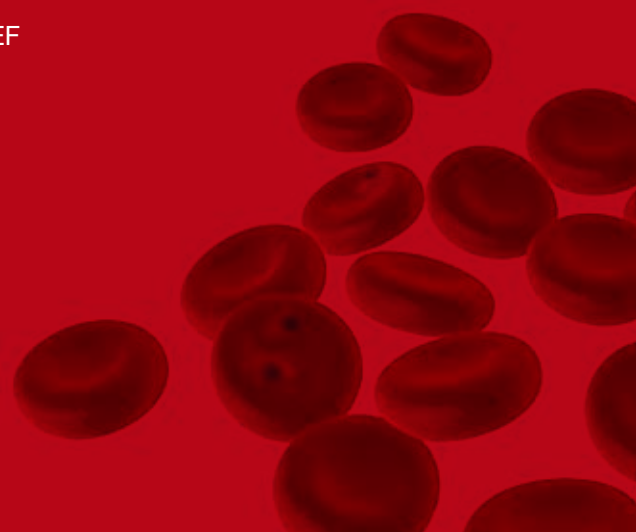




Intermittent preventive treatment for infants using sulfadoxine-pyrimethamine (SP-IPTi) for malaria control in Africa: IMPLEMENTATION FIELD GUIDE

WHO Global Malaria Programme (GMP) and
Department of Immunization, Vaccines & Biologicals (IVB) and UNICEF



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**INTERMITTENT PREVENTIVE TREATMENT FOR
INFANTS USING SULFADOXINE-PYRIMETHAMINE
(SP-IPTI) FOR MALARIA CONTROL IN AFRICA:
An Implementation Field Guide**

September 2011
WHO/IVB/11.07

WHO Global Malaria Programme (GMP) and
Department of Immunization, Vaccines & Biologicals (IVB) and UNICEF

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Abbreviations

ACT	Artemisinin-based combination therapy
ADR	Adverse drug reactions
AE	Adverse event
AEFI	Adverse event following immunization
BCC	Behaviour change communication
CHW	Community Health Worker
Combo	A combination vaccine containing more than one antigen
cMYP	Comprehensive Multi-Year Plan
DHS	Demographic Health Survey
DTP	Diphtheria, Tetanus, Pertussis vaccine
EPI	Expanded Programme on Immunization
GFATM	Global Fund for AIDS, TB, and Malaria
GMP-TEG	Global Malaria Program Technical Expert Group
Hib	<i>Haemophilus influenzae</i> type b vaccine
HIV	Human Immunodeficiency Virus
HW	Health workers
ICC	Inter-Agency Coordinating Committee
IEC	Information, Education, and Communication
IPTi	Intermittent Preventive Treatment for Infants
IPTp	Intermittent Preventive Treatment in Pregnancy
IRS	Indoor residual spraying
ITN	Insecticide-treated bed net
MICS	Multi-indicator coverage survey
MoH	Ministry of Health
NGO	Non-Governmental Organization
OPV	Oral Polio Vaccine
Penta	Pentavalent combination vaccine containing Diphtheria, Tetanus, Pertussis, HepB, and Hib
PCV	Pneumococcal conjugate vaccine
<i>Pfdhps</i>	<i>Plasmodium falciparum</i> <i>dyhydropteroate synthase</i>
PMTCT	Prevention of Mother-to-Child Transmission of HIV
PV	Pharmacovigilance
Rota	Rotavirus vaccine

SAE	Serious Adverse Event
SJS	Steven-Johnson Syndrome
SP	Sulfadoxine-Pyrimethamine
SP-IPTi	Intermittent Preventive Treatment for Infants with Sulfadoxine-Pyrimethamine
SP-IPTi1	First dose of Intermittent Preventive Treatment for Infants with Sulfadoxine-Pyrimethamine
SP-IPTi2	Second dose of Intermittent Preventive Treatment for Infants with Sulfadoxine-Pyrimethamine
SP-IPTi3	Third dose of Intermittent Preventive Treatment for Infants with Sulfadoxine-Pyrimethamine
TEN	Toxic Epidermal Necrolysis
UNICEF	United Nations Children's Fund
WHO	World Health Organization
YF	Yellow Fever

1. INTRODUCTION

Malaria remains a leading cause of ill health, causing an estimated 225 million cases of clinical malaria and 781 000 deaths¹. More than 85% of malaria cases and 90% of malaria deaths occur in Africa south of Sahara. In Africa, the vast majority of cases and deaths occur in young children.

Key interventions currently recommended by WHO for the control of malaria are the use of insecticidal treated nets (ITNs) or indoor residual spraying (IRS) for vector control, and prompt access to diagnostic testing of suspected malaria and treatment of confirmed cases. An additional intervention which is recommended for pregnant women, a high risk group in areas of high malaria transmission, is Intermittent Preventive Treatment in pregnancy (IPTp), which involves the administration of at least two doses of sulphadoxine-pyrimethamine (SP) during the second and third trimesters of pregnancy.

Recently, WHO has recommended a new intervention against *Plasmodium falciparum* malaria targeting another high risk group: Intermittent Preventive Treatment for Infants, specifically using SP (SP-IPTi). In Sub-Saharan Africa it is the very young children who suffer the brunt of malaria in terms of severity of illness and death².

SP-IPTi is the administration of a full therapeutic course of SP delivered through the Expanded Programme on Immunization (EPI) at intervals corresponding to routine vaccination schedules for the second and third doses of DTP/Penta³, and measles vaccination — usually at 8-10 weeks, 12-14 weeks, and ~9 months of age — to infants at risk of malaria.

SP-IPTi reduces clinical malaria, anaemia and severe malaria in infants in the first year of life. EPI provides a ready made and generally well functioning delivery system that reaches a high number of infants. Through EPI the scale-up of IPTi coverage can be rapidly achieved and its impact accelerated.

¹ World Malaria Report 2010. Geneva, World Health Organization http://www.who.int/malaria/world_malaria_report_2010/worldmaliareport2010.pdf

² Carneiro I, Roca-Feltre A, Griffin JT, et al. Age-patterns of malaria vary with severity, transmission intensity and seasonality in sub-Saharan Africa: a systematic review and pooled analysis. *PLoS One* 2010;**5**(2):e8988.

³ Many countries are introducing pneumococcal conjugate vaccine (PCV) and rotavirus vaccines (Rota) into their infant immunization programmes also. Depending on the national schedule SP-IPTi may also be given alongside these new vaccines.

Country studies have demonstrated that with minimal training SP-IPTi is easy to administer at the time of vaccination, and its acceptability with health workers and communities is very high. Immunization monitoring and reporting forms and systems can be adapted to include SP-IPTi without difficulty. As SP is inexpensive, integrating the delivery of SP-IPTi with immunization services is highly cost effective.

When given at the same time it has been confirmed that SP-IPTi has no negative effect on the protective efficacy of EPI vaccines.

The successful implementation of SP-IPTi requires that national malaria control and EPI programmes work together. This implementation guide provides the necessary technical and operational information and tools for country-level policy-makers and programme managers to decide on how to include SP-IPTi with immunization services. This implementation guide draws upon the experience and lessons learned from large pilot implementation projects in Benin, Ghana, Madagascar, Malawi, Mali, Senegal, and Tanzania. Countries that decide to introduce SP-IPTi are encouraged to adapt this Implementation Guide to their national situation.

2. WHO POLICY RECOMMENDATION FOR SP-IPTi⁴



WHO recommends the co-administration of SP-IPTi with DTP2/Penta2, DTP3/Penta3 and measles immunization to infants, through routine EPI in countries in Sub-Saharan Africa, in areas

- a. with moderate-to-high malaria transmission (Annual Entomological Inoculation Rates ≥ 10), and
- b. where parasite resistance to SP is not high - defined as a prevalence of the *Pfdhps* 540 mutation of $\leq 50\%$.

Contra-indications

SP-IPTi should not be given to infants receiving a sulfa-based medication for treatment or prophylaxis, including co-trimoxazole (trimethoprim-sulfamethoxazole) which is widely used as prophylaxis against opportunistic infections in HIV-infected infants.

Considerations and caveats for implementation

- In situations where a National-scale implementation may not be feasible due to varying levels of the *Pfdhps* 540 mutation, SP-IPTi may be implemented at a Provincial or District scale, targeting areas with *Pfdhps* 540 mutation prevalence $\leq 50\%$.
- Programmes implementing the SP-IPTi strategy should regularly monitor and evaluate the impact on immunization services and performance.
- Pharmacovigilance systems to monitor potentially serious adverse reactions to SP should be strengthened.
- Surveillance of parasite resistance to SP based on prevalence of *Pfdhps* 540 mutations should accompany the implementation of SP-IPTi as a surrogate measure of its efficacy.

⁴ The recommendation was made at the fourth consultative meetings of the Technical Expert Group (TEG) of Preventive Chemotherapy, GMP, WHO, April 2009 (<http://malaria.who.int/docs/IPTi/TEGConsultIPTiApr2009Report.pdf>). The recommendation and programmatic experiences from 7 Africa countries was subsequently reviewed and endorsed by WHO's Strategic Advisory Group of Experts on Immunization (SAGE), in October, 2009 (<http://www.who.int/immunization/sage/previous/en/index.html>).

SP-IPTi delivered through EPI is an additional malaria control strategy for countries in sub-Saharan Africa, and should complement the on-going scale-up of core malaria control interventions:

- Diagnosis of suspected malaria and treatment of confirmed cases with an artemisinin-based combination therapy (ACT)
- Vector control (Insecticide-treated bednets (ITNs) or /and Indoor residual spraying (IRS)).

3. KEY INFORMATION ABOUT SP-IPTi

What is SP-IPTi?

Intermittent preventive treatment in infants (IPTi) is the delivery of a treatment dose of an anti-malarial drug to infants at pre-specified times during the first year of life, irrespective of the child being infected with *Plasmodium falciparum* parasites. A similar strategy is used for prevention of malaria during pregnancy (IPTp)⁵. Research has shown that IPTi using SP (SP-IPTi) can now be safely and effectively used for infants at the time of vaccination. Currently, sulphadoxine-pyrimethamine (SP) is the recommended drug for both pregnant women (IPTp) and infants (SP-IPTi).

When will SP-IPTi be given?

In areas where SP-IPTi is implemented each child will be given SP three times in their first year of life when they receive routine vaccinations as follows:



- First SP-IPTi dose (SP-IPTi1) when **DTP2/Penta2** (or combo) vaccination is given (i.e. 8-10 weeks of age)
- Second SP-IPTi dose (SP-IPTi2) when **DTP3/Penta3** (or combo) vaccination is given (12-14 weeks of age)
- Third SP-IPTi dose (SP-IPTi3) at the time of **measles** vaccination (9 months)

The exact timing of the doses may vary according to the national immunization schedule for DTP and measles vaccination.

