## Module 2: Conducting a Delivery Unit Survey

**A Delivery Unit Survey is designed to determine the magnitude of the problem of malaria, specifically:**

- **What is the prevalence of peripheral, placental, and umbilical cord parasitemia in pregnant women?**
- **What is the prevalence of low birth weight and premature delivery?**
- **Is there a relationship between parasitemia and low birth weight or premature delivery?**
- **Does the prevalence of placental parasitemia vary by gravidity or locale?**

**Contents**

This module contains sample materials for a Delivery Unit Survey. These materials can and should be adapted to suit local needs. General guidance for conducting a Delivery Unit Survey and managing data can be found in Chapters 3 and 4 of the manual.

**Consult Resource 3 for presentations that address some of the topics below**.

A. Delivery Unit Survey Timetable
B. Selecting Sample Sizes
C. Eligibility Criteria
D. List of Supplies and Equipment
E. Assessment Teams
F. Assessment Team Training (Resource 3)
G. Supervisor's Check List for Assessment Start-Up
H. Supervisor's Guide to Conducting Antenatal Clinic and Delivery Unit Surveys
I. Supervisor's Guide to Data Management for Antenatal Clinic and Delivery Unit Surveys
J. Sample Logbooks: Enrollment and Laboratory
K. Handbook for Assessment Teams
L. Guide for Night-time Admissions to the Delivery Unit
M. Ballard Score Sheet for Determining Gestational Age (see also Resource 3)
N. Blood Test Procedures: Making Thick and Thin Films for the Microscopic Detection of Malaria Infection
O. Taking Blood Samples from a Finger, Placenta, and Umbilical Cord
P. Making a Placental Impression Smear
Q. Information Sheet
R. Analysis of Delivery Unit Survey Data

## A. Delivery Unit Survey Timetable

**The timetable below outlines key steps in planning for and conducting Delivery Unit (and antenatal clinic) survey activities and the approximate length of time to allow for these steps. Note that this timetable is the same as that for the ANC survey and that these preparations and activities should be undertaken simultaneously.**

| Period | Time | Activities |
|---|---|---|
| Planning the assessment | 2-4 weeks | • Determine what assessment components, if any, need to be conducted<br>• Determine what approvals (ethical, scientific, other ministerial) are needed and initiate approval process |
| Preassessment | 2-3 weeks | • Select site(s)<br>• Explain the assessment to the community<br>• Procure assessment equipment and supplies<br>• Hire assessment team and/or identify existing staff<br>• Adapt and translate questionnaires<br>• Pretest questionnaires<br>• Identify site for training<br>• Identify responsible persons for all presentations (See Resource 3 for sample presentations)<br>• Manage logistics of training, including per diem, transportation, meals, and lodging<br>• Arrange for on-site training in DUs and in ANCs |
| Assessment training | 1 week | • Conduct training course<br>• Finalize questionnaires based on pretest and make adequate copies for final day of training<br>• Meet with supervisors to coordinate assessment start-up in clinical facilities |
| Start-up of assessment | 2 weeks | • Make adequate copies of ANC and Delivery Unit questionnaires, enrollment logbooks, and laboratory logbooks, and ensure questionnaires are at assessment sites<br>• Distribute supplies to each assessment site and ensure a system of re-stocking supplies is in place<br>• Establish quality control mechanism for data collection, including clinical and laboratory procedures, transport, and storage<br>• Establish a supervisory system that addresses logistics (staffing, supplies), quality of interviewing, quality of questionnaires, quality of obtaining specimens, laboratory quality (slide and staining, Hemocue calibration), logbook maintenance |
| Assessment | 8-9 weeks | • Enroll women and collect data<br>• Ensure supervisory system and quality control mechanisms are functioning<br>• Ensure adequate supplies and equipment are available and functioning at each assessment site |
| Postassessment | 8 weeks | • Conduct data entry, cleaning, and analysis<br>• Write final report<br>• Disseminate results<br>• Initiate policy discussions |

## B. Selecting Sample Sizes

**The sample size needed for the Delivery Unit Survey depends on**

1) **the estimated prevalence of women with placental parasitemia and of LBW babies,**
2) **the acceptable margin of error, and**
3) **the design effect**

The sample size required to measure each of the survey's main indicators (placental parasitemia and low-birth-weight babies) can be calculated by using Statcalc in EPI-INFO. The EPI-INFO calculation should include an adjustment (i.e., design effect [see note at end of this section, Selecting Sample Sizes]) for the fact that the survey uses cluster sampling, rather than random sampling.

If the sample size required to measure one indicator is larger than the sample size required for the other indicator, the larger of the two sample sizes should be selected. The sample size may need to be modified to account for other factors (see example below).

Determination of the sample size for the Delivery Unit Survey begins with

1. Point estimates of the proportion of women with placental parasitemia and the proportion of babies with LBW

2. The level of accuracy desired, for example $\pm$ 10%, and

3. The design effect

**Delivery Unit Survey Sample Size Calculation: An Example**

Point estimates: The prevalence of placental parasitemia during high transmission season among women of all gravidities is estimated at 35%, and the prevalence of LBW is estimated to be 14%.

Level of accuracy: The assessment coordinator determines that it is acceptable if the survey can estimate the prevalence of placental parasitemia within 10% (that is, the prevalence of parasitemia could be between 25% and 45%) and the prevalence of low birth weight within 5% [that is, low birth weight could be between 9% and 19%].

These numbers are then entered in Statcalc, with a design effect=2 (to correct for the fact that this is not a random community sample) for each indicator. The design effect of 2 is chosen on the basis of previous similar studies. EPI-INFO then calculates sample sizes: 174 for placental parasitemia and 370 for LBW. The larger of these two is 370, and thus this is the sample size for the Delivery Unit Survey.

| | Estimated prevalence | Margin of error | Needed sample size (from Statcalc) | Other factors | **Sample size (after adjusting for other factors)** |
|---|---|---|---|---|---|
| Placental parasitemia during high transmission season | 35% | 10% | 174 | --- | 174 |
| LBW | 14% | 5% | 370 | --- | 370 |
| **Total delivery unit** | | | | | **370** |

Note: If the prevalence of placental parasitemia during high transmission season is unknown, assume a level of 50% for calculating sample size. This level is the most conservative estimate, as it yields the largest required sample size. If the prevalence of LBW is unknown, countries could use the following estimates from UNICEF and WHO to calculate sample sizes: East Africa, 13.5%; Middle Africa, 12.3%; Southern Africa, 14.6%; and Western Africa, 15.4%.

Note: If the assessment is being used as a baseline that will be repeated after an intervention in order to demonstrate impact, the sample required will be larger and the sample size calculations more complex. It is advisable to consult a statistician for further guidance.

**Note on design effect:**

Large surveys are often conducted using cluster surveys, meaning that the population is divided into clusters and sampled accordingly. Clusters are selected by random sampling and then random samples are taken within the selected clusters. The benefits of cluster sampling are that it is often easier and less expensive to conduct than simple random sampling as the needed sample size is smaller. However, its disadvantage is that there is a loss of precision because the elements within the cluster are generally more correlated (similar) than those between the clusters. Selecting an additional member from the same cluster adds less new information than would a completely independent selection. As the cluster size and intracluster correlation increase, cluster variances increase more than one would find in a simple random sample. The benefits of cluster sampling often outweigh the disadvantage of the loss in precision.

Because cluster sampling results in a loss of precision and a smaller sample size, an adjustment called the design effect should be used to determine survey sample size when clustering is involved. The design effect is basically the ratio of the actual variance[1], under the sampling method actually used, to the variance computed under the assumption of simple random sampling. The main components of the design effect are the intraclass correlation and the cluster sample sizes. The design effect is calculated as follows:

$$DEFF = 1 + \rho\,(n - 1),$$

where *Deff* is the design effect, $\rho$ is the intraclass correlation for the statistic in question, and *n* is the average size of the cluster. The interpretation of a value of *DEFF* of, say, 3.0 is that the sample variance is 3 times bigger than it would be if the survey were based on the same sample size but selected randomly. It can be seen that the design effect increases as the cluster sizes increase, and as the intraclass correlation increases. The square root of the design effect shows how much the sample standard error, and consequently the confidence

1 Variation measured in a set of data for one variable, defined as the sum of squares of the deviation of each data point from the mean for the data, divided by the degrees of freedom (sample observation – 1).

intervals, will increase because of the clustering. The intraclass correlation represents the likelihood that two elements in the same cluster have the same value, for a given statistic, relative to two elements chosen completely at random in the population. A value of 0.10 is interpreted, therefore, to mean that the elements in the cluster are about 10% more likely to have the same value than if the two elements were chosen at random in the survey.

