QUANTIFICATION of Health Commodities

RMNCH Supplement

Forecasting Consumption of Select
Reproductive, Maternal, Newborn, and Child Health Commodities

Updated June 2016

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JSI Research & Training Institute, Inc., and Management Sciences for Health

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JSI Research & Training Institute, Inc. (JSI) is a U.S.-based health care consulting firm committed to improving the health of individuals and communities worldwide. Our multidisciplinary staff works in partnership with host-country experts, organizations, and governments to make quality, accessible health care a reality for children, women, and men around the world. JSI's headquarters are in Boston, Massachusetts, with U.S. offices in Washington, D.C.; Atlanta, Georgia; Burlington, Vermont; Concord, New Hampshire; Denver, Colorado; Providence, Rhode Island; and San Francisco, California. JSI also maintains offices in more than 40 countries throughout the developing world.

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and

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SUMMARY

This guide will assist program managers, service providers, and technical experts when conducting a quantification of commodity needs for the 13 reproductive, maternal, newborn, and child health commodities prioritized by the UN Commission on Life-Saving Commodities for Women and Children. This quantification supplement should be used with the main guide—*Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement.* [*] This supplement describes the steps in forecasting consumption of these supplies when consumption and service data are not available; after which, to complete the quantification, the users should refer to the main quantification guide for the supply planning step.

[*] USAID | DELIVER PROJECT, Task Order 4. 2014. *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4.

ACRONYMS

ACS	antenatal corticosteroids
ANC	antenatal care
ARI	acute respiratory infection
Beta-AC	betamethasone acetate
Beta-PO4	betamethasone phosphate
Beta	betamethasone
CH	child health
CHERG	Child Health Epidemiology Reference Group
CHW	community health worker
COC	combined oral contraceptive
CPR	contraceptive prevalence rate
CSO	Civil Society Organization
CYP	Couple-Years of Protection
Dexa	dexamethasone
DHS	Demographic and Health Survey
DT	dispersible tablet
EC	emergency contraception
ECP	emergency contraceptive pill
EML	Essential Medicines List
EMLc	Essential Medicines List of Children
FP	family planning
FSW	female sex worker
GBV	gender-based violence
HBB	Helping Babies Breathe
HMIS	health management information system
iCCM	Integrated community case management
ICEC	International Consortium for Emergency Contraception
IDPIG	International Drug Price Indicator Guide (MSH publication)
IM	intramuscular
IU	international units
IV	intravenous
JSI	JSI Research & Training Institute, Inc.
LAPM	long acting and permanent methods
LARC	long acting reversible contraception
LMIS	logistics management information system
MCH	maternal and child health
MEC	Medical Eligibility Criteria (WHO publication)
MH	maternal health
MICS	multiple indicator cluster survey
MNCH	maternal, newborn, and child health
MSH	Management Sciences for Health
MWRA	married women of reproductive age
NAC	National AIDS Council *or* Commission *or* Control program
NGO	nongovernmental organization
OC	oral contraceptive
ORS	oral rehydration salts
OTC	over the counter
PAC	post-abortion care
PE/E	pre-eclampsia and eclampsia
PPH	postpartum hemorrhage

PSBI	possible severe bacterial infection
RSD	respiratory distress syndrome
RH	reproductive health
RHS	Reproductive Health Survey
RHSC	Reproductive Health Supplies Coalition
RMNCH	reproductive, maternal, newborn, and child health
SIAPS	Systems for Improved Access to Pharmaceuticals and Services [Program]
SOH	stock on hand
SRH	sexual and reproductive health
STG	standard treatment guideline
STI	sexually transmitted infection
TFR	total fertility rate
UNCoLSC	United Nations Commission on Life-saving Commodities for Women and Children
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization
WRA	women of reproductive age

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SECTION 1. INTRODUCTION

Background on the UN Commission on Life-Saving Commodities for Women and Children

The United Nations Commission on Life-Saving Commodities for Women and Children (the Commission), a part of the Every Woman, Every Child movement, aims to increase access to 13 life-saving commodities in 50 of the world's poorest countries. The Commission identified and endorsed an initial list of 13 overlooked reproductive, maternal, newborn, and child health (RMNCH) commodities that, if more widely accessed and properly used, could save the lives of more than 6 million women and children per year.[1]

These 13 commodities have diverse characteristics: some are new products that are in the process of being introduced at scale and some are products that have been in use for many years but are under-used or not available when needed or in the recommended formulation. However, one commonality shared by all is the need to increase access to these commodities among the women and children who need or want them. A major component of access is availability and to ensure availability, accurate estimates of supply requirements are needed. At the global level, this information can inform both donors' plans for procurement and manufacturers' plans for production. At the national level, this information is also essential for budgeting, resource mobilization, and planning for procurement and supply chain operations.

Currently, accurate estimates of need are unavailable for many of the 13 commodities at either the global or national levels. Therefore, many of the Commission's work plans have included activities related to collecting this information through market sizing or quantification exercises. The Commission's 2012 report also notes that improved quantification efforts are needed as part of supply chain improvement. This guide provides practical guidance on estimating the quantities of supplies needed by programs as part of a national quantification exercise. While this guidance was developed primarily for public sector and nongovernmental program (NGO) programs, the methodology presented could also be relevant for forecasting of commodity needs for the private sector.

Key Terms in Quantification

Since many terms related to quantification and forecasting were used in the work plans of the Commission working groups and technical resource teams in different ways, the following working definitions were agreed upon to delineate the focus of the activities and to attempt to harmonize vocabulary across all Commission activities. These definitions are consistent with those used in the general quantification guide, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement*.

Quantification answers the question, "How much should be procured and when should it be delivered?" Quantification includes both forecasting and supply planning. It is the process of estimating the quantities and costs of the products required for a specific health program (or service), and determining when the products should be delivered to ensure an uninterrupted supply for the program. Quantification takes into account the expected demand for commodities, unit costs, existing stocks, stock already on order, expiries, lead time, minimum and maximum stock levels, and shipping costs. Using this information, the total commodity requirements and costs for the program are calculated and compared with the available financial resources to determine the final quantities to procure.

The two sub-processes of quantification, forecasting and supply planning, are defined as follows:

- Forecasting answers the question: “How much is needed, in quantities, to meet the health demand of the population?” Forecasting is the process of estimating the quantities of products that will actually be dispensed or used to meet the health needs of the targeted population during a specific future period of time. Forecasting can be based on historical consumption (quantities dispensed or used), services, morbidity and/or demographic data, and assumptions about future demand, program plans, and performance. When historical data are unavailable or unreliable, assumptions will also be needed to estimate program performance and product consumption.

- The supply plan is the final output of the quantification, and details the total product quantities and costs required to fill the supply pipeline to ensure optimal procurement and delivery schedules, taking into account lead times, minimum and maximum stock levels, and desired arrival dates of shipments.

For definitions of additional terms related to forecasting and supply planning, please consult the Glossary at the end of this document.

Purpose of this Guide

This guide will assist program managers, service providers, and technical experts involved in quantification of RMNCH commodities with detailed guidance on best practice demographic and morbidity-based forecasting methodologies, in order to improve the quality of national-level forecasts of life-saving commodities when consumption and services data are not available. This document serves as a supplement to and should be used in conjunction with *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement* produced by the USAID | DELIVER PROJECT and updated in 2014(hereafter referred to as *Quantification of Health Commodities)*.

This document is not meant to provide general guidance on managing maternal and child health or family programs, nor does it offer programmatic guidance on selecting or administering the products used in a country. Rather, this guide will assist stakeholders to—

- Gather and analyze the data needed to prepare the forecast
- Build forecasting assumptions to account for data gaps, programmatic considerations, and environmental factors
- Organize the data and assumptions to be able to calculate the quantities of each product expected to be consumed by clients during the forecast period.

We recommend preparing annual estimates for a two-year forecast period.

The outputs of the forecasting methodologies outlined within this document should not be used directly for procurement. The supply planning step is where estimated needs are compared with existing stocks, pending shipments, available budgets, product shelf life, and other critical inputs to plan procurement and shipment schedules. Once the forecast is prepared, the quantification team should refer to the original *Quantification of Health Commodities* for guidance on supply planning.

Basic Contents

For each of the 13 priority commodities, this document provides information and guidance on—

- Product description, indications, and considerations for use

- Types of data needed for forecasting and potential sources of those data
- Building the forecasting assumptions and calculating forecasted consumption using a forecasting algorithm
- Incorporating product- and program-specific considerations into the forecasting assumptions
- Additional products, consumables or equipment required

This guide also includes general considerations for forecasting for these commodities, references, and an inventory of tools.

How to Use this Guide

In the weeks and months before a quantification exercise for any of the 13 Commission commodities, facilitators and technical staff should review the relevant sections of this document to inform data collection and exercise planning.

During the quantification exercise, this guide can serve as a reference to participants to explain applied methodologies. The quantification team will need to adapt the sample forecasting algorithms to fit the country context and the scope of the quantification being undertaken.

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This guide is intended to help program managers, service providers, and technical experts use what they know about the products they manage and the programs they are implementing to estimate the quantities of products that will be needed to serve their programs' clients in a given time period. The programmatic examples are meant to illustrate the process of building the forecasting assumptions based on programmatic planning decisions and best estimates of expected demand and use of products, but will need to be adapted by the quantification team for the local scope and context.

Because there may not be reliable historical consumption or services data to allow forecasting for programs, the forecasting methodology will be based on many assumptions. According to *Quantification of Health Commodities: Contraceptive Companion Guide,* "If you do not have historical consumption or services data – for example, when a new program or new services are to be implemented, or when a new contraceptive method or product will be introduced—forecasting…becomes an assumptions-driven exercise that requires inputs from a broad range of key stakeholders. You should draw informed assumptions from research data; from experiences from other countries; and from the knowledge and experience of program managers, implementing partners, service providers, and technical experts. The forecasting assumptions and results should be formulated, agreed upon, and vetted by key decision-makers, implementers, and service providers who will be responsible for managing and providing the specific…services and products."

There may be a need to account for data that are missing or of questionable quality, such as unreliable, outdated, or incomplete data. How severely accuracy is affected and how this influences decisions will depend upon the seriousness of the data problems, but should be noted. These limitations do not mean that quantification cannot be performed with less-than-perfect data. However, limitations do require a closer review of the available data, assumptions, and results and an understanding of the deficiencies, the application

limitations, and the risks—financial and otherwise—of using such assumptions, data, and results.

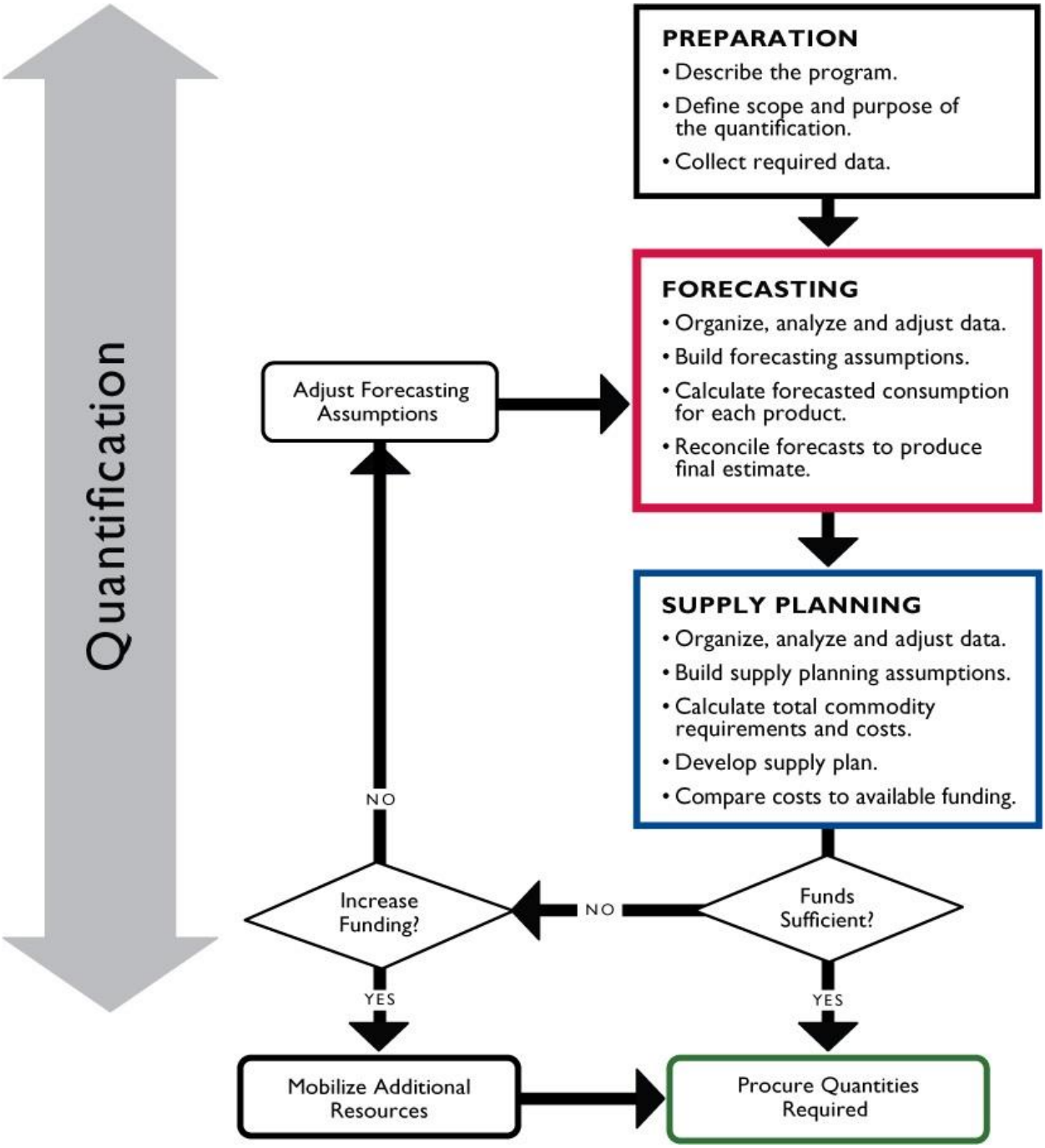
Therefore, forecasts should be frequently reviewed and revised as more data becomes available—to either validate the assumptions that were made or revise them and make adjustments to the forecast and supply plan as needed.

We recommend that a range of people form a quantification team or coordination committee, particularly for the forecasting portion of the exercise. The coordination committee can include program representatives from both the public and private sectors familiar with the products and plans, logistics and warehousing staff, procurement staff, pharmacy unit staff, technical experts, and donors/funders.[2] In addition, members (or at least one member) of the quantification team should be comfortable using MS Excel™ or other software applications used to manage the forecasting data and calculations.

The figure below from *Quantification of Health Commodities* illustrates the steps in quantification—guidance on forecasting for the 13 Commission products is represented in the "Preparation" and "Forecasting" boxes. (For another view of the quantification process, including the inputs and outputs for each step, refer to annex A.) Users of this guide should refer to *Quantification of Health Commodities* to prepare supply plans for each product.

Quantification cannot be a one-time event; it is a recurring process. Supply plans should be monitored closely and forecasts updated regularly as new/better information becomes available to check all inputs and assumptions used and revise as needed. This is particularly true for new or emerging programs/products where historical data is weak and forecasts are heavily based on assumptions to predict demand/use.

Steps in quantification



Source: USAID | DELIVER PROJECT. *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement*

Types and Sources of Forecasting Data

The choice of forecasting methodology will be dictated by the type and quality of the data available to the quantification team. Types of data include—

- Consumption data (or proxy consumption data)
- Services data

- Morbidity data and/or demographic data
- Program targets

Please refer to annex B for a description of each type of data and related forecasting methodology, and to the *Quantification of Health Commodities* for a detailed review of data types and the merits of using different methodologies. For family planning products, the sources, strengths, and challenges associated with each type are further discussed in the *Quantification of Health Commodities: Contraceptive Companion Guide*.

Using data on actual consumption of products is the standard for well-established products and programs where historical consumption data are reliable and available and viewed as representative of future program needs. The consumption-based methodology is covered thoroughly in *Quantification of Health Commodities*, *Quantification of Health Commodities: Contraceptive Companion Guide* (for family planning products),[3] and *Quantification of Health Commodities: Community Case Management Products Companion Guide* (for child health products).[4] In many countries consumption data may exist but with limitations, in which case we would strongly recommend conducting multiple forecasts and comparing the outputs; this too is covered in the main guide.

Since not all programs capture, report, or otherwise have visibility into consumption data, this guide is meant to offer forecasting possibilities when consumption data are limited or when programs are introducing or scaling up new or less-used products. The nature of the 13 overlooked or under-used commodities prioritized by the Commission suggests that they are not currently used or available in sufficient quantities to achieve their maximum health impact, so historical data would in many cases underestimate their potential demand. The potential data items and possible sources of those data are detailed in the forecasting algorithms for each product.

A caveat: *Quantification of Health Commodities* notes that demographic- and morbidity-based estimates are often used to estimate the total unmet need for a service or treatment in a program or country without taking into consideration program capacity, or the actual volume of services provided or quantities of products used. Therefore, demographic and morbidity-based forecasts may represent the uppermost bounds of the potential drug requirements for a program. This upper limit estimate should be tempered with realistic assumptions of service provision/uptake as program planners use these methodologies in the absence of reliable consumption or services data.

Product and Source Mix

Product Mix

If the same product appears in different forms in the country (e.g., different brands or designs) such that the quantification team believes that programmatic efforts or other drivers of use might affect different brands or designs unequally, it might be necessary to break the forecast down by brand/design so that separate assumptions can be applied to each. Similarly, brands may be procured from different vendors. Depending on the product, the brand choices may be driven by health programs, providers, or client preferences. Programs managing different brands may also have different plans for demand creation, provider capacity building, provision of equipment to facilities, or assignment of mobile units for more complex procedures, , etc. Therefore, the quantification team may need to build separate assumptions about growth (or decline) by brand.

