

Guide to iCCM PSM Planning for **Global Fund Grants**

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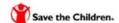
iCCM Financing Task Team, PSM Sub-Team





















§ The Global Fund

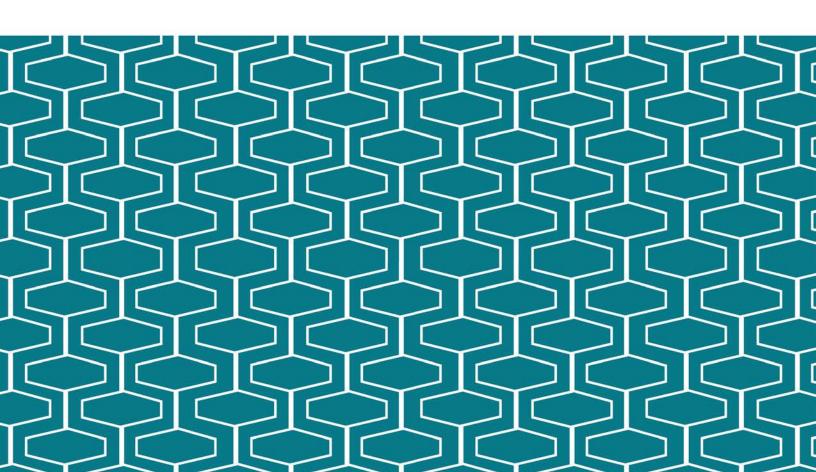


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ACRONYMS AND ABBREVIATIONS

ACT artemisinin-based combination therapy

CHW community health worker

Global Fund Global Fund to Fight AIDS, Malaria and Tuberculosis

HHS health systems strengthening

iCCM integrated Community Case Management LMIS logistics management information system

M&E monitoring and evaluation

MIS management information system

MOH Ministry of Health
ORS oral rehydration salts
PR Principal Recipient

PSM Procurement and supply and management

QA/QC quality assurance/quality control

RDTs rapid diagnostic tests

WHO World Health Organization

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INTRODUCTION

Context of the Global Fund 's New iCCM Funding Opportunity

Through the Global Fund's new funding model (NFM), countries have the opportunity to leverage further resources to support core program components of their integrated Community Case Management (iCCM) programs through their Global Fund Malaria and Health Systems Strengthening (HSS) grants. iCCM improves access to health care for children under five who live far away from functioning health facilities by training and supervising community health workers (CHWs) and supplying them with essential commodities to diagnose and treat certain illnesses— most commonly malaria, pneumonia, and diarrhea, but sometimes also severe acute malnutrition, neonatal sepsis prevention, and other high impact interventions. The inclusion of iCCM activities in Global Fund grants represents a significant opportunity for Ministries of Health (MOHs) to scale up essential child health interventions to reduce child mortality and morbidity rates.

Essential iCCM program components eligible for Global Fund support include training, supervision, monitoring and evaluation (M&E), and malaria commodities. However, the commodity costs of non-malaria services, e.g., diarrhea and pneumonia commodities and health products, cannot be funded using Global Fund resources and must be co-financed by other development partners and national resources. This co-financing arrangement, while representing an exciting step forward in child health, also presents coordination challenges, especially related to PSM planning.

Role of PSM in new iCCM Funding Opportunity

A key component of ensuring the success of any Global Fund concept note submission and program implementation is timely planning and the development and validation of strong procurement and supply management (PSM) arrangements. PSM planning is part of implementation planning that begins during the Global Fund's concept note development and is finalized during the grant-making phase before grant signature.

The co-financed nature of these iCCM programs makes robust and integrated PSM planning even more critical. In addition to the above standard requirements, the Global Fund Principle Recipient (PR) should also reference how non-malaria iCCM commodities will be procured with the support from other cofunders (including the MoH), and how the supply chains for Global Fund-supported and non-Global Fund-supported products will be aligned to ensure on-time, coordinated, and cost-effective delivery. As per the malaria commodities, the concept note should indicate other PSM costs associated with storing and distributing pneumonia and diarrhea medicines, as well as any other non-malaria commodities, and who will finance these costs for each type of commodities.

Purpose

This document highlights and proposes strategies to address challenges that may arise when integrating commodities and PSM activities and implementing iCCM programs that are co-funded by the Global Fund and other donors. The issues addressed in this report will guide MOHs, Country Coordinating Mechanisms (CCMs), PRs and Sub Recipients, UNICEF, other partners' regional and country offices, and PSM consultants in sound, integrated PSM planning processes for their proposed iCCM programs within the broader context of the Global Fund's new funding model. It highlights and proposes strategies to address challenges that may arise when integrating commodities and PSM activities, and implementing iCCM programs that are co-funded by the Global Fund and other donors.

This document is not intended to be a comprehensive resource for iCCM PSM planning but rather focuses on the unique challenges that co-funding presents to iCCM PSM planning. It is recommended that these tips be considered during the concept note phase so that the submitted budget allows for a

supply chain that is robust enough to support iCCM implementation and ensure that a continuous supply of essential medicines is available at the community level. During the grant-making phase, these tips can be revisited to help finalize implementation plans. More in-depth PSM resource documents already exist and are referenced herein.

WHAT PSM-RELATED INFORMATION SHOULD BE SUBMITTED TO THE GLOBAL FUND?

The following table and figure describe the purpose and timing of useful aids and documents, some of which are required for Global Fund applications, all of which include PSM planning activities¹.

Table 1. Tools to Prepare for Global Fund PSM-Related Requirements.

