USAID | DELIVER PROJECT

Treatment Uptake and Availability of Antimalarial Drugs for Intermittent Preventative Treatment in Pregnant Women in Malawi

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Treatment Uptake and Availability of Antimalarial Drugs for Intermittent Preventative Treatment in Pregnant Women in Malawi

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USAID | DELIVER PROJECT, Task Order 7
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Abstract
The USAID | DELIVER PROJECT Task Order Malaria analyzed the relationship between coverage of sulfadoxine-pyrimethamine for intermittent preventative treatment of malaria in pregnant women with the sulfadoxine-pyrimethamine stockout rates in Malawi for the same period. This analysis was performed to explore the relationship between stock availability and intervention coverage.

Cover photo: Zambia, Illustration at health facility.

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Acronyms

ACT	artemisinin-based combination therapy
ANC	antenatal care
ART	antiretroviral therapy
DFID	Department for International Development (U.K.)
DHS	Demographic and Health Survey
HIV	human immunodeficiency virus
IPTp	intermittent preventative treatment in pregnancy
KfW	German Development Bank
LMIS	logistics management information system
MICS	Multiple Indictor Cluster Survey
MiP	malaria in pregnancy
MIS	Malaria Indicator Survey
SCMgr	Supply Chain Manager
SP	sulphadoxine-pyrimethamine
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WHO	World Health Organization

Acknowledgments

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Executive Summary

Throughout Africa, 30 million pregnant women are exposed to malaria each year (WHO 2003). Malaria in pregnancy (MiP) carries increased risk of low birthweight, severe maternal anemia, maternal mortality, miscarriage, premature delivery, and stillbirth (Schantz-Dunn and Nour 2009; Murphy and Breman 2001). To address this challenge, the Roll Back Malaria Consortium advocates a three-pronged approach delivered through the antenatal care (ANC) model. This approach includes distribution of long-lasting insecticide-treated nets and promotion of their correct and consistent usage; delivery of intermittent preventive treatment in pregnancy (IPTp) with sulphadoxine-pyrimethamine (SP); and implementation of malaria case management to ensure prompt and effective diagnosis and treatment (Roll Back Malaria, n.d.).

While prevention of MiP is a key focus of global malaria interventions, trends in the use of SP to prevent malaria during pregnancy have largely stagnated or declined in sub-Saharan Africa. Poor product availability and stockouts are listed in multiple studies as barriers to IPTp service delivery (Mbonye, 2013) (Exavery A, 2014) (Pell C, 2011). Yet despite these studies citing SP product availability at health facilities as a barrier to improving IPTp coverage, there remains a lack of quantitative analysis on the impact of SP availability on IPTp coverage.

To address the gap in current research, this analysis explores the relationship between SP product availability and IPTp uptake among pregnant women. This relationship is explored by examining trends between SP availability using logistics data and ANC service statistics and household survey data on IPTp coverage in Malawi. Based on a background literature review and USAID|DELIVER PROJECT knowledge, we hypothesize a correlation between IPTp uptake and SP availability at the health facility level. We test this hypothesis by considering individual, cultural, and health system factors, with a focus on the supply chain, that may affect a woman's choice to access and use SP in Malawi. We then analyze three complementary data sources: SP availability at heath facilities using the country's logistics management information system (LMIS); SP uptake at health facilities using ANC service statistics; and IPTp coverage of pregnant women as reported in household surveys.

Quantitative and qualitative data, along with contextual knowledge, support the hypothesis of a correlation between SP availability at the facility level and IPTp uptake. Malawi's health services data show that despite strong IPTp coverage as reported in household surveys, trends from one quarter to the next demonstrate a vulnerability to fluctuations in product availability. Health service data show a low coverage of 28 percent of eligible pregnant women receiving any SP in early 2012; this occurred after months of ongoing stockouts and just after the essential medicines kits program began. The peak coverage of 70 percent of pregnant women receiving any SP is more than double the uptake of the lowest point. These health service data correspond with the LMIS data, which show peaks in SP stockouts in 2011 and early 2012, followed by the lowest levels of stockouts in late 2012 and throughout 2013. While reporting rates for SP are relatively low, our analysis suggests that LMIS SP reporting challenges are nationwide, with data missing from facilities and districts throughout the country.

Factors contributing to stockouts must be addressed to sustain any gains made in IPTp coverage.

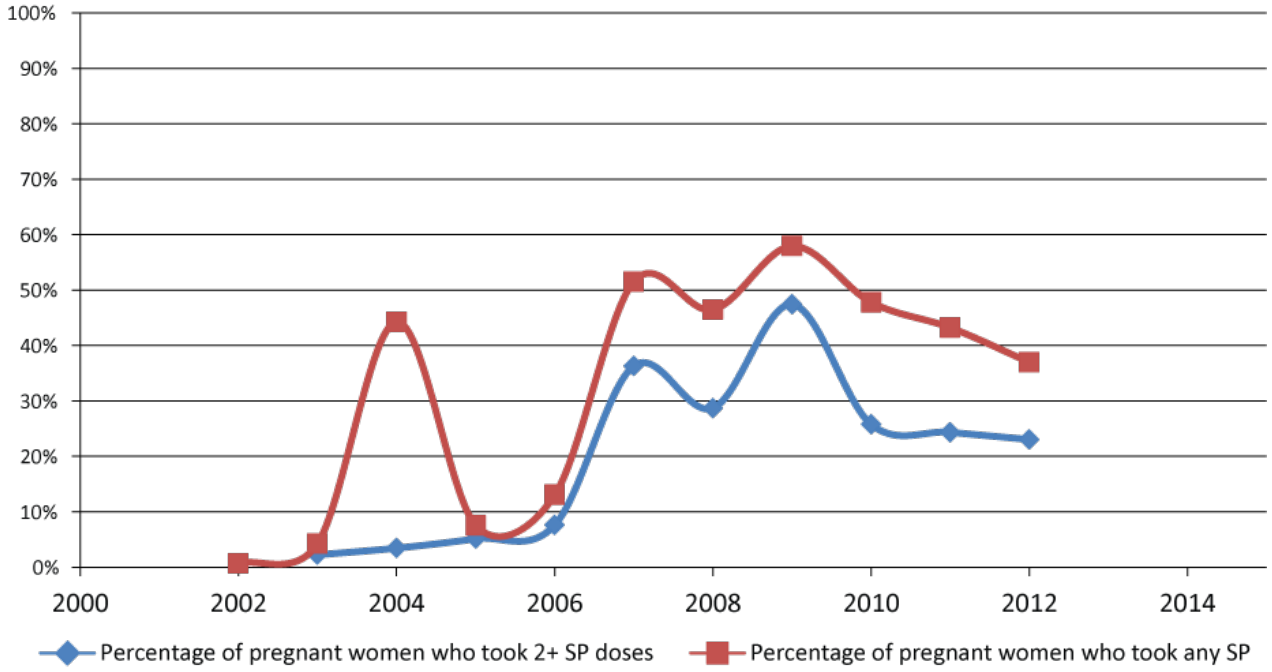
Introduction

Throughout Africa, 30 million pregnant women are exposed to malaria each year (WHO 2003). Malaria in pregnancy (MiP) carries increased risk of low birthweight, severe maternal anemia, maternal mortality, miscarriage, premature delivery, and stillbirth (Schantz-Dunn and Nour 2009; Murphy and Breman 2001).

The Roll Back Malaria Consortium has proposed fighting MiP through a three-pronged approach delivered through the antenatal care (ANC) model. This approach includes distribution of long-lasting insecticide-treated nets and promotion of their correct and consistent usage; delivery of intermittent preventive treatment (IPTp) in pregnancy with sulphadoxine-pyrimethamine (SP); and implementation of malaria case management to ensure prompt and effective diagnosis and treatment (Roll Back Malaria, n.d.). In October 2012, WHO updated its recommendations for IPTp from at least two doses of SP after the first trimester to delivery of SP at each antenatal visit after the first trimester in moderate- to high-malaria transmission areas (WHO-Roll Back Malaria 2012). Currently, 34 countries have IPTp programs (WHO 2014).

While prevention of MiP is a key focus of global malaria interventions, trends in the use of SP to prevent malaria during pregnancy have largely stagnated or declined in sub-Saharan Africa (see figure 1). Extensive research has been conducted throughout the region to identify major factors impeding adherence to IPTp policies. Key barriers to uptake include individual factors (socioeconomic status, gender, cultural norms, and access to health facilities) and provider factors (training and supervision of staff, provider knowledge, quality of care, and drug supply) (Hill et al. 2013). Health systems strengthening components have been identified as key to the success of malaria prevention in pregnancy efforts: "As ANC remains largely a facility-based healthcare, the observation corroborates earlier findings about the imperative role of the health system in accelerating uptake of interventions, including SP against MiP, thus calling attention to strengthening the health system in such aspects as workforce sufficiency, skills, availability of equipment and supplies" (Exavery et al. 2014).

Figure 1. Trends in SP Coverage from 30 African Countries[1], 2002–2012 (DHS Program)[2]



Lack of product availability and stockouts are listed in multiple studies as barriers to IPTp service delivery (Mbonye et al. 2013; Exavery et al. 2014; Pell et al. 2011). While the impact of stockouts on IPTp coverage is largely unknown, qualitative data indicate that it is significant. A pregnant woman in Nigeria notes: "At times, if drugs are not available in the health facility, they (providers) do write (prescriptions) and give [them] to us to go and buy in the chemist or pharmacy, but we don't understand what they write" (Diala et al. 2013). Despite multiple studies citing SP product availability at health facilities as a barrier to improving IPTp coverage, there remains a lack of quantitative data and analysis of the impact of SP availability on IPTp coverage.