Design effects vary from survey to survey and even within the same survey will vary from question to question. In summary, using a cluster sample generally requires either a larger sample size than a simple random sample or a wider confidence interval. The design effect is used to determine how much larger the sample size or confidence interval needs to be. In general, for a well-designed study, the design effect usually ranges from 1 to 3. It is not uncommon, however, for the design effect to be much larger.

The survey methodology recommended for both the antenatal clinic surveys and the Delivery Unit Surveys use cluster sample methodology and thus require that a design effect be used.

### C. Eligibility Criteria

**All women who are delivering babies should be asked to participate in the survey.**

**Women are eligible for the survey if they meet the following requirements:**

**Gravidity:** All gravidities. Although primigravidae and secundigravidae are the groups typically most affected in high transmission areas, women of **all** gravidities should be eligible so that the burden of malaria during pregnancy can be estimated for all pregnant women.

**Age:** The youngest age at which women are eligible to participate should be the age at which most women in the assessment area have their first child. This is to ensure that primigravidae and secundigravidae (the groups at highest risk) are included in the assessment. The usual minimum age is 15 years. The age of the youngest participants may well be less than the age of majority and should be consistent with any country policy or norm regarding this type of survey.

**Notes:** Women who participated in the ANC survey <u>are</u> eligible to also participate in the Delivery Unit Survey, but should not be selected for the Client Exit Interview.

**D. List of Supplies and Equipment**

**Make sure that each delivery unit has the necessary supplies and equipment before the start of the survey.**

| Item | Quantity | Comments/Use | # in stock/ Balance needed | Date Ordered |
|---|---|---|---|---|
| | | | | |
| ***Screening & Clinical Evaluation*** | | | | |
| Electronic thermometers | 2 | Temperature collection; if electronic thermometers are unavailable, mercury glass thermometers are an acceptable alternative. | | |
| Baby scale | 1 | Ideally, an electronic digital scale. A well-calibrated balance scale is also acceptable. | | |
| Tape measure | 1 | Mother's mid-upper arm circumference. | | |
| Height stick | 1 | Can make height measuring area on wall of DU. | | |
| | | | | |
| ***Laboratory*** | | | | |
| Count-down timer | 1 | For laboratory use. | | |
| Slides | 3/participant | Allow extras for waste | | |
| Lancets | 2/participant | Allow extras for waste; 1 for peripheral blood film and 1 to pierce the umbilical cord. | | |
| Isopropyl alcohol | Enough to clean 1 finger/ participant | Premoistened alcohol wipes are an acceptable alternative. | | |
| Cotton wool or gauze | Enough to clean 1 finger/ participant | Gauze is preferable to wool as it leaves fewer fibers on the placenta and therefore on the slide. | | |
| Giemsa stain | | Based upon sample size. In addition to Giemsa powder, need all other materials to mix stain, including distilled water, buffer, glycerol, and glassware to mix and store. | | |
| Toilet paper (or slide boxes) | Sufficient to wrap (or store) all slides from assessment | | | |
| Container for used lancets | 1 | Sharps container | | |
| Staining jars | 2/lab | | | |
| Slide drying rack | 1/lab | | | |
| Hair dryer | 1/lab | May be needed, depending on climate. Optional. | | |
| Microscope | 1/lab | | | |
| Surgical scissors | 6 pairs/site | | | |

| | | | | |
|---|---|---|---|---|
| Forceps | 6/site | | | |
| Wooden applicator sticks or plastic transfer pipettes | 1/participant | To transfer placental blood to slide | | |
| Spare light bulbs for microscope | 1/lab | | | |
| Immersion oil | 3 tubes/lab | | | |
| Lens cleaner | | | | |
| Lens cleaning tissue | | | | |
| Sharpie markers (ultra fine) | | | | |
| Examination gloves | 3 pairs/ participant | Need 1 pair for peripheral film and 2 pairs for placental sampling. Need extra for laboratory and extra for breakage | | |
| Tally counters | 2/laboratory | | | |
| Computer (with at least Windows 2000) | 1-2 | 2 is ideal, 1 is adequate | | |
| Epi-Info or another statistical software package (Epi Info is preferred) | 1-2 | Installed on each computer | | |
| | | | | |
| Goggles | 2 pairs/site | For use when handling placenta to prevent splashes to eyes. | | |
| Tray | 1/site | | | |
| Tissue paper | | | | |
| Filter paper | | | | |
| Bleach | | | | |
| Beaker and basin | 1/site | | | |
| ***Office Supplies*** | | | | |
| AA batteries | | If using digital baby scale. | | |
| Clipboards | 1/interviewer | | | |
| Pencils | 1/interviewer | Only if preparing thin films. | | |
| Pencil sharpener | 1/interviewer | Only if preparing thin films. | | |
| Pens | 2/interviewer | | | |
| Stapler | 1 | | | |
| Staples | 2 boxes | | | |
| Ink pad/Ink | 1/site | For fingerprinting women if signature needed and woman cannot sign. Should be bound books, not spiral-bound or perforated. | | |
| Logbooks | 1/site and 1/lab | | | |

## E. Assessment Teams

**The number of assessment teams depends on the number of delivery units used.**

The following example assumes that 4 delivery units will be used.

| Title | Number needed |
|---|---|
| | |
| Assessment coordinator | 1 |
| Laboratorian supervisor | 1 |
| Site supervisors | 4 (1 per site) |
| Interviewers | 8 (2 per site) |
| Laboratorians | 4 (1 per site) |
| Data management coordinator | 1 |
| Data entry clerks | 2 |

*Note:* At least one assessment team member should be available 24 hours per day to enroll all women who are delivering and promptly process placentas. If this is not possible, a cooler and icepacks should be available in order to store placentas.

## F. Assessment Team Training

**The training for site supervisors, interviewers, and laboratorians should be held after preassessment activities. Training will take approximately 4-5 days.**

**Below is a detailed explanation of how to conduct the training. A sample schedule follows the explanation.**

**Note: If both antenatal clinic (ANC) and Delivery Unit (DU) surveys will be conducted, it is more efficient to conduct training for both surveys simultaneously. Therefore, this module describes simultaneous training. If only one of the surveys is conducted, this module will need to be modified accordingly.**

**Note: If qualitative studies will be conducted about the same time as the quantitative studies, it would be beneficial to conduct the training simultaneously. Consult the qualitative training manual (or the modules that accompany the qualitative surveys) for guidance on how to combine the two.**

**Day 1:**
Morning: The assessment coordinator should present background information on malaria during pregnancy and assessment objectives. (*See Resource 3 for sample presentations)*

Afternoon: The assessment coordinator reviews ANC policies and procedures located in the assessment team member's handbook *(see K in this Module)*. This provides a general overview of the assessment. Once the overview is complete, the assessment coordinator should split the interviewers into teams. Each team will rotate through ANC and delivery unit clinical procedures. Depending on the size of the assessment team, the logistics can be varied. In a small team, everyone might work together to go through all procedures. In a large team with a sufficient number of facilitators, it may be worthwhile to divide teams into groups that rotate around a series of workstations. The important thing is that each staff member have the opportunity to learn and practice each procedure that he/she will be conducting.

ANC procedures include: [2]

- Exercise universal precaution for handling blood
- Take and read axillary temperature
- Collect blood samples (fingersticks) from each other
- Prepare slide (recording date and ID number on slide)
- Prepare thick films (and thin films in an area with substantial *P. vivax* transmission)
- Prepare Hemocue cuvette for hemoglobin reading; or Measure Hb or Hct by methods used in that clinic

Delivery unit procedures include:

- Measure women's mid-upper arm circumference
- Measure woman's height
- Prepare slides—peripheral, placental, and cord blood
- Weigh newborn using scale
- Conduct the Ballard examination and apply the scoring system (See Resource 3 for Ballard video)

**Day 2:**
Morning: The assessment coordinator arranges for interviewers to visit a delivery unit site for practice of delivery unit procedures. At the same time, the laboratorian supervisor trains assessment laboratorians on how to read peripheral, placental and cord films. *(See N and O in this module)*

Afternoon: In a group setting, the assessment coordinator reviews each question on ANC and delivery unit questionnaires and the information sheet (or consent form), depending on which is being used. The coordinator also describes why there is a consent form if a consent form has been determined necessary. Interviewers should be encouraged to ask questions and offer suggestions. After reviewing each questionnaire, the interviewers should break into small groups and practice each questionnaire one-on-one using copies of actual ANC cards from the clinic. Any discrepancies regarding data extraction from ANC cards should be addressed with the assessment coordinator, and questionnaires revised as necessary.