Source Mix

Utilization of related services offered by the public and private sectors may differ slightly and this can affect estimates. If there is more than one programmatic source (e.g., public sector, social marketing, private clinic) providing these commodities in the country, it will likely be necessary to break out the estimated number of clients by source of supply—at minimum to specify the number of clients that will be served or cases that will be treated by the sources included in the forecasting exercise. For instance, if the public sector is the only program considered in the quantification, then you need only calculate the number of clients to be served or cases to be treated by that sector; clients or cases to be treated in other sectors should be excluded.

You need only calculate the number of clients to be served or cases to be treated by the sector(s) in scope for the quantification; clients or cases to be treated in other sectors should be excluded.

Commodities in this Guide

The 13 Commission products fall into four categories: family planning, maternal health, newborn health, and child health. Due to the demographic/morbidity-based forecasting methodology covered in this guide, it is important to take into account the characteristics and usage patterns for each product. The products are listed below; detailed sections for each product follow.

Family Planning Products

The Commission prioritized three family planning products: emergency contraceptive pills, female condoms, and contraceptive implants.

There are a number of existing guidance documents on forecasting for contraceptive methods. *Quantification of Health Commodities: Contraceptive Companion Guide* is an important resource. In addition, the *Forecasting Guide for New and Underused Methods*[5] discusses assumption-building for forecasting when there is no trend data, and thus is a particularly relevant source of information for the three family planning products on the Commission list. Users of this guide are strongly encouraged to refer to these resources.

Maternal Health Products

The three maternal health products are oxytocin and misoprostol for preventing or treating postpartum hemorrhage, and magnesium sulfate for eclampsia and severe pre-eclampsia in pregnancy.

Newborn Health Products

The four newborn health products are antenatal corticosteroids (ACS) for Respiratory Distress Syndrome for preterm babies, chlorhexidine for newborn cord care, injectable antibiotics for newborn sepsis, and resuscitation equipment for newborn asphyxia.

Child Health Products

The three child health products are amoxicillin for pneumonia, and oral rehydration salts (ORS) and zinc for diarrhea.

For additional information about quantification of child health products administered at the community level, please refer to *Quantification of Health Commodities: Community Case Management Products Companion Guide* developed by the Supply Chains for Community Case Management (SC4CCM) project.

References

[1] UN Commission on Life-Saving Commodities for Women and Children. Commissioners' Report, September 2012.

[2] JSI Research & Training Institute, Inc. 2014. *Guidance and Resources for Inclusion of Reproductive, Maternal, Newborn, and Child Health (RMNCH) Commodities in National Commodity Supply Coordination Committees*. Arlington, Va: JSI Research & Training Institute, Inc., for the UN Commission on Life-Saving Commodities for Women and Children, Supply and Awareness Technical Reference Team

[3] USAID | DELIVER PROJECT, Task Order 4. 2011. *Quantification of Health Commodities: Contraceptive Companion Guide. Forecasting Consumption of Contraceptive Supplies*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4.

[4] JSI Research & Training Institute, Inc. 2012. *Quantification of Health Commodities: Community Case Management Products Companion Guide*. Arlington, Va.: Supply Chains for Community Case Management (SC4CCM).

[5] Institute for Reproductive Health, Georgetown University (IRH/GU), John Snow Inc. (JSI), and Population Services International (PSI) for the Reproductive Health Supplies Coalition (RHSC). 2012. *A Forecasting Guide for New & Underused Methods of Family Planning: What to Do When There Is No Trend Data?* Washington, DC: IRH/GU, JSI, and PSI for the RHSC.

SECTION 2. FORECASTING ALGORITHMS

This section provides a detailed description of each product and factors to consider when estimating the quantities needed to meet program/client needs. It also includes a forecasting algorithm for each product to guide the assumptions-building process to arrive at the quantity of product needed.

For each product, this section provides information and guidance on—

- Product description, indications, and considerations for use
- Types of forecasting data needed and potential data sources
- Building the forecasting assumptions and calculating the forecasted consumption using a forecasting algorithm
- Incorporating product- and program-specific considerations into the forecasting assumptions
- Information on additional products, consumables, or equipment required

Section 2.1 Forecasting Algorithms for Family Planning Products

Emergency Contraceptive Pills

Product Description, Indications, and Considerations for Use

Emergency contraceptive pills (ECPs) are typically progestin-only oral contraceptives indicated for use to prevent pregnancy after unprotected or inadequately protected sex. Applicable circumstances could be when no contraceptive was used, a contraceptive was used incorrectly, or a contraceptive was used but was immediately observed to have failed.[1] Most ECPs can be taken up to five days after unprotected intercourse, though their effectiveness decreases the longer after unprotected sex they are taken. ECPs do not work if a woman is already pregnant, as they work primarily by preventing or delaying ovulation.

Three regimens of oral contraceptives are packaged and labeled specifically for emergency contraception (EC):

- 1 tablet of levonorgestrel 1.5 mg or 2 tablets of levonorgestrel 0.75 mg
- 1 tablet of ulipristal acetate 30 mg
- 1 tablet of mifepristone 10–25 mg (not widely available)

The Commission specifically mentions the levonorgestrel-only formulations on its list of life-saving commodities. In developing countries, the levonorgestrel-only formulations are the most widely available form of ECPs. This forecasting guidance covers the levonorgestrel-only formulations, although the methodology could also apply for the other ECP regimens if those products were managed by a country program.

Certain types of ordinary combined oral contraceptives can also be used as EC (known as the "Yuzpe regimen"). The following forecasting algorithm does not consider the Yuzpe regimen, as those pills are reported and resupplied through combined oral contraceptive supplies. Insertion of an intrauterine device (IUD) is the most effective form of emergency contraception but is not the focus of this guidance.

ECPs are safe for all women of reproductive age (including adolescents and older women during the peri-menopausal period). In addition to IUD, they are the only post-coital method a woman can use to prevent pregnancy after unprotected sex or method failure; however, efficacy depends on correct dose and use by the end user. Most efficacy estimates for levonorgestrel ECPs suggest that they prevent between 59% and 95% of expected pregnancies.[2] EC is important not only for women who have had no control over their exposure to sex, as in the case of sexual violence, but also for couples who find themselves in need of contraception after unprotected sex (including method failure).

Forecasting Considerations

Demand for ECPs is unpredictable because ECPs are not typically used for routine or continuous use as a family planning method. Furthermore, use is heavily contingent on client and provider awareness. The population that uses ECPs is likely a subset of the total population interested in using—or already using—a modern method of contraception. For example, if a woman is using a condom and it breaks, if she forgets to take her pill, or if she receives her injection late, she would know immediately that her short-acting method had failed. If she knew about ECPs, she could use it as a back-up method. However, a woman using a long-acting method would not necessarily know immediately if her method failed; long-acting methods are also typically less likely to fail and, therefore, users of long-acting methods are less likely to use ECPs. In addition, ECPs may also be used as part of post-

rape care and in refugee and humanitarian crisis settings,[3] as well as for other women not using a method.

Knowledge continues to be an important barrier to uptake, ECP is often one of the least known, least available, and least used modern family planning methods in developing countries. Many countries still do not include emergency contraceptive pills on their national essential medicines list (NEML). The Contraceptive Security Indicators compiled for 2013 indicate that 25 out of 43 surveyed countries (58%) have ECPs on their NEMLs.[4] It appears that countries are increasingly recognizing the importance of this method and adding it to their respective lists when updates take place. For example, according to a 2011 survey, Rwanda and Senegal added ECPs to their NEMLs during their latest list revision.[5]

Uptake in the public versus private/commercial sectors has been different in some countries, leading to challenges for public sector/government forecasting and procurement. According to the 2013 CS Indicators, 55% of surveyed countries managed ECPs in the public sector, 73% in NGO sector, 36% in the social marketing sector, and 93% in the commercial sector. In surveyed countries, ECPs are offered on average in two out of these four sectors. In Kenya, for example, the commercial sector market for ECPs is vibrant and sales are high, but public sector distribution has lagged. Reasons for this slow uptake in the public sector may include that women prefer the speed and privacy offered by private pharmacies and are willing to pay for it, and that public sector procurement has not often been accompanied by appropriate training and orientation of public clinic staff or demand generation activities among women.

In addition, ECPs may be offered via traditional as well as nontraditional outlets such as hospital emergency rooms, refugee and internally displaced persons camps, pharmacies, prisons, and schools. Access and availability can be influenced by issues such as licensing and registration of products, and whether clients are able to obtain the method without a prescription.

A recent analysis of forecast accuracy from several African countries revealed that in 2009, ECPs had the highest percent of forecast error among all new and underutilized methods.
Source: *A Forecasting Guide for New & Underused Methods of Family Planning*[6]

Because ECP is a new method for many public sector programs, emergency contraceptive pills can be difficult to forecast because of a lack of routine reliable consumption and other data. To the extent possible, we recommend that real sources of data or examples from past quantification exercises be used as the foundation to build assumptions. Estimates should be realistically aligned with programmatic plans and capacity for introducing or expanding provision of ECPs in a given sector, especially if EC is well established in other sectors. For instance, the private commercial sector plays a strong/established role in EC provision in some countries; quantification teams should use caution in extrapolating commercial sector demand for ECPs to the public sector. The quantification team will need to decide which data and evidence-based assumptions best fit its country or program situation. Thus not all of the types of data mentioned below may be applicable or needed for every country or forecasting exercise.

Box 1. Summary of Data Needed for Forecasting Consumption of Emergency Contraceptive Pills

- Target population
  - Percentage of women of reproductive age (WRA), i.e., women at risk for pregnancy
  - Contraceptive prevalence rate (CPR) (modern methods)
  - Percentage of WRA reporting ever use of ECPs
  - Percentage of modern method users using short-term contraceptive methods
  - Percentage of WRA experiencing unmet need for contraception
  - Percentage of WRA not using contraception
  - Incidence of rape (or rates of gender-based violence)
  - Short-term method failure rates
  - Percentage of women aware of EC
  - Percentage of women with access to EC
  - Health services-seeking behavior
- Product mix (brands/formulations managed and their proportional share)
- Source mix (the sources of supply and their proportional share)
- Dispensing protocols, (i.e., how many ECPs are dispensed per episode requiring EC)
- Other estimates of likelihood of use/repeat use of EC
- Programmatic changes that would affect demand for or consumption of ECPs (change in dispensing protocols, increase in service provision, demand generation activities, changes in the number of providers trained and number of facilities equipped to offer the method, increase in number of women willing to seek ECP)

See table 1 for possible sources of this data. It is critical to document all data and assumptions that are used in forecasting so that others can review, understand, and also update or revise data and assumptions as better information becomes available. This documentation can also serve as a reference for future forecasts or adjustments.

The standard forecasting methodology using demographic data involves estimating the number of users of the method, (stratified by brand and by source if relevant) and multiplying by the method-specific Couple-Years of Protection (CYP) factor. The CYP factor is the estimated number of doses required to protect a couple from pregnancy for one year. However, since ECP is not commonly used as a primary contraceptive method for annual protection as very few women in Africa who have ever used EC use it more than once,[7] the quantification team may choose to instead estimate the number of women experiencing an episode requiring ECPs and convert to quantities required by multiplying by one dose (pack) per episode (or other conversion factor based on dispensing protocols in the country).

Table 1. Potential Sources of Data for Forecasting Consumption of ECPs using Demographic Method

Data	Source	Limitation
Forecasting		
Total population	National census data, US Census Bureau International Database,[8] DHS	May be outdated (true of any listed data source); may need to apply estimated annual growth rate to project to forecast years
Percentage of population that women comprise	Census data, DHS, Reproductive Health Survey (RHS)	May be outdated (true of any listed data source); may need to apply estimated annual growth rate to project to forecast years

Data	Source	Limitation
Number or percentage of women who are of reproductive age (15–49)	Census data, DHS, RHS	May be outdated (true of any listed data source); may need to apply estimated annual growth rate to project to forecast years
Contraceptive prevalence rate (CPR) (modern methods)	Family health surveys, DHS, RHS, national health surveys	May be outdated (true of any listed data source); may need to apply estimated annual growth rate to project to forecast years
Short-term method prevalence (female condoms, male condoms, oral contraceptives, injectables)	Family health surveys, DHS, RHS, national health surveys	May be outdated (true of any listed data source); may need to apply estimated annual growth rate to project to forecast years
Short-term method failure rates	Contraceptive technology[9]	Contraceptive efficacy may differ from US standard
Unmet need	DHS or similar surveys	Data may be underestimated
ECP ever use	DHS (DHS between 2009 and 2014 do not include ever use of ECP) or similar surveys	Data may be underestimated
Incidence of rape or GBV	DHS, country studies	Data may be underestimated
Awareness of emergency contraception	DHS or similar surveys	Data may be underestimated
WRA with access to health services	DHS, SARA (services availability and readiness assessment), country studies	Data may be unavailable or outdated
WRA likely to seek EC (health services-seeking behavior)	Behavioral studies, Key informants	Data is not always available or reliable, and may differ by product
Product mix	MoH Reports, LMIS records, Facility records, DHS, multiple indicator cluster survey (MICS)	May not be representative if product is newly introduced
Source mix (percentage of share of public sector, social marketing sector, etc.)	Key informants/Social Marketing, DHS	Data may be incomplete
ECP dispensing protocols /quantity of ECPs dispensed per episode	National formulary, essential medicines list, standard treatment guidelines, WHO recommended guidelines, MoH, surveys	Non-adherence by provider could skew forecast
CYP	MEASURE Evaluation PRH Family Planning and Reproductive Health Indicators Database[10]	CYP factor for ECP is 20 doses, which may overestimate quantities needed if WRA use ECPs only for episodic, and not annual, protection.
Programmatic plans	Programs managing ECPs or working with current/potential users	Program targets do not always align realistically with program and system capacity; May be anecdotal and not accurately reflect reality of introducing a new product

Steps for Forecasting using Demographic Data

1. Determine the scope of the quantification
2. Calculate target population estimates for women who are likely to need and use emergency contraceptive pills
3. Estimate product/brand mix
4. Estimate source mix
5. Calculate the estimated quantity of ECP doses to be consumed per year in the forecast period

Each step is explained in detail below. We recommend preparing annual forecasts for a two-year period.

1. Determine the scope of the quantification — types of facilities and sectors (public, private, NGO, social marketing)

Clarify whether the quantification will cover the product needs for all programs and sectors in the country, or a subset of the channels through which ECPs are provided. Clarify at what levels of the health system ECPs are managed.

2. Calculate target population of women likely to use emergency contraceptive pills

Estimate the number of women of reproductive age (WRA) between ages 15 and 49 who are at risk for needing ECP (including those experiencing a short-term method failure, those not using a modern contraceptive method, and if relevant, those receiving ECP as part of post-rape care), who are aware of ECP, have access to it, and will seek treatment. In some cases, the quantification team may deem it worth the effort to disaggregate WRA into different groups based on reason for using ECP because demand is distinct by reason, or because assumptions about awareness, access, and treatment-seeking behavior might be different based on each reason for use. For example, secondary analysis of DHS or other data may provide the quantification team with the basis for assumptions about differing use of ECPs based on WRA age, marital status, level of education, income, or other characteristics.

- **WRA in the country/program catchment area.** To estimate the population of WRA (if this information is not already available from a reliable data source), review census data and multiply the number of women in the population by the percent of women who are of reproductive age.

  If census data is outdated, you may need to adjust the total population for growth by applying the annual population growth rate up to and through the years of the forecast and base further calculations on these to obtain the number of WRA in each year of the forecast. The example in this section applies this method for estimating the total population based on census data from a previous year.

- **WRA at risk for pregnancy.** To estimate the number of WRA at risk for pregnancy, multiply the number of WRA by the combined proportion of WRA in union (sometimes called “currently married”) and WRA who are unmarried but sexually active, if these data are available. The quantification team may also choose to consider non-sexually active women in the target population since women who report not being sexually active may still be at risk for pregnancy due to rape (and thus might use ECPs as part of post-rape care) – see the bullet below for “Remaining women not using or not in need of a modern method.”

Disaggregating WRA
WRA using a long-acting or permanent method of contraception are highly unlikely to use ECPs. Women using short-acting methods such as condoms (male and female), oral contraceptives, and injectables might use ECPs if they suspect they did not use their method properly or their method failed. Women with unmet need might elect to use ECPs if they knew about them and had access to them. Women not using any method (even if they do not express unmet need) might use ECPs in the case of rape. Thus the quantification team might choose to break down WRA by these groups. See the sample forecasting algorithm for a visual depiction of these separate flows.

Note: in countries with a high prevalence of use of traditional contraceptive methods, the quantification team could choose to use total CPR (rather than only modern methods CPR) and break out traditional methods users. Otherwise, in the sample algorithm described here, women using traditional methods are taken into account in the calculations for women at risk of pregnancy due to rape.

- **Contraceptive use**
  - **Women using a modern method**. Multiply the number of WRA at risk for pregnancy times the percentage of women who report using a modern method of contraception.

  - **Women with unmet need for contraception**. Multiply the number of WRA at risk for pregnancy times the percentage of WRA with unmet need (depending on the group (women in union, sexually active women, or both) for which unmet need data are available). These are the women who are not using another method and may choose to use ECPs if they have unprotected intercourse. (Note: for the sample algorithm, these women are included in the flow at "need for ECP" and filtered by awareness of EC, access to EC, and likelihood of seeking treatment. The quantification team could instead choose to assume might use ECP at the rate of "ever use" of ECPs, and next include it in the flow at treatment- or health services-seeking).

  - **Remaining women not using or not in need of a modern method**. Multiply the number of WRA at risk for pregnancy times 100 minus the sum of the percentage of women who report using a modern method of contraception and the percentage with unmet need.

    WRA x (100 – [% CPR + % Unmet Need])

    Add to these the number of WRA not considered "at risk for pregnancy," as they should be included in the women that, though they do not express unmet need or may not be sexually active, may use ECPs in case of rape.

