U.S. President's Malaria Initiative

AFRICAN STRATEGIES FOR HEALTH

FACILITY LEVEL FACTORS INFLUENCING THE UPTAKE OF INTERMITTENT PREVENTATIVE THERAPY FOR MALARIA IN PREGNANT WOMEN

Report on a formative assessment conducted in Uganda

September 2016

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ACRONYMS

ACT	Artemisnin-based Combination Therapy
ANC	Antenatal Clinic
ARV	Antiretroviral
ASH	African Strategies for Health Project
CTX	Cotrimoxazole
DHO	District Health Office
DHS	Demographic Health Survey
DOT	Directly Observed Therapy
FANC	Focused Antenatal Care
GoU	Government of Uganda
HC	Health Centre
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information Systems
HW	Health Worker
IPTp	Intermittent Preventive Treatment of Malaria During Pregnancy
IRS	Indoor Residual Spraying
ITN	Insecticide Treated Nets
LMP	Last Menstrual Period
M&E	Monitoring and Evaluation
MIP	Malaria in Pregnancy
MIS	Malaria Indicator Survey
MOH	Ministry of Health
MSH	Management Sciences for Health
NGO	Non-Governmental Organization
NMCP	National Malaria Control Program
OIC	Officer-in-Charge
PI	Performance Improvement
QI	Quality Improvement
RMNCH	Reproductive Maternal Newborn Child Health
SP	Sulfadoxine-Pyrimethamine
USAID	United States Agency for International Development
WHO	World Health Organization

CONTENTS

1. EXECUTIVE SUMMARY

Background

Reducing the burden of malaria in Uganda is a priority for The National Malaria Control Program (NMCP). While significant strides have been made, some components have not progressed to the same extent, including malaria in pregnancy, specifically intermittent preventive therapy in pregnant women (IPTp).

Objectives and Methodology

This assessment was undertaken by the USAID/African Strategies for Health (ASH) project to assess facility-based factors that influence the coverage of IPTp among pregnant women. The purpose of the assessment was to design a quality improvement (QI) tool that will enable providers and facility managers to track facility-level trends, identify and address service delivery bottlenecks, and incorporate QI and/or performance improvement (PI) strategies on an ongoing basis. Components such as district official/heath facility staff and client knowledge, attitudes, practices and perspectives, observations of health worker/client interactions and review of select Health Management Information System (HMIS) forms were included and reviewed in the formative study. The assessment met requirements of and was approved by the Uganda National Council for Science and Technology in January 2015. The assessment team was trained for five days, during which the tools were pilot tested and finalized. Data collection occurred February 9th through February 27th, 2015. A total of two District Health Offices (DHO), 25 Officers in Charge (OIC), 46 health workers (HW) and 89 antenatal clients agreed to participate in the assessment. A total of 690 facility-level HMIS records were extracted and reviewed as part of the assessment.

Key Findings

Although the Uganda Ministry of Health (MOH) had accepted the key guidelines of the new World Health Organization (WHO) recommendations for IPTp, there was little awareness of these at the district and sub-district levels. No specific training related to IPTp had taken place in the past year. Despite a high level of knowledge about IPTp, there were nuanced knowledge gaps among HWs, the majority of whom were actually keen to be updated on IPTp implementation (82.6 percent, n=46). Systems were in place both at district and sub-district levels for external and internal supervision/ mentoring in the form of site visits and meetings. Factors such as lack of motivation, inadequate resources for travel, and challenges in covering the diverse program areas in integrated supervision were key deterrents. Staff conducting internal supervision lacked appropriate knowledge related to the management of IPTp. However, internal supervision was better established compared to external supervision.

Stock-outs of sulfadoxine-pyrimethamine (SP) in the preceding 12 months were not a major issue. Besides adequate supplies, supportive initiatives enabling OICs to obtain medications from neighboring centers when in acute need have helped decrease stock-outs. While HWs were well aware of Directly Observed Therapy (DOT) and 91.3 percent (n=46) reported to mostly using this approach, the misconception of not giving SP on an empty stomach and the absence of safe drinking water did lead them in some cases to dispense SP tablets to take home. This practice could potentially lead to doses being missed and therefore missed opportunities. Direct observations of client provider interactions showed reuse of used cups without washing, and HWs giving advice but frequently being in a hurry, not

being able to spend adequate time on counseling nor ensuring the women had understood the advice given. Clients were more familiar with the use of insecticide treated nets (ITN) rather than IPTp.

Major challenges exist at the facility level related to HMIS including limited availability of necessary HMIS forms, inconsistent target setting and sub-optimal management, review and monitoring of data, which is important to help identify problems and institute remedial interventions. This issue is clearly demonstrated by observation of client provider interactions where data for slightly more than 25 percent of consultations (n=89) were not entered into the ANC register by the provider at the end of the consultation. Similarly, in less than half of consultations (n=89) was information recorded in the mother retained card.

Key Recommendations

The assessment tools successfully identified key issues requiring attention. It is unlikely that a single intervention will bring about increased IPTp coverage. A draft tool, that incorporates key elements required to address diverse issues identified through the assessment (Annex B), could provide the basis for facility level supervisors to improve IPTp coverage with limited support from the DHO level (provision of training and job aids). Priorities include strengthened messaging for IPTp, improved client provider interaction and accurate and complete data collection. The facility level is also ideal point of entry to strengthen links between the facility and community with emphasis on community mobilization strategies for the increased coverage of IPTp.

2. BACKGROUND

In Uganda, malaria is one of the leading causes of morbidity and mortality, accounting for 25-40 percent of outpatient visits and almost half of inpatient pediatric deaths.[1] Malaria is highly endemic in Uganda with 95 percent of the country experiencing stable, perennial transmission[2] and approximately 90 percent of the population (estimated at 32 million people) at risk.[3] In response to this public health issue, the National Malaria Control Program (NMCP) was established in 1995 by the Government of Uganda (GoU) to direct and guide the day-to-day implementation of the National Malaria Control Strategic Plan.[4] The institution's primary focus is to support the implementation of the strategic plan through policy formulation; setting standards and promoting quality assurance; mobilizing resources; developing capacity and providing technical support; carrying out malaria epidemic control activities; coordinating malaria research; and monitoring and evaluation. The strategy for prevention and control employs various proven interventions to address malaria including prevention of malaria in pregnancy (MIP) through ITNs, IPTp and case management during pregnancy.

Malaria in pregnancy

The risks associated with the occurrence of malaria during pregnancy are well documented. [5,6] The global recommendation outlined in the WHO guidelines recommends that IPTp should be given at every ANC visit starting in the second trimester if not given in the prior four weeks.[7] Moreover, the provision of IPTp with sulfadoxine-pyrimethamine (SP) provides substantial benefits for newborns, resulting in a 26 percent reduction in low birthweight and a 16 percent reduction in neonatal mortality, under program conditions.[8]

Like many other countries with high burden of malaria, Uganda has national strategies in place that include prevention of malaria among expectant women. According to the preliminary report on key indicators from the 2014-2015 Malaria Indicator Survey[9] (MIS), the Ministry of Health (MOH) of Uganda

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[1] President's Malaria Initiative, 2013. *Uganda Malaria Operational Plan FY 2013*. [online] Available at: http://www.pmi.gov/docs/default-source/default-document-library/malaria-operational-plans/fy13/uganda_mop_fy13.pdf?sfvrsn=8.

[2] Uganda Bureau of Statistics (UBOS) and ICF Macro, 2010. *Uganda Malaria Indicator Survey 2009.* Available at: http:// http://dhsprogram.com/pubs/pdf/MIS6/MIS6.pdf.

[3] President's Malaria Initiative, 2013. *Uganda Malaria Operational Plan FY 2013*. [online] Available at: http://www.pmi.gov/docs/default-source/default-document-library/malaria-operational-plans/fy13/uganda_mop_fy13.pdf?sfvrsn=8.

[4] Government of Uganda, Ministry of Health, 2010. *National Malaria Control Strategic Plan 2010/11-2014/15.* [online] Available at: https://www.k4health.org/toolkits/uganda-stop-malaria/uganda-national-malaria-strategic-plan.

[5] Kiwuwa M, Mufubenga P**.** Use of antenatal care, maternity services, intermittent presumptive treatment and insecticide treated bed nets by pregnant women in Luwero district, Uganda. *Malaria Journal* 2008, **7**:44 doi:10.1186/1475-2875-7-44. http://www.malariajournal.com/content/7/1/44

[6] Eisele TP, Larsen DA, Anglewicz PA, et al, 2012. 'Malaria prevention in pregnancy, birthweight, and neonatal mortality: a meta-analysis of 32 national cross-sectional datasets in Africa', *Lancet Infectious Diseases*, [online] 12(12), 942-9. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22995852.

[7] World Health Organization, 2012. *Updated WHO Policy Recommendation: Intermittent Preventative Treatment of malaria in Pregnancy using Sulfadoxine-Pyrimethamine (IPTp-SP).* [online] Available at: http://www.who.int/malaria/iptp_sp_updated_policy_recommendation_en_102012.pdf.

[8] Eisele TP, Larsen DA, Anglewicz PA, et al, 2012. 'Malaria prevention in pregnancy, birthweight, and neonatal mortality: a meta-analysis of 32 national cross-sectional datasets in Africa', *Lancet Infectious Diseases*, [online] 12(12), 942-9. Available at: http://www.ncbi.nlm.nih.gov/pubmed/22995852

[9] Uganda Bureau of Statistics (UBOS) and ICF International, 2015. *Uganda Malaria Indicator Survey 2014-15: Key Indicators.* [online] Kampala, Uganda and Rockville, Maryland, USA: UBOS and ICF International. Available at: http://dhsprogram.com/pubs/pdf/PR64/PR64.pdf.

has adopted this recommendation, but it is stated that "to reduce the risks of pregnant women getting malaria, the current policy under the NMCP calls for all pregnant women to receive at least three doses of SP, at a minimum of one month apart after quickening".[10] In Uganda, IPTp is integrated with and operationalized through the *Reproductive Health Unit Focused ANC policy*, which recommends that women with a normal pregnancy make four visits to an ANC clinic prior to delivery and that IPTp be given as directly observed therapy (DOT).

Uganda's MOH, in collaboration with donors and implementing partners, has supported the strengthening of IPTp programming. The President's Malaria Initiative (PMI) has supported increased IPTp coverage through a variety of interventions including the development of a comprehensive malaria-in-pregnancy module incorporated into the focused antenatal care (FANC) training, training and on-the-job supervision of HWs in integrated management of malaria including MIP, the procurement and distribution of safe drinking water commodities for IPTp to health facilities, and monitoring of SP stock levels in health facilities to help maintain adequate SP supplies for IPTp.[11] Although malaria in pregnancy is recognized and efforts to reduce the burden of malaria among this key population have been outlined in national guidelines and addressed through various initiatives, there remains a gap in uptake of IPTp.

The MIS in Uganda indicate that 59.3 percent of women received one or more doses of SP during their most recent pregnancy while only 25.2 percent of women received the recommended three doses.[12] Approximately half of all pregnant women (48.1%) make four or more ANC visits during their pregnancy, with the median gestational age of 5.1 months at the time of the first visit to ANC during that pregnancy. Gaps in uptake of IPTp have also been highlighted in different perspectives in studies.

A number of community-based studies examined IPTp from the perspective of the client in Uganda. Sangare et al[13] sought to identify determinants of preventive use of SP during pregnancy among recently pregnant women. Findings suggest that women will take SP for IPTp if it is offered during an ANC visit. Missed opportunities to administer IPTp-SP during ANC were common in the study, suggesting provider-level improvements are needed. Hill et al[14] conducted a literature review which identified key barriers to the provision of IPTp and ITNs. The challenges highlighted include unclear policy and guidance on IPTp; general healthcare system issues such as stock-outs and user fees; health facility issues stemming from poor organization, leading to poor quality of care; poor healthcare provider performance, including confusion over the timing of each IPTp dose; and women's poor antenatal attendance, affecting IPTp uptake.

In 2013, the Malaria Consortium conducted a study exploring demand and supply side issues and their contribution to low IPTp coverage in Uganda.[15] On the demand side, user fees and persisting negative

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[10] Ibid

[11] President's Malaria Initiative, 2013. *Uganda Malaria Operational Plan FY 2013*. [online] Available at: http://www.pmi.gov/docs/default-source/default-document-library/malaria-operational-plans/fy13/uganda_mop_fy13.pdf?sfvrsn=8.

