USAID
FROM THE AMERICAN PEOPLE

MCHIP Maternal and Child Health Integrated Program

Clinical Observer Training

Learner's Guide

September 2013

Developed by: Barbara Rawlins, Alice Christensen, and Julia Bluestone

The development of this manual and training material was drawn from the knowledge of many technical experts. The following people are gratefully acknowledged as contributors and/or technical reviewers of this manual:

Eva Bazant, Enriquito Liu, Megan Wysong, Stella Abwao, Goldy Mazia, Mary Drake, Serge Raharison, Laura Fitzgerald, Laban Tsuma, Magdalena Serpa, Sheena Currie, Patricia Gomez, and Joseph de Graft-Johnson

We would also like to acknowledge the following people for their various contributions:

Video talent: Blami Dao, Cherrie Evans, Laura Fitzgerald, Julia Bluestone, Chandrakant "Rupe" Ruparelia, Sara Chace, and Goldy Mazia

Videography and editing: Leonard Frankford and Dale Levitz

Field testing: Gaudiosa Tibaijuka and Marya Plotkin for field testing the pilot version of this training in Tanzania

We would also like to acknowledge the inspiration drawn from an observational assessment training manual (Training Evaluation Handbook for JHPIEGO Program Staff & Master Trainers, September 1999), authored by Susan Blake, PhD, consultant, and Sue Griffey, DrPH, BSN (Director of the Research and Evaluation Office at JHPIEGO at that time and now Vice President, Social & Scientific Systems). That unpublished manual was developed under USAID's Training in Reproductive Health Program, led by JHPIEGO.

Editor: Deborah Stein
Desktop Publisher: Trudy Conley

This program and report were made possible by the generous support of the American people through the U.S. Agency for International Development (USAID), under the terms of the Leader with Associates Cooperative Agreement GHS-A-00-08-00002-00. The contents are the responsibility of Maternal and Child Health Integrated Program (MCHIP) and do not necessarily reflect the views of the USAID or the United States Government.

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.

Table of Contents

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	

Learner's Guide

Session 0: Optional Pre-Quiz

HANDOUT: REVIEW QUIZ

1. Name three methods for collecting data.

   a.

   b.

   c.

2. Name three reasons we collect data.

   a.

   b.

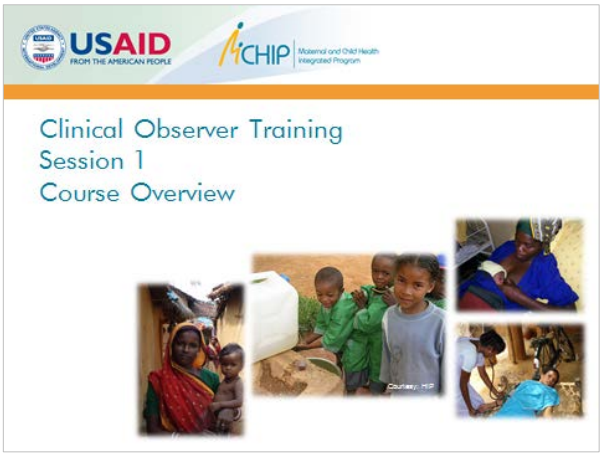
   c.

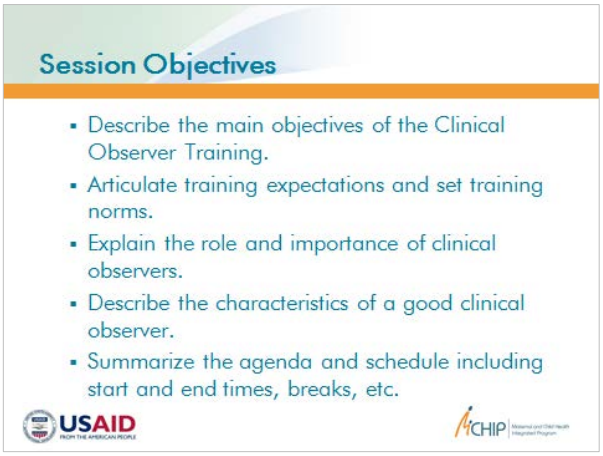
3. Match the term in column 1 with the correct definition in column 2. Each item is only used once.

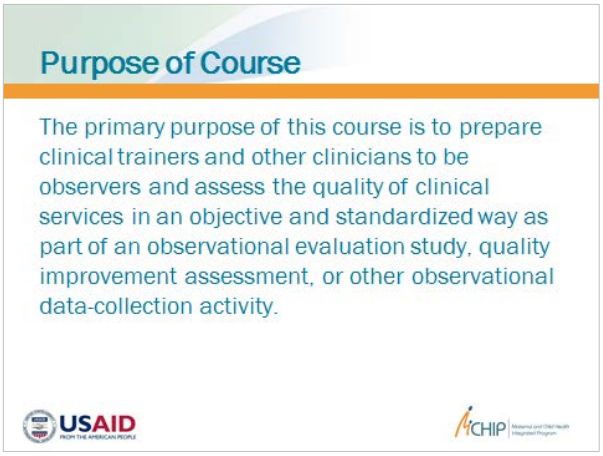
Term	Definition
1. Quantitative data	a. The financial, human, and material resources used in a program/intervention.
2. Qualitative data	b. The extent to which a measurement test accurately measures what is intended to be measured.
3. Validity	c. A quantitative or qualitative variable that provides a 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.