Tools including PSM-related information	Description	Instructions	Link	Required for Global Fund application? Y/N
Gap analysis tool	Excel spreadsheet to calculate quantities of products, program implementation costs, and existing resources secured for iCCM	Quantities developed will inform Concept Note (including budget) as well as a modular template during grant making. It is important to collect accurate data and include all partners from the beginning to avoid making too many changes later in the application process.	 iCCM Gap Analysis Tool² Malaria Gap <u>Table</u> HSS Gap Table 	N
iCCM PSM checklist	Intended to provide an overview of helpful considerations for country teams preparing concept notes and integrated supply plans for iCCM commodities (and for maternal/HIV commodities)	Identify key actions needed to promote integrated supply chain planning and management. To be used as a planning tool in advance of Capacity Assessment Tool during Grant Making.	iCCM PSM Checklist ³	N
Global Fund Concept Note	Necessary to apply for a Global Fund grant. Applicants provide an analysis of the current disease and country context, the current and anticipated funding landscape, and prioritized funding needs for the Global Fund.	Must be developed through a consultative, multistakeholder process, and must clearly demonstrate alignment with the country's national disease prevention and control plans.	Standard Concept Note	Y
	-	Where possible, the concept note should include a high level description of the integration/coordination of the supply chain for both antimalarial and other iCCM		

¹ Complete Global Fund application materials can be found at: http://www.theglobalfund.org/en/fundingmodel/single/applicationmaterial/ Complete Global Fund grant-making resources can be found at: http://www.theglobalfund.org/en/fundingmodel/grantmaking/

² The gap analysis spreadsheet and its instructions can be found at http://ccmcentral.com/iccm-global-fund/

³ The checklist can be found here http://ccmcentral.com/documents/checklist-for-psm-planning-draft/

Tools including PSM-related				Required for Global Fund application?
information	Description	Instructions products, e.g. pneumonia and diarrhea commodities. The gap analysis tool and iCCM PSM checklist may be used when developing the Concept Note.	Link	Y/N
Modular Template	Consists of an integrated performance framework and budget. It describes interventions and outlines the main goals, objectives, modules, interventions, activities, associated indicators and targets, costs and cost assumptions. Also contains quantities of health products to be procured on an annual basis, estimated unit costs, related PSM costs, and expected procurement schedules on a quarterly basis.	This Global Fund template includes the cost and indicators related to the malaria commodities. May also include details about technical assistance (TA) and capacity-building activities requested to enhance the in-country supply chain systems during grant implementation. Estimated quantities and indicators of all iCCM health products (both non-malaria as well as malaria) should be included as an attachment, and should be consistent with the Gap Analysis to demonstrate the integrated approach of the supply planning for iCCM activities	Modular Template	Y* *pneumonia and diarrhea quantities and indicators are not required but it is recommended that they be included as an addendum
Global Fund Capacity Assessment Tool	Includes a section describing the PSM arrangements used in the context of the grant, outlining the roles and responsibilities along the supply chain with key indicators and process description. The CAT is completed by the arrangements mapping	This Global Fund tool is meant to describe how the PRs will assure adherence to each of the Global Fund's PSM policies particularly for commodities procured using Global Fund funds. It is initially completed by the PRs and then reviewed by the Local Fund Agent (LFA), as decided by the Global Fund Country Team and finally approved by the Country Team.	Capacity Assessment Tool Guidance	Y at grant making, may be tailored to reflect grant activities, as decided by the country team.
Implementation /arrangement mapping	A diagrammatic representation of the supply chain, including relevant activities and entities describing product, information and financial flows, from the central level to the community level.	This should be initially completed by the Principal Recipients and then reviewed by the LFA, as decided by the Global Fund Country Team and finally approved by the Country Team.	Implementation Arrangement Mapping Guidelines	Y at grant making stage

Figure 1. Chronologic order of PSM related documents within the Global Fund application process.

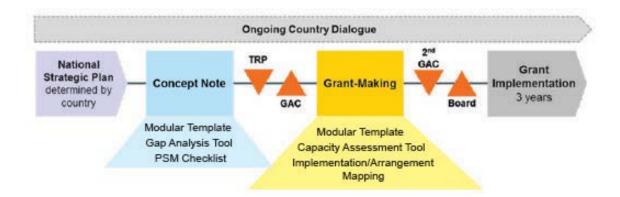


Figure 1 shows at which points the PSM tools mentioned in Table 1 above fit into the Global Fund New Funding Model process of grant approval: some being useful or required before the review of the Concept note by the Technical Review Panel (TRP) and others prior to the 2nd review by the Grant Approvals Committee (GAC) and the decision by the Global Fund Board.

DONOR COORDINATION AND GRANT ACCOUNTABILITY

Securing the Co-Funding Commitment Early

To effectively plan a fully integrated program, countries should identify and secure sources of co-funding for the non-malaria components of iCCM **before** the concept note is submitted. The co-funder's commitment should be linked to a specific quantity of commodities or funds (see columns 2 and 3 in table 2 below) for a specific period of time. PSM planning requires very specific inputs; implementers must know exactly what the co-funders' commitments are, and be able to confirm that co-funders' scopes for financing and timelines are aligned.

While the exact breakdown of the co-funded iCCM program will need to be negotiated on a country-by-country basis among the relevant stakeholders, an illustrative example follows below. It is important to note that the co-funder role can and ideally should be filled by the MOH, where possible, no matter how small the contribution.

Table 2. Illustrative Split of Program and Commodity Funding

To be supported by the Global Fund	To be supported by co- funder(s)	To be funded by the Global Fund, co-funder(s) or both, depending on country negotiations
 Malaria Commodities Rapid diagnostic tests (RDTs) Artemisinin-based combination therapies (ACTs) Gloves and RDT waste management materials Procurement fees, taxes and customs costs, insurance, freight, and other costs associated with bringing commodities into country as well as quality assurance/quality control (QA/QC) for malaria commodities 	 Non-Malaria Commodities Dispersible amoxicillin for pneumonia treatment as well as for severe acute malnutrition or newborn sepsis (depending on the iCCM package) Respiratory timers and counting beads for pneumonia diagnosis ORS and zinc for diarrhea treatment Chlorhexidine for neonatal sepsis Mid-upper arm circumference (MUAC) strips for severe acute malnutrition screening Procurement fees, taxes and customs costs, insurance, freight, and other costs associated with bringing commodities into country as well as QA/QC for non-malaria commodities 	 Human resources for iCCM (salaries, recruitment costs etc) Domestic supply management (storage, distribution systems, security) for all iCCM commodities M&E, MIS, and monitoring tools for the entire iCCM program CHW incentives (monetary or non-monetary) Supervision for iCCM Training and curriculum development for iCCM including supply chain management Other support commodities such as job aids, respiratory timer batteries, ORS dispensing equipment BCC and demand generation activities

N.B.: The Global Fund will <u>not</u> support non-malaria commodity costs (column 2 above). For guidance on national, bilateral, and multilateral co-funding options and contact information, see annex A.