[12] Uganda Bureau of Statistics (UBOS) and ICF International, 2012. *Uganda Demographic and Health Survey 2011*. [online] Kampala, Uganda: UBOS and Calverton, Maryland: ICF International. Available at: http://dhsprogram.com/pubs/pdf/FR264/FR264.pdf

[13] Sangaré L, Stergachis A, Brentlinger P, et al, 2010. 'Determinants of Use of Intermittent Preventive Treatment of Malaria in Pregnancy: Jinja, Uganda'. *PLoS ONE*, [online] 5(11). Available at: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0015066.

[14] Hill J, Hoyt J, van Eijk AM, D'Mello-Guyett L, ter Kuile FO, et al, 2013. 'Factors Affecting the Delivery, Access, and Use of Interventions to Prevent Malaria in Pregnancy in Sub-Saharan Africa: A Systematic Review and Meta-Analysis'. *PLoS Med*, [online] 10(7). Available at: http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001488.

[15] Malaria Consortium, 2013. *Assessing and addressing barriers to IPT2 uptake in Uganda – Formative Research*. [online] Available at: http://www.malariaconsortium.org/resources/publications/237/assessing-and-addressing-barriers-to-iptp-uptake-in-uganda---formative-research.

attitudes towards modern care are likely to impede uptake of ANC services. Acceptability of IPTp may also be affected by concerns about side effects and a reluctance to take SP on an empty stomach. Interviews with community and opinion leaders suggest that supply side issues are likely to act as key barriers to IPTp uptake. The document and record review found sources of data inaccuracy along the recording and reporting chain, suggesting that available IPTp uptake figures are unreliable.

This assessment, *Facility Level Factors Affecting the Delivery and Use of Intermittent Preventive Therapy for Malaria for Pregnant Women,* aimed to provide an in depth review of service delivery practices, quality of care, missed opportunities, and bottlenecks at the facility level that impede the provision and use of IPTp. The assessment reviews perspectives from facility staff, clients and district health officials about how uptake can be improved. The findings will contribute to the design of a QI tool that will enable providers and facility managers to track facility-level trends, identify and address service delivery bottlenecks, and incorporate QI and/or PI strategies on an ongoing basis.

3. STUDY OBJECTIVES

The overall objectives of the ASH study were to identify:

- Quality of care issues that impact IPTp service provision at the facility level
- Facility-level factors that may impede delivery of IPTp
- Perspectives on how service delivery and uptake can be improved

Specific objectives of the assessment were to:

- Understand the level of knowledge and practices among facility staff related to IPTp and ANC
- Determine availability of guidelines, tools, policies, standards, and supplies for the administration of IPTp
- Gather recommendations from service providers and clients on improving IPTp services
- Provide evidence-based recommendations for improving IPTp administration and uptake in Uganda

Support for this assessment was provided by the United States' President's Malaria Initiative (PMI) and was implemented by Management Sciences for Health (MSH) through the USAID-funded African Strategies for Health (ASH) project. This study examines gaps in service delivery that prevent the efforts to reduce the burden malaria among pregnant women. Uganda was selected for this facility assessment as it was one of the first countries to benefit under PMI.

4. METHODOLOGY

4.1 OVERVIEW

This formative research study primarily focused on the issues that affect provision of IPTp through ANC services at the facility-level. Two districts (among a sampling frame of 112 districts in Central, Eastern and Western regions in Uganda) were randomly selected to be included in the formative study: Buyende District and Kabermaido District. Within the selected districts, public health facilities (specifically health centers levels II, III and IV) routinely offering ANC services were selected for inclusion in the

assessment. Facilities providing care to military and prison populations were excluded, as well as non-public facilities. Data collection tools were developed to capture information on various aspects including human resources, training, supervision, drugs and other supplies, data records, provider and client knowledge, and practices.

This study also aimed to collect information to guide the development of a QI tool, which could contribute to the improvement of these services and the overall program. As such, the study design is a "one shot case study" using standard health facility assessment tools, described in Table 1.

Table 1

Description of tools		
Tool	**Respondent**	**Target number**
DHO questionnaire	DHO officials	1 per district
OIC questionnaire	(Facility) OIC	1 per facility
HW questionnaire	HWs	4 per facility
HW Client Observation tool	HWs and clients	4 per facility
ANC Client Exit Interview	Clients	4 per facility
HMIS Record Review	Extraction from HMIS records (data anonymized)	1 per facility

In this study, both primary and secondary quantitative data were gathered from the respondents of interest. Select district health officials were interviewed to gain their perspective on facility-level challenges. Select health facility staff members (up to four) were observed and interviewed and a sample of clients (up to four) was interviewed in each facility setting through exit interviews. Data records were also reviewed to gather information for key variables. Permission to carry out the study was obtained from national level and district level by January 2015. The assessment field team (comprised of six data collectors and two data entrants) carried out the work from February 9th through February 27th, 2015. Prior to the data collection, pre-survey site visits were conducted to gather additional information for planning purposes, the field team underwent five day training and the data collection tools and data entry screens were pilot tested and finalized. Further details of the methodology (including sampling, training, team composition and description of the data collection tools) are provided in Annex A.

4.2 LIMITATIONS

After the assessment was planned, there were some setbacks, delaying the start date of the activity. As part of preparation for the assessments in Uganda, an MSH Uganda staff member conducted pre-survey site visits and collected information about the sites. The daily schedule for data collection was based on this information, aiming to ensure the team was well informed about the facilities participating in the survey. However, when the field work commenced, the study team was informed that there had been redistribution of HWs among the selected health facilities. Moreover, when the field work phase of the activity began, not all the selected facilities offered ANC services. Therefore, the staff composition and availability of the services in the selected facilities was notably different at the time of data collection, from initial information collected during planning phase of the assessment.

5. RESULTS

A brief overview of the numbers and types of facilities visited, categories of persons working the antenatal clinics in the selected health centers, and the number of interviews are noted in Table 2.

Table 2

Overview of Districts and Facilities Included in the Assessment			
Key variables	**District A**	**District B**	**Total**
Total number of health centers	10	15	25
Level 2	5	6	11
Level 3	4	7	11
Level 4	1	1	2
No. of Hospitals	0	1	1
Number of days ANC was available/week			
Two days a week	2	5	7
Three days a week	4	5	9
Four days a week	4	1	5
Five days a week	0	4	4
Number of staff working in the ANC	29	38	67
Total number of persons interviewed			
Number of OICs	10	15	25
Number of HWs in the ANC	28	18	46
Number of HW-client observations	40	49	89
Number of clients interviewed	40	49	89
Number of records reviewed			690

5.1 KEY FINDINGS AT THE DISTRICT LEVEL

General Information

The study teams met with representatives from the two DHOs. Interviews explored the district perspective on IPTp implementation. A copy of the 2012 MOH national guidelines/standards was available in one of the districts, but the representatives were not aware of the revised WHO 2013 guidelines. The other district was unable to provide information on guideline availability.

Training

Both districts had systems in place to train and update staff on new guidelines and protocols for antenatal care and IPTp. One district felt it would be feasible to disseminate revised guidelines through existing Performance Improvement Meetings mechanism. These meetings are held quarterly at the DHO and attended by OICs. The second district conducted continuing medical educational sessions weekly, focusing on priority areas of need.

Supervision and on-site mentoring

Both districts supported facility supervision and provided on-site mentoring.

Supply chain and equipment

One district reported that no stock outs of SP occurred during the previous year. The other district mentioned the usage of the national Medicines Management System, through which a facility with an inadequate supply of drugs, including SP is able to access them from other facilities with excess supplies.

One district indicated that centers had access to the Primary Health Care Fund that enabled OICs to procure supplies such as cups for DOT if the supply was inadequate.

Coverage data related to ANC visits and IPTp coverage

Both districts provided coverage data for the first and fourth ANC visits and the first and second doses of IPTp (Table 3).

Table 3

District Level Data (January-December 2014)		
Key data	**District A**	**District B**
ANC Visit Coverage		
ANC 1	67.0%	57.0%
ANC 4	28.0%	28.3%
IPTp Coverage (women with at least one ANC visit)		
IPTp 1	Not Maintained	71.1%
IPTp 2	40.0%	43.9 %

DHO perspectives on implementation challenges and suggestions to improve IPTp coverage

Box 1 captures comments about the challenges faced by districts in achieving IPTp targets with suggestions to improve IPTp coverage.

Box 1: Perspectives on implementation challenges and suggestions to improve IPTp coverage (DHO interviews)

DHO perceptions of key challenges for achieving targeted IPTp coverage:

- Mothers not aware of the benefits of IPTp
- Mothers not motivated to complete 4 ANC visits
- Inadequate male partner participation in visits by pregnant women to the ANC
- Traditional birth attendants do not refer mothers to the ANC
- All DHO offices and facilities not aware of updates/changes to national policy and guidelines
- Limited resources (fuel, per diem and vehicles) affects timely and effective supervision
- Inadequate knowledge of IPTp among new staff
- Heavy workload among HWs affects their attitudes towards their work

DHO suggestions to improve IPTp coverage:

- Increase sensitization of mothers and communities, particularly on
  - Encouraging regular attendance of ANC
  - Promoting the benefits of IPTp
- Promote peer education of mothers in the community
- Improve policies and advocacy for male involvement
- Provide DHO with adequate updates, guidelines and tools relevant to IPTp
- Ensure that supportive supervision occurs for DHO staff
- Increase resources for transport to enable the DHO team to supervise sub-district facilities
- Offer integrated 'one stop' service for pregnant women to access all tests and treatment at the same facility
- Offer ANC on a daily basis to 'spread out' the workload
- Increase training activities on IPTp
- Recruit more staff to support ANC service provision
- Train and counsel HWs on 'customer care' to improve attitudes and behavior

5.2 KEY FINDINGS AT THE FACILITY LEVEL

Facility level findings incorporate data collected through interviews with the OIC, HWs who provide ANC service delivery, and clients attending ANC. These findings were complemented by client provider observations during ANC service delivery and an HMIS record review. Unless specified in the tool, all answers noted were offered spontaneously by the person interviewed and not through prompting.

5.2.1 Facility management of IPTp provision

Administrative responsibility for IPTp implementation; availability of guidelines

OICs were asked about the administrative responsibility for IPTp implementation at the national level. Twenty four percent (n=25) said IPTp was associated with the Reproductive Maternal Newborn Child Health (RMNCH) Unit, 12.0 percent said IPTp was associated with the NMCP and eight percent said IPTp was associated with both RMNCH and NMCP. Forty percent of OICs (n=25) had no knowledge about which national department(s) was responsible for IPTp implementation. Eight facilities had a copy of the national guidelines covering information on IPTp and all the documents were readily accessible.

Training and job aid availability

Close to half (47.8%, n=46) of the HWs reported previous training by the NMCP and 19.5 percent (n=41) reported routine training on antenatal care by the RMNCH Unit. Six percent of HWs (n=45) reported training on avoiding and managing stock-outs. In the last year, 6.5 percent (n=46) of HWs received training on IPTp. This finding was not triangulated with review of finalized training materials or guidelines from the national level authorities. Most respondents (82.6%, n=46) requested training on IPTp on a variety of topics (see Box 2).

Box 2: IPTp training updates requested by OICs (n=25)

- Number of doses of SP to be given (23.9%)
- Timing of the 1st dose of SP (10.9%)
- Prevention of malaria in HIV infected pregnant woman (10.9%)
- Prevention and management of stock-outs (4.1%)
- How to address allergies related to SP (2.2%)

Job aids for IPTp were available in 16.0 percent (n=25) of health centers. These tools provided guidance on the calculation of gestational age, determination of eligibility for SP administration and provision of advice to pregnant women. Only 11.1 percent (n=45) of HWs reported that they had access to job aids. When job aids were available, 100 percent (n=5) said they used them sometimes or frequently. The assessment did not specifically assess if the available job aids and tools aligned with the current national policies, guidelines and recommendations related to IPTp.

Supervision

Box 3: Comparison of spontaneous and prompted OIC responses to the question "What aspect of IPTp do you focus on during internal supervision"?