MiP Programming in Malawi

In 1993, Malawi became the first country to include IPTp as part of its ANC program (Wallon et al. 2011)—several years ahead of WHO's IPTp recommendation. Malawi's 2011–2015 Malaria Strategic Plan aims for 80 percent of pregnant women to receive at least two doses of IPTp during the second and third trimesters of the pregnancy (NMCP 2011). An in-depth analysis of factors relating to IPTp coverage in Malawi found that nearly 80 percent of women who started IPTp completed the second dose at the next visit, while 66 percent of women who received only one dose of IPTp made a single ANC visit. This analysis of ANC registers in Malawi found that among women who completed two doses of IPTp, 63 percent completed the second dose of IPTp by the second antenatal visit, 93 percent by the third visit, and 100 percent by the fourth visit (Thetard 2014).

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[1] Among pregnant women who had a live birth in the two years preceding the survey. The countries selected included any country in sub Saharan Africa with household survey data on SPO coverage available through MacroDHS' StatCompiler. The list includes Angola, Benin, Burkina Faso, Burundi, Cameroon, Comoros, Republic of Congo, DRC, Cote d'Ivoire, Ethiopia, Gabon, Guinea, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe.

A case study in 2011 of Malawi's MiP program found five key factors that set it ahead of others in the region: integration of MiP interventions within the ANC model at facility level; leadership in the study of and implementation of MiP and malaria case management interventions; a well-developed malaria communications strategy; accessible delivery of maternal health services, including MiP education and referral; and coordination of funding for MiP programming through the health sector-wide approach (Wallon et al. 2011). That being said, the program is not immune to similar challenges of other programs in the region, including stockouts of SP (Wallon et al. 2011).

In fact, Malawi has faced periodic stockouts of SP in recent history. In Malawi, SP is primarily procured through the Government of Malawi's Central Medical Stores—re-established as the Central Medical Stores Trust in 2011—and distributed to health facilities monthly via the three Regional Medical Stores. During October to December 2010, 33 percent of facilities reported experiencing stockouts of SP (Thetard, 2014). Throughout 2011, as a result of funding shortages, Malawi experienced significant shortages of essential medicines in general. (Central Medical Stores usually procured the essential medicines.) During this period, 75 percent of facilities were believed to have experienced significant stockouts of key medicines (Wild and Cammack 2013). In January 2012, a group of coordinated donors, including USAID, DFID, KfW, UNICEF, and Norway, co-funded an emergency response to the shortage by procuring, kitting, and delivering essential medicines, including SP, to health facilities nationally. The program ran through mid-2013.

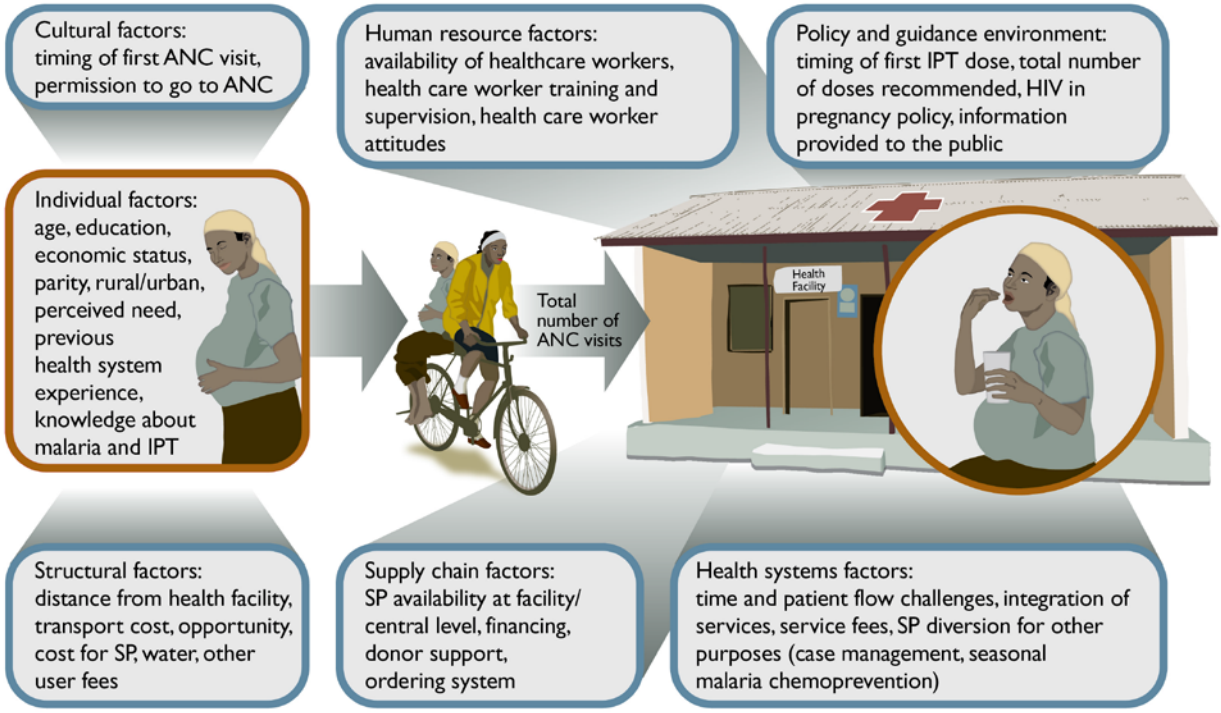
Given the lack of quantitative analysis of SP availability data, this study aims to explore the impact stockouts of SP have had on Malawi's otherwise strong MiP programming.

Theoretical Framework and Research Questions

This study specifically explores the relationship between SP product availability and IPTp uptake among pregnant women. This relationship is explored by examining trends between SP availability in logistics data and ANC service statistics and household survey data on IPTp coverage in Malawi. While it seems logical to infer that IPTp uptake would decline in the absence of product availability, no previous studies demonstrate the degree to which stock availability affects IPTp uptake.

Figure 2 depicts the individual, cultural, and health systems factors that determine access to and uptake of SP for IPTp. A variety of structural factors have an impact on women's access to antenatal services. They include women's physical access to a health center, costs to access antenatal services, and cultural barriers to access, such as when a woman decides to begin ANC. Once a pregnant woman reaches an antenatal clinic, her experience is shaped by a new set of factors relating to MiP policy and guidelines, healthcare workers' number and capacity, and other health systems factors, including wait time and patient flow. Finally, supply chain factors have a significant impact on whether the necessary commodities are available on the day of a woman's visit to the health facility. This paper focuses on supply chain factors, exploring the relationship between availability of SP for IPTp and uptake of IPT among pregnant women in Malawi.

Figure 2. Conceptual Framework: Factors affecting a woman's choice to access and use ANC and IPT services



This research addresses the following questions:

- What has IPTp uptake been at the facility level over time?
- What has SP availability been at the facility level over time?
- Does a correlation exist between SP availability at the facility level and IPTp uptake?

Methodology

Data Sources and Limitations

To answer our research questions, we used data from three complementary data sources: SP availability at heath facilities using Malawi's logistics management information system (LMIS); SP uptake at health facilities using national ANC service statistics; and IPTp coverage of pregnant women as reported in household surveys.

LMIS Data

LMIS data are currently captured through the Supply Chain Manager (SCMgr) stand-alone software application. Approximately 650 facilities submit paper forms to the district level. Facility workers at the district level are responsible for entering data into SCMgr, which is then sent electronically to the central level (the Ministry of Health's Health Technical Support Services). Significant investments (in training, supervision, collection and delivery of paper forms, as well as Internet and airtime access) have been made to improve data reporting and quality; as a result, reporting rates have substantially improved over time, particularly between 2011 and 2013. However, challenges have persisted with the application (e.g., crashes, error messages), which often prevent the transmission of data from the district level to the central level. Because the application is not networked, if the computer on which the application is installed is down or Internet is not available, the data collected cannot be transmitted.

Challenges with SCMgr are considered the biggest challenge in submitting data from the district level to the central level. As a result, while facilities may submit their paper-based reports on time, because of SCMgr issues, districts often cannot submit their reports to Health Technical Support Services. This results in entire districts not reporting for certain months (Kamunyori and Stewart 2013). Challenges at the central level with database storage and management compound the aforementioned challenges. Another challenge with SP reporting may be the lack of emphasis on accounting for this drug compared with the focus on reporting on other high-value antimalarials, such as artemisinin-based combination therapies (ACTs).

To address these considerable reporting problems, substantial effort was made in the data cleaning process and analysis of missing data. The primary indicator of interest from this data source is "Percentage of facilities stocked out of SP", defined as having a zero closing balance of the product. Numerous SP duplicate records were identified and removed from the working dataset. Another limitation with the dataset is the identification of records of non-reporting facilities (often entered as "0") with facilities that are actually reporting stockouts of product. Non-reporting facilities often display product records in the LMIS by registering all zeros for all fields; hence a non-reported product record may be confused with a product record that is reporting a stockout.

