Module 1: Conducting an Antenatal Clinic Survey

An Antenatal Clinic (ANC) Survey is designed to determine the magnitude of the burden of malaria during pregnancy, specifically:

- What is the prevalence of peripheral parasitemia in pregnant women?
- What is the prevalence of maternal anemia?
- Does the prevalence of peripheral parasitemia vary by gravidity or locale?

Contents

This module contains sample materials for an Antenatal Clinic Survey (and in some cases for the Delivery Unit Survey also). These materials can and should be adapted to suit local needs. General guidance for conducting an Antenatal Clinic Survey and managing data can be found in Chapters 3-4 of the manual.

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

- A. Antenatal Clinic Survey Timetable
- B. Selecting Sample SizesC. Eligibility Criteria
- D. List of Supplies and Equipment
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- H. Supervisor's Guide to Conducting Antenatal Clinic and Delivery Unit Surveys
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- J. Sample Logbooks: Enrollment and Laboratory
- K. Handbook for Assessment Teams
- Blood Test Procedures: HemoCue for Determination of Hemoglobin Level
- M. Blood Test Procedures: Thick and Thin Films for Microscopic Diagnosis of Malaria Infection/Finger-Stick Blood Collection
- N. Antenatal Clinic Survey Information Sheet
- O. Analysis of Antenatal Clinic Data

A. Antenatal Clinic Survey Timetable

This timetable outlines key steps in planning for and conducting Antenatal Clinic and Delivery Unit Surveys and the approximate length of time to allow. Many key steps will require advance planning.

Period	Time	Activities
Planning the assessment	2-4 weeks	 Determine what assessment components, if any, need to be conducted Determine what approvals (ethical, scientific, other ministerial) are needed and initiate approval process Secure funding
Preassessment	2-3 weeks	 Select site(s) Explain the assessment to the community Procure assessment equipment and supplies Hire assessment team and/or identify existing staff Adapt and translate questionnaires Pretest questionnaires Identify site for training Identify responsible persons for all presentations that will be given during training (See Resource 3 for sample presentations) Manage logistics of training, including per diem, transportation, meals, and lodging Arrange for on-site training in delivery units and antenatal clinics
Assessment training	1 week	 Conduct training course (4-5 days) Finalize questionnaires based on pretest and make adequate copies for final day of training Meet with supervisors to coordinate assessment start-up in clinical facilities
Start-up of assessment	2 weeks	 Make adequate copies of antenatal clinic and delivery unit questionnaires, enrollment logbooks, and laboratory logbooks, and ensure questionnaires are at assessment sites Distribute supplies to each assessment site and ensure a system of re-stocking supplies is in place Establish quality control mechanism for data collection, including clinical and laboratory procedures, transport, and storage Establish a supervisory system that addresses logistics (staffing, supplies), quality of interviewing, quality of data collected on questionnaires, quality of obtaining specimens, laboratory quality (slide and staining, HemoCue calibration), logbook maintenance
Assessment	8-9 weeks	 Enroll women and collect data Ensure supervisory system and quality control mechanisms are functioning Ensure adequate supplies and equipment are available and functioning at each assessment site
Postassessment	8 weeks	 Conduct data entry, cleaning, and analysis Write final report Disseminate results Initiate policy discussions

B. Selecting Sample Sizes

The sample size needed for the Antenatal Clinic Survey depends on

- 1) the estimated prevalence of women with parasitemia and with anemia,
- 2) the acceptable margin of error, AND
- 3) the design effect

The sample size required to measure each of the survey's main indicators (peripheral parasitemia and anemia) 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).

The sample size for the Antenatal Clinic Survey can be determined using

- 1. Point estimates of the proportion of women with peripheral parasitemia and the proportion with anemia. Because hemoglobin levels change throughout pregnancy, the prevalence of anemia should be estimated for women in the same trimester (e.g., third). If no estimates are available from the district or region where the survey is being conducted, data from a neighboring area or national data could be used.
- 2. Level of accuracy desired, for example \pm 10%.
- 3. The design effect.