**Day 3:**
Morning: After the survey instruments are adapted, the survey instruments, as well as the information sheet (or informed consent form if used), should be translated into the national language and the primary language spoken by women in the assessment area, if different. This initial translation should be followed by a back-translation (by individuals who did not produce the original translation) into the national language to check the adequacy of the translation. Once the translation is complete, pretesting can begin. While the surveys are being pretested, laboratorians could practice film reading.

Note: If the primary language is not a written language, it will be important to use correct, consistent phrasing of survey questions and information on the information sheet (or informed consent form) so that questions are asked in a standardized manner. All interviewers should work together to achieve correct, consistent phrasing of the questions and have the opportunity to practice.

Afternoon: The assessment coordinator arranges for interviewers to visit two ANC sites to practice the ANC questionnaire with clients. NOTE: Since the delivery unit questionnaire is very similar to the ANC questionnaire, it is not necessary to pretest the delivery unit questionnaire due to ethical considerations related to practicing interviewing women in labor without their being enrolled in the assessment.

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2 In some circumstances it may be possible to conduct polymerase chain reaction (PCR) on filter paper samples or to examine tissue specimens preserved in formalin. However, in many settings these are neither possible nor necessary.

Divide the interviewers into two teams. Each team should visit one of the selected sites to pretest the ANC questionnaires with at least 15 clients (total, not per interviewer) in each facility.

**Day 4:**
Morning: The assessment coordinator will explain the purpose of ANC and delivery unit enrollment and laboratory logbooks. Then, the coordinator should demonstrate and review these logbooks. Many people may not understand that the logbooks are used to record everyone who is enrolled in the assessment as well as those who are excluded for any reason. The interviewers should be divided into pairs to practice the revised questionnaires. The rest of the morning should be used to resolve outstanding issues, and conclude the training.

**Day 5:**
If training is scheduled for 5 days, Day 5 can be reserved for work on any remaining issues.

**Sample Training Schedule**

| | **Day 1** | **Day 2** | **Day 3** | **Day 4** |
|---|---|---|---|---|
| | *Introduction/ Overview* | *Delivery Unit Clinical Procedures* | *Pretest questionnaires* | *Wrap-up* |
| Morning | -Welcome<br>-Training objectives<br>-Malaria situation in country<br>-Epidemiology of malaria during pregnancy<br>-Rapid assessment objectives<br><br>*See Resource 3 for sample presentations.* | Microscopy training for laboratorians<br><br>On site delivery unit clinical procedures training and practice for interviewers | Practice questionnaires and consent form administration in local language(s) with translator<br><br>Practice questionnaires and consent form administration in local language(s) in small groups | Introduce enrollment and laboratory registers<br><br>Practice questionnaires in pairs (using ANC cards and ANC and delivery unit registers).<br><br>Conclusion of training |
| Afternoon | Policy and procedures in ANC and delivery unit (worker's handbook)<br><br>Practice clinical procedures for ANC and delivery unit (video of Ballard) if available. Use live demonstrations using an adult model before practicing on live newborns. | Review ANC and delivery unit questionnaires and consent forms<br><br>Practice questionnaires in pairs (using ANC cards). Resolve discrepancies regarding data extraction from ANC cards. | Pretest questionnaires on site in ANC facilities | Meet with supervisors to discuss assessment start-up:<br>-Make copies of ANC and delivery unit questionnaires<br>-Ensure ANC and delivery unit log books are at each assessment site<br>-Distribute supplies to each assessment site<br>-Establish quality control mechanism<br>-Establish a supervisory system |
| Evening | Read questionnaires and consent forms | | Assessment coordinator finalizes ANC and delivery unit questionnaires based on pretests. | |

## G. Supervisor's Check List for Assessment Start-Up

**The following contains worksheets to assist the supervisor during the start-up phase of the assessment. These sheets pertain to both Antenatal Clinic and Delivery Unit Surveys, as most likely both will be conducted. If only one of the surveys is conducted, the list will need to be modified accordingly.**

Explain the purpose of the assessment to the "community," through direct communication where possible, and also through the display of malaria posters in the clinic, and any other communication means.

Set up the supply management system:
- Verify that all supplies on the list are available.
- Provide the delivery unit, antenatal clinic unit, and the lab each with a set of supplies (papers, laboratory materials, examination materials, antimalarial drugs and hematinics) to last at least one week.
- If supply shortages (batteries, slides, etc.) are noticed, find a solution to continue the assessment uninterrupted.
- Keep spare supplies in a safe place, preferably a locked cupboard or box.
- Keep the record of available stocks.

Have planning meeting with the assessment team:
- Make sure every person understands what is expected of him/her.
- Draw up a time and duty schedule for each team member, aiming for 8 hrs/day antenatal clinic presence, and 24 hrs/day delivery room presence.
- Rehearse every team member's interviewer number, and go over the patient number system once more.
  Also:
  - Instruct the night staff of the delivery room to routinely store ALL placentas for the assessment in individually marked plastic bags in the ice box if no assessment team member happens to be present
  - Assign responsibility for the ice box and for replacing the ice packs to an assessment team member
  - Arrange additional laboratory support, if needed
  - Identify possible translators for local languages among the hospital staff. Where possible, make them familiar with the questionnaire beforehand.

Set up instruments:
- Set up measuring tape, scales and Ballard chart in the delivery room
- Set up Hemocue instructions in the antenatal clinic room, if using Hemocue. Set up the Hemocue and calibrate. Recalibrate daily.
- Find a safe and stable place for the infant weighing scale. Make sure that it is never lifted by the cradle, as this will damage it.
- Keep instrument instructions in a safe place for future reference.

Set up data management system:
- Provide staff with enough information sheets (or consent forms, if used) and questionnaires for at least one week.
- Make the arrangements for daily review of assessment results by the supervisor together with the antenatal clinic and delivery unit staff.
- Make arrangements for daily storing of papers and slides (and filter papers and test tubes, if being used).
- Make arrangements for weekly storing of papers and slides (and filter papers and test tubes, if being used).
- Go through the data management system with the team members.
-

Set up assessment logs:
- Antenatal clinic logbook, delivery unit logbook, laboratory logbooks (one for malaria, one for anemia)

## H. Supervisor's Guide to Conducting Antenatal Clinic and Delivery Unit Surveys

**The following guide contains worksheets to assist the supervisor in noting the progress of the survey, reminding the supervisor of important tasks (e.g., calibrating the Hemocue machine daily), and guiding the supervisor in reviewing questionnaires.**

**These worksheets should be filled out on a regular basis, as determined by the supervisor.**

**Note: The worksheets pertain to both Antenatal Clinic and Delivery Unit Surveys, as most likely both will be conducted. If only one of the surveys is conducted, the forms can be modified accordingly.**

Site: _____

Date: ___ ___ / ___ ___ / ___ ___

### 1. Enrollment and rates of positivity

Antenatal clinic enrolled to date (No): _____ Number positive: _____

Last antenatal clinic ID number used: ___ ___ - ___ ___ ___

Delivery enrolled to date (No):_____ Number positive (Maternal): _____

Number positive (Placental): _____ Number positive (Cord): _____

Last delivery ID number used: ___ ___ - ___ ___ ___

### 2. Staff, supplies and samples

Have any staff left the assessment?

Are all nights on the delivery unit being covered by the assessment team? _____

If this is not possible, are sufficient coolers (with icepacks) available for placental storage?
_____

Using the supply list above, note if supplies are adequate.
**YES =1 NO = 2**

Any other missing supplies: _____

If any supplies are needed, what is the plan for restocking? _____

_____

Are questionnaires and samples well organized and in a safe place?

