

<table>
<tr><th>Date:</th><th>Venue:</th><th>Session Number:2</th><th>Duration: 30 Minutes</th></tr>
<tr><td colspan="4">Step 1: Understand the purpose, objectives, and plans for assessment and/or study that needs clinical observations. Recognize the value of reliable and high-quality data.

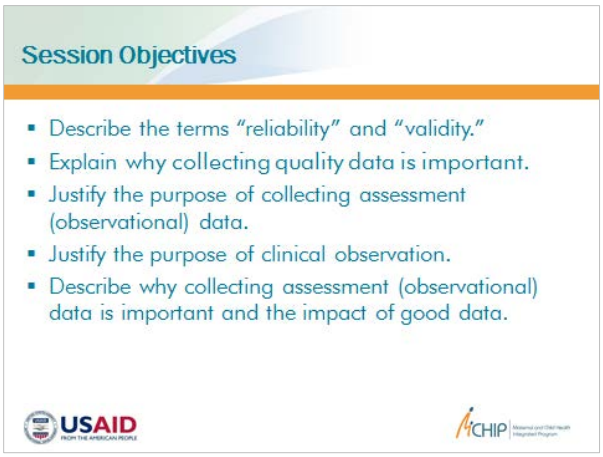
Session Title: Clinical Observer Training: Why are high-quality data important?</td></tr>
<tr><td colspan="4">Session Objective:
At the end of the session, participants should be able to
▪ describe the terms “reliability” and “validity,”
▪ explain why collecting quality data is important,
▪ justify the purpose of collecting assessment (observational) data,
▪ justify the purpose of clinical observation, and
▪ describe why collecting assessment (observational) data is important and the uses of good data.</td></tr>
<tr><th colspan="3">Methods and Activities</th><th>Materials/Resources</th></tr>
<tr><td colspan="3">Format:
Large group discussion
Small group activity

Content:
Present Session 2 PowerPoint, “Why are high-quality data important?,” on importance of high-quality data. NOTE: Use primarily discussion, and reinforce with presentation.

Activity:
1. Refer participants to Handout: Ensuring High-Quality Data, Data Quality Activity 1, and Data Quality Activity 2 in their Guides.
2. Divide participants into two or four groups (depending on number of participants).
3. Have half work on Activity 1 and half work on Activity 2.
4. Ask volunteer presenters to share with the larger group one or two examples they discussed.
5. Reinforce key points pertaining to audiences for data, what data quality is, and why these are important.

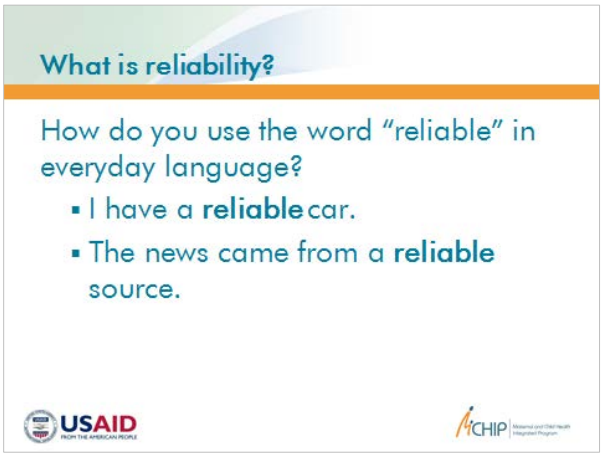
Summary:
Ask the group if they have any questions on data terms or data variability.</td><td>▪ Session 2 PowerPoint
▪ Handout: Ensuring High-Quality Data</td></tr>
</table>

WHY ARE HIGH-QUALITY DATA IMPORTANT? NARRATION NOTES



The primary objective when observing any skill is to make sure that your observations are valid and reliable and that every effort is made to reduce errors in measurement.

Clinical observers must be able to collect data that are reliable and related to specific standards/criteria; observers use the criteria and standards defined in the tools.

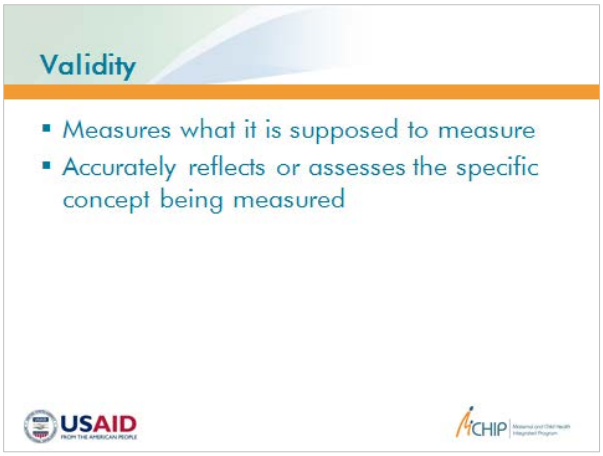


Ask participants about how we use the word "reliable" in everyday language. You might give a hint. For instance, we often speak about a machine as reliable: "I have a reliable car." Or journalists talk about a "usually reliable source." Reinforce participants' answers. The word "reliable" usually means "dependable" or "trustworthy."

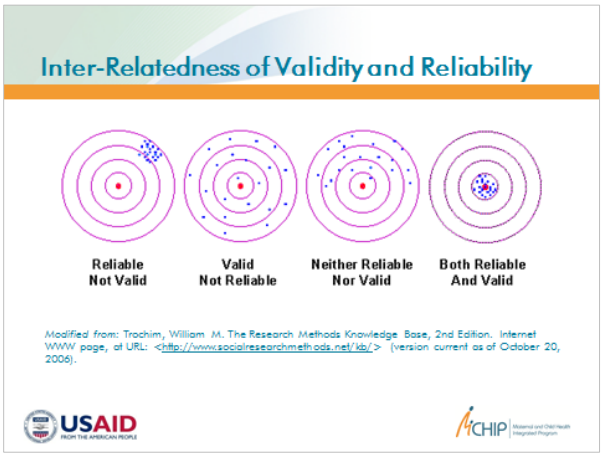
In research, the term "reliable" also means "dependable" in a general sense, but that's not a precise enough definition. What does it mean to have a dependable measure or observation in a research context? The reason "dependable" is not a good enough description is that it can be confused too easily with the idea of a valid measure.

In research, the term reliability means "repeatability" or "consistency."

A measure is considered reliable if it would give us the same result over and over again. Explain that the terms "reliability" and "validity" are often described as separate ideas, but they are inter-related.



"Validity" refers to the degree to which the tool measures what it is supposed to measure, and to the degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure.

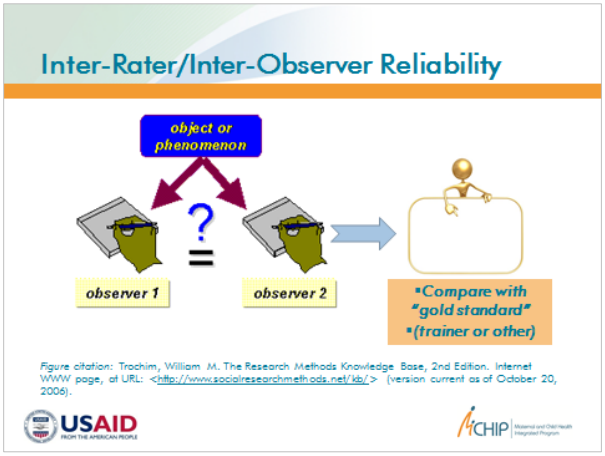


The figure above shows four possible situations. In the first one, you are hitting the target consistently, but you are missing the center of the target. That is, you are consistently and systematically measuring the WRONG VALUE for all respondents. This measure is reliable, but not valid (it's consistent but wrong).

The second target shows hits that are randomly spread across the target. You seldom hit the center of the target; on average, you are accurately measuring the concept for the group, but not very well for individuals. In this case, you get a valid group estimate, but you are inconsistent or unreliable. Here, you can clearly see how the consistency of the measure is directly related to the variability of your measure.

The third scenario shows a case where your hits are spread across the target and you are consistently missing the center. Your measure in this case is neither reliable nor valid.

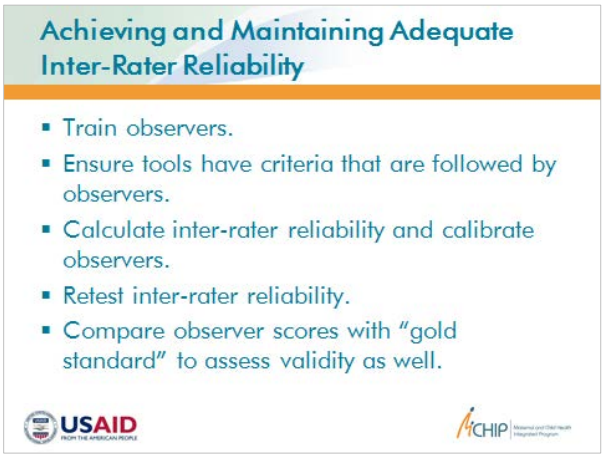
The last target is what we want—the measure is both reliable (consistent and reliable) and valid (measures what it is meant to measure).



Inter-rater reliability is the extent to which two or more individuals (observers or raters) 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 studies involving clinical examinations, it is likely that multiple examiners will need to be employed and that each examiner will need to conduct examinations. Under these circumstances, it is essential to ensure that, to the extent it is possible, different examiners will have reliable results.

In our observer training, however, we are not just comparing observers to each other, but also to a "gold standard"—either a trainer's score or a pre-filled answer sheet if the observers are scoring against one of the video demonstrations or a scripted live demonstration by a trainer.

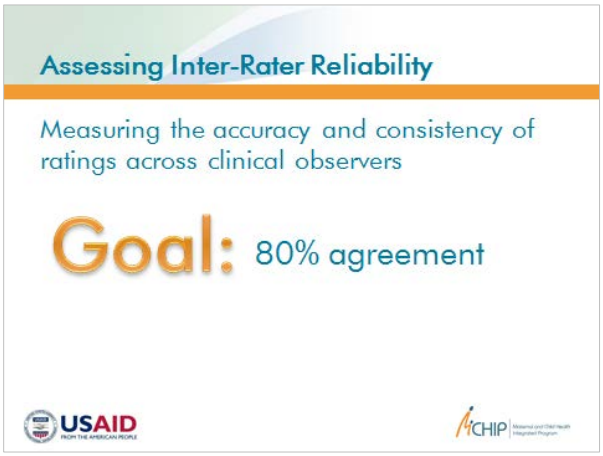


How do we ensure adequate inter-rater reliability?

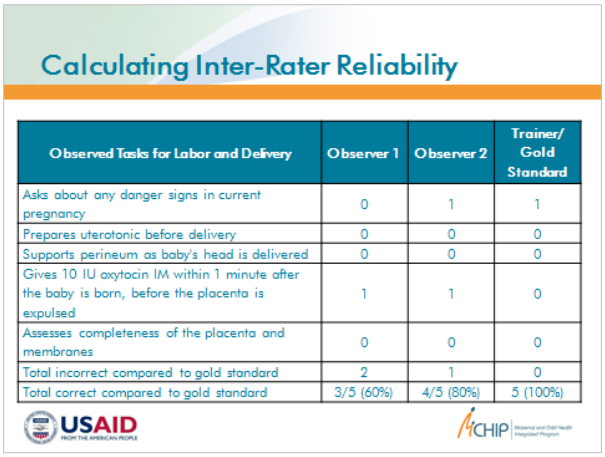
Train observers to be competent in observation.

Calculate inter-rater reliability and calibrate observers as needed. "Calibrating observers" refers to a process of assessing observers' consistency and addressing any inconsistencies.

For longer formal studies, consider retesting inter-rater reliability from time to time to ensure observers are not experiencing drift (the tendency of an observer to change over time, thus changing the quality of data the observer collects).



Goal is for observers to score clinical performances with at least 80% agreement (preferably 90%)—that is, 8 times out of 10 they correctly score the step observed. Observers won't need to calculate inter-rater reliability or calibrate observers, but facilitators and research study leaders will.



Observed Tasks for Labor and Delivery	Observer 1	Observer 2	Trainer/ Gold Standard
Asks about any danger signs in current pregnancy	0	1	1
Prepares uterotonic before delivery	0	0	0
Supports perineum as baby's head is delivered	0	0	0
Gives 10 IU oxytocin IM within 1 minute after the baby is born, before the placenta is expulsed	1	1	0
Assesses completeness of the placenta and membranes	0	0	0
Total incorrect compared to gold standard	2	1	0
Total correct compared to gold standard	3/5 (60%)	4/5 (80%)	5 (100%)

Review and discuss as a large group:
What is the inter-rater reliability between Observers 1 and 2 and the gold standard (the clinical trainer's score or, if using one of the video demonstrations, a pre-scored checklist)?

Does it fit into the standard of 80% and above—that is, do observers have 80% correspondence with the gold standard?

Question: What are three ways to calibrate Observers 1 and 2 to improve data quality?

Possible answers:

- Review items where agreement was low and determine the observers' common mistakes.
- Discuss areas of low agreement with both observers to come to an agreement.
- Ensure that the observers are comfortable and understand the study tools or observer checklists.
- Repeat the exercise with observers.
- Use the perfect/flawed performances to have observers practice (see Session 7 and Appendices C and D).

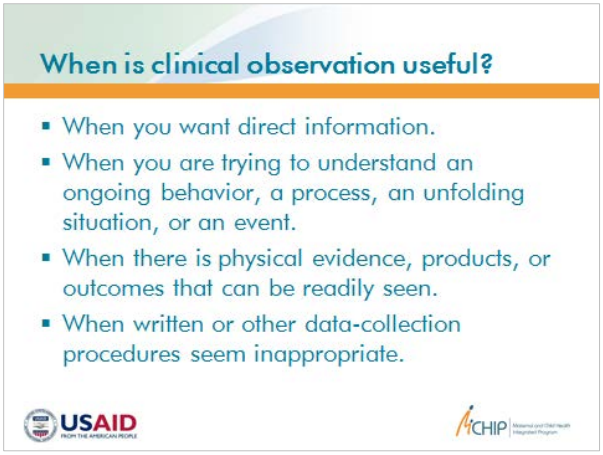
Observers will not need to do this, but we will be doing it as you practice using the tool in simulation and later in a clinical setting.

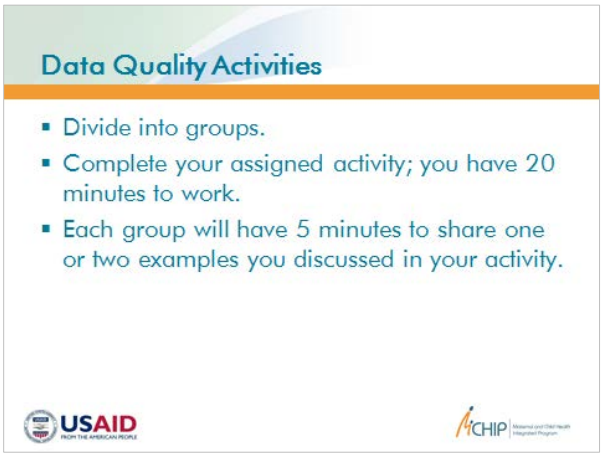
Emphasize the importance of high-quality data. Data are only valuable if they are high quality; low-quality data are not useful because they do not accurately reflect what is going on in the program, research, etc. THE QUALITY OF THE DATA DETERMINES THE USEFULNESS OF THE RESULTS.

High-quality data can affect high-level decisions that in turn affect programs, policy decisions, and funding. For example: Data that are collected on maternal mortality that show there is a decrease in maternal deaths after a specific intervention allow governments and donors to decide when and how to scale up the intervention to save more lives. If the data are low-quality and suspect (have errors), people are less likely to believe the data and may not make decisions based on this data.

Ask the class what the advantages of clinical observation are.
Possible answers:

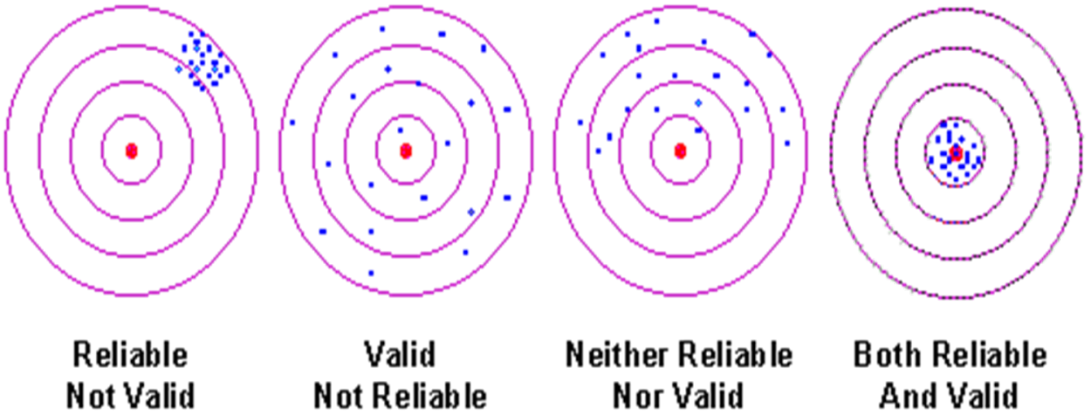
- See what is actually happening on the ground versus review of records.
- Can ensure the data are high quality; not dependent on using secondary data sources.
- Can capture more in-depth data, and get a situational analysis. SEEING and LISTENING are key to observation.
- Observation provides the opportunity to document activities, behavior, and physical aspects without having to depend on people's willingness and ability to respond to questions.





Divide participants into two or four groups (depending on number of participants) to complete Data Quality Activities 1 and 2. Have half work on Activity 1 and half work on Activity 2. Ask for volunteers from each group to present on their answers to the larger group. Reinforce key points pertaining to who the audiences for data are, what data quality is, and why these factors are important.

HANDOUT: ENSURING HIGH-QUALITY DATA



Modified from: Trochim, William M. The Research Methods Knowledge Base, 2nd Edition. Internet WWW page, at URL: http://www.socialresearchmethods.net/kb (version current as of October 20, 2006).

There are several types of variability that can affect the accuracy and reliability of results. These include (1) variability in an individual subject, (2) INTRA-rater variability, (3) variation due to the method of measurement / instrument / tool, (4) INTER-rater variability, and (5) data entry errors. A description of these types of variability and examples of how they may present themselves during clinical observation are in Table 1.