We addressed this challenge in two ways. First, we made the determination that any record that reported zeros across all variable fields of interest (receipts, dispensed, adjustments, and closing balance), was tentatively considered a non-reporting record, rather than a record indicating a stockout of SP. To test whether this approach was sound, we also looked at reporting on two commodities we

expected to be in stock at facilities: amoxicillin and paracetamol. Because nearly 100 percent of reporting facilities had at least one of these two drugs in stock at all times during the period of study, these two drugs were chosen to test whether a facility was reporting at all, as opposed to not reporting on SP alone. Of facilities that were initially considered non-reporting on SP, we tested to see if the facility also reported all zeros for either amoxycillin or paracetamol. We selected either of these products, since occasionally a facility may not report on one of the two products (total absence of record) at all, but all facilities reported on at least one of these products all of the time.

If a facility reported all zeros for both (or one, if only reporting one) of these tracer products, then the facility was considered a non-reporting facility and the SP "stockout" was actually a record of non-reporting. If, however, a facility was reporting some data on at least one of the products, the zero SP closing balance record was considered to be a true stockout. The assumption we made on a record of all zeros is that SP may not have been available for some period of time at certain facilities; this is supported through anecdotal information in Malawi; in this case, a facility reporting all zeros across all fields would make sense.

For the missing data analysis, we looked for any patterns in the missing data, including geographic patterns (one area with no data for a long period of time, defined as a gap of three months or more) and temporal patterns (specific months that are missing almost everywhere). We then stratified facilities by reporting rate to make comparisons of stockout rates among facilities that were reporting "well" versus those reporting "poorly." This comparison was made to intuit whether the missing data were likely causing a bias and the likely direction of that bias. While bias in the data cannot be removed, identifying the bias can help analyze and interpret the data. This takes into account its limitations and areas that may be in need of further examination.

Household Surveys

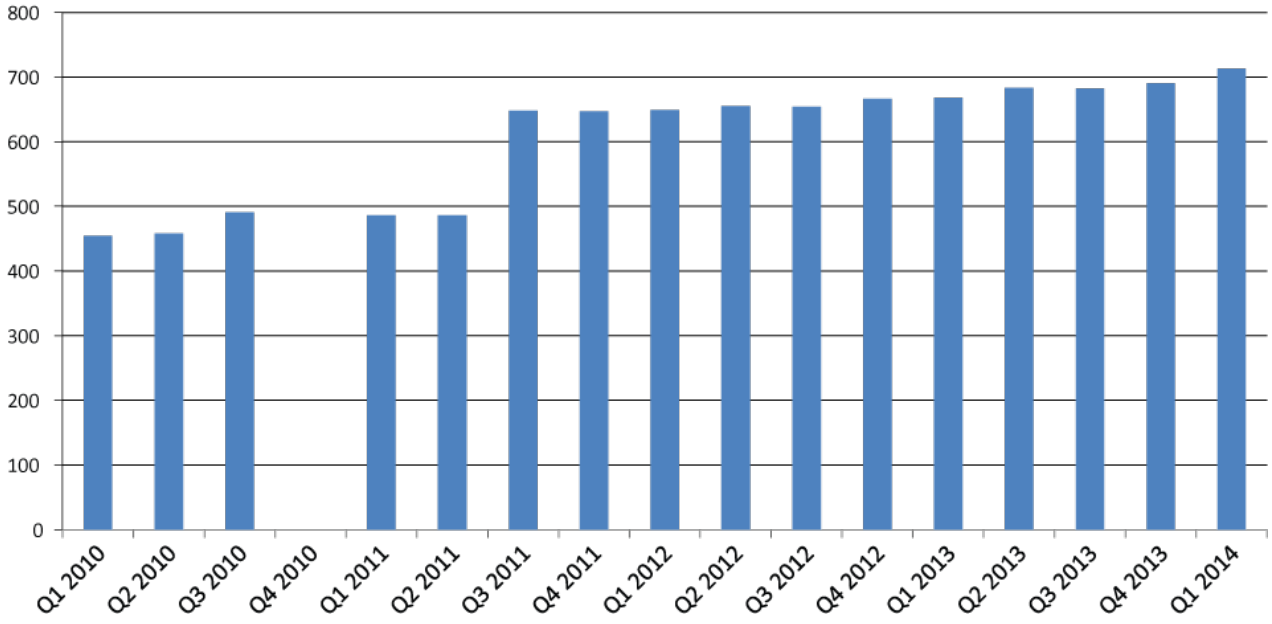
Malawi's National Statistical Office conducted Demographic and Health Surveys (DHS) in 2004 and 2010 and a Multiple Indictor Cluster Survey (MICS) in 2006. In 2012, the National Malaria Control Programme supported a Malaria Indicator Survey (MIS). All these surveys are nationally representative household surveys. These surveys provide a comparable source of data over time and collect a wide range of information on women of reproductive age, their children, and their households. Data on malaria care-seeking behaviors are also available.

The standard question regarding IPTp varies slightly between the MICS and other surveys. While the DHS and MIS inquire about pregnant women taking any antimalarial, any SP and two or more doses or SP, the MICS asks about any antimalarial, one dose of SP, and two or more doses of SP. This makes direct comparison between the data sets slightly challenging. Given the little difference between the responses about having taken "any antimalarial" and "any SP" in 2004, 2010, and 2012, "any antimalarial" is used as a proxy for women who took "any SP" in 2006.

Health Services Data[3]

Health services data were drawn from the Integrated HIV Program Reports, an output of the Ministry of Health-HIV Unit's quarterly supervision program. The reports contain an appendix devoted to IPTp. The quarterly supportive supervision visits include all health facilities that have had antiretroviral therapy (ART) services since the start of the national treatment program in 2004. During 2010–2014, Malawi significantly scaled up ART services, so the number of general health facilities (with ANC clinics) that offered ART services—and were therefore included in the sample—increased steadily over time. Each report specifies the number of public and private health facilities visited (see figure 3). With such a significant percentage of all active health facilities included in each quarter, significant bias in the sample[4] is unlikely.

Figure 3. Number of Health Facilities Included in Quarterly Supervision Reports



Supervision teams include HIV clinicians, nurses, and M&E staff from health facilities in the public and private sectors, district and zonal prevention of mother-to-child transmission of HIV and ART coordinators, program officers and technical staff from the HIV Unit, and implementing partners. The ANC data included in these reports were taken from patient records at the facility level. The Malawi ANC register implemented in 2010 tracks pregnant women longitudinally throughout their

[3] Health services data were drawn from the Integrated HIV Program Reports as opposed to the health management information system (HMIS) because data from these reports are collected through supervision each quarter, and the data are consistently released in a timely fashion. The HMIS data often experience more of a lag between reporting and release of the data for public use. In addition, not all districts report routinely to the HMIS, but the HIV Program collects data from all facilities visited. Because of this, Integrated HIV Program Reports were selected as the data source for health services data. The two sources use the same primary data from ANC registers.

[4] Malawi is often cited as having approximately 650 health facilities. The exact number of operational facilities in Malawi is not consistent from quarter to quarter, as not all facilities are consistently operational. In addition, the total number of health facilities in Malawi increased between 2010 and 2014. Because the HIV Unit conducts this survey, HIV-only sites are also included in figure 3. At most, the HIV Unit supports 713 facilities/units with ANC services.

pregnancies. The reports include women from a cohort of antenatal attendees who complete their ANC during each quarter[5].

Quarterly reports were available for all quarters from quarter 1, 2010 (January–March) to quarter 1, 2014. Data on ANC attendance statistics and IPTp uptake were available for all quarters during this period; however, the exact IPTp indicators collected changed over time (see table 1).

Table 1. IPTp Indicators Collected during Integrated HIV Program Reports

IPTp Indicator Reported	Quarter	Analysis of Usability
Women receiving 0 SP doses	Q1–Q2 2010	This is clear but lacks coverage over the quarters.
Women receiving any SP dose	Q1–Q2 2010	This is clear but lacks coverage over the quarters. It can be recoded to include "1 SP Dose" OR "2 or more SP Doses"
Women receiving 1SP dose	Q2 2012–Q1 2014	This is clear but lacks coverage over quarters. It cannot be combined with 0-5 SP tablets since it includes 0 and cannot be combined with 0-1 doses since it includes 0.
Women receiving 0–1 SP doses	Q3 2010–Q2 2011	This is not clear in that it encompasses women who received SP and those who did not.
Women receiving 2 or more SP doses	Q3 2010–Q2 2011	This is clear and provides data consistently over time.
Women receiving 0–5 SP tablets	Q2 2012–Q1 2014	This is not clear in that it encompasses women who received SP and those who did not.
Women receiving 6+ SP tablets	Q2 2012–Q1 2014	This is clear and provides data consistently over time.

While all the data provide some insight into IPTp coverage over the last four years, the indicators collected from Q2 2012 to Q1 2014 present the most clear and consistent measure of insight into the number of women receiving one dose of SP for IPTp versus two or more.

To make use of all the quarters of data available, the data were also aggregated to show the number of patients receiving any SP (at least one SP dose)[6]. They then were divided by the total number of women in the cohort minus the number of HIV-positive women on cotrimoxizole therapy (and therefore not eligible to receive IPTp). While this measure is not the most nuanced, it was determined to be the best method for including the most data available over time.

A more in-depth analysis was conducted with the last two years of data. In that analysis, the first and second or more doses of IPTp were clearly separated in the indicators recorded.

[5] The health facility register system aggregates women's outcome data after they have completed their ANC visits. While this ensures that each woman is counted only once in each clinic, the system is still prone to a small degree of double-counting caused by women who access multiple clinics in the course of one pregnancy.

[6] This is an aggregation across quarters of the indicators "Women receiving any SP" (only directly available in Q1 and Q2 of 2010),"Women receiving 6+ SP tablets" (Q3 2010-Q1 2012), "Women receiving one dose of SP," or "Women receiving two or more doses of SP," whichever is greater (Q2 2012 to Q1 2014).