- **Method mix**
  - Some women using short-term methods may elect to use ECP if their primary method fails. To calculate the number of WRA using short-term methods, multiply the number of WRA using a modern method times the percentage *of contraceptive users* using each short-term method:
    - Male condoms
    - Female condoms
    - Oral contraceptives (all brands and presentations)
    - Injectables (all brands and presentations)

    Note: if you have data on modern method use in terms of % of WRA using each method, be sure to adjust this percentage so it represents the ***% of modern***

contraceptive users *using each method. For example, if 5% of WRA are using implants in a country where mCPR is 45%, then the % of users using implants is 5/45 = 11%.*

- **Method failure.** To calculate the number of short-term method users experiencing method failure, multiply the number of WRA using each short-term method times the method-specific failure rate. (Long-acting method users may not know immediately if their method failed; long-acting methods are also typically less likely to fail and, therefore, users of long-acting methods are less likely to use ECPs.)

  Note: if the quantification team has chosen to break out traditional methods users in a previous step, it could apply estimated failure rates for traditional methods and include that in the calculation at this step.

- **Post-rape care.** In countries with high rates of sexual violence that dispense ECP as part of post-rape care, or if ECP is only available for post-rape care, the quantification team might elect to consider this group of WRA in the forecast. Estimates of the number of women seeking ECP for this purpose may depend on reported cases of sexual violence, the age distribution of cases, and the proportion of survivors seeking care. If data on incidence of rape are not available, the quantification team might choose to use data on the proportion of women at risk of gender-based violence as a proxy. Sources of such data might include organizations that provide post-rape care and/or work with refugee camps or statistics on violence, if available.

  For this calculation, multiply the remaining WRA not using a modern method by the percent of WRA who are likely to experience rape or gender-based violence. Add to this the number of WRA not in union or not sexually active, as they might choose to use ECPs in case of rape.

  Note: In the sample algorithm, use of ECP for this reason is only included in the flow of WRA not using a modern method and not experiencing unmet need. The assumption is that use of ECP by women using a modern method or with unmet need, including for reasons of rape, is already captured in the algorithm.

- **Awareness of EC.** In many countries, low levels of awareness of EC may have a significant impact on the number of women who actually seek EC, even if they need it. The quantification team may consider factoring in the awareness of EC as another variable. DHS data on awareness of ECP may be available. In addition, consider current and planned demand generation interventions that are expected to increase awareness of EC by interviewing the Ministry of Health (MoH) and social marketing organizations that might be able to provide this data.

  For this calculation, multiply the sum of the number of women experiencing unmet need, the number of women experiencing method failure and the number of women needing post-rape care by the percent of women who are aware of emergency contraception. See the sample algorithm for a visual depiction of this step.

- **Access to EC.** The quantification team may elect to factor in likely access to EC, such as the percentage of WRA needing EC who live in urban areas which infers that they will more likely have access. In urban settings, knowledge of EC may be higher and the population may have more disposable income to be able to purchase ECPs, meaning pharmacies/drug shops in urban settings may be more motivated to keep a stock of ECPs.[11] This point may be especially relevant in settings where there are public sector user fees or if the forecast includes the social marketing sector. Another

option would be to consider the proportion of women attending antenatal care as a proxy for access.

To calculate this, multiply the number of women who need EC and are aware of its availability by the percentage of women who have access. See the sample algorithm for a visual depiction of this step.

- **Treatment or health services-seeking.** Another critical factor to refine the target population is to estimate the percentage of women aware, with access, who will actually seek EC. There may be studies in the country about health services-seeking behaviors, but in the absence of these types of data, the quantification team may need to make an educated guess about the proportion of women in need who will actually seek EC.

  If the quantification team believes rates of treatment-seeking might differ by reason for use, conduct interviews with advocacy groups that work with victims of post-rape care and/or refugee and crisis camps on use of EC to estimate frequency of use in these situations.

  For this calculation, multiply the number of WRA needing EC, who are aware and have access, by the estimated percentage who will seek treatment. See the sample algorithm for a visual depiction of this step.

3. Source mix—estimate the number of women accessing ECP by source of supply

Determine the percentage of the target population that obtains ECPs from different supply sources such as the public, social marketing, NGO, and private sectors. Your calculations should include those sectors relevant to the scope of the quantification. Take into consideration current "share" and whether the quantification team expect that the "share" of the total ECP supply that women will access by source will change in the forecast period, e.g., due to programmatic plans or campaigns, removal of regulatory barriers.

When consumption, services, or survey data (like the DHS) are not available, interviews with social marketing organizations and the private sector will be useful in determining an estimate of current source mix. If EC is being introduced for the first time in a program and there is no available data, information about the experience of the same or like-products (including earlier generations of a product) in similar markets/countries may be useful.[12] That said, particularly in countries where commercial sector provision of ECPs is well-established, use caution in using commercial sector demand as basis for assumptions about potential program growth or marketing of a new brand of ECPs in other sectors.

Multiply the number of WRA by brand times the proportion accessing EC from each source (sector) of supply. The sample algorithm puts the source mix step before brand mix; the quantification team will need to determine the proper sequence, if multiple brands are managed in the country, and/or the same brands are managed by more than one source (sector) of supply.

4. Product mix—estimate the number of women accessing ECP by brand

To figure out how many users of each different ECP the program will need to serve, you will need to know how many types (different brands or formulations) of ECPs are offered, and have data on the product mix (the proportion of the total ECP supply made up by each brand or formulation) or make assumptions about it. If only one brand/formulation of EC is managed by the program participating in the forecasting exercise, you can

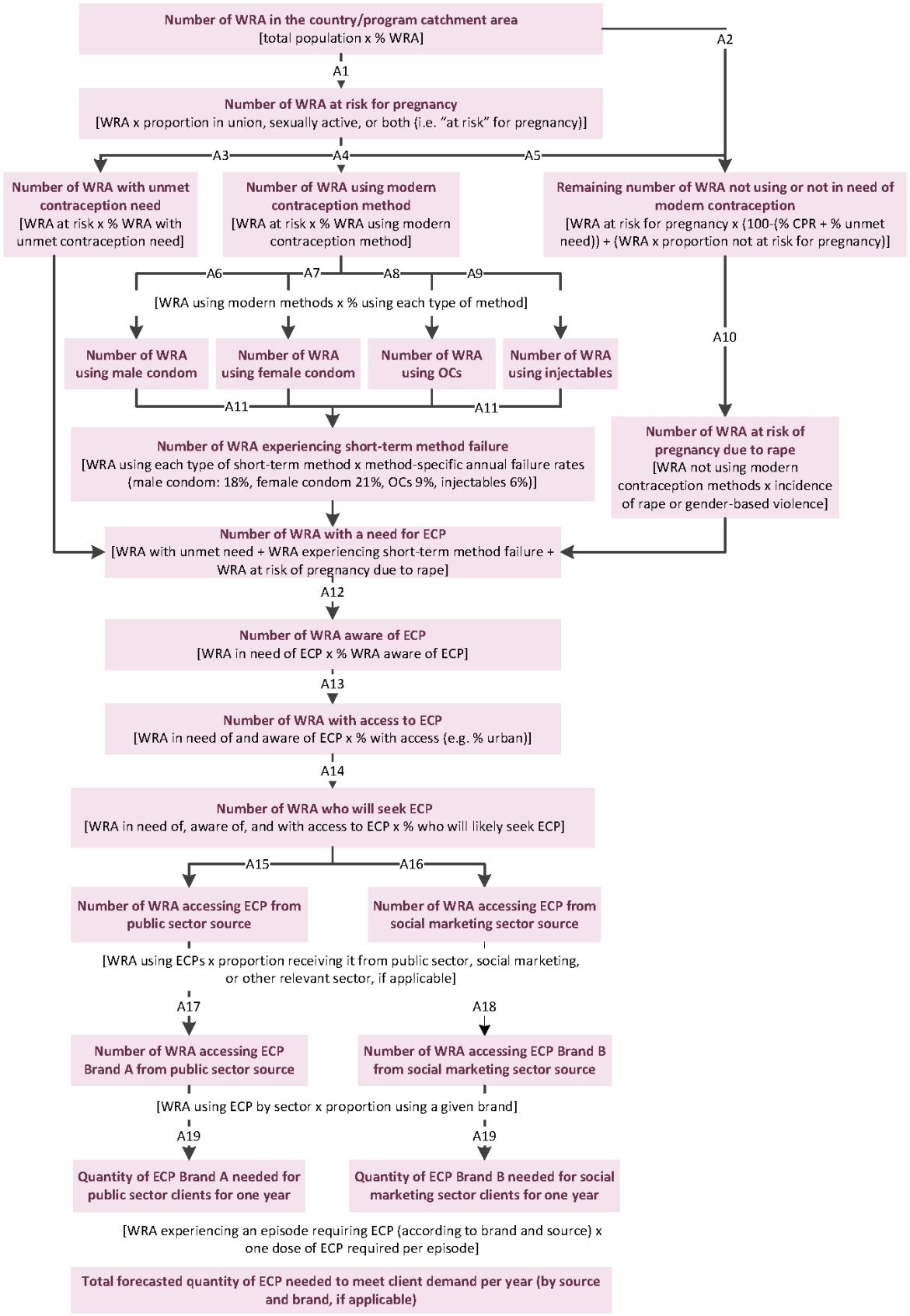
assume that 100% of ECP needs will be covered by that type, and you can skip this step. For countries where multiple brands or formulations of ECPs are managed, multiply the number of WRA (needing EC, are aware, have access, will seek EC) times the proportion each brand makes up of the total. See the sample algorithm for a visual of this step.

5. Calculate the quantities of ECP needed for client consumption
   Convert the number of women who will use ECPs to the quantities of each product that will be needed by multiplying the number of WRA (by brand and sector of supply) by the quantity of each product needed per episode. See the sample algorithm for a visual depiction of this step.

Forecasting Algorithm for Emergency Contraceptive Pills

The following sample algorithm, in Figure 1, illustrates a country scenario in which the public, social marketing, and private sectors all manage ECPs. The scope of the forecast includes the public and social marketing sectors, each of which manage one brand of ECPs.

Figure 1. Sample algorithm for forecasting consumption of emergency contraceptive pills for public sector and social marketing sector programs



Assumptions for Figure 1

A1	Proportion of WRA in union/sexually active
A2	Proportion of WRA not in union/sexually active
A3	Unmet need for contraception
A4	Contraceptive prevalence rate (modern methods)
A5	Percentage of women neither using a modern contraceptive method nor reporting unmet need for contraception: 100 - (% CPR + % unmet need)
A6,7,8,9	Method mix (% of modern method users, using each short-term method)
A10	Incidence of rape
A11	Method-specific failure rates (% of users experiencing short-term method failure in a year, by method)
A12	Percentage of WRA aware of ECP
A13	Percentage of WRA with access to ECP
A14	Percentage of WRA who will seek treatment
A15	Percentage of users accessing EC from public sector
A16	Percentage of users accessing EC from social marketing sector
A17	Percentage of brand mix of ECPs in public sector
A18	Percentage of brand mix of ECPs in social marketing sector
A19	Conversion factor (quantity of doses required per episode)

Figure 1 illustrates a scenario of steps to follow when forecasting for ECP for the prevention of pregnancy in women of reproductive age. The final result is the total estimated quantities of ECPs that are expected to be dispensed to clients in each year of the forecast period. This alone should not be used for procurement. In addition to this figure, other data will be used during the supply planning step. Refer to the original *Quantification of Health Commodities* for guidance on the supply planning step.

Additional Products, Consumables, or Equipment Required

None required.

Product Availability

Levonorgestrel-only ECPs appear in the World Health Organization (WHO) Essential Medicines List (EML).[13] As of October 2013, WHO had prequalified Gedeon Richter's two-pill levonorgestrel ECP and FamyCare's one- and two-pill levonorgestrel ECPs. Several ECPs are also approved by other stringent regulatory authorities, such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). In addition, a number of manufacturers are producing generic equivalents of ECPs. Some are currently going through the WHO prequalification process and being procured by international organizations and country governments.[14]

Access and availability of ECPs are influenced by a number of issues including licensing, registration, cost, whether clients are able to obtain the method without a prescription, and hours and geographical convenience of facilities to ensure that clients can access EC within five days after unprotected sex. Levonorgestrel emergency contraceptive pills are registered for sale and distribution in over 140 countries. Even in countries where no dedicated product has been registered, EC may sometimes be supplied with a special import license, and

women can always use a higher dose of regular birth control pills for EC, as mentioned. The following site compiles data on the status of EC in many countries—www.emergencycontraception.org.[15]

Box 2. Example of Country Forecast for Emergency Contraceptive Pills based on Demographic Data

Country X would like to estimate the quantities of emergency contraceptive pills to be consumed by clients of its public sector RH/FP program as well as a social marketing program over the next two years.

Available data (all DHS data are from "current year")

- Total population as of current year (Population Reference Bureau): 16,000,000
- Population growth rate (PRB): 3.1%
- Percentage of population who are women (DHS): 51
- Percentage of women who are of reproductive age (DHS): 44.3
- Percentage of WRA using a modern method of contraception (CPR) (DHS): 42
- Percentage of WRA using male condom (DHS): 2.70
- Percentage of WRA using female condom (DHS): 0.10
- Percentage of WRA using oral contraceptives (DHS): 1.90
- Percentage of WRA using injectables (DHS): 19.20
- Percentage of WRA experiencing unmet need for contraception (DHS): 27
- Percentage of clients accessing ECP by source (DHS: public sector: 82, social marketing: 15
- Percentage of WRA aware of EC (DHS): 35

Assumptions the quantification team agreed upon for the forecast period timeframe

- No projected change in the proportion of the population that is women
- No projected change in the proportion of women that are of reproductive age
- All WRA are at risk of pregnancy
- Estimated percentage of annual increase in CPR (due to increases in long-acting methods): 1
- No projected change from current year in short-term method mix as % of WRA
- No projected change in unmet need
- Estimated percentage of annual increase in awareness of EC: 1
- Estimated percentage of urban WRA (more likely to have access): 15
- Percentage treatment-seeking (women having access and need who will seek ECPs): 20
- Health services-seeking behavior not differentiated among e.g. age groups or purposes for seeking ECP
- Percentage product (brand) mix and source mix: Brand A (public sector): 15; Brand B (social marketing sector): 60 (i.e., 25% is commercial sector, which is not considered in this example)
- Product/Source mix unchanged in the forecast period
- Conversion factor for episodic use: 1 dose/treatment required per episode

(box 2 continued on following page)

Box 2. Continued

	Input		Current year	Forecast year 1	Forecast year 2
1. Population	*pop. growth rate*	*3.1%*	16,000,000	16,496,000	17,007,376
2. Number of women in the population	*% of pop. that is women*	*51.0%*	8,160,000	8,412,960	8,673,762
3. Women of Reproductive Age (WRA)	*% of women that are 15-49*	*44.3%*	3,614,880	3,726,941	3,842,476
4. CPR (modern methods)	*est. annual CPR increase*	*1.0%*	42.0%	43.0%	44.0%
5. WRA using a modern method of contraception			1,518,250	1,602,585	1,690,690
6. Method mix - converted from % of WRA to % of contraceptive users	*male condom*	*2.7%*	*6.4%*	*6.3%*	*6.1%*
	female condom	*0.1%*	*0.2%*	*0.2%*	*0.2%*
	oral contraceptives	*1.9%*	*4.5%*	*4.4%*	*4.3%*
	injectables	*19.2%*	*45.7%*	*44.7%*	*43.6%*
7. Number of method users	*m condom*		97,602	100,627	103,747
	f condom		3,615	3,727	3,842
	ocs		68,683	70,812	73,007
	inj		694,057	715,573	737,755
8. WRA with unmet need	*unmet need*	*27.0%*	976,018	1,006,274	1,037,469
9. Remaining WRA not using modern contraception	*100-(%CPR+ %unmet need)*		1,120,613	1,118,082	1,114,318
10. WRA experiencing short-term method failure	*m condom failure rate*	*18.0%*	17,568	18,113	18,674
	f condom failure rate	*21.0%*	759	783	807
	oc failure rate	*9.0%*	6,181	6,373	6,571
	inj failure rate	*6.0%*	41,643	42,934	44,265
11. Unprotected WRA at risk for pregnancy due to rape	*incidence of GBV (proxy for rape)*	*14.0%*	*156,886*	*156,532*	*156,005*
12. Total WRA with a need for ECP (total items 8 + 10 + 11)			1,199,056	1,231,009	1,263,791
13. Awareness of ECP	*est. annual increase in awareness*	*1.0%*	35.0%	36.0%	37.0%
14. Number of WRA with a need, who are aware			419,669	443,163	467,602
15. Number of WRA with a need, who are aware, who have access	*% urban dwellers (proxy for access to ECP)*	*15.0%*	62,950	66,474	70,140

(box 2 example continued on following page)

Box 2. Continued

	Input		Current year	Forecast year 1	Forecast year 2
16. total WRA who will seek ECP	*likelihood of seeking ECP*	*20.0%*	12,590	13,295	14,028
17a. Number of WRA seeking ECP using brand A (public sector	*% brand A (public sector)*	*15.0%*	1,889	1,994	2,104
17b. Number of WRA seeking ECP, using brand B (social marketing sector)	*% brand B (social marketing sector)*	*60.0%*	7,554	7,977	8,417
18a. Estimated annual consumption (quantities of product) - brand A (public sector	*conversion factor for episodic use (1 dose per episode)*	*1*	1,889	1,994	2,104
18b. Estimated annual consumption (quantities of product) - brand B (social marketing sector)			7,554	7,977	8,417

The final result for each year represents the forecast demand for ECPs required for client consumption. The next step is to conduct supply planning to take into account existing stocks, quantities on order, other supply chain considerations, and available funding to determine the quantities of contraceptives required for procurement. Refer to the original *Quantification of Health Commodities* for guidance on the supply planning step.

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Female Condoms

Product Description, Indications, and Considerations for Use

Female condoms are barrier devices that are inserted inside the vagina before sexual intercourse to prevent unintended pregnancy and reduce the transmission of the human immunodeficiency virus (HIV) and other sexually transmitted infections (STIs). Female condoms are the only woman-initiated method providing dual protection against unintended pregnancy as well as transmission of HIV or other STIs. Female condoms do not require a prescription or clinician involvement beyond initial insertion training.