Table 1. Types of variability, descriptions, and examples

Type of Variability	Description	Examples
1. Variability in an individual subject	Over the course of a day or week, a subject may vary in what he/she is being observed for.	The blood pressure reading of a patient may vary over the course of the day. Among health providers being observed performing a service, the "Hawthorne effect" may affect performance.*
2. Intra-rater variability	The same observer may observe differently over the course of a day, or from one facility to the next.	An observer may not be familiar with a long observation checklist with 100+ items. S/he may start out observing with little familiarity with the tool and after doing many observations, s/he is more familiar with the tool. An observer is tired after a meal, or after many hours of observations and is less observant; s/he does not "see" everything that is occurring. Daydreaming or personal biases may affect observation.
3. Variation due to the method of measurement/ instrument/ tool	The observation checklist or the medium (such as paper versus hand-held electronic device) changes.	An observer may start out using paper checklists and then be asked to switch to recording data on a hand-held device. S/he is not familiar with how to scroll from beginning to end or switch views. A tool with a poor translation from one language to another may not accurately convey what aspects should be observed. An observer is asked to use a 20-item newborn resuscitation checklist and later is asked to switch to a more streamlined 15-item checklist.

Type of Variability	Description	Examples
4. Inter-rater variability	Different observers may carry out observation differently.	Observers have different interpretations of key terms. An observer may think that some items on the checklist are less important to observe than other observers do. Some observers may be less comfortable with observation or with the content of the checklist than others. Some observers may be recording items as "Not applicable" while others may leave items blank/missing.
5. Data entry errors	Variation in how results are recorded and entered in electronic database.	Written responses are illegible. Responses are not complete (some cells left blank without reason why). Written data not carefully entered to a database; typographical errors.

*Hawthorne effect: When a participant being observed changes her/his behavior or seems to have better performance than what is normal simply because s/he is being observed.

DATA QUALITY ACTIVITY 1: AUDIENCES FOR DATA

Directions: In your small group, identify as many different audiences for the data as you can and list these in the cells in column 1. Then, for each audience you identified, answer the questions in columns 2 and 3.

Who are the various audiences for the data?	Why does this audience need quality data?	Who benefits from this audience's view of and conclusions drawn from the data? How?

DATA QUALITY ACTIVITY 2: DEFINING QUALITY

Directions: In your small group, answer the following questions regarding data quality.

A. Quality is…

Take a few minutes and think about the concept of quality—what it is and how we recognize it. (For this part of the activity, think about quality in general, NOT as it relates to data collection and reporting. For example, how do you ensure your child is attending a quality school? What do you look for in high-quality foods?) Fill in some thoughts for the sentence completion below.

Quality is…

1.

2.

3.

4.

B. Characteristics of Quality Data

Now, with your group, consider your discussion of quality and relate it to data collection and reporting. Use the space below to jot down adjectives or characteristics of quality data.

1.

2.

3.

4.

Session 3: Clinical Observer Training: How do I collect good-quality data?

SESSION PLAN

Date:	Venue:	Session Number: 3	Duration: 60 Minutes

Step 1: Understand the purpose, objectives, and plans for assessment and/or study that needs clinical observations. Recognize the value of reliable and high-quality data.

Session Title: Clinical Observer Training: How do I collect good-quality data?

Session Objective:
At the end of the session, participants should be able to

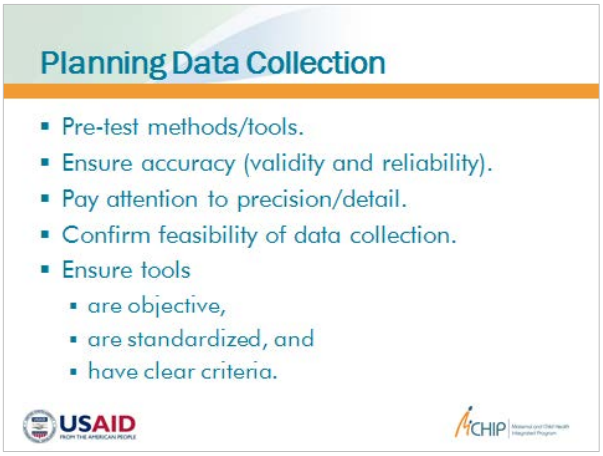
- describe the terms related to data quality, standardization, and reliability;
- defend the importance of objective, standardized observation of clinical service delivery;
- explain how inconsistencies and incomplete or incorrect data impact data quality;
- describe how criteria are used to determine skills performance; and
- summarize key components of competent and quality assessment collection.

Methods and Activities	Materials/Resources
Format: Lecture Small group work **Content**: 1. Explain to the group that this session will cover data quality, data standardization, and reliability. Data quality can be affected by various factors. This session will look at two phases that can affect the quality of data collection: the planning phase and the collection phase. Reinforce that an objective of this course is to prepare participants in data collection to ensure that the data collected are standardized and reliable. 2. Present Session 3 PowerPoint, "How do I collect good-quality data?" **Activity**: 1. Activity where they will determine specific data quality issues and work as a group on how to resolve the issues. 2. Ask participants to break up into small groups made up of participants from various institutions/organizations and to turn to Handout: Case Studies. 3. Hand out flip chart markers and paper to each group. 4. Assign a scenario to each group. Ask the small groups to discuss their assigned scenario and answer the questions at the bottom of the scenario. 5. Explain to the groups they will have one person present the small group findings to the larger group. Each group should write brief bullets showing its answers for its scenario on the flip chart. 6. Allow 20 minutes for the groups to work on the case scenarios. 7. Direct everyone's attention to the front of the room. Ask for a presenter from each group to present the group's findings. For the first group to present on a given scenario, have the presenter read the scenario out loud. 8. Reinforce why objective and standardized data collection is important. Use examples from the groups' bullets.	▪ Session 3 PowerPoint ▪ Handout: Case Studies ▪ Flip charts and markers ▪ Handout: Improving Data Quality as a Clinical Observer

9. Ask the larger group to identify the key components to objective and standardized data collection and to reinforce their responses with the answers the smaller groups had presented from their scenarios. 10. Explain to the group that there will be reinforcement of these concepts throughout the course. Ask if there are any questions before transitioning to the next session. **Summary**: ▪ Review the answers from the case studies. ▪ Ask the group if they have any questions regarding the case studies. ▪ Reinforce the point that good-quality data are needed to make key decisions. If the quality is not good, the final decisions may not be appropriate.	

HOW DO I COLLECT GOOD-QUALITY DATA? NARRATION NOTES

Explain to the group that during this session we will cover data quality, data standardization, and reliability.



PLAN WELL for data collection. Review Handout: Ensuring High-Quality Data from Session 2.

DATA QUALITY CHECK. Review Handout: Ensuring High-Quality Data from Session 2.

Incorporate throughout data collection process: are tools complete? Are answers legible? Are answers consistent? Ensure there are checks in place to identify errors.

Define "drift" for participants: the tendency of an observer to change over time, thus changing the quality of data the observer collects. Explain that an objective of this course is to train observers in data collection to ensure that the data collected are standardized and reliable.

HANDOUT: CASE STUDIES

Clinical Observer Scenarios

1. Joyce and Champion are two clinical observers who are performing independent observations on Sally, a student nurse who is performing a urinary catheter insertion. Joyce and Champion are using a Yes/No answer key as they observe the maintenance of sterile technique during the procedure. Joyce rates Sally as a “Yes" but Champion rates Sally a "No."

What type of data quality error is occurring?

What is the effect of this type of data quality error?

How would you correct this data quality error?

2. Stella has been observing clinical officers at three district hospitals. At the first hospital, she observed John, a clinical officer, massage a woman’s uterus after delivering a baby. Based on her observations, Stella rated John’s skill a “Yes.” At the third district hospital, she observed Martha, a clinical officer, massage a woman’s uterus after delivering a baby and realized that John was more efficient and had better technique than Martha. She marked Martha in the “No” category even though Martha was performing at an acceptable skill level. She felt she shouldn’t mark Martha with “Yes” because John was more proficient at performing the skill than Martha.

What type of data quality error is occurring?

What is the effect of this type of data quality error?

How would you correct this data quality error?

ANSWER SHEET FOR FACILITATORS: CASE STUDIES

Scenario 1, question a: This scenario indicates there is a problem with inter-rater reliability. **Inter-rater reliability** is the extent to which two or more individuals (observers or raters) agree. Joyce and Champion are not in agreement with their observation of Sally's maintenance of sterile technique.

Clinical observers may have problems with inter-rater reliability due to a variety of issues including improper training or lack of training as well as observers being inconsistent, easily distracted, tired of doing repetitive tasks, or biased. Observers might also be daydreaming or misinterpreting things.

Scenario 1, question b: These data would not be of a good quality and would affect the results of the study. Remember, **THE QUALITY OF THE DATA DETERMINES THE USEFULNESS OF THE RESULTS**.

Scenario 1, question c: In studies involving clinical observations, it is likely that multiple observers will need to be employed. Under these circumstances, it is essential to ensure that, to the extent possible, different observers have reliable results. It is important for supervisors to calibrate observers throughout data collection to ensure that inter-rater reliability is maintained at 80% or higher. Further training or skills review for clinical observers may also be necessary.

Scenario 2, question a: This is an intra-rater reliability error, where a clinical observer may change over the course of the study and individual data collectors may develop specific idiosyncrasies or "drift" in their measurements. Drift is the tendency of an observer to change over time, thus changing the quality of data the observer collects.

Scenario 2, question b: These data would not be of a good quality and would affect the results of the study. Remember**, THE QUALITY OF THE DATA DETERMINES THE USEFULNESS OF THE RESULTS.**

Scenario 2, question c: It is important for supervisors to calibrate observers throughout data collection to ensure that intra-rater reliability is maintained at 80% or higher. Further training or skills review for clinical observers may also be necessary.

HANDOUT: IMPROVING DATA QUALITY AS A CLINICAL OBSERVER

- **Clear definitions**—Ensure that the terms are clearly defined and you, as an observer, understand the relevant terms.
- **Pre-tested tools—Confirm with your supervisor that tools have been pre-tested, or be involved in pre-testing as part of your training.**
- **Precision and detail**—Pay attention to precision/detail. Data should have sufficient detail (e.g., notes in comment boxes).
- **Objectivity**—Tools are designed to measure OBJECTIVE data. "Objective" means not influenced by personal feelings, interpretations, or prejudice; based on facts; or unbiased, as in "an objective measure."
- **Standard tools/methods—Ensure tools and methods are standardized**. Data collection methods must ensure that subjects are observed in the same way.
- **Translation**—Ensure tools have been translated appropriately; try back translation to ensure original intent is captured.
- **Completeness**—The complete set of data includes all units / eligible persons or sites and not just a fraction of the list.
- **Timeliness**—Data are timely when they are up-to-date (current) and when the information is available on time and provides measurement at time intervals relevant and appropriate in terms of program goals and activities (such as a monthly reporting form or quarterly reports capturing data from previous months).
- **Legibility**—Ensure your answers are legible for other persons to read and interpret and for use in data entry.

Common Data-Collection Errors

- **Missing/unreadable data**—Either data are missing on the tool or the data are illegible.
- **Data entered incorrectly**—The observer hits the wrong key on an electronic device, selects the wrong box, or is unfamiliar with the tool.
- **Delay in data entry**—Time passes between data collection and entry, leading to errors.
- **Misunderstanding about when "Not applicable" or "Don't know" can be used—** "Not applicable" is marked when it should not be, or an entry is left blank when it should have been completed.

Session 4: Clinical Observer Training: What's the plan?

SESSION PLAN

Date:	Venue:	Session Number: 4	Duration: 60–120 Minutes
Step 2: Review data collection instruments **Session Title**: Clinical Observer Training: What's the plan?			
Session Objective: At the end of the session, participants in a research study or formal assessment should be able to ▪ summarize the study goals, study questions, and evaluation design; and ▪ discuss the current data-collection plan as it relates to the study goals. At the end of the session, participants in a general assessment data-collection program should be able to ▪ summarize the goals of the assessment program, and ▪ discuss the current data-collection plan as it relates to the goals of the program.			
Methods and Activities			**Materials/Resources**
Format: Large group work Pair work **Content**: ▪ Tell participants that you will now review the specific goals and purpose of the particular assessment/study that is covered in this course. ▪ For research study or formal assessment, review Handout: Study Plan Overview Template. Note: The extent to which the following information is reviewed will depend upon the familiarity the training participants have with the monitoring/evaluation that is planned. Less review is better if the information has been covered before. ▪ Clearly specify how the results from the assessment will be used to improve outcomes, safety, quality, etc. Use this information to motivate the participants. **Activity for all participants**: ▪ Explain to the group that during this session they will have the opportunity to talk about the data collection practices they will experience after this course. ▪ Ask participants to pair off. Ask the pairs to discuss the following questions on the data collection practices that were reviewed in the session. - What TYPES OF DATA will be collected? - What TOOLS will be used to collect and collate this data (examples include facility registers, summary reporting forms, patient treatment cards)? - Who will be RESPONSIBLE for filling out these forms? - Who will INPUT the data? - Who will the data get REPORTED to? - Who will USE the data collected? - How will it be used?			▪ Flip chart paper and easel ▪ Facilitator-developed handout (see Handout: Study Plan Overview Template or protocol) ▪ Use the Session 4 Powerpoint, "What's the plan?," as a template to create a presentation or handout summarizing the study protocol or data collection plan

- What are some of the CHALLENGES participants may face in collecting this data? ▪ Direct everyone's attention to the front of the room. Ask for volunteers to give example answers from their pair work. Document each answer on flip chart paper at the front of the room. ▪ Have the larger group discuss their experiences and challenges they have faced in collecting data. Record on a flip chart. ▪ What may be some of the CHALLENGES of data collection, management, and reporting? ▪ Summarize the challenges highlighted. ▪ Reinforce why data collection is important. Use an example from one volunteer's answers. ▪ How could data be USEFUL to participants at the site level? District level? National level? ▪ Why does this data collection matter? Public health good, reporting to donors in order to get more funding, improving the facility they work in, improving outcomes for Millennium Development Goals, etc. ▪ Explain the big picture about the study and the data collection including what happens to the data and how it will be cleaned, input, and analyzed. ▪ Tell participants that their responses to these questions and many of the answers to these questions will be discussed throughout the training. **Summary**: ▪ Provide an overview of the study or assessment goals and objectives. ▪ Ask if there are any questions before transitioning to the next session.	

WHAT'S THE PLAN? NARRATION NOTES (TO BE DEVELOPED BY FACILITATOR)

HANDOUT: STUDY PLAN OVERVIEW TEMPLATE

Use this to guide you in developing a handout overview for the research study or formal assessment that is planned. This handout can accompany or be based upon the approved study plan. Handouts can be developed for this presentation directly from the evaluation planning activities.

The handout should provide participants an overview of the study. Develop a study plan handout (or PowerPoint overview) that will address each point listed below and provide it to participants during Session 4. Include clear information on each of the following in your handout.

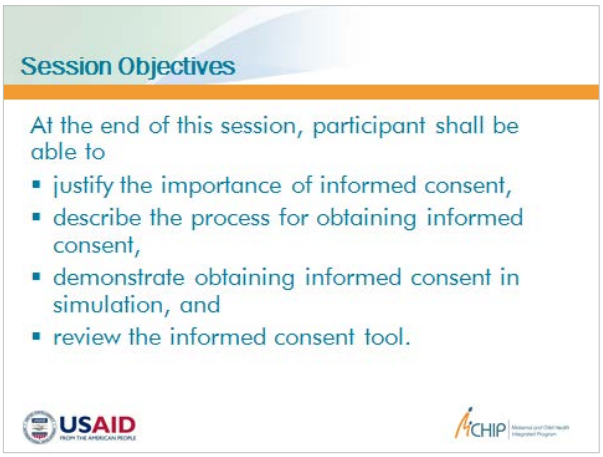
- Specific goal and objectives for this particular evaluation
- Why these data or indicators are being collected
- Program description (if results of a program are being assessed)
- Relevant background information
- Specific evaluation questions
- Evaluation design and timeframe
- Who will participate in the evaluation
- What the evaluation content will consist of
- How the data will be analyzed
- Content of informed consent and related tools
- How the findings will be disseminated and used

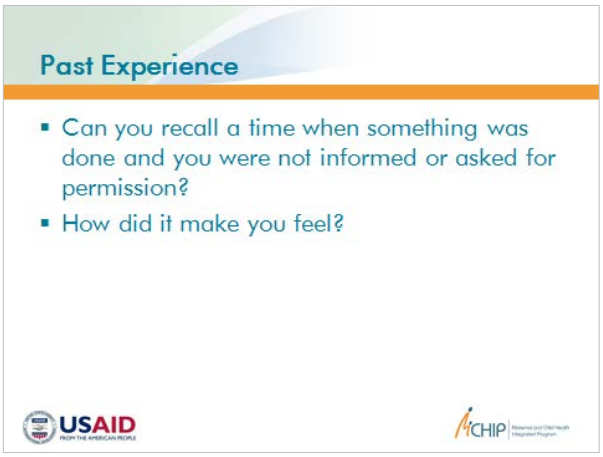
Session 5: Clinical Observer Training: How do I obtain informed consent?

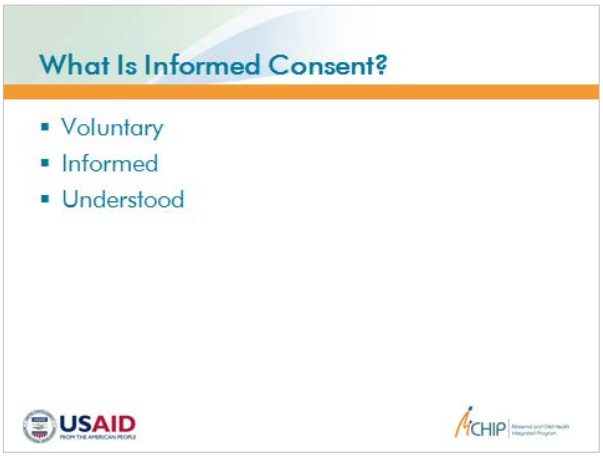
SESSION PLAN

Date:	Venue:	Session Number: 3	Duration: 60 Minutes
Step 2: Review data collection instruments **Session Title**: Clinical Observer Training: How do I obtain informed consent?			
Session Objective: At the end of the session, participants should be able to ▪ justify the importance of informed consent, ▪ describe the process for obtaining informed consent, ▪ demonstrate obtaining informed consent in simulation, and ▪ review the informed consent tool.			
Methods and Activities			**Materials/Resources**
Introduction: Ask the group to recall a time when something was done and they were not informed or asked for permission. How did it make them feel? Ask someone to define informed consent. **Activity**: Reinforce discussion with the Session 5 PowerPoint, "How do I obtain informed consent?"; briefly demonstrate informed consent using your research study consent forms or the Handout: Sample Written Consent Form for Study Participants. Provide time for the group to practice Handout: Role Play in trios (about 15 minutes total). **Summary**: ▪ Informed consent must be obtained in relative privacy and remain confidential (e.g., not from a health care worker in front of her/his boss). ▪ Informed consent is not required for coaching/follow-up, but asking permission to observe is important. ▪ For a study approved by an institutional review board (IRB), most IRBs will provide a stamp on the approved consent forms; it is important to use these versions.			▪ Session 5 PowerPoint ▪ Handout: Role Play ▪ Handout: Sample Written Consent Form for Study Participants OR your research study consent forms

HOW DO I OBTAIN INFORMED CONSENT? NARRATION NOTES





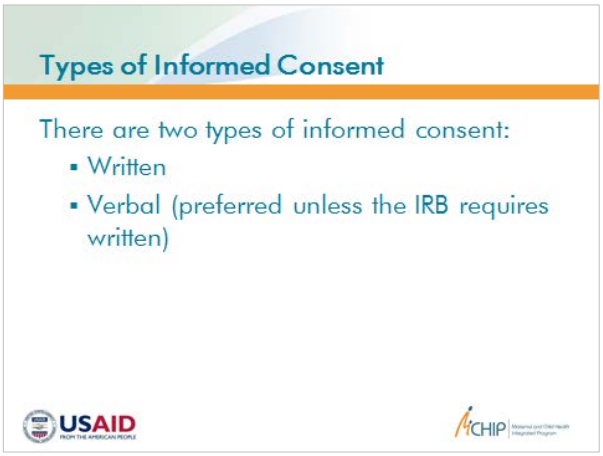


An individual's (or their guardian, if subject is a child) voluntary agreement to participate in a research study is based on a complete understanding of the purpose of the study and the potential risks and benefits of participation. An explanation to the patient or research study participant about the study includes information, comprehension, and voluntariness. The explanation must be conducted in a language that is appropriate for the participant and understood.