Literature Review Methodology

The background literature review process provided us with the justification for conducting this analysis; namely, we found this analysis fills a current gap in the literature: a lack of quantitative data and analysis on the impact of SP availability on IPTp coverage. The following provides our methods and some key details to describe our process.

Search Terms

We identified a set of search terms in the subject area of MiP pertinent to the study question and identified those components: IPTp, SP, uptake, availability, and malaria. The following search terms were used to query PubMed, the database selected for use: *(ipt or sp) AND (uptake or availability) AND (malaria)*.

Screening

The search initially returned 67 articles. The search was narrowed to include only studies published within the last five years, which reduced the returned articles to 40. Studies focused outside of sub-Saharan Africa were eliminated for relevancy. Laboratory-based studies and other studies not focused on MiP program implementation also were eliminated. Studies focusing on the private sector and on other non-IPTp-related uses of SP were eliminated, as well. Using these criteria, 22 studies were eliminated. The remaining 18 articles were reviewed, of which 6 were retained as relevant to the topic at hand.

Additional resources, including both journal articles and technical reports, were subsequently located through Google searches for supplemental background information. The search terms *WHO*, *intermittent preventative treatment*, *malaria in pregnancy*, and *Malawi* were used. These searches yielded an additional four relevant sources.

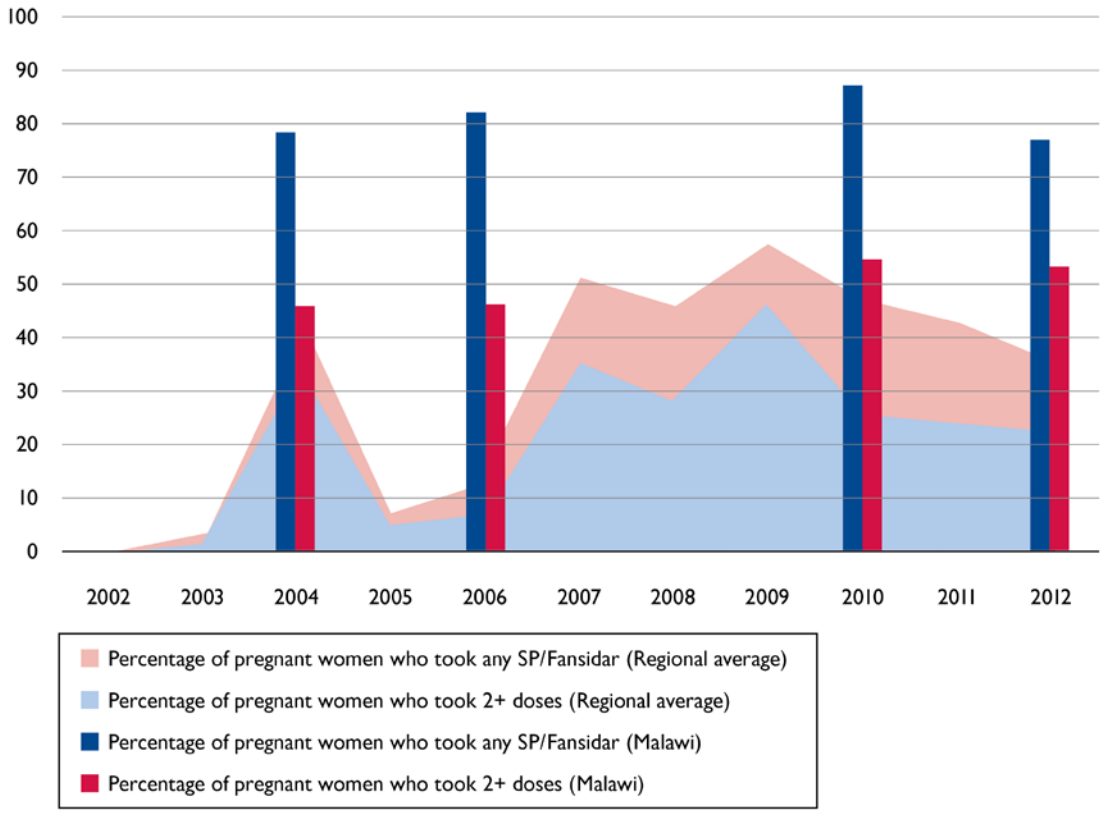
Results

IPTp Uptake Analysis

Household Survey Analysis

Malawi's historically strong IPTp program has received ongoing support since its inception in 1993; however, discussion lingers as to whether the investment has produced results. Although Malawi's IPTp coverage as shown in figure 4 appears higher than the overall average for sub-Saharan Africa[7], household survey data show intervention coverage peaking around 2010. Intervention coverage has faltered since then, much like the rest of the region (see figure 4). While IPTp2 use in Malawi appears to have stagnated between 2010 and 2012 (hovering at approximately 54 percent), use of any SP substantially declined during this same time period from 88 percent to 77 percent.

Figure 4. IPTp Coverage Rates in Malawi across Four Household Surveys[8]



[7] Average includes data from Angola, Benin, Burkina Faso, Burundi, Cameroon, Comoros, Congo (Brazzaville), DRC, Cote d'Ivoire, Ethiopia, Gabon, Ghana, Guinea, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe.

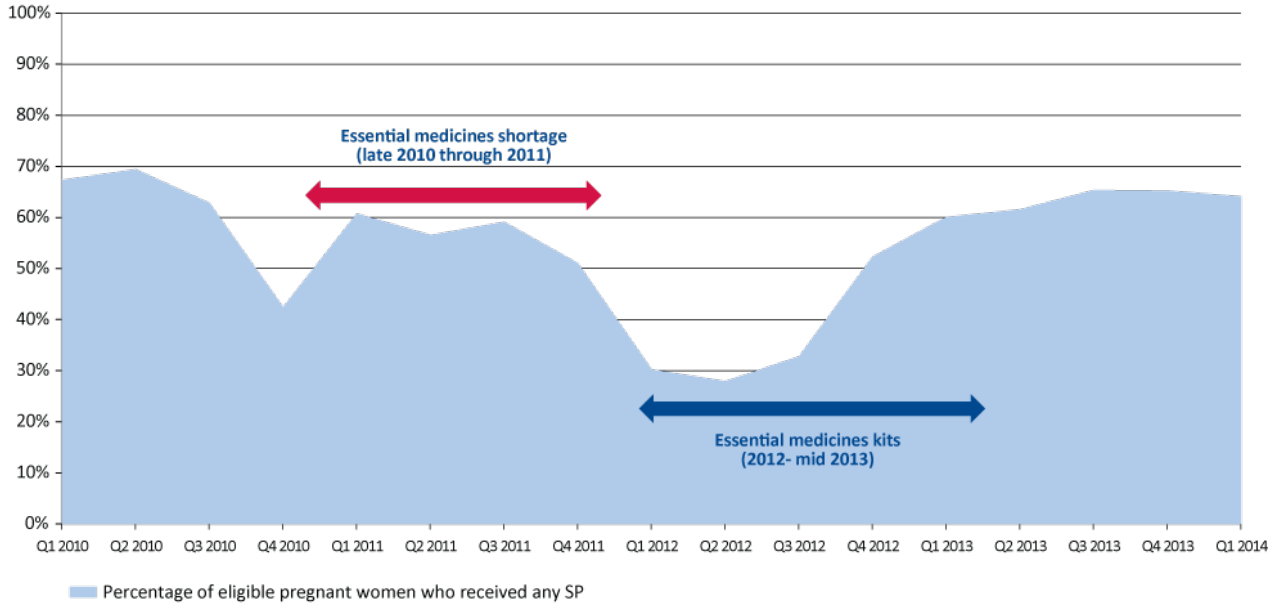
[8] For 2006, pregnant women who took any antimalarial were used as a proxy for pregnant women who took any SP.

Health Services Data Analysis

Household survey data remain the most reliable source for obtaining ongoing IPTp coverage information on pregnant women. Because household surveys take up significant financial and human resources, they cannot be conducted as often as the collection of health services data. As such, quarterly health services data from the Integrated HIV Program Reports are used to elucidate trends in program coverage between survey years.

Figure 5 shows the percentage of eligible pregnant women who attended ANC in Malawi's public sector facilities who received any SP (at least one dose) between January 2010 and March 2014. The decline in percentage of women receiving any SP between 2010 and 2012 coincides with an essential medicines shortage, which began in late 2010. (This is also consistent with the declining trends in uptake of any SP reported through the household surveys over the same time period.) The steady rise in coverage of pregnant women receiving any SP over the course of 2012 coincides with the distribution of emergency essential medicines kits[9], which included SP, beginning in early 2012 and ending in September 2013. By the second half of 2012, SP uptake began to increase, reaching a plateau by the second half of 2013.

Figure 5. Percentage of Eligible Pregnant Women Receiving Any SP, 2010–2014



[9] A full product list of medicines included in the kits is available in appendix A.