Antenatal Clinic Survey Sample Size Calculation: An Example

Point estimates: In this example, the assessment coordinator estimates the prevalence of peripheral parasitemia in the area to be 35%, on the basis of a previous study done in the area. The prevalence of anemia (Hgb<11 Gm/dl) in the third trimester is estimated at 50%.

Level of accuracy: The country or district conducting the survey determines that it is acceptable if the survey can estimate the prevalence within 10% (that is, the prevalence of parasitemia could be between 25% and 45%, and the prevalence of third trimester anemia could be between 40%-60%).

These numbers are entered in Statcalc, with a design effect=2 (to correct for the fact that this is not a random community sample) for each indicator. A design effect of 2 is chosen on the basis of previous similar studies. EPI-INFO then calculates sample sizes: 174 for peripheral parasitemia and 192 for third trimester anemia. The larger of these two is 192, and this would be the sample size if no adjustments were made. However, it is estimated that only half of the women attending antenatal clinic are in their third trimester. Thus, approximately 384 women total will need to be screened (by months gestation) to obtain the required sample size to estimate the point prevalence of anemia. Therefore, in this example, the Antenatal Clinic Survey will require a sample size of 384 women so that it can adequately estimate the prevalence of both peripheral parasitemia and anemia.

	Estimated prevalence*	Margin of error	Needed sample size (from Statcalc)	Other factors	Sample size (after adjusting for other factors)
Peripheral parasitemia	35%	10%	174		174
Third trimester anemia	50%	10%	192	% women attending antenatal clinic during third trimester: 50%	384
Total					384

sample size			

* If the prevalence of peripheral parasitemia during the 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 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 quidance.

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 variance¹, 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, ρ 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 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

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.

if the two elements were chosen at random in the survey.

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.

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).

C. Eligibility Criteria

Women who participate in the assessment should be as representative as possible of all women attending the antenatal clinic.

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

Stage of Gestation: Women who have experienced "quickening" (i.e., the recognition of fetal movement).

Gravidity: All gravidities. Although primigravidae and secundigravidae are typically most affected in high transmission areas, women of **all** gravidities should be eliqible so that the local situation can be confirmed.

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 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. Many countries consider a woman with a child and her own household to be an emancipated minor regardless of age. However, 15 years is often chosen as a minimum age.

Note: Women who have not yet experienced quickening should not be included in the survey. This exclusion criterion helps avoid use of drugs in the first trimester other than what would be recommended in the national policy. For example, in this survey, women may be treated for asymptomatic parasitemia, but would not otherwise, according to national policy.

D. List of Supplies and Equipment

Make sure that each antenatal clinic has the necessary supplies and equipment before the start of the survey.

Item	Quantity per ANC	Comments/Use	# in stock/ Balance needed	Date Ordered
Screening & Clinical Evaluation				
Electronic thermometers	2	Temperature measurement; if electronic thermometers are unavailable, mercury glass thermometers are an acceptable alternative.		
Laboratory				
Count-down timer	1	For laboratory use.		
Slides	1/participant	Allow extras for waste.		
Lancets	1/participant	Allow extras for waste.		
Isopropyl alcohol	Enough to clean 1 finger/ participant	Premoistened alcohol wipes are an acceptable alternative.		
Cotton wool or gauze	Enough to clean 1 finger/participa nt			
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	2/site	Sharps container; should only be used for lancets (or other sharps), microcuvettes, and microhematocrit tubes.		
Staining jars	2/lab			
Slide drying rack Basin/bleach	1/lab 1 basin	Bleach for disinfecting and cleaning spreader slides if using thin films.		
Hair dryer	1/lab	May be needed, depending on climate. Optional.		
Microhematocrit tubes	1/participant			
Centrifuge for microhematocrit tubes	1	HemoCue machine and microcuvettes may be substituted when available.		
Microscope	1/lab			
Spare light bulbs for microscope	3/lab			