If there is a stock-out of vaccine when the child comes to the clinic, **do not miss the opportunity to still give SP-IPTi alone!**

Research has shown that children who have received the first two doses of SP-IPTi are better protected from malaria than those who have never received SP-IPTi before.

⁵ IPTp requires the administration of at least two doses of SP during the second and third trimesters of pregnancy.

Regardless of whether SP-IPTi has been given or not, whenever infants/children fall sick from malaria, they should be treated with the appropriate ACT as per national treatment guidelines.

What are the expected benefits of SP-IPTi?

Results from studies in Africa have confirmed that SP-IPTi is safe and effective.

In areas of moderate to high transmission of malaria, during the first year of life SP-IPTi has been shown to⁶:

- Reduce clinical malaria by 30%.
- Reduce anemia by 21%.
- Reduce hospital admissions associated with malaria parasitemia by 38%.
- Reduce all-cause hospital admissions by 23%.

SP-IPTi protects against malaria for a period of approximately 35 days following the administration of each dose, although this is likely to vary with level of drug resistance.

Where should SP-IPTi be used?

The implementation of SP-IPTi should not detract from the core malaria control efforts to scale-up access to: prompt confirmation of diagnosis; early treatment with ACTs; insecticide-treated bednets (ITNs); and indoor residual spraying (IRS).

WHO recommends that SP-IPTi delivered through EPI should be considered for implementation as an additional malaria control strategy in sub-Saharan African countries/districts with moderate to high transmission (Annual Entomological Inoculation Rates (EIR) ≥ 10) and where parasite resistance to SP is not high (*Pf dhps* 540 mutation of ≤ 50),

In situations where a national-scale implementation may not be feasible due to varying levels of SP drug resistance, SP-IPTi may be an important strategy to implement in selected provinces or districts that do not have high parasite resistance to SP.

⁶ See Aponte, J., Schellenberg, D., et al. *Efficacy and safety of intermittent preventive treatment with sulfadoxine-pyrimethamine for malaria in African infants: a pooled analysis of six randomised, placebo-controlled trials*. Lancet 2009; 374 (9700): 1533-42. Reduction of clinical malaria 30.3% (95% CI: 19.8%-39.4%), anemia 21.3% (95% CI: 8.3%-32.5%), hospital admissions associated with malaria parasitemia 38.1% (95% CI: 12.5%-56.2%), and all-cause hospital admissions 22.9% (95% CI: 10.0%-34.0%).

Why use SP-IPTi when the effectiveness of SP is questionable?

In areas with low to moderate SP resistance, SP still remains effective for prevention purposes, even where it is not useful or recommended for the treatment of clinical cases of malaria.

The mechanism of action of SP-IPTi is likely to be predominantly one of chemoprevention. Protective efficacy of SP-IPTi is related to the half-life of the medicine and the susceptibility of the malaria parasite to SP. Therefore, parasite resistance to SP serves as a guide to adoption of a policy on SP-IPTi.

The threshold not to recommend IPTi for use in areas where the prevalence of the *pfdhps* 540 mutation is 50% or greater is based on the following:

- The presence of mutations at codons 437 and 540 of *pfdhps* together with the triple mutation of *pfdhfr* (quintuple mutation) is a significant predictor of SP treatment failure. The *pfdhps* 540 mutant is a useful epidemiological marker of the quintuple mutation in Africa.
- In areas with up to 50% prevalence of the *pfdhps* 540 parasite mutant in infants and children, clinical trials showed a 30% protective efficacy of SP-IPTi over one year against clinical malaria.
- One trial conducted in an area where the prevalence of the *pfdhps* 540 parasite mutant was approximately 90% found no demonstrable protective efficacy for SP-IPTi.

WHO recommends that above 50% prevalence of *pfdhps* 540 mutations SP-IPTi should not be used. It is therefore important to implement surveillance of molecular markers of SP resistance in countries implementing SP-IPTi. This can be done by looking for *pfdhps* mutations in samples obtained from routine *in vivo* studies for therapeutic efficacy of other antimalarial medicines, and could be complemented by molecular analysis of parasite-positive samples obtained at cross-sectional surveys e.g. Multi-Indicator Cluster Surveys (MICS), Demographic Health Surveys (DHS).

How common are adverse reactions to SP-IPTi and what safety monitoring is needed?

SP has been used in infants for over 30 years and is generally safe and well tolerated. However, adverse reactions can occur anytime after the use of SP if the child/person is allergic to sulfonamide containing drugs. Generally, these reactions are rare with less than 1% of the population reacting to SP or any

sulfur containing drugs. The most severe adverse drug reactions to SP, which occur less frequently, are dermatological reactions, specifically:

- Erythema Multiform
- Stevens-Johnson syndrome (SJS)
- Toxic epidermal necrolysis (TEN).



For any serious adverse event, the national guidelines for treatment should be followed.

Large-scale implementation studies of SP-IPTi in seven countries in Africa have observed no increased incidence of adverse events other than the ones regularly seen after vaccination.

However, SP-IPTi should NOT be given to infants receiving (or having received within the last four weeks) a sulfa-based medication for treatment or prophylaxis, including co-trimoxazole (trimethoprim-sulfamethoxazole) which is widely used for HIV-exposed or HIV-infected infants⁷ in Prevention of Mother-to-Child Transmission of HIV (PMTCT). As co-trimoxazole is another sulfonamide, when taken together with SP-IPTi the risk of adverse reactions can increase. Additionally, co-trimoxazole already has an anti-malaria effect.

There is no evidence of adverse effects of SP-IPTi on infants serological responses to EPI vaccines (DTP, OPV, Hepatitis B, Hib, yellow fever and measles).

When implementing SP-IPTi, it is necessary to strengthen surveillance systems for drug safety to monitor and report any serious adverse reactions that may occur. As SP and vaccination are given together, it is recommended that the adverse events following immunization (AEFI) surveillance systems be adapted to include SP-IPTi adverse events monitoring. Health workers need to be trained to recognize, respond and report severe adverse reactions, especially skin reactions.

⁷ World Health Organization. *Guidelines on co-trimoxazole prophylaxis for HIV-related infections among children, adolescents and adults. Recommendations for a public health approach*. Geneva, WHO, 2006. Available at: www.who.int/hiv/pub/guidelines/ctxguidelines.pdf ; and World Health Organization. *Co-trimoxazole prophylaxis for HIV-exposed and HIV-infected Infants and Children: Practical Approaches to Implementation and Scale-Up*. Geneva, WHO, 2009. Available at: www.unicef.org/aids/files/CotrimoxazoleGuide_2009.pdf.

Why should EPI be used as the delivery system for SP-IPTi?

The WHO/UNICEF *Global Immunization Vision and Strategy (GIVS)*⁸ encourages the integration of other important child health interventions with immunization. SP-IPTi is a natural fit, given that the target group for SP-IPTi and EPI is the same — that is, infants under one year of age. In most countries, EPI programmes achieve high coverage (80%) and provide functioning logistics, delivery, and recording/monitoring systems into which SP-IPTi can be integrated. Through EPI, the rapid scale-up of SP-IPTi coverage can be achieved and its impact accelerated in areas where it is most needed.

Country studies have demonstrated that with minimal training, SP-IPTi is simple to administer at the time of vaccination — adding only 15 minutes to the average vaccination session and not requiring staff to work overtime⁹. The acceptability with health workers and communities was very high. Immunization monitoring and reporting forms and stock management systems can be adapted to include SP-IPTi without difficulty. As SP is very inexpensive, using EPI as the delivery channel for SP-IPTi is highly cost effective.

Most importantly, when given at the same time it has been confirmed that SP-IPTi has no negative effect on the protective efficacy of EPI vaccines.

How much does SP-IPTi cost?

Detailed costing studies conducted in five districts of southern Tanzania estimated that the financial cost to both start-up and run SP-IPTi in the whole country in 2005 would cost US\$ 1.5 million¹⁰. The cost of starting SP-IPTi at the national level was US\$ 36 000: these costs were mainly the development of Behaviour Change Communication (BCC) materials (i.e. training leaflets, job aids, and posters), stakeholders' meetings, and other consultations. Start-up costs were approximately US\$ 8 000 per district, with the majority (94%) of this expenditure spent on training. The estimated annual running costs at the national level were US\$ 460 000, and included programme management, monitoring, as well as SP drug purchase. Annual running costs at the district level were low at US\$ 170 per district mainly for the printing of BBC materials. No incremental financial expenditure was needed to deliver the SP-IPTi in

⁸ WHO/UNICEF *Global Immunization Vision and Strategy (GIVS)*, Geneva, WHO, 2005 available at: <http://www.who.int/immunization/givs/en/>

⁹ Manzi, Fatuma, Schellenberg, Joanna, Hamis, Y., et al. Intermittent preventive treatment for malaria and anaemia control in Tanzanian infants; the development and implementation of a public health strategy. *Royal Society of Tropical Medicine and Hygiene*, 2009. Vol. 103, 79-86.

¹⁰ Manzi Fatuma, Hutton Guy, Schellenberg Joanna, et al. From strategy development to routine implementation: the cost of Intermittent Preventive Treatment in Infants for malaria control. *BMC Health Services Research* 2008, 8:165.

health facilities, as supplies were delivered alongside routine vaccinations and available health workers performed the administration of SP-IPTi without working overtime.

In Tanzania the economic cost was estimated at US\$ 0.23 per SP-IPTi dose, a low cost compared with other malaria control strategies.

Although the cost of SP-IPTi implementation is likely to vary between countries, the intervention appears to be affordable even within the budget constraints of Ministries of Health of most countries in sub-Saharan Africa.

Financial support for the implementation of SP-IPTi is available from the Global Fund for AIDS, TB and Malaria (GFATM) through the country application process, the President's Malaria Initiative (PMI), and other donors.

4. PLANNING TO IMPLEMENT SP-IPTi

Decision-Making, Policy, and Financing

In formulating a national policy decision on SP-IPTi, it is important that all relevant stakeholders are consulted and that an informed decision-making process is followed. These stakeholders include: the National Malaria Control Programme, EPI, country-decision makers, international organizations, donors, and the academic community.

Many countries already have one or more advisory committees that provide technical and programmatic advice to national malaria control and immunization programmes. For countries that do not already have such a committee, establishing one should be considered to help with the assessment of introducing SP-IPTi. Committee members are usually selected from the scientific community, programme managers/implementers, and partners.

The key steps in the decision-making process are suggested as follows:

- Identify stakeholders, including those involved in the SP-IPTi policy adoption.
- Establish a task force to bring together all the parties. An existing committee could be used as a forum for this purpose.
- Examine the policy and programmatic issues by reviewing evidence and experiences within the National context.
- Identify funding sources (government and/or donors).
- Formulate and disseminate policy recommendation on SP-IPTi.