If not, plan to improve situation: _____

_____

Samples and questionnaires taken to central location:

**ANC:**

Questionnaire numbers ___ ___ - ___ ___ ___ to ___ ___ - ___ ___ ___

Slide numbers: ___ ___ - ___ ___ ___ to ___ ___ - ___ ___ ___

**Delivery**

Questionnaire numbers ___ ___ - ___ ___ ___ to ___ ___ - ___ ___ ___

Slide numbers (M,P,C): ___ ___ - ___ ___ ___ to ___ ___ - ___ ___ ___

Tissue sample numbers, if collected: ___ ___ - ___ ___ ___ to ___ ___ - ___ ___ ___

Filter paper numbers (M,P), if collected: ___ ___ - ___ ___ ___ to ___ ___ - ___ ___ ___

**3. Antenatal Care**

Is the Hemocue machine being calibrated daily? _____

Check calibration today: _____

Examine the logbooks. Are they being filled out correctly? _____
(Note: Enrollment logbooks should contain all patients, whether or not enrolled in assessment]

Note any problems with logbooks: _____

_____

What is the plan to correct any problems with logbooks? _____

_____

What is the average enrollment per day? (look at last 10 days): _____

If it is too high or too low, examine reasons, and make a plan for correction:
_____

_____

Are enrollments evenly spaced throughout the day (i.e., not all in the a.m. or p.m.)?
_____
_____

Examine at least 5 questionnaires per assessment team member. Note any problems, and discuss with that person. Pay particular attention to whether hemoglobin, temperature, and blood smear results are completed.

Note any important problems and what measures were taken to fix them:

_____
_____

_____
_____

Are women with anemia receiving iron or iron/folate? _____

If not, why not?
_____

Are women with positive blood smears receiving treatment for malaria?_____

If not, why not?
_____

If consent forms are used, examine. Have women signed them in accordance with assessment/country policy? Is the name of a contact person for questions written in as instructed?
_____

**4. Delivery Unit**

Examine logbooks. Are they being filled out correctly? _____
(Note: Enrollment logbook should contain all deliveries, whether or not enrolled in assessment)

Note any problems with logbook: _____

_____

What is the plan to correct any problems with the logbook: _____

_____

What is the average enrollment per day? (look at last 10 days): _____

If it seems very low, examine reasons, and make a plan for correction:
_____

_____
Examine at least 5 questionnaires per assessment team member. Note any problems, and discuss with that person. Pay particular attention to ensure that the following are completed: height, arm circumference, baby weight, Ballard gestational age, blood smear results and treatment.

Note any specific problems and what measures were taken to fix them:
_____

_____

Is the baby's sex being documented on the Delivery Unit questionnaire ?_____

Are women with positive blood smears receiving treatment for malaria?_____

If not, why not?
_____

If consent forms are used, examine. Have women signed them in accordance with assessment/country policy? Is the name of a contact person for questions written in as instructed?
_____

Are sample sets complete for each delivery patient (that is, do they contain a questionnaire, 3 slides (M, P, C), and, if collected, 2 filter papers (M, P), and a tissue sample? _____

If not, why not?
_____

**5. Laboratory**

Examine the results books. Are the books being completed correctly? _____

If problems are found, document here, and make a plan for correction: _____
_____

Are the results for mothers from antenatal clinic with fever, and mothers and babies from delivery, being given promptly to assessment team? _____

If not, what steps can be taken to improve the speed of obtaining results? _____

_____

Reread 10% of the slides of each type (ANC, Delivery M, Delivery P, Delivery C).

Rate the accuracy of slides:
Thick: (1 to 5, 5 is highly accurate):_____

Thin: (1 to 5, 5 is highly accurate): _____

If quality is poor, examine reasons (e.g., smears badly done, thick specimen is fixed, or stain coloration is bad), and try to find a solution to the problem: _____

_____

Are slides being stored in a good manner (in slide boxes or, if slide boxes cannot be obtained, rolled in tissue paper)?: _____

If not, plan for correction: _____

Does the laboratory have adequate supplies? _____

If not, plan to correct the problem: _____

_____

**7. Data Entry**

Review at least 5 questionnaires that have been entered in the computer.

Number of errors found in 5 ANC: _____

Number of errors found in 5 Delivery: _____

Is the record number being written at the top of each questionnaire on each page? _____

**Other comments, observations or problems not mentioned above_____**
_____
_____
_____

## I. Supervisor's Guide to Data Management for Antenatal Clinic and Delivery Unit Surveys

**The following guide contains worksheets to assist the supervisor in managing and collecting data. Worksheets outline tasks for assessment team members, as well as the supervisor.**

**Note: The worksheets pertain to both Antenatal Clinic and Delivery Unit Surveys, as most likely both will be conducted. If only one of the surveys is conducted, the forms will need to be modified accordingly.**

**Enrollment targets:**

- ***List for each site:***

Desired # of antenatal clinic visits: at least x/day
Desired # of deliveries: at least x/day

**Target data collection period:**

- ANC List months during which to collect these data
- Deliveries List months during which to collect these data

**Assigning an ID number:**

***1st digit:* assessment site**

| | |
|---|---|
| Site #1 | 1 |
| Site #2 | 2 |
| Site #3 | 3 |
| Site #4 | 4 |

***2nd digit*: type of health service**

| | |
|---|---|
| ANC | A |
| Delivery | D |

***3rd – 5th digit*: consecutive number identifying each patient**

Example: 35th antenatal clinic woman in Site#3 = 3A – 035
46th delivery in Site#1 = 1D – 046

Note: If the woman has been assigned an ID number but enrollment has to be abandoned for whatever reason, file all related papers and test results, and assign the next woman the next number. ID numbers should only be used once. All ID numbers should be accounted for at the final data analysis.

- All data must be entered in computer
- All data items must be returned to designated location for re-entering into computer (for double data entry) and quality control of slide readings

**Mark ID NUMBERS on each item and each page!!**

**Assigning an interviewer number:**

The supervisor should assign each interviewer a unique number to be used throughout assessment.

**For example:**

| | |
|---|---|
| Site #1 | 01 – 20 |
| Site #2 | 21 – 40 |
| Site #3 | 41 – 60 |
| Site #4 | 61 – 80 |

**Hints to provide interviewers for filling out questionnaires:**

- Keep all pages of the consent forms (if used) and of the questionnaires stapled together
- Number all pages immediately with the ID number
- Write clearly
- …….. is a connecting line
- _____ is a line to write on
- Feel free to make notes in the margin of the questionnaire form if the answer you got was not very clear or if you have doubts. The more information the better.
- If it states "check all that apply," please do not enter dashes for negative. Just leave those spaces blank. Otherwise it may confuse the data entry.
- Make sure to get the right information in the right places: Some information comes from asking the woman, some from the antenatal clinic card, and some from the examination done for the assessment.

**Completed consent forms (if used), questionnaires, slides, filter papers (if used), placenta tubes (if used), and logbooks should be guarded very carefully: Any missing or mislabeled items will compromise the final interpretation of the assessment.**

## Antenatal Clinic Survey

**Each antenatal clinic enrollment will have at least 2 loose pieces of information**

- Signed consent form, if used
- Completed questionnaire (…pages)
- 1 blood slide (thick and thin)

**Data management tasks of antenatal clinic staff:**

*Each enrollment:*

- Mark patient number clearly on each item and each page
- Mark patient number clearly on blood slide result from the lab

*Before woman leaves:*

- Verify that questionnaire is completed, and iron/folate given as indicated

- If woman is febrile or had a fever recently: Ensure that lab results are returned as soon as possible and treat the woman with appropriate antimalarial drug as per national policy before she leaves the clinic that day (Monica has a question here) if the slide was positive

*During the day:*

- Obtain lab results from all other women and if any were positive, prepare for treatment when the woman returns that afternoon or the next day

**Data management tasks of supervisor:**

*At the end of each day:*

- Keep antenatal clinic log of enrollment and refusals up to date
- Collect and review for completeness all data items
- File all forms together each day

*Each week:*

- Store all papers chronologically by assessment number
- Store all slides chronologically by assessment number
- Mark patient number range on each set of items, e.g.: 41.001 – 41.035
- Put all items aside in a safe place

**<u>Delivery Unit Survey</u>**

**Each delivery will have at least 4 and as many as 8 loose pieces of information**

- Signed consent form, if used
- completed questionnaire (…pages)
- 3 blood slides:
  - **M**other (thick and thin)
  - **P**lacenta (thick and thin)
  - **C**ord (thick and thin)
- 2 filter papers:, if used:
  - **M**other
  - **P**lacenta
- Placenta tissue in tube, if used:

**Data management tasks of delivery unit staff:**

*Each enrollment:*

- Mark patient number clearly on each item and each page
- Mark **M** or **P** or **C** clearly on blood slides and filter papers, if used
- Mark patient number + **M** or **P** or **C** in the laboratory logbook

*Before woman leaves:*

- Verify that questionnaire is completed
- Verify that **M** and **C** slide results are back from laboratory, and treat her if positive

**Data management tasks of supervisor:**

*At the end of each day:*

- Keep delivery log of enrollment and refusals up to date

- Collect and review all data items for completeness
- File all forms together each day

*Each week:*

- Store all papers chronologically by assessment number
- Store all slides chronologically by assessment number
- Mark patient number range on each set of items, e.g.: 41.001 – 41.035
- Put all items aside in a safe place

## J. Sample Logbooks: Enrollment and Laboratory

- **Enrollment logbook: Records a list, by facility, of the pregnant women visiting the site each day of the survey, her survey number, and whether or not she was enrolled (and if not, why not).**
- **Laboratory logbooks: One records information about enrolled women's malaria blood films, and the other records information about enrolled women's hemoglobin or hematocrit, by facility.**

During the assessment start-up, the *assessment coordinator* is responsible for ensuring that each site has prepared enrollment and laboratory logbooks. During the assessment, *site supervisors* are responsible for monitoring the use of the logbooks and preparing additional books as necessary.