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Immersion oil	3 tubes/lab			
Lens cleaner	1 bottle/lab			
Lens cleaning	2 sheets/day of			
tissue	survey			
Sharpie markers	3/team/site			
(ultra fine)				
Examination	1 pair	Extra for breakage, extra for		
gloves	/participant	lab personnel.		
Trash can/trash	1 can and bags	For non-sharp waste (gloves,		
bags	as needed	cotton, etc.).		
Tally counters	2/laboratory	If using 2-channel counter, 1 is sufficient.		
Computer	1-2	2 is ideal, 1 is adequate; with at least Windows 2000.		
Epi-Info or	1-2	Installed on each computer.		
another statistical				
software package				
(Epi Info is				
preferred)				
Office Supplies				
AA batteries		If using HemoCue.		
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.		
Logbooks	2/clinical site	Should be bound books, not		
	and 1/lab	spiral-bound or perforated. 2		
		in clinical site: 1 for register,		
		1 for hemoglobin. 1 in lab for		
		slide results.		
Drug Supplies				
Antimalarials for				
IPTp (if IPTp is				
the policy);				
should be				
available as part				
of routine ANC				
supplies				
Antimalarial for				
treatment				
Iron and folate				

E. Assessment Teams

The number of assessment teams depends on the number of antenatal clinics used.

The following example assumes that 4 antenatal clinics will be surveyed.

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	1
coordinator	
Data entry clerks	2

There is no magic formula for how to staff the assessment. If the antenatal clinic sites see patients every day, it may be advantageous to staff them continuously, and therefore have a complete team at each site. If there are antenatal clinic sites that are not open daily, then it may be more efficient to have a team of newly hired staff who rotate among two or more sites.

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.

The text below explains how to conduct the training. A sample schedule follows the explanation.

Note: If both Antenatal Clinic and Delivery Unit 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 antenatal clinic and delivery unit 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 antenatal clinic 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 has the opportunity to learn and practice each procedure that he/she will be conducting.

Antenatal clinic procedures include: 2

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.

- Exercise universal precaution for handling blood (prior to this exercise, presentation on lab safety [see Resources] could be shown)
- Take and read axillary temperature
- Collect blood samples (fingersticks) from each other
- Prepare slide (recording date and ID number on slide) (see M)
- Prepare thick films (and thin films in an area with substantial *P. vivax* transmission) (see M)
- Collect blood on cuvette and use HemoCue machine to perform the Hb reading (see L)

Delivery unit procedures include: 3

- Take woman's temperature
- Measure woman'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; see also Module 2 for Ballard check list)

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.

Afternoon: In a group setting, the assessment coordinator reviews each question on antenatal clinic 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 antenatal clinic cards from the clinic. It is important that the antenatal clinic cards have had all identifiers removed. Any discrepancies regarding data extraction from antenatal clinic 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 antenatal clinic sites to practice the antenatal clinic questionnaire with clients.

NOTE: The delivery unit questionnaire is very similar to the antenatal clinic questionnaire, which will have been pretested. Because of this, it is not necessary to pretest the delivery unit questionnaire. This avoids the need to ask women who may be in physical discomfort to practice interviews.

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

Day 4:

³ 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.

Morning: The assessment coordinator will explain the purpose of antenatal clinic and delivery unit enrollment and laboratory logbooks. Then, the coordinator should demonstrate and review these log books. It is important that all assessment team members understand that the enrollment 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 continue practicing the revised questionnaires. The rest of the morning should be used to resolve outstanding issues, and conclude the training.

Day 5: If the 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 -Training objectives -Malaria situation in country -Epidemiology of malaria during pregnancy -Rapid assessment objectives See Resource 3 for sample presentations	Microscopy training for laboratorians On site delivery unit clinical procedures training and practice for interviewers	Practice questionnaires and consent form administration in local language(s) with translator Practice questionnaires and consent form administration in local language(s) in small groups	Introduce enrollment and laboratory registers Practice questionnaires in pairs (using antenatal clinic cards and antenatal clinic and delivery unit registers). Conclusion of training
Afternoon	Policy and procedures in antenatal clinic and delivery unit (worker's handbook) Practice clinical procedures for antenatal clinic and delivery unit (show video of Ballard) if available. Live demonstrations using an adult model before practicing on live newborns can be useful.	Review antenatal clinic and delivery unit questionnaires and consent forms Practice questionnaires in pairs (using antenatal clinic cards). Resolve discrepancies regarding data extraction from antenatal clinic cards.	Pretest questionnaires on site in antenatal clinic facilities	Meet with supervisors to discuss assessment start- up: -Make copies of antenatal clinic and delivery unit questionnaires -Ensure antenatal clinic and delivery unit log books are at each assessment site -Distribute supplies to each assessment site -Establish quality control mechanism -Establish a supervisory system
Evening	Team members to read questionnaires and consent forms		Assessment coordinator finalizes both questionnaires based on pretests.	, 500.50