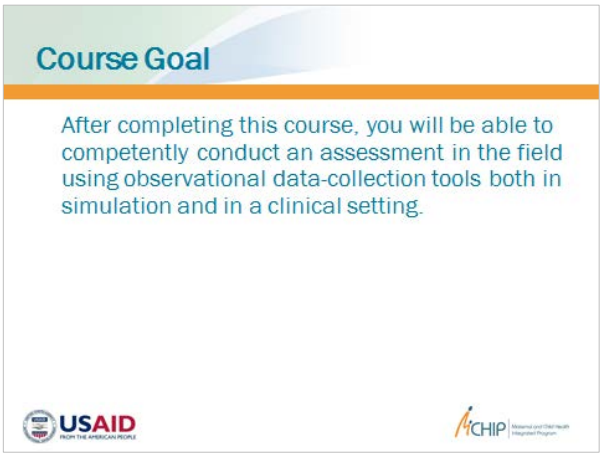
Session 1: Clinical Observer Training: Course Overview

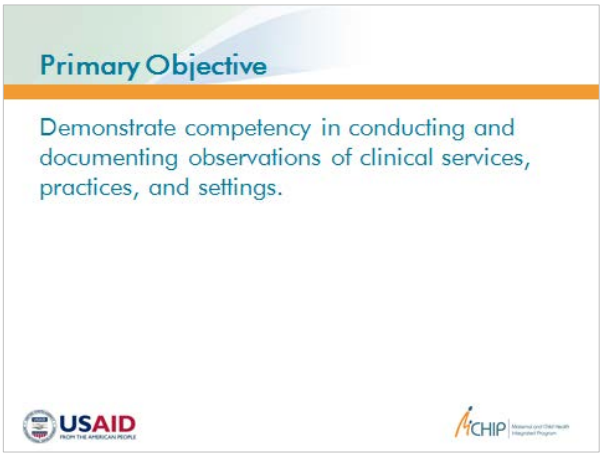
COURSE OVERVIEW: THUMBNAILS

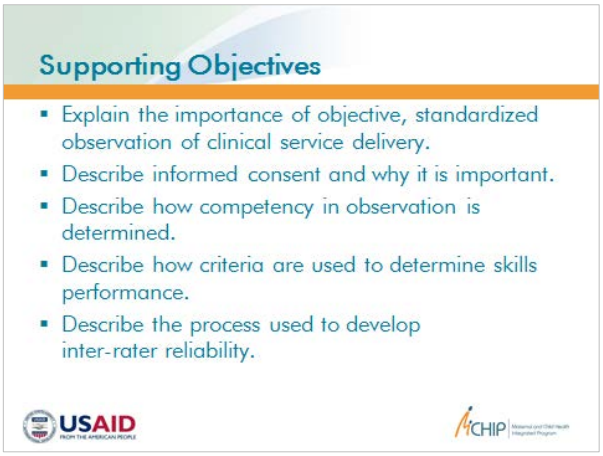






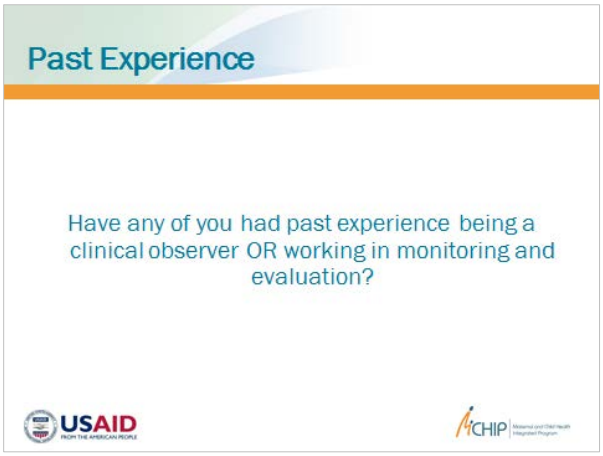

Course Goal
After completing this course, you will be able to competently conduct an assessment in the field using observational data-collection tools both in simulation and in a clinical setting.
USAID
4CHIP