**Malaria During Pregnancy Rapid Assessment - Enrollment Delivery Unit Logbook**
**Facility: _____**
**District/Region: _____**

| Date | Woman's DU number | Name of Woman | Age | G/P* | Mother tongue | Enrolled? Yes/No | Woman's ID number | Comments** |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |

*Gravidity/parity

**It may be helpful to make a list of reasons for nonenrollment, along with a code number for each reason, and place it on the face page of the logbook. For example, if the first reason on the list was "woman refused to participate" and the code for that reason was "1," "1" could be written in the comments column above.

**Malaria During Pregnancy Rapid Assessment – Laboratory Delivery Unit Logbook for Malaria**
**Facility: _____**
**District/Region: _____**

| Date | Woman's ID number | Blood smear +/- | Species* | Density (only for maternal sample) | Pigment | Comments |
|---|---|---|---|---|---|---|
| | | Maternal:<br>Placenta:<br>Cord: | | | | |
| | | M:<br>P:<br>C: | | | | |

*Some settings may need a column for malaria species.

## K. Handbook for Assessment Teams

**Each member of the assessment team should receive a handbook during assessment training.**

**The handbook briefly describes the enrollment procedure and postenrollment activities, including the questionnaire, measurements and laboratory specimens, medications, and follow-up activities.**

**Note: The team member's handbook has space for including the number of women to be enrolled each day.**

**Throughout woman's stay at delivery unit: Follow normal procedures to ensure safety of mother and baby. Ensure proper medical care.**

**Ensure that either an interviewer is available 24 hours/day in the delivery unit to enroll all women and process placentas OR that an ice pack and cooler is available for storage and the interviewer arriving in the morning can retrospectively enroll women who arrived during the night.**

| ***Procedures*** | ***Comments*** |
|---|---|
| **Enrollment** | |
| 1. Identify eligible women.<br>• Confirm information with woman<br><br>*Note:* Enroll all women at delivery, even those who may have participated in the ANC survey. | All deliveries<br>Mothers at least 15 years old (or minimum age limit)<br><br>*Note:* Record for **all** women attending delivery unit in the enrollment logbook:<br>Date<br>Woman's delivery unit number<br>Name<br>Age<br>Gravidity/parity<br>Mother tongue<br>Whether or not enrolled<br>Woman's ID number<br>Reasons for no enrollment:<br>• Refused to participate, placenta not available, left delivery unit without being enrolled, less than minimum age. |
| 2. Verify criteria. | Exclusion criteria:<br>• Allergic to antimalarial drugs being used or related drugs<br>• Age <15 years<br>• Refused to participate<br>• Placenta not available<br>• Left delivery unit without being enrolled |
| 3. Read information sheet or obtain informed consent, depending on local requirements for the assessment, as soon as mother is able to talk with interviewer (preferably before delivery) | Assessment explained by interviewer<br><br>Woman agrees to participate and she or witness signs form, if needed. |

| | |
|---|---|
| *Note:* Depending on setting and local ethics requirements, consent may be verbal or written. | |
| **Postenrollment** | |
| **<u>Mother</u>**<br>4. Complete the questionnaire, collecting information on the current pregnancy.<br><br>Note: Peripheral blood samples are taken before and after delivery. Parasitemia often clears quickly after delivery. | • Administer questionnaire.<br>• Mark the thick film slide with the date, woman's enrollment number, and the letter "M" to indicate that slide is mother's peripheral blood film.<br>• Take mother's height and midupper arm circumference |
| **<u>Baby</u>**<br>5. Examine the baby within 24 hours of delivery.<br><br>Note: Nonlive births should be enrolled, if feasible and culturally appropriate. | If live birth:<br>• Determine sex<br>• Weigh (in grams)<br>• Assign a Ballard score (see directions later in this module)<br>• Determine gestation age in weeks<br>• Note any physical abnormalities<br><br>If nonlive birth:<br>• Take placental and umbilical cord samples<br>• Weigh<br>• Record probable cause of death<br><br>Note re: night-time deliveries: Ideally, interviewers will be available 24 hours/day to enroll women who deliver at night and to promptly process placentas. If not, ensure that ice packs and coolers are available for placenta storage. |
| **<u>Placenta</u>**<br>6. Take placenta samples (see directions later in this module) | Mark two separate slides with the following information:<br>• Mark the placental thick film slide with the date, woman's enrollment number, and the letter "P" to indicate that this slide is the mother's placental film.<br>• Mark the umbilical cord thick film slide with the date, woman's enrollment number, and the letter "C" to indicate slide as cord film. |
| 7. Give treatment to the mother if she has a positive peripheral blood film and to the baby if the baby has a positive umbilical cord film. | • Provide treatment according to the country policy. |

- A thin blood film may be required in areas with high prevalence of mixed or pure non—*P. falciparum* species.

## L. Guide for Night-Time Admissions to the Delivery Unit

**Ideally, interviewers will be available 24 hours per day to enroll women who deliver at night and to promptly process placentas, but this is not always possible. Coolers (with ice packs) should be available for storing placentas.**

**The following describes how to handle enrollment and placenta samples for women who are admitted during the night if no interviewer is present.**

*At night if no team member is present:*

- Store all placentas in individual bags in the cooler (outfitted with ice packs). Mark patient name and hospital registration number on the bag.
- Enter patient data in the hospital's delivery ward admissions book.
- Encourage women to stay in the hospital until the assessment team arrives in the morning.

*In the morning on arrival of the assessment team member:*

- Check hospital's delivery ward admissions book for deliveries, copy into assessment log.
- Check placenta box to see if all are there.
- See if mothers and newborns are still on the ward.
- Enroll patients for whom placentas are available. Do questionnaire, obtain **M**other's thick and thin blood smear and examine mother and child. Encourage mother to wait for slide results from the laboratory. Submit **M** slide with priority to the laboratory.
- Once all questionnaires and clinical examinations are done, take the placenta samples. Batch placenta testing together, submit **C** slide with priority to the laboratory.
- Get lab results back and treat mother and newborn if slides were positive.

Note: *Leave the placenta tests for <u>after</u> you have finished with the mother and baby. The placentas will stay in the ice box, but the mother might otherwise leave the hospital ….*

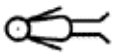
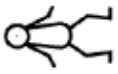
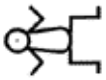
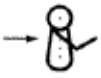
## M. Ballard Score Sheet for Determining Gestational Age

**The Ballard score sheet can be used to determine gestational age.**

**Some researchers have proposed a modification of the Ballard examination in which only the external criteria are evaluated and the neurologic examination is not performed [Verhoeff FH, Milligan P, Brabin BJ, Mlanga S, Nakoma N. 1997. *Gestational age assessment by nurses in a developing country using the Ballard method, external criteria only. Annals of Tropical Paediatrics, 1997.* 17: 333-342]. The resulting score is then doubled to arrive at a total Ballard score with which an estimated gestational age may be correlated. This modification can be useful for stillbirths. While the results from these researchers suggest that the approach compares favorably with other approaches for estimating gestational age, there is less experience with the Ballard external-only method than there is with the standard Ballard examination.**

**Note: If several or many interviewers are working on the rapid assessment in one site, the Ballard score results should be assessed by a smaller subset of interviewers. This would help improve consistency of the results by reducing the possibility of interpersonal differences. In addition, those who are assigned the responsibility of determining gestational age will gain substantial experience. The supervisor should check to make sure that age is being assessed consistently.**