In situations where a national-scale implementation is not appropriate due to varying malaria transmission intensity or varying levels of SP drug resistance¹¹, a policy decision to implement SP-IPTi at a sub-national level in certain provinces or districts may be made. In such instances, it is important that a correct decision-making and policy process should be followed to review all the options.

¹¹ WHO recommends SP-IPTi in sub-Saharan African countries/districts with moderate to high transmission (Annual Entomological Inoculation Rates (EIR) ≥ 10) and where parasite resistance to SP is not high (*Pfdrps* 540 mutation of ≤ 50).

Once a decision to implement has been taken, the rationale, strategy and activities needed for SP-IPTi should be identified and integrated into the National Malaria Control Strategy, and/or the national comprehensive immunization multi-year plan (cMYP). This can either be done by updating an existing plan (e.g. with an Addendum), or developing a new one if the timeframe of the existing plan is close to the end.

Define, in the implementation plan for SP-IPTi, the person(s) and programme(s) responsible, the budget, and timelines for implementation. Identify all the critical activities that need to happen before the start of SP-IPTi. Include time and resource requirements to develop the training materials, updated reporting forms and supervision checklists and the requirements for training of staff and IEC activities, in the overall plan for SP-IPTi implementation.

SP is an inexpensive and readily available antimalaria medicine. Delivery of SP-IPTi through the EPI system is also an efficient and cost-saving strategy. Nevertheless, as part of the decision-making and planning process, the costs of implementing SP-IPTi should be carefully calculated and the financing secured. A cMYP Costing and Financing Tool has been developed to estimate the costs and financing of immunization (including financing gaps). This tool, which can be easily incorporate SP-IPTi, is accompanied by a User-Guide which provides an overview of financing components for immunization, as well as a step-by-step instruction on how to use the tool.

For further information, please refer to the WHO-UNICEF cMYP Guidelines and Tools (2005) which can be found at the following link:
http://www.who.int/immunization_financing/tools/cmyp/en/index.html

Long-term sustainable financing is required for successful implementation and continuous increases in coverage of any programme, including SP-IPTi. This funding can come from sources that are either domestic (government) or international (donors).



It will be useful to consider the points below when preparing or updating a National Malaria Control Strategy or a comprehensive Multi-Year Plan (cMYP) to include SP-IPTi.

1. Experience from previous interventions that have been integrated into EPI (e.g. vitamin A supplementation, deworming, ITN distribution, etc).
2. Information on malaria:
 - surveillance data and trends
 - disease burden
 - public health importance and public demand
3. Programmatic objectives:
 - expected SP-IPTi coverage
 - disease-reduction goals attributable to SP-IPTi
4. Implementation aspects:
 - vaccination schedule and contacts to be used for SP-IPTi
 - strategy for introducing SP-IPTi into the EPI system.
 - supply needs
 - adverse events after immunization (AEFI) monitoring
 - revision of recording forms and reporting tools
 - staff training and supervision
 - information, education and communication
 - budget and financial sustainability
 - monitoring and impact evaluation

Logistics and Forecasting Supplies

When the logistics of any programme are well-managed, it can help save on programme costs by ensuring programme implementation is efficient without sacrificing the quality of service delivery. Poorly managed logistics systems can lead to high and/or unnecessary wastage rates, stock outs, resulting in significant operational programme costs, as well as a negative impact on public health.

As SP-IPTi is to be administered to the same target groups, at the same time and place as vaccination, it is programmatically efficient to integrate the distribution, delivery and management of the supplies. Most national immunization programmes have well developed and functioning logistics systems in place. Rather than establishing parallel systems for SP-IPTi, as much as possible SP-IPTi should “piggy back” on the logistic processes and supply channels used by the immunization programme.

Storage: SP is most frequently available in bottles/containers of 1 000 tablets. If this volume is too much for a particular health centre or outreach then the SP tablets may be separated into smaller containers or packages (e.g. zip-locked bags). When stored in its original, airtight container, the expiry date for SP is typically five years. SP can be stored at room temperature in a dry place. The tablets for SP-IPTi should always be kept with the materials and supplies that are used by the immunization and preventive child health clinics.

Supplies: Estimating the SP-IPTi supply needs for the first time is based on the **target population, coverage, and wastage factor**. Often there is considerable uncertainty about these, however, it is better to overestimate rather than to underestimate the initial supply needs (provided the shelf-life of the SP is long enough to avoid the risk of expiry). The subsequent orders must be adjusted based on actual usage and current stock levels. The supply estimate also needs to be adjusted continually with any new data on population, coverage, or wastage.

Calculation of total SP-IPTi doses to be administered per year:

$$\text{Doses of SP-IPTi to be administered per year} = \text{Target population (the annual birth cohort)} \times \text{Coverage (in \%)} \times \text{Number of SP-IPTi doses per child (3)}$$

Coverage of SP-IPTi will need to be initially estimated based on the coverage of the vaccines that are given at the same time (DTP2/Penta2, DTP3/Penta3 and measles). Commonly there is a drop-out between DTP3/Penta3 and measles vaccination (i.e. some of the children vaccinated with DTP3/Penta3 do not return for measles vaccination at 9 months of age), however, it is hoped that SP-IPTi may help provide an additional incentive for mothers/caregivers to complete the vaccination of their children beyond DTP3/Penta3. Therefore, it is preferable to use the coverage of DTP2/Penta3 to avoid any potential stock-outs. Although this method leads to some overestimation in the first year, the quantities are adjusted in the subsequent years when the end-of-year-balances are factored into the next order.

To avoid stock-outs due to delays in shipments or higher than expected coverage, it is recommended that an annual **buffer stock of 10%** be maintained. Additionally, as it is likely that some SP tablets will be dropped, or some children may vomit the tablets and need a repeat dose, a **wastage rate of 5%** should be included.

The calculation is divided by two because each SP tablet is split in half — that is one tablet of SP can provide SP-IPTi to two children.

Calculation of total of SP tablets to order in the first year of implementation:

$$\text{Number of SP tablets to order in the first year} = \frac{\text{Doses of SP-IPTi to be administered per year} \times \frac{1.05}{(5\% \text{ wastage})} \times \frac{1.10}{(10\% \text{ buffer or reserve stock})}}{\text{divided by 2}}$$

See Annex 1 for an example of a how to forecast a three-year supply for SP-IPTi.



A word on splitting SP-tablets:

SP comes in tablets containing 500 mg of sulfadoxine and 25 mg of pyrimethamine. The correct dosage depends on the weight of the child.

- **Children weighing less than 5 kg should be given $\frac{1}{4}$ of a tablet.**
- **Children weighing 5 kg or more should be given $\frac{1}{2}$ a tablet.**

Most manufacturers of SP score (mark with a line) the tablets in half, and sometimes quarters.

By three months (12 weeks) of age, most infants weigh more than 5 kg, but this is not the case in areas where malnutrition is present. Therefore weighing babies is helpful to determine the correct dosage of IPTi to give, especially as most immunization sessions will have weighing scales available.

For the first dose of IPTi (at DTP2/Penta2 normally given around 10 weeks of age) some children will receive $\frac{1}{4}$ of a SP tablet. For the subsequent two IPTi doses, if malnutrition is not a problem, children will likely receive $\frac{1}{2}$ a tablet.

For ease of instruction to the health worker and for calculation of supply:

- **One tablet can be used for 2 children (i.e. one tablet split into 2 = two $\frac{1}{2}$'s).**
- **If the child is to receive a $\frac{1}{4}$ tablet dose, then the remainder (the other $\frac{1}{4}$) of the tablet should be discarded.**

If the split tablet breaks unevenly or crumbles the health worker should be instructed to:

- **Use the tablet only if they are certain that they can give the correct dosage to the child.**
- **Throw away remaining fragments of any crumbled tablet.**
- **Alternatively, if they are not sure that they can estimate the correct dosage, they should discard the entire broken tablet and start again with a new tablet.**

This type of “wastage” of tablets is anticipated, and has been accounted for in the calculation of supplies. The most important thing is to provide children with the correct dose of SP-IPTi.

Training and Supportive Supervision

Before implementing SP-IPTi, health staff will need to receive training. If well prepared and organized, it is feasible to cover all the necessary background information, operational issues, and hands on practice in one day of training. Ideally, rather than organizing a special SP-IPTi training, it is desirable to schedule the implementation so that the SP-IPTi training can be included as part of any regular annual or refresher training. However, training should not be conducted too far in advance of the actual start-up of SP-IPTi.

Training for SP-IPTi should include the following:

- Brief overview of the National Malaria Control Strategy and the rationale for introducing SP-IPTi.
- Context of linking SP-IPTi to immunization (experience of linking other interventions such as vitamin A or deworming, performance of immunization programme, etc).
- Key messages/materials for communities and mothers/care-givers about SP-IPTi.
- Adverse events - how to detect and how to handle.
- Instruction and practice on how to administer SP-IPTi with immunization, including schedule, dosage, splitting and preparation of SP tablets.
- Record keeping and reporting of SP-IPTi doses administered, including calculation of coverage and use of coverage wall monitoring chart.
- Stock management of SP supplies.

Training materials need to be prepared (or translated) in the appropriate local language and in sufficient quantities. Summarized reference materials and job aids should be developed and provided to the participants attending training so that they have information to review themselves and with others they work with when they return to their post.

Studies suggest that for more effective learning interactive and hands-on training like field visits, showing videos of correct practices, small group discussions, demonstration and skills practice is generally more successful than passive classroom lectures.

Once deployment of SP-IPTi begins in a country, implementation should be periodically reviewed through supportive supervision¹², which includes “on-the-job-training”.

¹² For more information see *Training for Mid-Level Managers (MLM), Module 4: Supportive Supervision*. WHO, 2008 (WHO/IVB/08.04).

EPI supervisory schedules and tools should be adapted to include SP-IPTi. Annex 2 provides an example of how an immunization supervisory checklist can be easily adapted to include SP-IPTi.



Supportive supervision:

- Encourages open, two-way communication;
- Builds team approaches that facilitate problem solving;
- Focuses on monitoring performance towards goals;
- Uses data for decision-making;
- Depends on regular follow-up with staff to ensure that new tasks are being implemented correctly.

Supportive supervision is helping to make things work, rather than checking to see what is wrong.

Information, Education, and Communication (IEC)

The development of information, education and communication (IEC) resources is needed for several purposes - advocacy, social mobilization, and for health worker training. Before preparing any material, there should be a needs assessment to make sure that the appropriate materials are developed. As well as developing new SP-IPTi material, existing IEC material that is used by the immunization programme may also need to be adapted.

Advocacy efforts for SP-IPTi can use the developed IEC materials in order to communicate the expected benefits of adding SP-IPTi to EPI, building trust and awareness with communities, and creating demand.