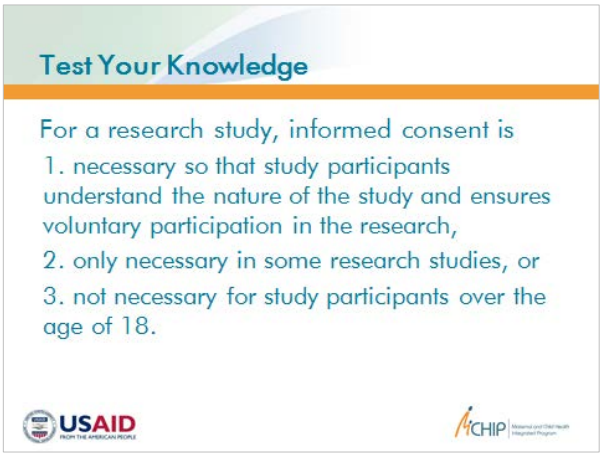
A research study consent form must explicitly address these points, and can be administered verbally or in writing.

Verbal consent: the interviewer / data collector reads the consent form to the subject. If the subject agrees to participate in the study, the interviewer / data collector signs two copies of the form and gives one to the subject.

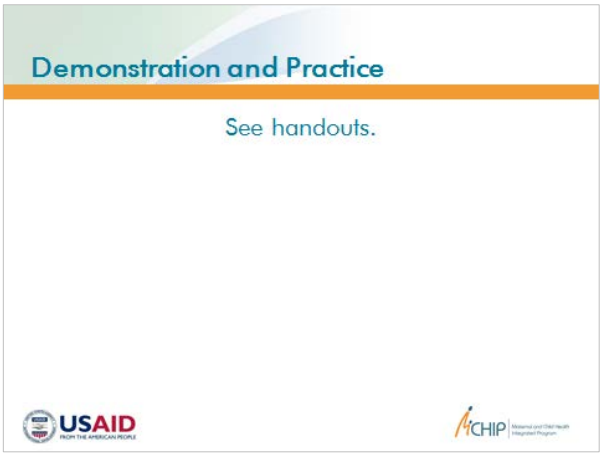
Written consent: the interviewer / data collector gives the consent form to the subject to read. If the subject agrees to participate in the study, the subject signs two copies of the form, gives one to the interviewer / data collector, and retains the other.



If using smart phones for consent—VERBAL consent is used. Read aloud and mark response on smartphone. Consent must be obtained for each health worker and client observed or interviewed. No names are recorded. Next of kin provides consent for a woman presenting with post-partum hemorrhage or convulsions who is unable to provide consent herself if this is an approved part of the study protocol. She will be asked for consent when that becomes possible.



Answer is 1.



Explain to the group that you will demonstrate how to obtain informed consent for your research study or formal evaluation. If you are preparing clinical observers who are not in a research study, demonstrate how to ask for permission to observe. Research studies: review the study-specific informed consent tools or Handout: Sample Written Consent Form for Study Participants. Use Handout: Role Play to practice in trios; each person gets 5 minutes to practice obtaining consent.

Clinical observers (not a research study): use Handout: Role Play to practice in trios; each person gets 5 minutes to practice obtaining verbal consent.

HANDOUT: ROLE PLAY

Objective: To give students the opportunity to practice obtaining informed consent.

Time: 15 minutes

Materials: informed consent forms

Instructions:

1. Break into teams of three.
2. Identify one person to be the data collector, one to be the potential research subject, and one person to be the observer. Each participant will have the opportunity to play each of the three roles: data collector, research subject, observer.
3. Conduct a role play using the consent forms and obtaining informed consent.
4. The data collector should obtain feedback on the role play from the observer.
5. If time allows, hold group discussion:
    - What was the experience of obtaining informed consent like?
    - What was difficult?
    - What was easy?

Ideas for scenarios if you are not using actual informed consent form/tools from study:

- A pregnant woman being asked to participate in a study on certain vitamin supplements and pregnancy
- A malaria patient being asked to participate in a study for a new drug
- A healthy person being asked to participate in a study for the development of a malaria vaccine

HANDOUT: SAMPLE WRITTEN CONSENT FORM FOR STUDY PARTICIPANTS

Title of the Study: The Effect of Primary Health Care Clinical Placements during Nursing and Midwifery Education on Clinical Practice

Researchers: Abraham Jones

Maternal and Child Health Integrated Program (MCHIP)/Jhpiego is conducting a study to understand the acceptability and usefulness of primary health care clinical placements for nursing and midwifery students. This study involves responding to questions asked by the researchers in questionnaires and in focus group discussions. In addition, data will be collected via observation and record review. There will be no harm inflicted to you and the information received will be kept confidential. The study has been approved by the Research and Ethics Committee of Ministry of Health and the Director General for Health Services in Lesotho.

Your participation in the study is voluntary and you are free to withdraw from the study at any time without supplying reasons. The withdrawal will have no effect on your work or your performance appraisal / student assessment. We estimate your involvement in the study will take approximately 20 hours.

Statement by the Participants:

I (participant's name).....have read the information and been provided with the necessary verbal explanation on the proposed study. I have also been provided with opportunity to ask questions and given adequate time to rethink the issues. I have not been pressured to participate in any way. I therefore, hereby give my consent to participate in the study.

.....	.....
Full name of the participant	Signature of participant
.....	.....
Date	Place

Statement by the researcher:

I have explained the study to the above-stated client, and I agree to answer any questions concerning the study. I will adhere to the approved protocol.

.....	.....	.....	.....
Name of researcher	Signature	Date	Place
.....	.....	.....	.....
Name of witness	Signature	Date	Place

HOMEWORK PLAN

NOTE TO FACILITATORS: Depending on the number of tools and/or elements in the tools, assigning homework for tool review may not be sufficient for participants to familiarize themselves with all the tools. Facilitators should take this into account and may need to build time into the training to go through the tools and clarify/answer questions about each tool.

Date:	Venue:	Homework Plan	Duration: Take Home
Step 2: Review data collection instruments **Homework Assignment**: Clinical Observer Training: Which tool do I use and how?			
Homework Objectives: At the end of the homework assignment, participants should be able to: ▪ summarize the methods and modes of data collection; ▪ describe the primary data-collection tools and relevant data variables; ▪ justify the collection of the data, why it is important, and what the data can be used for; and ▪ determine adequacy of criteria in data collection tools.			
Methods and Activities			**Materials/Resources**
Format: Take home assignment **Activity**: 1. Refer participants to Handout: Tool Review Homework. 2. Hand out the specific data-collection tools related to the study. 3. Review the instructions of the homework assignment with the participants. 4. Ask participants if they have any questions. 5. Tell participants that they will have a short quiz at the beginning of Day 2 regarding their homework assignment.			▪ Relevant data-collection tools (enough for 1 copy for each participant) ▪ Handout: Tool Review Homework

HANDOUT: TOOL REVIEW HOMEWORK

1. Your assignment is to review the different tools that will be used in the specific study.
   - Review specific data-collection tools related to the study.
   - Review every data variable on the data collection tools.
2. During review of variables, you should think about why the data variable is being collected and its importance. You should critique the tools based on the following tool guidance:
   - Is the tool designed to collect objective information? If not, why not?
   - Is the language appropriate? If it has been translated, do the questions still accurately reflect the original intent of the questions?
   - Do the criteria provide adequate guidance to verify competence / task completion? If not, why not?
   - Are there enough criteria for rating or completion of tool and are they understandable? If not, why not?

Session 6: Clinical Observer Training: Which tool do I use and how?

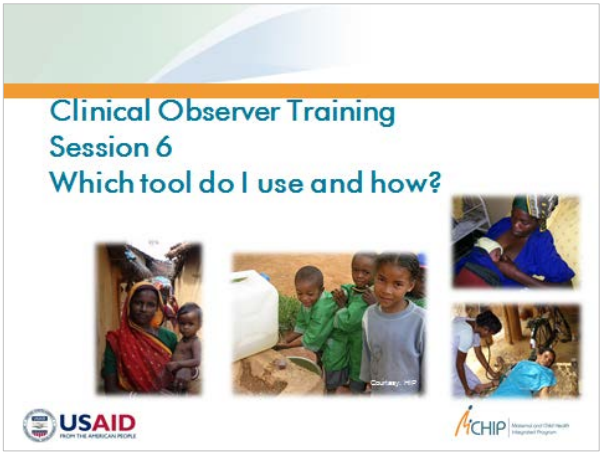
SESSION PLAN

Date:	Venue:	Session Number: 6	Duration: 60 Minutes*
Step 2: Review data collection instruments **Session Title**: Clinical Observer Training: Which tool do I use and how?			
Session Objective: At the end of the session, participants should be able to ▪ justify the collection of the data, why it is important, and what the data can be used for; ▪ explain the various sections of the tools and any specialty collection methods; and ▪ describe when tools can and can't be modified.			
Methods and Activities			**Materials/Resources**
Format: Lecture Large group work **Content**: 1. Explain to the group that during this session, they will cover the specific tools that they will be using during their observation. These are the tools they reviewed as their homework assignment on Day 1. 2. Present Session 6 PowerPoint, "Which tool do I use and how?," on data collection methods. Use primarily discussion and reinforce with presentation. **Activity**: 1. Explain to participants that now the group will review the different tools that will be used in the specific study (hand out the relevant data-collection tools or have them refer to tools that were used for the homework). 2. Briefly review the tools by sections and ask if participants had any questions during their homework assignment. 3. For each data collection tool, have a participant read aloud every data variable. Critique the tools based on tool guidance: - Is the tool designed to collect objective information? If not, why not? - Do the criteria provide adequate guidance to verify competence / task completion? If not, why not? - Are there enough criteria for rating or completion of tool and are they understandable? If not, why not? 4. As the data variables are introduced, discuss the following examples of specialty cases: - Multi-response questions and skip patterns - When only one item can be checked in a section (for example, a person's status is either HIV-positive, HIV-negative, or unknown) - When they need to rate a specific item, for example on a Likert scale (tell participants that criteria for rating will be discussed in a subsequent section) - Anywhere there is a straight line after "Other" or "Reason" that should be completed			▪ Session 6 PowerPoint ▪ Handout: Role Play ▪ Handout: Sample Written Consent Form for Study Participants OR your research study consent forms

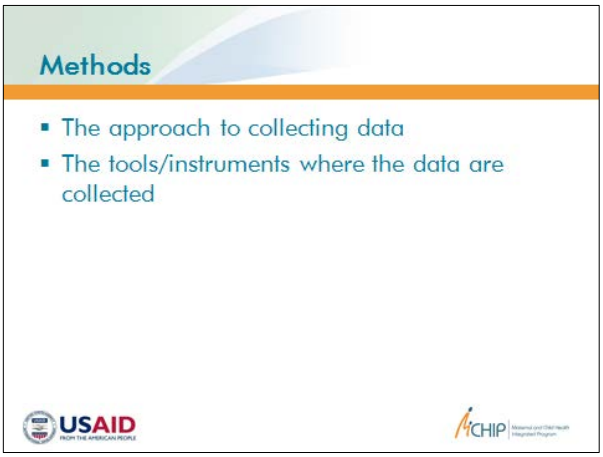
5. This is also an opportunity for participants to give feedback on tools if appropriate. 6. Review specific study guidance on when clinical observers CAN and CAN'T revise/modify tools. **Summary**: ▪ Ask participants if they have any questions. ▪ Tell them that they will have an opportunity to practice using the forms later in the course.	

*NOTE: Depending on class size and complexity of tools/study, this session may take longer than one hour.

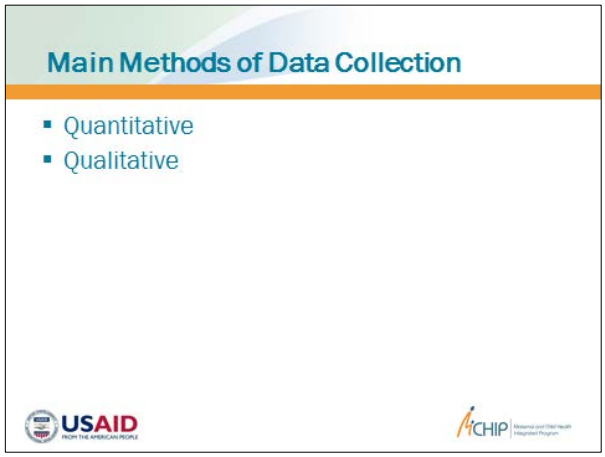
WHICH TOOL DO I USE AND HOW? NARRATION NOTES



Explain to the group, "During this session, we will cover the specific tools that you will be using during your observation."



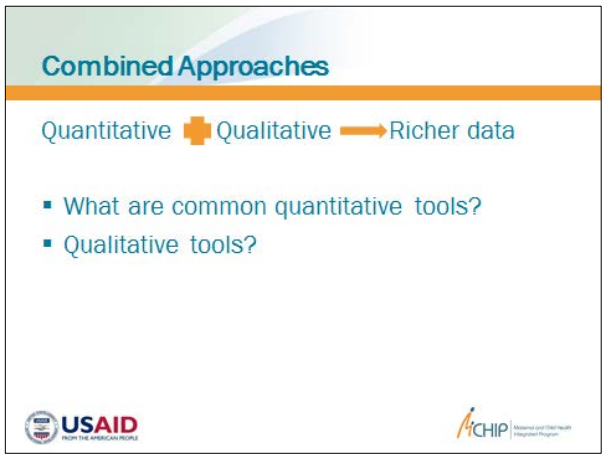
There are various research methods that can be implemented to monitor and evaluate programs, facilities, etc. Ask the group, "Can anyone name the two main scientific methods of data collection?"



Quantitative methods are those that are based on structured or standardized approaches. Quantitative data are data that can be analyzed using statistical methods. Quantitative methods are used to collect and analyze numerical data. Quantitative methods are the most common method of data collection.

Qualitative methods are those that generally use semi-structured or open-ended methods to produce in-depth, descriptive information. Qualitative data provide understanding of social situations and interactions.

Ask group if they can name a qualitative method of collecting data. (Possible answers: interviews, focus groups, key informants.)



Quantitative and qualitative methods can be used separately or together to investigate the same phenomenon.

This can add depth and breadth to a study. Can you think of examples where qualitative data could enrich quantitative data?

For instance, quantitative data can be collected on the percentage or "how much" of the community has been tested for HIV and qualitative data can be collected to explain "why."

Combined approaches allow for the quantitative data to show what is happening and the qualitative data to determine why. Example: Quantitative data indicates that younger men are seeking circumcision more than older men. Qualitative data teases out why this is: interviews with older men indicate this is because they believe circumcision is a rite of passage for younger men.

Checklists may include a standardized clinical observation checklist of client-provider interactions, a supply and equipment checklist, or an inventory form. Activity forms vary substantially, but are often designed to collect basic information about specific activities. Structured, coded questionnaires can be used to capture quantitative data while qualitative (semi-structured) questionnaires can use open-ended questions to gather more qualitative data.
Are there other tools that have not been mentioned?

Objective: Not influenced by personal feeling, interpretations, or prejudice; based on facts, unbiased

Standardized: To compare with a standard/criterion

Criterion: A standard by which something can be judged or decided. "Criterion-referenced" means that tools link directly to standards.

Session 7: Clinical Observer Training: How do I standardize my skills observations?

SESSION PLAN

Date:	Venue:	Session Number: 7	Duration: 90 Minutes*
Step 3: Train in the performance of clinical skills observation **Session Title**: Clinical Observer Training: How do I standardize my skills observations?			
Session Objective: At the end of the session, participants should be able to demonstrate competency in conducting observations of clinical practices.			