## Neuromuscular Maturity

| Score | −1 | 0 | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|---|---|
| Posture | |  |  |  |  |  | |
| Square window (wrist) |  >90° |  90° |  60° |  45° |  30° |  0° | |
| Arm recoil | |  180° |  140°–180° |  110°–140° |  90°–110° |  <90° | |
| Popliteal angle |  180° |  160° |  140° |  120° |  100° |  90° |  <90° |
| Scarf sign |  |  |  |  |  |  | |
| Heel to ear |  |  |  |  |  |  | |

## Physical Maturity

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Skin | Sticky, friable, transparent | Gelatinous, red, translucent | Smooth, pink; visible veins | Superficial peeling and/or rash; few veins | Cracking, pale areas; rare veins | Parchment, deep cracking; no vessels | Leathery, cracked, wrinkled |
| Lanugo | None | Sparse | Abundant | Thinning | Bald areas | Mostly bald | |
| Plantar surface | Heel-toe 40–50 mm: −1 <40 mm: −2 | >50 mm, no crease | Faint red marks | Anterior transverse crease only | Creases anterior 2/3 | Creases over entire sole | |
| Breast | Imperceptible | Barely perceptible | Flat areola, no bud | Stippled areola, 1–2 mm bud | Raised areola, 3–4 mm bud | Full areola, 5–10 mm bud | |
| Eye/Ear | Lids fused loosely: −1 tightly: −2 | Lids open; pinna flat; stays folded | Slightly curved pinna; soft; slow recoil | Well curved pinna; soft but ready recoil | Formed and firm, instant recoil | Thick cartilage, ear stiff | |
| Genitals (male) | Scrotum flat, smooth | Scrotum empty, faint rugae | Testes in upper canal, rare rugae | Testes descending, few rugae | Testes down, good rugae | Testes pendulous, deep rugae | |
| Genitals (female) | Clitoris prominent, labia flat | Clitoris prominent, small labia minora | Clitoris prominent, enlarging minora | Majora and minora equally prominent | Majora large, minora small | Majora cover clitoris and minora | |

**Maturity Rating**

| Score | Weeks |
|---|---|
| −10 | 20 |
| −5 | 22 |
| 0 | 24 |
| 5 | 26 |
| 10 | 28 |
| 15 | 30 |
| 20 | 32 |
| 25 | 34 |
| 30 | 36 |
| 35 | 38 |
| 40 | 40 |
| 45 | 42 |
| 50 | 44 |

## N. Blood Test Procedures: Making Thick and Thin Films for the Microscopic Diagnosis of Malaria Infection[3]

**The following describes how to make thick and thin films for the determination of malaria infection. If there are a substantial number of non–*Plasmodium falciparum* infections in the area, both thick and thin films should be made. Otherwise, thick films are generally adequate.**

**Note: Rapid tests are available that can detect the presence of malaria parasites in peripheral blood. These tests, although expensive, perform well when conducted by trained personnel. They show decreased sensitivity in persons/settings with low parasite load. There are currently not enough data to recommend the use of rapid tests to detect malaria infection in placental blood.**

Organize the supplies you need:

- lab coat
- gloves
- cotton
- disinfectant swab
- 2 slides (labeled slide & swipe slide)
- lancet
- sharps disposal container
- hospital waste basket
- slide marker

Thick blood films are more sensitive in detecting malaria parasites because the blood is concentrated, allowing a greater volume of blood to be examined. However, thick films are difficult to read. Thick films are stained unfixed after drying.

Thin films should be used if there are a substantial number of non—*P. falciparum* infections in the area, as thin films make it easier to identify species. The thin film should be air-dried, fixed with methanol, and allowed to dry before staining.

For best results, both thick and thin films should be stained with a 3% Giemsa solution (pH of 7.2) for 30--45 minutes. A Wright-Giemsa stain can also indicate malaria parasites but does not demonstrate Schüffner's dots as reliably as Giemsa.

*Plasmodium* parasites are always intracellular, and they demonstrate, if stained correctly, blue cytoplasm with a red chromatin dot. Common errors in reading malaria films are caused by platelets overlying a red blood cell and the misreading of artifacts as parasites.

Thick blood films are more sensitive in detecting malaria parasites because the blood is concentrated, allowing a greater volume of blood to be examined. WHO recommends that at least 100 fields, each containing approximately 20 white blood cells (WBCs), be screened before calling a thick smear negative.

To quantify malaria parasites against WBCs (i.e., determine parasite density) on the thick smear: Tally the parasites against the WBCs, until you have counted 500 parasites or 1,000 WBC, whichever comes first. Express the results as parasites per microliter of blood, using the WBC count if known, or otherwise assuming 8,000 WBCs per microliter blood.

Parasites/microliter blood = (parasites/WBCs) x WBC count per microliter (or 8,000).

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3 We have slightly adapted the following article for this section: Shah S, Filler S, Causer L et al. MMWR. Surveillance Summary. Malaria surveillance --- United States, 2002. April 30, 2004. 53 (SS01); 21-34.

Thin smears are useful for species identification of parasites already detected on thick smears. They are also useful for screening for parasites if adequate thick smear are not available and as a rapid screen while the thick smear is still drying.

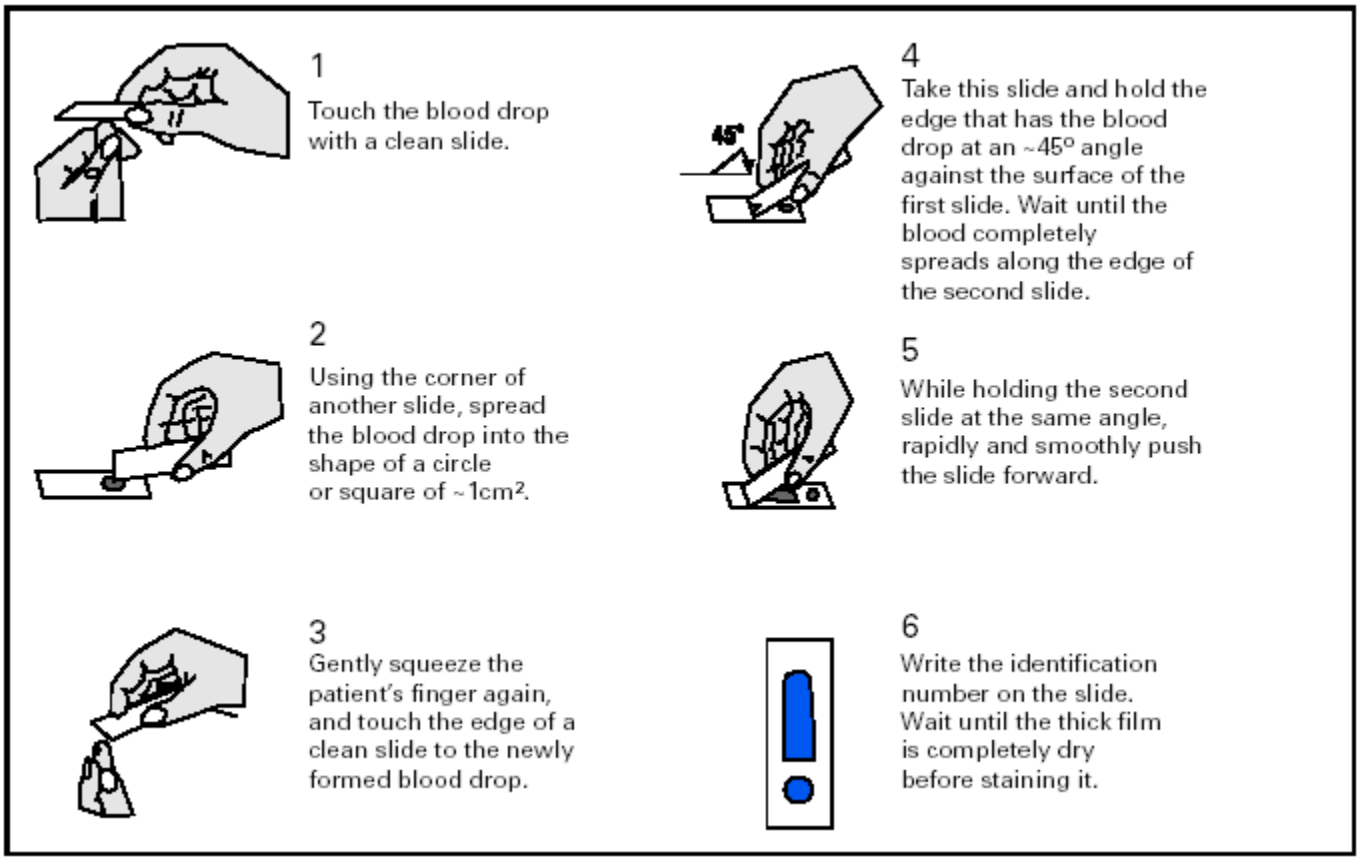
To quantify parasites (i.e., determine parasite density) against red blood cells (RBCs) on thin smear: Count the parasitized RBCs among 500-2,000 RBCs on the thin smear and express the results as % parasitemia.