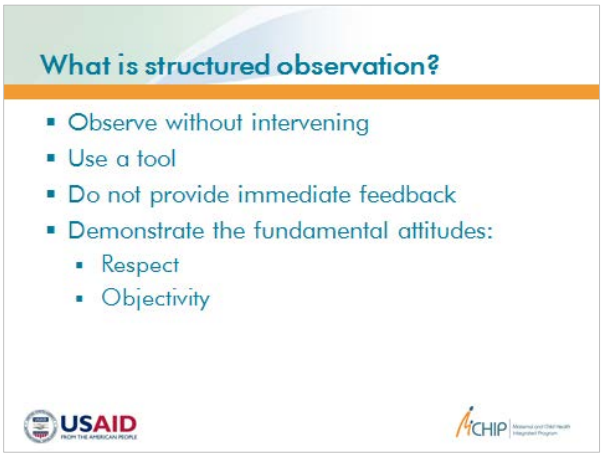

Primary Objective
Demonstrate competency in conducting and documenting observations of clinical services, practices, and settings.
USAID
4CHIP

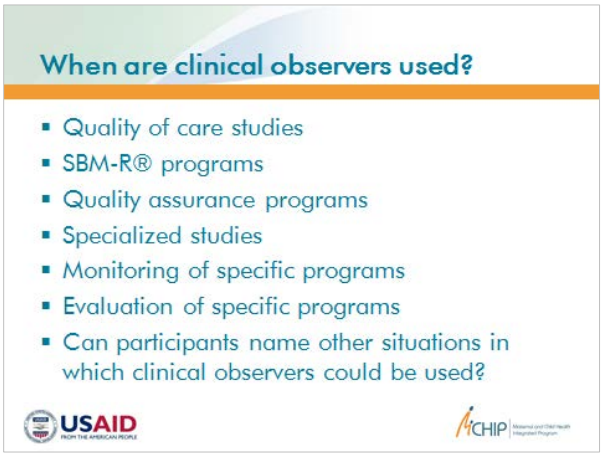

Supporting Objectives
Explain the importance of objective, standardized observation of clinical service delivery.
Describe informed consent and why it is important.
Describe how competency in observation is determined.
Describe how criteria are used to determine skills performance.
Describe the process used to develop inter-rater reliability.
USAID
4CHIP

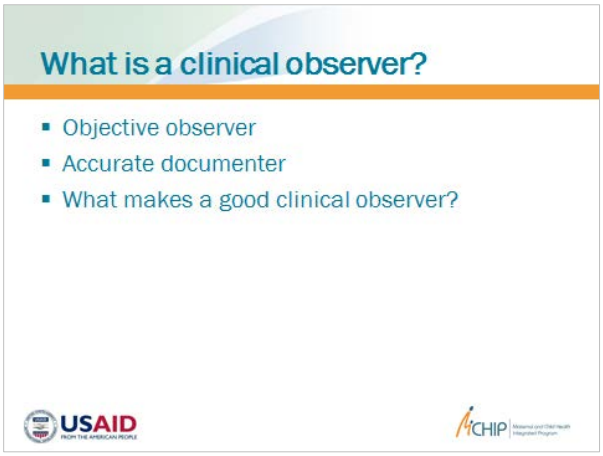

Norms of the Workshop
Brainstorm activity
USAID
MCHIP


Icebreaker
Football
USAID
MCHIP


Past Experience
Have any of you had past experience being a clinical observer OR working in monitoring and evaluation?
USAID
MCHIP


What is structured observation?
Observe without intervening
Use a tool
Do not provide immediate feedback
Demonstrate the fundamental attitudes:
Respect
Objectivity
USAID
MCHIP


When are clinical observers used?
Quality of care studies
SBM-R® programs
Quality assurance programs
Specialized studies
Monitoring of specific programs
Evaluation of specific programs
Can participants name other situations in which clinical observers could be used?
USAID
MCHIP


What is a clinical observer?
Objective observer
Accurate documenter
What makes a good clinical observer?
USAID
MCHIP

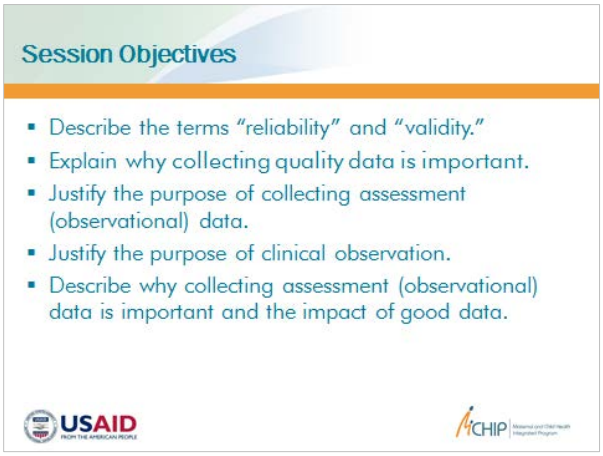

What makes a competent observer?
Objective and standardized observations
Process of standardizing observation of skills
Review tools
Practice skills observations of flawed performances
Assess observer competency in clinical skills observation in the classroom
Practice clinical skills observation at the facility
USAID
MCHIP