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

The following guide contains worksheets to assist the supervisor during the start-up phase of the assessment.

Note: This list pertains 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.

<u>Explain the purpose of the assessment to the "community,"</u> 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 a 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 hemoglobin results)

H. Supervisor's Guide for 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 will need to 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 (Mother):
Number positive (Placenta):	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 cover	ered 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 YES =1 NO = 2	are adequate.
Any other missing supplies:	
If any supplies are needed, what is the plan	for restocking?
Are questionnaires and samples well organize	zed and in a safe place?
If not, plan to improve situation:	
Samples and questionnaires taken to centra	I location
ANC:	
Questionnaire numbers	to
Slide numbers:	to
Delivery	
Questionnaire numbers	to

Slide numbers (M,P,C): to to
Tissue sample numbers, if collected: to
Filter paper numbers (M,P), if collected: to to
3. Antenatal Care Survey
Is the HemoCue machine being calibrated daily?
Check calibration today:
Examine the logbooks. Are they being filled out correctly? (Note: Enrollment logbook 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:
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?
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 Survey
Examine logbooks. Are they being filled out correctly? (Note: Enrollment logbook should contain all women who deliver, 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:
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 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 (Supervisor may need assistance from Laboratory Supervisor on first few items below.)
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):

If quality is poor, examine reasons (e.g., smears badly done, thick specimen is fixed,	ou atain calcustion 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 o paper)?:	
If not, plan for correction:	
Does the laboratory have adequate supplies?	
If not, plan to correct the problem:	
6. 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 can be modified accordingly.

1. Enrollment targets:

> List for each site:

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

2. Target data collection period:

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

3. 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	Α
Delivery	D

$3^{rd} - 5^{th}$ digit: consecutive number identifying each patient

 35^{th} antenatal clinic woman in Site#3 = 3A - 035Example: 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!!

4. Assigning an interviewer number

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

For example:

01 – 20
21 - 40
41 - 60
61 - 80

5. 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 received 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 write 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 ID number clearly on each item and each page
- > Mark ID 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. If the slide was positive, treat the woman with appropriate antimalarial drug as per national policy before she leaves that clinic that day (or when you visit the woman at home with results.)

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

Delivery Unit Survey

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:

Mother (thick and thin)
 Placenta (thick and thin)
 Cord (thick and thin)

- > 2 filter papers:, if used:
 - Mother
 - Placenta
- 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.: 42.001 42.035
- > 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 antenatal clinic number, and whether or not she was enrolled (and if not, why not). • Laboratory logbooks (two): One records information about the malaria blood films of enrolled women 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.

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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.

HANDBOOK FOR ASSESSMENT TEAMS Antenatal Clinic Survey

Contents

I. Enrollment

Identification of eligible women
Inclusion criteria
Exclusion criteria
Provision of information or consent (if necessary)

II. Postenrollment

Questionnaire Measurements and laboratory specimens Medications Follow-up

(Throughout woman's stay at antenatal clinic unit: follow normal procedures to ensure safety of mother and baby. Ensure proper medical care.)