A range of channels should be used to deliver the messages about SP-IPTi, including community volunteers and health workers, as well as the mass media. At the national level, the Inter-Agency Coordinating Committee (ICC) is the primary body to be involved in advocacy at that level. Obtaining the support of Non-Governmental Organizations (NGOs), ministries of finance and education, other donor agencies, the private sector, universities, and community and religious leaders is important.

Advocacy and communication plans also need to be prepared to address possible adverse events following SP-IPTi when given at the same time as immunization. These efforts need to deal with community concerns about safety, respond to rumours and other negative publicity about SP-IPTi and vaccination.

See Annex 3 for examples of the IEC materials for SP-IPTi used in Tanzania.

Monitoring

Implementing SP-IPTi will require adaptation and updating of the forms, vaccination or child health cards, tally sheets and registers used for recording and reporting vaccine administration, forms for ordering vaccines and vaccine stock ledgers, among others.

Beyond the cards and forms, the various systems and databases that collect and use immunization information will also need to be updated to monitor the implementation and analyze the impact of SP-IPTi. In many countries these data are not managed by the immunization programme, but by a national health information system or similar. Early communication with the national health information system is needed to ensure an adequate lead time to change the system to include SP-IPTi.

As with other aspects of the immunization programme, addressing the additional information needs for monitoring SP-IPTi is an opportunity to review how information is gathered and used for the National Immunization Programme. It is important to improve the quality of routinely reported data and to use that data to improve programme performance at all levels.

AEFI Monitoring¹³

An Adverse Event Following Immunization (AEFI) is defined as a medical incident that takes place after an immunization, that causes concern, and may be caused by the immunization. Some AEFI's may be due to the vaccine, some due to error in the administration of the vaccine, and some the result of unrelated coincidence.

As SP-IPTi will be given at the same time as immunization, and because SP can sometimes cause adverse reactions in some children, it is important to make sure that AEFI surveillance mechanisms are in place to detect any events.

¹³ For more information see Training for Mid-Level Managers (MLM), Module 3: Immunization Safety. Pages 20-24. WHO, 2008 (WHO/IVB/08.04).

AEFI surveillance includes:

1. Detecting and monitoring AEFI events. For example, by investigating the possible cause of the event (programme error, vaccine related issues, coincidental events) and testing hypotheses with controlled studies.
2. Responding to AEFI by appropriate and immediate action to correct any unsafe practices in order to lessen the negative impact on the health of individuals and the reputation of the immunization programme.
3. Maintaining confidence in the programme by properly responding to parent/community concerns.
4. Estimating AEFI rates in local populations.
5. Formulating and adjusting contraindications, risk-benefit equations, and provider and patient information.

The following policies and standard operating procedures will ensure that effective safety surveillance is maintained:

- Specific roles and responsibilities for the staff;
- Standardized case definitions;
- Clear guidelines for reporting and investigating any AEFI (data management rules);
- Standard reporting and investigation forms;
- Standard forms for line listing of cases;
- An AEFI database for comprehensive analysis (from the lowest practicable level in the system up to national level).

Whenever AEFI are detected, they must be promptly reported regardless of whether or not they are linked to the vaccine and SP-IPTi.

Peripheral health workers may fail to report AEFI for one or more of the following reasons:

1. Not considering the event as related to immunization.
2. Not knowing about the reporting system and process.
3. Fear that the report will lead to personal consequences.
4. Guilt about having caused harm and being responsible for the event.
5. Uncertainty about reporting an event when not confident about the diagnosis.

A manager can overcome these reporting barriers by:

- Increasing awareness of the importance of reporting;
- Teaching staff how to report AEFI;
- Encouraging staff to report, even in cases of uncertainty;
- Emphasizing that investigations are about finding problems with the system, not blaming individuals;
- Giving positive feedback to health workers for reporting AEFI.

Managers should ensure that their staff monitor and report an agreed list of adverse events including those that may be associated with SP-IPTi. Health workers should know to monitor and report at least the following AEFI:

1. All injection site abscesses.
2. All cases of BCG lymphadenitis.
3. Drug reactions to SP.
4. Choking as a result of SP-IPTi administration.
5. All deaths that are believed by health workers, or the public, to be related to immunization or SP-IPTi.
6. All cases requiring hospitalizations that are believed by health workers, or the public, to be related to immunization or SP-IPTi.
7. Other severe or unusual medical incidents that are believed by health workers, or the public, to be related to immunization or SP-IPTi.

The above types of categories of AEFI are sometimes called 'trigger' events because their presence should stimulate or trigger a response from a manager to take action.

5. HOW TO GIVE SP-IPTi DURING AN EPI SESSION

When should SP-IPTi be given?

In areas where it has been decided to implement SP-IPTi, all infants coming for their DTP2/Penta2, DTP3/Penta3, and measles vaccination should receive SP-IPTi if they are eligible (i.e. did not receive a dose of SP or other sulfonamide within the last four weeks for treatment; are not enrolled in a PMTCT programme that is providing Co-trimoxazole; have not previously had an adverse reaction to a sulfa-containing drug; has no symptoms of malaria.

Note: Children with confirmed malaria should be treated with appropriate ACT according to the National Policy, and the dose of SP for SP-IPTi should be given at the next eligible immunization contact with the child. This should be noted on the child health or vaccination card.

Infants (i.e. children under one year) who are delayed in their immunization schedule (for example do not come for their first vaccination on time) should be given SP-IPTi with DTP2/Penta2, DTP3/Penta3, and measles vaccination, irrespective of their age. For ease of implementation, the administration of SP-IPTi should be linked with the time of vaccination of the child for DTP2/Penta2, DTP3/Penta3, and measles, not the age of the child.

Operationally, it may be best to give SP-IPTi before the injection as it is easier for the child to swallow the SP-IPTi solution when they are not crying, and the risk of choking is less. However, SP-IPTi and vaccination can be given in either order.

If a child comes for a scheduled vaccination and there is a stock-out of vaccine, the child should still receive SP-IPTi. Similarly, if there is a stock-out for IPTi the child should certainly still receive all vaccinations that are due.

What dosage of SP should be given?

SP comes in tablets containing 500 mg of sulfadoxine and 25 mg of pyrimethamine. The correct dosage depends on the weight of the child.

- Children weighing less than 5 kg should be given $\frac{1}{4}$ of a tablet.
- Children weighing 5 kg or more should be given $\frac{1}{2}$ a tablet.

By three months (12 weeks) of age, most infants weigh more than 5 kg, but this may not be the case in areas where malnutrition is present. Therefore weighing babies is helpful to determine the correct dosage of SP-IPTi to give.

Figure 1: Health worker weighing child



How should the solution of SP be prepared ?

Once the SP tablet is cut into either $\frac{1}{4}$ or $\frac{1}{2}$, it needs to be dissolved on a spoon in a small amount of potable drinking water. Some brands of SP tablets dissolve readily, but others will need to be crushed into powder (either between two spoons or a folded piece of paper). Where necessary water should be boiled and allowed to cool first thing in the morning while the health workers prepare for the immunization session. Potable water should be taken together with the other supplies for outreach clinics.

Figure 2: Water to mix with SP tablets needs to have been boiled and let cooled



Figure 3: SP tablets are mixed with clean water to dissolve



How should SP-IPTi be administered?

The health worker must directly observe that the spoonful of SP-IPTi solution is swallowed by the infant. Do not give the tablet/or the solution to the mother to take home.

Figure 4: Administration of SP-IPTi to infants must be directly observed by health worker



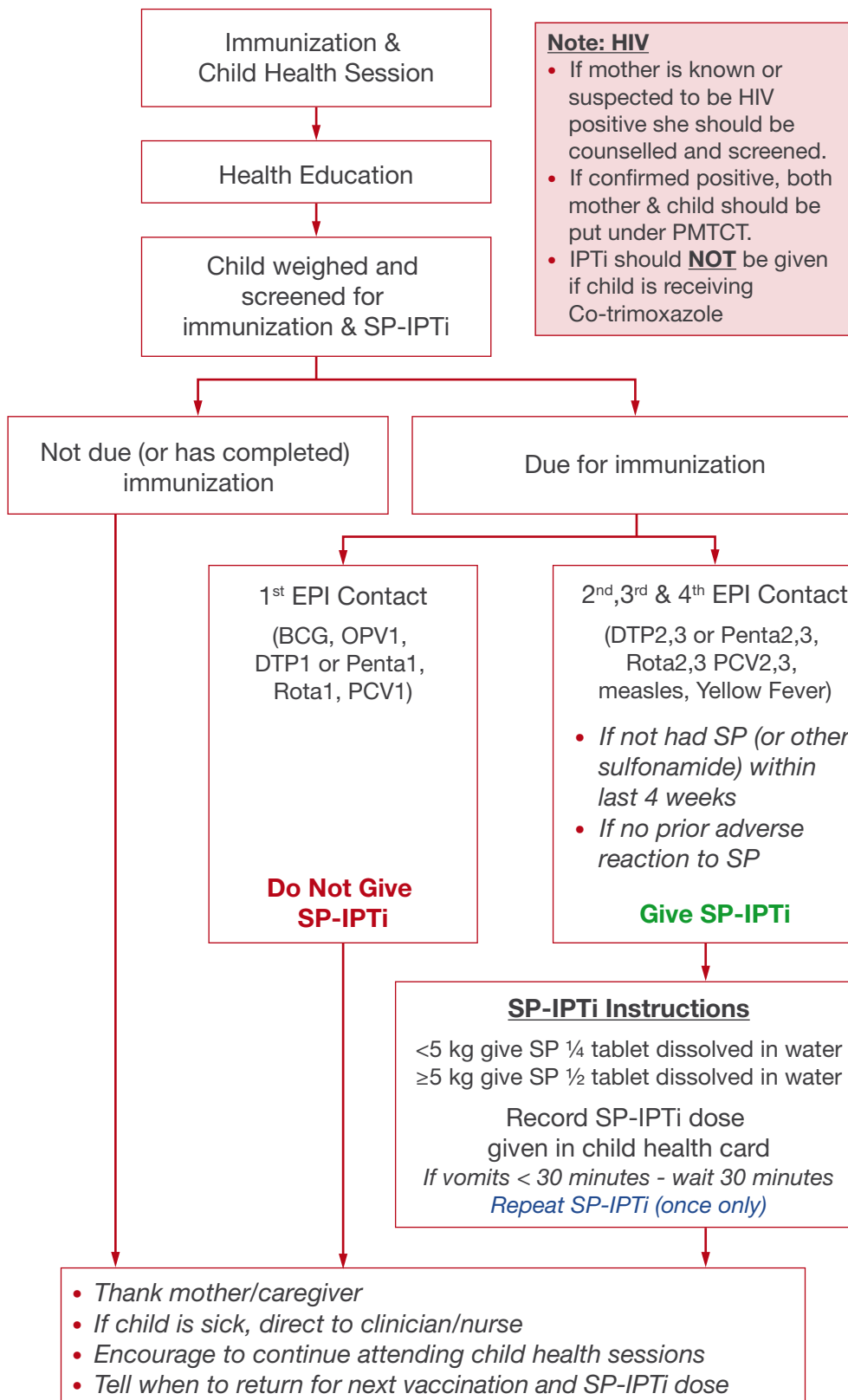
What if the child vomits the solution administered?