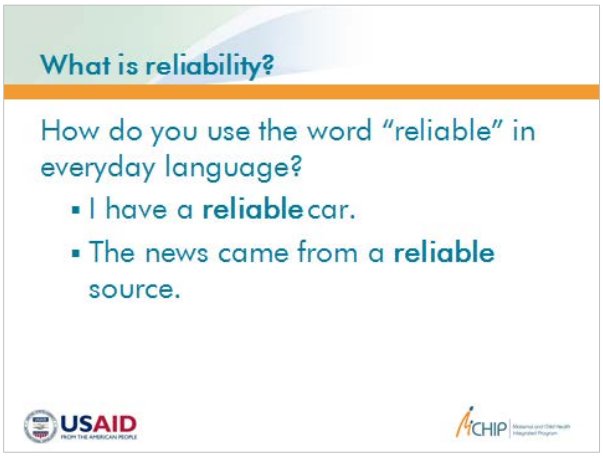

How do clinical observers become competent in the process of clinical observation?
Practice, practice, practice
Knowledge of the standards or tools used for observation and how to apply them
Calibration with other observers
USAID
MCHIP


Thank you!
wwww.mchip.net
Follow us on:
Blog
USAID
MCHIP

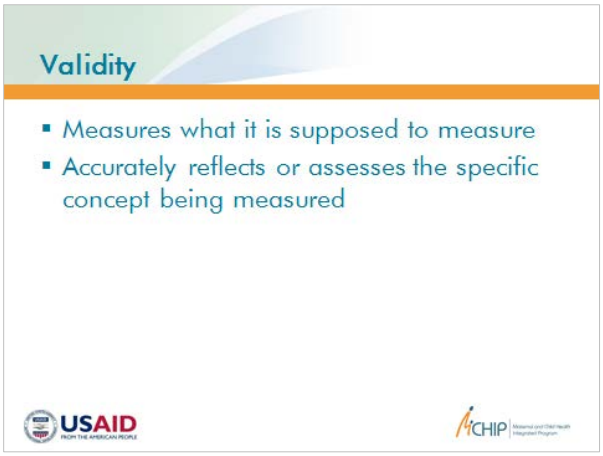
Session 2: Clinical Observer Training: Why are high-quality data important?

WHY ARE HIGH-QUALITY DATA IMPORTANT? THUMBNAILS

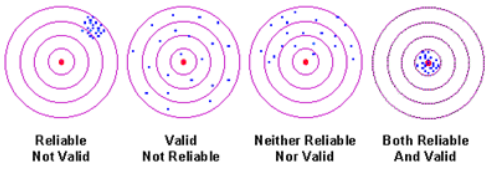



What is reliability?
How do you use the word "reliable" in everyday language?
I have a reliable car.
The news came from a reliable source.
USAID
MCHIP


Reliability
Repeatability
Consistency
USAID
MCHIP


Validity
Measures what it is supposed to measure
Accurately reflects or assesses the specific concept being measured
USAID
MCHIP

Inter-Relatedness of Validity and Reliability



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).

USAID FROM THE AMERICAN PEOPLE

MCHIP Maternal and Child Health Integrated Program

Inter-Rater/Inter-Observer Reliability

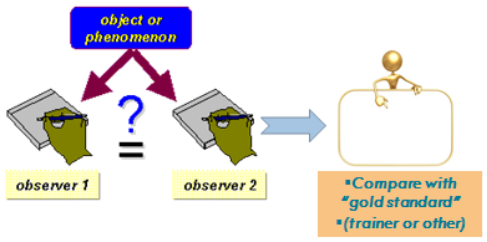


Figure citation: Trochim, William M. The Research Methods Knowledge Base, 2nd Edition. Internet WWW page, at URL: <http://www.socialresearchmethods.net/kb/> (version current as of October 20, 2006).

USAID FROM THE AMERICAN PEOPLE

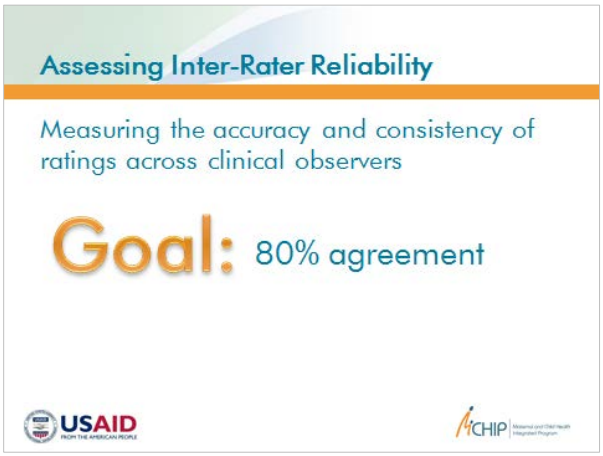
MCHIP Maternal and Child Health Integrated Program