Spontaneous responses (n=25):

- Check availability of SP (44.0%)
- Verification of DOT (44.0%)
- Verification ANC register for completeness of data (28.0%)
- Verification completeness of mother retained cards (24.0%)

Prompted responses (n=25):

- Verification of health education/counseling sessions (44.0%)
- Verification of the mother retained cards (44.0%)
- Verification of the antenatal register for completeness of data (36.0%)
- Verification of DOT (24.0%)

Both OIC and HW interviews explored the nature of supervision provided to HWs. Supervision of health facilities occurred through external visits by DHO and NGO staff and internal visits conducted by OICs or OIC representatives. Twenty percent of facilities reported that external supervision occurred during the last six months. Most OICs (68.0%, n=25) reported that they review quality of care for ANC and IPTp during internal supervision. HWs supervised by OICs included midwives (enrolled, assistant and registered), clinical officers,

enrolled and registered nurses and other supporting staff (lab workers, record clerks and cleaners). OICs were asked about the focus of supervision for IPTp (Box 3). Spontaneous responses were followed by prompted responses to understand the scope of internal supervision. Among the supervision priorities, the most frequent spontaneous responses included checks on the availability of SP and verification of DOT; most frequent responses when prompted were verification of health education/counseling and mother retained cards.

Based on HWs responses, 80.4 percent (n=46) verified that they had received internal supervision or mentorship. Regarding the frequency of supervision, 21.7 percent (n=46) said it was monthly and 50.0 percent (n=46) quarterly.

Internal facility meetings

OICs were asked about the periodicity and content of internal facility meetings. Eighty seven percent (n=23) said that they had internal meetings with their staff. Regarding the frequency of meetings during the last six months, responses were available for 20 facilities that had had the internal meetings. Two facilities held five to six internal meetings, 11 facilities held three to four internal meetings and seven facilities conducted one to two internal meetings.

Box 4: Comparison of spontaneous and prompted OIC responses to the question "What elements related to IPTp have you covered in internal meetings?"

Spontaneous responses:

- Review of problems (20.0%, n=20)
- Provision of updates (20.0%, n=20)
- Review of data trends (16.7%, n=18)
- Brainstorming on how to improve IPTp coverage (10.0%, n=20)

Prompted responses:

- Brainstorming on how to improve IPTp coverage (90.0%, n=20)
- Review of data trends (83.3%, n=18)
- Review of problems (80.0%, n=20)
- Provision of updates (80.0%, n=20)

OICs were asked what elements of IPTp were focused on during their internal meetings. Spontaneous responses were less frequent (maximum of 20%) than prompted responses (maximum of 90%). The distribution of topics covered in internal supervision meetings are illustrated in Box 4.

Management of SP supplies

Regarding SP availability, only eight percent (n=25) of all health facilities participating in the assessment experienced stock-outs during the preceding 12 months (from January-December 2014). Most stock-out days were in February 2014 and the mean period of stock-outs was 5.5 days.

Stock out cards (HMIS Form 15) or registers are used to monitor SP stock levels in the facility drug stores and not at the service delivery point. In two facilities, the study team identified instances of "zero" in stock cards, with varying periods before the new stock had been received. The study team was informed that during this time, these health centers did not experience actual stock-outs, as medication was available in the antenatal clinics.

Community-based activities and outreach

Out of the 25 health facilities included in the assessment, 12 percent provided outreach services and 16 percent carried out home visits. Close to half (48.0%, n=25) were involved in community based activities such as community mobilization, promotion of ANC visits and using IPTp services. Group counseling was offered by eight percent (n=25) of the facilities.

5.2.2 Knowledge and practices reported by HWs

Forty-six HWs responded to questions about knowledge and practices related to IPTp.

Efficacy and timing of initiation of SP

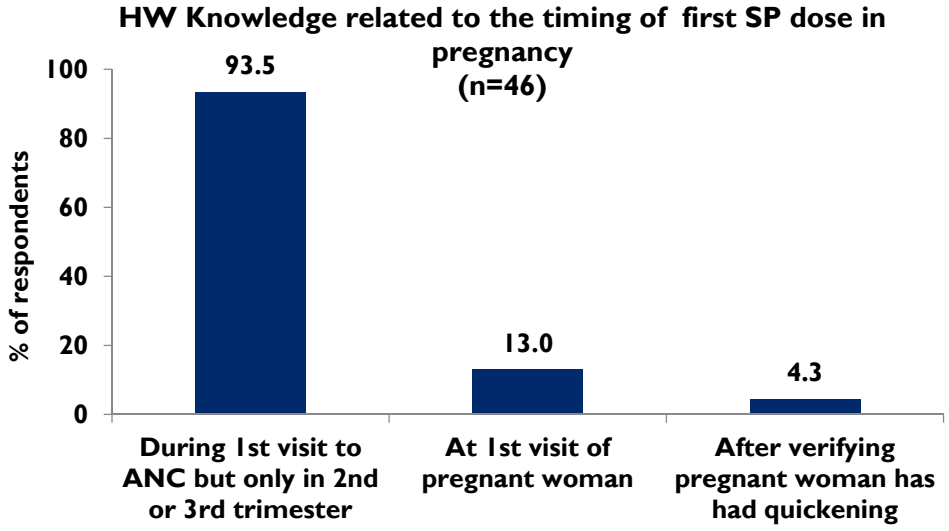
Over 60 percent (n=46) of HWs interviewed believed that SP was very effective in the prevention of malaria in pregnant women. The majority of HWs (96%, n=46) knew that one dose of IPTp consists of three tablets of SP. HWs were asked how many times during pregnancy an HIV negative woman should receive SP and how many times during pregnancy an HIV positive woman should receive SP. Over 92 percent (n=46) of health workers said that a pregnant HIV negative woman should be given two doses. However for HIV positive women who were not on cotrimoxazole (CTX), there was a wider range of responses among the respondents, outlined below in Table 4.

Table 4

HW knowledge of frequency of doses for a pregnant HIV+ woman not taking CTX	
Frequency of dose	**Total (n=46)**
Do not give	13.0%
1 dose	4.3%
2 dose	28.3%
3 dose	39.1%
4 dose	4.3%
Don't know	13.0%

When asked when the first dose of IPTp should be administered, 93.5 percent of respondents answered at the first ANC visit but only in the second or third trimester (see Figure 1).

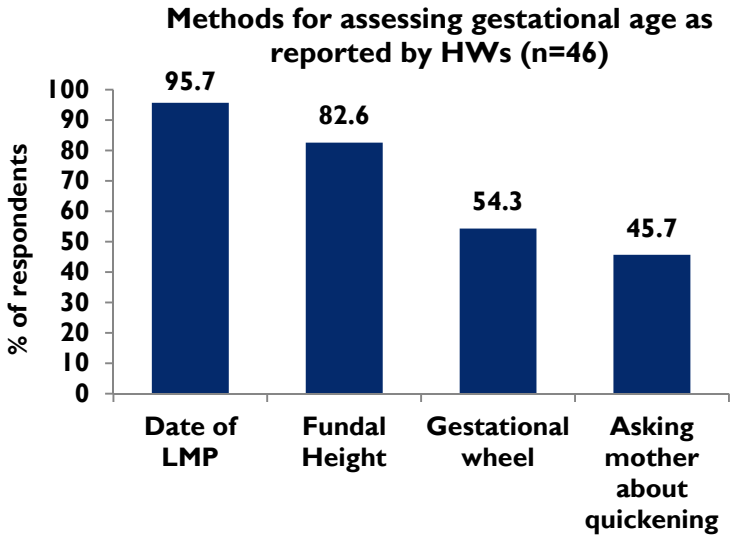
Figure 1



Determination of gestational age

Gestational age is an important determinant for administration of the first dose of IPTp. Respondents determined gestational age utilizing various methods including through estimation based on the date of the last menstrual period (LMP) (95.7%, n=46) and through manual palpation of fundal height (82.6%, n=46) (Figure 2).

Figure 2



Eligibility for IPTp

Regarding the eligibility criteria for administration of SP, HWs provided multiple answers. Seventy six percent (n=46) of respondents said that SP should not be given to a pregnant woman during the first trimester while 63 percent (n=46) said she should not receive SP if she is HIV positive and/or taking CTX. Other responses included when the client's gestational age was 34 weeks or later, and if she had allergies or a history of sensitivity.

When uncertain about a pregnant woman's eligibility, 73.9 percent (n=46) of HWs said they would not give SP, primarily because they were worried that it might harm the mother or the baby. Over 90 percent (n=46) of HWs stated that SP should be administered twice to a woman who is HIV negative. Other responses included that a pregnant woman should receive one dose of SP and another respondent said the pregnant woman should receive three doses of SP.

Application of Directly Observed Therapy (DOT)

All respondents were aware of the use of DOT for provision of SP. Key details relevant to DOT administration are noted in Table 4. Ninety one percent (n=46) of HWs stated they always or mostly use DOT to administer IPTp. Ninety five percent (n=43) stated that water was always or mostly available for DOT.

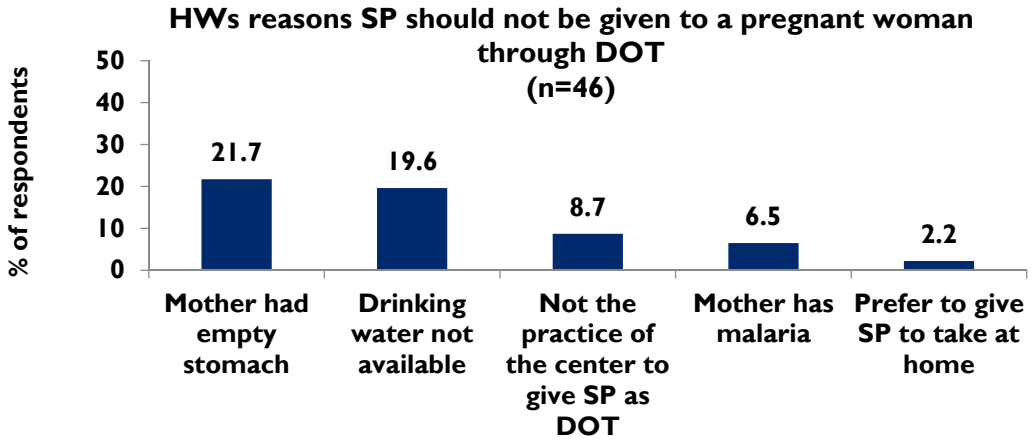
When asked about water sources and the distance needed to travel to collect water, HWs responded that boreholes were the most frequent (93.0%, n=43), followed by water stored in tanks (harvested rain water) (2.3%, n=43), piped water (2.3%, n=43), and a lake (2.3%, n=43). In the dry season, additional supplies needed to be bought in containers ('jerry cans'). Thirty three percent (n=43) of HWs reported that the water source was within the facility compound, while 67 percent (n=43) indicated that HWs needed to travel at least one kilometer to collect water. Ninety seven percent of respondents (n=40) said that drinking cups were always or mostly available for DOT.

Table 5

HWs' knowledge, attitudes, and practices related to DOT	
Key variables of interest	**Total**
Usage of DOT	**(n=46)**
Always used DOT for IPTp	32 (69.6%)
Mostly used DOT	10 (21.7%)
Did not or rarely used DOT	4 (8.7%)
Practices associated with DOT	**(n=43)**
The same health worker (physician, nurse, midwife) who examined and provided care to the woman, administered SP through DOT	25 (58.1%)
A different health worker, other than the person who examined and provided care to the woman, administered SP through DOT*	14 (32.6%)
Availability of water for DOT	**(n=43)**
Water always available for DOT	35 (81.4%)
Water mostly available for DOT	6 (14.0%)
Water mostly **not** available for DOT	2 (4.6%)
Availability of cups for DOT	**(n=41)**
Always available	36 (87.8%)
Mostly available	4 (9.8%)
**Includes "Other" responses, which include three responses of "mentor mother"*	

HWs were asked when they would not give SP as DOT. Major reasons for not providing SP through DOT included when the women had an empty stomach (21.7%, n=46), and when drinking water was not available (19.6%, n=46) (see Figure 3).

Figure 3



Health education on malaria prevention given to mothers during antenatal care

Health education is provided during the client provider interaction and through group sessions while waiting to be attended by HWs. Box 5 summarizes the HWs perspective on key topics covered during health education sessions. The importance of using ITNs and taking SP was most commonly reported for individual interactions (97.8%, n=46) while this was mentioned in 30.4 percent of instances for group sessions. The protective effects of SP was the second most frequent health education topic for individual interactions and the most frequent topic for group sessions.

In less than 50 percent of instances, the topics of taking SP after three months of pregnancy and taking the recommended number of doses SP were addressed in individual interactions and group sessions.