% parasitemia = (parasitized RBCs/total RBCs) x 100. If the parasitemia is high (>10%) examine 500 RBCs; if it is low (<1%) examine 2,000 RBCs or more.; count asexual blood stage parasites and gametocytes separately.

**Peripheral blood smear:** For the purpose of the rapid assessment, both a determination of positive/negative AND a calculation of parasite density may be obtained. **Placental and umbilical cord blood smears:** It is not necessary to calculate parasite densities; a determination of positive or negative is sufficient.

For additional information about placental infection, an impression smear can be made. For an impression smear, the level of infection should be reported as density of parasitemia rather than number of parasites/ul of blood. Although both impression smears and thick smears require taking blood samples, impression smears require more manipulation of the placenta than do thick smears. Thus, the benefit of the additional information gained from an impression smear needs to be balanced against the potential risk incurred.

FIGURE A-2. Preparation of a thin and a thick blood film on the same slide




* In Figure A-2, the hands are shown ungloved to better indicate their placement during the procedures. However, wearing gloves while processing blood specimens is strongly recommended to prevent transmission of bloodborne pathogens (*MMWR 1988;37:377--82, 387--8* and *MMWR 1987;36[No. S2]*).

**O. How to Take Blood Samples from a Finger, Placenta, and Umbilical Cord**

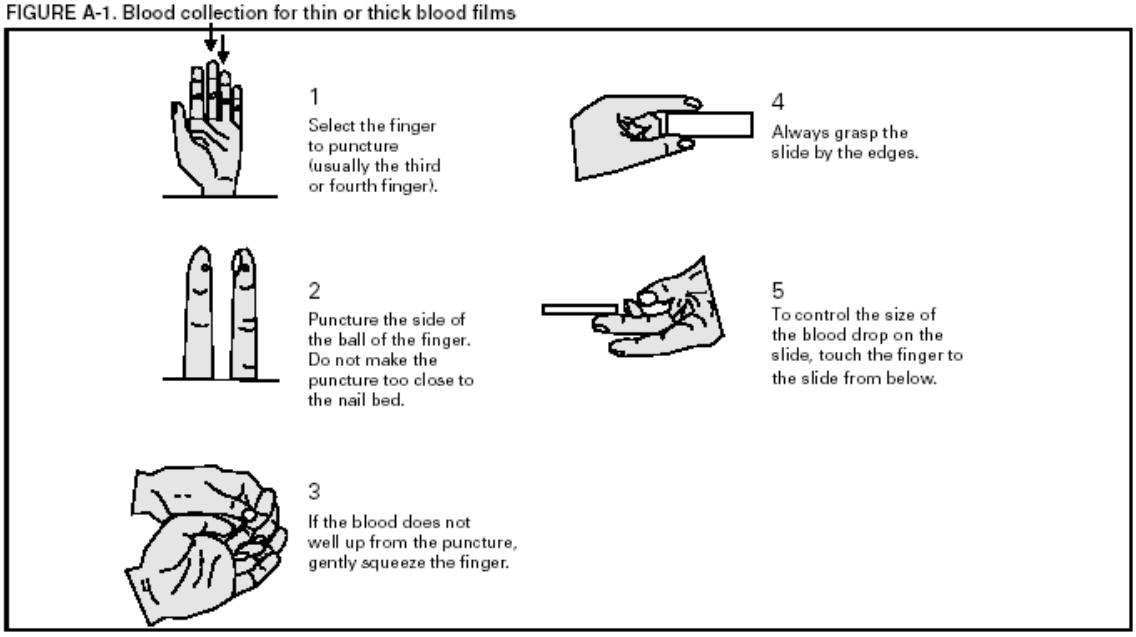
**Finger Prick:**

Organize the supplies you will need:

- gloves
- cotton gauze
- 2 slides per finger-stick (1 labeled **M** for maternal peripheral blood and 1 swipe slide)
- lancet
- sharps disposal container

The figure below shows how blood may be obtained by pricking the patient's finger.

FIGURE A-1. Blood collection for thin or thick blood films




*** In Figure A-1, the hands are illustrated ungloved to better indicate their placement during the procedures. However, wearing gloves while processing blood specimens is recommended to prevent transmission of bloodborne pathogens (*MMWR 1988;37:377--82, 387--8* and *MMWR 1987;36[No. S2]*).**

**Placenta and Umbilical Cord:**

Organize the supplies you need:

- gloves
- cotton gauze
- 3 slides per placenta (1 labeled **P** for placenta, 1 labeled **C** for cord, and 1 swipe slide)
- tweezers
- scissors
- lancet
- sharps disposal container
- basin with disinfectant for tweezers, scissors

1. Label all slides with ID number, date, and site obtained (i.e., P or C)

2. Put on gloves

3. Keep placentas in plastic bags whenever possible

4. Wipe cord

5. Use lancet to puncture cord

6. Obtain cord slide by touching from above, make thick and thin film

7. Turn placenta over and find maternal side

8. Wipe off placenta

9. Make placenta thick and thin film

10. Clean up and be careful with sharps

**If more than one placenta is done at once: Be careful not to cross-contaminate. Change gloves and instruments after sampling each placenta.**

**P. Making a Placental Impression Smear**

**Although both impression smears and thick smears require taking blood samples, impression smears require more manipulation of the placenta than do thick smears. Thus, the benefit of the additional information gained from an impression smear needs to be balanced against the potential risk incurred.**

Materials and equipment needed to collect the sample:

- Tray
- Blunt-ended scissors
- Forceps with blunt tips
- Scissors/scalpel knife
- Gloves
- Marking pen
- Absorbent material such as paper towel
- Safety cover or transparent disposable plastic face shield to cover the face to protect against any blood splash
- Beaker containing 10% bleach

How to make a smear:

1. Label the slide with a marking pen, include the sample/placenta number and date.
2. Place the whole placenta in the tray.
3. Open up the membranes covering the maternal side of the placenta and move them aside.
4. Holding the piece of placenta with forceps, cut a small (about $5mm^3$) piece with scissors or a scalpel knife.
5. Absorb the excess blood with absorbent material.
6. Blot several times on a piece of absorbent material.
7. Make 3 to 6 impressions of the tissue along one long edge of the slide by gently dabbing the tissue. The blood impression should be no thicker than a thin smear.
8. For increased surface area for smear reading, make smears along the other long edge of the slide using short, diagonal strokes.
9. Place the forceps and scissors/scalpel knife in the beaker containing 10% bleach.
10. Allow the slide to dry.
11. Process as for thin blood smears.

For an impression smear, the level of infection should be reported as percent parasitemia rather than number of parasites/ul of blood.

**Q. Delivery Unit Survey Information Sheet**[4]

**The following information sheet should be given to each potential survey participant. If the potential survey participant cannot read or has low literacy skills, the information should be read aloud to her. All potential participants should receive a copy of the information sheet to take home.**

**Note to Interviewer: If the potential survey participant cannot read or has low literacy skills, read this information aloud to her. Give all potential participants a copy of this information sheet to take home.**

Introduction

The [Ministry of Health] is doing an assessment to find out how many pregnant women in this [assessment area] have malaria. This will help us find the best ways to prevent the effects of malaria on pregnant women and their babies. As you know, sometimes you may get malaria and feel sick. What you may not know is that sometimes you may have malaria without feeling sick. When you are pregnant and you have malaria, the baby can be born small and weak, even if you have not felt sick. The only way for us to know how many women may have this problem is to check blood from the placenta (afterbirth) after the woman gives birth. We plan to assess this problem in about _____ women in the [assessment area].

Purpose of the Survey

We plan to check blood from the placenta for malaria to know how many women in the [assessment area] are infected. This will help us plan and measure the effects of programs to decrease malaria in pregnant women.