Small infants easily vomit solutions that are not completely dissolved. If the SP tablets being used do not dissolve easily, then they will first need to be well crushed before dissolving to avoid vomiting reactions. In the event that the child vomits within 30 minutes of administration, the child should be allowed to rest for 30 minutes before a second attempt is made. In the event that the child vomits for the second time, no further attempt should be made. In this case, you should record in the child's health card and other registers that two attempts were made and the child did not receive SP-IPTi.

The mother should be told when to return for the next scheduled vaccination and dose of SP-IPTi.

The spoon or medicine cup should be preferably sterilized, or at least washed with soap and water, between use for each child.

Figure 5: Immunization and SP-IPTi Flowchart



6. INSTRUCTIONS FOR HEALTH WORKERS

When a child comes for immunization;

1. Explain to the parent/guardian:

- SP-IPTi is the delivery of intermittent treatment to protect infants against malaria when they receive routine vaccination for the second and third doses of DTP/Penta and measles vaccine, at the approximate ages of 8-10 weeks, 12-14 weeks, and 9 months¹⁴.
- The objective of SP-IPTi is to reduce the possibility of infants suffering from malaria and anaemia.

2. Check that the child:

- Has never had adverse reaction due to the use of any drug since birth.
 - If they have, find out to which drug?
 - If the reaction was caused by SP (e.g. Fansidar) or other sulfa-containing drugs, for example cotrimoxazole (Bactrim) and Metakelfin, the child should not receive SP-IPTi.
- Has not received SP, or other sulfonamide, within the last 4 weeks (SP includes the following drugs: Novidar SP, Fansidar, Malafan and Suldox).
- Is not born from a HIV positive mother, and is not participating in a Prevention of Mother-to-Child Transmission of HIV (PMTCT) programme. If the child is in a PMTCT programme and is receiving Co-trimoxazole, do not give SP-IPTi.

3. Check the dose of SP-IPTi to give:

- If the child weighs less than 5 kg, the dose is ¼ tablet of SP.
- If the child weighs 5 kg or more, the dose is ½ tablet of SP.

4. Give SP-IPTi to the child

- On a spoon dissolve the SP tablet with small amount of clean and safe water. Depending on the manufacturer, it might be necessary to crush the SP tablet first if it does not readily dissolve.
- Administer the solution to the child, when held semi-reclined in the mother's arms.

¹⁴ Adapt this timing to whatever ages the national EPI schedule is for DTP2/Penta2, DTP3/Penta3 and measles vaccination.

- Observe that the child swallows all of the liquid SP mixture.
- Follow Infection Prevention measures by cleaning (ideally sterilizing, or at least washing with soap and water) the spoon (or medicine cup if used) after each child is given SP-IPTi.

5. Follow-up the child

- If the child vomits within 30 minutes of SP-IPTi administration, wait half an hour, and then give another dose of SP-IPTi.
- Do not give another dose of SP-IPTi if there is repeat vomiting following the second attempt.
- Advise the parent of the possibility of Adverse Events occurring, and the need to report to the health center.
- Tell the parent when to return for the next vaccination and SP-IPTi dose.

6. Record SP-IPTi administration

- The dose of SP-IPTi and the date of administration should be recorded in the child health card, as well as in the health centre registers, and tally forms.

7. At end of the session

- Discard any unused portions (1/4's and 1/2's) of the SP tablets.

SP-IPTi Schedule with Vaccination and SP-IPTi Dose Recording		
Immunization Contact/Age of Infant ¹⁵	Immunizations due	SP-IPTi Dose
Birth (< 24 hrs after birth)	BCG, HepB	<i>(Do not give SP-IPTi)</i>
1 st contact (6-8 weeks old)	DTP1 or Penta1, Rota1 ¹⁶ , PCV1 ¹⁷ , OPV1	<i>(Do not give SP-IPTi)</i>
2 nd contact (8-10 weeks old)	<u>DTP2</u> or Penta2, Rota2, PCV2, OPV2	SP-IPTi1
3 rd contact (12-14 weeks old)	<u>DTP3</u> or Penta3, Rota3, PCV3, OPV3	SP-IPTi2
4 th contact (9 months old)	<u>Measles</u> + Yellow fever	SP-IPTi3

If there is a stock-out of vaccine when a child comes for a scheduled vaccination, SP-IPTi should be given alone and recorded on the child's health card. Similarly, if there is a stock out of SP for IPTi, then the child should still receive all scheduled vaccinations.

¹⁵ This is an illustrative schedule only; follow the national immunization schedule in your country and link SP-IPTi with the 2nd and 3rd contacts for DTP/Penta (or combo), and measles vaccination.

¹⁶ Number of doses of rotavirus vaccine depends on the type of vaccine used: Rotarix requires only two doses, whereas RotaTeq requires three doses.

¹⁷ Pneumococcal conjugate vaccine (PCV).

7. ADAPTING BASIC RECORDING TOOLS TO INCLUDE SP-IPTi¹⁸

The main recording tools that are used for immunization-related activities should be adapted to include SP-IPTi. At the service delivery level these are:

1. Immunization or child health card
2. Tally sheet
3. Register
4. Defaulter register
5. Stock record
6. Integrated monthly report.

1. Immunization or child health card

The immunization or child health card records the child's immunization history and status. The immunization card is important, and should be adapted to include SP-IPTi, for many reasons:

- It serves as a reminder for parents to return to the health facility for the next scheduled vaccination and SP-IPTi dose.
- It helps the health worker determine a child's immunization and SP-IPTi status.
- It is useful when coverage surveys are conducted.

The card may be the only record of immunization and SP-IPTi history and status available for health workers if facility registers are not well maintained or if clients move from one health facility to another.

Each child should have a card with immunization and SP-IPTi doses marked correctly. See Figure 6.

¹⁸ For further information on immunization monitoring see *Training for Mid-Level Managers (MLM), Module 5: Monitoring the immunization system*. WHO.2008 and *Immunization in Practice: A Practical Guide for Health Staff (2004 Update)*. WHO.2004.

Figure 6: Child Health Card: Example from Tanzania showing where SP-IPTi (called MKINGE in local language) is recorded

Jamhuri ya Muungano wa Tanzania					
Wizara ya Afya					
KADI YA KLINIKI YA WATOTO					
Jina la Kliniki				Na. ya Mtoto	
Jina la Mtoto				Mms/Mke	
Tarehe ya Kuzaliwa		Uzito alipozaliwa (kilo)			
Mahali alipozaliwa		Hospitali/Nyumbani/Njiani			
Jina la Mama/Miezi					
Jina la Baba/Miezi					
Mahali mtoto anapoishi sasa		Kijiji/Kitongoji/Mtaa			
CHANJO					
(Andika Tarehe aliyopata)					
AINA YA CHANJO	Anapozaliwa au mara ya kwanza afikapo kliniki	Marudio miezi 3 baada ya chanjo kama kovu hakuna			
BCG (Kifua Kikuu) (Sindano/Bega)					
POLIO (Kupooza) (Matone/Mdomoni)	0	1	2	3	
	Anapozaliwa	Mwezi 1	Miezi 2	Miezi 3	Miezi 9
DPT-HB (Donda koo, Kifaduro, Pepopunda na hepatitis B) (Sindano/paja)					
SURUA (Sindano/paja)					
VITAMINI A					
VITAMINI A (Matone/Mdomoni)	Miezi 9	Miezi 15	Miezi 21		
MKINGE					
MKINGE (Kidonge/Mdomoni)		Miezi 2	Miezi 3	Miezi 9	

↓

Dose 1	Dose 2	Dose 3
↓	↓	↓

MKINGE				
MKINGE (Tablet/oral)		2 months	3 months	9 months

2. Tally Sheet

Tally sheets are the forms that health workers use to document an immunization session, by making a record for every dose of vaccine given. Tally sheets should be used for all sessions whether fixed, outreach or conducted by mobile teams. It is always worthwhile for a supervisor to spend time reviewing tally sheets with staff to improve the quality of reporting.

Tally sheets should be adapted to include SP-IPTi (see Figure 7 for example).

Figure 7: Sample tally sheet including vitamin A supplementation and SP-IPTi

Name of health facility _____ Date of session _____

Fixed Name of site _____ Outreach/Mobile Name of site _____

Children	Less than 1 year		More than 1 year	
	Tally	Total	Tally	Total
BCG				
DTP1				
DTP2				
DTP3				
SP-IPTi1				
SP-IPTi2				
SP-IPTi3				
OPV0				
OPV1				
OPV2				
OPV3				
Measles				
Vit. A				
HepB-birth				
HepB1				
HepB2				
HepB3				
Protected at Birth (ask at DPT1)	Yes		No	
	Tally	Total	Tally	Total
Women	Pregnant women		Non pregnant women	
	Tally	Total	Tally	Total
TT1				
TT2				
TT3				
TT4				
TT5				
Total TT				
TOTAL TT2+TT3+TT4+TT5				

Names of staff conducting session

3. Immunization Register

While tally sheets record the doses given for each session, the immunization register records doses given to each individual and helps health workers keep track of the immunization services that they have given each child (and pregnant woman). The register should be adapted so that the same can be done for SP-IPTi. Each dose of vaccine and SP-IPTi given to every child (or pregnant woman) in the catchment area should be recorded against their names in the register.

In this way, the immunization register is the basis for tracking individual immunization status (should for example, the child health or vaccination card be lost), and defaulters.



What to include in the register

The register is a permanently available record of a child's vaccination (and SP-IPTi) history. It should include the following information, as well as any information required by your health facility:

- a unique identification number
- registration date (usually the date of the first visit)
- name of infant
- infant's birthdate
- infant's sex
- name and address of mother/parent
- vaccinations, vitamin A supplementation, and SP-IPTi doses that have been provided

Figure 8: Example of Immunization Register adapted to include SP-IPTi

CHILD REGISTER														Village/Street.....		
INFORMATION WRITTEN DURING FIRST VISIT														MKINGE		
Date	Identi- fication number	Date given BCG vaccine	Child Name	Mothers Information		Chairman of hamlet/ Street	Date given DPT- HB3	Date given Polio 3	Date	Measles Vaccine			Vit A	Mkinge Date when 2 month	Mkinge Date when 3 month	Mkinge Date when 9 month
				Name	Received TT					< 60%	60 - 80%	80%+				
					Y N ?											
					Y N ?											
					Y N ?											
					Y N ?											
					Y N ?											