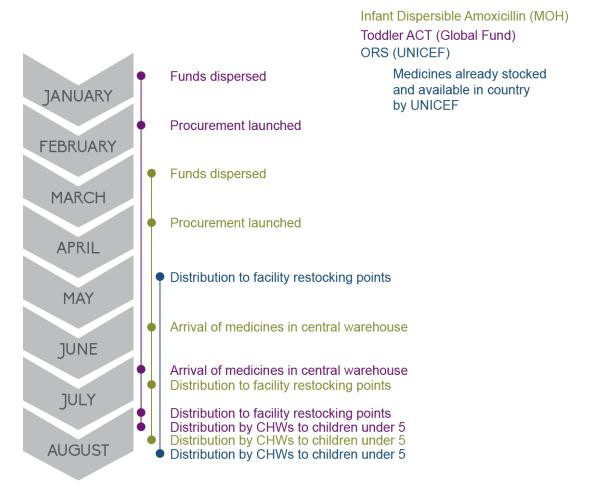
Coordination of Funds Disbursements and Medicine Arrival and Delivery

Once the co-funding has been secured and confirmed, it is important to coordinate the complex timing of disbursements, arrival, and delivery of commodities from the different donors as shown in Figure 2 below, taking into account procurement lead times, product shelf lives, and funding availability. This requires early communication, starting with the joint forecasting of all iCCM commodities (non-malaria –malaria) and a joint supply plan (see pages 22-23). Where possible, initial supplies for all the iCCM program should be scheduled to be available and maintained in sufficient quantities in the designated warehouse at the same time, so that the entire iCCM program can commence and maintain a complete package of services without interruptions. If the iCCM program is just starting up, a flexible shipment schedule is recommended to allow for adjustment of quantities as consumption patterns change and demand increases. This is not necessary in a mature iCCM program where consumption patterns have stabilized. In the event that the co-funder is contributing funds in addition to, or instead of in-kind commodities, the funds should be disbursed to closely match the timing of the disbursements of the Global Fund. This is especially applicable for co-funders whose funding cycles only last one year, whereas the Global Fund has three-year cycles⁴.

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⁴ More information on the Global Fund's funding cycles can be found on http://www.theglobalfund.org/en/fundingmodel/.

Figure 2. Sample Timeline for Coordination of Disbursement, Arrival, and Distribution of iCCM Medicines



NB: Timeline is incomplete, with only a fraction of possible products, donors, and PSM steps. To be used strictly for illustrative purposes.

The complexity of coordinating funds and shipments from different donors underscores the importance of an accurate and frequently updated supply plan (described on page 22).

It is recommended that the MOH designate a focal person or committee to coordinate the various shipments of malaria and non-malaria iCCM commodities to support the relevant PRs and take part in the forecasting/quantification committee throughout the life of the grant(s). This focal person or committee and the forecasting committee should use medicine forecasts and the available logistics management information system (LMIS) data to carry out regular revisions of the forecast and supply plan and related assumptions. There should be a mechanism for the person/committee to flag shortages or misalignments early enough to take corrective action. This should be integrated into the existing PSM system.

Accountability/Indicators

The Global Fund requires careful reporting of the commodities procured with their funding and it is possible that the donors of the non-malaria iCCM commodities will require similar careful reporting on their commodities and outcomes. In both cases, the reporting responsibility will likely lie with the respective implementing agencies. Where possible, measurement frameworks, reporting templates, and

reporting timelines between all funders should be coordinated and transparent. One option would be to roll up all iCCM indicators, including the non-malaria ones, into a single document with a single verification process. This would inform both Global Fund and other funders' performance frameworks and their overall assessment of iCCM. It could be included as an annex to Global Fund (and other funder's) proposals if it is found that this approach is more effective than current practice. Note that it is not possible to include non-malarial indicators into the Global Fund performance frameworks as the performance framework is used as a management tool by the Global Fund and is related to Global Fund supported inputs only; all coverage and output indicators are used for performance assessments and will determine annual disbursement decisions to the PR.

Discussions on how best to jointly monitor and evaluate the overall iCCM program should take place between the Global Fund Portfolio Managers (FPMs), the PRs, and the co-funder(s) during the grant-making process, so that the optimal reporting structure can be established to meet all requirements without overburdening the MOH, PRs, or other implementing partners.

For a list of recommended integrated indicators of iCCM programs, see annex B.

PSM INTEGRATION AND COORDINATION FOR ICCM

The commodities supply plan and tracking system will need to be integrated across all relevant disease areas. This integration is expected to streamline operations, avoid duplication, and cut costs, as well as to reduce overstock and stockouts, if information systems are used correctly and human resources and financing are aligned to promote continuous availability. It will also ensure that targeted children have continuous access to the full package of iCCM services and commodities.

PSM for iCCM should be aligned to the national PSM strategy or plans and, where possible, iCCM plans should include interventions to strengthen the national PSM system.

Coordination between relevant country stakeholders is crucial to successful integrated PSM planning. Many stakeholders, as illustrated in figure 3, will need to be involved in complex PSM decision making, and sufficient time must be allocated to build consensus. Entities involved in procurement might not necessarily be the same as those involved in distribution or monitoring. Particular emphasis should be placed on establishing good communication and a regular feedback loop between entities monitoring the supply chain, entities revising the supply plan, and entities initiating and carrying out procurement.