More than half of the respondents were aware that CTX is protective against MIP (56.5%, n=46) and informed HIV positive pregnant women of its protective effects.

Box 5: Health education provided to pregnant women

Advice given to women through individual sessions (n=46):

- Recommend the use of ITNs and to take SP (97.8%)
- Inform women about the protective effects of IPTp (50.0%)
- Make four ANC visits (41.3%)
- Take SP only after completing 3 months of pregnancy (37.0%)
- Take the recommended number of doses of SP (32.6%)

Topics covered during group sessions (n=46):

- Protective effects of IPTp (63.0%)
- Taking the recommended number of doses of SP and timing (monthly intervals) (46.0%)
- Commencing SP only after completing 3 months of pregnancy (37.0%)
- Use of ITNs and taking SP (30.4%)
- SP can be taken on an empty stomach (26.0%)

Advice given to HIV+ pregnant women during individual sessions (n=46):

- Inform women about the protective effects of CTX (56.5%)
- Inform women that CTX can be taken on an empty stomach (21.7%)
- Advise women on need to inform HWs about all the medications the pregnant woman is taking (17.4%)
- Advise women on taking ARVs and other aspects related to the HIV positive status (10.9%)
- Recommend appropriate care seeking for illnesses (4.3%)

HW perspectives on implementation challenges and suggestions to improve IPTp coverage

Factors identified by HWs that prevented eligible women from taking SP are noted in Box 6. When asked to identify steps/processes that could increase the IPTp uptake, counseling on the importance of IPTp in protecting the pregnant mother and the baby against malaria, additional capacity building for HWs and community mobilization and home visits were most frequently recommended.

Box 6: HW perspectives on implementation challenges and suggestions to improve IPTp coverage

Factors preventing eligible women from receiving 2nd or 3rd doses of SP (n=46):

- Coming in very late in pregnancy or only when in labor (93.5%)
- Mothers do not return for the ANC visits (67.4%)
- Other* (43.5%)

** Other response included distance/transport issues, fear of potential side effects of SP, absence of male escort*

HWs' ideas for improving IPTp coverage (n=46):

- Counseling session for mothers in the ANC including explaining the importance of SP in preventing malaria in pregnancy (78.3%)
- Capacity building of HWs including updating IPTp guidelines and follow-up supervision (69.6%)
- Community mobilization and home visits (47.8%)

Other findings

The study team was informed by HWs that in Uganda there is a very strong emphasis on male involvement to the extent that some centers will not see the woman unless accompanied by a male. Women who visit ANC clinic late during their pregnancy are believed to come in only to get documentation of at least one visit to avoid being scolded by the facility HW when they come in for the actual delivery. There was no user fee for ANC service provision among the facilities that were included in the assessment.

5.2.3 Practices of HWs ascertained through observation

At each facility, four individual interactions between the HW and pregnant women were observed during the antenatal clinic resulting in a total of 89 observations. Key actions observed are listed in Table 6.

Gestational age was mostly assessed through the manual palpation of fundal height (74.2%, n=89). SP was provided through DOT in 40.4 percent (n=89) of observed interactions. Cups for DOT were not available for 14.6 percent (n=89) of observed interactions while in 13.5 percent (n=89) of interactions cups were re-used without washing. Almost 45 percent of HWs (n=89) were observed documenting information in the health register during the encounter, while 25.8 percent documented information in the register after the encounter. Less than half (44.9%, n=89) documented information in the mother retained ANC card/notebook.

HWs gave advice to the pregnant women during and after the clinical assessment. Key topics and advice provided are outlined in Table 6. During the individual client provider observation, information on whether the HW asked the woman about her use of folic acid was captured. Only 7.8 percent (n=89) of women were asked if they were taking a high dose of folic acid and even fewer clients (4.5%, n=89) were asked by the HW if they were on folic acid at all. Only one client was asked what dose of folic acid she was taking. The main focus of client provider interactions in both districts was on advising when the women should return for the next visit. Messaging for IPTp was not consistently provided; the most common message provided was about the protection provided by SP for the prevention of MIP (46.1%, n=89).

Table 6

Key issues observed during client provider interaction	
Interaction/behavior observed	**Total (n=89)**
HW checked the antenatal card/notebook	87 (97.8%)

HW determined the eligibility of the mother to receive SP by:
• Assessing gestational age through
  o Manual palpation of fundal height
  o Calculation from LMP
• Asking the mother if she had
  o Completed the first 3 months of pregnancy
  o Experienced quickening
	
	66 (74.2%)
	36 (40.4%)
	
	10 (11.2%)
	2 (2.2%)

HW asked/checked if the women was HIV positive/took CTX	17 (19.1%)
HW asked if the woman was on high doses of folic acid	7 (7.9%)
DOT implemented	31 (34.8%)
No. of cups available for DOT • Zero • 1-3 • 4 or more	 13 (14.6%) 41 (46.1%) 25 (28.1%)
Reuse of unwashed cups	12 (13.5%)
HW documented information in the clinic register during encounter	40 (44.9%)
HW documented information in the clinic register after the encounter	23 (25.8%)
HW documented information in the mother-retained card/notebook	40 (44.9%)
Communication between HW and client	**Total (n=89)**
• Asked the client to return after one month	64 (71.9%)

• Provided advice but did not ask the client if she had any questions nor paused to give time for the client to respond	27 (30.3%)
• Was in a hurry to finish and move onto the next client	17 (19.1%)
• Specifically asked the pregnant woman if she had any questions	17 (19.1%)
• Provided some time for the client to ask questions	14 (15.7%)
Most common topics on which HW provided IPTp-related advice	**Total (n=89)**
• Protection provided by SP in the prevention of MIP	41 (46.1%)
• Safety of SP	15 (16.9%)
• SP can be taken on an empty stomach	5 (5.6%)

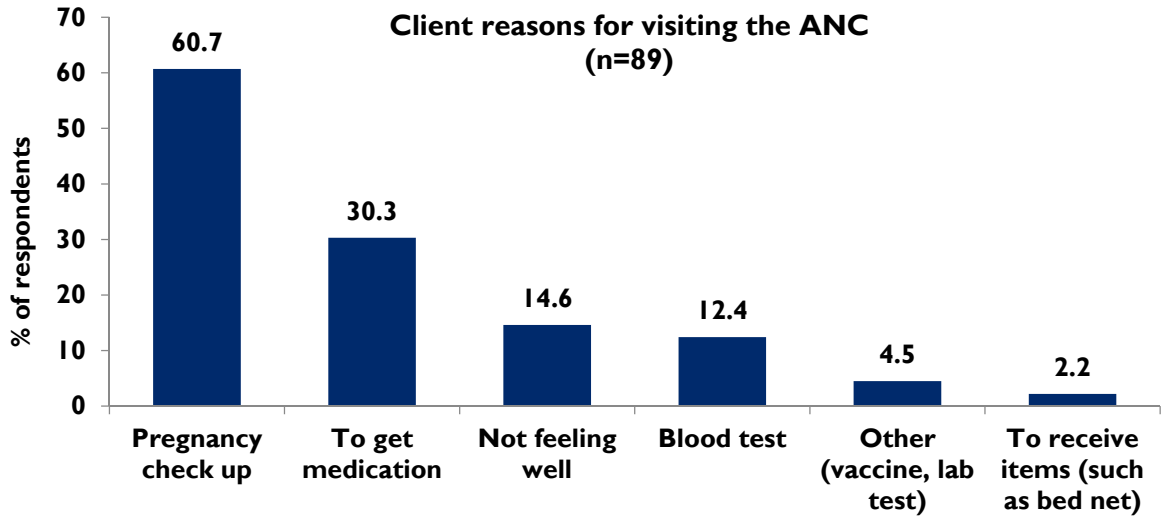
5.2.4 Client knowledge and experiences at the ANC

Exit interviews were conducted following ANC visits to determine the knowledge and experience of pregnant women. At each facility, four women were interviewed (except where fewer women came to the clinic). It was not feasible to consistently interview women who had been part of the observation of the HW/client interaction and, hence, attempts were not made to correlate findings between the two components of the survey. A total of 89 women agreed to participate in the assessment and were included in the exit interview.

Client perceptions of the purpose of ANC visits

Forty nine percent (n=89) of clients knew that they needed to come for four ANC visits. The reasons for attending ANC are noted in Figure 4, the most common being for a pregnancy checkup (60.7%, n=89).

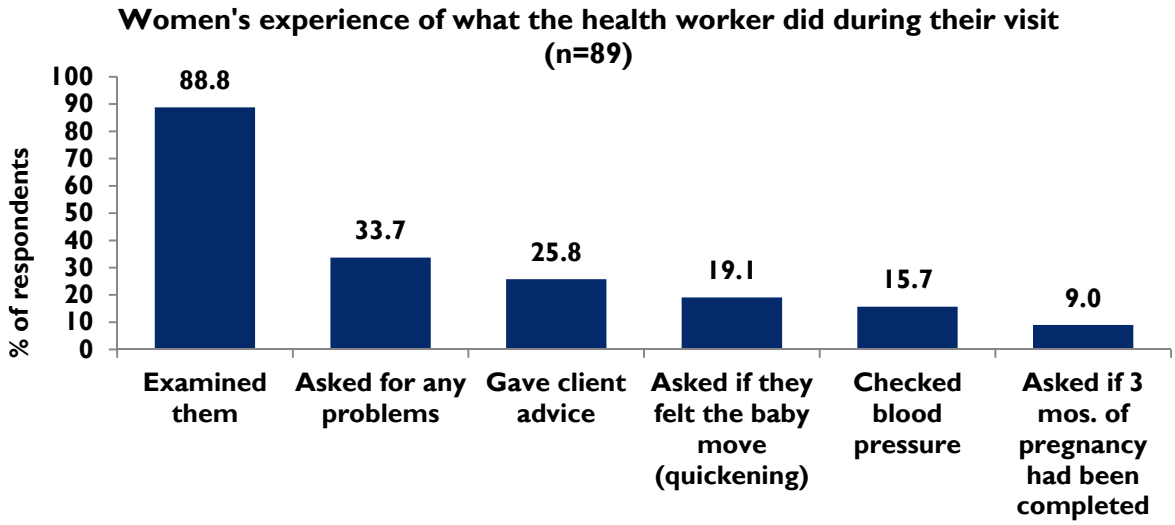
Figure 4



Client perception of what HWs do during the ANC visit

Women's experience of what HWs did during ANC visits are noted in Figure 5. Most often (88.8%, n=89), the women indicated that they had been examined and asked if they had any problems (33.7%, n=89). In contrast, few women reported having been asked whether they had felt the baby move (19.1%, n=89) or if she had completed three months of the pregnancy (9.0%, n=89).

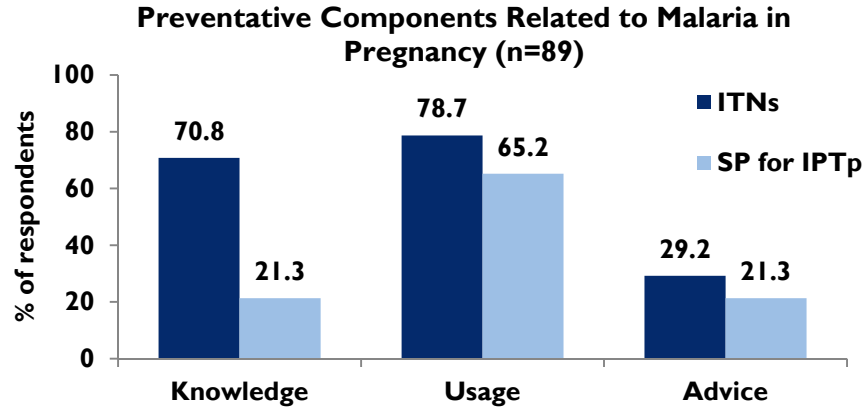
Figure 5



Using ITNs and IPTp to prevent MIP: women's knowledge, practices and advice received during the visit

Figure 6 compares women's knowledge on the use of ITNs and IPTp with described practice and advice received during the visit. More women were aware of (70.8%, n=89) and actually used ITNs (78.7%, n=89) than SP for IPTp (aware 21.3%, used 65.2%, n=89). Twenty nine percent of women reported that they received advice on ITNs and 21.3 percent reported receipt of advice on SP use. Among the pregnant women interviewed (n=89), 65.2 percent had received SP during that pregnancy. Close to half had received one dose of SP during the pregnancy and 12.4 percent received two doses of SP.