Methods and Activities	Materials/Resources
Introduction: Ask the group to recall when they were standardized in the skill(s) they will be observing. Why is this important? It is important that they recognize the desired and correct performance of the target skills for observation. Trying to capture clinical practice using study tools or observer checklists is challenging and imperfect. Tell the participants that in this session, they are going to practice observing flawed performances in order to compare findings and improve their observation skills. Explain to participants that in order for an assessment to be valid and reliable, agreement must be reached on what constitutes a complete and correct performance of each skill. Determine what an optimal performance should look like (e.g., through modeling, demonstration, videotapes, discussion). **Activity**: 1. This activity varies depending if you have a specific assessment tool you are preparing observers to use or if you are preparing clinical observers for a larger research study. **A. Using a specific assessment tool** Use the provided specific assessment tool (or video demonstrations if they are consistent with your purpose). You will do the following: a. CORRECT DEMONSTRATION: Demonstrate a specific portion of the skill correctly to show the participants what is expected (15 minutes). b. FLAWED DEMONSTRATION: Explain to participants that the course is going to work on an activity of scoring flawed performances. c. Pass out or direct the participants to the relevant checklist. Explain to the participants that they will observe the performance or video and record their observations. d. Tell the participants that they will be working individually and documenting the details on the checklist. They should NOT talk with their neighbors as they complete the tool. e. Tell participants they will then compare their individual results with other participants to ensure standardized/reliable data. f. Play the related video or perform the flawed script. g. At the end of the video/performance, ensure that each participant has completed her/his checklist. h. Have the participants exchange checklists with other participants. They will grade each other's tools. i. Review the checklist, going through each step and calling out the correct answer.	▪ Flip chart and markers ▪ Observation Checklist for each clinical activity ▪ Various videos on flash drive or via Internet (see Appendix C) OR 1–2 facilitators prepared with script and appropriate clinical equipment (see Appendix D) OR 1–2 facilitators able to perform skill spontaneously and appropriate clinical equipment ▪ Final Knowledge Assessment (1 copy for each participant) ▪ Videos (see Appendix C): - ANC & PMTCT Visit Perfect http://youtu.be/pUsDpaKGJJo - ANC & PMTCT Visit Flawed http://youtu.be/LYUJF3IfHIc - Counseling for Cervical Cancer Prevention Perfect http://youtu.be/MX9ao6EnyUw - Counseling for Cervical Cancer Prevention Flawed http://youtu.be/8XXNKzK_7IU - Six Week Post-Partum Follow-Up

j. Ask the group if they concur with the correct answer. If there is a discrepancy in the results, discuss with the group why there is a discrepancy and come to a consensus. k. Ask if any of the participants have any uncertainty on how to mark the checklist. Make sure everyone is comfortable and consensus is reached on documentation. l. Have participants return the checklists to the original participants so they can see their results. m. Reinforce the importance of inter-rater reliability and how to standardize the results among different observers. Have participants write their names on their checklists and hand the tools to the facilitator(s). n. Review the markings with the co-facilitators and calculate inter-rater reliability using Facilitator Directions: Calculating Inter-Rater Reliability of Participants for Sessions 7 and 8. If it is not 80% or higher, continue to calibrate the participants by doing another flawed performance. If there are inconsistencies, discuss why and resolve them. **B. Research study or formal evaluation observation practice** Use this if you are facilitating this training for a research study or formal evaluation approved by an institutional review board (IRB). NOTE: This activity can take from 1 hour to several days, depending on the length and complexity of the tools. Adjust the schedule accordingly. a. Provide time to review study or evaluation tools if needed. b. Pass out or direct the participants to the relevant tool. Explain to the participants that they will observe the performance or video and record their observations. c. Tell the participants that they will be working individually and documenting the details on the tool. They should NOT talk with their neighbors as they complete the tool. d. Tell participants they will then compare their individual results with other participants to ensure standardized/reliable data. e. Using the tools, demonstrate the critical skills CORRECTLY. Follow each correct demonstration with a FLAWED performance in which you perform 3–5 steps INCORRECTLY. The participants should observe and mark a copy of the tool. f. Have the participants exchange tools with other participants. They will grade each other's tools. g. Review the tool, going through each step and calling out the correct answer. h. Ask the group if they concur with the correct answer. If there is a discrepancy in the results, discuss with the group why there is a discrepancy and come to a consensus. i. Ask if any of the participants have any questions on any uncertainty on how to mark the tool. Make sure everyone is comfortable and consensus is reached on documentation. j. Have participants return the tools to the original participants so they can see their results. k. Reinforce the importance of inter-rater reliability and how to standardize the results among different observers. Have participants write their names on their tools and hand the tools to the facilitator(s). l. Review the markings with the co-facilitators and calculate inter-rater reliability using Facilitator Directions: Calculating Inter-Rater Reliability of Participants for Sessions 7 and 8. If it is not 80% or higher, continue to calibrate the participants by doing another flawed performance. If there are inconsistencies, discuss why and resolve them.	Visit Perfect http://youtu.be/LG_65GegMVM - Six Week Post-Partum Follow-Up Visit Flawed http://youtu.be/JgzoFUbw9XE - Managing Second Stage and Active Management of Third Stage of Labor Perfect http://youtu.be/omJJnrQtseE - Managing Second Stage and Active Management of Third Stage of Labor Flawed http://youtu.be/otT-YUvBiEk - Newborn Resuscitation Perfect http://youtu.be/PH9fCTu1POM - Newborn Resuscitation Flawed http://youtu.be/RCVjWMYmNOs

2. Hand out and have participants take the Final Knowledge Assessment. 3. Collect the Final Knowledge Assessments and have a co-facilitator score the assessments. Inform participants that if they score less than 80%, they will need to take the test again prior to completion of the course. 4. Spend some time reviewing logistics in preparation for Session 8 site visit to health facilities. Ensure that all facilitators and participants are clear on where they are meeting for their pre-clinical meeting and the objectives of the day(s). 5. Prior to travel to health facilities, it is important that facilitators discuss the following with participants: **A.** Participants may observe care that does not comply with standards, but they should not intervene (verbally or physically) unless it is a life-threatening situation. If a life is in danger and the provider does not recognize the seriousness of the situation or is not performing the required lifesaving interventions, the observer should summon help from the provider's onsite supervisor or other senior colleague. If observers decide to intervene, they have stepped out of their roles as observers, and are then practicing as clinicians licensed by their related professional body and governed by the requirements and restrictions of their license and practice in their country. If such a situation occurs, it is very important that the observer make a note about this on the data collection form **B.** If facility staff asks the observers how staff performance was, an example response is, "The team does not report individual evaluations, but all data will be collated and given to Ministry of Health staff participating in the survey. The Ministry will determine how it is used." **Summary:** ▪ Review key themes and common reasons for inconsistency. ▪ Review key points for critical skills, common problem areas to watch for. ▪ Review the study tools or observer checklists. ▪ Explain what is expected of clinical observers when using these tools/checklists.	

*NOTE: The length of time required for standardizing skill observations depends on the assessment tool(s). It may take anywhere from 1 extra day to 1 week for complex and detailed assessments where multiple services (e.g., antenatal care, delivery care, sick child care) are being observed. Revise the schedule accordingly. Assessment of each service area will require about 60–90 minutes of practice. For further guidance, please see Appendix E for a sample schedule from a complex assessment.

In addition, although clinical observer participants should be clinically up-to-date and practicing clinicians, some may not be familiar with the exact guidelines/checklists that are being used for clinical observations. For example, if World Health Organization (WHO) guidelines are being used for the study but the national guidelines differ, the clinician may not be familiar with the WHO guidelines. Some facilitators have found it necessary to conduct short technical updates in key areas as part of the clinical observer training; this helps standardize all the clinical observers. If you anticipate the need for key clinical updates, build time for them into the schedule.

FACILITATOR DIRECTIONS: OBSERVATION CHECKLISTS

TRAINER NOTE: There are three ways the practice observations can be done:

1. Videos—Using video of skills, if possible, is one way of practicing standardization of data collection. Participants will watch the video and use appropriate tools to score the video performance. Please see Appendix C for a list of available training videos that may be appropriate for your data collection study.
2. Scripted performances —Using 1 or 2 trainers/facilitators to demonstrate a clinical skill with scripts that have been developed in advance is an alternate way of practicing standardization of data collection. Participants will watch the scripted performance and use the appropriate tools to score the performance. (See Appendix D for scripts.)
3. Spontaneous performances—Spontaneous performances are similar to scripted performances except that the people demonstrating the clinical skill do not use a script.

Training Observers to Rate against a Standard Criterion

The principle underlying this approach is to establish a standard of performance, train clinicians to achieve that standard of performance, and then train observers to be able to accurately and reliably rate the quality of that performance during observations of clinical practice. Experts establish the criteria or performance standards (for example, quality of care tools or skill checklists), and observers are trained until they are able to consistently rate the practice against these standards—or in the same way experts would. It will probably be necessary to do a series of flawed performances, videos, or demonstrations. Learners' skills on scoring will improve with practice. Resources for scoring inter-rater reliability among participants can be found in Facilitator Directions: Calculating Inter-Rater Reliability of Participants for Sessions 7 and 8. It is important to calculate inter-rater reliability among participants during both Sessions 7 and 8 in order to calibrate participants as needed.

NOTE: Whether you use videos or performances, the same observer tool(s) can be used and will serve as a standard against which the clinical observers will mark their results.

Observation Checklist: ANC & PMTCT Visit

Watch the video or performance and mark if each step was done or not. Blacked-out rows are not done; skip over those.

	Yes	No	Don't Know (DK)	Go To
A107: Did the health worker wash his/her hands with soap or use hand rub prior to examination?	1	0	8	
A108: Did the health worker perform any of the following procedures?				
[redacted]				
02) Take the client's blood pressure	1	0	8	No/DK→A108_03
02a) Take client's blood pressure in sitting or lateral position	1	0	8	
02b) Take blood pressure with arm at heart level	1	0	8	
03) Examine hands for edema	1	0	8	
04) Perform or refer for urine test	1	0	8	No/DK→A108_05
04a) Test for proteinuria	1	0	8	
04b) Test for bacteruria	1	0	8	
04c) Test for glucose	1	0	8	
05) Check for signs of anemia	1	0	8	
06) Perform or refer for anemia test	1	0	8	
[redacted]				
A109: Did the health worker ask about or the client mention her HIV status?	1	0	8	
A110: Did the health worker perform, inquire about, or refer for an HIV test?	1	0	8	
A111: Is client HIV-positive? (Observer: Listen and record answer. Circle "Don't Know" if HIV status is unknown or status is not discussed.)	1	0	8	
A112: Did the health worker provide any counseling on HIV or prevention of mother-to-child transmission (PMTCT)?	1	0	8	No/DK→A114
A113: Did the health worker provide counseling on the following HIV/PMTCT topics?				
01) Explain the purpose of antiretroviral prophylaxis	1	0	8	
02) Explain when to collect NVP	1	0	8	
03) Explain when the baby takes NVP and for how long	1	0	8	
04) Explain how to take antiretroviral therapy (ART)	1	0	8	
05) Explain the advantages and side effects of ART	1	0	8	
06) Explain feeding options for exposed babies	1	0	8	
07) Explain about importance of bringing exposed infant back for testing	1	0	8	
A114: Did the health worker refer the client to care and treatment center?	1	0	8	

ANC & PMTCT Visit Answer Key

PERFECT: All steps in the checklist were covered in the PERFECT video or performance.
FLAWED: See checklist below for answers **(in bold)** to FLAWED video/performance.

	Yes	No	Don't Know (DK)	Go To
A107: Did the health worker wash his/her hands with soap or use hand rub prior to examination?	1	**0**	8	
A108: Did the health worker perform any of the following procedures?				
[redacted]				
02) Take the client's blood pressure	1	**0**	8	No/DK→A108_03
02a) Take client's blood pressure in sitting or lateral position	1	0	8	
02b) Take blood pressure with arm at heart level	1	0	8	
03) Examine hands for edema	**1**	0	8	
04) Perform or refer for urine test	1	**0**	8	No/DK→A108_05
04a) Test for proteinuria	1	0	8	
04b) Test for bacteruria	1	0	8	
04c) Test for glucose	1	0	8	
05) Check for signs of anemia	1	**0**	8	
06) Perform or refer for anemia test	1	**0**	8	
[redacted]				
A109: Did the health worker ask about or the client mention her HIV status?	**1**	0	8	
A110: Did the health worker perform, inquire about, or refer for an HIV test?	**1**	0	8	
A111: Is client HIV-positive? (Observer: Listen and record answer. Circle "Don't Know" if HIV status is unknown or status is not discussed.)	**1**	0	8	
A112: Did the health worker provide any counseling on HIV or prevention of mother-to-child transmission (PMTCT)?	**1**	0	8	No/DK→A114
A113: Did the health worker provide counseling on the following HIV/PMTCT topics?	**1**	0	8	
01) Explain the purpose of antiretroviral prophylaxis	**1**	0	8	
02) Explain when to collect NVP	1	**0**	8	
03) Explain when the baby takes NVP and for how long	1	**0**	8	
04) Explain how to take antiretroviral therapy (ART)	**1**	0	8	
05) Explain the advantages and side effects of ART	1	**0**	8	
06) Explain feeding options for exposed babies	1	**0**	8	
07) Explain about importance of bringing exposed infant back for testing	1	**0**	8	
A114: Did the health worker refer the client to care and treatment center?	1	**0**	8	

Observation Checklist: Counseling for Cervical Cancer Prevention

Watch the video or performance and mark if each step was done or not.

Take a Reproductive History for a Cervical Cancer Client	Yes	No	Don't Know (DK)
Age			
Parity			
Last menstrual period			
Menstrual history			
Current use of contraceptive methods			
History of sexually transmitted infections including HIV			
Pertinent surgical history (cesarean section, hysterectomy, other pelvic surgery)			
Counsel for VIA Screening			
Provide general information about cervical cancer			
Discuss importance and nature of cervical cancer as a disease and consequences of human papillomavirus infection			
Explain risk factors for the disease / mode of prevention			
Provide information about visual inspection with acetic acid (VIA) procedure: role and importance of testing and how test is done			
Explain consequences of not being tested			
Discuss treatment options if the VIA test if abnormal			
Explain how VIA test and cryotherapy prevent cervical cancer			
Ask about any attitudes or beliefs that will affect the woman's decision to have a VIA test			
Discuss the woman's needs, concerns, and fears in a thorough and sympathetic manner			
Help the woman to decide to have a VIA test			

Counseling for Cervical Cancer Prevention Answer Key

PERFECT: All steps in the checklist were covered in the PERFECT video or performance.
FLAWED: See checklist below for answer key to FLAWED video/performance.

Take a Reproductive History for a Cervical Cancer Client	Yes	No	DK
Age	X		
Parity	X		
Last menstrual period	X		
Menstrual history		X	
Current use of contraceptive methods	X		
History of sexually transmitted infections including HIV		X	
Pertinent surgical history (cesarean section, hysterectomy, other pelvic surgery)		X	
Counsel for VIA Screening			
Provide general information about cervical cancer	X		
Discuss importance and nature of cervical cancer as a disease and consequences of human papillomavirus infection	X		
Explain risk factors for the disease / mode of prevention		X	
Provide information about VIA procedure: role and importance of testing and how test is done	X		
Explain consequences of not being tested		X	
Discuss treatment options if the VIA test if abnormal		X	
Explain how VIA test and cryotherapy prevent cervical cancer		X	
Ask about any attitudes or beliefs that will affect the woman's decision to have a VIA test	X		
Discuss the woman's needs, concerns, and fears in a thorough and sympathetic manner	X		
Help the woman to decide to have a VIA test	X		

Observation Checklist: Six Week Post-Partum Follow-Up Visit

Watch the video or performance and mark if each step was done or not.

RAPID INITIAL ASSESSMENT	Yes	NO	Don't Know (DK)	Go To
Q115: Did the health worker or the client discuss any of the following danger signs about the mother?	1	0	8	
1) General well-being of the mother	1	0	8	
2) Complications during delivery (pre-eclampsia/eclampsia, post-partum hemorrhage, sepsis, prolonged labor)	1	0	8	
3) Abdominal pain since delivery	1	0	8	
4) Blurred vision / severe headaches				
5) Convulsions/fits	1	0	8	
6) Unconsciousness/dizziness	1	0	8	
7) Difficulty breathing	1	0	8	
8) Excessive vaginal bleeding	1	0	8	
9) Fever	1	0	8	
10) Malodorous, green/yellow discharge	1	0	8	
11) Severe depression or desire to harm self or baby	1	0	8	
12) Severe fatigue	1	0	8	
Q116: In the event of any danger signs, did the health worker ensure the urgent and priority attention or referral of the woman?	1	0	8	
Provided urgent care	1			
Referred woman for urgent care	2			
No dangers were observed	3			
Don't know	8			
Q117: Did the health worker or the client discuss any of the following newborn danger signs?	1	0	8	
1) Fever	1	0	8	
2) Lethargy	1	0	8	
3) Weak, absent, or abnormal cry	1	0	8	
4) Breathing difficulty	1	0	8	
5) Convulsion	1	0	8	
6) Irritability	1	0	8	
7) Eye discharge	1	0	8	
8) Pale or bluish color	1	0	8	
9) Yellow or orange color	1	0	8	
10) Redness of cord / cord discharging pus	1	0	8	
11) Abscess on any part of the baby's body	1	0	8	
12) Hypothermia or baby feeling cold to the touch	1	0	8	
Q118: In the event of any danger signs, did the health worker ensure the urgent and priority attention or referral of the baby?	1	0	8	
Provided urgent care	1			
Referred baby for urgent caring	2			
No danger signs were observed	3			
Don't know	8			
DISCUSSION BETWEEN PROVIDER AND CLIENT ABOUT THE NEWBORN (may not include counseling on the provider's part)	Yes	NO	DK	Go to
Q120: Did the health worker or the client discuss any of the following about the baby?	1	0	8	
1) General well-being of the baby	1	0	8	

RAPID INITIAL ASSESSMENT	Yes	NO	Don't Know (DK)	Go To
2) Pre-term conditions	1	0	8	
3) Delivery complications	1	0	8	
4) Respiratory distress upon delivery	1	0	8	
5) Condition of the cord stump	1	0	8	
6) Use of insecticide-treated net for mother and baby	1	0	8	
7) Breastfeeding practices	1	0	8	
8) Feeding ability	1	0	8	
DISCUSSION BETWEEN PROVIDER AND CLIENT ABOUT THE MOTHER (may not include counseling on the provider's part)	Yes	NO	DK	Go to
Q122: Did the health worker or the client discuss any of the following about the mother?	1	0	8	
1) Return to sexual activity	1	0	8	
2) Fertility return / risk of pregnancy	1	0	8	
3) Spacing of pregnancy	1	0	8	
4) Lactational Amenorrhea Method (LAM) and/or other method(s) of family planning compatible with breastfeeding	1	0	8	
5) Transition from LAM to other methods	1	0	8	
6) Use of insecticide-treated net for mother and baby	1	0	8	
7) Personal hygiene	1	0	8	
8) Difficulty breastfeeding	1	0	8	
9) Handwashing	1	0	8	

Six Week Post-Partum Follow-Up Visit Answer Key

PERFECT: All steps in the checklist were covered in the PERFECT video or performance.
FLAWED: See checklist below for answers **(in bold)** to FLAWED video/performance.