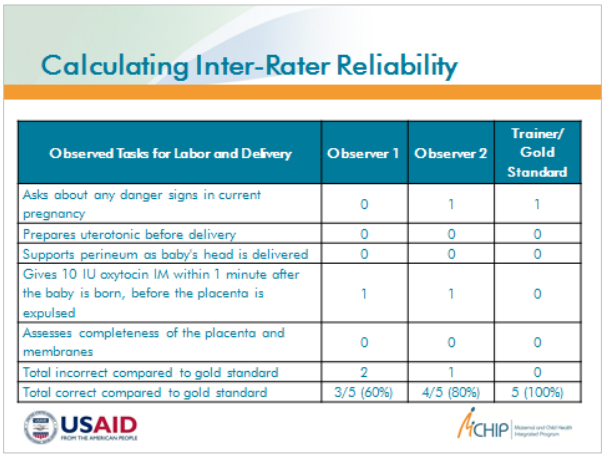
Achieving and Maintaining Adequate Inter-Rater Reliability

- Train observers.
- Ensure tools have criteria that are followed by observers.
- Calculate inter-rater reliability and calibrate observers.
- Retest inter-rater reliability.
- Compare observer scores with "gold standard" to assess validity as well.

USAID FROM THE AMERICAN PEOPLE

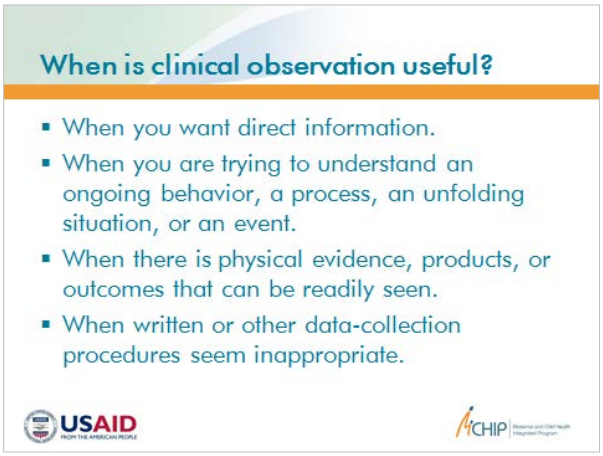
MCHIP Maternal and Child Health Integrated Program

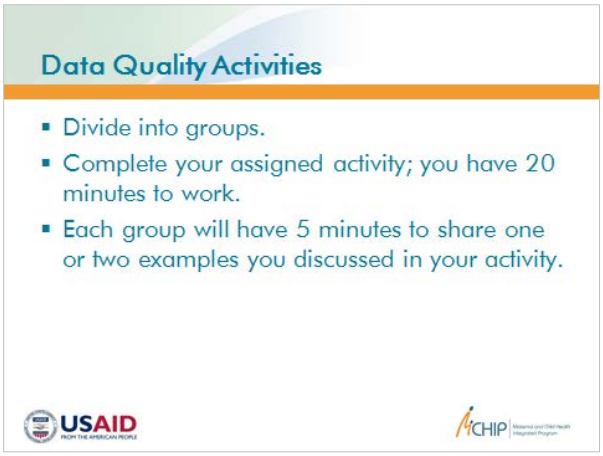




Observed Tasks for Labor and Delivery	Observer 1	Observer 2	Trainer/ Gold Standard
Asks about any danger signs in current pregnancy	0	1	1
Prepares uterotonic before delivery	0	0	0
Supports perineum as baby's head is delivered	0	0	0
Gives 10 IU oxytocin IM within 1 minute after the baby is born, before 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%)

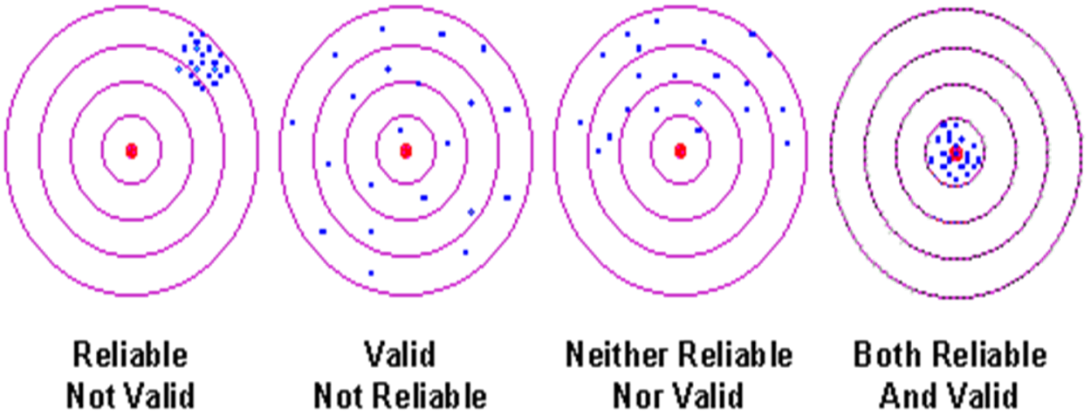

Why are clinical observations important?
USAID
MCHIP


When is clinical observation useful?
When you want direct information.
When you are trying to understand an ongoing behavior, a process, an unfolding situation, or an event.
When there is physical evidence, products, or outcomes that can be readily seen.
When written or other data-collection procedures seem inappropriate.
USAID
MCHIP


Data Quality Activities
Divide into groups.
Complete your assigned activity; you have 20 minutes to work.
Each group will have 5 minutes to share one or two examples you discussed in your activity.
USAID
MCHIP


Thank you!
wwww.mchip.net
Follow us on:
Blog
USAID
MCHIP

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.