Figure 6. Percentage of Pregnant Women Receiving One and Two or More Doses of SP, April 2012–March 2014

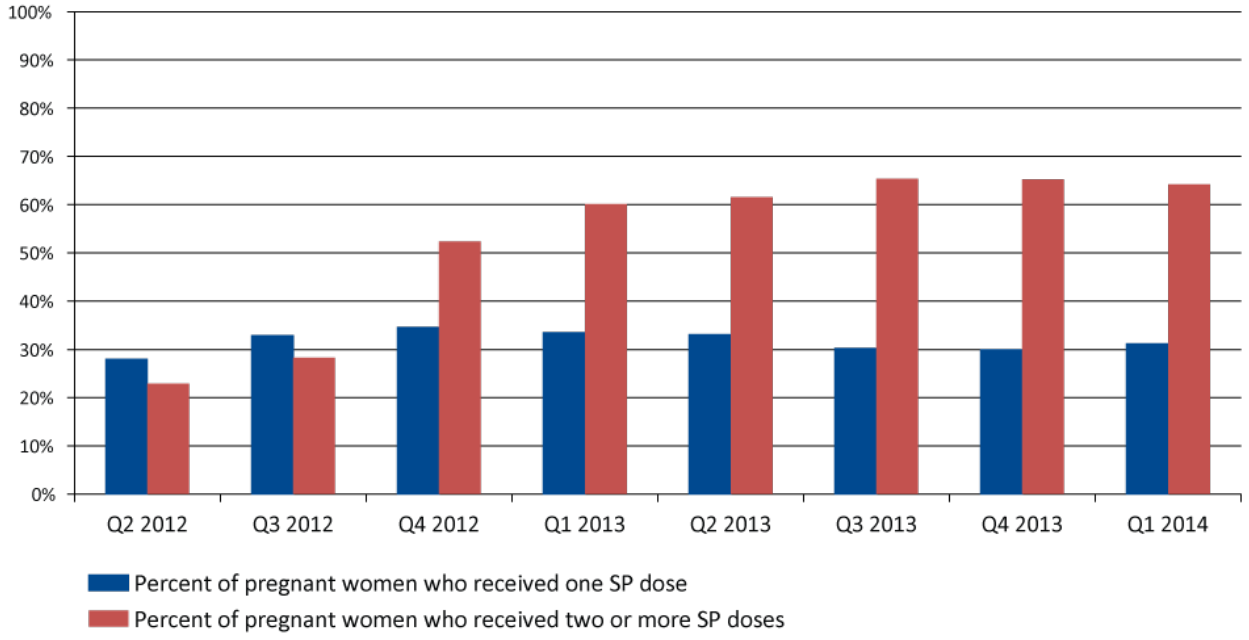


Figure 6 highlights the percentage of women receiving one dose and two or more doses of SP over a two-year period from 2012 to 2014. While the percentage of women receiving only one dose of SP remained relatively constant, the percentage of pregnant women receiving at least two doses of SP had improved since early 2012; however, it appears to have plateaued in the last several quarters.

It should be noted that because of the length of a normal pregnancy, many women will receive SP doses over a period of two or more quarters. For example, if a woman begins ANC at 12 weeks in June, she may receive a dose of SP in Quarter 2 (June), Quarter 3 (August), and Quarter 4 (October). However, her cohort—and therefore her intervention coverage—will only be reflected when her pregnancy "completes" in Quarter 4.

Substantial differences exist between household surveys and health services data regarding the percentage of women receiving any SP (see table 2). Household surveys rely on information received in response to survey questions; health services data rely on record reviews from health facilities. A difference of 27 percentage points in 2010 and a difference of 31 percentage points in 2012 can be seen between these two data sources (see table 2). The difference in the 2012 figure is likely explained by the transition from a period of high stockouts to the implementation of the essential medicines kit program. The quarterly health services data from Integrated HIV Program Reports for women receiving any SP in 2012 are 23 percent, 28 percent, 52 percent, and 60 percent. As such, it is likely that it took until the second half of 2012 for SP uptake to recover from the ongoing stockouts of 2011.

Table 2. Percentage of Women Receiving Any SP from Household Survey Results versus Health Service Data

	2010	2011	2012
Household Survey (DHS 2010, MIS 2012)	87.6%	-	77.4%
Health Service (Patient Records)	60.4%	56.9%	35.9%[10]
Regional Average (DHS Surveys, for Reference)	47.8%	43.2%	37.0%

Regarding the overall differences in coverage rates, while some difference can be accounted for through recall bias among household survey respondents or respondents' desire to give the "right" reply, it is unlikely that this accounts for the full difference. Other possible explanations include poor record taking at the facility level or biased sampling of health facilities during supervision planning. As the sample size ranged from 454 to 713 for the integrated supervision, which generated the reports, biased sampling seems unlikely. The possibility that the general population is more likely to take SP for IPTp than the population attending ANC also seems unlikely, as the reverse scenario (ANC clients more likely to take SP) seems more plausible. Finally, errors in data collection and management could also have contributed to the discrepancy in either data set. In particular, regarding the health service data where information is collected from a longitudinal patient register, errors could have been made in the transcription of patient data.

LMIS Data Analysis

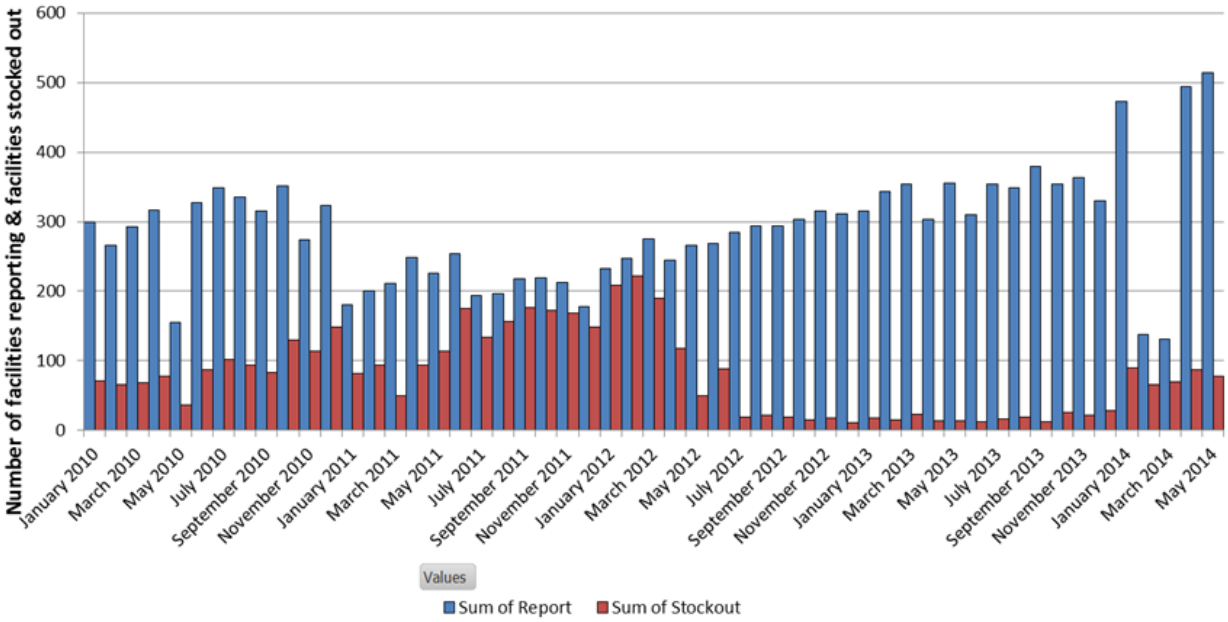
Figure 7 provides a national picture of the total number of facilities reporting over time, as well as the total number of these facilities stocked out of SP at the time of reporting. Reporting rates have gradually improved over time. Stockouts peaked in 2011 through the beginning of 2012, which is consistent with our knowledge of severe stockouts of essential medicines during that same time.[11] While reporting rates for SP during 2011 are very low (approximately 33 percent), it is important to note that the total number of stockouts reported is also relatively high, both compared with other years of data collected and the percentage of the total number of facilities reporting.

After peaking in 2011, stockouts declined over the course of 2012; SP reporting rates during 2012 improved, although they were still relatively low (approximately 44 percent). This stockout decline coincided with the introduction of donor-funded emergency essential medicine kits, which included SP.

[10] This data point may be somewhat deceptive. The quarterly data are 23 percent, 28 percent, 52 percent, and 60 percent of pregnant women receiving any SP. As such, it is likely that it took six months for the uptake to recover from the ongoing stockouts of 2011.

[11] As noted in the introduction, throughout 2011, as a result of funding shortages, Malawi experienced significant shortages of essential medicines, which the Central Medical Stores usually procured. During this period, as many as 75 percent of facilities were believed to have experienced significant stockouts of key medicines (Wild and Cammack 2013). Donors stepped in to support and facilitate the procurement of emergency medicines kits, which included SP.

Figure 7. Total Health Facilities Reporting and Facilities Stocked Out of SP, National Level, 2010–2014



Because of relatively low reporting rates overall, the number of facilities stocked out of SP is underestimated and should be considered the minimum estimate. Typically, reporting rates are lower among lower-performing facilities and often lower during challenging situations. Generally, those facilities with lower rates of reporting (in general or during specific periods of time) may be those more likely to be stocked out. However, Malawi presents a unique situation because of the pervasive challenges with SCMgr. These challenges are countrywide and often specifically affect entire districts' reporting. Still, there is anecdotal speculation that facilities tend not to report when medicine shortages exist, as they do not expect their reporting to result in restocking; however, data are inadequate to confirm this.