4. Defaulter Register

It is important to follow-up and track children who fail to present for immunization and SP-IPTi. If many in the catchment area of the health facility are defaulting, then this may indicate a widespread lack of confidence in vaccines or SP-IPTi, poor outreach services, or problems with stock-outs. A system to track drop-outs is an integral part of the Reaching Every District (RED) strategy and is well described in *Microplanning for immunization service delivery using the Reaching Every District (RED) Strategy* (2009, WHO). The RED approach can, and should, be used for planning the delivery of IPTi too.



The “Reaching Every District” approach focuses on improving five components:

- Planning and managing resources
- Outreach services
- Supportive supervision
- Reinforcing community links with services
- Monitoring of services for action at the district level

There are many ways to monitor and follow-up on defaulters. Two of the most common ways are:

1. Using the immunization register - at the end of each month, review the immunization register to identify infants who may have failed to receive doses of vaccine or SP-IPTi when due. For example, if an infant received its DTP2/Penta2 and SP-IPTi1 dose in February check to see whether he/she received DTP3/Penta3 and SP-IPTi2 in March when the next dose was due.

- Reminder cards - another way to identify “drop-outs” is to make “reminder cards”, which are copies of the infant’s immunization cards. File the copy of the immunization card in a box with dividers for each month as in Figure 9.

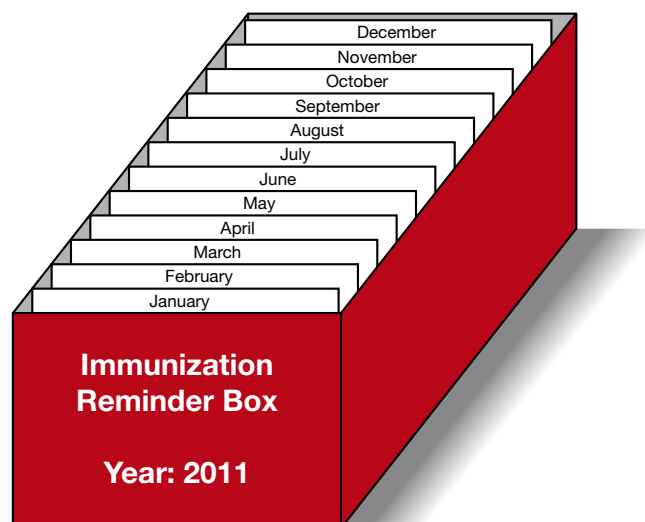
When an infant receives DTP2/Penta2 and SP-IPTi1 in January, place the reminder card in the February section, the month when DTP3/Penta3 and SP-IPTi2 is due. In February if the infant comes when they are due and are given the 3rd dose of DTP and 2nd dose SP-IPTi, update the reminder card and place it in the August section when measles vaccination and SP-IPTi3 are due at 9 months of age.

Every month, review the reminder cards and follow-up those who did not attend when due.

Whatever system is used, it will only be effective if you make sure every infant receives the vaccination and SP-IPTi doses that are overdue. If you track defaulters regularly every month it will make the task of follow-up much easier. To follow up defaulters you may be able to contact the mothers or ask members of the community to help you.

Module 8 of *Immunization in Practice: A practical guide for health staff (2004, WHO)* describes ways of working with the community. For example you may be able to give a list of infants and mothers to a community leader or volunteer who can then advise mothers to return for the vaccine and SP-IPTi doses that are due.

Figure 9: Box for filing reminder cards



5. Stock record

Just as with vaccines, a system of stock management for malaria drugs, including SP for IPTi must be in place to record the stocks received, dispatched and used. This will help ensure that:

- SP drug supply is used before their expiry date;
- There are no stock-outs, or over-stocking.

For areas where SP-IPTi is to be delivered, the stock records for vaccines can be adapted to include the stock of SP-IPTi. This is efficient because as SP-IPTi is to be given at the same time as DTP2/Penta2, DTP3/Penta3, and measles vaccination, the stock of SP available needs to match the stock of these vaccines (since the target groups are the same). Whenever possible the stock records should be adapted to include the monitoring of SP stock for SP-IPTi.

Stock records can be maintained using a simple exercise book or using separate cards¹⁹. It is a good practice to record the balance of stock available on the Monthly Report which is completed by the health centre and sent to the district or provincial level (see Section 6 below).

Consideration should also be given to planning the distribution and delivery of SP drugs “bundled” with the vaccines, so it is assured that the supply of the two interventions that are intended to be administered together are available in matching quantities in the same place, at the same time.

6. Integrated monthly report

Traditionally, immunization data are collated into a monthly report at each level of the health service. The monthly report contains critical data on most of the components of the immunization system, without being too detailed and without putting too much burden on health staff. Where SP-IPTi is integrated into EPI, the monthly report should also be adapted.

The health facility compiles the data it collects into a monthly report that is forwarded to the district. The district then consolidates data from all the health facilities into a monthly report, and forwards this on to the provincial or regional level. Finally, the province/region consolidates all the district data into a provincial monthly report, which is then sent up to the national level.

¹⁹ Stock records are discussed in more detail in *Training for Mid-Level Managers: Module 1: Cold chain, vaccines and safe-injection equipment management* (2008, WHO) and in *Immunization in practice: A practical guide for health staff* (2004, WHO)

Figure 10 provides an example of a monthly report, including SP-IPTi, that is sent from the health facility. It shows:

- the number of vaccines and SP-IPTi doses administered in the month, including the number of fixed and outreach sessions;
- stocks received and used, including vaccines, injection equipment, and SP;
- disease surveillance (cases and deaths in the month);
- number of adverse events following immunization (AEFI) identified.

Note that this is an “integrated” monthly report, meaning that it includes immunization data, as well as disease data. In some countries, however, the disease data is completed in a separate report. For a manager both types of data are important to help monitor the progress and impact of services, and to take action when problems are identified.

Ideally, data collected from monthly reports and other sources should be consolidated into a computer database for easy reference and to generate useful tables and graphs.

The database should be sufficiently comprehensive to include all the quantitative data provided in the monthly report; for example immunization and SP-IPTi doses, disease incidence, AEFI, vaccine/injection equipment and SP drug supplies and stock levels, etc.

There are many examples of computerized databases available in various countries. One example is an Excel-based database that has been developed at WHO-HQ to include the quantitative data likely to be collected in a monthly report. It can be readily adapted to include IPTi. (Available from EPI Team, Department of Immunization, Vaccines & Biologicals (IVB), WHO, Geneva).

Figure 10: Example of Monthly Report adapted to include SP-IPTi

EPI-TENGA MoH

(Full spelling of the national Immunization Programme)

MONTHLY VACCINATION

1. SYNTHESIS OF MONTHLY VACCINATIONS GIVEN

VACCINATION STRATEGIES	No. of sessions	TT VACCINATIONS TO PREGNANT WOMEN					BCG		POLIOMYELITIS VACCINATION						
		1st dose	2nd dose	3rd dose	4th dose	5th dose	0-11 mos	≥1 year	at birth	< 1 year			> 1 year		
Fixed															
Outreach															
Total month															
Total doses opened															

2. FACILITY/ DISTRICT STOCK MANAGEMENT DATA

Vaccines & injection equipment	Quantity received each month	Stock balance at the end of the month	Vaccine doses discarded due to VVM change	Temperatures at which vaccines have been exposed	
				Min (°C)	Max (°C)
Vaccines & Vitamine A					
BCG					
DTP					
OPV					
Measles					
TT					
YF					
HepB					
Hib					
Vitamin A					
SP(IPTi)					
Injection equipment					
AD Syringes 0.05ml					
AD Syringes 0.5ml					
Syringes dilution, 2ml					
Syringes dilution, 5ml					
Safety boxes					

3. SYNTHESIS OF DISEASES

Targeted diseases	0-11 months	
	cases	deaths
AFP		
Measles		
MNT		
Diphtheria		
Pertussis		
Yellow Fever		
Meningitis		
Malaria		
Others		
Type of AEFI (Events)		
Abscesses		
Anaphylaxis		
Other allergic reactions		
BCG Lymphadenitis		
Deaths		

INSTRUCTIONS : This template is the only monthly reporting tool for all levels.

at service & sub-district levels:

the health workers fills in the form by making a synthesis of all vaccination session tally sheets of the month, the stock received and the completed template should be sent to the higher level before the 10th of each month.

at district level:

for item 1. & 3., the manager should make the summary of the data items for all peripheral vaccination units. For item 2. & 4. should be reported. The completed template should be sent to the higher level latest the 10th of next month.

at provincial & national level:

provincial & national levels received the reports from districts. Managers at those levels will make the required standard summary.

8. MONITORING PROGRESS AND PERFORMANCE

The data that are collected and compiled are only useful if they are used to improve the programme performance. Immunization programmes have several tools that are widely used by managers and health staff at all levels to analyse and display data, and identify problem areas. These include:

1. Coverage/drop out monitoring charts;
2. Bar charts;
3. Maps and tables.

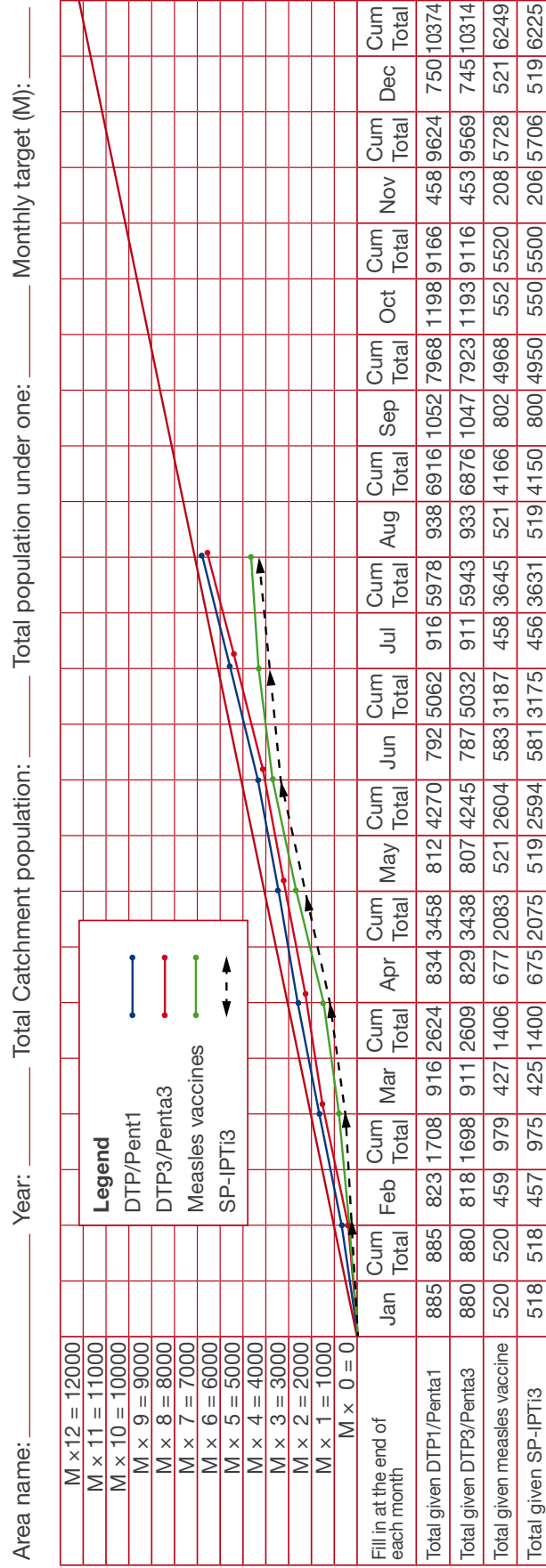
1. Coverage/drop-out monitoring chart

A coverage/drop-out monitoring chart is a simple and effective tool for visually monitoring the progress towards immunization coverage targets in one area (health facility catchment, district, or region). These “wall monitoring charts” are found in health facilities around the world. Given that the coverage targets for SP-IPTi are the same as those for immunization, a coverage monitoring tool can be easily adapted to display SP-IPTi progress also. The following information is presented on a graph:

- The number of vaccines (and SP-IPTi doses) administered on a month-to-month basis compared with the number of children who should have received them (the target population).
- Plotting the coverage rates of each vaccination (or selected doses) on the same graph makes it possible to monitor the drop-out rates between different vaccines or doses (i.e. the number of infants that started receiving immunization or SP-IPTi compared to the number of infants that completed all their vaccine or SP-IPTi doses).

Figure 11 shows an example of a coverage/drop-out monitoring chart including SP-IPTi. See Annex 4 for step-by-step instructions and a blank chart that may be adapted for country use.

Figure 11: Example of Immunization coverage “wall” monitoring chart including SP-IPTi coverage

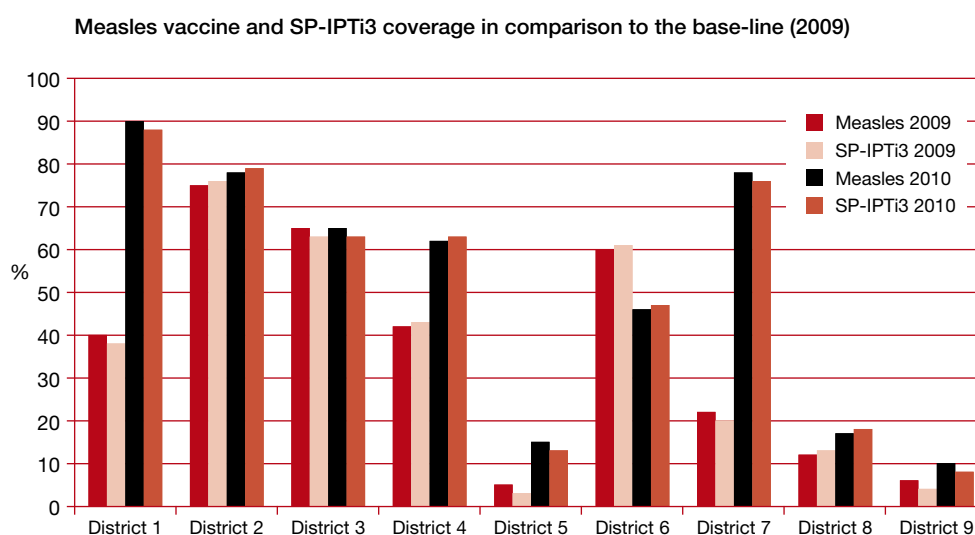


2. Bar charts

Although the coverage/drop-out monitoring chart can display information for one area such as a health facility or province, usually mid-level managers need to compare data across several areas which cannot be done using monitoring charts.

The bar chart is easy to prepare and interpret, and can be used for the presentation of simple numbers, rates, or percentages across a number of districts, or more complex analysis involving a number of different indicators. A bar chart should always include information about the time period covered by the chart, including the year.

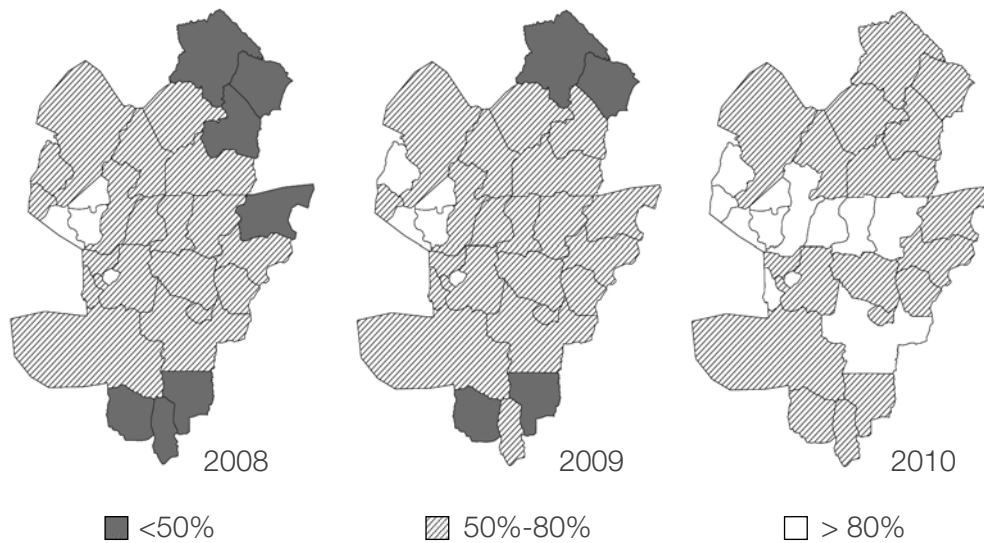
Figure 12: Example bar chart - Measles vaccination and SP-IPTi3 coverage by year 2009-2010 (baseline year 2009)



3. Maps and tables

Mapping is a very useful tool for displaying data on immunization and SP-IPTi programme performance. Simple maps, such as shaded maps, can illustrate coverage data very effectively. Maps should always be labelled with a description of the indicator being measured by the map, and details of the time period covered, including the year.

Figure 13: Shaded map showing low, medium and high SP-IPTi3 immunization coverage in a hypothetical Province, 2008–2010



Simple tables can also be effective tools. For example, an easy way to compare quarterly performance is to divide the number of doses given during that quarter by the target population for that quarter. This method is the simplest way to compare performance within each district quarter-by-quarter and to make a real comparison between several districts.

Figure 14 shows how data (for vaccination and SP-IPTi) from different districts can be entered into a single table for easy display and analysis by the mid-level manager.

District one has an annual target population of 2 400 infants and the quarterly measles and SP-IPTi coverage is calculated using the following values of numerator (i.e. number of measles and SP-IPTi3 doses given). The monthly target is 200 infants; the quarterly target is 600 infants.

District 1	Q1 (Jan-Mar)	Q2 (Apr-June)	Q3 (July-Sept)	Q4 (Oct-Dec)
Does given measles	500	450	380	550
Doses given SP-IPTi3	500	450	300	500
Quarterly coverage measles	82	75	63	91
Quarterly coverage SP-IPTi3	82	75	50	83

Note that the annual coverage will be the total of all doses given in the four quarters divided by the annual target population.

For example: Measles (500 + 450 + 380 + 550) divided by 2 400 = 78%
 SP-IPTi3 (500 + 450 + 300 + 500) divided by 2 400 = 73%

Note that the coverage for SP-IPTi3 is lower than the measles vaccination coverage. This suggests that there is a problem (some infants who are being vaccinated for measles are not receiving SP-IPTi at the same time) which needs to be investigated.

Below (Figure 15) is a blank table that can be used to monitor, analyse, and display the quarterly vaccination and SP-IPTi coverage for multiple districts.

Figure 15: Quarterly coverage data analysis, for vaccination and SP-IPTi
 For each district: At the end of each quarter, enter the reported coverage for each antigen and SP-IPTi

	BCG				DTP1				DTP3				IPTi1				IPTi3				OPV3				Measles				HepB3				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
District 1																																	
District 2																																	
District 3																																	
District 4																																	
District 5																																	
District 6																																	
District 7																																	
District 8																																	
District 9																																	
District 10																																	



DON'T FORGET TO INCLUDE SP-IPTi IN SURVEYS

Period immunization coverage surveys, Malaria Indicator Surveys, Demographic and Health Surveys (DHS) and Multi-Indicator Cluster Surveys are all opportunities to include an assessment of SP-IPTi coverage.

9. KEY REFERENCES

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10. ANNEXES

Annex 1: How to forecast a three-year supply of SP-IPTi

Table 1	Definitions and formulas	Year 1	Year 2	Year 3
Target population to receive SP-IPTi (birth cohort)	a	100 000	102 000	104 040
Number of SP-IPTi doses per child	b	3	3	3
Estimated coverage with first dose (SP-IPTi1)	c	75%	80%	85%
Wastage rate	d	5%	5%	5%
Wastage factor	$e=1/(1-d)$	1.05	1.05	1.05
Annual need	$f=(a*b*c*e)/2$			
Buffer stock (<i>f'</i> is the Annual need for the previous year)	$g=(f-f') \times 1.10$			
Total forecast	$h=f+g$			
End-of-year-balance	i	0		
Total	$j=h-i$			

Key to table 1:

- a: **Target population to receive SP-IPTi** can be based on the same as is used to estimate the target population for DTP/Penta vaccination. Normally, this is the estimated births (birth cohort) adjusted each year with growth projections. If SP-IPTi is to be progressively phased in, or delivered in selected areas only, the target population must be adjusted accordingly.
- b: **Number of doses of SP-IPTi per child** is three (with DTP2/Penta2, DTP3/Penta3 and measles vaccination).
- c: **Estimated SP-IPTi coverage** should be initially estimated based on the coverage of DTP2/Penta2 (when the first dose of SP-IPTi is to be given). If DTP2/Penta2 coverage is not available use DTP1/Penta1 as a proxy.
- d: **Wastage rate** of 5% (0.05) should be included in order to cover tablets that are broken, dropped, or otherwise damaged, and those doses which are vomited by children and need to be repeated.
- e: **Wastage factor** of $1/(1-5\%)=1.05$: this factor includes wastage that is expected during distribution and administration of SP tablets.
- f: **Annual need** equals $(a \times b \times c \times e)$ divided by 2, because one SP tablet can provide IPTi for two children (one tablet split into two $\frac{1}{2}$'s).
- g: **Buffer (or reserve) stock** is usually accepted as 10% of the annual need. It is a rolling stock to be maintained over the years. In the first year, the buffer stock (10%) is added to the annual need. In subsequent years, the annual need of the previous year (*f'*) is subtracted from the annual need of the current year (*f*), which is then multiplied by 1.10 (10%).
- h: **Total forecast**: the amount of stock forecasted to be needed annually including buffer stock.
- i: **End-of-balance**: the amount of stock remaining (unconsumed) in store at the end of each year. This amount should be carried over to be used in the subsequent year.
- j: **Total to be ordered**: the total amount forecasted (h) minus the end-of-year balance (i).