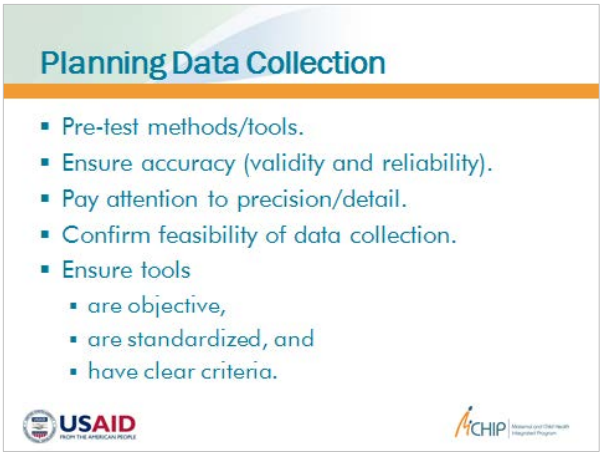
2.

3.

4.

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

HOW DO I COLLECT GOOD-QUALITY DATA? THUMBNAILS




Ensuring Quality Data Collection
Train appropriate staff on quality data collection:
Precision/detail
Reliability (inter-rater reliability)
Completeness
Timeliness
Legibility
USAID
MCHIP


Improving Data Quality as a Clinical Observer
Review Handout: Improving Data Quality as a Clinical Observer.
USAID
MCHIP


Thank you!
wwww.mchip.net
Follow us on:
Blog
USAID
MCHIP

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?

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?

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

HANDOUT: STUDY PLAN OVERVIEW TEMPLATE

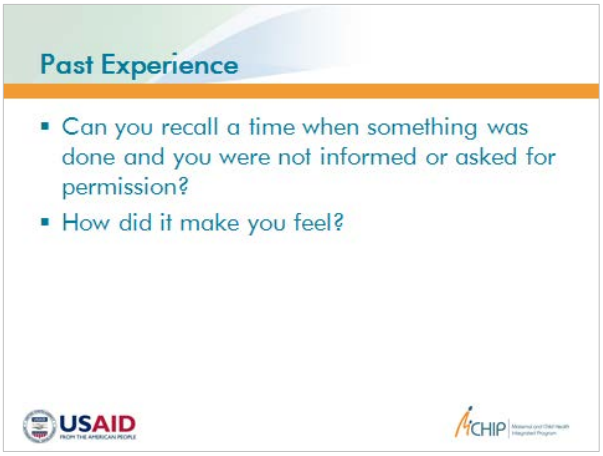
Use this to guide you in developing a handout overview for the research study or formal assessment that is planned. This handout can accompany or be based upon the approved study plan. Handouts can be developed for this presentation directly from the evaluation planning activities.

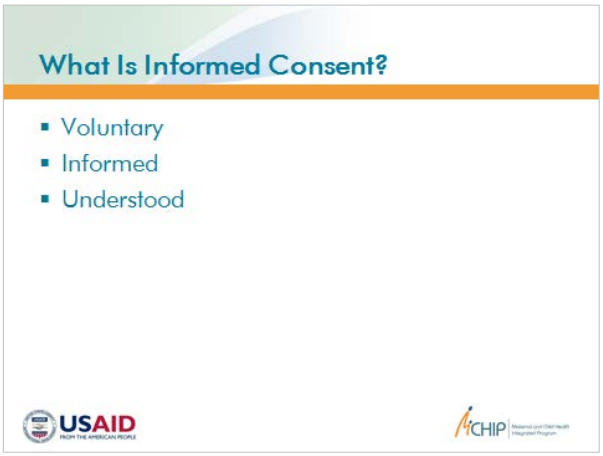
The handout should provide participants an overview of the study. Develop a study plan handout (or PowerPoint overview) that will address each point listed below and provide it to participants during Session 4. Include clear information on each of the following in your handout.

- 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?

HOW DO I OBTAIN INFORMED CONSENT? THUMBNAILS

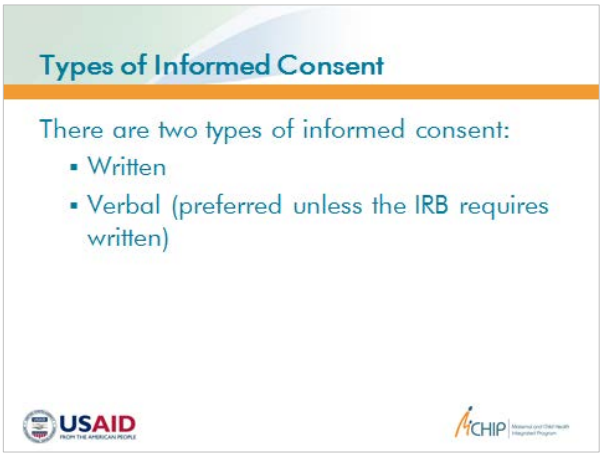



What Is Informed Consent?
Voluntary
Informed
Understood
USAID
4CHIP


When Is Informed Consent Needed?
Informed consent MUST be obtained from all individuals
undergoing a procedure with risk of harm and/or
participating in research.
USAID
4CHIP