To aid in data analysis, the next three graphics aim to elucidate any patterns, or bias, in the missing data, either geographically or over time. They address the percentage of reporting facilities stocked out over time at the regional level, as well as the total number of facilities reporting. Each region mirrors the national-level stockout trends presented in figure 7, with similar patterns in stockout rates. Overall, the South Region appears to have slightly higher rates of reporting, with the lowest rates overall in the Central Region. From a temporal perspective, the North experienced the lowest reporting rates in 2011 (approximately 20 percent to 30 percent compared with the South at 35 percent to 45 percent). However by 2012, the North's reporting rates were highest (45 percent to 62 percent) compared with the Central Region (40 percent). In 2013, reporting rates were highest in the South (approximately 60 percent to 70 percent) and in the North (50 percent to 62 percent); they were lowest in Central (40 percent declining to 32 percent in the latter half of the year). By May 2014, all regions experienced peaks in reporting, up to nearly 90 percent in the South, 82 percent in the North, and 70 percent in the Central Region.

Figure 8. Percentage of Reporting Facilities Stocked Out and the Number of Facilities Reporting— Central Region[12]

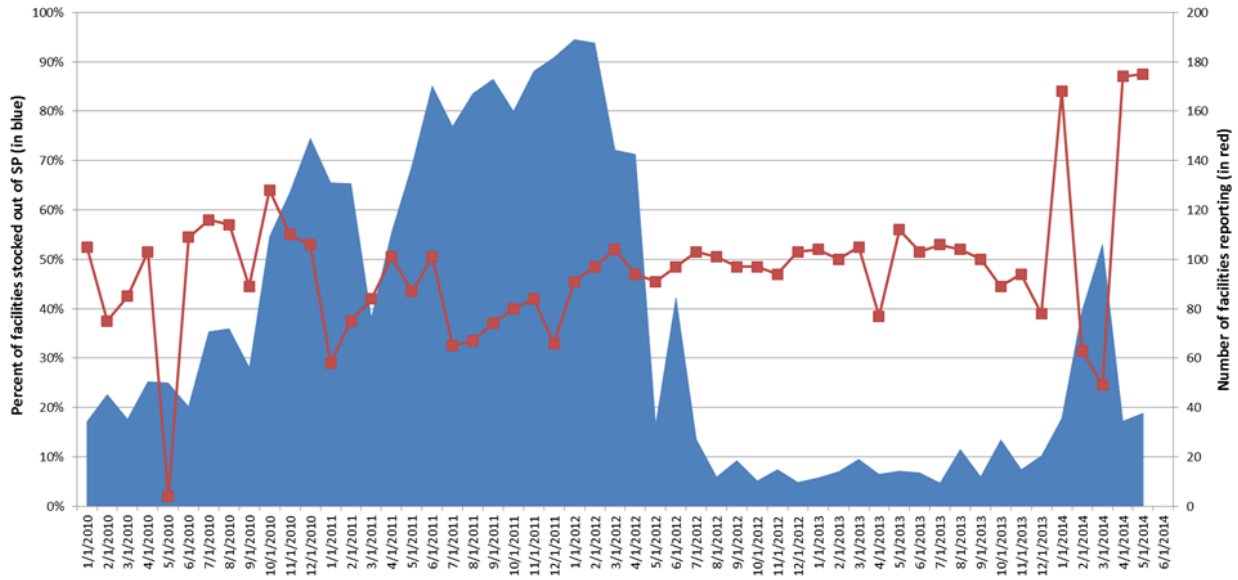
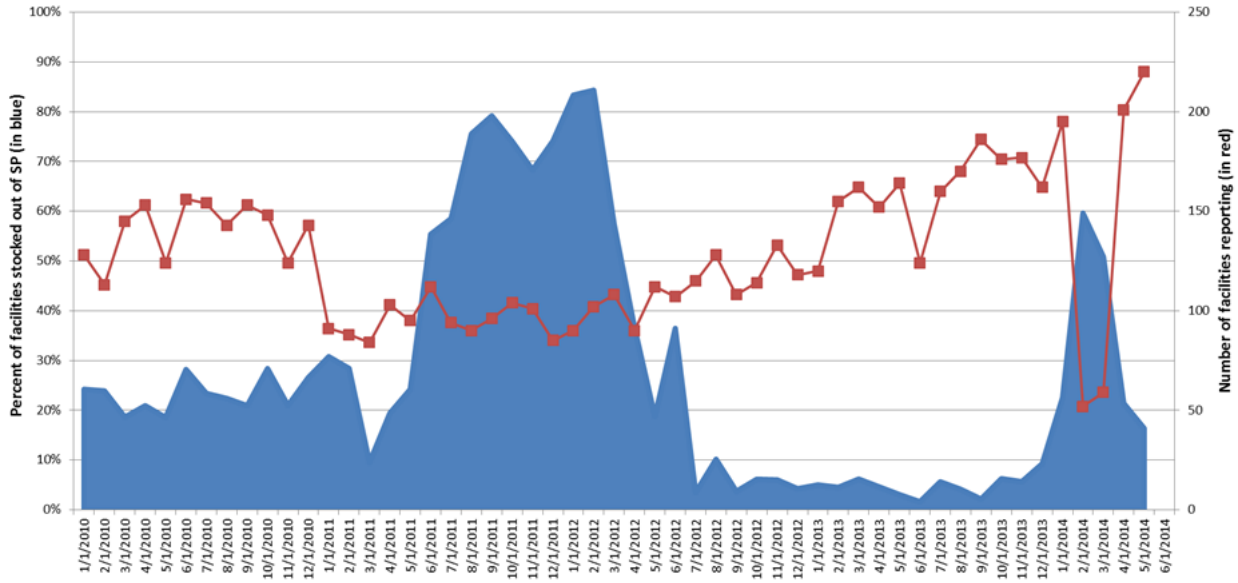


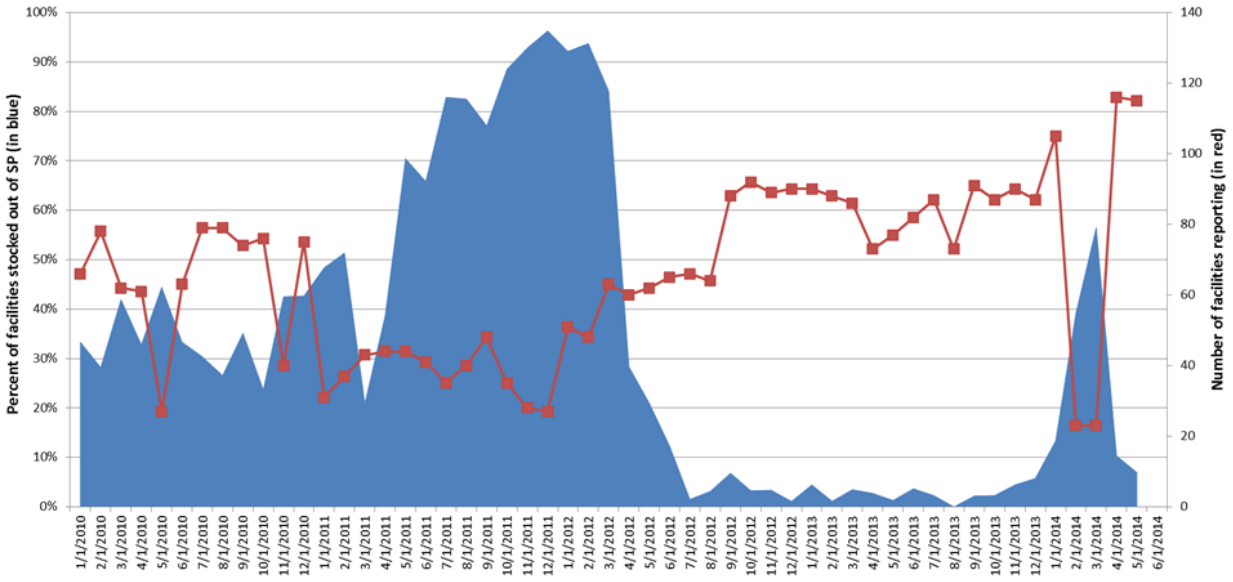
Figure 9. Percentage of Reporting Facilities Stocked Out and the Number of Facilities Reporting[13]—South Region



[12] The Central Region has approximately 249 unique facilities.

[13] The South Region has approximately 260 unique facilities.

Figure 10. Percentage of Reporting Facilities Stocked Out and the Number of Facilities Reporting—North Region[14]



At the district level, from a geographic perspective, we found challenges in all three regions. Approximately 55 percent of districts in the North and South regions experienced substantial lapses in data (defined as having gaps of at least three months or more over time). In the Central Region, the lapses in data were greater: Approximately 70 percent of districts experienced such gaps in data. A few districts are highlighted here because they reported very little data over time: Zomba (South), Karonga (North), Mchinji (Central), Nkhota-kota (Central), and Kasungu (Central).

As expected from the previous analyses at the national and regional levels, from a temporal perspective and across all regions, far less data were available in 2011 and early 2012. The reporting of missing data throughout the country is seen in previous reports (Kamunyori and Stewart 2013), as is the particular challenge with the Central Region data (Inglis 2013).

IPTp Coverage versus Stockouts

Figure 11 combines the previously presented data sources, depicting the percentage of pregnant women who received any SP compared with health facilities stocked out of SP. It would be ideal to present the percentage rather than the number of facilities stocked out over time, but the numbers of facilities reporting fluctuate, which distorts the percentage.

For the service data, each quarter's data are collected on a cohort of women followed over the preceding nine months (or current quarter plus preceding two quarters). While SP should be taken after the first trimester, we cannot exclude that quarter from consideration because the current quarter's cohort captures over an entire three-month period, including the beginning of that period, all women who have given birth. Therefore, the IPTp uptake service data should be interpreted with a lag. The data should be interpreted this way because they actually reflect three quarters of information on IPTp uptake, two of which are historical and not current.