Goal: Enroll _____ women/day

Procedures	Comments
Enrollment	
Identify eligible women. Check antenatal clinic card Confirm information with woman	Not previously enrolled in this assessment All pregnancies; have experienced quickening.
Note regarding gravidity: All pregnancies count, not just live births. Inquire if the woman has had any pregnancies end in death of the fetus for completeness of gravidity history.	Note: Record for all women attending antenatal clinic in the enrollment logbook: Date Woman's antenatal clinic number Name Age Gravidity/parity Mother tongue Whether or not enrolled Woman's ID number Reasons for nonenrollment: • refused to participate, already enrolled, not selected, etc.
2. Ask every eligible woman to participate.	Note: If antenatal clinic volume is high, it may be necessary to select every other eligible woman to avoid selection bias. It is not a good idea to select the first 10 women for example, as those who come early for antenatal clinic may be different from women who come later in the day.
3. Verify criteria.	Exclusion criteria:

	,
	 Gestational age before quickening Age <15 years (or decided-upon lower age limit) Refused to participate Already enrolled
4. Read information sheet or obtain informed consent, depending on local requirements for the assessment. Note: Depending on setting and local ethics requirements, consent may be verbal or written.	Assessment explained by interviewer Woman agrees to participate and she or witness signs form, if needed.
Postenrollment	
5. Complete the questionnaire.	Interviewer or site supervisor must check the questionnaire for completeness and accuracy before woman leaves the ANC.
6. Conduct blood tests, take temperature.	 Take axillary temperature Use HemoCue test Make thick blood film*
7. Give medications for treatment if indicated. Ask if woman has had IPTp already and if so follow country policy for use of correct antimalarial drug.	If patient is anemic, Follow the country's treatment protocol. If patient is febrile or has history of fever in the last 7 days, treat according to country guidelines.
8. Thank the woman for her time and give her follow-up instructions.	

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

L. Blood Test Procedures: HemoCue for Determination of Hemoglobin Level

The following describes how to take a blood sample for use in a HemoCue machine.

Note: Not all countries and sites routinely use the HemoCue method and so should use the method currently used. However, if a choice exists, use of the HemoCue system is preferable as it allows a quick assessment of hemoglobin level that can be easily compared across countries and sites.

- > Organize the supplies you need:
 - o gloves
 - o cotton
 - disinfectant swab
 - lancet
 - o HemoCue
 - HemoCue cuvette
 - sharps disposal container
 - o hospital waste basket
 - o slide marker
- > Take one HemoCue cuvette from the container and close the lid again.
- > Switch HemoCue ON and open cuvette holder to loading position.
- > Put on gloves.
- > Use the third or fourth finger for sampling. Clean puncture site with disinfectant and allow to dry.
- > Use your thumb to lightly press the finger from top of the knuckle to the tip (to increase blood flow).
- > Using disposable lancet, prick the side of the fingertip. (See steps 1-3 in Figure A-1 in the next section.) Immediately dispose of the lancet in a sharps container.
- Wipe away the first 2-3 drops of blood. If necessary, apply light pressure again, until another drop of blood appears. Avoid "milking."
- > Fill HemoCue cuvette in one continuous process. Wipe off excess blood on outside of cuvette tip. Place in cuvette holder. Push HemoCue cuvette holder into the measuring position.
- > Wipe and clean puncture site.
- Note Hb value (within 10 minutes of reading).
- > Take cuvette out of holder and throw away.
- Clean up and be careful with sharps.
- Switch HemoCue OFF.

M. Blood Test Procedures: Thick and Thin Films for the Microscopic Diagnosis of Malaria Infection⁴

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.

⁴ 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.

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).

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) \times 100. If the parasitemia is high (>10%) examine 500 BBCs; 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.

Figure A-1 below shows how blood may be obtained by pricking the patient's finger. Figure A-2 shows how to make a thick and thin film on the same slide. A slide can also be made from placental or cord blood. (See Module 2 and Resource 3)

* In Figures A-1 and A-2, the hands are illustrated 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]).