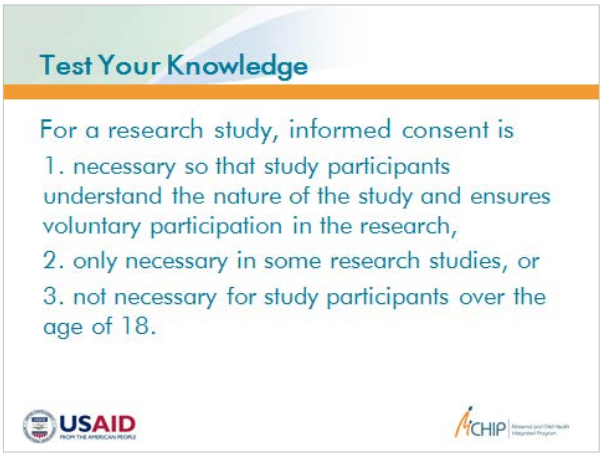

Research Study Consent Forms
A research study consent form must include:
purpose of the study,
what the participant is being asked to do,
potential risks and benefits,
how much time is required,
participation is voluntary, and
invitation to ask questions about the study.
USAID
4CHIP

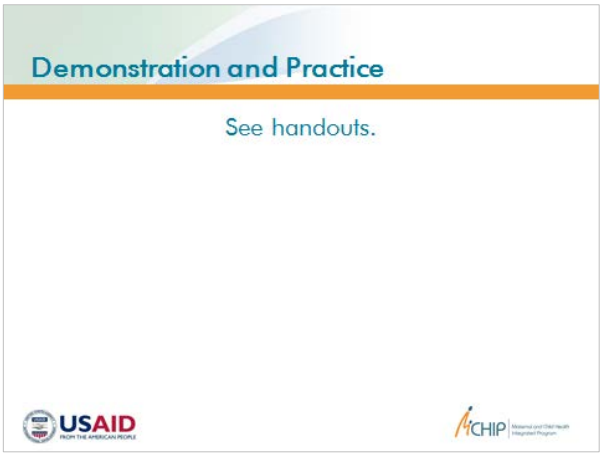

Using Approved Consent Forms
Written informed consent must be obtained using the consent forms that were submitted to the institutional review board (IRB) that reviewed the research study (when applicable).
Most IRBs will provide a stamp or seal on the approved consent forms; it is important to use these versions.
USAID
4CHIP


Types of Informed Consent
There are two types of informed consent:
Written
Verbal (preferred unless the IRB requires written)
USAID
4CHIP


Other Consent Processes: Mobile
Read aloud and mark response on smartphone.
Consent must be obtained for each participant interviewed. No names are recorded.
Ask next of kin for consent if clients are unable to provide consent themselves.
USAID
4CHIP


Informed Consent
…is vital to ensure that all patients and/or study participants understand the nature of the study and have voluntarily agreed to receive the procedure and/or participate in the research.
USAID
MCHIP


Test Your Knowledge
For a research study, informed consent is
1. necessary so that study participants understand the nature of the study and ensures voluntary participation in the research,
2. only necessary in some research studies, or
3. not necessary for study participants over the age of 18.
USAID
MCHIP


Demonstration and Practice
See handouts.
USAID
MCHIP


Thank you!
wwww.mchip.net
Follow us on:
Blog
USAID
MCHIP

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.

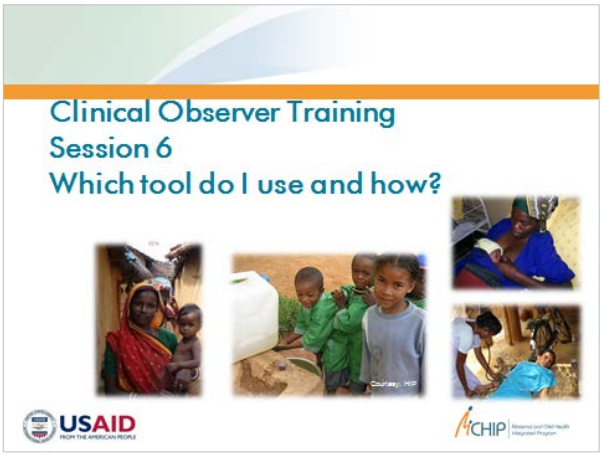
.....	.....	.....	.....
Name of researcher	Signature	Date	Place
.....	.....	.....	.....
Name of witness	Signature	Date	Place