Figure 6



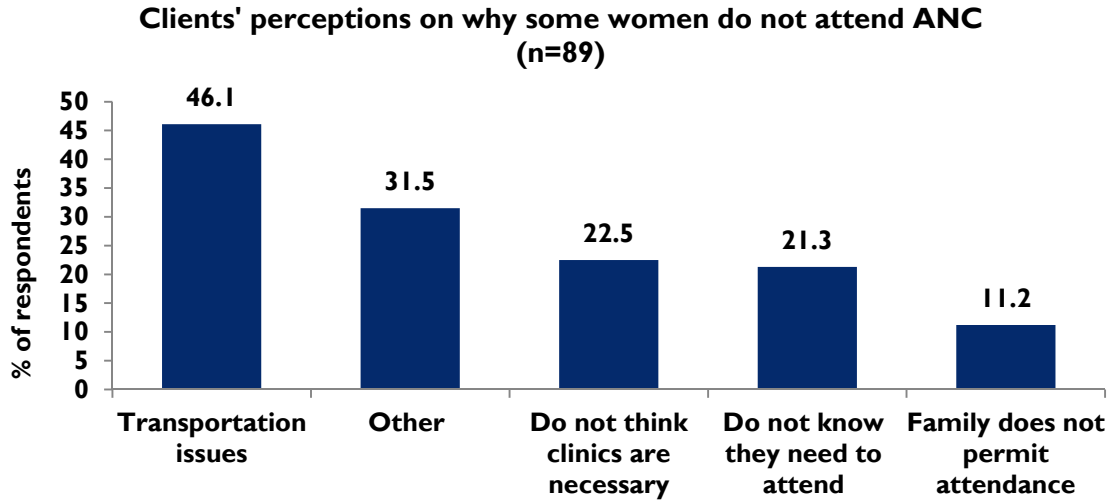
Timing of initiation of IPTp

Related to the women's understanding of the timing of IPTp initiation, 25.8 percent (n=89) said SP should be given as soon as possible and 21.3 percent (n=89) said SP should be given whenever she visited the ANC and 21.3 percent (n=89) after three months of pregnancy. Ten percent (n=89) said SP should be given during the first three months of pregnancy. There was also variation among clients' knowledge of how many times a woman should receive SP during pregnancy. The three most frequent responses among clients interviewed were "I don't know" (27.0%, n=89), the woman should receive two doses (21.3%, n=89) and the woman should receive three doses (13.5%, n=89).

Client perception of reasons why women do not attend ANC

Figure 7 notes reasons why some women do not attend ANC, as reported during client exit interviews. Distance to the facility and challenges with transport (46.1%, n=89), and women or their families don't think it is necessary to attend ANC (22.5%, n=89) constituted the most common answers.

Figure 7



Other includes: fear of finding out HIV status (four responses), they're not sick (five responses) and health workers are strict on persons coming without spouses" "They cannot work on you if you don't come with your spouse" (four responses), Six persons responded that they don't know why some women do not attend ANC and two women responded that fear of medication is a barrier to ANC attendance.

Receiving advice and asking questions during the client provider interaction

Women acknowledged receiving advice on a number of subjects such as, among others, preparation for the delivery, diet, additional rest and prevention of MIP. During exit interviews, they were asked if they had posed any questions to the HW. Only 16 mothers responded. Among the respondents, 12.5 percent (n=16) said they asked questions, one on contraception and the other about a problem she had. Both indicated that they had been satisfied with the answers they had received.

Availability and use of ANC card/notebooks

ANC clients usually carry an ANC card/booklet such as the Mother Baby Passport. In addition to the characteristics of the woman and points relevant to care during pregnancy, delivery and postnatal period, the booklet/passport retains other important information such as results of laboratory tests and some of the key services received such as doses of SP. During the visits to the facilities, it was observed that there was a shortage of these tools, in lieu of which ordinary notebooks were used for the same purpose. However, unlike the official mother-retained cards, the notebooks did not have the printed guidelines and title-designated spaces to fill in the necessary information/data.

5.2.5 HMIS review

Effective monitoring of quality improvement processes requires effective use of data. Bearing this in mind, the study extracted data from ANC registers (Uganda HMIS Form # 071) with the objective of determining whether the ANC register could provide a source of data for monitoring quality improvement interventions.

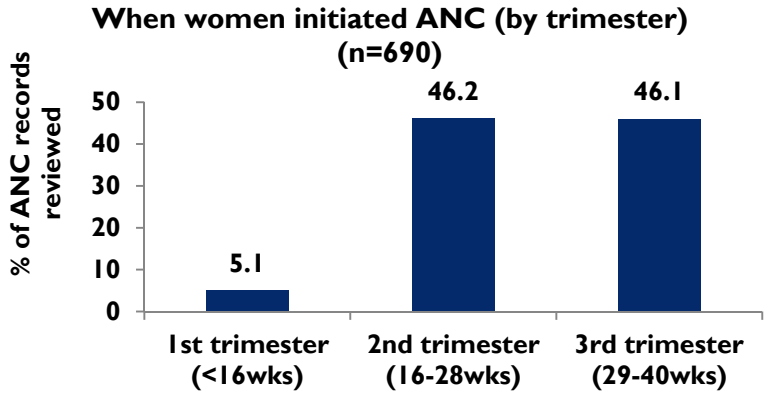
Public health facilities in Uganda collect data used for monitoring services, particularly ANC, utilizing various national HMIS forms, including: HMIS Form 020, HMIS Form 071, HMIS Form 105, Table 2b, Table 15 and Table 106B. A key finding was that not all health facilities had these HMIS forms. Regarding targets, in one district, the DHO informed the study team that health centers had to set their own targets again based on guidance provided for its calculation. During facility visits, it was observed that few of the participating health centers had set their targets, and in some instances, targets were set based on numbers and not percentages or proportions.

In all the centers visited, select cross sectional data were collected. Data from the available integrated antenatal register, for up to a maximum of 30 ANC attendees on the day the study team visited the facility, were extracted and analyzed. Data on which ANC visit (1st, 2nd, 3rd or 4th), gestational age, IPTp dose received and confirmation of taking CTX, were collected. A total of 690 records were analyzed. The key findings are noted below.

Timing of ANC initiation

Based on the WHO definitions of three trimesters during pregnancy[16] and according to the records reviewed, 92.3 percent (n=690) of the women first accessed ANC during their 2nd trimester (46.2%) or 3rd trimester (46.1%). The records also highlight that 5.1 percent (n=690) of the women first accessed ANC during their 1st trimester, as indicated in Figure 8.

Figure 8

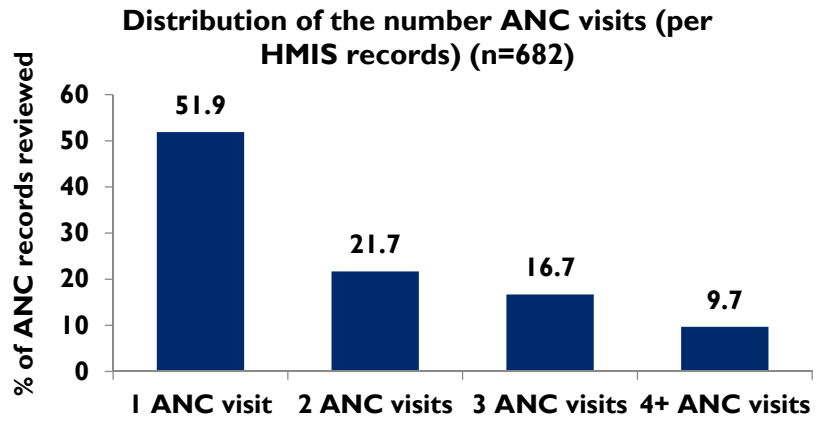


Number of ANC visits per woman

Figure 9 indicates the distribution of ANC visits during pregnancy. Slightly over half (51.9%) completed least one ANC visit and less than ten percent (9.7%) had completed four or more ANC visits.

[16] World Health Organization, 2006. *Integrated Management of Pregnancy in Childbirth (IMPAC) Pregnancy, Childbirth, Postpartum and Newborn Care: A guide for essential practice.* [online] Available at: http://www.who.int/maternal_child_adolescent/documents/924159084x/en/.

Figure 9



Distribution of ANC visits

According to WHO's approach to Focused Antenatal Care (FANC), four antenatal visits are recommended: at 8-12 weeks, 24-26 weeks, 32 weeks, and 36–38 weeks during the pregnancy. The assessment found that mean gestational age at first ANC visit took place at 24.7 weeks and the fourth visit, at 34.4 weeks.

Coverage of IPTp1, IPTp2, and IPTp3

The coverage of the first dose of IPTp was 47.0 percent, coverage for the second dose of IPTp was 19.9 percent, and 21.5 percent received a third dose of IPTp (n=675).

Missed opportunities, untimely administration of IPTp, and joint administration of SP and CTX

Needless administration of SP was determined by noting women who received SP in the first trimester and those who received SP even when they were on CTX. Ninety seven percent (n=33) who initiated ANC in the first trimester received SP. Among all of the extracted records (n=690), it was observed that 3.5 percent received both SP and CTX. Among the respondents, 3.5 percent (n=690) women received CTX.

6. FINDINGS AND RECOMMENDATIONS

This assessment was undertaken to determine facility-based factors that influence the coverage of IPTp among pregnant women. The purpose was to design a QI tool that will enable providers and facility managers to track facility-level trends, identify and address service delivery bottlenecks and incorporate QI and/or PI strategies on an ongoing basis. The assessment tools successfully identified key issues requiring attention.

It is unlikely that a single intervention will bring about increased IPTp coverage and an approach is required that will address the variety of issues that impact IPTp service delivery. The assessment indicates that input support is required for aspects such as the distribution of guidelines and job aids and the provision of in-service training to providers on the updated IPTp guidelines developed by WHO and accepted by the NMCP. Input support in itself is not sufficient to increase IPTp coverage – assisting facility managers and providers to understand the programmatic requirements can contribute towards improved service delivery. A draft tool/checklist is attached and highlights the issues that facility

managers and service providers need to review on a regular basis to ensure optimal service delivery for IPTp.

Key findings and recommendations are highlighted below. These are based on findings from the assessment and are focused on issues that require attention largely from the district and facility levels. A "hands on" approach with high levels of attention to detail could bring substantial improvements in coverage.

6.1 CAPACITY BUILDING FOR IMPROVED IPTp SERVICE DELIVERY

Findings

HW knowledge about the application of IPTp to prevent MIP is generally good. HWs are clear about the efficacy, dosage, eligibility, timing of initiation and use of DOT when providing SP. Knowledge gaps are nuanced as demonstrated by the misconception in about one in five respondents that SP should not be provided on an empty stomach and limited provision of key messages about IPTp during client provider interactions.

There is lack of awareness about new WHO Guidelines for IPTp at the district and sub-district levels although accepted at the national level. The survey indicated that updates and training for IPTp did not occur during the year prior to the survey. Existing national guidelines are not available in most of the centers. HWs specifically expressed a desire to be updated on IPTp implementation. There is an absence of job aids on IPTp to support HWs during service delivery.

Recommendations

- Disseminate national guidelines along with updated information based on new WHO guidelines to district and sub-district levels.
- Organize updates for district and health center staff on a comprehensive/holistic plan to improve implementation including all the key components, both technical and management.
- Take advantage of existing systems such as Performance Improvement Meetings to introduce updates.
- Provide and disseminate user-friendly job-aids and checklists to promote correct application and usage of IPTp guidelines. Ensure that the job aids are visibly posted or easily available to staff.

6.2 SUPERVISION

Findings

Two types of supervision occur in the surveyed facilities. An external supervision mechanism exists whereby DHO staff supervise and mentor HWs. Findings from the assessment indicate that the quality and regularity of supervision is not optimal. Challenges include lack of motivation, financial constraints and difficulties in covering the large number of technical areas addressed through the integrated supervisory approach.

There are encouraging signs that internal supervision conducted by OICs occurs on a fairly regular basis, although the areas covered and quality can definitely be improved. There are also regular staff meetings at the facility level. IPTp appears not to be adequately addressed during supervision activities or regular meetings. This is demonstrated by the findings that most supervisors had to be prompted to indicate the focus of supervision and the items for discussion during meetings.