Annex 2: Example of supervisory checklist adapted to include SP-IPTi

	Question	Y/N	Comment (problems observed)	On site corrective action	Longer term corrective action
1	Is the session organized efficiently?	Y			
2	Is the screening for SP-IPTi eligibility conducted properly?	N	<i>Not asking if SP given within 4 weeks.</i>		
3	Are immunization cards in use for every infant and pregnant woman?	Y			
4	Is the register used for recording information on each child/mother/pregnant woman?	Y	<i>Not filled correctly</i>		
5	Are parents advised on when to return for the next immunization and next SP-IPTi dose?	N			
6	Does the health facility have a monitoring chart displayed? Does it include SP-IPTi coverage?	Y/N	<i>IPTi coverage not calculated or monitored</i>		
7	Does the health facility have a map of the catchment area displayed?	N			
8	Does the health facility have a workplan for the quarter?	Y	<i>Available but not used</i>		
9	Are planned sessions monitored for completeness/timeliness?	N			
10	Is there a system for tracking defaulters? Are defaulters for SP-IPTi tracked?	Y			
11	Does the health facility display a spot map of measles cases?	Y			
12	Is a temperature monitoring chart in use?	Y			
13	Are the vaccines stacked properly inside the refrigerator?	N	<i>HepB vaccine kept too close to freezer</i>		
14	Are there any expired vaccines inside the refrigerator?	N			

15	Are there any vaccines with VVM reaching the discard point?	Y			
16	Do the health workers know how to read and interpret the VVM? Ask them to describe the stages of the VVM and what they mean.	Y			
17	Ask them does the staff member know WHEN to perform the shake test? Can he/she correctly perform the shake test? (Ask them to demonstrate how they would do it).	Y			
18	Can he/she is there an adequate supply of AD syringes for the planned sessions?	Y			
19	Are AD syringes used for every immunization?	Y			
20	Is the injection technique appropriate? Is the technique for giving SP-IPTi correct? Is clean water used?	Y			
21	Are safety boxes used for each AD syringe and needle?	Y			
22	Is the spoon for SP-IPTi washed after each child?				
24	Are immunization and SP-IPTi posters displayed on the health-facility wall?	Y			
25	Is there a schedule of community meetings?	N			
26	Is there a community volunteer involved with immunization?	N			
27	Is there a stock register? Is SP supply for SP-IPTi being monitored?	Y			
28	Does the stock register show adequate vaccines, injection equipment and SP-IPTi supplies?	N	<i>AD syringes out of stock; and SP supply for SP-IPTi does not match vaccine stock.</i>		

Annex 3: Examples of IEC materials used in Tanzania (Translations of originals in Swahili)

Posters

MKINGE (IPTi)
Protect your child against MALARIA



IPTi is the administration of SP to small children when they receive vaccinations at 2, 3 and 9 months of age.

MKINGE (IPTi) Coordinator
Ifakara Health Research & Development Centre
P.O. Box 78373, Dar es Salaam

MKINGE (IPTi)
Protect your child against MALARIA



IPTi reduces malaria and anaemia.

Many children have already used IPTi.

MKINGE (IPTi) Coordinator
Ifakara Health Research & Development Centre
P.O. Box 78373, Dar es Salaam

Health worker Information Sheet

MKINGE (IPTi)

Protect your child against MALARIA

What is MKINGE

MKINGE (IPTi) is the delivery of a treatment dose of an anti-malarial drug at pre-specified times, even if there are no symptoms of malaria and no *P falciparum* parasites in the blood.

Each child will be provided with SP 3 times in their first year of life when they receive routine vaccinations as follows:

- Dose 2 of DPT-HB & POLIO
- Dose 3 of DPT-HB & POLIO
- Measles



INSTRUCTIONS FOR THE HEALTH WORKER

When a child attends for **MKINGE**

1. Explain to the parent:

- MKINGE is the delivery of intermittent treatment to protect infants against malaria when they receive routine vaccination at the age of 2, 3 and 9 months.
- The objective of **MKINGE** is to reduce the possibility of infants suffering from malaria, anaemia or convulsions.

2. Check that the child :

- Since she/he was born, has never had an adverse reaction due to use of any drug?
 - If yes, which drug?
 - If SP or other sulphur-containing drugs, for example cotrimoxazole, is mentioned, the child should not be given **MKINGE**.
- Has not used SP in the last 2 weeks
 - SP includes the following drugs: Metakelfin, Fansidar, Orodar.

3. Check the dose of MKINGE

- If the child weighs less than 5kg, the dose is ¼ tablet of SP
- If the child weighs 5kg or above, the dose is ½ tablet of SP

4. Give MKINGE to the child

- Crush **MKINGE** in a spoon. Mix with a small amount of clean and safe water
- Give this drug to the child, when held semi-recumbent in his/her mother's arms.

5. Follow-up the child

- If she/he vomits before half an hour has elapsed, then she/he could be given another dose. Do not give another dose of SP if the child vomits more than half an hour after being given **MKINGE**.

- 6. Record every **MKINGE** dose in its place in the child health card and in HMIS forms F202 (Tally Sheet) and Book 7 (Child Register).

REMINDER FOR ALL HEALTH WORKERS WHO TREAT CHILDREN

For all infants, check whether they received SP, including MKINGE, in the previous 2 weeks, before prescribing SP for malaria treatment.

This is where MKINGE is recorded on the Child Health Card

This is where MKINGE is recorded in the Child's register

This is where MKINGE is recorded on the Vaccination Tally Sheet

For more information

If you have comments or questions please contact any member of the district health management teams (CHMTs) or any representative of the **MKINGE** team from Ifakara Health Research and Development Centre (IHRDC).

MKINGE is also known as Intermittent Preventive Treatment in infants (IPTi). This information sheet is sponsored by MKINGE (IPTi) stakeholders

MKINGE (IPTi) Coordinator
Ifakara Health Research & Development Centre
P.O. Box 78373, Dar es Salaam

Annex 4: How to prepare a coverage/drop out monitoring chart including IPTi

SP-IPTi1 and SP-IPTi2 is administered when DTP2/Penta2 and DTP3/Penta3 vaccinations are given, while SP-IPTi3 is given at the time of measles vaccine administration. This allows for SP-IPTi coverage to be monitored with DTP/Penta and measles vaccine coverage, and helps you to determine whether your target population is receiving the full series of SP-IPTi doses or not. It also allows you to compare coverage and drop out of SP-IPTi in relation to the vaccines administered at the same time.

The following steps will help you to prepare a chart for monitoring the number of doses of SP-IPTi administered to infants less than one year of age. Using the standard immunization coverage monitoring charts, it is possible to modify them to include spaces for monitoring SP-IPTi doses.

In order not to make the chart too complicated, we suggest that only SP-IPTi3 be added (and compared to measles vaccination), however, if you wish SP-IPTi1 can be included and compared to DTP2/Penta2.

1. Calculate the annual and monthly target population of infants less than 1 year of age to receive immunization services (and SP-IPTi)

The annual and monthly target population for SP-IPTi will be the same as the target population for DTP/Penta and measles vaccine.

a) *Annual target population*

Use existing population figures for infants under one year of age obtained from official census data or your own community census. If you do not have these numbers, obtain an estimate by multiplying the total population by 4% or 0.04. (which is the estimated percentage of infants less than one year of age in any given population). If you have a more precise percentage for your country or region, use this number instead.

For example: If the total population is 300 000 then the annual target population of infants less than one year would be $300\,000 \times 0.04 = 12\,000$.

b) *Monthly target (M)*

To get a monthly target population, divide the annual number of infants under one year of age by 12.

For example: If the annual target under one year is 12 000, then the monthly target is $12\,000/12 = 1\,000$.

2. Label the chart with the cumulative monthly target

- a) Label the left side of the chart with the monthly cumulative target figures.
- b) Always ensure that the chart has a title written across the very top so that it does not obscure the chart. Example title: *“DTP1/Penta1 and DTP3/Penta3, measles, and SP-IPTi3 doses administered in infants less than one year of age - Pretend Province - 2011”*.
- c) Label the boxes at the bottom for DTP1/Penta1, DTP3/Penta3, measles, and SP-IPTi3, as shown in the example.
- d) Draw a diagonal line from zero to the top right-hand corner to show the ideal coverage rate if every targeted infant is immunized on time.

3. Plot immunization and SP-IPTi3 data on the chart

- a) Locate the row of boxes underneath the graph. Locate the spaces for the month you are recording. Enter the monthly total of the DTP1/Penta1, DTP3/Penta3, measles, and SP-IPTi3 doses given.
- b) Add the current month's total doses to the previous cumulative total to calculate the current cumulative total and enter it on the right side of the month column you are recording. Cumulative means the total number of doses of vaccines given in the current month plus the monthly totals for all the previous months. (Note: For the first month (January) the monthly total and cumulative total are the same).

For example: The monthly total for SP-IPTi3 in March is 911, the previous cumulative total (in February) is 1 698, so the cumulative total for March is $1\ 698 + 911 = 2\ 609$.

- c) Make a dot on the graph for the cumulative total recorded on the right side of the month column you are recording.
- d) Connect the new dot to the previous month's dot with a straight line.
- e) Repeat above (a to d) every month until the end of the year.

4. Compare doses of measles vaccine and SP-IPTi3 given

Any differences in coverage between measles vaccination and SP-IPTi3 can be easily detected visually via the lines plotted on the chart.

Ideally, the number of doses of measles vaccine and SP-IPTi3 given should be the same or very similar because they are suppose to be given at the same contact. If this is the case, then the lines on the chart for measles vaccine and SP-IPTi3 will be very close together (or even overlapping) indicating that the coverage rates are the same.

However, if there is a large gap between the measles vaccine and the SP-IPTi3 lines this will indicate that there are implementation problems with co-administration and this needs to be investigated and resolved.



- Put the monitoring chart at a place that can be seen easily by the health staff every day.
- Plot the monthly figures on the graph each month to monitor progress.