Women of all ages can use the female condom; however, it is particularly attractive to women who experience side effects from hormonal methods; high-risk behavior groups, such as female sex workers and other women with multiple sexual partners; people who want to protect themselves from STIs, HIV, and unintended pregnancy; men who dislike the use of male condom; women who cannot negotiate the use of male condoms; and people who are allergic to latex (some female condoms are latex-free). Female condoms may be used in conjunction with the IUD, hormonal methods, and sterilization, but never with a male condom.

Studies provide important evidence that the female condom is complementary to the male condom and contributes to increased cumulative protected sex (i.e. female condoms do not simply substitute for male condoms that would be used,; they contribute to greater total condom use of both male and female condoms).

Forecasting Considerations

Female condoms are not as well-known and are used much less than male condoms.[1] They are classified as “underutilized” by the Reproductive Health Supplies Coalition’s Caucus on New and Underutilized Methods. Because demand for and use of female condoms are low, existing consumption or distribution data are a poor predictor of future demand or use. Female condoms have a significantly higher per-unit cost than male condoms.

Both male and female condoms may be artificially differentiated between condoms procured for family planning programs versus condoms procured for HIV and STI prevention programs. Since male and female condoms prevent both pregnancy and transmission of HIV and STIs, this distinction is unnecessary and may actually hamper access to condoms.

In addition, if there are stock-outs, users may obtain condoms from a different program. For example, a patient at an antiretroviral (ART) site might obtain condoms from a family planning counselor at the same hospital, or a family planning client may obtain condoms from the HIV testing and counseling service. Ultimately, while users may intend to use condoms for pregnancy prevention, prevention of disease transmission, or both, the users’ intention is not relevant for forecasting purposes.

Accordingly, an appropriate quantity of female condoms needs to be available to users regardless of their purpose. There are also benefits to coordinated forecasting among programs (e.g., potential for more/better data on use and drivers of use can allow the quantification team to build better assumptions). Nevertheless it is possible to break the forecast down by program (e.g., at the “source mix” level) if that is needed for financial, reporting, or other programmatic reasons.

It makes sense for different programs to forecast their condom needs together; or at least share their data. This will help each program avoid duplication, minimize overstocking, and shortages in its forecast, and plan for the transfer of products between programs if there are stock-outs. If you cannot avoid having to provide a separate forecast for condoms for a family planning program versus an HIV and STI prevention program, distinguish which program needs the separate forecast and adjust the assumptions accordingly. In addition, having separate forecasts for condoms for different programs would require that all data be differentiated by program at the service delivery level.

As with other contraceptive methods, historical consumption data are usually the best basis for forecasting needs, with the exception of programs that are scaling up, introducing new methods or products, or planning other initiatives that would significantly change consumption.

Quantification of Health Commodities: Contraceptive Companion Guide covers logistics-based forecasting. Since demand for and use of female condoms is low in many developing countries, consumption or distribution data may be a poor predictor of future demand or use. This section thus provides a possible methodology for forecasting for female condoms when logistics data are not available or not considered predictive of future consumption.

A caution on using demographic data for forecasting both male and female condoms is that the question about contraceptive use in the DHS is hierarchical; it will not reflect additional use of condoms for HIV and STI prevention if the user has already indicated the use of another contraceptive method.

Be cautious when using demographic and behavioral data about the prevalence of high-risk behavior or frequency of unprotected sex acts for determining program targets. Estimates based on this type of data about potential users, while valid and useful for advocacy or goal setting, may significantly overestimate actual demand. Female condoms especially have a higher incidence of over-forecasting. [2] Program targets should align realistically with program capacity when estimating quantities; it is not advisable for programs to use targets as the basis for procurement.

Box 3. Summary of Data Needed for Forecasting Consumption of Female Condoms:

- Scope (regional, national, district; programs; sectors)
- Target population
  - Population census data and rate of growth
  - Percentage or number of sexually active women (or women ages 15-59); if the forecast is for female condoms for family planning only, use percentage or number of women of reproductive age, 15-49)
  - Percentage or number of female sex workers (FSW)
  - Contraceptive prevalence rate (CPR)
  - Percentage of modern method users using female condoms
  - Percentage of women that used female condom in last sex act
- Product mix (if more than one type/brand of female condoms is being quantified for)
- Source mix (distribution or service delivery source and its proportional share)
- Couple-Years of Protection (CYP) factor
- Coital frequency (among women on average, among FSW)
- Clients per year per FSW
- Programmatic changes that would affect consumption of female condoms (changes in service provision or service delivery strategy, demand generation activities, changes in the number of providers trained, and number of facilities equipped to offer the method)

See table 2 below for possible sources of this data. All data and assumptions that are used in the process of forecasting must be documented. This makes it possible for others to review, understand, and update or revise data and assumptions as better information becomes available. This documentation can also serve as a reference for future forecasts or adjustments.

The forecasting formula involves estimating the number of users of female condoms (may be further stratified by brand and by source), and then multiplying by the method-specific CYP factor or another estimate of annual quantities of female condoms needed to protect one user, to convert to quantities of product required. An alternative for converting from users to quantities of product required is to estimate the number of sex acts requiring a female condom and multiply by one female condom per act of intercourse.

The quantification team will need to agree upon and document the assumptions it makes and attempt to assess the impact that these assumptions will have on the final forecast. To make the best estimate of future consumption, the team should try to build assumptions that are as accurate and as reasonable as possible.

Table 2. Potential Sources of Data for Forecasting Consumption of Female Condoms

Data Point	Source	Limitation
Total population; rate of population growth; percentage or number of women of reproductive age (15–49)	Census data, DHS, RHS	Data may be outdated and may need to be adjusted for the forecast years
Number or percentage of female sex workers (FSW)	Programs working with FSW, NACs, World Bank	Data may not be representative
Contraceptive prevalence rate	Family health surveys, Reproductive Health Surveys, National Health Surveys, DHS, MICS	Data quality is not always known, may be outdated
Contraceptive use among FSW	Programs working with FSW, DHS	Data may not be representative, may be outdated
Method mix (percentage currently using female condom or percentage women using condom in last sex act)	DHS, MICS; could be estimated from MoH Reports, LMIS records, Facility records	Not always complete, data quality is not always known, and may be outdated
Coital frequency	Sexual behavior surveys, DHS	May not be available for country of interest; may be outdated; special analyses of data may be required to generate frequency
Clients or sex acts per FSW per time period	Programs working with FSW, NACs, World Bank	Data may not be representative
Couple-years of protection (CYP) factor	MEASURE Evaluation PRH Family Planning and Reproductive Health Indicators Database[3]	CYP factor is 120 units
Product mix	Key informants, program records	Program records may be incomplete or unavailable.
Source mix, e.g., public sector	Key informants/Social Marketing DHS	May be anecdotal and not accurately reflect reality of introducing a new product
Programmatic plans	Programs managing female condoms or working with current/potential users (e.g. MOHs, NACs, NGOs)	Program targets do not always align realistically with program and system capacity

Steps for Forecasting Using Demographic Data

1. Determine the scope of the quantification
2. Estimate the target population
3. Determine use of contraceptive method by the target population
4. Determine the number of women using female condoms
5. Determine product mix (if applicable)
6. Determine source mix
7. Adjust for programmatic changes
8. Estimate quantity of female condoms required per user per year

1. Determine the scope of the quantification — types of facilities, sectors (public, private, NGO)

Clarify whether the quantification will cover the product needs for all programs and sectors in the country, or a subset of the channels through which female condoms are provided, e.g. public sector, social marketing. Clarify at what levels of the health system female condoms are managed.

The decision to prepare a forecast for female condoms for all uses (i.e. prevention of pregnancy and reducing STI transmission) vs. for family planning only or for STI prevention only is a key choice in determining the scope of the quantification and has implications at every step.

In the following steps, be prepared to make adjustments based on assumptions about program changes that are happening or planned for the forecast period. Ascertain if there will be interventions to increase contraceptive use overall, and use of female condoms in particular. If so, what demand building interventions have been planned? How will they affect sub-populations, brands (product mix), or sources of supply (sector mix) differently? Considerations might include the scale and reach or geographical scope of these interventions. These assumptions may be different depending on the product (if more than one type of female condom is managed in the country by the programs participating in the quantification) or the client's source of supply.

2. Estimate the target population

- **Sexually active women ages 15-59.** To estimate the population of sexually active women (those who might use female condoms not only to prevent unintended pregnancy but also to reduce transmission of STIs or HIV), obtain census data and multiply the percent of the population that is women by the proportion between the ages 15-59. We generally recommend assuming that all women 15-49 in union (or "currently married") as well as unmarried sexually active women are at risk for pregnancy, and all sexually active women 15-59 (married or unmarried) are at risk for STIs or HIV, though this may not be applicable in all contexts. (If the forecast is for female condoms for family planning only, use women of reproductive age (WRA) 15-49 instead – in union, sexually active, or both, depending on the data available).

  If the census data are outdated, you may need to adjust for population growth by applying the annual population growth rate up to the year of the forecast; document your assumption.

- **Female sex workers or other sub-populations to disaggregate.** If the quantification team determines that there is a population of female sex workers (FSW) or another sub-population (e.g., unmarried women, younger women) whose use of female condoms may differ substantially from use by women in general, the team may elect to disaggregate these women for the forecast. That is, the

quantification team may create different assumptions to estimate the commodity needs for this population.

As background for any assumptions about the number of FSW and their female condom use, interview organizations that work with, or provide legal protection services to FSW, and review studies of their contraceptive/condom use. If provided with the percentage of women 15-59 who are FSW, multiply this percentage by the number of women 15-59 to arrive at the number of women who are FSWs. Subtract the number of WRA who are FSWs from the number of WRA in general so they are not double-counted.

3. Determine use of contraceptive methods of the target population

If the quantification team has elected to forecast female condom needs for all sexually active women 15-59, for all uses, skip this step.

- **Use of contraceptives among WRA.** To obtain the number of women of reproductive age using a contraceptive method, multiply the number of WRA by the CPR.

- **Use of contraceptives among female sex workers**. To obtain the number of sex workers using a contraceptive method, multiply the number of female sex workers by the CPR. Consider collecting CPR data from organizations that work with, train, or provide legal protection services to female sex workers (if available) since CPR for FSWs may be different from that of the general population.

  If data is available on the rate of female condoms used per client (or per number of clients seen), combine this step with the next as one frequency.

4. Determine the number of women using female condoms

Two methods for determining this step are frequency of female condoms used in the last sexual encounter or female condoms as a percentage of method mix. If there is data available on condoms used in the last sexual encounter, this would be preferable as it might provide a better estimate of female condoms used for any purpose (contraception, HIV or STI prevention).

Multiply the number of women by the frequency of female condoms used in the last sexual encounter. (If the forecast is for female condoms for family planning only, multiply the number of women using a contraceptive method by the percent of CPR represented by female condoms). This calculation will determine the number of women using female condoms. *Note: if using method mix data specified in terms of percent of WRA using female condoms, be sure to adjust so that the figure you use at this step represents the* ***percentage of modern contraceptive method users*** *using female condoms. For instance if CPR (% of WRA using a modern method) were 30% and % of WRA using female condoms were 1%, then % of modern method users using female condoms would be 1/30 = 3.3%.*

Since condoms (male or female) may be used in conjunction with other contraceptive methods, female condoms as percent of CPR may be difficult to determine and may not be fully accurate; i.e., condom use may not be recorded in demographic surveys if a survey respondent mentions using another modern method of contraception.

Data on use of condoms in the last sexual encounter may be available in reports by organizations providing socially marketed condoms, HIV and AIDS surveys (data on female condom use for HIV prevention will be mainly based on study reports) or other census or demographic reports. Although these reports typically do not distinguish

between male and female condoms and assume the condom use is male, there may be some statistics available on use of female condoms. Advocacy groups working on educating potential users on use of condoms to determine the frequency of female condom use may also have data available.

If no other data are available, you might estimate female condom use as a percentage of male condom use, based on the proportion that female condoms represent of all condom distribution, if those data are available. You might also reference the percent of female condom use per WRA in another country that has experience with this product and shares similar demographics and socio-cultural context with your country. You might also reference data on awareness of the method and access to services among WRA.

If disaggregating FSWs from women in general, and evidence on FSW use of female condoms is available, multiply the number of FSW by the proportion using female condoms at last sexual encounter.

5. Determine product mix (if applicable)

If there is differentiation among female condoms in the country (e.g., different brands or designs) such that the quantification team believes that the effect of programmatic efforts or other drivers of use might affect different brands or designs unequally, it might be necessary to break the forecast down by brand/design so that separate assumptions can be applied to each. If all female condoms managed in the country are in essence substitutes, then this step can be skipped.

6. Determine source mix

Estimate the number of women accessing female condoms from different sources, such as public sector program or social marketing program. If the forecast covers both FP and HIV programs, which finance or manage these products separately such that the forecast end result needs to be separated into condoms for FP and condoms for HIV prevention, you can apply an assumption about the proportion of users served by the FP vs HIV program here. Note however that this allocation between programs for financing reasons can also be accomplished at the supply planning step (after forecasting).

For this calculation, multiply the number of women using female condoms by the proportion of women that obtain product from each source that manages female condoms. If logistics data from the national program or survey data are not available, interviews with key informants may provide information."

7. Estimate quantity of female condoms required per user per year

There are a number of options for converting “users of female condoms” to “quantities of female condoms required to meet users’ needs.” Coital frequency represents the frequency of intercourse per year and thus could be a proxy for the number of times condoms are used to prevent an unintended pregnancy, an STI or HIV. If available, this figure may be used to estimate the quantities of female condoms needed per user per year.

Surveys on coital frequency are rare, but if there are HIV and AIDS or reproductive health and contraceptive surveys that ask about coital frequency—in particular frequency of protected sex acts—this is the preferred data to use for this calculation. If data on coital frequency is not available, then the CYP factor[4] is the measure typically used to determine the quantity of a product required to protect one user (one couple) from unintended pregnancy for one year. Even when forecasting for all uses (not only family

planning), quantification teams may choose to use the CYP factor for this conversion if no other reliable conversion factor is available.

- **Sexually active women (age 15-59).** Convert the number of women to quantities of product required by multiplying the number of women using female condoms (by brand and source, if applicable) by the CYP factor of 120 female condoms.

  If data are available, frequency of protected sex may be a better figure to use. Multiply the number of women using female condoms by the frequency of protected sex acts (annual).

- **Female sex workers.** For female sex workers, determining the number protected sex acts for a period of time (such as in a week or in a month, then adjusted to be annual) would be a better figure to use than the CYP or the coital frequency of the average woman. This information might be available from local studies, key informant interviews with organizations that work with FSW, or a focus group discussion with FSW networks.

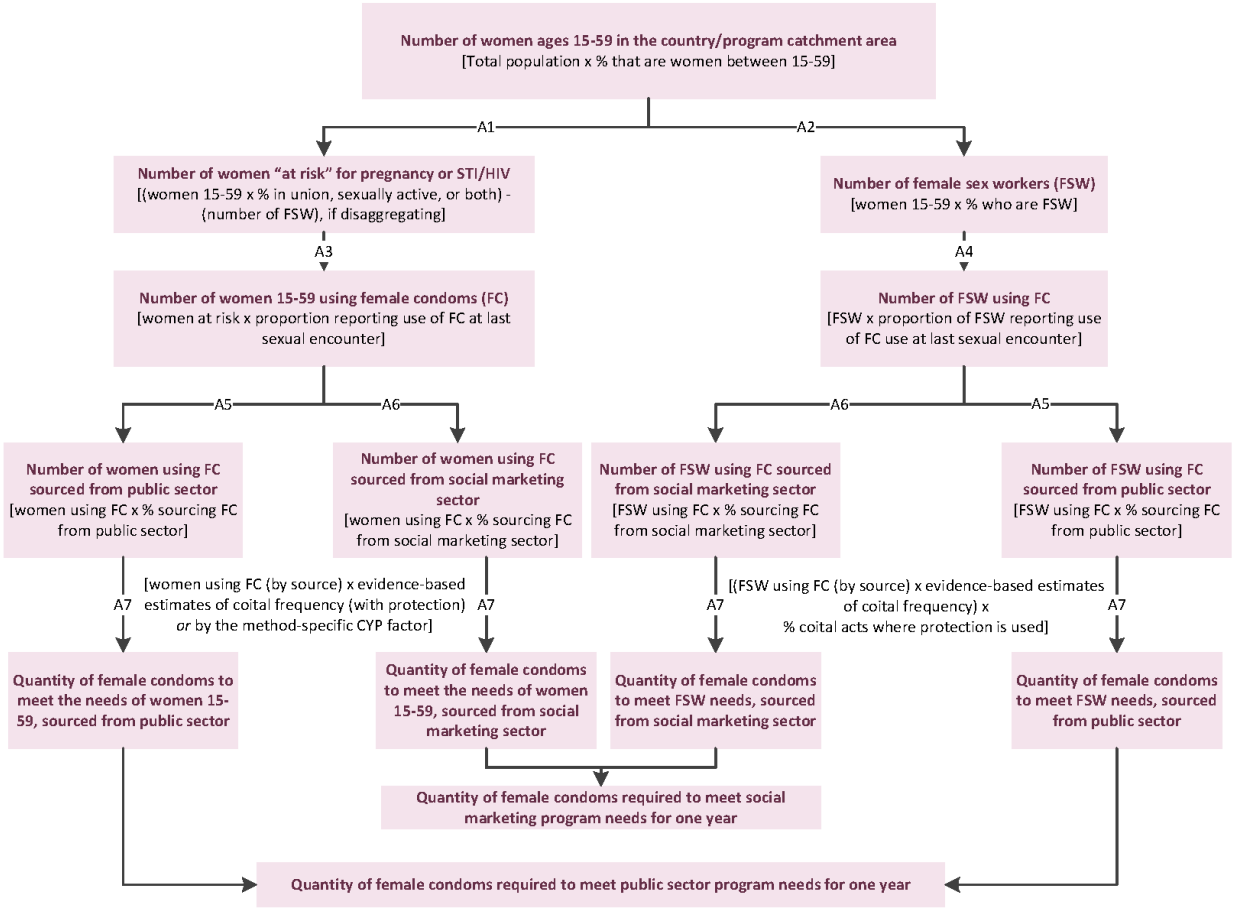
  For this calculation, convert the number of women to the quantity of products required by multiplying the number of FSW using female condoms by the number of protected sex acts per year.