Figure 3. Example web of stakeholder coordination for PSM of iCCM medicines



NB: Intended strictly for illustrative purposes. Country customization will vary widely.

Product Selection

Detailed descriptions of product procurement specifications including quality criteria of products for iCCM should be clearly outlined and adhered to in procurement. Product specifications should be stated in generic (non-proprietary) terms when possible to provide opportunity for competitive bidding from multiple sources.

Dispersible oral amoxicillin is the first-line antibiotic recommended by WHO for the treatment of non-severe child pneumonia at the community level. Some countries comply with these guidelines whereas some have not yet made the move from co-trimoxazole. The 250mg amoxicillin dispersible tablet is recommended over suspensions and syrups which are bulkier and therefore more costly to ship, more challenging to distribute and more complicated to dispense.

It is worth noting that the WHO recommendation for amoxicillin formulation for use in children at the community level differs from that for use at the facility level. In the community, CHWs are authorized to treat only simple pneumonia and there are two age bands of treatment of amoxicillin:

2–11 months (under one year): 1 x 250 mg dispersible tablet twice a day for 5 days (total of 10 tablets per course of treatment)

12–59 months (1-5 years): 2 x 250 mg dispersible tablet twice a day for 5 days (total of 20 tablets per course of treatment)

At the facility, where both simple fast-breathing pneumonia as well as more severe chest in-drawing pneumonia can be treated with amoxicillin, there are three age bands of treatment rather than just two.

- 2–11 months (under one year): 1 x 250 mg dispersible tablet twice a day for 5 days (total of 10 tablets per course of treatment)
- 1–3 years: 2 x 250 mg dispersible tablet twice a day for 5 days (total of 20 tablets per course of treatment)
- 3-5 years: 3×250 mg dispersible tablet twice a day for 5 days (total of 30 tablets per course of treatment)

If cotrimoxazole is still first line treatment for pneumonia, then a transition plan needs to be developed to coordinate all the required steps for amoxicillin to be introduced as first line treatment. This transition plan needs to include detailed plans for quantification, procurement and distribution allowing for a phase in of amoxicillin, the revision of reporting forms, stock management tools, training materials and job aids as well as training in prescription, dispensing and use of amoxicillin.

While RDTs are considered malaria commodities, they are essential for iCCM in order to rationalize the use of antibiotics as well as antimalarials. If RDTs are not available, the CHW may treat fever with amoxicillin instead of an antimalarial.

Oral rehydration salts (ORS) for three days and zinc for 10 to 14 days are currently recommended by WHO for the treatment of non-bloody diarrhea in children. The recommended dose of ORS is 1 liter of prepared solution, sipped frequently as tolerated until finished in one day, for three days. One sachet of ORS powder is used for every 1 liter of water to make the optimal solution. The dose of zinc can be administered using 20mg tablets which are more frequently available or 10mg tablets which make dose administration easier in the smaller age group but are more costly.

2-6 months (infants): 10 mg of zinc once per day for 10-14 days

7 months to 5 years (infants and children): 20 mg of zinc once per day for 10-14 days

Note: This infant-toddler age breakdown is different from the breakdown used to administer the correct dose of amoxicillin and ACTs.

Bundles of ORS and zinc (co-pack) have been piloted successfully⁵ as a means to promote treatment with the two commodities. The cost of the co-pack should be lower than the separate commodities for this to be an effective option and the expiry dates of the individual components should be carefully monitored.

To promote rational use and treatment adherence, and for improved safety, iCCM medicines should be:

- Presented in dosage form and dosage strength suitable for use by children under 5. The common
 practice of splitting or crushing adult solid oral dosage forms does not guarantee accurate dosing
 for children since the active substance is often not uniformly distributed. In addition, the dosage
 form for adults is not pharmacokinetically designed and tested for children and the safety of the
 excipients in the adult dosage form is not evaluated for children.
- Flexible solid oral dosage forms such as dispersible tablets⁶ or tablets for oral suspension are the
 preferred solid oral dosage forms for medicines for children. These offer the following
 advantages—
 - Onset of therapeutic action is similar to oral liquids.
 - They retain the ability to account for child development and growth; can be dosed across weight bands.
 - Require minimal manipulation that can safely be handled by the end-user.
 - Easy to dispense and use as they do not require calibrated dose measuring devices.
 - Solid state physical and chemical stability allows for longer shelf lives over higher temperatures compared to oral liquids or powders that are reconstituted into liquids.
 - Do not require cold storage, since only the required dose is reconstituted at a time and consumed immediately.
 - Optimal for the supply chain because of reduced weight, volume and cost.

 Note: It is advisable to source for dosage strengths that can be administered in multiples to avoid use of scored tablets. Ideally, and if available, amoxicillin should be in 250 mg tablets (rather than 125 mg tablets which require a large quantity of pills per treatment course) and zinc should be in 10 mg tablets (rather than 20 mg tablets that must be split for infants 2–6 months). In the event that this is not feasible, functionally scored tablets that facilitate product use by children must be supported by evidence of uniformity of distribution of the active pharmaceutical ingredient in the tablet and the stability of the unused portion. This applies to both amoxicillin and zinc. If tablets are to be split, the quantification should assume that full tablets will be dispensed for the caregiver to split and take that into consideration in the calculation of numbers of tablets per treatment.
- Pre-packed in course-of-therapy packaging containing complete treatments per patient per episode of illness along with instructions for use. This facilitates both medicine inventory management and dispensing of products by the CHW and ensures the child does not receive too little or too much of the medicine.⁷

Note: Customization of packaging such as color coding for different age bands can make it easier for CHWs, especially in low literacy settings, to dispense medicines. However, because customization takes longer to develop and costs more, careful advance planning is needed. The planning must take into account the potential pitfalls of customization such as reduced flexibility with the use of the products. For example, when one color code is out of stock, the CHWs may not have the ability to re-distribute existing stocks to other weight bands, so the result is an

⁵ Medicines and Diagnostics For Community Case Management: Options for Selection. UNICEF. September 2014.