RAPID INITIAL ASSESSMENT	Yes	NO	Don't Know (DK)	Go To
Q115: Did the health worker or the client discuss any of the following danger signs about the mother?	**1**	0	8	
1) General well-being of the mother	**1**	0	8	
2) Complications during delivery (pre-eclampsia/eclampsia, post-partum hemorrhage, sepsis, prolonged labor)	**1**	0	8	
3) Abdominal pain since delivery	**1**	0	8	
4) Blurred vision / severe headaches	**1**	0	8	
5) Convulsions/fits	**1**	0	8	
6) Unconsciousness/dizziness	**1**	0	8	
7) Difficulty breathing	**1**	0	8	
8) Excessive vaginal bleeding	**1**	0	8	
9) Fever	1	**0**	8	
10) Malodorous, green/yellow discharge	**1**	0	8	
11) Severe depression or desire to harm self or baby	1	**0**	8	
12) Severe fatigue	**1**	0	8	
Q116: In the event of any danger signs, did the health worker ensure the urgent and priority attention or referral of the woman?	1	**0**	8	
Provided urgent care	1			
Referred woman for urgent care	2			
No dangers were observed	3			
Don't know	8			
Q117: Did the health worker or the client discuss any of the following newborn danger signs?	**1**	0	8	
1) Fever	**1**	0	8	
2) Lethargy	**1**	0	8	
3) Weak, absent, or abnormal cry	**1**	0	8	
4) Breathing difficulty	**1**	0	8	
5) Convulsion	**1**	0	8	
6) Irritability	**1**	0	8	
7) Eye discharge	1	**0**	8	
8) Pale or bluish color	1	**0**	8	
9) Yellow or orange color	1	**0**	8	
10) Redness of cord / cord discharging pus	**1**	0	8	
11) Abscess on any part of the baby's body	1	**0**	8	
12) Hypothermia or baby feeling cold to the touch	1	**0**	8	
Q118: In the event of any danger signs, did the health worker ensure the urgent and priority attention or referral of the baby?	1	**0**	8	
Provided urgent care	1			
Referred baby for urgent caring	2			
No danger signs were observed	3			
Don't know	8			
DISCUSSION BETWEEN PROVIDER AND CLIENT ABOUT THE NEWBORN (may not include counseling on the provider's part)	Yes	NO	DK	Go to

RAPID INITIAL ASSESSMENT	Yes	NO	Don't Know (DK)	Go To
Q120: Did the health worker or the client discuss any of the following about the baby?	**1**	0	8	
1) General well-being of the baby	**1**	0	8	
2) Pre-term conditions	1	**0**	8	
3) Delivery complications	**1**	0	8	
4) Respiratory distress upon delivery	**1**	0	8	
5) Condition of the cord stump	**1**	0	8	
6) Use of insecticide-treated net for mother and baby	1	**0**	8	
7) Breastfeeding practices	**1**	0	8	
8) Feeding ability	**1**	0	8	
DISCUSSION BETWEEN PROVIDER AND CLIENT ABOUT THE MOTHER (may not include counseling on the provider's part)	Yes	NO	DK	Go to
Q122: Did the health worker or the client discuss any of the following about the mother?	**1**	0	8	
1) Return to sexual activity	**1**	0	8	
2) Fertility return / risk of pregnancy	**1**	0	8	
3) Spacing of pregnancy	**1**	0	8	
4) Lactational Amenorrhea Method (LAM) and/or other method(s) of family planning compatible with breastfeeding	**1**	0	8	
5) Transition from LAM to other methods	**1**	0	8	
6) Use of insecticide-treated net for mother and baby	1	**0**	8	
7) Personal hygiene	1	**0**	8	
8) Difficulty breastfeeding	**1**	0	8	
9) Handwashing	1	**0**	8	

Observation Checklist: Managing Second Stage and Active Management of Third Stage of Labor

Watch the video or performance and mark if each step was done or not.

Question	Yes	No	Don't Know (DK)	Go to
Record whether the provider carried out the following steps and/or examinations (some of the following steps may be performed simultaneously or by more than one provider).				
PREPARATION FOR DELIVERY				
Q301: Washes his/her hands with soap and water or uses hand rub before any examination of woman *(observer: circle yes if done previously and no contamination)*	1	0	8	
Q302: Wears 2 pairs high-level disinfected or sterile surgical gloves *(yes if no contamination)*	1	0	8	
Q303: Puts on clean protective clothing in preparation for birth (goggles, gown or apron) *(yes if no contamination)*	1	0	8	
Q304: Performs episiotomy	1	0		
Q305: Presentation of baby is cephalic (head first)	1	0	8	
DELIVERY & UTEROTONIC				
Q306: As baby's head is delivered, supports perineum	1	0	8	
Q307: Observer: record time of the delivery of the baby				
Q308: Vigorously dries baby with clean towel	1	0		
Q309: Checks for another baby prior to giving the uterotonic	1	0	8	
Q310: Second baby present? (observer: circle yes if multiple babies)	1	0		
Q311: Administers uterotonic?	1	0		No → Q318
Q312: Observer: record time uterotonic given				
Q313: Timing of administration of uterotonic	**Code**			
At delivery of anterior shoulder	1			
Within 1 min of delivery of baby	2			
Within 3 min of delivery of baby	3			
More than 3 min after delivery of baby	4			
Q314: Which uterotonic given				
Oxytocin	1			
Ergometrine	2			
Syntometrine	3			
Misoprostol	4			
Q315: Observer: record dose of uterotonic given (if necessary, ask afterward)				
Q316: Units of medication (observer: if necessary, ask afterward)				
International units	1			
Milligrams	2			
Milliliters	3			
Micrograms	4			
Q317: Route uterotonic given:				
Intramuscularly	1			
Intravenously	2			
Oral	3			
Other	4			
Q318: Observer: record time the cord was clamped				
Q319: Applies traction to the cord while applying suprapubic counter-traction	1	0	8	

Question	Yes	No	Don't Know (DK)	Go to
Q320: Performs uterine massage immediately following the delivery of the placenta	1	0	8	
Q321: Was placenta delivered before administration of uterotonic? *(observer: circle Don't Know if no uterotonic was given)*	1	0	8	
Q322: Assesses completeness of the placenta and membranes	1	0	8	
Q323: Assesses for perineal and vaginal lacerations	1	0	8	

Managing Second Stage and Active Management of Third Stage of Labor Answer Key

PERFECT: All steps in the checklist were covered in the PERFECT video or performance.
FLAWED: See checklist below for answer key to FLAWED video/performance.

Question	Yes	No	Don't Know (DK)	Go to
Record whether the provider carried out the following steps and/or examinations (some of the following steps may be performed simultaneously or by more than one provider).				
PREPARATION FOR DELIVERY				
Q301: Washes his/her hands with soap and water or uses hand rub before any examination of woman *(observer: circle yes if done previously and no contamination)*	1	0	**8**	
Q302: Wears 2 pairs high-level disinfected or sterile surgical gloves *(yes if no contamination)*	1	0	**8**	
Q303: Puts on clean protective clothing in preparation for birth (goggles, gown or apron) *(yes if no contamination)*	**1**	0	8	
Q304: Performs episiotomy	1	**0**		
Q305: Presentation of baby is cephalic (head first)	**1**	0	8	
DELIVERY & UTEROTONIC				
Q306: As baby's head is delivered, supports perineum	1	**0**	8	
Q307: Observer: record time of the delivery of the baby				
Q308: Vigorously dries baby with clean towel	**1**	0		
Q309: Checks for another baby prior to giving the uterotonic	1	**0**	8	
Q310: Second baby present? (observer: circle yes if multiple babies)	1	**0**		
Q311: Administers uterotonic?	**1**	0		No → Q318
Q312: Observer: record time uterotonic given				
Q313: Timing of administration of uterotonic	**Code**			
At delivery of anterior shoulder	1			
Within 1 min of delivery of baby	**2**			
Within 3 min of delivery of baby	3			
More than 3 min after delivery of baby	4			
Q314: Which uterotonic given				
Oxytocin	1			
Ergometrine	2			
Syntometrine	3			
Misoprostol	4			
Q315: Observer: record dose of uterotonic given (if necessary, ask afterward)				
Q316: Units of medication (observer: if necessary, ask afterward)				
International units	1			
Milligrams	2			
Milliliters	3			
Micrograms	4			
Q317: Route uterotonic given:				
Intramuscularly	**1**			
Intravenously	2			
Oral	3			
Other	4			
Q318: Observer: record time the cord was clamped				

Question	Yes	No	Don't Know (DK)	Go to
Q319: Applies traction to the cord while applying suprapubic counter-traction	1	**0**	8	
Q320: Performs uterine massage immediately following the delivery of the placenta	1	**0**	8	
Q321: Was placenta delivered before administration of uterotonic? *(observer: circle Don't Know if no uterotonic was given)*	1	**0**	8	
Q322: Assesses completeness of the placenta and membranes	1	**0**	8	
Q323: Assesses for perineal and vaginal lacerations	**1**	0	8	

Observation Checklist: Newborn Resuscitation

Watch the video or performance and mark if each step was done or not.

Section 5: Checklist for Newborn Resuscitation				
Question	**Yes**	**No**	**Don't Know (DK)**	**Go to**
Record whether the provider carried out the following steps and/or examinations (some of the following steps may be performed simultaneously or by more than one provider)				
Q500: Observer: Record time resuscitation started (Please use 24-hour clock)				
Q501: Rubs and dries the baby vigorously with a clean cloth/towel	1	0	8	
Q502: Clears the airway by suctioning the mouth first and then the nose	1	0	8	
Q503: Stimulates baby with back rubbing	1	0	8	
Q504: *Observer:* does newborn start to breathe or cry spontaneously?	1	0		Yes→Q531
Q506: Ties or clamps cord immediately	1	0	8	
Q507: Cuts cord with clean blade or clean scissors	1	0	8	
Q508: Places the newborn on his/her back on a clean, warm surface or towel	1	0	8	
Q509: Places the head in a slightly extended position to open the airway	1	0	8	
Q510: Tells the woman (and her support person) what is going to be done	1	0	8	
Q511: Listens to woman and provides support and reassurance	1	0	8	
Q512: Checks mouth, back of throat, and nose for secretions, and clears if necessary	1	0	8	
Q513: Places the correct-sized mask on the newborn's face so that it covers the chin, mouth, and nose (but not eyes)	1	0	8	
Q514: Checks the seal by ventilating two times and observing the rise of the chest	1	0	8	
Q515: *Observer:* is newborn's chest rising in response to ventilation?	1	0		Yes→Q524
Q515a: Calls for help	1	0	8	
Q516: Checks the position of the newborn's head to make sure that the neck is in a slightly extended position (not blocking the airway)	1	0	8	
Q517: Checks mouth, back of throat, and nose for secretions, and clears if necessary	1	0	8	
Q518: Checks the seal by ventilating two times and observing the rise of the chest	1	0	8	
Q519: *Observer:* is newborn's chest rising in response to ventilation?	1	0		Yes→Q524
Q520: Checks the position of the newborn's head again to make sure that the neck is in a slightly extended position	1	0	8	
Q521: Repeats suction of mouth and nose to clear secretions, if necessary	1	0	8	
Q522: Checks the seal by ventilating two times and observing the rise of the chest	1	0	8	

Section 5: Checklist for Newborn Resuscitation				
Question	**Yes**	**No**	**Don't Know (DK)**	**Go to**
Q523: *Observer:* is newborn's chest rising in response to ventilation?	1	0		Yes→Q524
If newborn's chest is not rising after two attempts to readjust, observer should call for supervisor to intervene. If a health worker competent in resuscitation is not available, observer may choose to intervene.				
Q524: Ventilates at a rate of 30 to 50 breaths per minute	1	0	8	
Q525: Conducts assessment of newborn breathing after 1 minute of ventilation	1	0		No→Q527

Newborn Resuscitation Answer Key

PERFECT: All steps in the checklist were covered in the PERFECT video or performance.
FLAWED: See checklist below for answer key to FLAWED video/performance.

Section 5: Checklist for Newborn Resuscitation				
Question	**Yes**	**No**	**Don't Know (DK)**	**Go to**
Record whether the provider carried out the following steps and/or examinations (some of the following steps may be performed simultaneously or by more than one provider)				
Q500: Observer: Record time resuscitation started (Please use 24-hour clock)				
Q501: Rubs and dries the baby vigorously with a clean cloth/towel	**1**	0	8	
Q502: Clears the airway by suctioning the mouth first and then the nose	**1**	0	8	
Q503: Stimulates baby with back rubbing	**1**	0	8	
Q504: *Observer:* does newborn start to breathe or cry spontaneously?	1	**0**		Yes→Q531
Q506: Ties or clamps cord immediately	**1**	0	8	
Q507: Cuts cord with clean blade or clean scissors	**1**	0	8	
Q508: Places the newborn on his/her back on a clean, warm surface or towel	**1**	0	8	
Q509: Places the head in a slightly extended position to open the airway	1	**0**	8	
Q510: Tells the woman (and her support person) what is going to be done	1	**0**	8	
Q511: Listens to woman and provides support and reassurance	1	**0**	8	
Q512: Checks mouth, back of throat, and nose for secretions, and clears if necessary	1	**0**	8	
Q513: Places the correct-sized mask on the newborn's face so that it covers the chin, mouth, and nose (but not eyes)	**1**	0	8	
Q514: Checks the seal by ventilating two times and observing the rise of the chest	**1**	0	8	
Q515: *Observer:* is newborn's chest rising in response to ventilation?	1	**0**		Yes→Q524
Q515a: Calls for help	1	**0**	8	
Q516: Checks the position of the newborn's head to make sure that the neck is in a slightly extended position (not blocking the airway)	**1**	0	8	
Q517: Checks mouth, back of throat, and nose for secretions, and clears if necessary	1	**0**	8	
Q518: Checks the seal by ventilating two times and observing the rise of the chest	**1**	0	8	
Q519: *Observer:* is newborn's chest rising in response to ventilation?	**1**	0		Yes→Q524
Q520: Checks the position of the newborn's head again to make sure that the neck is in a slightly extended position	1	0	8	
Q521: Repeats suction of mouth and nose to clear secretions, if necessary	1	0	8	

Section 5: Checklist for Newborn Resuscitation				
Question	**Yes**	**No**	**Don't Know (DK)**	**Go to**
Q522: Checks the seal by ventilating two times and observing the rise of the chest	1	0	8	
Q523: *Observer:* is newborn's chest rising in response to ventilation?	1	0		Yes→Q524
If newborn's chest is not rising after two attempts to readjust, observer should call for supervisor to intervene. If a health worker competent in resuscitation is not available, observer may choose to intervene.				
Q524: Ventilates at a rate of 30 to 50 breaths per minute	1	**0**	8	
Q525: Conducts assessment of newborn breathing after 1 minute of ventilation	1	**0**		No→Q527

FINAL KNOWLEDGE ASSESSMENT

1. A measurement is considered **valid** when it:
   a. Results in consistent scores
   b. Is based on an objective
   c. Measures what it intends to measure
   d. Doesn't fluctuate over time
2. A measurement is considered to be reliable when it:
   a. Results in consistent scores
   b. Is based on an objective
   c. Is an accurate measurement
   d. Matches the behavioral objectives
3. The **MOST IMPORTANT** purpose of having clinical observers practice using an assessment tool before actual clinical observation is to:
   a. Identify any formatting errors
   b. Validate the tool
   c. Improve consistency among clinical observers' ratings
4. For each statement regarding informed consent, select True or False (1 point/item)

Statement	True	False
Human subjects research requires informed consent.		
A client is read the informed consent form in a language the client DOES NOT understand. The client says yes to the procedure. Informed consent has been obtained.		
For observation of services that ARE NOT considered human subjects research and do not carry risk of patient harm, obtaining verbal permission for the patient(s) being observed is sufficient.		
You ask a health care worker for informed consent when the facility director is present. This meets the criteria for informed consent.		

Pass Score: 6/7

FINAL KNOWLEDGE ASSESSMENT ANSWER KEY

1. A measurement is considered **valid** when it:

   c. Measures what it intends to measure

2. A measurement is considered to be reliable when it:

   a. Results in consistent scores

3. The **MOST IMPORTANT** purpose of having clinical observers practice using an assessment tool before actual clinical observation is to:

   c. Improve consistency among clinical observers' ratings

4. For each statement regarding informed consent, select True or False (1 point/item)

Statement	True	False
Human subjects research requires informed consent.	**TRUE**	
A client is read the informed consent form in a language the client DOES NOT understand. The client says yes to the procedure. Informed consent has been obtained.		**FALSE**
For observation of services that ARE NOT considered human subjects research and do not carry risk of patient harm, obtaining verbal permission for the patient(s) being observed is sufficient.	**TRUE**	
You ask a health care worker for informed consent when the facility director is present. This meets the criteria for informed consent.		**FALSE**

FACILITATOR DIRECTIONS: CALCULATING INTER-RATER RELIABILITY OF PARTICIPANTS FOR SESSIONS 7 AND 8

See Appendices A and B for more details.

One of the objectives of this course is to increase the inter-rater reliability of the clinical observers. As a facilitator, it is important that you ensure the course participants observe and document their observations. You will measure the inter-rater agreement among course participants' observations of a service and resolve any issues identified to improve inter-rater agreement.

You should calculate inter-rater reliability during Sessions 7 and 8. Calculate inter-rater reliability among the course participants and, if needed, calibrate by providing more training to resolve the inconsistencies.

At the end of these activities, you should be able to do the following:

- Review items that are observed and recorded differently by the observers.
- Calculate inter-rater agreement among all participants.
- Resolve inconsistencies in inter-rater agreement among participants.

Activity 1: Collecting Data

1. Pair up participants at the clinical site for at least one data observation activity.
2. Distribute the study tool / clinical observation checklist. Tell the participants that they will be working individually. They should NOT talk with their partner during or after observation.
3. Explain to the participants that they will observe the clinical activity and record their observations on the tool/checklist.
4. Observe the observers; sit alongside the participant pair and record your observations of the clinical activity.
5. Collect tools/checklists and mark.
6. Tell participants that you will use their tools to ensure standardized and reliable data collection.

Activity 2: Calculating Percentage Agreement for Inter-Rater Reliability

Inter-rater reliability measures the validity and consistency in ratings of clinical performances across clinical observers. The goal is for observers to score clinical performances with at least 80% agreement (preferably 90%) with the gold standard (trainer score or pre-scored performance checklist)—that is, for 8 items out of 10, they correctly score the step observed.

Necessary documents to complete this handout:

- Observation Checklists / observer tools from Sessions 7 and 8
- Calculator

Fill in Table 3 using the observer's completed study tools/checklists for Sessions 7 and 8.

1. For Observer 1, place the number of observations in relevant column. Then repeat for Observer 2 and place in relevant column. If you write "1," then the correct answer is "1." If you write "0," the correct answer is "0."
2. Compare each item score to the trainer/gold standard score and mark as correct or incorrect.
3. At the bottom of the table, for each observer, sum the number of incorrect scores.
4. At the bottom of the table, for each observer, sum the number of correct scores.
5. Calculate the percentage agreement for each observer. Was the percentage agreement equal to or greater than 80% for the individual?
6. Calculate overall percentage agreement of all observers in the course by taking the average (sum of all the observers' percentages divided by the number of observers). Was the percentage agreement equal to or greater than 80% for the class?