**Procedures**

If you agree to be in this assessment, we will ask you some questions about yourself and your health since you have been pregnant. We will not be telling anyone about your individual answers to the questions, and we will keep all assessment information about you safe and secure. You also do not need to answer any questions on the survey forms that you do not want to. We will review your clinic card. You will be measured for height and have a measurement done of the width of your arm. Before you have the baby, we will take a few drops of blood from a finger stick to check your blood for malaria. After you give birth, we will weigh and examine your baby. We will also take another finger stick to look for malaria, and we'll also be looking for malaria in the placenta and in the cord that goes to the baby after you have the baby.

*[Note: The two paragraphs that follow have been used in assessments in areas of high transmission; they should be adapted to reflect policy and practice in the country where the assessment is being conducted. ]* If we find malaria in your blood before you give birth, we will treat you with _____ (enter appropriate drug name).

We rarely find malaria in the cord that goes to the baby but, if we do, we will treat the baby with_____ (enter appropriate drug name).

If you join the assessment, it will probably take about x number of minutes more than if you didn't join the assessment. How much extra time will depend on if we find malaria in your blood or the cord that goes to your baby.

4 It is very important that the country's human subjects or ethics requirements be followed with regard to provision of information and documentation of participant's consent.

If you do not wish to join in the assessment, you and your baby will still get the best possible care from the hospital. If you join the assessment, but then decide you don't want to be in the assessment, you can withdraw yourself from the assessment at any time. This will not affect the health care you get here.

Risks or discomforts
You will feel a "pinch" that lasts for a few seconds when the finger stick is done to take blood.

Benefits
You and/or your baby will be treated if you or the baby has malaria after birth. The information we get from the assessment will help us know how best to prevent malaria in pregnant women in this [assessment area].

Treatment
_____ (enter appropriate drug name) works well to treat malaria and has been used safely to treat malaria in adults and in children. If you or the baby has any side effect which you think might be due to _____ (enter appropriate drug name), please come back to the hospital right away to be checked and treated by one of the doctors.

If you join the assessment and have questions later, please feel free to ask. You can ask me today or if you have questions later, you can ask _____ (responsible assessment team member).
Thank you very much for your time. Would you like to join in the assessment?

**Please keep this information sheet in case you have questions later.**

**R. Analysis of Delivery Unit Survey Data**

**Below are outcome variables for the Delivery Unit Survey and summary tables of survey results. Further data analysis may be helpful, but is not necessary for decision making.**

**Tables can be useful for showing relationships between outcome variables.**

- **Table 1 shows how representative the women in the survey are of the women in the country.**
- **Table 2 shows women's reported use of prevention and control measures, such as IPTpp, ITNs, and antimalarial drugs for treatment of illness.**
- **Table 3 focuses on prevalence of parasitemia and fever among pregnant women and low birth weight, and prematurity among their babies.**
- **Table 4 looks at the relationship between placental and peripheral malaria parasitemia, low birth weight, and premature delivery.**

| ***No.*** | ***Outcome Variable*** | ***Numerator/Denominator*** |
|---|---|---|
| 1. | Women with peripheral parasitemia | Number of pregnant women with a positive result of peripheral blood film/<br>Total number of pregnant women with peripheral blood films |
| 2. | Women with placental parasitemia | Number of pregnant women with a positive result of placental blood film/<br>Total number of pregnant women with placental blood film |
| 3. | Infants with umbilical cord parasitemia | Number of infants with positive result of umbilical cord blood film/<br>Total number of infants with umbilical cord blood film |
| 4. | Infants with low birth weight (<2500g) | Number of singleton infants with low birth weight (<2500g)*/<br>Total number of singleton live births that had a weight taken |
| 5. | Infants who are premature (<37 weeks) | Number of singleton premature infants (<37 weeks)**/<br>Total number singleton live births |
| 6. | Women who report fever or malaria during pregnancy and used an antimalarial drug | Number of women who report fever or malaria during pregnancy and used an antimalarial drug/<br>Total number of pregnant women who answered this question |
| 7. | Women who report taking any medicine to prevent malaria during pregnancy | Number of women who report taking any medicine to prevent malaria during pregnancy/<br>Total number of pregnant women who answered this question |
| 9. | Proportion of women who reported taking an antimalarial for treatment during pregnancy | Number of women who reported taking an antimalarial for treatment during pregnancy/<br>Total number of women who report fever or malaria during pregnancy |
| 10. | Proportion of pregnant women who report sleeping under a bed net during pregnancy | Number of pregnant women who report sleeping under a bed net during pregnancy/<br>Total number of pregnant women who answered this question |
| 11. | Proportion of pregnant women | Number of pregnant women who report sleeping under a bed net the previous night/ |

| | | |
|---|---|---|
| | who report sleeping under a bed net the previous night | Total number of pregnant women who answered this question |
| 12. | Proportion of women who reported fever 7 days before enrollment | Number of women who reported fever 7 days before enrollment/<br>Total number of pregnant women who answered this question |

*Singleton live-born infants only.
**Only singleton live-born infants with a Ballard examination within the first 24 hours.

**Table 1**. **Characteristics of Women in the Delivery Unit Survey and Women Country-Wide**

| Characteristic | Women in Delivery Unit Survey*<br>(n= # ) | Women in national DHS** |
|---|---|---|
| Median age in years [range] | | |
| Median gravidity [range] | | |
| ANC visits, median no. [range] | | |
| Able to read | | |
| Attended school (any) | | |
| Married | | |
| Owns own home | | |
| Owns moped | | |
| Owns bike | | |
| Owns radio | | |
| Works for cash | | |
| Grows cash crops | | |
| TOTAL | | |

*Data are % of participants unless otherwise indicated.
**If available, national data (e.g., Demographic and Health Surveys) can be used to compare how similar women in the assessment are to women nationally.

**Table 2. Use of Prevention and Control Measures by Women in the Delivery Unit Survey**

| Treatment and Prevention Measures | (#sites) (#women) |
|---|---|
| | |
| Gestational age at 1st ANC visit | |
| Owns insecticide-treated bed net (ITN) | |
| Uses ITN | |
| Slept under ITN previous night | |
| Used antimalarial drug during pregnancy for prevention (IPTpp) | |
| Used antimalarial drug during pregnancy for treatment of malaria illness | |
| Used the correct dose of antimalarial drug for treatment | |

**Table 3. Rates of Peripheral and Placental Parasitemia, Reported Fever, Low Birth Weight, and Prematurity among Delivering Women**

| **Characteristic** | **All women (n= )** | **Use of IPTp or Chemoprophylaxis** | | | ***P*** |
|---|---|---|---|---|---|
| | | **Complete (n= )** | **Incomplete (n= )** | **None (n= )** | |

| | | | | | |
|---|---|---|---|---|---|
| Peripheral parasitemia | | | | | |
| Overall | | | | | |
| Primigravidae | | | | | |
| Secundigravidae | | | | | |
| Multigravidae | | | | | |
| Placental parasitemia | | | | | |
| Overall | | | | | |
| Primigravidae | | | | | |
| Secundigravidae | | | | | |
| Multigravidae | | | | | |
| Umbilical cord parasitemia | | | | | |
| Fever during pregnancy | | | | | |
| Self-reported use of an antimalarial for treatment during pregnancy | | | | | |
| Fever within week before enrollment | | | | | |
| Singleton live-born birth weight (g) ± SD | | | | | |
| Low birth weight (live- born singletons <2,500 g) | | | | | |
| Overall | | | | | |
| Primigravidae | | | | | |
| Secundigravidae | | | | | |
| Multigravidae | | | | | |
| Premature delivery (liveborn singletons <37 weeks gestation) | | | | | |
| Overall | | | | | |
| Primigravidae | | | | | |
| Secundigravidae | | | | | |
| Multigravidae | | | | | |

**Table 4. Relationship between Placental Malaria Parasitemia and Peripheral Malaria Parasitemia, Low Birth Weight, and Premature Delivery among Delivering Women**

| Characteristic | Result of placental blood film examination | | Risk ratio | 95% Confidence interval | *P* |
|---|---|---|---|---|---|
| | Positive (n = ) | Negative (n = ) | | | |
| Positive result of peripheral blood film | | | | | |
| Low birth weight | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| (<2,500 grams)* | | | | | |
| Birth weight (mean g ± SD) | | | NA | NA | |
| Premature delivery (<37 weeks)** | | | | | |

*Singleton live-born infants only. **Singleton live-born infants with Ballard examination within first 24 hours only. NA = not applicable