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

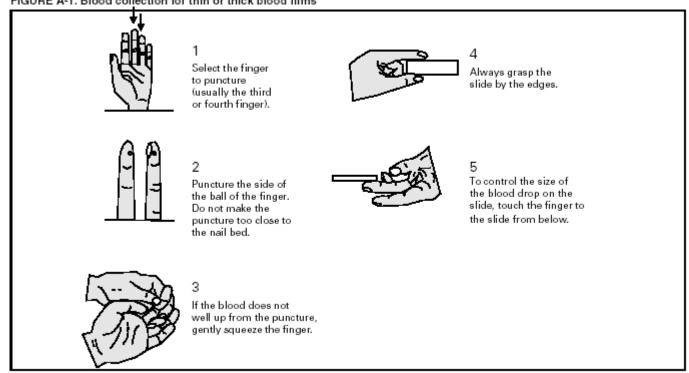
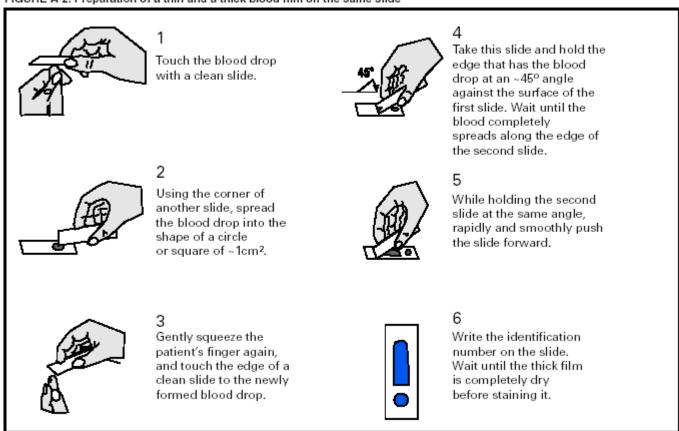


Figure A-2

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



N. Antenatal Clinic Survey Information Sheet 5

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 if she has low literacy skills, read this information aloud to her. Give each potential survey participant 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. The only way for us to know how many women may have this problem is to check women's blood. We plan to assess this problem in about _____ women in antenatal clinics in the [assessment area].

Purpose of the Survey

We plan to check women's blood 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 participate in this survey, 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 and take your temperature. We will take a few drops of blood from a finger stick to check your blood for anemia and malaria. You will still go through the usual clinic exam by the clinic staff. If we find that you have malaria, we will treat you with a drug called ______ (enter appropriate drug name). If we find you need treatment for anemia, we will inform the clinic staff so they will be sure to give you treatment for it. If you participate in the survey, it will take about x number of minutes more than if you did not.

If you do not wish to participate in this survey, it will not affect the care given to you by the clinic. If you 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).

Risks or discomforts

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

Benefits

One of the benefits to you of participating in this survey is that if we find that you have malaria, we will give you______ (enter appropriate drug name) to cure it. If you have anemia, you'll receive treatment for it.

Treatment

_____ (enter appropriate drug name) works very well to treat malaria. Studies have shown that this drug is very safe for you to take while you are pregnant and that it will not harm your baby. We believe that treating you for the malaria and recent fever outweighs any risk from the drug.

We are always concerned that abnormal events may occur when you are pregnant that might affect the baby inside of you. You may have seen babies that were born with some defects. Most of these we cannot do

⁵ 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.

anything about and it was no fault of the woman or clinic workers. If we treat you with any drug, we would only use one that we think is very safe and would not cause any of these problems. If you have any questions about this, please ask now, or you can ask (assessment team member) at the clinic at any time during the assessment. (Be sure to give enough information so that the woman can find them.) If you have any questions about your rights as a survey participant, you may contact (name and address to be filled in). Thank you very much for your time. Would you like to participate?
Please keep this information sheet in case you have questions later on.

O. Analysis of Antenatal Clinic Data: Key Indicators and Summary Tables

Below are key indicators for the Antenatal Clinic Survey and summary tables of survey results. Further data analysis may be helpful, but it is generally 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 IPTp,
 ITNs, and antimalarial drugs for treatment of illness.
- Table 3 focuses on parasitemia, fever, and anemia by use of antenatal clinics and malaria prevention interventions.
- Table 4 looks at the relationship between peripheral parasitemia, fever, and anemia.