  These calculations result in the quantity of product required to meet client needs for each year of the forecast period as shown in figure 2. Please refer to *Quantification of Health Commodities* for guidance on the supply planning step.

Forecasting Algorithm for Female Condoms

The sample algorithm (figure 2) illustrates the steps to follow when forecasting for female condoms for public sector and a social marketing program.

Figure 2. Sample algorithm for forecasting consumption of female condoms for public sector and social marketing sector programs



Assumptions for figure 2

A1	Percentage of women 15-59 in union, sexually active, or both
A2	Percentage of women who are FSW
A3	% of women 15-59 reporting female condom use at last sexual encounter
A4	% of FSW reporting female condom use at last sexual encounter
A5	Percentage sourcing female condoms from public sector (Note: if source mix is different among women in general and FSW, use different assumptions for the disaggregated groups)
A6	Percentage sourcing female condoms from social marketing sector
A7	Evidence-based estimate of coital frequency where female condom was used or method-specific CYP factor

The final result is the estimated quantities of female condoms needed to meet client demand for each year of the forecast; however, this alone should not be used for procurement. In addition to this figure, other data will be used during the supply planning step. Refer to the original *Quantification of Health Commodities* for guidance on supply planning.

Additional Products, Consumables, or Equipment Required

- Lubricant may be necessary with some brands.
- Pelvic models are necessary at service delivery points for demonstration of proper insertion.

Product Availability

A number of different female condoms are available on the market. As of June 2013, two female condom brands were prequalified by the WHO/United Nations Population Fund (UNFPA). Additional designs are under review or development.

If programs in a country manage more than one type/brand of female condom that must eventually be purchased from different vendors, then the quantification should take this into account. That is, each type or brand of female condom must ultimately be treated separately in the calculation, so that the end result will allow the team to proceed to the supply planning step for each product separately.

Box 4. Example of country forecast for female condoms based on demographic data

Country *X* would like to estimate the quantities of female condoms to be consumed by clients of their public sector RH/FP and National AIDS Control programs and social marketing program over the next two years

Available data includes (DHS data from current year)**:**

- Total population as of current year (Population Reference Bureau): 9,125,500 million
- Population growth rate (DHS): 3.23%
- Percentage of population that is women (DHS,): 51
- Percentage of women ages15-59) (DHS: 49%
- Estimated proportion of female sex workers (FSW) (local study, a year old): 0.5% of urban women
- Percentage of women using female condom at last intercourse: 0.2%
- Percentage of clients accessing female condoms by source: public sector (DHS): 50; social marketing: 40
- CYP Factor: 120

Assumptions the quantification team agreed on:

- The number of FSW is too small to warrant forecasting separately
- There is no estimated change in the proportion of the population that is women or the proportion of women that are ages 15-59
- All sexually active women are at risk of pregnancy and STI/HIV transmission
- Estimated annual percentage increase in percentage of women using female condom at last intercourse: %0.05
- Source mix remains stable
- CYP factor is the best estimate currently available for the quantity of FC needed per user per year

	Input		Current year	Forecast year 1	Forecast year 2
1. Population	*Pop. Growth Rate*	*3.23%*	9,125,500	9,420,254	9,724,528
2. Number of women in the population	*% of population that is women*	*51%*	4,654,005	4,804,329	4,959,509
3. Number of women ages 15-59	*% of women that are 15-59*	*49%*	2,280,462	2,354,121	2,430,160
4. % of women using FC at last intercourse	*annual increase in % of women using FC*	*0.05%*	0.20%	0.25%	0.30%
5. Number of women using female condoms			4,561	5,885	7,290
6a. WRA using female condoms from public sector	*source mix - public sector*	*50%*	2,280	2,943	3,645
6b. WRA using female condoms from social marketing sector	*source mix - social marketing*	*40%*	1,824	2,354	2,916
7a. Estimated annual consumption of female condoms - public sector	*Couple-Years of Protection Factor*	*120*	273,655	**353,118**	**437,429**
7b. Estimated annual consumption of female condoms - social marketing sector			218,924	**282,495**	**349,943**

References

[1] USAID | DELIVER PROJECT, Task Order 4. 2011. *Quantification of Health Commodities: Contraceptive Companion Guide. Forecasting Consumption of Contraceptive Supplies*. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4.

[2] Institute for Reproductive Health, Georgetown University (IRH/GU), John Snow Inc. (JSI), and Population Services International (PSI) for the Reproductive Health Supplies Coalition (RHSC). 2012. *A Forecasting Guide for New & Underused Methods of Family Planning: What to Do When There Is No Trend Data?* Washington, DC: IRH/GU, JSI, and PSI for the RHSC.

[3] Measure Evaluation PRH. Family Planning and Reproductive Health Indicators Database. Couple-Years of Protection. http://www.cpc.unc.edu/measure/prh/rh_indicators/specific/fp/cyp

[4] The RESPOND Project technical meeting. *New Developments in the Calculation and Use of CYP and Their Implications for Evaluation of Family Planning Programs*. September 8, 2011. New York: EngenderHealth (The RESPOND Project). Also available at http://www.cpc.unc.edu/measure/prh/rh_indicators/specific/fp/cyp. Accessed 30 October 2013.

Contraceptive Implants

Product Description, Indications, and Considerations for Use

Contraceptive implants are a highly effective hormonal family planning method used by women of reproductive age to prevent pregnancy. The product is a small, flexible plastic matchstick-sized rod (or rods) inserted under the skin of a woman's upper arm that releases a progestin hormone over the course of the implant lifespan (3-5 years). Based on the WHO medical eligibility criteria for contraceptive use (2009),[1] implants are suitable for nearly all women. Please refer to the WHO criteria for the full list of contraindications. Insertion should be per the labeled indication.

Furthermore, implants should be administered in a setting in which the client has received "adequate information in order to make an informed, voluntary choice of a contraceptive method." Skills-based and knowledge-based training are required to ensure the implant is administered safely according to medical criteria guidelines and to ensure that the woman is informed about possible risks and side-effects (e.g., bleeding pattern changes). Insertion and removal of implants requires a minor surgical procedure, which should be undertaken by "appropriately trained personnel in adequately equipped and accessible facilities."

The Commission case study notes that with "appropriate training, a wide variety of health care providers can provide implants safely and effectively. These cadres of providers include physicians, midwives, nurses, nurse auxiliaries, clinical officers, and, depending on educational and professional standards in each country, physician's assistants and associates." There are examples of community-level provision of implants as well as provision via mobile clinics. Please refer the WHO recommendations *Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting*[2] for more information.

Though the Commission explicitly includes two-rod 150 mg levonorgestrel implants on its product list, the Commission's Technical Reference Group on contraceptive implants includes all implants in its work plan regardless of brand, presence of the formulation on the WHO EML, or WHO prequalification status.[3] Accordingly all implants are considered in this guidance document as well.

The Commission product case study notes that the two-rod 150 mg levonorgestrel implants are included in the WHO EML (2011) but the one-rod 68 mg etonogestrel implants are still not included.

Table 3 summarizes characteristics of the implants currently available.

Table 3. Summary of Implants Currently Available [4]

	Implanon NXT™[a]	Jadelle®	Sino-implant (II)®[b]
Manufacturer	Merck Sharp & Dohme B.V.	Bayer Pharma AG	Shanghai Dahua Pharmaceuticals Co., Ltd.
Active ingredient and amount	68 mg etonogestrel	150 mg levonorgestrel	150 mg levonorgestrel
Labeled duration of effective use	3 years	5 years	4 years
No. of rods	1	2	2
Trocars	disposable	disposable	disposable[c]
Shelf life	5 years	5 years	4 years
CYP[5]	2.5	3.8	3.2

a Implanon NXT™ is progressively replacing Implanon in all countries.
b Sino-implant (II) is sold under various trade names by different distributors: as Zarin® by Pharm Access Africa, Ltd.; as Trust Implant® by DKT Ethiopia; as Femplant™ by Marie Stopes International; and as Simplant® by WomanCare Global.
c With the exception of China and India, Sino-implant (II) is provided with a disposable trocar.

One-rod implants from Merck and two-rod implants from Bayer have been prequalified under the WHO Prequalification of Medicines Programme.[3] Implants are ideally stored at controlled room temperature of 20-25°C.

Forecasting Considerations

For well-established implant programs where data are available on product consumption, a logistics- or trend-based forecast should be prepared. Services data that describe the number of clients using implants are another alternative, but may underrepresent current users since implants rarely require a visit to a provider after insertion. Please refer to *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement*[6] and *Quantification of Health Commodities: Contraceptive Companion Guide. Forecasting Consumption of Contraceptive Supplies*[7] for thorough guidance and examples of consumption and services data-based forecasting methodologies. Note that if financing has been a limiting factor for procurement and provision of implants in the past, the recent price reductions for implants may also mean that historical consumption data are not a reliable predictor future consumption, even for well-established programs.

In the absence of robust consumption or services data, estimates based on demographic data, program plans/targets, or service capacity may be used to estimate the quantities required. A forecast based on program targets or plans, service provider capacity, or demographic data will tend to overestimate the quantity required because these methodologies require multiple assumptions about actual demand. The more assumptions are made in forecasting, the higher the chance for error. In addition, program plans for scale up may not match available funding or service provider training. Thus the resources that would be required to meet program targets should be reviewed stringently. To avoid overestimates, be realistic in estimates of service provision and client demand.

No matter what forecast method is used, monitoring stock levels and demand regularly and maintaining a flexible supply chain are important to allow program planners to act if either too few or too many products are in the pipeline.

A discussion of these methodologies and an extensive example of using them for forecasting implants consumption for a new program are detailed in *Quantification of Health*

Commodities: Contraceptive Companion Guide. A sample algorithm for demographic forecasting for an existing program that does not have reliable logistics or services data will be sketched out below.

The *Quantification of Health Commodities: RMNCH Supplement* focuses on the demographic forecasting method, but for new or expanding programs, two additional forecasting methodologies may be relevant and could be used to triangulate or validate forecasts: program targets and services capacity methods.

Quantification of Health Commodities: Contraceptive Companion Guide offers examples of both for methods when forecasting of implants: p. 44 for forecast based on program targets and p. 45 for forecast based on service capacity.

Training on implant insertion and removal requires competency-based training that includes supervised practice, usually through a combination of simulations on model arms and supervised observation of live insertions/removals in the clinic setting. This means that even if not using the service capacity forecast methodology, the forecast needs to take into consideration the number and distribution of trained health providers.

Box 5. Summary of Data Needed for Forecasting Consumption of Hormonal Implants

- Target population
  - Total population
  - Population growth rate
  - Percentage of population that is women
  - Percentage of women who are of reproductive age (WRA), i.e., women at risk for pregnancy
  - Contraceptive prevalence rate (CPR)
  - Method mix (proportion of CPR attributable to implants)
  - Product mix (proportion(s) of method mix by product/brand)
  - Source mix (proportion of method or product mix by service delivery source, e.g., public, NGO/social marketing, private sector)
- Programmatic plans or changes that would affect consumption of implants such as increase in service provision, additional providers trained in counseling, and knowledge-based skills; a new cadre of providers such as CHWs authorized to insert; campaigns to expand provision of method, or constraints on service provision, such as number of trained providers or adequate facilities; new restrictions on who is authorized to insert)
- Couple-Years of Protection (CYP) conversion factor by product/brand or estimated insertion and removal rates
- Estimated number of insertions and removals a trained provider (or facility) will do in a given time period
- Estimated wastage rate if wastage at the point of consumption is deemed to be material
- Availability of medical instruments, expendable medical supplies, and infection prevention supplies required to provide contraceptive implants

Table 4 shows the likely sources of data for each of the steps. All data and assumptions that are used in the process of forecasting should be documented. This makes it possible for others to review, understand, and to update or revise data and assumptions as better information becomes available. This documentation can also serve as a reference for future forecasts or adjustments.

Table 4. Potential Sources of Data for Forecasting Consumption of Hormonal Implants

Data	Source	Limitation
Total population	National census data, DHS	May be outdated; may need to apply estimated annual growth rate to project to forecast years
Percent of population that is women	DHS, census data, RHS	Data quality is not always known, may be outdated
Number or percent that are women of reproductive age (15–49)	Census data, DHS, RHS	Data quality is not always known, may be outdated
Contraceptive prevalence rate, method mix	DHS, MICS, RHS, national health surveys, census data	Data quality is not always known, may be outdated; may only report CPR for WRA in union
Product mix	MoH reports, LMIS records, facility records, DHS, MICS, MoH or NGO program records, RHInterchange (myaccessrh.org/rhi-home)	Not always complete, data quality not always known, may be outdated or not collected; shipment information by product/brand (from RHInterchange) is not a direct proxy for dispensed-to user information
Source mix (Service provision source where client is provided with product)	DHS, key informants e.g. NGOs	Not always accurate or may have changed since survey was carried out
Couple-Year of Protection (CYP) factor	USAID-endorsed standard factors[5,8]	May not reflect country-specific continuation/discontinuation rate: CYP offers a proxy for global continuation rates, but continuation can vary dramatically by country and health system. CYP is affected by counseling, age, and intentions of the user and the availability of skilled providers for removal.
Service provider capacity for appropriate counseling, insertion and removal procedures	Program records (e.g., from sample sites), training records, research from other countries on number of insertions possible per day	Research from other countries may not reflect country- or health service delivery-level possibilities or constraints. Data from sample sites may not be nationally representative.
Program plans	Program records, key informants	Ensure that funding and appropriate human resources are available to support the program plans, and are in place before increases in consumption are forecast.
Availability of required instruments/supplies	MoH Reports, LMIS records, facility records, program records	If equipment, instruments, or supplies are used for other purposes than insertion/removal of implants then their availability may not be guaranteed

The demographic forecasting calculation typically involves the number of clients who will be users of implants in each year of the forecast period divided by the method/brand-specific CYP factor to determine the quantity of implants that would be needed to serve that number of clients. We present here a second option for converting from numbers of users to quantities of product. This second option may be more appropriate for newly instituted or growing programs and involves estimating the numbers of new insertions and reinsertions among implants users.

If research indicates that wastage at the point of consumption (insertion) is significant e.g. products contaminated, damaged or discarded due to errors in insertion, then this can be built into the forecast. The total quantity needed for the forecast period can be used as the basis for calculating the quantities of equipment, instruments and supplies needed for insertion and removal procedures. For more on this, please refer to *Quantification of Health Commodities: Contraceptive Companion Guide* pages 35 and 51-52.

Forecasting Method using Demographic Data

1. Determine scope of quantification—types of facilities, sectors (public, private, NGO, etc.)
2. Determine assumptions that will affect the target population that will use implants in the forecast period
3. Calculate the target population that will use implants in the forecast period
4. Estimate the number of implants clients by brand
5. Estimate the number of implants clients by source
6. Calculate the quantity of implants (sets) needed in the forecast period, by brand and source

1. Determine the scope of the quantification – types of facilities, sectors (public, private, NGO, etc.)

Clarify whether the quantification will cover the product needs for all programs and sectors in the country, or a subset of the channels through which implants are provided, e.g., public sector, social marketing.

2. Determine the assumptions that will affect the target population using implants during the forecast period

Survey data, for example from a DHS or MICS, can give planners an idea of the current situation regarding implant use, i.e., implants as a proportion of the contraceptive prevalence rate (CPR). If implants programs have existed for some years, it may even be possible to see a trend in implants use between two survey periods. Keep in mind that growth in use of implants has been rapid in many countries but as programs become established, increases may not be as dramatic.

If implants programs are new or yet to be introduced, planners may need to do some educated guessing and come to consensus on figures to use in estimating the number of users. *Quantification of Health Commodities*: *Contraceptive Companion Guide* pages 33-35 offers an example of the types of assumptions they may need to discuss and come to agreement on. For instance, they may need to consider the following questions and how these will affect the indicators and assumptions used in the coming steps:

Demographic forecast:

- Will planners use WRA in union or all WRA to represent current and potential users of contraceptive methods? Note: We recommend using all WRA since many unmarried WRA are sexually active, but this assumption may not be appropriate in all countries.
- Will the population of WRA grow at the same rate as the overall population (if adjusting outdated population figures)?
- What is the projected increase (or decrease) in CPR?
- What is the projected increase (or decrease) in implants as a proportion of the method mix? (Will all methods increase or decrease by the same proportion or will some users switch from other methods to implants, for example?)

- Is CYP a good proxy for continuation/discontinuation, or if not, what might the rates of insertion and removal be in the forecast period?

Services capacity and program plans:

- How many trained providers there are/how many will be trained (Is there funding for this training?)
- Are there properly equipped facilities for training and for implants insertion/removal?
- How many insertions and removals is it expected that providers will do?[*] When deciding how many insertions providers can do (per day, per month, etc.) consider what other duties the targeted providers must perform. Do their regular duties leave them time enough for the insertion/removal process? How many procedures might a provider realistically do within the limits of his or her other responsibilities each day?
- What types of information, education, and communication or other demand-creation activities are planned?
- How many new implants users does the program expect to serve?
- How many users are expected to continue into the next year? How many new users will there be the next year?

In addition, the program's ability to offer implants will also depend on whether the implants and all the instruments and supplies needed for insertion are available when and where needed in the country. Planners will need to determine (or create an assumption about) whether the required medical instruments, expendable medical supplies, and infection prevention supplies will be available. Related, some countries elect to procure kits that include implants as well as the medical supplies required for insertion.

3. Calculate the target population that will use implants in the forecast period

The target population is the number of WRA who will be users of implants in the forecast period. This includes both new adopters and continuing users. The assumptions built in the previous step and their effect on the following data elements will guide calculation of this figure.