Recommendations

- Strengthen OIC capacity to effectively support IPTp and implementation. This requires orientation of the key aspects of IPTp service delivery and developing their ability to guide data analysis to interpret coverage trends for IPTp. Assist the OICs to incorporate key aspects of IPTp into regular meetings that occur at facilities.
- Link QI approaches such as Plan Do Study Act cycles supported by appropriate checklists and analytic methods (see attached materials as Annex 2) to internal supervision approaches. The focus of checklists and analytic methods should be on the specifics of IPTp service delivery – for instance strengthening the quality of DOT, the quality of the client provider interaction and ensuring accuracy of data recording and management.
- Strengthen the District Health Team to provide appropriate, continued supervision to the health center staff and increase capacity for effective internal supervision. This requires joint collaboration between MOH's Family Health Division and NMCP, to enhance joint programming, capacity building and supportive supervision at the district- and facility-levels.

6.3 MESSAGING FOR IPTp

Findings

Several elements of messaging around IPTp need to be addressed. These include messaging that occurs during the client-provider interaction, the delivery of messages in waiting areas prior to seeing HWs, and at the community level. HWs reported a large number of components on which advice was given to women. Observation during ANC consultations, however, showed that while HWs gave advice on fewer topics, they were frequently rushed and in a hurry to deal with all the waiting clients. Very few women attempted to ask questions. There was a paucity of visual materials promoting prevention of MIP, notably on IPTp. The components and quality of IPTp messaging during group health education sessions were not studied. Far more pregnant women knew about use of ITNs than SP for IPTp. About half of the facilities reported that they were involved in community based activities such as community mobilization and promotion of ANC visits. Outreach services and home visits were not common in assessed districts.

Recommendations

- Utilize the period of waiting in the ANC for health education sessions of the 'captive' audience. Ensure that content of messaging is clear with relevant content, delivery is supported by posters and relevant job aids and that delivery is provided to all mothers and partners in waiting areas. Less skilled HWs, including community HWs with effective training, can convey the key messages to the women.
- Promote effective communication between providers and clients during one-on-one sessions. Ensure that providers are able to communicate appropriate content and messaging to mothers.
- Incorporate appropriate messaging for IPTp in community outreach activities and those delivered through Village Health Teams.
- Male involvement is strongly promoted by GoU. Instances were reported when pregnant women were turned away by HWs as they were not accompanied by their spouse or partner. This is due to misperceptions of HWs that the spouse or partner always needs to accompany the pregnant woman when attending ANC. These misperceptions need to be addressed.

6.4 DATA MANAGEMENT

Findings

A large number of forms are available as noted in the HMIS training manual with clear instructions for their use. Many health centers did not have the required forms including mother retained ANC cards. Centers did not set targets that were necessary to calculate proportions /percentages for data to be able to document how far they had come to achieving their set goals so as to plan necessary interventions. There was no obvious review of data and internal discussions for improvement based on the findings. Despite the absence of data related to ANC and IPTp coverage in some centers, consolidated data related to these indicators were available at the DHO. Data collection is not consistent as demonstrated by the observation component of the survey where HWs did not always enter data into the ANC registers nor into the mother retained records.

Recommendations

- Implement training and mentoring of staff at the DHO and health centers on the management of the forms, data collection, setting targets, review of data, onward transmission and feedback from district and national levels.
- The DHO should play an important facilitatory role in supporting centers to set and monitor targets.
- The DHO should work with facility staff to ensure that all relevant data is collected and sent from the facility to the DHO.

6.5 IMPLEMENTATION OF DOT

Findings

Despite a strong understanding by HWs about the use and value of DOT there is evidence that DOT implementation is hamstrung by factors such as an inadequate supply of water, lack of equipment such as cups, unhygienic practices, and the quality of messaging provided to mothers and clients.

Recommendations

- Provide guidance to DHOs to support the officers in charge of health center including a more careful supervision to ensure routine and safe administration of DOT.

6.6 SUPPLY CHAIN FOR DOT

Findings

Most of the centers did not experience stock-out during the last year. National supportive strategies can be used by centers in need to obtain medication from nearby centers with adequate/excess stock to avoid stock-outs. Two centers, however, did experience stock-outs despite the above support mechanisms. Even in some of the centers, even when no stock-outs were reported over the year, examination of the stock-cards did document a "zero stock" at some points with varying gaps before the net lot was received. This was because medication was still available at the service delivery points at these centers.

Recommendations

- Disseminate information, guidance and reminders to all centers regarding available support mechanisms to plan ahead, order adequate medication to maintain a 'minimum balance' in the stock cards. Maintain records both in the stores and at service delivery sites in order to monitor drug availability and take timely, appropriate actions in order to avoid stock-outs. These elements should also be included in the capacity building process noted above.

6.7 FINAL COMMENTS

- IPTp is an integral part of a larger and more comprehensive package of MIP interventions. District and facility-level decision makers need to consider to what extent an integrated approach is followed with focus on the use of ITNs and case management in pregnant women when addressing the IPTp issue.
- The findings did highlight a limited understanding by providers about programmatic responsibility for the implementation of the IPTp program. A higher level discussion is required to clarify relationships between the NMCP and RMNCH Programs and to ensure that facility managers and providers are clear about responsibility for implementation.
- HMIS data was extracted with the purpose to determine to what extent it can be used to facilitate monitoring of interventions that may be implemented through the QI process. This will be addressed through the development of the QI tool. The data is not optimal to make comments about IPTp coverage although it does suggest that there is low attendance during the first trimester of pregnancy, that the first ANC visit occurs fairly late during pregnancy and that a low proportion of women complete four ANC visits. These aspects ultimately impact on IPTp coverage and will require an alternative set of interventions with the objective of earlier and more frequent ANC attendance. Current activities in the areas of vouchers and community-based health insurance represent interesting opportunities in Uganda.

ANNEX A. METHODOLOGY

Overview

This study is formative research, primarily focusing on the issues that affect provision of Intermittent Preventive treatment for malaria in pregnancy (IPTp) in antenatal care (ANC) services, at the facility level.

The study will examine inputs, processes and access to services in each of the target service areas with regard to their influence on provision of IPTp service delivery in a health facility. The assessment broadly examines the human resources for health, infrastructure, available services, drugs, logistics and supplies, equipment, records, reference documents, training & supervision and health worker practices during ANC service delivery. The tools are designed to assess IPTp services of health facilities at the level of Health Centre II, III, IV and the general hospitals in two districts (Buyende and Kaberamaido) in the Eastern Region of Uganda.

The findings of this study will inform the development of a quality assurance tool, which would greatly contribute to the improvement of these services and overall programme. As such, its design is a "one shot case study" using standard health facility assessment tools that include:

1. Antenatal Care Worker interview questionnaire
2. Officer-in-Charge interview questionnaire
3. Antenatal clinical observation guide
4. Antenatal client exit interview questionnaire
5. DHIS2 (district level) and HMIS record (facility level) review guides

In this study, both primary and secondary quantitative data will be gathered from the district health offices (DHO), select health facilities and hospitals, which provide antenatal care and IPTp services, in Buyende and Kaberamaido Districts. Select health facility staff will be observed and interviewed while a sample of clients will be interviewed in the facility-setting. Select District Health Officials will be interviewed to gain their perspective on facility-level challenges.

After completion of preparations and necessary approvals obtained, the activity is anticipated to commence in October 2014 and will take an estimated 1 month to complete (from training of field team to completion of data collection). The study will occur in the selected areas, subsequently, being conducted in one district followed by the other district.

Study Area, Sampling, Research Design

A two-stage sampling approach will be used selecting: districts and health facilities. The basic sampling unit, however, is the facility (Health Center and District-level Hospital).

Sampling Districts

Among the 7 regions in Uganda, 3 regions (Central, Eastern and Western) were selected to be included in the sampling frame.

Out of these 3 regions, 112 districts were initially included in the sampling frame for specific district selection. Management Sciences for Health (MSH) implementing the STRIDES for Family Health Project in Uganda and the interventions are aimed to address antennal care and intermittent preventive Treatment of malaria in pregnancy (IPTp) gaps, ensuring full functional service delivery system (FFSDS). Within the 3 regions, STRIDES activities in 15 districts (Bugiri, Fort Portal, Kalangala, Kamuli, Kamwenge, Kasese, Kayunga, Kumi, Kyenjojo, Luwero, Mayuge Mityana, Mpigi, Nakasongola and Sembabule Districts). It was felt that MSH should exclude districts in which it was working to avoid a conflict of interest and biased results. Therefore, a total of 97 districts were selected for inclusion into the sampling frame.

All 97 districts in the sampling frame were assigned numbers on ascending order from 1 to 97, and by running the computerized random number generator, Buyende (number 26) and Kaberamaido (number 39) were randomly selected as IPTp study districts.

From the 97 districts, specific districts for inclusion in the study were randomly selected, using the online random number generator at random.org through which the numbers 26 and 29 were generated at random. Counting from the top of a list of the 97 districts in the sampling frame from the 3 regions, Buyende District (26) and Kaberamaido Districts (39) in Eastern Region were selected as the districts for study implementation

Sampling Facilities

After excluding facilities for the care of military and prison populations and non-public facilities, a total of 25 public health centers at levels II, III, and IV and one hospital have been selected from each of the two randomly-selected districts for this study. All public health facilities that offer ANC services are included as study sites in each district. The Health Facility Assessment (HFA) focuses on Intermittent Preventive treatment for malaria in pregnancy (IPTp) as one of the essential interventions in antenatal care (ANC) services in each health facility defined as study site. The assessment appraises inputs, processes and access to services in each of the target service areas with regard to their influence on quality of service delivery in a health facility. The following facilities have been selected for inclusion:

Sampling of Health Facility Staff

At the health facility level, 25 officers-in-charge, one at each health facility referred to as "study site", will be interviewed along with 1 to 4 Antenatal Care Health Workers (ANC HWs) from each facility, depending upon the number available for interview on the day of the survey. The health workers interviewed will represent a mix of the levels and cadre of staff serving as antenatal care workers in the facility, (e.g., registered midwife, clinical officer, enrolled midwife, registered nurse). If there is more than one ANC HW at the same level, one will be selected at random by using a random number table. Interviewer will assign number to each person, obtain the range, and then randomly select a number from the random number table. In smaller facilities where the officer-in-charge is also an ANC HW, he/she will be interviewed using both the interview instrument for the ANC HW and for the officer-in-charge.

Selection of the encounters to be observed will be done using methodology developed by MEASURE Evaluation[17] as follows:

[17] Turner, Anthony G., *et. al.,* **Sampling Manual for Facility Surveys,** MEASURE Evaluation Manual Series, No. 3, July 2001.

If fewer than four clients come to the facility for antenatal visits on the survey day, all Antenatal Care Worker-Client encounters will be observed, after obtaining informed consent. If more than four ANC HWs are on duty during the survey day, the observer will randomly select four ANC HWs for observation and observe one encounter with each of the four. The interviewer will assign numbers to each ANC HW, obtain a range, and then randomly select a number from the random number table provided. The selected represents the ANC HW to be observed during the client- provider encounter. The encounters observed will not be randomized; rather, the observer/interviewer will simply observe any encounter for each randomly-selected ANC HW. If three staff are on duty, the observer will observe one encounter for each and select one ANC HW at random for a second observation. If two staff are on duty, the observer will observe two encounters for each ANC HW, and if only one staff is on duty, the observer will observe four encounters with the one ANC HW.

Sampling Clients (ANC clients)

Exit Interviews will be conducted with four clients who will be selected by using the following methodology that was developed by MEASURE Evaluation:[18]

If fewer than four clients come to the facility for antenatal visits on the survey day, all who come will be interviewed after they have received services and consent is obtained, as they leave the health center. If more than four clients visit the facility on the survey day, a member of the survey team will obtain information on the total number of clients who visited the facility on the same day of the week during the last four weeks. He/she will then divide that number by four, to calculate the daily average. The result is again divided by four (the number of interviews to be done) to obtain the sampling interval for selecting clients for exit interviews.

For example, if the survey day is Tuesday and attendance at the last four antenatal clinics on Tuesday was 15, 20, 12, and 28, the average number of patients per day is calculated to be 18.75. The sampling interval for four exit interviews is then calculated to be 4 (18.75/4=4.69 – rounded back to 4). The interviewer will then interview the 4th client of the day and every fourth client thereafter until reaching a total of 4 clients. Therefore, the data collector will interview the 4th, 8th, 12th and 16th clients. The facility ANC data necessary for these calculations will be obtained by the facility assessment team leader, a day before the actual survey date to allow early computations. If possible, Information about the expected number of clients may also be obtained by telephone when the visit to the facility is scheduled.