Note: The tables can also break down the numbers and percentages by locale (e.g., region, site, urban vs. rural).

1. Outcome Variables

No.	Outcome Variable (%)	Numerator/Denominator
1	Pregnant women with peripheral parasitemia	Number of pregnant women with positive peripheral parasitemia blood films/ Number of women with valid blood films
2	Pregnant women with anemia (Hb<11g/dL)	Number of pregnant women with anemia (Hb<11g/dL)/ Number of women with valid hemoglobin readings
3	Pregnant women with moderate to severe anemia (Hb<8g/dL)	Number of pregnant women with severe anemia (Hb<8g/dL)/ Number of women with valid hemoglobin readings
4	Pregnant women who report taking any medicine to prevent malaria during pregnancy	Number of pregnant women who report taking any medicine to prevent malaria during pregnancy/ Number of women who answered this question
5	Pregnant women who report fever or malaria during pregnancy and used an antimalarial drug	Number of pregnant women who report fever or malaria during pregnancy and used an antimalarial drug/ Number of women who answered this question
6	Pregnant women who report fever in the seven days prior to enrollment	Number of pregnant women who report fever in the seven days prior to enrollment/ Number of women who answered this question
7	Pregnant women with fever at antenatal clinic visit (>37.5°C)	Number of pregnant women with fever at antenatal clinic visit/ Number of women with valid temperature readings
8	Pregnant women who report sleeping under a bed net during pregnancy	Number of pregnant women who report sleeping under a bed net during pregnancy/ Number of women who answered this question

9	Pregnant women who report sleeping under a bed net the previous night	Number of pregnant women who report sleeping under a bed net the previous night/ Number of women who answered this question
10.	Women who reported taking an antimalarial for treatment during pregnancy	Number of women who reported taking an antimalarial for treatment during pregnancy/ Total number of women who report fever or malaria during pregnancy

Table 1. Characteristics of Women in the Antenatal Clinic Survey and Women Country-Wide

Characteristic	Women in Antenatal Clinic Survey* (n= #)	Women in national DHS**
Median age in years [range]		
Median gravidity [range]		
Antenatal clinic 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.

Table 2. Use of Prevention and Control Measures by Women in the Antenatal Clinic Survey

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

Table 3. Status of Peripheral Parasitemia, Fever, and Anemia among Women in the Antenatal Clinic Survey

All women (n=#)	Women with no prior ANC (n=#)	Women with at least 1 prior antenatal clinic visit	Slept under bednet previous night (n=#)	Use of antimalarial drug for IPTp during pregnancy among women with at least 1 prior antenatal clinic visit (n=#)
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^{**}If available, national data (e.g., from Demographic and Health Surveys) can be used to compare how similar women in the assessment are to women nationally.

	(n=#)		Complete	Incomplete	None
	(,)			255	
Parasitemia					
Overall					
Primigravidae					
Secundigravidae	+				
Multigravidae					
(≥3 pregnancies)					
Fever					
Reported fever or					
malaria during					
pregnancy and					
took antimalarial					
drug					<u> </u>
Reported fever					
within 7 days of					
enrollment					
Fever (<u>></u> 37.5°C)					
at visit					
Anemia (Hb<11 g/dL)					
Overall					
Primigravidae					
Secundigravidae					
Multigravidae					
(<u>></u> 3 pregnancies)					
Moderate to					
severe anemia					
(Hb <8 g/dL)					
Overall	+				
Primigravidae		-			-
Secundigravidae	1				-
Multigravidae					
(≥3 pregnancies)					-
Severe anemia					
(Hb<7 g/dL)					
Overall					
Primigravidae					
Secundigravidae					
Multigravidae					
(<u>></u> 3 pregnancies)					

Table 4. Relationship between Peripheral Parasitemia, Fever, and Anemia among Women in the Antenatal Clinic Survey

Characteristic	Parasitemic (n=#)	Aparasitemic (n=#)	Risk ratio	95% Confidence interval	Р
Reported fever within week before enrollment					

Anemia (Hb <11 g/dL)			
Moderate to severe anemia (Hb <8 g/dL)			