- Total population of the country
- Percentage who are women
- Percentage who are of reproductive age
- Percentage who use modern methods of contraception (CPR) – *Note: if CPR data are only available for women in union, apply this proportion to women in union only; if the quantification team has elected to consider all WRA in the quantification, but CPR data are only available for women in union, discuss and reach consensus on an assumption about use of contraception among unmarried WRA.*
- Percentage who use implants (method mix) – *Note: if using method mix data stated in terms of % of WRA using implants, be sure to adjust so that you use a figure that represents the* ***% of contraceptive users*** *who use implants. For example, if CPR (% of WRA using a modern method) is 30% and % of WRA using implants is 2.5%, then % of CPR due to implants is 2.5/30 = 8.3%.*

Please refer to the sample forecasting algorithm for a visual depiction of these steps.

[*] Anecdotally, PSI reported that a dedicated family planning provider on a specific event day could do the following number of insertions: 10 (Zambia), 15 (Togo), 30 (Mali, with an assistant). On a regular service provision day (not a dedicated event), Togo reported 2 insertions per day. Also anecdotally, in 2012, MSI Uganda inserted 143,762 implants, primarily through 24 mobile outreach teams. Personal communication with Maxine Eber, PSI and Rehana Gubin, Jhpiego, September 2013.

4. Estimate the number of implants clients by brand

More than one implant brand may be used in the country. Since brands may be procured from different vendors, you will need to make separate estimates of the numbers of clients that programs will provide with each brand. In the case of implants, it may be likely that program or provider product selection or training decisions (rather than client preferences) are driving the demand for different brands. Perhaps the public sector has chosen to manage one brand while a social marketing organization offers another. In addition, survey data does not typically break down implants by brand, so data on current use by brand may not be representative (or predictive of future use). Thus it is quite possible that the quantification team will need to build separate assumptions about growth (or decline) **by brand**, if programs managing different brands also have different plans for demand creation, provider capacity building, equipping facilities, or devoting mobile units to implants procedures.

If the product is newly introduced, you will also need to consider the magnitude of scale-up expected in the coming years (whether based on a target or on trends in demand) and build those assumptions into the estimated client numbers for future years of the forecast period.

This calculation is based on the result from the previous step, using:

- Percentage of WRA using each brand of implants
- Percentage of WRA receiving their contraceptive methods from public/social marketing/private/other sector

5. Estimate the number of implants clients by source

If there is more than one programmatic source (e.g., public sector, social marketing, private clinic) providing women with implants in the country and included in the forecasting exercise, it will also be necessary to segment the estimated number of clients by source—at minimum to specify the number of clients that will be served by the sources included the forecast (as determined in step 1). For instance, if public sector is the only program considered in the quantification, then you need only calculate the number of clients to be served by that sector.

6. Calculate the quantity of implants (sets) needed in the forecast period, by brand and source – 2 options

In theory, the only implant clients who require product in a given period are (1) new adopters and (2) clients who have reached the useful life of their implants and elect to have them removed and a new set inserted. To convert from the number of clients in a period to the quantity of products needed to serve them, you need to know what proportion of users are new insertions in the period, and what proportion of users who have had implants inserted in the period will have them removed and new ones inserted.

Option 1: When using demographic data for forecasting, and in the absence of actual study data on discontinuation rates for a country (which may differ by brand), you can use the CYP factor as a proxy. The CYP is the quantity of product needed to protect a couple from pregnancy for one year. See table 4 for the CYP factors for each implant brand.

Implants have a CYP factor greater than one because their useful life is longer than one year per item or set. That is, a single item or set can provide more than one year of protection from pregnancy. For example, if 100 women are users of Jadelle implants in a given year, the calculation is:

$$\frac{\text{100 users (i.e., couples)}}{\text{3.8 years of protection per implant per couple}} = 26.3 \text{ implants per year}$$

Therefore, 27 sets of Jadelle will be needed to meet the insertion/reinsertion needs of 100 WRA using Jadelle implants, because some current users are in the middle of their use life and do not need a new set. Using the CYP factor to convert from users (where CPR includes all users at a given time no matter where they are in the use life of the product) accounts for this.

Option 2: The CYP factor for implants takes into account the average duration of time that a woman uses the implant. For example, the CYP for the Jadelle implant is 3.8 years. This means that on average, a woman will use Jadelle for 3.8 years even though its duration of effective use is 5 years. Since the CYP is based on the average duration of use, it can also be used to estimate the percentage of women who are discontinuing the use of implants each year. This discontinuation rate can then be used to determine the number of users needing a new implant each year.

The formula[8] to determine the number of users who will need a new implant in year X is the following (based on the RESPOND/EngenderHealth's Reality Check tool calculations):

a. Number of users in the current year (year X) – number of users in the previous year = Net difference in the number of users
b. Number of users in the previous year * 1/CYP (the discontinuation rate) = the number of users in the previous year who have discontinued use
c. Net difference in the number of users (step a) + Number of users in the previous year who have discontinued use (step b) = Total number of users needing a new implant in year X

This formula gives you an estimate of the number of users who are new to implants and will therefore need a new implant, and the number of users who have removed an old implant and who may need to reinsert a new implant. To find the number of implants needed in year X to meet this need, multiply the answer to the formula above (Total number of users needing a new implant in year X) x 1 implant per user.

An example to illustrate: let's say our demographic forecast for the public sector estimates 10,000 users of Jadelle in the current year, 12,000 users in forecast year 1, and 14,000 users in forecast year 2.

Calculation for forecast year 1

(12,000 – 10,000) + (10,000 * 1/3.8 [0.263]) =	4,632 users (new and discontinuing/reinserting) needing a new Jadelle implant in forecast year 1
4,632 * 1 =	4,632 sets of Jadelle required to meet need in forecast year 1

Calculation for forecast year 2

(14,000 – 12,000) + (12,000 * 0.263) =	5,158 users (new and discontinuing/reinserting) needing a new Jadelle implant in forecast year 2
5,158 * 1=	5,158 sets of Jadelle required to meet need in forecast year 2

If you have country-specific representative data on implants continuation rates for your country (which may differ by brand), you may elect to use that information in place of the CYP factor in the above calculation to estimate the quantities of product needed to serve new and continuing (or discontinuing, for removals) users each year.

Option 2 is a way to estimate the number of new users (new insertions) for each year of the forecast period as well as the number of removals/reinsertions to maintain the projected CPR due to implants. This makes it possible to use a 1:1 ratio of new insertions and reinsertions to sets of implants required to meet the product needs as well as estimate the quantities of instruments and supplies needed for the expected insertions and removals. Option 2 yields higher commodity needs than Option 1 and may be more appropriate for new/growing implants programs that are not yet well established with a stable number of users from year to year.

Additional Equipment, Instruments, or Supplies Required

Insertion and removal of implants are minor surgical procedures that require additional medical instruments, expendable medical supplies, and infection prevention supplies. As such, forecasting for implants must take into account not only the device (implant) itself, but also the quantities of instruments and supplies required for insertion or removal. As of this writing, disposable trocars or insertion devices for implants insertion are provided with all implants (with the exception of Sino-implant (II)® in China and India). Applicators/trocars and other expendable instruments or supplies should be disposed of per country guidelines for medical contaminated waste. Please see table 5 for a list of instruments and supplies for insertion and removal of hormonal implants.

In addition to this list, for programs that are expanding and training new clinicians, Merck notes that training placebos (placebo implants) are available. Merck recommends a minimum of at least one placebo per trainee, noting that three is optimal. Furthermore, Merck recommends 10-15 training kits per master trainer (assuming that each master trainer trains between 10-15 health professionals per training session).[†]

Table 5. Equipment, instruments, and supplies for insertion and removal of hormonal implants

Instruments and Supplies	Insertion	Removal	Expendable or Reusable
Unique			
Implants (Implanon NXT™, Jadelle® or Sino-implant (II))	X		Expendable
(1) Trocar and cannula or pre-filled insertion applicator (As of this writing, all implants come with disposable trocar or applicator, with the exception of Sino-implant (II) in China and Indonesia)	X		Expendable

[†] Personal communication with Koen C. Kruytbosch, Merck, 11-Mar-2014. Merck also notes that the current cost of Implanon NXT™ placebo is 4.5 USD and the cost of the training kit is around 55 Euros.

Instruments and Supplies	Insertion	Removal	Expendable or Reusable
Indispensable			
(1) Scalpel, handle, #3, graduated in cm with blade (#11)		X	Reusable or expendable (handle) Expendable (blade)
(1) Forceps, mosquito (5 inch or 12.7 cm, curved, delicate)		X	Reusable
(1) Forceps, mosquito (5 inch or 12.7 cm, straight)		X	Reusable
Common			
Light source (if no natural light at service site)	X	X	Reusable
(1) Clean tray	X	X	Reusable
(1) Cup, bowl or gallipot	X	X	Reusable
(1) Forceps, Rampley, sponge-holding, Straight (5.5 inch or 14 cm)	X	X	Reusable
Alcohol-based handrub or soap and water (for hand hygiene)	X	X	Expendable
Small towel (for hand drying if soap and water were used)	X	X	Reusable
(1) Sterile surgical drape, small (to rest the client's arm on)	X	X	Expendable
(1) Sterile surgical drape, fenestrated*	X	X	Expendable
(1) Pair of sterile gloves	X	X	Expendable
Antiseptic solution, such as iodine	X	X	Expendable
Local anesthetic such as lidocaine, (without epinephrine, 1% or 2%)	X	X	Expendable
Distilled water to dilute lidocaine (if 2% lidocaine is used)	X	X	Expendable
(1) 5 ml syringe with 1.5 inch and 21 gauge needle	X	X	Expendable
Sterile gauze sponges	X	X	Expendable
Skin bandage or band-aid	X	X	Expendable
Arm bandage (to apply pressure to the incision)	X	X	Expendable
Drapes (for packing instruments)	X	X	Expendable
Bleach (for decontamination solution)	X	X	Expendable
Safety box for sharps disposal	X	X	Expendable (once full)

*According to Merck, sterile fenestrated drape is not required for Implanon insertion.
Source: Adapted from Cagatay, Levent, Carmela Cordero, and Roy Jacobstein, 2013[9] and *Quantification of Health Commodities: Contraceptive Companion Guide,* 2011.[10]

A product is classified as "Unique" if it is used exclusively to provide that particular method of contraception

A product is classified as "Indispensable" if it is essential to provide the method, without which the service cannot be rendered.

A product is classified as "Common" if it has multiple uses across a variety of surgical procedures and techniques.

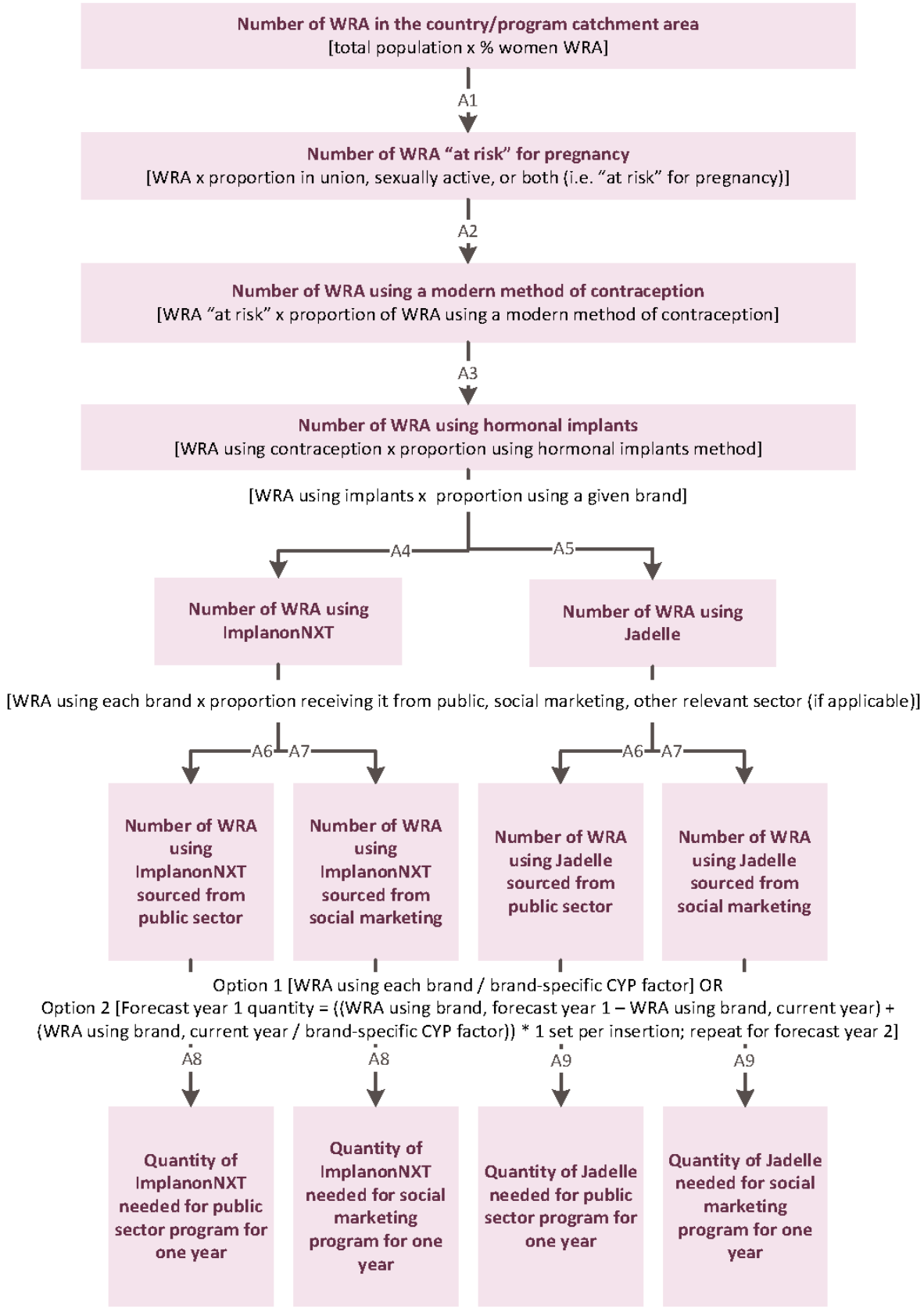
Product Availability

As noted, there are currently three manufacturers/suppliers of hormonal implants. Recent efforts have achieved price reductions or volume-based discounts for Jadelle and ImplanonNXT for many countries. As of this writing, both USAID and UNFPA procure both Jadelle and ImplanonNXT. Sino-implant (II) is marketed under a variety of names by different distributors: as Zarin® by Pharm Access Africa, Ltd.; as Trust Implant® by DKT Ethiopia; as Femplant™ by Marie Stopes International; and as Simplant® by WomanCare Global.[11]

Forecasting Algorithm for Contraceptive Implants

This sample algorithm illustrates the steps a quantification team might follow when forecasting consumption of hormonal implants. In this example, the quantification team must consider the quantities needed for more than one program, as well as more than one brand.

Figure 3. Sample algorithm for forecasting consumption of hormonal implants



Assumptions for figure 3

A1	Percentage of WRA in union and sexually active
A2	Contraceptive prevalence rate (modern methods)
A3	Method mix (percentage of CPR attributable to implants)
A4,5	Product/brand mix (percentage of users who use each brand)
A6	Source mix (percentage of users who receive product by source of supply) – public sector
A7	Source mix – social marketing sector
A8,9	Brand-specific CYP factor (Option 1) OR Calculation of new + discontinuing/reinserting users * 1 set of implants per insertion (Option 2)

The final result is the estimated annual demand for hormonal implants, by brand and source (sector), however, these figures should not be used for procurement. The forecast figures will be used along with other data during the supply planning step. Please refer to *Quantification of Health Commodities* for guidance on supply planning.

Box 6. Example of country forecast for implants based on demographic data

Country X would like to determine how many implants are needed for its public sector and social marketing family planning programs for the next two years.

Available data includes (all DHS data is from current year)**:**

- Total population as of current year (Population Reference Bureau): 16,000,000
  - Percentage of population that is women (DHS): 51
  - Percentage of women that are of reproductive age (DHS): 44.3
  - Percentage of WRA using a modern method of contraception (CPR) (DHS): 42
  - Percentage of CPR due to implants (DHS): 1
  - Percentage of clients accessing implants by source (DHS): public sector: 82, social marketing: 15

Assumptions the quantification team agreed upon:

- There is no projected change in the proportion of the population that is women
- There is no projected change in the proportion of women that are of reproductive age
- All WRA are at risk of pregnancy
- Estimated percentage annual increase in CPR: 1
- Estimated CPR increase is the same regardless of implant brand or source of supply
- Estimated percentage increase in implants as a proportion of CPR: 0.2
- Percentage product (brand) mix: ImplanonNXT—35%, Jadelle—65%
- No projected change in the source mix from theDHS, applied the same to both brands
- CYP is an accurate-enough reflection of local discontinuation rates

(box 6 continued on following page)

Box 6. Continued

	Input		Current year	Forecast year 1	Forecast year 2
1. Population	*Pop. Growth Rate*	*3.1%*	16,000,000	16,496,000	17,007,376
2. Number of women in the population	*% of population that is women*	*51%*	8,160,000	8,412,960	8,673,762
3. Women of Reproductive Age (WRA)	*% of women that are 15-49*	*44.3%*	3,614,880	3,726,941	3,842,476
4. CPR	*est. annual increase in CPR*	*1%*	42.0%	43.0%	44.0%
5. WRA using a modern method of contraception			1,518,250	1,602,585	1,690,690
6. Method Mix - implants	*est. annual increase in method mix due to implants*	*0.2%*	1.0%	1.2%	1.4%
7. Implants users as proportion of all contraceptive method users			2.38%	2.79%	3.18%
8. Number of WRA using implants			36,149	44,723	53,795
9a. Number of WRA using ImplanonNXT	*product mix - Implanon*	*35%*	12,652	15,653	18,828
9b. Number of WRA using Jadelle	*product mix - Jadelle*	*65%*	23,497	29,070	34,967
10a. Number of WRA receiving ImplanonNXT from public sector	*source mix - public sector*	*82%*	10,375	12,836	15,439
10b. Number of WRA receiving ImplanonNXT from social marketing	*source mix - social marketing*	*15%*	1,898	2,348	2,824
10c. Number of WRA receiving Jadelle from public sector	*source mix - public sector*	*82%*	19,267	23,838	28,673
10d. Number of WRA receiving Jadelle from social marketing	*source mix - social marketing*	*15%*	3,525	4,361	5,245
11. Estimated annual consumption - OPTION 1	*(# users/CYP factor)*				
a. ImplanonNXT - public sector	*CYP factor - ImplanonNXT*	*2.5*	4,150	5,134	6,176
b. ImplanonNXT - social marketing			759	939	1,130
c. Jadelle - public sector	*CYP factor - Jadelle*	*3.8*	5,070	6,273	7,545
d. Jadelle - social marketing			928	1,148	1,380
12. Estimated annual consumption - OPTION 2	*(# users forecast yr 1 - # users current yr) + (# users current yr/CYP factor)*				
a. ImplanonNXT - public sector	*CYP factor - ImplanonNXT*	*2.5*	*	6,611	7,738
b. ImplanonNXT - social marketing			*	1,209	1,415
c. Jadelle - public sector	*CYP factor - Jadelle*	*3.8*	*	9,641	11,108
d. Jadelle - social marketing			*	1,764	2,032

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[11] Caucus on New and Underused Reproductive Health Technologies, 2013. *RHSC Product Brief: Contraceptive Implants*. Brussels: July 2013.