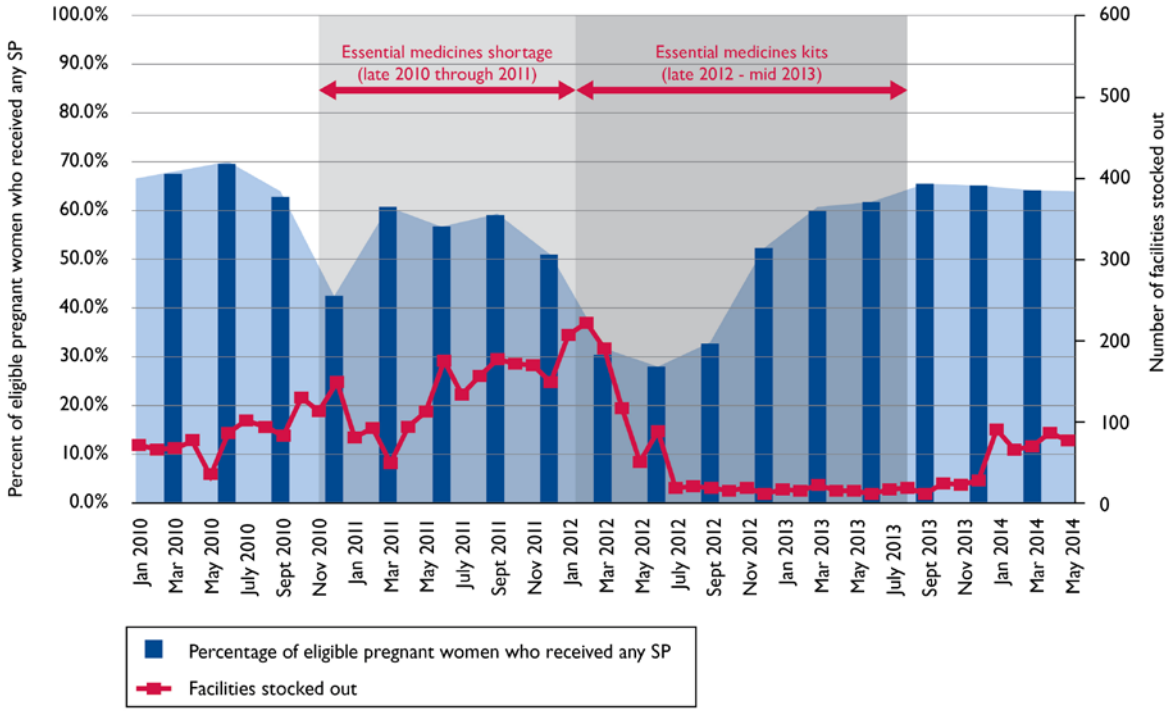
[14] The North Region has approximately 142 unique facilities.

Rates of IPTp coverage generally declined from the start of 2010 to mid-2012, falling from 70 percent to 28 percent in June 2012. Each bar in figure 11 reflects intervention coverage for pregnant women over the previous two quarter periods. After this point, rates of IPTp quickly climb to 65 percent, at which point IPTp uptake rates plateau. The drop in uptake of any SP is consistent with household survey estimates that showed a decline over the same 2010–2012 time period.

Regarding SP availability, a peak of facilities stocked out in 2011. Because stockouts reported are highly likely to be an underestimate, we can say the LMIS data suggest that at a minimum approximately 30 percent to 40 percent of facilities were stocked out of SP in 2011 and early 2012. We do not have data on whether SP rationing occurred in facilities with low stock levels, although this is possible. By mid-2012, the numbers of facilities stocked out declined (at minimum, less than 5 percent of facilities were stocked out); at the same time, the number of facilities reporting began to increase. During this period, our data quality improved, providing more confidence that a decline in stockouts actually happened.

Available household survey data reveal the same trend of a 10 percent drop in uptake of any SP between 2010 and 2012, indicating that when SP availability is limited, IPTp uptake rates appear to be affected.

Figure 11. Coverage of Women Receiving Any SP Drops Following Period of Increased Stockouts, January 2010–May 2014



Discussion

This analysis provides quantitative data, along with qualitative, contextual knowledge, in support of a correlation between SP availability at the facility level and IPTp uptake. Given that Malawi's overall ANC coverage is reported as 95 percent (National Statistical Office and ICF Macro 2011), the health system has the opportunity to reach nearly all pregnant women with IPTp at least once. However, Malawi's health services data show that despite strong IPTp coverage as reported in household surveys, trends from one quarter to the next demonstrate a vulnerability to fluctuations in product availability. Health service data show a low coverage of 28 percent of eligible pregnant women attending ANC clinics who received any SP in early 2012 (also reflecting 2011). This coincides with months of ongoing stockouts and the beginning of the essential medicines kits program. The peak coverage was nearly 70 percent of pregnant women attending ANC who received any SP in 2010, more than double the uptake of the lowest point.

The health service data and household data correspond with the available LMIS data. These data show that stockouts peaked in 2011 and early 2012, followed by the lowest levels of stockouts in late 2012 and throughout 2013. When SP availability is limited, such as in 2011 and early 2012, this appears to affect rates of IPTp uptake. The rates were lowest during this same time, particularly when accounting for the lag in coverage as a result of the cohort analysis of IPTp coverage.

A stall in IPTp uptake among women attending ANC as it approaches 65 percent, when stockouts of SP appear lower (such as in 2013), could signal a number of other challenges other than SP availability. Given that 95 percent of pregnant women in Malawi visit the ANC clinic at least once, it is likely that other facility-based factors still prevent all pregnant women visiting ANC from receiving the full complement of SP doses. Additional potential barriers to IPTp uptake in Malawi include weak collaboration between the National Malaria Control Programme and Reproductive Health Unit, inadequately skilled and dedicated personnel, and patients' and providers' skepticism of SP efficacy (Wallon et al. 2011).

> At the peak of IPTp coverage, the percentage of eligible pregnant women receiving any SP never exceeded 70 percent. While stockouts have remained low over the past 18 months, the percentage of women receiving any SP has not significantly increased. This indicates that additional factors are at play. Given the high percentage of women attending ANC in Malawi, these factors are likely facility based. These factors likely relate to other factors such as policy, human resources, and health systems as described in the conceptual framework.

While LMIS reporting rates are relatively low, our analysis suggests that reporting challenges are nationwide, and data are missing from facilities and districts throughout the country. This suggests limited bias in the data; however, the Central Region in particular may be under-represented. While 2011 had the lowest reporting rates, this time period also had the highest stockout rates. This suggests that the estimate of stockouts during this time period is substantially lower, and stockouts were a real challenge for health facilities throughout the country.

With 95 percent of Malawian women receiving ANC from a skilled attendant (National Statistical Office and ICF Macro 2011) and the gap between percentage of women attending ANC versus

percentage of those receiving SP widening, a major barrier to IPTp uptake appears to be facility based rather than community based. When SP availability is limited, this appears to affect IPTp uptake. This analysis highlights that at any given time and regardless of cause, a minimum of 35 percent of women attending antenatal clinics are not receiving any SP or cotrimoxizole. What is not clear from the available data is the exact reason for this: whether this is a result of providers failing to offer IPTp, for example, or a patient refusing to take a medication that is known to have unpleasant side effects, such as nausea.

Trends from Malawi, as well as from DHS data throughout the region, show a strong degree of instability in IPTp coverage. This indicates that consistent efforts must continue to strengthen MiP programming to ensure that gains achieved in IPTp coverage are sustained over time. Malawi health service data and stockout rates demonstrate that stockouts are a substantial risk to IPTp coverage in Malawi, and likely across the region. Factors contributing to stockouts must be addressed to sustain any gains made in IPTp coverage.

Next Steps

This analysis of trends in SP availability and IPTp uptake presents several opportunities to improve visibility of MiP activities and IPTp uptake moving forward.

Improving Data Quality

The Integrated HIV Program Reports[15] provide an excellent source of data, including statistics on cohorts of ANC clients over time, which are not readily available in most countries in sub-Saharan Africa. To assist in the analysis and application of these data and future decisionmaking purposes, it would be ideal if the report provided some additional definitions in the IPTp annex. A detailed explanation of methodology, including data sources at the facility level, would be instructive. Additionally, information on when pregnant women took SP would aid in the transition to WHO's new policy intended to increase the number of SP doses given per pregnancy. Finally, clarity is needed on whether women listed as having two or more doses of SP are distinct from the number of women receiving one dose of SP. This would help analysts better understand the data presented. This issue could be further elucidated by accessing the raw data on which these reports are based. In light of the 2012 WHO policy change, it also would be helpful for DHS and MIS to move toward on tracking each potential dose of IPT over the course of a pregnancy[16].

The LMIS also potentially provides an excellent source of data; however, work is needed in improving the quality of reports received. Basic data quality assurance checks—such as those outlined in the methodology of this paper, for example—would be extremely beneficial in improving the quality of data for analysis at a point in time and over time. In addition, Malawi has made major investments in infrastructure and human resources, which have led to improvement in reporting rates; however, the current SCMgr technology remains in need of improvement. A business case has been made for implementation of a new electronic LMIS (Kamunyori and Stewart 2013); this analysis provides further evidence for this argument. An electronic LMIS would make reporting easier for facilities and districts.