Table 2. Example

Scoring: 1=yes, performed; 0=no, did not perform; 8=not observed

Observed Tasks for Labor and Delivery	Observer 1	Observer 2	Trainer/Gold Standard
Asks about any danger signs in current pregnancy	0	1	1
Prepares uterotonic before delivery	0	0	0
Supports perineum as baby's head is delivered	0	0	0
Gives 10 international units oxytocin intramuscularly within 1 minute after the baby is born, before the placenta is expulsed	1	1	0
Assesses completeness of the placenta and membranes	0	0	0
Total incorrect compared to gold standard	2	1	0
Total correct compared to gold standard	3/5 (60%)	4/5 (80%)	5 (100%)

Table 3. Blank table to use

Observed Tasks	Observer 1	Observer 2	Trainer/Gold Standard
Total incorrect compared to gold standard			0
Total correct compared to gold standard			(100%)

Examples of ways to calibrate Observers 1 and 2 to improve data quality:

- Review items where agreement was low and determine the observers' common mistakes.
- Discuss areas of low agreement with both/all observers to come to an agreement.
- Ensure that the observers are comfortable and understand the study tools or observer checklists.
- Repeat the exercise with observers.
- Use the perfect/flawed performances to have observers practice (see Session 7 and Appendices C and D).

Session 8: Clinical Observer Training: Time to practice!

SESSION PLAN

Date:	Venue:	Session Number: 8	Duration: To be determined
Step 4: Obtain competence in observing clinical skills **Step 5**: Conduct data collection assessments as a clinical observer **Session Title**: Clinical Observer Training: Time to practice!			
Session Objective: At the end of the session, participants should be able to demonstrate competency in conducting observations of clinical services, practices, and settings.			

Methods and Activities	Materials/Resources
Note to Facilitators: Clinical observation sites (health facilities) for pre-testing/practice using the data collection tools should have been confirmed in advance and the staff should be aware the participants are coming. A facilitator should escort the participants to each clinical observation site and ensure that the necessary introductions with the manager or administrator are made. **Format**: Practical activity in the hospital/clinic or relevant data-collection setting **Introduction**: Now is the observers' chance to practice in the health facility. Review the study tools or observer checklists that describe their expected performance. Remind the observers that we know they will observe care that does not comply with standards, but they should not intervene (verbally or physically) unless it is a life-threatening situation. If a life is in danger and the provider does not recognize the seriousness of the situation or is not performing the required lifesaving interventions, the observer should summon help from the provider's onsite supervisor or other senior colleague. If observers decide to intervene, they have stepped out of their roles as observers, and are then practicing as clinicians licensed by their related professional body and governed by the requirements and restrictions of their license and practice in their country. If such a situation occurs, it is very important that the observer make a note about this on the data collection form. **Content**: Now that observers have been trained to reliably observe skills performances and/or collect data, they should have an opportunity to practice. If you are conducting multiple practical days, you may use the following optional homework assignment: Have participants write a journal (one page) regarding their practical experience. Have them highlight one positive item and one item they can improve upon. Have volunteers share at the next practical meeting. **Activity**: ▪ The practical day will consist of: ▪ Pre-clinical meeting	▪ Self-Evaluation ▪ Checklist: Clinical Observation Skills: Session 8

▪ Clinical observations / data collection ▪ Post-clinical meeting Pre-clinical meeting ▪ Pair up participants. ▪ Hand out study tools or observer checklists. ▪ Review the study tools or observer checklists—this is how their clinical observation skills will be assessed. ▪ Remind them of criteria and standards. ▪ Set assignments (how many clinical observations / data collections each participant will undertake). ▪ Notify participants that facilitators will be checking on them throughout the day. ▪ Answer any questions. ▪ Set up a pre-lunch check-in. When, where? Clinical observations / data collection ▪ Check on participants throughout the day. ▪ Fill out study tools or observer checklists for each participant. ▪ Have each participant fill out a self-evaluation. Post-clinical meeting ▪ Debrief participants on observation activities. What went well? What was challenging? Any issues throughout the day? ▪ Collect data collection tools for calibration (ensure names are on each sheet). ▪ Review participants' self-evaluations. **Summary**: ▪ Review key themes and common reasons for inconsistency. ▪ Review key points for critical skills, common problem areas to watch for. ▪ Review the study tools or observer checklists. ▪ Explain what is expected of clinical observers when using these tools/checklists.	

SELF-EVALUATION

1. Please indicate your own assessment of your overall clinical observation / data collection by placing an "X" along this continuum:

1	2	3	4	5	6	7	8	9	10
I need a lot of additional practice and guidance				I need some additional practice and guidance				I can function independently	

2. Please list what you feel are your strengths:

3. Please list the primary clinical areas in which you feel like you need additional practice, guidance, and support:

4. Other comments:

CHECKLIST: CLINICAL OBSERVATION SKILLS: SESSION 8

	Checklist for Clinical Observers	Yes	No
1	Participates in introductions to facility director or management and obtains permission to collect information at their facility.	1	0
2	Requests informed consent or asks permission from client and provider to observe if informed consent is not required.	1	0
3	Follows the research study or data collection protocol. Does not deviate from the protocol.	1	0
4	Conducts observations without social or personal bias or influence.	1	0
5	Does not comment on the quality of performance, either good or bad, while observing execution of the skill.	1	0
6	Respects provider and client confidentiality and dignity; that is, does not discuss the skills performance of any specific provider or berate someone for poor performance.	1	0
7	Does not intervene during observation unless a life-threatening situation occurs. (NOTE: if observers intervene, they have stepped out of the role of observer, and are now subject to their legal scope of practice requirements based on their license or certification in their country.)	1	0
	Achieved at least 80% on the inter-rater reliability test. (MUST ACHIEVE TO PASS)	Pass	Fail

Pass Score = 6/7 AND 80% on inter-rater reliability test

Training Participant Score = _____

Pass? Yes No

Appendix A: Types of Variability that Affect the Reliability of Results

There are several types of variability that can affect the accuracy and reliability of results. These include: (1) variability in an individual subject, (2) intra-rater variability, (3) variation due to the method of measurement / instrument / tool, (4) inter-rater variability, and (5) data entry errors. A description of these types of variability and examples of how they may present themselves during clinical observation are in Table A-1.

Table A-1. Types of variability, descriptions, and examples

Type of Variability	Description	Examples
Variability in an individual subject	Over the course of a day or week, a subject may vary in what he/she is being observed for.	The blood pressure reading of a patient may vary over the course of the day. Among health providers being observed performing a service, the "Hawthorne effect" may affect performance.*
Intra-rater variability	The same observer may observe differently over the course of a day, or from one facility to the next.	An observer may not be familiar with a long observation checklist with 100+ items. S/he may start out observing with little familiarity with the tool and after doing many observations, s/he is more familiar with the tool. An observer is tired after a meal, or after many hours of observations and is less observant; s/he does not "see" everything that is occurring. Daydreaming or personal biases may affect observation.
Variation due to the method of measurement / instrument / tool	The observation checklist or the medium (such as paper versus hand-held electronic device) changes.	An observer may start out using paper checklists and then be asked to switch to recording data on a hand-held device. S/he is not familiar with how to scroll from beginning to end or switch views. A tool with a poor translation from one language to another may not accurately convey what aspects should be observed. An observer is asked to use a 20-item newborn resuscitation checklist and later is asked to switch to a more streamlined 15-item checklist.
Inter-rater variability	Different observers may carry out observation differently.	Observers have different interpretations of key terms. An observer may think that some items on the checklist are less important to observe than other observers do. Some observers may be less comfortable with observation or with the content of the checklist than others. Some observers may be recording items as "Not applicable" while others may leave items blank/missing.
Data entry errors	Variation in how results are recorded and entered in electronic database.	Written responses are illegible. Responses are not complete (some cells left blank without reason why). Written data not carefully entered to a database; typographical errors.

*Hawthorne effect: When a participant being observed changes her/his behavior or seems to have better performance than what is normal simply because s/he is being observed.

It is important to remember: a program or study manager can guard against these sources of variability in the planning phase. Some ideas are provided below.

Table A-2. Ways to prevent variability in accuracy and reliability of observation data

How can we guard against variability in data observation, or correct for it, with advance planning?
1. Variability in an individual subject: - Observe multiple cases in a health facility over several days if possible, rather than just performing one observation. - Reassure the provider that the result of observation will not affect her/his job (if that is true) and that s/he can act as if the observer is not there. - Observer can be as unobtrusive as possible to minimize worry among providers being observed. - Ensure that the facility director or manager has given approval for observer to be there.
2. Intra-rater variability: - Ensure, in the training workshop and pre-testing, that all observers know the content and skip patterns of the tools as much as possible; practice makes perfect. - Make sure any actual tools have only essential items to begin with (best to validate the tools prior to giving them to observers). - Come up with strategies for observers to be as observant as possible throughout the day: ensure shifts are not too long, let observers take short breaks when needed. - Discuss with observers what latent biases may affect observation.
3. Variation due to the method of measurement / instrument / tool: - Ensure that the data collection instrument has been vetted by content experts and monitoring and evaluation experts. Consider skip patterns (for example, items that apply only to HIV-positive clients). Validate the tool prior to using with many observers. - Ensure that the data collection tools / checklists and their medium does not change. If it has to change (for example, a hand-held device is lost), make sure that this is noted for the record. - Ensure accurate translation and review of the translation.
4. Inter-rater variability: - Ensure in the training workshop that the terms are explained and that there is a shared understanding of terms. Discuss how comfortable each observer is with observation in general and with the tools; adjust training workshop and pre-test as appropriate. - Carry out an inter-rater reliability exercise and provide extra training (calibration, as needed). - Clarify definitively when “Not applicable” can be recorded.
5. Data entry errors: - Ensure that a supervisor reviews each completed checklist (the same day or next day) for completeness and any things written down or recorded incorrectly. - Have a written plan for how the data will flow, from the observer to the supervisor to the data entry clerk. - Have tips and guidelines for data entry. - Cross-check 10% of records against the paper forms (if appropriate). Have data consistency and plausibility checks built into the hand-held device software programs or the electronic database.

Appendix B: Validity, Reliability, and Inter-Rater Reliability

Much of this appendix is adapted from Leon Gordis's *Epidemiology* (2nd ed. Philadelphia, WB Saunders Co., 2000. pp. 75–80).

It is important that the data collected be both valid and reliable, to the greatest extent possible. These terms are defined in Table B-1.

Table B-1

Term	Another Term	Definition
Validity	Accuracy	The definition of validity is often made in reference to a screening test for a disease. The validity of the test is the ability of the test to distinguish between who has the disease and who does not. For clinical observation, valid data would be data that distinguish whether an aspect of a clinical service was performed or not.
Reliability	Repeatability	The reliability of a test is its ability to be repeatable or to consistently give the same result. For clinical observation, the question is, "Can the results obtained be replicated if the service being performed/observed is repeated?"

Our goal is for results of clinical observation to be both valid and reliable. However, observation results can sometimes be consistently incorrect (that is, reliable but not valid). They can also be valid but not reliable.

A test that is unreliable cannot be valid. The converse is not true, however; the test could simply be consistently incorrect. Reliability does not ensure validity, but lack of reliability constrains validity. See Table B-2 for further details.

Table B-2

Results Are	What It Means
Valid, but not reliable	The observation results cluster close to or on the "true value" but not consistently in one observer, or across observers.
Not valid, but reliable	The observation data do not reflect the "true value," if it could be known, but the same wrong data are obtained consistently.
Valid and reliable	Observation data that are on or close to the "true value" all or most of the time. This is what we'd like to achieve.

In clinical observer training, we would like the observer to observe the steps the trainer has performed on a given service or standard (e.g., active management of the third stage of labor [AMTSL]). One way to examine quantitatively the extent that the observer observes a practice consistently with the way that the trainer performs the practice is "percentage agreement" (Section A below). Further analysis can take into consideration the element of chance in the percentage agreement by calculating Cohen's Kappa statistic (Section B below).

SECTION A: PERCENTAGE AGREEMENT: HOW TO CALCULATE IT?

Table B-3. Grid to calculate percentage agreement

		Trainer:	
		Performed Item	Not Performed Item
Observer:	Observed item	a.	b.
	Not observed item	c.	d.

Approach 1

To calculate percentage agreement, add the cells in which the data from the observer and the trainer (or gold standard) agreed. (Agreement on an item performed and observed means both observer and trainer would record the item with the code 1. Agreement on an item not performed and observed means both observer and trainer would record the item with the code 0). Then, divide the sum by the total number of agreed items (verification criteria). Multiply by 100 to yield a percentage.

Percentage Agreement (Approach 1) = (a + d) / (a + b + c + d) × 100

Approach 2

If a service, for example AMTSL, has 30 verification criteria or items, most of the items will be carried out. The trainer may PURPOSEFULLY OMIT some items to see if the observers catch these flaws. But the number of flaws may be small compared to the total number of items. So the percentage agreement may be high simply because of the large number of items that are performed. Another way to analyze the percentage agreement data is to examine only the flawed items. Then the trainer would know how often the observer caught the flaws.

Percentage Agreement (Approach 2) = d / d + b × 100

Approach 3

Another approach to the analysis is to DISREGARD the items that were recorded as "observed" or "performed" by BOTH the observer and the trainer (cell a). Percentage agreement is calculated for the items that were recorded as "not observed" or "not performed" by either the observer or the trainer (cells b, c, and d).

Percentage Agreement (Approach 3) = d / (b + c + d) × 100

SECTION B: COHEN'S KAPPA STATISTIC

Percentage agreement is also significantly affected by the fact that even if two observers use completely different criteria for recording items as "performed" or "not performed," agreement may occur on items purely BY CHANCE. For example, if you asked someone walking down the street to complete the clinical observation of an AMTSL service, for some items, that person would agree with the trainer's reporting of items performed—just by chance, not because of previous knowledge or training.

A study manager may want to know to what extent the data recordings agree with the trainer, BEYOND what is expected by chance alone. The Kappa statistic, proposed by Cohen in 1960, can be applied.

Kappa is defined as follows:

$$\text{Kappa} = \frac{\text{(Percentage Agreement) – (Percentage Agreement Expected by Chance Alone)}}{\text{100\% – (Percentage Agreement Expected by Chance Alone)}}$$

The 100% in the denominator represents full agreement, meaning the observer and the trainer agree completely. The MOST the observer could IMPROVE his or her results above and beyond the results expected by chance alone is the difference between full agreement and percentage agreement expected by chance alone. Therefore, Kappa quantifies the extent to which the agreement EXCEEDS that which would be expected by chance alone; this is expressed as the proportion of the maximum improvement that could occur beyond the agreement expected by chance alone.

Table B-4

		Trainer:		
		Performed Item	Not Performed Item	Totals by Observer
Observer:	Observed item	41	3	44 (58.6%)
	Not observed item	4	27	31 (41.4%)
	Totals by trainer	45 (60%)	30 (40%)	75 (100%)

In the scenario given in Table B-4, we first calculate Percentage Agreement using Approach 1:

Percentage Agreement = (41 + 27) / 75 total × 100 = 90.7%

To calculate Kappa, the Percentage Agreement Expected by Chance Alone needs to be calculated, as in the following steps:

1. Look at the trainer's "performed item" column: 60% (45/75) of the total items were performed.
2. Hypothetically, if the trainer's performance of tasks/items was not related to (i.e., was independent of) the rating by the observer, we would expect that the trainer would have performed 60% of the items that the observer recorded as "observed" (top row) AND 60% of the items that the observer recorded as "not observed" (middle row).
   So we would expect that 60% of the 44 items (=26.4) recorded as "observed" by the observer ("observed item" row total) would be performed by the trainer, and that 60% of the 31 items (=18.6) recorded as "not observed" by the observer ("not observed item" row total) would also be performed by the trainer.
3. Create a new table (Table B-5) using the results calculated in step 2 and use the numbers in the new table to calculate Percentage Agreement by Chance Alone.

Table B-5

		Trainer:		
		Performed Item	Not Performed Item	Totals By Observer
Observer:	Observed item	26.4	17.6	44 (58.6%)
	Not observed item	18.6	12.4	31 (41.4%)
	Totals by trainer	45 (60%)	30 (40%)	75 (100%)

4. Now all the numbers are available to calculate Kappa for this example:

Percentage Agreement by Chance Alone = (**26.4** + **12.4**) / 75 = **51.7**%

Kappa = (90.7% – **51.7**%) / (100% – **51.7**%) = 81%

Some researchers have suggested that Kappa above 75% is excellent, and above 40% and below 75% represents acceptable agreement. Therefore, in the scenario above, acceptable agreement was achieved.

Appendix C: Videos

This appendix provides facilitators with the information they need to use videos for Session 7 activities.

Materials Needed

VIDEOS ARE AVAILABLE on flash drives and are also hosted on YouTube at the URLs indicated below.

TO PLAY THE VIDEOS you will need a laptop with a USB port OR with a good Internet connection, a projector, and speakers. Depending on class size, laptops may be too small for everyone to see, so a projector may be necessary.

The following videos are available for Session 7 activities:
ANC & PMTCT Visit Perfect http://youtu.be/pUsDpaKGJJo
ANC & PMTCT Visit Flawed http://youtu.be/LYUJF3lfHIc

Counseling for Cervical Cancer Prevention Perfect http://youtu.be/MX9ao6EnyUw
Counseling for Cervical Cancer Prevention Flawed http://youtu.be/8XXNKzK_7IU

Six Week Post-Partum Follow-Up Visit Perfect http://youtu.be/LG_65GegMVM
Six Week Post-Partum Follow-Up Visit Flawed http://youtu.be/JgzoFUbw9XE

Managing Second Stage and Active Management of Third Stage of Labor Perfect
http://youtu.be/omJJnrQtseE
Managing Second Stage and Active Management of Third Stage of Labor Flawed
http://youtu.be/otT-YUvBiEk

Newborn Resuscitation Perfect http://youtu.be/PH9fCTu1POM
Newborn Resuscitation Flawed http://youtu.be/RCVjWMYmN0s

All videos closely follow the scripts in Appendix D. If there are technical difficulties playing videos, facilitators can perform the procedures using the scripts in Appendix D.

Appendix D: Scripts

NOTE TO FACILITATORS: The scripts were developed using guidelines in effect at the time they were written. Because guidelines are always rapidly changing, some of the information in the scripts may be out of date. Please review the scripts and checklists and revise appropriately.

This appendix provides facilitators with the information they need to conduct perfect and flawed performances for Session 7 activities. The following scripts are for live demonstration of perfect and flawed performances consistent with the Observation Checklists included in Session 7.

ANC & PMTCT VISIT

Objective

Demonstrate a portion of an antenatal care (ANC) visit with integrated prevention of mother-to-child transmission (PMTCT) counseling.

Scene

ANC clinic setting. Provider and a client are at a table; provider should have relevant charting paperwork. Provider can have the script on his/her clipboard.

Materials Needed

- Blood pressure cuff and stethoscope
- Provider in white coat
- Client needs to look pregnant
- Clipboard
- ANC counseling flip chart
- Bag of antiretroviral drugs

Perfect Script

Provider should be warm, professional, and efficient.