Section 2.2. Forecasting Algorithms for Maternal Health Products

Magnesium Sulfate

Product Description, Indications, and Considerations for Use

One of the most common, yet treatable, causes of maternal death and disability worldwide is pre-eclampsia/eclampsia (PE/E)—characterized by the rapid elevation of blood pressure during pregnancy, decreased kidney function, and disseminated intravascular coagulation. It is estimated that 2–8 percent of all pregnancies are complicated by preeclampsia; however, according to WHO, in Africa and Asia, nearly one-tenth of all maternal deaths are associated with hypertensive disorders of pregnancy, whereas one-quarter of maternal deaths in Latin America have been associated with those complications.[1] Eclampsia can occur in the second half of pregnancy, during labor, or after the birth, and is more common in low- and middle-income countries than in high-income countries. The pathogenesis of eclampsia is partially understood: it is related to inflammation and endothelial damage, and to placental development. Approximately 5–8 percent of women with pre-eclampsia present with this condition (eclampsia) in developing countries.[2] For hypertensive disorders of pregnancy, the second most common cause of maternal death, greater use of magnesium sulfate is clearly called for.[3]

Magnesium sulfate ($MgSO_4$) is an anticonvulsant and is the safest and most effective option for the prevention and treatment of pre-eclampsia and life-threatening seizures of eclampsia According to a WHO survey, although 85% of countries have magnesium sulfate available, there are various socio-cultural and policy-based issues hindering its use. Some providers are hesitant to administer it because of perceived side effects. In addition, there are sometimes delays in the patient receiving the second dose during transfer to a higher level facility. WHO recommends magnesium sulfate for the prevention of eclampsia in women with severe pre-eclampsia in preference to other anticonvulsants.[4]

Magnesium sulfate is available in various formulations; the WHO recommended presentation is 50% weight/volume which is equivalent to 0.5 g in 1 mL.[5] The product is administered for 24 hours after last convulsion or delivery, whichever occurs later. The duration of treatment depends on clinical progression.

Forecasting Considerations

There is evidence that this product may be underutilized in some countries as providers may not be aware of magnesium sulfate as a treatment option, do not know how to administer it correctly, or are concerned about potential issues with toxicity and side effects to the patient.[40,43] Current practices as well as plans to increase use of magnesium sulfate should be taken into account during forecasting.

Country-level data on the number of pregnant women who develop PE/E are limited; therefore, there is often a need to use proxy data. Regardless of the presentation, providers will be required to calculate the correct amount of magnesium sulfate to administer according to the dosing regimen selected (Pritchard's or Zuspan's regimens). For the purposes of forecasting, the use of the product for 24 hours after start of administration is considered; however, many patients are treated longer for up to a total of 48 hours.

In some settings, patients may receive a loading dose from a lower level facility and then be referred to a higher level facility for continued treatment. In some cases, the patient may only receive the loading dose or an incomplete regimen if the provider determines that the patient has improved and does not require further treatment. These considerations should be discussed with national experts during the forecasting exercise.

Quantification teams may find the following programmatic assumptions relevant for estimating the number of cases of PE/E and the quantity of product required to treat them.

- Pre-eclampsia complicates 2%–8% of pregnancies;[6,7] however, a proxy figure of 2% that will require treatment severe PE/E with magnesium sulfate is used as a global average.
- Every health facility in which births are attended should have available stocks of magnesium sulfate to deal with emergency cases of PE/E.

Box 7. Summary of Data Need for Forecasting for Magnesium Sulfate

- Target population
- Total number of pregnant women in population
- Total number of births at facilities
  - Number of pregnant women developing PE/E likely to be given magnesium sulfate for prevention and treatment among facility-based births
- Standard or average treatment regimen, i.e., amount of magnesium sulfate needed to prevent or treat each case of PE/E
- Programmatic issues that may affect consumption (e.g., training of providers in administration of magnesium sulfate or scale-up in use)

Table 6 shows the likely sources of data. All data and assumptions that are used in the process of forecasting should be documented. This makes it possible for others to review, understand, and to update or revise data and assumptions as better information becomes available. This documentation can also serve as a reference for future forecasts or adjustments.

Table 6. Potential Sources of Data for Forecasting Consumption of Magnesium Sulfate using Morbidity Method

Data	Source	Limitation
Forecasting		
Total population	Census data, DHS, RHS, US Census Bureau International Database	May be outdated; may need to apply estimated annual growth rate to project to forecast years
Proportion of pregnant women	DHS, health management information system (HMIS), national maternal morbidity and mortality surveys, special surveys	DHS data usually an underestimate
Proportion of facility-based deliveries/births	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually an underestimate
Percentage of pregnant women who have severe pre-eclampsia or eclampsia	HMIS, national maternal morbidity and mortality surveys, special surveys	Data limited. Literature indicates that pre-eclampsia complicates 2%-8% of pregnancies; however, 2% is often used as a global average when country level figures are not available.
Percentage of pregnant women with PE/E who are likely to be given $MgSO_4$	HMIS, national maternal morbidity and mortality surveys, special surveys	Data may be incomplete or underestimates

Data	Source	Limitation
Dosage recommended	WHO or national MNCH guidelines National essential medicine program, WHO, MoH, NMCP, surveys	Providers may not always follow dosage recommended Guidelines may propose different medicines for the same condition; parenteral treatment duration varies between patients depending on clinical evolution; STGs not always used by health providers
Programmatic factors		
Interventions/factors affecting future changes in demand (e.g. scale up plans)	MNCH program	If strategies to increase use or encourage facility-based delivery are underway, the forecast may fall short

Forecasting Method using Morbidity Data

The forecasting formula involves multiplying the number of pregnant women developing PE/E who will receive magnesium sulfate for prevention or treatment by the average quantity of magnesium sulfate required for each case. The steps in this calculation are as follows:

1. Determine the scope of the quantification (e.g., types of facilities
2. Calculate the target population that will be given magnesium sulfate for the prevention and treatment of PE/E
3. Calculate the amount of magnesium sulfate needed for each case for the prevention and treatment of PE/E/establish standard or average treatment regimen
4. Calculate the quantity of magnesium sulfate needed for prevention and treatment of PE/E for the forecast period

1. Determine the scope of the quantification

The quantification team needs to determine what types of facilities are currently authorized to administer magnesium sulfate and how many of these facilities are to be supplied with the planned procurement. During this step, the team should also collect information on plans to scale-up use of magnesium sulfate and take these plans into consideration when preparing the forecast.. If the forecast is only for public sector facilities, the total number of births at facilities should be multiplied by the percentage of births occurring in only public sector facilities.

2. Calculate the target population that will need magnesium sulfate for the prevention and treatment of PE/E

The target population for which magnesium sulfate should be used depends on the national maternal, neonatal, and child health (MNCH) guidelines. It should be administered to both women who develop seizures due to eclampsia and women who develop a severe rise in blood pressure during pregnancy to prevent possible development of the life-threatening seizures of eclampsia[8]. Magnesium sulfate should be available at all levels of the health care system where deliveries occur.
Ideally, data on the number of pregnant women that develop PE/E and will receive magnesium sulfate should be used. This can sometimes be obtained from health services data, national maternal morbidity and mortality surveys, or special surveys. However, in practice, in most countries these data are not routinely collected and often difficult to obtain. In the absence of these data, we recommend using a proxy figure of 2% of all pregnancies that might result in severe preeclampsia or eclampsia and require treatment with magnesium sulfate.[9]

3. Calculate the amount of magnesium sulfate needed for each case for prevention and treatment of PE/E and establish standard or average treatment regimen

The amount of magnesium sulfate needed for each case depends on what is recommended in the national MNCH guidelines. Currently, there are two commonly used regimens of magnesium sulfate that can be used to manage preeclampsia and eclampsia:

Table 7. Pritchard and Zuspan Regimens for Administration of Magnesium Sulfate

	Pritchard Regimen (IV/IM)	Zuspan Regimen (IV/IM)
Loading dose	4 g in 20 mL (20% solution) administered IV over 15-20 minutes, followed by 5 g in 10 mL solution (50%) IM injection in each buttock.	4 g in 20 mL (20% solution) administered IV over 15-20 minutes
Maintenance dose	5 g in 10 mL (50% solution) IM injection every 4 hours in alternate buttocks.	1g per hour IV infusion
Duration	24 hours after last convulsion or delivery, whichever occurs later	

NOTE: If convulsions occur after the loading dose is given, administer 2g in 4mL (50%) IV over five minutes

The WHO-recommended formulation is a 50% weight/volume solution which is equivalent to 0.5g / mL. Other common presentations include 1 g/2 mL (50%) and 5 g/10 mL (50%). The presentation(s) available in a country will determine the regimen that can be administered.

Required Quantities: This will depend on the regimen most commonly used in the country. For the two most common regimens, assuming administration for 24 hours, the total amounts required are:

Pritchard regimen: loading dose = 4 g+ 10 g; maintenance dose = 30 g. **Total = 44 g**
Zuspan regimen**:** loading dose = 4 g; maintenance dose = 24 g. **Total = 28 g**

Number of ampoules 1 g/2 mL: Pritchard = 44
Zuspan = 28
5 g/10 mL: Pritchard = 9
Zuspan = 7

4. Calculate the quantity of magnesium sulfate needed for prevention and treatment for the forecast period

The period that the forecast is meant to cover needs to be determined. A two-year forecast that can be broken down into two 12-month periods is recommended. To calculate the quantity required for this period, multiply the number of facility based births expected during that period by 2% (proxy figure: percentage of all pregnancies that develop severe preeclampsia or eclampsia, from step 1) and then multiply by the amount of magnesium sulfate needed for a single case (number of ampoules, from step 2.

Additional Products, Consumables, or Equipment Required

The supplies required for administration of magnesium sulfate depend on the regimen used and may include in addition to syringes, an IV infusion set and drip. Also, calcium gluconate should be available in facilities where magnesium sulfate is administered.

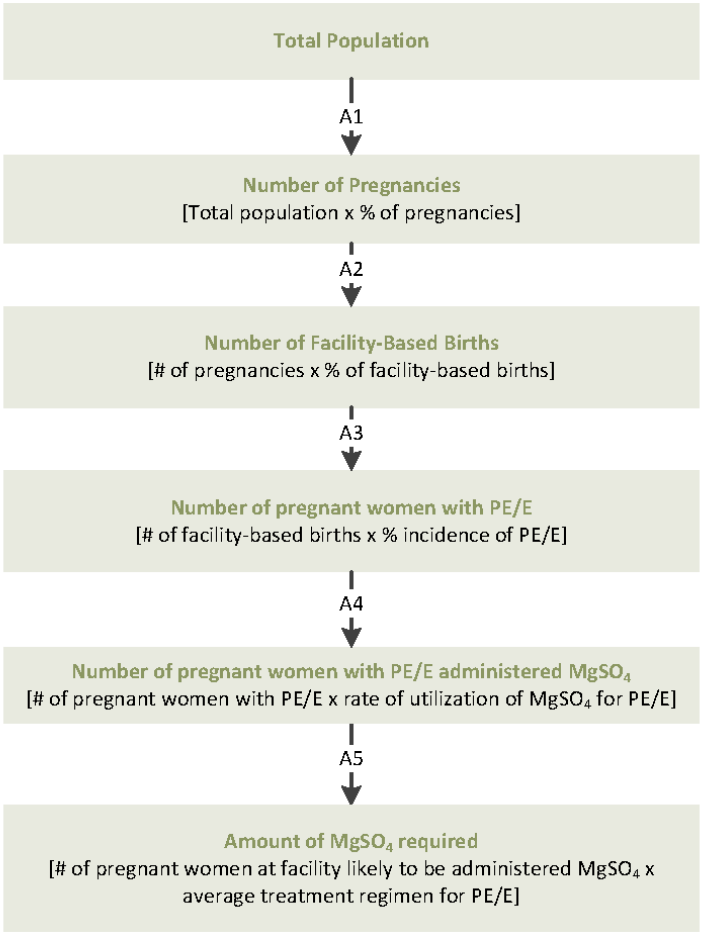
Product Availability

Magnesium sulfate is widely available as it is produced by over 35 manufacturers globally.

Forecasting Algorithm for Magnesium Sulfate

The figure below illustrates an example of the steps to follow when quantifying for magnesium sulfate for PE/E including the data needed to reach each subsequent step. As mentioned above, the quantification team will need to define the best assumptions to use for forecasting based on the local context.

Figure 4. Sample algorithm for forecasting consumption of magnesium sulfate



Assumptions for figure 4

A1	Percentage of population likely to become pregnant or percentage of births
A2	Percentage of pregnant women giving birth in facilities
A3	Incidence of PE/E. In absence of country level data, proxy data from similar countries or global estimates, e.g., published literature indicates that pre-eclampsia complicates 2–8% of pregnancies (2% is often used as a global average).
A4	Percentage of women who give birth in facilities and develop PE/E, and are likely to be treated with magnesium sulfate
A5	Average treatment regimen for $MgSO_4$
A6	Rate of expected programmatic change, e.g. scale-up or losses

Once the amount of magnesium sulfate required to meet program needs in the forecast period is calculated, this is entered into a supply planning matrix which takes into account

current pipelines, losses; price and supplier lead times to determine the amount to be delivered for each specific time period. Please refer to *Quantification of Health Commodities* for guidance on the supply planning step.

Box 8. Example of Country Forecast for Use of Magnesium Sulfate based on Demographic Data

Country *X* recommends the use of magnesium sulfate ($MgSO_{4)}$ for the prevention and treatment of PE/E. Compliance to this recommendation is 50%; however, there are plans to scale-up the use to 90% over 5 years. There are no data on the percentage of pregnant women that develop PE/E.

Available data include:

- Total population: as of current year: 10,000,000
- Percentage increase in population per year: 2%
- Percentage of pregnant women out of total population: 2%
- Percentage of facility births: 70%
- Recommended dosage: Pritchard regimen
- No. of ampoules administered per patient in 24 hours = 9 (5g/10ml)

Assumptions:

- Each patient requires 9 ampoules for management.
- Proxy figure of 2% of all pregnancies that will require treatment for severe PE/E with magnesium sulfate is used as a global average.
- All cases of PE/E are treated at the facility level.
- All cases of PE/E are treated with magnesium sulfate

From the data above, we can calculate the quantity of $MgSO_4$ to be administered over next 2 years

	Input		Current Year	Forecast year 1	Forecast year 2
Population	*Pop. Growth rate*	2%	10,000,000	10,200,000	10,404,000
No. of pregnancies	*% of women pregnant from pop.*	2%	200,000	204,000	208,080
No. of facility births	*% of facility births*	70%	140,000	142,800	145,656
No. of pregnant women developing PE/E	*% of pregnancies that will require treatment for PE/E*	2%	2,800	2,856	2,913
Percentage of PE/E cases likely to be treated with $MgSO_4$	*% increase from 50%-90% in 5 years*	10% increase per year	50%	60%	70%
No. of PE/E cases likely to be treated with $MgSO_4$	*# of cases of PE/E to be treated at facilities*	10% increase per year	1,400	1,714	2,039
Adjusted amount of $MgSO_4$ needed (ampoules)	*# of ampoules needed per case*	9	12,600	15,422	18,353

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Misoprostol

Product Description, Indications, and Considerations for Use

Globally, more than half of women give birth at home without a skilled birth attendant. The management of postpartum hemorrhage (PPH) worldwide is particularly challenging in home deliveries. Primary PPH, defined as blood loss equal to or greater than 500 ml within 24 hours after birth, is identified as a major killer of women during childbirth. Therefore, the 24-hour period after birth is the most dangerous for the mother and active management during this period is called for with every birth irrespective of where it happens. WHO recommends that all women giving birth should have access to an uterotonic, preferably oxytocin, but in situations where oxytocin is not available, misoprostol can be used to prevent postpartum hemorrhage. A recent statement issued by the International Confederation of Midwives and the International Federation of Gynecology and Obstetrics also describes the benefits of misoprostol for treatment of PPH in settings where oxytocin is not available.[1]

PPH has a prevalence rate of approximately 10.5 percent in women who do not receive an uterotonic.[2] It is difficult to predict who will have PPH based on risk factors**;** two-thirds of women who have PPH present no risk factors. Therefore, all women are considered at risk, and hemorrhage prevention must be incorporated into care provided at every birth. The World Health Organization (WHO) affirms that most deaths due to PPH can be avoided with proper diagnosis and use of essential medicines, such as oxytocin in every delivery and misoprostol in settings where oxytocin cannot be administered.[3]

Misoprostol, a synthetic prostaglandin, is taken orally in a tablet form. Misoprostol is currently in use in many countries for the treatment of gastric ulcers and management of incomplete abortions or miscarriages.[4]

Introduction and scale up of misoprostol for PPH is underway in a number of countries.