Sampling District Health Officials

The most senior district health official responsible for supervising facility-based antenatal care services in each of the two districts will be interviewed, so as to capture data on district perspectives about IPTp services. The District Health Office is of interest given their lead role in coordinating the program strategic planning, implementation, monitoring and reporting of program successes, and therefore familiarity with the successes and challenges at the district level. One of their key responsibilities is to review data and therefore they are strategically placed to have "big picture" view of all facilities and trends in district.

[18] Turner, Anthony G., *et. al.,* **Sampling Manual for Facility Surveys,** MEASURE Evaluation Manual Series, No. 3, July 2001.

Summary of Sampling Approach

The two-stage sampling approach and selections are summarized in the following table:

Level	Activity	Survey population	Number	Total
District (2)*	DHO Focal point interview	District focal point	1 per district	2
	HMIS Review of district level data (DHIS2 & HMIS Annual Report)		1 per district	2
Facility (25)**	HMIS data review		1 per facility	25
	Officer in Charge interview	Officer in Charge	1 per facility	25
	ANC Health Worker interview	ANC Health Worker	1-4 per facility (The highest level cadre to be selected)	25-100
	ANC HW-client encounter	ANC Health Worker	1-4 per facility (Up to 4 per facility; selecting ANC HWs at random)	25-100
	Client exit interview	Client	4 per facility (Using an interval based on the average daily number of patients expected at the clinic on the survey day. In facilities with fewer than 4 clients observed, all will be interviewed.)	100
Anticipated total number of completed data forms				**204 - 354**

* Buyende and Kaberamaido Districts were selected at random using an online random number generator (Random.org) from a sampling frame consisting of all districts in Uganda, except for those in which MSH is working.

** All public health centers, levels II through IV and the district hospital will be included in the study, except for health centers for military and prison populations. These include 10 health centers in Buyende District and 14 health centers and the hospital in Kaberamaido District hospitals, for a total of 24 facilities, listed in Section 2.2.2. The "Health Center and District Hospital" comprise the basic unit for data collection.

Data Collection Tools

As listed in the overview, a total of six tools will be used to capture quantitative data, to answer the key questions of the survey. All the instruments are in English except the Client Exit interview questionnaire, which has been translated into select local languages (Ateso and Lusoga) to minimize any potential language barriers when communicating with clients who reside in these districts. The tools are described below:

1. **Officer-in-Charge questionnaire:** a semi-structured questionnaire that is aimed at capturing information, from the OIC's perspective, on overall management and provision of services in the health facility, specifically related to IPTp. Key areas of focus include: Staff Composition, Supervision, Supply Chain/Stock out, Policies, Guidelines and Standards, ANC Outreach

services, Community Interactions and Interventions. The tool consists of a total of 49 questions and will be administered in English by data collection team.

2. **Antenatal Care Worker questionnaire:** a semi-structured questionnaire that is aimed at capturing information, from the ANC Health Workers's perspective, on overall knowledge and practice regarding and provision of services in the health facility, specifically related to IPTp. Key areas of focus include: Knowledge of IPTp, ANC Services, Administration of SP/Fansidar, General Opinions, Capacity Building and Supervision. The tool is comprised of 55 questions and will be administered in English the data collection team.

3. **Clinical observation guide:** a tool that is aimed at guiding the field team in observations of service provision. The instrument will capture information from select variables and indicators from a total of 6 national HMIS forms, specifically: ANC Register, Monthly Maternal Health Attendance Summary form, Stock Book, Output Performance and Workplan Format, Reproductive Health Quarterly Assessment Report, Quarterly Indicator Summary. The guide will be administered by the data collection team.

4. **Antenatal client exit interview questionnaire:** a semi-structured questionnaire that is aimed at capturing information, from the client's perspective, on overall knowledge and practice regarding and provision of services in the health facility, specifically related to IPTp. Key areas of focus include: Background information, Access to services, Awareness about malaria prevention during pregnancy and ANC services received to date. The tool consists of a total of 21 questions and will be administered in English by the data collection team.

5. **HMIS record review guide:** a tool that is aimed at guiding the field team in extracting data from existing data sources to use for analysis to answer the key study questions. The instrument will capture information on 10 key variables based on the health care worker's demonstrated knowledge and ability to provide services.

6. **District Health Officer Questionnaire:** a semi-structured questionnaire that is aimed at capturing information, from the District Health focal points' perspective, about IPTp-focused aspects of the health program at the district level. Key areas of focus include: IPTp coverage, Capacity Building, Challenges and Possible Solutions. The tool consists of a total of 6 questions and will be administered in English by data collection team.

These instruments are included in the Appendix 1, including translations of the Antenatal Client Exit Interview into Lusoga for use in Buyende District and into Kuman and Ateso for use in Kaberamaido District.

Data Collection

This formative study broadly examines the human resources for health, infrastructure, available services, drugs, logistics and supplies, equipment records, reference documents, training & supervision, IEC materials and health worker practices during ANC/IPTp service delivery. The data collection tools are designed to assess IPTp services of health facilities at the level of Health Centre II, III, IV and the general hospitals in two districts (Buyende and Kaberamaido). Data are captured using the HFA tools (questionnaires and checklists) with pre-coded questions to enable transfer into an electronic database, systematic analysis and storage. The in-charge of the assessed health facility is briefed on interim findings before the data collection team leaves the facility. While at the health facility, the arrangement of a three person team during data collection may be as follows:

Interviewer 1: Officer-In-Charge interview & ANC Client exit interviews
Interviewer 2: Antenatal Care Health Worker interview& HMIS records review
Interviewer 3: Provider- client observation

Once the facility begins attending to pregnant mothers in an antenatal care clinic, the provider – client observation questionnaires should be prioritized first, as these are the most time-consuming. Often, exit interviews cannot begin immediately, so this time may be used to conduct Officer-In-Charge interviews. If the team has arrived early, it may be possible to complete the ANC worker interviews concurrently with in charge interviews, and then records/HMIS register reviews.

After completing all the questionnaires modules, the team should meet to review the work before leaving the facility. The team supervisor will check each interviewer's completed questionnaire to ensure completeness. Pay special attention to making certain that all questions are completed. The supervisor will then perform a final check of all of the questionnaires, organize them in order, and return them to their envelope together with the completed clients consent form. After facility level interviews, the data collection teams, then will visit the district health office, to conduct interviews with district health official in charge maternal and child health, as well as conducting records reviews of HMIS reports/DHIS2 data.

Interviews

The total number of interviews will not exceed 227 as detailed in the table below, but the number could be fewer if fewer than four health care workers are available on the survey day or if fewer than four antenatal clients come for services on the survey day.

Level	Activity	Survey population	Number	Total
District (2)*	DHO Focal point interview	District focal point	1 per district	2
Facility (25)**	Officer in Charge interview	Officer in Charge	1 per facility	25
	ANC Health Worker interview	ANC Health Worker	1-4 per facility (The highest level cadre to be selected)	25-100
	Client exit interview	Client	4 per facility (Using an interval based on the average daily number of patients expected at the clinic on the survey day. In facilities with fewer than 4 clients observed, all will be interviewed.)	100
Anticipated total number of interviews* **				**152 - 227**

Data Review

Facility level data review

Data will be extracted from facility records, which will allow researchers to determine:

- Missed opportunities – any pregnant woman coming to an assessed health center for antenatal care eligible for IPTp who did not receive it

- Inappropriate use of IPTp – any pregnant woman coming to an assessed health center for antenatal care who should not have received IPTp but who was given it anyway (dose too soon, HIV positive pregnant woman receiving cotrimoxazole, etc.)
- Factors that hinder the delivery of IPTp, which can be documented in the HMIS system, e.g. stock outs of SP.

Records will be reviewed and information extracted from the beginning of July 2013 to the last complete month before the survey day, although in a few cases records will be reviewed for another time period, as specified. For instance, if the survey day is March 15th, records will be reviewed through February as long as the data have been aggregated and the February monthly report has been completed. If the data have not yet been aggregated for February, records will be reviewed through January. The record review begins in July because the Ugandan government HMIS is set up to collect data for the Financial Year (i.e. fiscal year) that runs from July 1st through June 30th. Exceptions to these dates are noted in the description for each record.

The records to be reviewed include:

1. HMIS Form 071: Integrated Antenatal Register
2. HMIS Table 2b: Health Unit Monthly Maternal Health Attendance Summary
3. HMIS 083: Stock Book (HMIS Form 015 Stock Card could be used if the Stock Book is not available)
4. HMIS Form 020: Output Performance and Workplan Format
5. HMIS 106b: Health Unit Quarterly Indicator Summary
6. HMIS Table 15: Unit Quarterly Indicator Summary

In addition, the Mother and Baby Passport or antenatal care cards/books, carried by each pregnant mother, will be reviewed during Exit Interviews.

District level data review

At the district level, qualitative and quantitative data will be extracted from the malaria program reports, reviewing data from DHIS2 and HMIS quarterly, annual reports for consistence.

Study Duration

The duration of the study a total of 25 days, allocating one day per facility, and all data collection will take place over a period of no more than one month.

The table below specifies proposed time allocated for study activities:

Activity	# of days
Training	5
Pilot testing	1
Data Collection	16
Data Review	4
Data entry	7
Data Analysis	5
Report writing	7
Dissemination	**2**

Pre-survey Site visit

Staff from MSH Uganda will travel to Buyende and Kabermaido Districts to gather information necessary for planning the data collection phase of the activity, as well as to notify the relevant authorities about the upcoming activities. In addition, MSH Uganda will officially communicate with district officials about selection of two additional districts (Tororo and Bugiri Districts) where the tools would be pilot tested. Information collected during these visits includes days and hours of ANC services, estimated number of staff, and distance to the facility. Data on the number of ANC attendees in the previous four weeks will also be collected and used for calculating sampling intervals. The pre-survey visit information will be used to plan the schedule for the field team, based on distance between district headquarters and facility, and estimated duration of travel to the facility and completion of all components of the work.

Organization and Training of Field Teams

The facility-level assessments will be led by the Principal Investigator and will carried out by three teams comprised of one senior and two mid-level local consultants who will be hired at a later date. The Principal Investigator will be in the field to train the interview teams and provide support to team supervisors during the assessments.

The field teams will be recruited and convened for a five day training, which includes one day pilot testing of the data collection tools. The training will cover key aspects of data collection including an overview of the study, approach to data collection, informed consent and ethical issues related to data collection and management, schedule of field visits and review of the data collection tools. Based on pilot testing and observations in select sites in Bugiri and Tororo districts, the tools and data entry screens will be edited to be well suited for the context in which they would be applied.

The data collection process entails grouping data collectors/interviewers into teams of 3 people per health facility. The data collectors/interviewer will be recruited through the standard MSH human resources recruitment process. They must have clinical or nursing skills, with a technical understanding of the IPTp services being assessed. A three person teams will consists of a supervisor and two data collectors. While at the health facility, the arrangement of a three person team during data collection may be as follows:

Interviewer 1: Officer-In-Charge interview & ANC Client exit interviews
Interviewer 2: Antenatal Care Health Worker interview& HMIS records review
Interviewer 3: Provider- client observation

Field/Pilot testing of tools

The research team will be trained on the survey instruments and rapid health facility assessment techniques for 4 days and one day for pre-testing tools. The research team will report at the training venue a day before the training date to be able to prepare for the training. Pretesting of the survey instruments will be done in two districts, Tororo and Bugiri. Questionnaires that have been translated into Ateso will be pretested in health facilities in Tororo whereas Lusoga translation will be Bugiri district health facilities. During pretesting, research team will be divided into two groups. One group responsible for Buyende district will pretest the tools translated into Lusoga, in one health facility in Bugiri, and another group responsible for Kaberamaido district, will pretest the tool with translated into Ateso in Tororo district, visiting one facility in Mukuju or Mela in Tororo County. Tools will be tested in site s that have not been included to participate in the study, to minimize response bias. The permission will be sought from the District Health Officer (DHO) of respective pretest districts, prior to pretesting.