Provider *washes hands with alcohol rub and says to client*: I see here your weight today is 70 kilograms; let me check your blood pressure. *Checks client's blood pressure.* Your blood pressure is fine, about 124 over 73. *Provider looks at client's hands to check for edema while saying* Your urine tested negative for protein, sugar, and bacteria, so that is fine. *Client nods.* I am just going to look at the palm of your hands and your eyes to check for anemia. *Provider checks client's palms and lower inner eyelid for anemia.* Are you having any trouble or complaints?

Client: No, I feel good, just a little tired.

Provider: I have a few other questions, then I'll ask you to move to the exam table so I can do your abdominal exam, OK? *Client nods.*

Provider: OK, Mrs. B, I see from your chart that you have tested positive for HIV, but your syphilis test was negative. How long ago were you diagnosed with HIV?

Client: Last year, during a community testing campaign.

Provider: Are you currently taking antiretroviral drugs or drugs to help slow down the progress of the disease?

Client: No, not yet. They said my blood count was still OK.

Provider: Well, now that you are pregnant, you will need to take the medicine, the antiretrovirals, to help prevent transmitting HIV to your baby. If you don't take them, the chances are much greater your baby will be HIV infected. We will test your blood count to check the level of your immune cells, the ones that fight infection. Irrespective of the level of your immune cells, we recommend that you start medicine now to prevent your infection's progress to AIDS as well as to prevent the transmission of the virus from you to your baby. You will need to remain on these drugs for life, which will keep you healthy as well as protect any future children you may have.

Client: What about my baby?

Provider: Your baby will also need to take some medicine. The drug your baby will take is called nevirapine or NVP. Your baby will need to take the drug daily until he or she is 6 weeks old. Since you are HIV-positive, and we don't offer formula, we recommend you provide only breast milk the first 6 months, then introduce complementary foods and wean the baby at 12 months.

Client: OK.

Provider: All right, Mrs. B, tell me what you understand about how these drugs are important.

Client: They will help prevent HIV being transmitted to my baby.

Provider: Yes, that's right. And we will give the drugs to you. You should start taking them at 14 weeks, which is only in a week for you. Let me explain how you will take them.

Client: Yes, please do.

Provider: Here are your drugs. You will be taking three drugs to help stop the progress of the infection but they are combined into one pill. The first drug is called tenofovir or TDF, the second drug is called emtricitabine or FTC, and the third drug is called efavirenz or EFV. You will take one pill once a day for the rest of your life. Your baby will also need to take NVP every day until he or she is 6 weeks old. It is very important your baby take the drugs also, to help make sure he or she has a significantly higher chance of getting no HIV infection. OK? *Client nods.* You will start your drugs next week, on Monday. You will take TDF/FTC/EFV once a day in the evening. The drugs are CRITICAL to help prevent transmitting HIV to your baby, but do have some side effects, which we can help you manage. There are some side effects of the drugs that I will review with you. EFV side effects could include the possibility of you having bad dreams. TDF generally has minimal side effects, but the drug can harm the kidneys so we will do a blood test today to check how well your kidneys are functioning. It is important that you note any side effects and we can discuss them at your next appointment. If the side effect is really bothering you, please feel free to come back to the clinic or call me and we can see how to resolve the side effect. It is important that you still take your drugs even with some side effects. Most side effects resolve within the first few weeks of taking your drugs.

Client: OK. How will I get the drugs for my baby?

Provider: As you continue to come here for follow-up and take more medications and deliver here or in the health facility of your choice, we'll make sure to provide your baby's drugs and explain how to give them right after you deliver. You will need to bring your baby back several times after delivery for HIV testing.

Client: OK, I understand.

Provider: Tell me your understanding of how to take these drugs.

Client: I will start on Monday, and take TDF/FTC/EFV (*looks at drugs and points to one of the pills*) once a day…for how long?

Provider: You'll take that for the rest of your life. The drug you will give the baby once he or she is born is called NVP. Your baby will take it until he or she is 6 weeks old. Do you have other questions now? *Client shakes head no.* OK, let me make sure you are linked to the care and treatment center which can provide support to you once you leave our care.

Flawed Script

Provider: I see here your weight today is 70 kilograms, that's fine. *Provider looks at client's hands to check for edema while asking* Are you having any trouble or complaints?

Client: No, I feel good, just a little tired.

Provider: I have a few other questions, then I'll ask you to move to the exam table so I can do your abdominal exam, OK? *Client nods.*

Provider: OK Mrs. B, I see from your chart that you have tested positive for HIV, but your syphilis test was negative. Are you currently taking antiretroviral drugs or drugs to help slow down the progress of the disease?

Client: No, not yet. They said my blood count was still OK.

Provider: Well, now that you are pregnant, you will need to take some medicine to help prevent transmitting HIV to your baby. If you don't take it, the chances are much greater your baby will be HIV infected. We will test your blood count to check the level of your immune cells, the ones that fight infection. Irrespective of the level of your immune cells, we recommend that you start medicine now to prevent your infection's progress to AIDS as well as to prevent the transmission of the virus from you to your baby. You will need to remain on these drugs for life, which will keep you healthy as well as protect any future children you may have.

Client: What about my baby?

Provider: Your baby will also need to take some medicine.

Client: OK.

Provider: All right, Mrs. B, tell me what you understand about how these drugs are important.

Client: They will help prevent HIV being transmitted to my baby.

Provider: Yes, that's right. And we will give the drugs to you. Let me explain how you will take them.

Client: Yes, please do.

Provider: Here are your drugs. You will be taking three drugs to help stop the progress of the infection but they are combined into one pill. You will take one pill once a day for the rest of your life. Your baby will also need to take medicine every day until he or she is 6 weeks old. It is very important your baby take the drugs also, to help make sure he or she has a significantly higher chance of getting no HIV infection. OK? *Client nods.* You will start your drugs next week, on Monday. You will take the pill once a day in the evening. The drugs are CRITICAL to help prevent transmitting HIV to your baby.

Client: OK. How will I get the drugs for my baby?

Provider: We'll explain and provide them later.

Client: OK, I understand.

Provider: Do you have other questions now? *Client shakes head no.*

COUNSELING FOR CERVICAL CANCER PREVENTION

Objective

Perform a complete cervical cancer prevention reproductive history and counseling session before visual inspection with acetic acid (VIA) with no flaws.

Scene

Clinic setting. Provider and a client are at a table; provider should have relevant charting paperwork. Provider can have the script on her/his clipboard.

Materials Needed

- VIA counseling flip chart
- Clipboard for charting

Perfect Script

Provider and client greet each other. Provider should be warm, professional, and efficient.

Provider *refers to the chart or card and uses client name*: Hello, please have a seat, Mrs. Safe. My name is Mary, how can I help you?

Client: I'm here to get screened for cervical cancer. My sister had it done last week and said I should come in. I have not had it done before.

Provider: Before we talk more about what you need, it's important you understand everything we talk about is confidential. It will be documented in your record, but not shared. OK?

Client: Yes, OK.

Provider: It's great you came in for the screening. Before we get to that, I will need some information from you regarding your health history, particularly around your reproductive health. Is that OK?

Client: Of course.

Provider: What is your age, Mrs. Safe?

Client: 38 years old.

Provider: Very good. At what age did you begin menstruating?

Client: I don't remember very well, but I believe I was 12. Yes, I remember now I was 12.

Provider: OK. And when was your last menstrual period?

Client: Hmmmm, I believe I started on October 12, it was a Monday.

Provider: Excellent. Now Mrs. Safe, do you have any children?

Client: Yes, I have two children: a boy and a girl aged 8 and 4.

Provider: Do you plan on having more children?

Client: No, my husband and I decided two was plenty! I had an intrauterine device placed after my second child.

Provider: Fine. Now this is a sensitive question but important. Please remember that this is a confidential health history. Have you ever had a sexually transmitted infection in your life?

Client: Not that I am aware of. My husband and I are monogamous.

Provider: Have you ever been tested for a sexually transmitted infection?

Client: No, I haven't.

Provider: Have you had any surgeries or procedures in your pelvic area? *Client shakes her head no.* OK, what do you already know about cervical cancer and screening for cervical cancer?

Client: My sister told me that cervical cancer can kill you, and that you have to have a pelvic exam to check for it.

Provider: She's right. Cervical cancer is caused by a sexually transmitted virus called "human papillomavirus" or HPV. If not found and treated, cervical cancer can and does kill many women every year. It is a major cause of death for women between the ages of 35 and 60 in developing countries. Women with many sexual partners, a history of many sexual partners, women with HIV, women who smoke, who started having sex early (before 20 years old), or who have a mother or sister with cervical cancer are at greater risk. HPV and cervical cancer can be prevented through vaccination against HPV where available and by limiting sexual partners and using a condom. If not tested and identified, cervical cancer will lead to death. Do you have questions on this?

Client: Not yet.

Provider: We test for cervical cancer using visual inspection with acetic acid. Basically, this means we wash your cervix with vinegar and look for abnormalities, anything unusual. Unhealthy cells will show up white with vinegar on them. If we find anything that looks abnormal, we will treat it by killing any abnormal cells by freezing them off with a special machine. This is called "cryotherapy," and it can prevent cervical cancer by killing abnormal cells or treating early stages of cancer. It is 90% effective for up to 5 years. What questions do you have about the test and possible treatment?

Client: Does the test hurt? Does the treatment hurt?

Provider: The test does not hurt. If you need treatment, there is some cramping and a feeling of cold in the vagina that passes quickly. This is treated with oral pain medicine, and is not that painful. Do you have any other thoughts or concerns about the test?

Client: No, not now. It sounds like my risk is low.

Provider: Yes it is, but better to be safe. So you are ready to have the test now? *Client nods.* OK, we'll set you up for the test in the next room. I'll be with you shortly.

Flawed Script

Provider and client greet each other. Provider should be warm, professional, and efficient.

Provider *refers to the chart or card and uses client name*: Hello, please have a seat, Mrs. Safe. My name is Mary, how can I help you?

Client: I'm here to get screened for cervical cancer. My sister had it done last week and said I should come in. I have not had it done before.

Provider: Before we talk more about what you need, it's important you understand everything we talk about is confidential. It will be documented in your record, but not shared. OK?

Client: Yes, OK.

Provider: It's great you came in for the screening. Before we get to that, I will need some information from you regarding your health history, particularly around your reproductive health. Is that OK?

Client: Of course.

Provider: What is your age, Mrs. Safe?

Client: 38 years old.

Provider: OK. And when was your last menstrual period?

Client: Hmmmm, I believe I started on October 12, it was a Monday.

Provider: Excellent. Now Mrs. Safe, are you married?

Client: Yes, I have been married for 15 years.

Provider: Do you currently use any family planning methods?

Client: I had an intrauterine device placed about 4 years ago.

Provider: Fine. Do you have any other health issues that you would like to talk about?

Client: No, I am a pretty healthy person.

Provider: Do you have any questions regarding your health?

Client: No, I don't.

Provider: OK, so what do you already know about cervical cancer and screening for cervical cancer?

Client: My sister told me that cervical cancer can kill you, and that you have to have a pelvic exam to check for it.

Provider: She's right, cervical cancer can and does kill many women every year. It is a major cause of death for women between the ages of 35 and 60 in developing countries. If not tested and identified, cervical cancer will lead to death. Do you have questions on this?

Client: Not yet.

Provider: We test for cervical cancer using visual inspection with acetic acid. Basically, this means we wash your cervix with vinegar and look for abnormalities, anything unusual. Unhealthy cells will show up white with vinegar on them. If we find anything that looks abnormal, we will discuss treatment options with you. What questions do you have about the test and possible treatment?

Client: Does the test hurt? Does the treatment hurt?

Provider: The test does not hurt. If you need treatment, there is some cramping and a feeling of cold in the vagina that passes quickly. This is treated with oral pain medicine, and is not that painful. Do you have any other thoughts or concerns about the test?

Client: No, not now. It sounds like my risk is low.

Provider: Yes it is, but better to be safe. So you are ready to have the test now? *Client nods.* OK, we'll set you up for the test in the next room. I'll be with you shortly.

SIX WEEK POST-PARTUM FOLLOW-UP VISIT

Objective

Demonstrate a portion of a six-week post-partum visit with integrated family planning counseling.

Scene

Clinic setting complete with hand rub, bed, scale, blood pressure cuff, stethoscope, etc. Provider on stool and a client on an exam bed; provider should have the relevant charting paperwork. Provider can have script on clipboard.

Materials Needed

- Exam table and clipboard
- Fake baby, wrapped
- Blood pressure cuff and stethoscope
- Provider wears white coat

Perfect Script

Provider *refers to the chart or card and uses client name*: Hello, please have a seat, Mrs. K. My name is Jane. It's nice to see you again. I can see you are here for your 6-week post-partum appointment. How is everything going so far?

Client: I'm doing well, as is my son John. I have learned a lot in the last month.

Provider: Yes, I'm sure you have. Before we talk more, I wanted to let you know what we discuss today is confidential. I will write it down in your chart but it will not be shared.

Client: Yes, OK.

Provider: It's great you came in today for your checkup. I see from your chart that you had a normal vaginal delivery and that there were no complications with John's birth. How have you been feeling?

Client: Tired, but OK.

Provider *washes her hands using hand rub*: I need to ask you about possible complications. Have you had any of the following: pain in your belly, blurry vision or severe headaches, fits, dizziness or convulsions, trouble breathing? *Client shakes her head no to all.* What about any very heavy vaginal bleeding or discharge? Feeling so tired you feel like you can't get up, or feeling very sad or worried?

Client: No, none of those.

Provider: That's good to hear. Are you still having any bleeding?

Client: No, my bleeding stopped about 10 days ago.

Provider: Good, sounds like everything is OK with you. What about your son John, have you noticed anything unusual with him?

Client: Not really anything out of the ordinary; he took a while to feed regularly, but now he is nursing really well.

Provider: So you haven't noticed any fever, rapid or troubled breathing, fits, pus from his cord, discharge from his eyes? Or feeling very cold to the touch?

Client: No.

Provider: Ok, that's great. Let's talk about how things are now. I see that John wasn't pre-term and there were no complications for you or John around delivery. Are you sleeping under an insecticide-treated net?

Client: No, we don't have one.

Provider: It is very important to prevent malaria and related complications. If I get you one today, will you use it?

Client: Yes.

Provider: Great, I will get you one before you leave. Are you exclusively breastfeeding John? Giving him nothing but breast milk?

Client: Yes I am, the nurse told me I should exclusively breastfeed until he was at least 6 months of age.

Provider: Before John was born were you tested for HIV?

Client: Yes, during my pregnancy I was tested for HIV and I am HIV-negative.

Provider: I just wanted to confirm this; otherwise, there are some precautions we would need to follow to reduce the risk of John contracting HIV through breastfeeding. It is important to continue to breastfeed exclusively for 6 months. Breast milk is the ideal food for John—it gives him all the nutrients he needs for healthy development and will help protect him from illnesses, such as diarrhea and pneumonia. After John is 6 months old you can add in complementary feeding. OK, have you and your partner resumed intercourse since John's birth?

Client: Not yet, my husband wants to but I'm a little nervous it's going to be painful.

Provider: It's OK to wait, especially at least 6 weeks. But if you want, you can resume sex anytime from now on. However, you can get pregnant if you don't take precautions. What do you know about healthy timing and spacing for pregnancy?

Client: I know it's best to wait at least 2 years before getting pregnant again.

Provider: How long would you like to wait before getting pregnant again?

Client: At least a year and a half. They told me during antenatal visits about the breastfeeding method—will that work?

Provider: You mean the Lactational Amenorrhea Method, or LAM?

Client: Yes, that one.

Provider: Tell me what you know about LAM.

Client: I know that you have to breastfeed only, giving no other fluids or food, and that you need to breastfeed all the time, including during the night. And that you shouldn't be getting your menstrual period.

Provider: That's correct—if you start bleeding, you may get pregnant—and you need to be breastfeeding during the day and night. You should come see us before your baby turns 6 months old to get a different family planning method because it really only works during the first 6 months of the baby's life.

Client: OK.

Provider: We will get you the insecticide-treated net for you and your family to sleep under. A few other things before I examine both you and John to make sure you are both fine. It's important you wash your hands before handling the baby, and keep both yourself and the baby clean in order to prevent infection. Do you have access to running water and soap?

Client: Yes, that's not a problem.

Provider: Now I would like to do a physical exam on both you and John, just to make sure you are both doing fine. I first am going to get John's weight, height, and head circumference.

Flawed Script

Provider *refers to the chart or card and uses client name*: Hello, please have a seat, Mrs. K. My name is Jane. It's nice to see you again. I can see you are here for your 6-week post-partum appointment. How is everything going so far?

Client: I'm doing well, so is John. I have learned a lot in the last month.

Provider: Yes, I'm sure you have. Before we talk more, I wanted to let you know what we discuss today is confidential. I will write it down in your chart but it will not be shared.

Client: OK.

Provider: It's great you came in for your checkup. I see you had a normal vaginal delivery and that there were no complications with John's birth. How have you been feeling?

Client: OK, a little tired.

Provider: That's normal. I need to ask you about complications. Have you had any pain in your belly? Any very heavy vaginal bleeding? Unusual discharge? What about blurry vision or headaches? Fits, dizziness, convulsions? Trouble breathing?

Client: No.

Provider: That's good to hear. Are you still having any bleeding?

Client: No, my bleeding stopped about 10 days ago.

Provider: OK, sounds like everything is OK with you. What about John? Anything unusual with him?

Client: Not anything out of the ordinary. It took him a while to feed, but now he is nursing well.

Provider: So you haven't noticed any fever, rapid or troubled breathing, fits, pus from his cord, discharge from his eyes? Or feeling very cold to the touch?

Client: No.

Provider: OK. Are you exclusively breastfeeding John?

Client: Yes I am, the nurse told me I should exclusively breastfeed until he was at least 6 months of age.

Provider: It is important to continue to breastfeed exclusively for 6 months. Breast milk is the ideal food for John—it gives him all the nutrients he needs for healthy development and will help protect him from illnesses, such as diarrhea and pneumonia. After John is 6 months old you can add in complementary feeding. OK, have you and your partner resumed intercourse since John's birth?

Client: Not yet, my husband wants to but I'm a little nervous it's going to be painful.

Provider: It's OK to wait, especially at least 6 weeks. Have you been told about using the Lactational Amenorrhea Method, or LAM, to prevent pregnancy?

Client: Yes, they told me about LAM during antenatal visits. Is it really effective?

Provider: Tell me what you know about LAM.

Client: I know that you have to breastfeed only, giving no other fluids or food, and that you need to breastfeed all the time, including during the night. And that you shouldn't be getting your menstrual period.

Provider: That's correct—if you start bleeding, you may get pregnant—and you need to be breastfeeding during the day and night. You should come see us before your baby turns 6 months to get a different family planning method. I would now like to do a physical exam on both you and John, just to make sure you are both doing fine. I first am going to get John's weight, height, and head circumference.