⁶ Dispersible tablets are uncoated or film-coated tablets that can be dispersed in liquid before administration giving a homogenous dispersion. The United States Pharmacopeia (USP) refers to these as tablets for oral suspension (with slightly different standards)).

⁷ ACT antimalarials are a good example of appropriately packaged commodities for the community channel. They are generally packaged in a blister or box with only a single treatment course inside, specially labeled for the correct age band.

artificial stock-out. Dispensing envelopes to place the blister in at the point of dispensing can be an alternative to consider to facilitate dispensing and adherence.

Some countries elect to keep facility and community medicine packaging identical, while others elect to procure a dedicated CHW product with distinct packaging. The former option keeps the medicine supplies of the facility and the community integrated and emphasizes the fact that CHWs are an extension of facilities; the latter helps keep inventory management and consumption calculations separate and organized, and reduces likelihood that medicines earmarked for community use will be diverted for facility use. Unintended consequences of the latter can be mitigated by clearly understood policies about what to do in the case of shortages of one type of packaging.

Useful Resources:

UNICEF Medicines and Diagnostics For Community Case Management: Options for Selection

WHO Priority medicines for mothers and children 2011. WHO/EMP/MAR/2011.1

JSI and SIAPS. 2015. Quantification of Health Commodities: RMNCH Supplement Forecasting Consumption of Select Reproductive, Maternal, Newborn and Child Health Commodities

Forecasting

Forecasting, the first stage of quantification, entails estimating the quantities and costs of the products required for a specific health program (or service) for a specific period of time. The forecasting will usually have been conducted in the preparation of the concept note as part of the gap analysis to determine the needs in commodities and programing for implementation of iCCM. However, during grant making, it is essential to review the forecast and ensure that the scale-up rate is feasible and that the coverage assumptions are reasonable. For example, assuming immediate service availability and service use at full scale will over-estimate need and risk misuse, or expiry of products.

The forecast should be guided by the national treatment protocols based on WHO guidelines for CHWs. For example, some country policies instruct CHWs to administer the first dose of antibiotic to a child with severe pneumonia before referral to health facility; in others, CHWs are told only to refer. These inputs will influence forecasting. Additionally, countries that already have malaria CCM programs but are now introducing RDTs, pneumonia treatment, and diarrhea treatment, might find a reduced consumption of ACTs at the community level, now that CHWs have a way to both diagnose malaria parasitologically and the ability to deliver a complete package of services to their patients.

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⁸ Integrated management of childhood illness: caring for newborns and children in the community, adaptation for high HIV or TB settings. WHO 2014 http://www.who.int/maternal_child_adolescent/documents/newborn-child-community-care/en/

There are three tiers of data to use when forecasting iCCM medicines, depending on the maturity and scale of the iCCM program (table 4). It is possible that the quality of data varies from product to product or region to region within a country. The best available data should always be used in these cases.

Table 4. Types of data used in forecasting

Program Maturity	Type of forecast data	Source of data	Desirability
Established and at scale, with low stock-out rates and robust LMIS	Reliable historic monthly consumption data	Caseloads at province, district, or facility level, or best: individual CHW level	Most accurate, precise, and useful
Established but still growing and/or with limited data systems: incomplete reporting or large scale stock-outs that mask true demand	Monthly consumption data with adjustments to take any lapses into account	Program experts determine which data are low quality and how best to compensate for them or which other data to use as proxy.	Of variable reliability
Just beginning	Demographic data, morbidity data, and other disease statistics	HMIS and facility records and household surveys: DHS, MICS, MIS	To be used only when consumption data are not available

A number of quantification resources exist and are helpful to quide the forecasting process for example:

JSI and SIAPS. 2015. Quantification of Health Commodities: RMNCH Supplement Forecasting Consumption of Select Reproductive, Maternal, Newborn and Child Health Commodities

<u>Quantification of Health Commodities: Community Case Management Products Companion Guide;</u> <u>Supply Chains for Community Case Management (SC4CCM); October 2014 Update; JSI.</u>

An additional tool for iCCM medicine forecasting is the iCCM Financing Task Team gap analysis to estimate pneumonia and diarrhea medicine needs as well as other iCCM supplies and programmatic budgets (also referenced in table on page 11).

Supply Plan

The supply plan follows the forecasting process and should guide coordination and procurement. It determines when the future products should be delivered to which storage area along the supply chain to prevent interruptions in supply. The plan also indicates when products are required in country to fill the pipeline and meet the forecast need. This is particularly important when there are various donors involved in funding the procurements.

The supply plan should be used by policymakers, program managers, procurement managers, and donors to make decisions and take action around:

- Program planning and budgeting decisions
- Mobilization and allocation of funding for product procurement
- Coordination of multiple sources and timing of funding for procurement
- Informing procurement actions on which products to procure, how much to procure, and when to
 procure. Products with large quantities or short expiry dates should be scheduled in staggered
 deliveries.

 Adjust timing of procurements and shipment delivery schedules based on consumption trends to ensure continuous supply, avoiding stock-outs and overstocks

The supply plan uses the forecasted consumption but also requires data on:

- Timing and availability of funding
- · Changing commodity costs
- Stock on hand of products currently in the system and any orders already placed
- Estimated donor/procurer and supplier lead-time for each product
- Global demand for product
- Expiration dates of medicines currently in stock, and those expected to be ordered
- Volume capacity of various warehouses and storage spaces
- Port backups
- QA/QC processes
- Desired stock levels
- New consumption data or other data that changes assumptions used to forecast consumption

If the same products are used at the community level as in health facilities, and if the health facility is the restocking point for community medicines, then the forecast and supply plan should cover both health facilities and community level requirements. Integrating the needs of the health facilities will promote availability of sufficient stock at the health facility (often the resupply point) and reduce the likelihood of health centers reserving stock for their own use rather than distributing to CHWs. Only if products are used exclusively at the community level then a forecast can be done independently without input from other levels and programs. Where possible, these activities should be integrated with other national forecasts and supply plans for essential medicines. This is especially critical if the medicines used for iCCM are also used for other indications (such as amoxicillin). For situating product management closer to the target beneficiaries, the supply plan can exist at multiple levels. Districts can each have their own supply plans that feed into a national supply plan.