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15 Reports are available by logging into the document management system at https://www.hiv.health.gov.mw/.

[16] Current WHO policy recommends that in areas of moderate to high malaria transmission, one dose of IPTp be administered at each ANC visit after the first trimester at least one month apart. WHO recommends a schedule of four ANC visits (WHO Global Malaria Programme, 2012).

Preventing SP Stockouts

This analysis indicates that SP stockouts clearly risk pregnant women's access to SP for IPTp. Prevention of stockouts at the facility level is an important area of intervention but encompasses a variety of disparate factors; some of these factors are in the control of malaria programmers. They include ensuring good recordkeeping and stock management practices and maintaining routine requisitioning of SP. Other factors, such as ensuring financial resources for purchasing SP and managing procurement lead times, are concerns at the national level.

At the global level, widespread SP shortages could take place. Barriers to market access for new suppliers, including lengthy and costly registration processes, are significant challenges to suppliers. As registration is required for each presentation of SP (tablets in bottles versus blisters, etc.), a change in a country's standard treatment guidelines for SP presentations has the potential to significantly disrupt procurement options.

As seasonal malaria chemoprophylaxis programming expands and WHO's new IPTp policy encourages faster consumption of SP, it may become more difficult for countries to procure an adequate national SP supply.

Additional Analyses

An additional next step of this analysis would be to pursue a point-in-time analysis, relating SP facility availability to IPTp uptake. The same complementary data sources would be used, including 2012 LMIS data, 2012 health services data, and the Malawi 2012 MIS.

Second, since Malawi's shift in first-line malaria treatment policy from SP to ACTs in 2007–2008, speculation has been widespread about the ongoing use of SP in cases of ACT stockouts and RDT-negative malaria testing. Additional analysis on this issue could explore whether these two events are a risk to SP stocks that should be reserved for IPTp.

Finally, further MiP research focusing on the health center should explore the reasons why some women attend ANC clinics but fail to receive IPTp. This information would better enable programmers to address barriers to SP uptake and to improve intervention coverage among this population.

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Appendix A

Contents of Essential Medicines Kits

A: STANDARD UNICEF KIT TO BE USED FOR PHASE I		
	Item	**Qty per kit**
1	Amoxicillin 250mg caps/PAC-1000	3
2	Amoxici.pdr/oral sus 125mg/5ml/BOT-100ml	15
3	Benzylpenicillin pdr/inj 3g vial/BOX-50	1
4	Ciprofloxacin 500mg tabs/PAC-10	15
5	Diazepam inj 5mg/ml 2ml amp/BOX-10	1
6	Doxycycline 100mg tabs/PAC-1000	3
7	Epinephrine 1mg/ml inj., 1ml amp/BOX-10	1
8	Erythromycin 250mg tabs/PAC-100	14
9	Glucose hypertonic 50% inj., 50ml vial/BOX-20	1
10	Hydrochlorothiazide 25mg tablets/PAC-100	10
11	Lidocaine inj. 2%, 50ml vial/BOX-5	2
12	Metronidazole 250mg tabs/PAC-1000	2
13	ORS, new formula, 1L sachet, box of 100	1
14	Paracetamol 500mg tabs/PAC-1000	4
15	Paracetamol elixir 125mg/5ml, 60ml	25
16	Povidone iodine soln 10%, 500ml bottle	4
17	Salbutamol 4mg tabs/PAC-1000	1
18	Sulfameth.+ trimeth. 400mg+80mg tabs/PAC-500	20
19	Sulf.100mg+Trimet.20mg disp.tab/PAC-100	50
20	Tetracycline eye ointment 1%, 5g tube	10
21	Water for injection, 10ml amp/BOX-50	1
22	Zinc 20mg tabs/PAC-100	2
23	Albendazole 400mg tabs/PAC-100	2
24	Fe(as fum.)+folic 60+0.4mg tab/PAC-1000	2
25	Miconazole nitrate cream 2%/TBE-30g	10
26	Bandage,gauze,8cmx4m,roll	10
27	Cotton wool,500g,roll,non-ster	5

28	Compress,gauze,10x10cm,n/ster/PAC-100	3
29	Tape,adhesive,Z.O.,2.5cmx5m	5
30	Syringe,dispos,2ml,ster/BOX-100	1
31	Syringe,dispos,5ml,ster/BOX-100	1
32	Needle,disp,19G(1.1x40mm),ster/BOX-100	2
33	Needle,disp,23G,ster/BOX-100	1
34	Sut,abs,DEC2,need 3/8,26mm,tri/BOX-36	1
35	Sut,nonabs,DEC3,need 3/8 30mm,tri/BOX-36	1
36	Needle,disp,21G(0.8x40mm),ster/BOX-100	1
37	Gloves,exam,latex,medium,disp/BOX-100	5

B. INDICATIVE KIT AND SUPPLIES CONTENT FOR MALAWI RURAL AND URBAN PRIMARY HEALTHCARE FACILITIES DURING PHASE II

#.	ITEM DESCRIPTION	Unit of Issue	Quantity for Urban HC kit	Quantity for Rural HC kit
1	Amoxycillin 250mg	1000	30	10
2	Hydrochlorothiazide 25mg	1000	6	2
3	Erythromycin 250mg	1000	18	6
4	Ferrous sulphate 200mg / folic acid 250 micrograms	1000	42	14
5	Magnesium trisilicate compound	1000	18	6
6	Metronidazole 200mg	1000	21	7
7	Paracetamol 500mg	1000	45	15
8	Promethazine hydrochloride 25mg	100	54	18
9	Zinc Sulphate Dispersible tablets	100	30	10
10	Salbutamol 4mg	1000	12	4
11	Sulphadoxine 500mg / pyrimethamine 25mg (SP)	1000	6	2
12	Cotrimoxazole 480mg	1000	54	18
13	Doxycycline 100mg	1000	21	7
14	Ibuprofen 200mg	1000	3	1
15	Adrenaline 1/1000, 1ml	each	30	10
16	Oxytocin 10 IU/ml, 1ml-non refrigerated	each	180	60
17	Benzylpenicillin 3g (5MU), PFR	each	150	50
18	Benzathine benzylpenicillin 1.44g (2.4MU), PFR	each	150	50

#.	ITEM DESCRIPTION	Unit of Issue	Quantity for Urban HC kit	Quantity for Rural HC kit
19	Phenobarbitone sodium 200mg/ml, 1ml	each	15	5
21	Quinine dihydrochloride 300mg/ml, 2ml	each	240	80
22	Dextrose (glucose) 5%, 500ml+ giving sets	each	60	20
23	Sodium chloride 0.9%, 500ml+ giving sets	each	60	20
24	Amoxycillin 125mg/5ml suspension	100ml	300	100
25	Benzyl benzoate application 25%	500ml	3	1
26	Oral rehydration salt, 20.5g satchet (WHO formula) for 1L solution (with orange flavour)-low osmolarity	each	900	300
27	Calamine lotion aqueous	500ml	6	2
28	Ferrous sulphate mixture paediatric 60mg/5ml	100ml	105	35
29	Nystatin oral suspension 100,000 IU/ml	20ml	75	25
30	Paracetamol syrup 120mg/5ml	100ml	300	100
31	Chloramphenicol eye ointment 1%	3.5g	300	100
32	Tetracycline eye ointment 1%	3.5g	150	50
33	Benzoic acid 6% + salicylic acid 3% ointment	500g	3	1
34	Bandage, WOW 7.5cm x 4m	10	30	10
35	Dressing, paraffin gauze 9.5cm x 9.5cm (square)	pack of 36	3	1
36	Gauze, swabs 8-ply 10cm x 10cm	100	30	10
37	Cotton wool, 500g	500g	30	10
38	Plaster, zinc oxide 10cm x 5m	**each**	9	3
39	Catgut chromic 0 needle round bodied ½ circle 40mm	12	3	1
40	Black braided non absorbable sterile silk 2/0 on needle cc 40mm	12	3	1
41	Dextrose 50%, 20ml	Each	15	5
42	Glove disposable latex medium	100	30	10
43	Glove disposable latex, large	100	15	5
44	Albendazole 400mg	**1000**	3	1
45	Cannula iv (winged with injection pot) 18	each	75	25
46	Cannula iv (winged with injection pot) 24	each	75	25
47	Catheter Foley's retention 10cc FG 16 2 way	each	6	2
48	Catheter Foley's retention 10-20cc FG 18, 2 way	each	6	2

#.	ITEM DESCRIPTION	Unit of Issue	Quantity for Urban HC kit	Quantity for Rural HC kit
49	Clips, umbilical cord, polythene	each	240	80
50	Glove surgeon's size 7½ sterile	pair	300	100
51	Mask face disposable paper 2-ply	100	6	2
52	Syringe, autodestruct, 2ml, disposable, hypoluer with 23g needle	each	300	100
53	Syringe, autodestruct, 5ml, disposable, hypoluer with 21g needle	each	600	200
54	Apron, disposable, polythene	100	6	2
55	Gentamicin 40mg/ml, 2ml	each	150	50
56	Clotrimazole 500mg vaginal (tablets/pessaries)	Each	60	20
57	Syringes, disposable, autodestruct, 10ml with 21G needle	Each	60	20
58	Diazepam 5mg/ml 2ml	*each*	30	10
59	Water for injection, 10ml	Each	600	200
60	Cannuls iv 22g		75	25
61	Lignocaine hydrochloride 1%,	each	30	10
62	Phenobarbitone 30mg tabs	28	30	10
63	Quinine sulphate 300mg	100	3	1

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