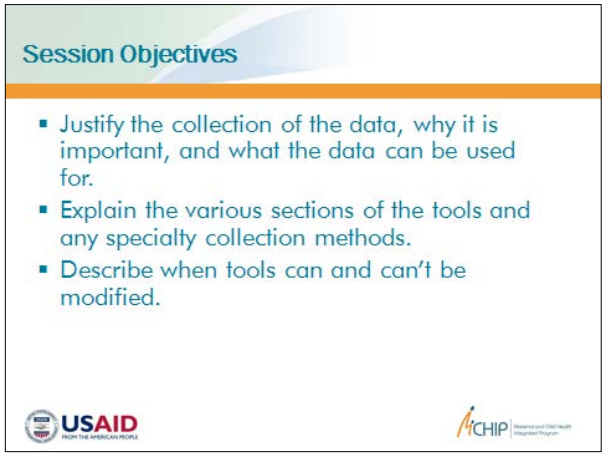
HANDOUT: TOOL REVIEW HOMEWORK

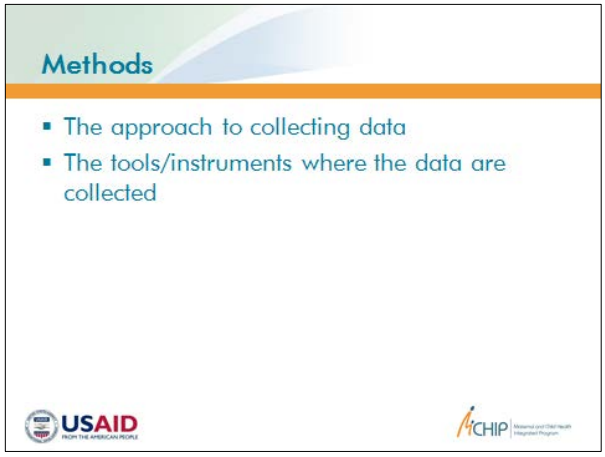
1. Your assignment is to review the different tools that will be used in the specific study.
   - Review specific data-collection tools related to the study.
   - Review every data variable on the data collection tools.
2. During review of variables, you should think about why the data variable is being 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?

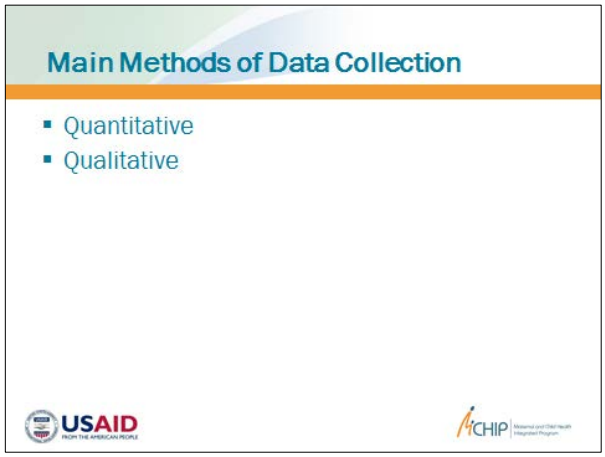
Session 6: Clinical Observer Training: Which tool do I use and how?

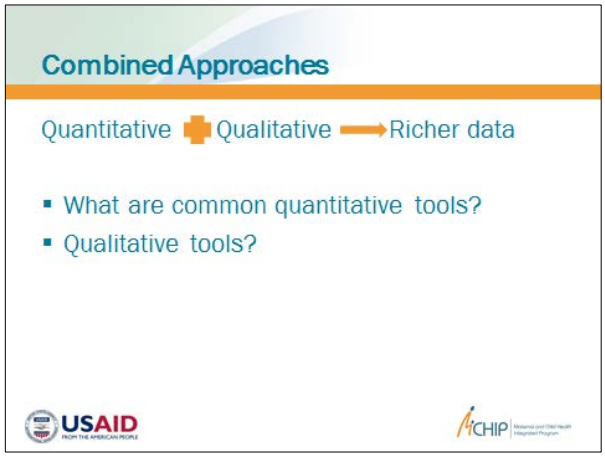
WHICH TOOL DO I USE AND HOW? THUMBNAILS








Main Methods of Data Collection
Quantitative
Qualitative
USAID
4CHIP


Combined Approaches
Quantitative + Qualitative → Richer data
What are common quantitative tools?
Qualitative tools?
USAID
4CHIP


Common Tools
Quantitative Tools:
Sign-in (registration) logs
Checklists
Program activity forms
Logs and tally sheets
Patient charts
Structured questionnaires
Qualitative Tools:
Focus group discussion guides
In-depth interview guide
Semi-structured questionnaires
USAID
4CHIP


What makes a good tool?
Objective
Standardized
Criterion-referenced
USAID
MCHIP


Review of Tools
USAID
MCHIP


Thank you!
wwww.mchip.net
Follow us on:
Blog
USAID
MCHIP

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

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	

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			

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	

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	

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

Session 8: Clinical Observer Training: Time to practice!

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.