It is important to consider combining both malaria and non-malaria iCCM commodities in a single, integrated supply plan so that there is a constant supply of products throughout the life of the program. Generally, the Global Fund will review the supply plan for the entire program, not just the malaria elements. There will be a need for the MOH and relevant PR(s) to coordinate delivery of commodities, taking into account the different funding cycles, especially when there is not a formal communication line between the Global Fund and the other donor(s) (refer to section above on "Coordination of funds disbursement and medicine arrival and delivery" page 15). If the supply plan for iCCM commodities is fully integrated into the national supply plan for essential medicines, it will facilitate monitoring of shipments and availability of products.

The supply plan usually covers a period of one to two years and should be reviewed and updated regularly (for example, quarterly) to adjust for changes in consumption, assumptions, stock levels, and upstream constraints. Available software packages such as Pipeline⁹ could facilitate and accelerate these calculations. It is important to keep records of supply and supply plans over time to analyze trends and use this data to developing future plans. For example, projected consumption might not match actual consumption and, if that is the case, action can be taken to delay or accelerate shipments as needed.

The focal person managing and updating the supply plan can be the same person who is monitoring medicine shipments and the LMIS, as described above.

⁹ http://deliver.jsi.com/dhome/resources/tools/pipeline

Procurement

Currently, the only maternal and child health commodity prequalified under the WHO prequalification scheme is zinc, and the Global Fund pooled procurement mechanism (PPM) does not include non-malaria iCCM commodities. Nonetheless, recognized and transparent procurement practices to obtain quality products must be adhered to. For more Global Fund guidance on procurement QA, see http://www.theglobalfund.org/en/procurement/quality/.

However, if UNICEF is the iCCM co-funder, the medicine procurement will normally be handled by the UNICEF Supply Division, which has extensive experience procuring iCCM medicines on a large scale. UNICEF's available product range and prices, categorized by disease area, can be found here.

For MOHs or implementing partners that will be procuring dispersible amoxicillin independently, or with support from bilateral donors, UNICEF Supply Division has established a WHO Expert Review Panel (ERP) that provides evidence on quality products from approved manufacturers for informed procurement decisions. UNICEF has signed long-term agreements (LTAs) with a number of manufacturers from whom they have been procuring. A list of UNICEF approved suppliers of amoxicillin dispersible tablets is available on line or on request from UNICEF Supply Division.

In all instances, procurement should be aligned between both international guidelines and nationally registered products. In the event that a good source of medicine is identified that is not locally registered, possibilities for fast track approval should be explored. All maternal and child health commodities should be manufactured at a site that is compliant with all standards of Good Manufacturing Practice (GMP) that apply to the relevant product formulation, as verified after inspection by a stringent regulatory authority (SRA)¹⁰ or a regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S)¹¹ or the National Regulatory Authority (NRA). Any special packaging layout or messaging should also be accepted by the authority well before finalization.

The International Medicine Price Indicator Guide¹² provides information on prices of pharmaceuticals from pharmaceutical suppliers, international development organizations, and government agencies. The guide is a resource for anyone involved in the procurement of pharmaceuticals as comparative price information is important for getting the best price.

Persons managing procurement should communicate clearly with persons determining product specifications and persons creating and revising supply plans. Product specifications (including formulation, dosage, packaging, etc.) must be adhered to during procurement. Depending on the supply plan, the expected medicine volume, and the available storage space, it may be advantageous to request a staggered shipment from the medicine manufacturer(s). This reduces the strain on limited warehouse space and avoids overstock which can lead to expired medicines.

¹⁰ Stringent Medicine Regulatory Authority (SRA) means a regulatory authority (in case of the European Union both the European Medicines Agency (EMA) and national competent authorities are included) which is (1) a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ICH (as specified on its website), or (2) an ICH Observer, being the European Free Trade Association (EFTA) as represented by SwissMedic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland, and Liechtenstein (as may be updated from time to time).

¹¹ http://www.picscheme.org/pics.php

¹² http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English

Distribution and Resupply

When increasing the iCCM commodity volume to include antibiotics, ORS, and zinc, where applicable, the required storage space and transport capacity will also increase. This must be taken into account at all stages of the distribution chain.

A resupply system for community health workers is complex as it extends the traditional supply system beyond its formal health system limits. The system should be designed to assure availability of products at the community level but also so as to not overload the resupply point (usually the health facility). If the resupply system is not carefully described in the concept note, it should be defined during grant making.

Resupply to Health Facility Restocking Points

CHWs' resupply and continuous access to iCCM medicines can only be as reliable as the systems resupplying the health center or other CHW resupply point. Any weaknesses in the health facility supply chain will inevitably weaken the iCCM program, so initiatives to strengthen health facility supply chains should go hand in hand with iCCM planning. When possible, the iCCM supply chain should build and improve upon existing national supply chains to assure tasks are conducted correctly throughout the supply chain as the CHWs are dependent on the supply chain above them. Or, in cases where the health facility supply chain is extremely weak, a disaggregated, parallel supply chain for iCCM may be necessary in the short term, while the former is strengthened.

It may be useful to consider quality improvement type approaches to improve supply chain management at different levels of the supply chain. Some examples of best practices and lessons learned in supply chain management for CCM can be found in the end of project report for SC4CCM implemented by JSI, funded by the Gates foundation¹³.