Data Processing and Analysis Plan

The data will be collected, reviewed and entered into a database on a daily basis. The study teams will be responsible for reviewing the data to ensure quality and flag any errors. Data will be entered into Epi Info (Version 3.5.4) data entry screens and entered data were reviewed periodically. Copies of the completed data sets will be sent to ASH for verification purposes. Once all queries areresolved, the data sets were prepared for analysis and the data were analyzed using SPSS (Version 22). Analysis of data will primarily be descriptive analyses, in addition to cross-tabulations of select results for each district. Data will not be reported in any way that will allow individual respondents to be identified.

Analysis of survey data

Data will be entered into an Excel spreadsheet and analysis will be done using a statistical package, such as SPSS. The data entry will include dropdown menus, which will reduce or eliminate data being entered outside the range of approved codes for each variable. In addition, data will be checked electronically to confirm that skip patterns were correctly observed.

Analysis of interview data will consist of tabulations of results for each type of facility, for each district, and for the total sample. Data will not be reported in any way that will allow individual respondents to be identified. In addition, cross tabulations will be done by district, level of health center, and some interviewee characteristics, such as job title (for staff), and education and HIV status (for clients).

Analysis of HMIS data/Secondary data

Data from the HMIS will be analyzed to answer the following questions:

- Missed opportunities – any pregnant woman coming to an assessed health center for antenatal care eligible for IPTp who did not receive it
- Inappropriate use of IPTp – any pregnant woman coming to an assessed health center for antenatal care who should not have received IPTp but who was given it.

Respondents and Ethical Considerations

Ethical clearance was obtained and received from Uganda National Council for Science and Technology (UNCST) approved the protocol on September 16, 2014 (UNCST approval Notice: SS 3609). Written approval was received January 12, 2015.

Informed Consent Process and Risks to Participants

The informed consent clauses vary by questionnaire and each is included in Appendix 1. Each addresses all elements of the informed consent process per Section 6.0 of the **National Guidelines for Involving Humans as Research Participants**[19].

- There is very little risk or discomfort associated with participation in the study. All participants will be interviewed in an area, slightly away from the health facility, in order to minimize their responses being heard by other staff or clients.

  For staff, this would provide an environment where they can share their opinions about the clinic reduce the chance that their opinions will be overheard by a senior member of the clinic staff who may have some power over the participant and could potentially make the work environment difficult for a participant. Responses will be aggregated, so there is little possibility that other workers may guess about a particular participant's response when the tabulated survey responses are later shared with the staff. Data that will allow an individual respondent to be identified will not be reported.

  For clients, there is also a small risk that clinic staff could overhear responses and treat the client differently, although every precaution will be taken to ensure auditory privacy. For all survey participants, they will be told that if they do not feel comfortable answering any question, that those questions will be skipped or the interview can be stopped at any time.

- There is only a one-time chance that any risk may occur, as this is a "one shot" study for formative research.
  - The steps we will take to avoid the risks identified include assuring privacy for interviews and observations, to the extent possible, and providing informed consent. Participants who fear being overheard or having their opinions guessed are free to not answer any question and are informed of this.
  - In addition, the study instruments for clients will not have identifiers recorded on the forms.
  - Thirdly, the tabulated data that will later be shared with ANC HWs and Officers-in-Charge will be aggregated such that individual respondents cannot be identified.
- The research burden for health workers is about 30 to 60 minutes for an interview, with the additional potential inconvenience of responding to requests of the study team (e.g., "Can you show me your patient registers?"). The time required to assess one facility is one day (estimated 8am – 4pm) or less.

- At the end of the day, data collection team will provide on spot feedback on key findings of the facility to health care workers and officers-in-charge who are interviewed, including district officials. Per Section 6.5.b of the National Guidelines for Research Involving Humans as Research Participants, however, provision of the results to those participating in exit interviews or the clients being observed during provider-client encounters is not considered to be

[19] Uganda National Council for Science and Technology 2007. National Guidelines for Involving Humans as Research Participants.

practical. An email address will be requested of clinic staff interviewed to facilitate sharing the results. The email address will be stored with the informed consent clause, separately from the responses to the questions.

Benefit to Study Participants

Participants are told that there is no direct benefit or cost for their participation in the study, but that they will be contributing to the improvement of future services and programs. There is no financial compensation for participation in the study.

The findings of this study will be shared with Antenatal Care Health Workers, Officers-In-Charge and district officials interviewed in this study, however. In addition, the tool being developed as a result of this research may be pilot tested in Uganda at a later time. Study clients and staff alike may benefit by improved access and decreased bottlenecks to IPTp services.

Participants and Withdrawal of Participants

All research will take place on one day at each facility; therefore, no procedures are necessary for withdrawal of participants from the study over time. Any refusal will be at the time of the informed consent process or during the interview. The informed consent process is described in detail at the beginning of each questionnaire in Appendix 1. As clearly stated in each informed consent clause, any participant can withdraw from the study at any time with no penalty or harm whatsoever.

If any staff selected for interview refuses to answer up to nine survey questions, data for those questions answered will be included in the dataset. A blank (i.e. missing data) will be recorded for those questions that were not answered. If any staff selected for interview refuses to participate, discontinues participation at any time, or asks to skip 10 or more questions, the next highest-level technical officer or ANC HW will be selected for interview and incomplete data will be shredded.

Provisions to Protect Confidentiality of Data

Each questionnaire will be labeled, using a unique format which does not contain names of respondents or the names of facilities. Any information which can be linked to the health center staff interviewed will be stored separately in a password-protected file or locked file drawer. Only the Principal Investigator will have access to the entire digital file or any paper files with identifying information. In order to provide further safeguards to clients, interviewed and observed, staff conducting the interviews will obtain a verbal consent but no written or signed informed consent clause will be obtained or stored. This is being done because clients may prefer not having their names recorded. This is consistent with IRB guidelines regarding the waiver of documentation of informed consent (Section 6.5).

Direct quotes from the interview, may be used in a report, but names of respondents participating in the study will not be included in the electronic dataset or in any report.

ANNEX B. DRAFT CHECKLIST AND GUIDELINES FOR OFFICER IN CHARGE

Draft IPTp CHECKLIST FOR FACILITY OFFICER IN CHARGE

		Y	N
	SERVICE PROVISION FOR IPTp		
	Service Availability		
	• ANC services are provided daily when the facility is open		
	Waiting area		
	Posted health education materials on IPTp		
	Health education discussions incorporates key messages		
	• Why SP/Fansidar is protective for mother and child		
	• Eligibility for IPTp (criteria for provision of IPTp)		
	• # Doses during pregnancy		
	• Need for supervised provision of IPTp/DOT		
	• Discusses use with ITNs		
	• Discusses protection against malaria in HIV infected		
	Consultation room (Observations)		
	HW assesses gestational age/ period since last dose of SP		
	HW assesses client for the HIV status		
	HW provides appropriate IPTp messaging to client		
	• Why SP/Fansidar is protective		
	• Eligibility for IPTp (criteria for provision of IPTp)		
	• # Doses during pregnancy		
	• Need for DOT		
	• Discusses use with ITN		
	• Discusses protection against malaria in HIV infected		
	HW records data in the ANC Register		
	HW records data in the ANC Card/ booklet		
	HW provides SP under direct supervision through DOT or describes where the client should proceed to receive supervised DOT		
	DOT is appropriately implemented; adequate supplies of water, sufficient mugs available and hygiene maintained		
	Client exit interviews		
	Confirm whether the client received SP today or was provided a reason why SP was not provided		
	Confirm whether mother knows when next dose of SP is due		
	Male involvement		
	• Male participation is encouraged		
	• Women who come to ANC without a partner are not turned away		
	MANAGING IPTp		
	Essential guidelines and job aids available		
	National Malaria guidelines available		
	Job aids posted in all consulting areas		
	Drug store		
	Confirm stocks on hand		
	Confirm stock card up to date		

	Community outreach		
	Outreach clinics occur for ANC; IPTp is provided and services incorporate messaging for IPTp		
	VHTs equipped to provide key messaging on IPTp		
	Data management		
	Essential HMIS supplies available		
	• ANC Register		
	• ANC Cards		
	Targets set and monitored (graphs or through regular feedback from officer responsible for HMIS)		
	Missed opportunity indicator tracked on a monthly basis		
	Facility meetings/ in-service training		
	• IPTp delivery and coverage discussed at staff meetings		
	• IPTp incorporated into in-service training programs and includes all staff engaged in service delivery to pregnant women		

Comments

Actions

GUIDELINES FOR USING THE OFFICER IN CHARGE IPTp CHECKLIST

	Intent/Purpose	**Information source**
Service Availability	Daily service availability facilitates access	Observation
Waiting area		
Posted health education materials	Pregnant women require information about the impact of malaria on the pregnant and the ways to prevent being infected with malaria	Observation
Health education discussions incorporates key IPTp messages	Pregnant women require information about the impact of malaria on the pregnant and the ways to prevent being infected with malaria	Direct observation of delivery of HE activities
Why SP/Fansidar is protective?		
Eligibility for IPTp (criteria for provision of IPTp)		
# Doses during pregnancy		
Need for DOT		
Use with ITN		
Protective against malaria in HIV infected		
Consultation room (Observations)		
HW assesses gestational age/ period since last dose of SP	Determine eligibility for SP provision for both initial and follow on doses. This may be done through variety of mechanisms – date of LMP, experience of quickening, use of gestational wheel, fundal height assessment	Questioning of client; examination of client; review of ANC card/ booklet
HW assesses client for the HIV status	HIV-infected women are preferably provided CTX; CTX is effective in the prevention of malaria	Questioning of client; review of ANC card/ booklet
HW provides appropriate IPTp messaging to client	Pregnant women require information about the impact of malaria on the pregnant and the ways to prevent being infected with malaria	Direct observation of health education
• Why SP/Fansidar is protective		
• Eligibility for IPTp (criteria for provision of IPTp)		
• # Doses during pregnancy		
• Need for DOT		

• Discusses use with ITN		
• Discusses protection against malaria in HIV infected		
HW records data in the ANC Register	Effective monitoring of IPTp implementation requires accurate and thorough collection of data	Register review
HW records data in the ANC Card/ booklet	As above	Review of ANC Cards
HW provides SP under direct supervision through DOT or describes where the client should proceed to receive supervised DOT	DOT is the preferred mechanism for the provision of SP	Observation
DOT is appropriately implemented; adequate supplies of water, sufficient mugs available and hygiene maintained	Clients are entitled to safe and hygienic practices when receiving SP	Observation
Client exit interviews		
Confirm whether the client received SP today or was provided a reason why SP was not provided	Means to confirm that the client has received adequate care and information	Conversation with client
Confirm whether mother knows when next dose of SP is due		
Male involvement		
• Male participation is encouraged		
• Women who come to ANC without a partner are not turned away	Ensure that women without a partner/spouse are not denied care	Observation, questioning of HW and client
MANAGING IPTp		
Essential guidelines and job aids available		
National Malaria guidelines available	Assists staff with service delivery	Observation
Job aids posted in all consulting areas	Facilitates quality of service provision	Observation
Drug store		
Confirm stocks on hand	Important to maintain close control on availability of supplies	Observation of available stocks
Confirm stock card up to date and entered quantities consistent with stock on shelves	Effective stock management is necessary to prevent stock outs	Review of stock cards
Community outreach		
Outreach clinics occur for ANC; IPTp is provided and services incorporate messaging for IPTp	Outreach services can play an important role in reaching out to hard to reach areas	Participate in outreach clinics. Confirm whether schedule for outreach clinics exists.
VHTs equipped to provide key messaging on IPTp	VHTs can play an important role in IEC for IPTp	Observe delivery of messages.

Data management		
Essential HMIS supplies available	Supplies are necessary for data capturing	Observe that facility has required stocks
• ANC Register		
• ANC Cards		
• Monthly and annual reporting formats		
Targets set and monitored (graphs or through regular feedback from officer responsible for HMIS)	Indicator driven approach is essential for effective monitoring	Confirm that graphs/ reports exist and are up to date
Missed opportunity indicator tracked on a monthly basis	Key indicator that can provide insight into service quality	Observe trends
Facility meetings/ in-service training		
• IPTp delivery and coverage discussed at staff meetings	Mechanism to engage staff to discuss challenges and suggest solutions for increasing or maintaining iPTp coverage	Meeting reports; discussion with staff
• IPTp incorporated into in-service training programs and includes all staff engaged in service delivery to pregnant women	All staff involved in IPTp service delivery should have required knowledge about IPTp	Review in-service training reports

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