MANAGING SECOND STAGE AND ACTIVE MANAGEMENT OF THIRD STAGE OF LABOR

Objective

Demonstrate active management of the third stage of labor (no flaws).

Format

Demonstration

Scene

Clinic setting complete with delivery table, clinic table, or chair. Need one facilitator to wear MamaNatalie and be the client. Provider is wearing two sets of gloves.

Materials Needed

- MamaNatalie and NeoNatalie
- Delivery table, clinic table, or chair for laboring client
- Oxytocin and syringe
- Delivery set: 2 clamps, 1 scissors, 3–4 cloths/towels
- Post-exposure prophylaxis and two sets of gloves for provider
- Basin

Perfect Script

Provider *as client is pushing and the baby is crowning*: Do you feel the urge to push? (*Client nods.*) OK, push slowly now. *Client pushes.*

Provider *has hands gently on the head continuing flexion and says to audience:* I'm keeping my hands on the baby's head, just applying gentle pressure to keep the head in a good position. *To client*: OK, you are pushing well, the baby is coming.

Provider demonstrates correct hand placement, checking for the cord, extracting anterior then posterior shoulder. Baby comes out, provider congratulates client and places the baby on the client's abdomen. (If the mother is unable to hold the baby, provider asks her birth companion or an assistant to care for the baby.) Provider thoroughly dries the baby with clean cloth and the baby starts crying (use the NeoNatalie bulb to make the crying sound). Provider removes the wet cloth, puts the baby back on the client's abdomen, and covers them both with a new, dry cloth.

Provider: Your baby is breathing and looks fine, it's a baby girl! *(Client nods and smiles.)* Are you OK holding the baby? Now I need to give you a drug to help your uterus contract so you stop bleeding.

Client *holds and rubs baby*: OK.

Provider *palpates abdomen*: I've palpated the abdomen and there's no second baby, so I can give you the oxytocin. *Takes a loaded syringe and alcohol swab, swabs leg, and pretends to give shot.* OK, now tell me when you feel your next contraction.

Provider *sits and watches (speaking to audience)*: You want to give oxytocin within the first minute, but not cut the cord until about 3 minutes after birth unless there is an emergency and you need to resuscitate the baby. It's been about 3 minutes, and the baby is crying well, so it's OK to cut the cord. *Provider removes top pair of gloves and throws them in bleach container, then cuts and clamps the cord.*

Client: Ohh, I feel another contraction coming now.

Provider *palpates the uterus*: OK, just relax and I will assist you to deliver the afterbirth. *(speaking to audience)* Notice that the flat side of my one hand "guards" the uterus, to prevent it from inversion during traction on the cord. Apply steady tension downward—not seesawing up and down—to follow the direction of the birth canal. *With one hand above pubic bone, provider applies pressure in an upward direction (toward the woman's head) to apply counter-traction and stabilize the uterus. At the same time, with the other hand, provider pulls with a firm, steady tension on the cord in a downward direction (following direction of the birth canal).*

Provider *to audience*: Continue to apply this pressure for about 30 seconds or so, and if the placenta does not come, then wait for the next contraction and try again. *Placenta comes out, provider holds it with both hands and twists slowly so the membranes are expelled intact.*

Provider *to audience*: As you are delivering the placenta, if the membranes do not slip out easily, twist them into a rope and gently move them up and down to help them separate and come out intact. Retained membranes will prevent uterine contraction and can lead to post-partum hemorrhage. *Provider puts placenta in the basin.*

Provider *to client:* Now I'm going to check your uterus to make sure it is nice and firm. *(Does so.)* It's nice and firm. Now I'm going to check for any tears and make sure everything is OK, all right?

Client: Yes, that's fine.

Provider *checks vagina and perineum, wipes the mother, changes the cloth, and applies a pad:* Looks like you have no tears. I'm going to wipe you off and give you a dry pad. *(Does so.)* Are you feeling OK?

Client: Yes, OK, just tired.

Provider *to client:* I'm going to make sure all of your placenta was delivered. Can you offer the baby the breast?

Provider *picks up placenta and checks it for completeness—checking for all the lobes, and then inverting to check for membrane completeness. To audience*: You first make sure no lobes are missing, then hold the placenta upside down and see if the membranes come together and are complete.

Provider *to client:* Looks like everything is fine! Do you need help getting your baby on the breast?

Flawed Script

Provider: OK, do you feel the urge to push? *(Client nods.)* Push slowly now. *Client pushes.*

Provider *has hands gently on the head continuing flexion, does not support the perineum*: OK, keep pushing with your contraction.

Provider demonstrates correct hand placement, checking for the cord, extracting anterior then posterior shoulder. Baby comes out, provider congratulates client and places the baby on the client's abdomen. (If the mother is unable to hold the baby, provider asks her birth companion or an assistant to care for the baby.) Provider thoroughly dries the baby with clean cloth and the baby starts crying (use the NeoNatalie bulb to make the crying sound). Provider removes the wet cloth, puts the baby back on the client's abdomen, and covers them both with a new, dry cloth.

Provider: Your baby is breathing and looks fine, it's a baby girl! *(Client nods and smiles.)* Are you OK holding the baby? Now I need to give you a drug to help your uterus contract so you stop bleeding.

Client *holds and rubs baby*: OK.

Provider *DOES NOT check for another baby*: I'm going to give you a shot now. *Takes a loaded syringe and alcohol swab, swabs leg, and pretends to give shot.* OK, now tell me when you feel your next contraction. *Provider sits and watches, then removes top pair of gloves and throws them in bleach container. Provider cuts and clamps the cord.*

Client: Ohh, I feel another contraction coming now.

Provider *to client*: OK, just relax and I will assist you to deliver the afterbirth. *Provider DOES NOT provide suprapubic counter-traction, but pulls with a firm, steady tension on the cord in a downward direction (following direction of the birth canal). Placenta comes out; provider holds it with both hands and twists slowly so the membranes are expelled intact, then puts placenta in the basin.*

Provider *to client*: Now I'm going to massage your uterus to make sure it is nice and firm. *(Does so.)* It's nice and firm. Now I'm going to check for any tears and make sure everything is OK, all right?

Client: Yes, that's fine.

Provider *checks perineum, wipes the mother, changes the cloth, and applies a pad:* Looks like you have no tears. I'm going to wipe you off and give you a dry pad. *(Does so.)* Are you feeling OK?

Client: Yes, OK, just tired.

Provider *to client*: I'm going to make sure all of your placenta was delivered. Can you offer the baby the breast? *Provider picks up placenta and checks it for completeness—checking for all the lobes, and then inverting to check for membrane completeness.* Looks like everything is fine! Do you need help getting your baby on the breast?

NEWBORN RESUSCITATION

Objective

Perform newborn resuscitation (no flaws).

Format

Demonstration

Scene

Clinic setting complete with newborn resuscitation equipment and post-exposure prophylaxis. Model baby on table and provider standing to the side, equipment on a nearby mayo tray.

Materials Needed

- Model baby for resuscitation (NeoNatalie)
- Mayo tray
- Examination gloves
- Something to simulate oxygen cylinder
- Neonatal mask
- Ambubag
- Suction tubing
- Clean blanket

Perfect Script

Provider: A woman has just given birth to a baby boy after a prolonged second stage of labor. At birth, the baby is not crying. *Immediately dries baby with towel and discards the wet towel.* The baby is not breathing or crying yet, so I need to start resuscitations.

Provider *visually checks nose and mouth to see if full of secretions*: The nose is full of secretions, so I need to suction. *Provider suctions mouth and then nose, simultaneously stimulating baby with back rubbing. Baby is NOT BREATHING. Provider ties and immediately clamps cord, then cuts cord with clean blade or clean scissors. Provider places the baby on his back on a clean, warm surface or towel.*

Provider *to the woman while placing the baby's head in a slightly extended position to open the airway:* The baby is still not breathing. We need to help your baby start breathing; we're going to give him some air with a bag and mask.

Provider *to the woman while visually checking baby's mouth, back of throat, and nose for secretions*: There's no more secretions, we don't need to suction your baby again. *Provider places the correct-sized mask on the baby's face so that it covers the chin, mouth, and nose (but not eyes) and checks the seal by ventilating two times and observing the rise of the chest. Baby's chest rises.*

Provider *to woman while ventilating at a rate of 30 to 50 breaths per minute*: I'm going to help your baby start breathing now. *Counts out loud*: 1 and 2 and breathe. *After about five ventilations, the baby begins breathing*. Your baby is breathing now! I'll just make sure that he is breathing well on his own.

Flawed Script

Provider: A woman has just given birth to a baby boy after a prolonged second stage of labor. At birth, the baby is not crying. *Immediately dries baby with towel and discards the wet towel.* The baby is not breathing or crying yet, so I need to start resuscitations.

Provider *visually checks nose and mouth to see if full of secretions*: The nose is full of secretions, so I need to suction. *Provider suctions mouth and then nose, simultaneously stimulating baby with back rubbing. Baby is NOT BREATHING. Provider ties and immediately clamps cord, then cuts cord with clean blade or clean scissors. Provider places the baby on his back on a clean, warm surface or towel.*

Provider *to the woman while placing the baby's head in a slightly extended position to open the airway*: The baby is still not breathing. We need to help your baby start breathing; we're going to give him some air with a bag and mask.

Provider *to the woman while visually checking baby's mouth, back of throat, and nose for secretions*: There's no more secretions, we don't need to suction your baby again. *Provider looks around for bag and mask, rushes over and grabs it from a nearby table. Provider places the correct-sized mask on the baby's face so that it covers the chin, mouth, and nose (but not eyes) but PUSHES ON ROUGHLY AND FLEXES THE BABY'S NECK so the mask does not seal correctly. Checks the seal by ventilating two times and observing the rise of the chest. The baby's chest DOES NOT rise.*

Provider *while checking the position of the newborn's head to make sure that the neck is in a slightly extended position (not blocking the airway)*: I've already suctioned secretions, so I don't need to check again. I'm repositioning to get a correct seal with the mask. *TRIES AGAIN; THE BABY'S CHEST RISES.*

Provider *to woman while ventilating at a rate of 30 to 50 breaths per minute*: I'm going to help your baby start breathing now. *Counts out loud*: 1 and 2 and breathe. *After about five ventilations, the baby begins breathing*. Your baby is breathing now! I'll just make sure that he is breathing well on his own.

Appendix E: Sample Training Schedule: Maternal and Newborn Quality of Care Study

Time	Session Title	Overview	Who Responsible	Materials Needed
Monday, July 12				
9:00–9:30	Welcome	Welcome and introductions; participants' expectations	Facilitator 1	Name tag materials
9:30–10:00	Study overview	Present the purpose of the study, an overview of when and where the study will be conducted, purpose of workshop	Facilitator 2	Powerpoint presentation
10:00–10:30	Inter-rater reliability	Inter-rater reliability	Facilitator 3	Powerpoint presentation
10:30–11:00	Role of observer	Review and discuss differences between observer and mentor or teacher (role play) and the importance of the observer role for the study	Facilitator 4	Powerpoint presentation
11:00–11:20 Tea				
11:20–11: 40	Introduce essential care section of labor and delivery (L&D) observation checklist	Introduce and read through the essential care section of the L&D checklist as a group	Facilitator 1	L&D checklist for participants x 35
11:40–1:00	Demonstrate and score using essential care section of L&D checklist	A demonstration of the childbirth simulator anatomic model will be conducted once without scoring and once with all participants scoring	1 group; Facilitators 1 and 2	1 station set up for demonstration; pencils x 35; filled-in partograph x 35
1:00–2:00 Lunch				
2:00–4:00	Practice of the essential care section of the L&D checklist	Using 3 stations, participants will practice doing the checklist with the models	3 groups; Facilitators 1, 2, 3, and 4	3 stations set up for demonstration
4:00–4:20 Tea				
4:20–4:45	Wrap-up	Review learning from Day 1 and assign homework on reviewing post-partum checklist	Facilitator 3	Post-partum checklist x 35
Tuesday, July 13				
8:30–9:15	Introduction to mobiles	Explain basic functions of phone, accessories, storage	Facilitator 1	Phones and accessories
9:15–10:15	Review of tool using mobile	Review L&D checklist on the phone	Facilitator 1	Phones and accessories
10:15–10:45 Tea				
10:45–11:00	Introduction of the pre-eclampsia/ eclampsia (PE/E) section of the L&D checklist	Introduce and read through the PE/E section of the L&D checklist as a group	Facilitator 2	L&D checklist for participants x 35
11:00–	PE/E role play and	Conduct a role play of a PE/E	Facilitator 2	1 station set up

Time	Session Title	Overview	Who Responsible	Materials Needed
12:30	scoring	patient once without scoring and once with all participants scoring and with a facilitator scoring using a mobile and the projector		for demonstration; pencils x 35; filled-in partograph x 35
12:30–1:30 Lunch				
1:30 - 4:00	Practice on scoring of the PE/E section	In 3 groups, practice scoring PE/E section, using mobiles	Group Facilitators 1, 2, 3, and 4	3 stations with scenario for PE/E patient (get from tool); phones
4:00–4:20 Tea				
4:20–4:45	Wrap-up	Review day's learning and present homework: reviewing the post-partum hemorrhage (PPH) section of the tools	Facilitator 1	Paper versions of the PPH section of the tools (x35)
Wednesday, July 14				
8:30–8:40	Introduction of the PPH section of the L&D checklist	Introduce and read through the PPH section of the L&D checklist as a group	Facilitator 1	L&D checklist for participants x 35
8:40–11:00	PPH role play and scoring	Conduct a simulation of manual removal of the placenta once without scoring and once with all participants scoring and with facilitator scoring using a mobile and the projector	Facilitator 1	1 station set up for demonstration to entire group
11:00–11:30 Tea				
	Practice on scoring of the PPH section	In 3 groups, practice scoring PPH section, using mobiles	Group Facilitators 1, 2, 3, and 4	3 stations with scenario for PPH patient (get from tool); phones
Lunch 1:00–2:00				
2:00–3:00	Informed consent overview	Review informed consent, how to do the different informed consent (paper and verbal); do role plays	Facilitators 2, 3, and 4	Paper versions of all informed consent forms
3:00–3:20	Introduction of the newborn resuscitation section of the L&D tool	Introduce and read through the newborn resuscitation section of the L&D checklist as a group	Facilitator 3	Newborn resuscitation section of L&D checklist for participants x 35
3:20–4:00	Newborn resuscitation simulation and scoring	Conduct a simulation of newborn resuscitation, with scoring by participants and by a facilitator using a mobile and the projector	Facilitator 3	2 stations set up for demonstration
4:00–4:45	Practice on scoring of the newborn resuscitation section	In 3 groups, practice scoring newborn resuscitation section, using mobiles	Group Facilitators 1, 2, and 3	3 stations with scenario for newborn resuscitation (get from tool); phones

Time	Session Title	Overview	Who Responsible	Materials Needed
4:45–5:00 Tea				
5:00–5:15	Wrap-up	Review day's learning and present homework: reviewing the antenatal care (ANC) section of the tools	Facilitator 2	Paper versions of the ANC section of the tools (x 35)
Thursday, July 15				
8:30–9:30	Introduction of the ANC checklist	Introduce and go over the ANC checklist (through reading through)	Facilitator 1	ANC checklist for participants x 35
9:30–10:00	ANC role play and scoring	Conduct a role play of an ANC patient with all participants scoring and with a facilitator scoring using a mobile and the projector	Facilitator 1	2 stations set up for demonstration; pencils x 35; filled-in partograph x 35
10:00–10:20 Tea				
10:20–11:30	Practice on scoring of the ANC section	In 3 groups, practice scoring ANC section, using mobiles	Group Facilitators 1, 2, and 3	3 stations with scenario for ANC; phones
11:30–12:30	Health worker interview / knowledge tests	Introduce the health worker knowledge tests; role play the administration of the tool; score on mobile phones	Facilitators 1 and 4	Hard copies of the scenario (x 35); hard copies of the list of acceptable health worker IDs
12:30–1:30 Lunch				
1:30–3:30	Health worker interview / knowledge tests *(continued)*	Introduce the health worker knowledge tests; role play the administration of the tool; score on mobile phones	Facilitators 1 and 4	Hard copies of the scenario (x 35); hard copies of the list of acceptable health worker IDs
3:30–4:00	Mobile maintenance	Review mobile maintenance, data backup, charging, removing memory card	Facilitators 2 and 3	Phones and accessories; phone sign-out form
4:00–4:20 Tea				
4:20–4:45	Wrap-up	Review day's learning and present homework: reviewing the maternal and neonatal health (MNH) record review tool	Facilitator 1	MNH record review tool
Friday, July 16				
8:30–10:00	Inter-rater Reliability exercise		Facilitators 1, 2, 3, and 4	3 stations with scenarios for PE/E, newborn resuscitation, and normal L&D; smartphones

Time	Session Title	Overview	Who Responsible	Materials Needed
10:00–10:20 Tea				
10:20–1:00	Inter-rater reliability exercise *(continued)*		Facilitators 1, 2, 3, and 4	3 stations with scenarios for PE/E, newborn resuscitation, and normal L&D; smartphones
1:00–2:00 Lunch				
2:00–3:30	Inventory form	Introduce inventory forms and discuss any concerns	Facilitator 1	Inventory form
3:30–4:30	Health worker line listing	Introduce health worker line listing and supervisor interview forms	Facilitator 2	Health worker line listing form
4:30–4:50 Tea				
5:00–5:15	Wrap-up		Facilitator 2	

PRE-TESTING OF THE TOOLS AT THREE HEALTH FACILITIES

Saturday, July 17—Practicum, Observation Using L&D Checklist, and Line Listing

Temeke and Ilala

Transport leaves Jhpiego office at 8:30 a.m.

Monday, July 19—Practicum, Health Worker Knowledge, ANC Observation, and MNH Record Review

Temeke, Mwananyamala, and Ilala

Transport leaves Jhpiego office at 8:30 a.m.

Facilitators meet back at Jhpiego office after lunch

Time	Session Title	Overview	Who Responsible	Materials Needed
Tuesday, July 20				
8:30–10:00	Debrief on experiences with practicum; note changes to tools from pre-test			
10:00–10:20 Tea				
10:20–11:30	MNH record review tool	Introduce record review tool; discuss any questions; practice on phones	Facilitator 2	Samples of all relevant registers and summary forms; phones
11:30–12:30				

Time	Session Title	Overview	Who Responsible	Materials Needed
12:30–1:00				
1:00–2:00 Lunch				
2:00–3:00	Protocol discussion	Discuss roles on teams, which ANC cases to observe, which providers to test on knowledge, which L&D cases to observe, shifts for observation	Facilitator 2	
3:00–4:00	Logistics discussion	Discuss transport and logistics for teams	Entire group, then break into teams as much as possible	
4:30–4:50 Tea				

Appendix F: Certificate Template