To avoid bottlenecks at the health facilities, be sure to align facility and community goals for treatment so that health facilities share/release products to CHWs—even when there are shortages. Some countries may elect to create separate bin cards for facility medicines and community medicines.

Resupply to CHWs

In designing a CHW resupply system, it is important to consider—

- The context of the program
- Geographic issues
- Literacy level and training of the CHWs
- Other responsibilities of the CHWs
- Number of products CHWs manage
- Frequency of reporting and orders
- Who will receive the supply information and how will it be used to adjust the supply plan

CHWs themselves need to be trained on their resupply systems and understand how to order their products. If they are responsible for determining the quantities, clear guidance in the form of written or pictorial job aids should be provided. They should be provided with simple tools that collect essential data that allows them to manage stocks and report on consumption. Reporting on stocks and consumption by CHWs should be linked to resupply. The initial stock set of commodities should be provided during the initial training. Examples of resupply tools are provided here.

¹³ <u>Strengthening Supply Chains at the Community Level. Findings from The SC4CCM Project In Malawi.</u> Rwanda and Ethiopia JSI December 2014.

Resupply systems for CHWs will vary according to location and organization. In some cases, CHWs meet at the health center each month for a monthly meeting and at that meeting they submit their reports and are also resupplied. If this is not possible due to large distances between the CHWs and the health facility, resupply may be instead assured by supervisors via visits on bicycle or motorcycle. These visits need to be regularly scheduled to assure that the supply is calculated appropriately depending on the frequency of the visit. In other cases, a peer CHW is appointed to consolidate reports and resupply quantities from all the CHWs in his/her locality and this consolidated order is presented at the health facility, such as is the case in Rwanda ¹⁴. This is particularly useful if the health facility has a large number of CHWs to resupply as it avoids overcrowding of the facility by CHWs. However, the disadvantage is that it reduces CHWs' contact with the health facility supervisor figure. Countries whose CHW cohorts have low literacy rates may elect to simplify the resupply process; for example, giving CHWs two boxes of each medicine and instructing them to come for resupply when one of the boxes is exhausted.

Use

Use of medicines in iCCM should be guided by the national treatment protocols based on WHO guidelines for CHWs. ¹⁵ CHWs need access to pictorial job aids of the treatment protocol as a simple to follow flow chart that guides them through their case management activities.

Adherence to the protocol should be assessed through ongoing observation strategy that is clearly defined as well as knowledge testing. Supportive supervision consists of:

- Oversight and continuous supportive supervision of the case management, which is generally conducted by someone with a clinical background, such as someone from the health center.
- Oversight and continuous supportive supervision/on the job training of the supply chain component (availability of commodities and filling in of resupply tools), which can be conducted by someone without a clinical background if needed, such as a designated peer CHW.

Interventions to facilitate adherence to treatment and appropriate use are strongly encouraged and should be built into the grant. Such interventions include selection of the adequate formulations, funding to support regular supportive supervision, and quality improvement interventions (collaborative problem solving, performance-based incentives, etc.).

Monitoring iCCM Commodities Using Integrated LMIS

Similar to the tracking of medicine forecasts, orders, shipments and arrivals into the country, it is advisable to make the focal person or committee also responsible for monitoring the domestic supply chain of all iCCM commodities together from the central warehouse, with the aim of avoiding all stockouts. Where possible this should be conducted as part of the monitoring of the national PSM system. The dangers associated with stockouts could be exacerbated in an iCCM setting if CHWs administer the wrong medicines to compensate for stock-outs of the correct medicine, for example, administering antibiotics to children who are diagnosed with malaria simply because ACTs are stocked out.

In addition, the focal person or committee should periodically analyze and report on LMIS and HMIS data to compare with orders in the pipeline to warn if there is a risk of stockout and to enable corrective action.

Data is essential in supply chain management for iCCM and should be used for—

Routine resupply

1

¹⁴ http://sc4ccm.jsi.com/em<u>erging-lessons/rwanda-resupply-procedures/</u>

¹⁵ Integrated management of childhood illness: caring for newborns and children in the community, adaptation for high HIV or TB settings. WHO 2014 http://www.who.int/maternal_child_adolescent/documents/newborn-child-community-care/en/

- Stock monitoring to prevent stock-outs
- Inform response to emergency situations
- Monitor supply chain performance
- Forecast quantities required to sustain CHW programs nationally

In an iCCM program, the data for malaria, pneumonia, diarrhea, and other diseases become much more unwieldy than just for malaria CCM. It is important to collect the necessary information in such a way that is simple, orderly, and efficient; and does not overburden the CHWs. The number of data items collected should be limited to what is essential. Typical data collected through LMIS are—

- Stock on hand
- Consumption (or issues) data (often from patient register)
- Losses and adjustments
- Days stocked out

It may not be necessary to collect all four data items listed above.

Using pictures in CHW-level forms is often a good way to improve accuracy of records. Examples of patient registers and other CHW-level stock management forms can be found on http://ccmcentral.com/about/iccm-task-force/supply-chain-management-subgroup/

It is essential that the system defines clearly how the LMIS will function and assure that community level data will be disaggregated throughout the system. If this was not clearly defined in the concept note it should be defined in the grant making phase. Where there are resources, the role of mobile technology should be considered to facilitate collection of data and ideally, automate calculation of resupply quantities to reduce burden on CHWs and HF staff, as has been implemented with CHWs in Malawi through the cStock program. There are several different examples to be considered such as those presented in the webinar of the supply chain subgroup of the CCM Taskforce¹⁶.

LMIS data should feed back into revisions of the supply plan so that all decisions and corrective actions are informed by data. Analysis of LMIS data should be done not only at the central level but also in decentralized administrative units. Capacity at that level may need to be strengthened so that data are collected, consolidated, and analyzed before being sent to higher levels.

It is also essential to integrate CHW LMIS data into whatever national database is being used (e.g., DHIS). This will allow all parties involved to understand iCCM's relative scale in the context of broader case management through all channels, as well as to inform national epidemiological-based decisionmakina.

Wherever possible, monitoring of iCCM commodities should be included into existing PSM monitoring tools.

¹⁶ http://ccmcentral.com/documents/webinar-series-mhealth-for-scm-for-ccm/

ANNEX A. CO-FUNDERS

Below is a list of donors that have funded non-malaria iCCM commodities or delivery.

Funder	iCCM Commodities/Delivery/Both
RMNCH Trust Fund	Both
Global Financing Facility	Both
Canada/DFATD	Both
World Bank	Both
UNICEF	Both
President's Malaria Initiative	iCCM Delivery costs
Global Fund	iCCM Delivery costs
USAID	Both, but primarily systems

This list changes constantly as do the target countries and the level of funding available.

This table is in draft form as it is still work in progress being compiled by the iCCM FTT

ANNEX B: INDICATOR RECOMMENDATIONS FOR GLOBAL FUND PROGRAMS WITH AN ICCM COMPONENT

Table 1. Recommended output and outcome indicators for iCCM from program <u>routine</u> systems for consideration

Serv	rice delivery	Indicator	Frequency*	Data collection tools	Glob al Fun d top 10	Glo bal Fun d PR
	Diagnosis	Percentage of suspected malaria cases that receive a parasitological test in the community	Monthly/ quarterly	CHW register and reports	X	X
Case management	Treatment	Percentage of confirmed outpatient malaria cases that received first-line antimalarial treatment according to national policy	Monthly/ quarterly	CHW register and reports	X	X
		Number of diarrhea cases treated with ORS at community level during reporting period (compare with expected number when reporting)	Monthly/ quarterly	CHW register and reports		
		Number of diarrhea cases treated with zinc at community level during reporting period (compare with expected number when reporting)	Monthly/ quarterly	CHW register and reports		
		Number of suspected pneumonia cases treated with first line antibiotics** at community level (compare with expected number when reporting)	Monthly/ quarterly	CHW register and reports		
Health systems strengthening	Procurement and supply chain management	Percentage of CHWs reporting no stock-out of key iCCM commodities (RDTs, ACTs, zinc, ORS, and amoxicillin DT) during the reporting period	Monthly/ quarterly	CHW reports (and periodic assessments)	X	X
	Routine data collection, analysis and use	Percentage of CHWs submitting timely and complete reports according to national guidelines	Monthly/ quarterly	CHW reports		X
	Health workforce	Percentage of CHWs who received supervision during the reporting period	Monthly/ quarterly	CHW reports (and periodic assessments)		
		Number of CHWs per 10,000 population	Annual	MOH and program records		
		Annual rate of retention among CHWs	Annual	MOH and program records		

*System should be able to analyze CHW treatment data monthly (especially since quarters may not correspond with seasonality of child illness and monthly will help with more real-time response.)

** WHO recommends amoxicillin DT as first-line antibiotic.

Table 2. Recommended outcome indicators for iCCM from household surveys, collected every 3-5 years.

Service Delivery Area	Indicator	Disaggregation	GLOBAL FUND Periodic Review
Diagnosis	Percentage of children under 5 years old with fever in the last 2 weeks who had a finger/heel stick for malaria testing	Geographical location, point of care (facility, community), sex	Х
Treatment	Percentage of confirmed outpatient malaria cases that received first-line antimalarial treatment according to national policy	Geographical location, point of care (facility, community), sex	
	Percentage of diarrhea cases among children under five that received ORS according to national policy	Geographical location, point of care (facility, community), sex	
	Percentage of diarrhea cases among children under five that received zinc according to national policy	Geographical location, point of care (facility, community), sex	
	Percentage of suspected pneumonia cases among children under five that received first line antibiotic according to national policy	Geographical location, point of care (facility, community), sex	
	Percentage of suspected pneumonia cases who sought care from an appropriate provider	Geographical location, point of care (facility, community), sex	

List of data elements for iCCM (taken from JOGH document - http://www.jogh.org/documents/issue201402/Guenther_Final.pdf)

Table 2. Overview of priority data elements for monitoring program performance by frequency of collection

DATA FLEMENTS TO CAPTURE ROUTINELY (MONTHLY

Core elements required to generate numerators:

- · Number of CHWs reporting
- · Number of CHW treatments by condition
- · Number of health facility treatments by condition
- Number of children referred by CHWs*
- · Number of CHWs reporting no stock-outs by commodity†
- Number of CHW supervision visits conducted

Programs using RDTs should include:

- Number of RDT-tested fevers
- Number of RDT+ fevers
- · Number of treatments for confirmed malaria
- · Number of treatments for presumptive malaria

DATA FLEMENTS REST CAPTURED DERIODICALLY (ANNUALLY OR LESS

Background data elements required to generate denominators (update at least annually):

- Number of children under-five (overall and in iCCM target areas)
- Number of expected cases by iCCM condition (overall and in iCCM target areas)
- Number of CHWs trained and deployed to provide iCCM
 Data best captured through household or CHW surveys and special studies:
- Gender of cases treated
- Follow-up visits for cases treated by CHWs
- · Referral completion and outcomes
- Skills/knowledge of CHWs
- Quality of care by provider type (first dose, counseling, use of RDT, use of timer,)
- Care—seeking behavior
- Timeliness of care-seeking/treatment and source of treatment
- Child deaths (total or by cause)

CHW – community health worker, RDT – rapid diagnostic test, iCCM – integrated community case management

*Data on the number of children visiting a CHW during the reporting period must be collected to calculate the referral rate by CHWs †The iCCM supply chain group recommends collecting three data elements for supply chain management through the Logistics Management Information System (LMIS) for resupply or quantification and monitoring a supply plan: CHW consumption by commodity; stock on hand by commodity; and number of days stocked out during reporting period by commodity.