Forecasting Considerations

There is planned global scale up for the use of misoprostol for the management of PPH. Many countries now have national policies listing misoprostol for the prevention of PPH; and many others are considering its introduction.[5]Some countries are in the pilot phase of distributing misoprostol to women by Community Health Workers, and a few are expanding distribution to the national level.

Scale up of programs tends to roll out much slower than expected and decisions on these factors must be made during forecasting so that neither stock-outs nor surplus is experienced after procurement.

National standard treatment guidelines may specify which level of trained health providers are authorized to administer misoprostol and at which facilities. These considerations will also affect the forecast.

Providers in some settings may use misoprostol for cervical ripening and induction of labor. The appropriate dosage for this indication is 25 µg and if that presentation is unavailable, providers may either cut pills (**not recommended**) or dilute them to achieve the proper dosage. In countries with legal indications for safe abortion, misoprostol may be used alone or in combination with mifepristone. Forecasting should take into account these other uses of misoprostol as well as indications unrelated to obstetric conditions. If different presentations

are used to different purposes, each presentation should be considered a completely different item and a separate forecast should be done.

With respect to product considerations, at present, most manufacturers of misoprostol are not producing a 3-tablet blister which may create distribution challenges. If misoprostol is to be used at lower levels of the system, particularly in home deliveries it may be necessary to re-package. While misoprostol does not require cold chain it is sensitive to humidity, so double-aluminium blister packages are best.

Since as stated above the use of misoprostol for management of PPH in most countries is new, the quantification team will need to develop and agree on assumptions about the factors and interventions that may affect future changes in demand for misoprostol, such as the population to be treated and scale-up goals. Some assumptions that will need to be defined include:

- Percentage of home deliveries that should receive 600 µg of misoprostol. This will most likely be a phased scale-up and quantification should try to include realistic time frames for achieving this target coverage rate
- Percentage of facility deliveries that will receive 600 µg misoprostol when oxytocin is unavailable
- Percentage of women who will experience PPH after prophylaxis and require treatment
- Percentage of women with PPH will require 800 µg misoprostol because oxytocin is unavailable where they present for care
- Percentage of pregnancies that may end up in miscarriages (studies indicate between 10 -15% of pregnancies end in miscarriage)[5]
- Percentage of miscarriages might require 600 µg misoprostol (studies indicate this may be around 28% of miscarriages)[6]
- Percentage of pregnancies might require misoprostol for post-abortion care (PAC) or unsafe abortion indication (studies indicate this may be around 1.4%) [6]
- Rate of unsafe abortion among of reproductive age (studies indicate this may be 14 per 1000)[7]

Box 9. Summary of Data Needed for Forecasting for Misoprostol

- Target population:

Number of pregnant women
Number of home births
    - No. of pregnant women delivering at home (or in settings where oxytocin is not an option) that are likely to be given misoprostol for the prevention of PPH
    - No. of PAC/unsafe abortion cases
    - No. of cases of miscarriage
    - No. of pregnant women that develop PPH that will be given misoprostol where oxytocin is not available
- Standard or average treatment regimen (i.e. amount of misoprostol needed for each case for prevention and treatment)
- Programmatic issues that can affect consumption (e.g., training and scale up)

Table 8 describes potential sources for the required data.

Table 8. Potential Sources of Data for Forecasting Consumption of Misoprostol using Morbidity Method

Data	Source	Limitation
Forecasting		
Total population	DHS, National census, US Census Bureau International Programs Database	May be outdated; may need to apply estimated annual growth rate to project for forecast years
Proportion of pregnant women	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually an underestimate
Proportion of home deliveries	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys, ANC attendance	DHS data usually an underestimate
Proportion of home deliveries given misoprostol	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	May not be included in current surveys; may be difficult to estimate
Proportion of cases with PPH requiring third-line treatment with misoprostol	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	May not be included in current surveys; may be difficult to estimate
Dosage recommended	MNCH guidelines	May not be listed in current national guidelines
Programmatic factors		
Health services reporting rate	MoH	This is usually an estimate of how complete health services reports typically are
Interventions/factors affecting future changes in demand e.g. scale up plans	MoH, MNCH guidelines	Planned scale up may be slower than actual implementation or uptake.
Records of losses product	CMSs, health facilities, LMIS	Data on losses are often not systematically recorded at central level, and facilities do not consistently report losses

The forecasting formula involves adding the number of pregnant women delivering where oxytocin is not available, that will be given misoprostol for the prevention of PPH multiplied by the average quantity of misoprostol tablets required for each case for prevention to the number of pregnant women likely to develop PPH and be given misoprostol for treatment where oxytocin is not available multiplied by the average quantity of misoprostol required for each episode, and the number of PAC cases given misoprostol multiplied by the average quantity of misoprostol required for each episode.

Forecasting Method using Morbidity Data

1. Calculate the population that will need misoprostol for prevention
2. Calculate the population that will need misoprostol for treatment
3. Calculate the population that will need misoprostol for PAC/unsafe abortion
4. Calculate the population that will need misoprostol for miscarriage
5. Calculate the amount of misoprostol needed for each case for prevention of PPH/establish standard or average treatment regimen
6. Calculate the amount of misoprostol needed for each case of treatment of PPH/establish standard or average treatment regimen

7. Calculate the amount of misoprostol needed for each case of PAC/unsafe abortion/establish standard or average treatment regimen
8. Calculate the amount of misoprostol needed for each case of miscarriage/establish standard or average treatment regimen
9. Calculate the total quantity of misoprostol needed for the forecast period

1. Calculate the target population that will need misoprostol for prevention

The target population for which misoprostol should be used depends on the national MNCH guidelines. According to WHO, misoprostol should be used in low resource settings where oxytocin or a skilled birth attendant is not available and for all home births for the prevention of PPH.

Obtaining data on the proportion of women giving birth at home is challenging. Estimates can be made using DHS data.

Many countries are working to promote facility births, which may mean that home births will decrease over time.

Once the numbers of births at home are calculated, it is necessary to estimate the proportions of home births with access to misoprostol administration for the prophylaxis of PPH. Assumptions may need to be made to scale up use of misoprostol phase by phase to ensure adequate training of service providers and acceptance by the public otherwise the forecast may result in overestimation and subsequent expiry and wastage of the product.

2. Calculate the target population that will need misoprostol for treatment

The population for which misoprostol should be used for the treatment of PPH depends on the national MNCH guidelines. In some cases, misoprostol may be recommended for prevention of PPH for home births, but the guidelines may indicate that if PPH develops, women are to be referred to facilities for treatment with oxytocin or other interventions like surgical repair of birth canal damage or removal of retained placenta. In other cases, misoprostol may be provided for both prevention and treatment in home births or in facilities where cold storage of oxytocin is not possible. Approximately 6% of women who received misoprostol for prevention of PPH may still go on to develop PPH. Based on national guidelines and this assumption (or local data if available), calculate:

- Number of women who may develop PPH who are likely to be given misoprostol for treatment of PPH

Not all the target population will actually be given misoprostol. The proportion likely to be treated with the product will depend on programmatic factors. For example, with misoprostol, many countries have recently introduced misoprostol for PPH and scale-up efforts are underway, including capacity building around administering it for home-based births. For forecasting and budgetary purposes, these programmatic issues will need to be taken into consideration.

3. Calculate the target population that will need misoprostol for post-abortion care or unsafe abortion

Again, the target population depends on the content of the national MNCH guidelines. In the absence of local data, proxy data may be used. The rate of unsafe abortions is 14 per 1,000 in women of reproductive age.[8] Therefore, 1.4% of pregnancies might require misoprostol for PAC.

5. Calculate the target population that will need misoprostol for miscarriages
   In the absence of local data, proxy data may be used. An estimated 10-15% of pregnancies result in miscarriages. Approximately 28% of these miscarriages might require misoprostol.

6. Determine the amount of misoprostol needed for PPH prevention/establish standard or average treatment regimen
   This also depends on the national MNCH guidelines. Misoprostol may be recommended for all home births, but may also be recommended for facilities where oxytocin is not available. The dosage depends on national MNCH guidelines. WHO recommends 600 µg (3 tablets of 200 µg) orally for the prevention of PPH.

7. Calculate the amount of misoprostol needed for each case for the treatment of PPH/establish standard or average treatment regimen
   WHO recommends 800 µg (4 tablets of 200 µg) of misoprostol sublingually for treatment of PPH, where oxytocin is not available.

8. Determine the amount of misoprostol needed for PAC or unsafe abortions/establish standard or average treatment regimen
   The dosage depends on national MNCH guidelines. WHO recommends 600 µg (3 tablets of 200 µg) orally.

9. Determine the amount of misoprostol needed for miscarriage management/establish standard or average treatment regimen
   The dosage depends on national MNCH guidelines. WHO recommends 600 µg (3 tablets of 200 µg) orally.

10. Calculate the total quantity of misoprostol tablets needed for all uses during the forecast period
    The forecast period needs to be determined. A two-year forecast that can be divided into two 12-month periods is recommended.

Additional Products, Consumables, or Equipment Required

The use of misoprostol does not require any other products, consumables, or equipment.

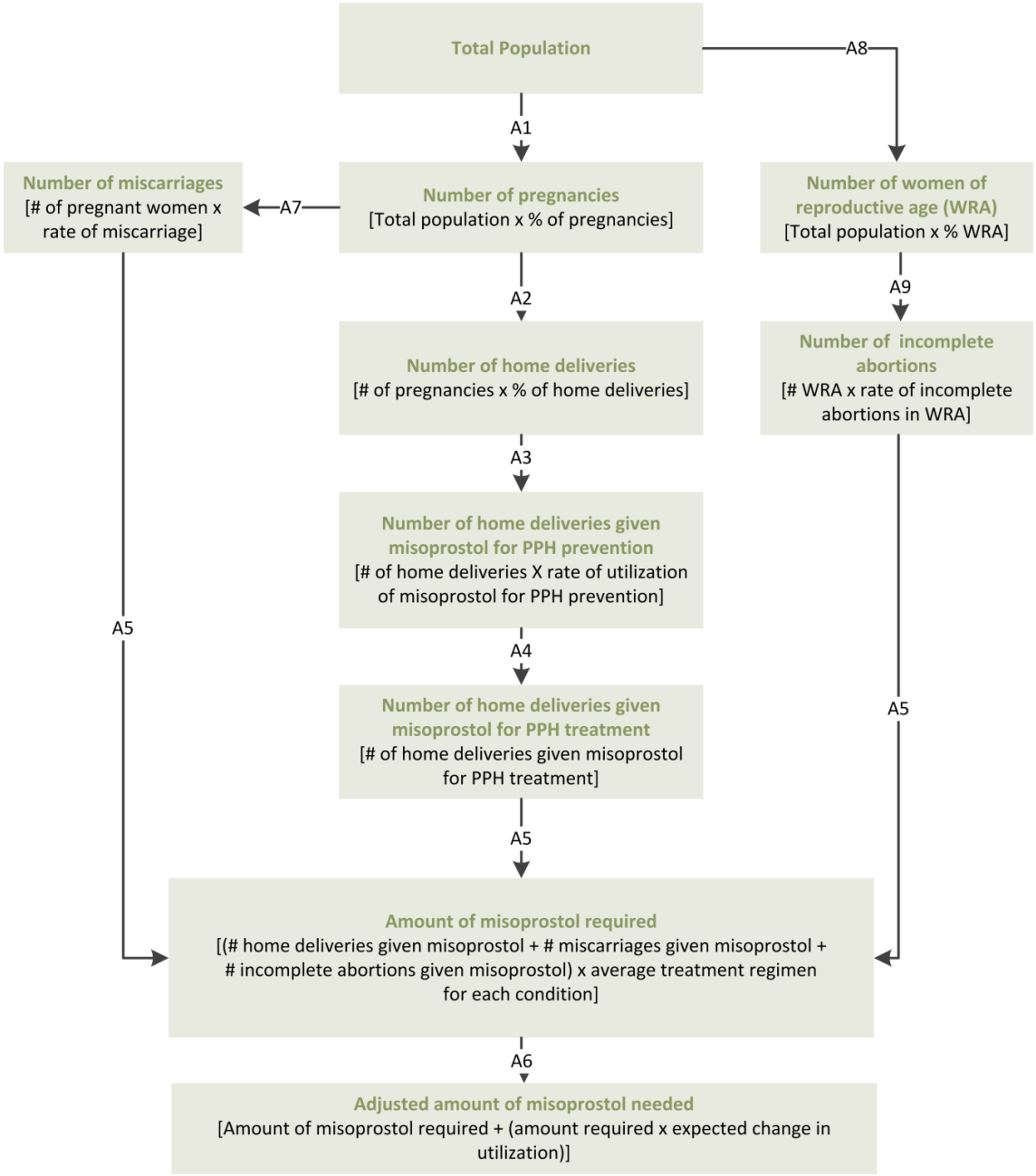
Product Availability

Misoprostol is manufactured by over 50 manufacturers globally, at least 35 of which are in developing countries.[9] There is currently one misoprostol product pre-qualified by the World Health Organization.[10]

Forecasting Algorithm for Misoprostol

Figure 5 is an example of the steps to follow when quantifying for misoprostol for the prevention and treatment of PPH including the data needed to reach each subsequent step.

Figure 5. Sample algorithm for forecasting consumption of misoprostol



Assumptions for figure 5

A1	Population likely to become pregnant, %
A2	Pregnant women likely to deliver at home, %
A3	Pregnant women likely to deliver at home that will be given misoprostol for PPH prevention, %
A4	Women who received misoprostol for prevention of PPH, who go on to develop PPH and require treatment, %
A5	Dosage of misoprostol (e.g., 3 x 200 microgram tablets)
A6	Rate of programmatic adjustments (anticipated increase or decrease in coverage), %
A7	Miscarriages, %
A8	Population that are women of reproductive age, %

Once the amount of misoprostol required for the program in the forecast period is calculated, this is entered into a supply planning matrix which takes into account current pipelines, losses; price and supplier lead times to determine the amount to be delivered for each specific time period. Please see *Quantification of Health Commodities* for guidance on the supply planning step.

Box 10. Example of Country Forecast for Misoprostol based on Demographic Data

Country *X* recommends the use of misoprostol as first line for all home births for the prevention of PPH at an average dose of 600 µg. Compliance to this recommendation is currently at 20% however, the target is to increase it by 20% yearly until 100% is reached. This target seemed reasonable to the quantification team given current efforts to intensify training of health workers.

Misoprostol is currently not recommended for the treatment of PPH in country X. Misoprostol is recommended for PAC and miscarriages. However, there are no data on these conditions.

Below is the data you have been given. Calculate the amount of misoprostol needed for the program in the next two years.

Data available

- Number of births per annum: 500,000
- Number of facility births per annum: 300,000
- Population growth rate: 5%
- Estimated % of pregnancies that end in miscarriage: 10%
- Estimated rate of unsafe abortion: 1.4%

From the data above, we can calculate:
Number of home births per annum = 200,000
Number of pregnancies = 550,000

	Input		Current year	Forecast year 1	Forecast year 2
No. of total pregnancies	Pop. Growth Rate	5%	550,000	577,500	606,375
No. of home deliveries	Pop. Growth Rate	5%	200,000	210,000	220,500
Uptake, %	% annual increase in uptake	20%	20	40	60
No. of pregnant women likely to be given misoprostol for prevention PPH			40,000	84,000	132,300
No. of misoprostol tablets required for PPH prevention	# of tablets per case	3	120,000	252,000	396,900
No. of unsafe abortions from total pregnancies	% rate of unsafe abortion	1.4%	7,700	8,085	8,489
No. of women requiring hospitlization for PAC	% of unsafe abortions requiring hospitalization for complications	23%	1,771	1,860	1,953

(box 10 continued on following page)

Box 10. Continued

	Input		Current year	Forecast year 1	Forecast year 2
No. of women likely to be given misoprostol for PAC	% of women hospitalized for PAC requiring misoprostol	92%	1,629	1,711	1,796
No. of pregnancies ending in miscarriage	Estimated rate of miscarriages from total pregnancies	10%	55,000	57,750	60,638
No. of women likely to be given misoprostol for miscarriage	% of miscarriages likely to need misoprostol	28%	15,400	16,170	16,979
No. of women likely given misoprostol for PAC and miscarriage	Sum of # of women given misoprostol for PAC and miscarriage		17,029	17,881	18,775
No. of misoprostol tablets required for PAC and miscarriages	Number of tablets per case	3	51,088	53,642	56,324
Total no. of misoprostol tablets required for all uses	Sum of misoprostol tablets needed for prevention + for PAC and miscarriage		171,088	305,642	453,224

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Oxytocin

Product Description, Indications, and Considerations for Use

Oxytocin has several obstetric uses: induction and augmentation of labor, and prevention and treatment of postpartum hemorrhage. For calculation, it is assumed that oxytocin is used only by skilled birth attendants in facility-based deliveries.[1]

Oxytocin is an uterotonic used for the *prevention* and *treatment* of postpartum hemorrhage (PPH). It is the first line medicine for all facility-based births.[2] If prostaglandins are not available, intravenous oxytocin is also recommended for the induction/augmentation of labor.[3]

According to WHO, "All women giving birth should be offered uterotonics during the third stage of labor for the prevention of PPH; oxytocin (IM/IV, 10 IU) is recommended as the uterotonic drug of choice." [4]

Oxytocin is currently registered in most countries,[5]and is included in national protocols for maternal health service provision or standard treatment guidelines, as well as on the Essential Medicines List in the majority of countries.[6]

Forecasting Considerations

Oxytocin is temperature sensitive, and loses effectiveness after three months of being stocked at temperatures greater than 30°C or 90°F; therefore cold chain storage is recommended.[7]Some manufacturers may indicate that their oxytocin product can be stored at room temperature, but regardless, efforts should be made to ensure that oxytocin is maintained at 30°C (90°F) or below, which is difficult in some countries.

Currently, most countries are not collecting routine data necessary for forecasting, so data on the number of women who require oxytocin for treatment may not be available. Similarly, in many countries, oxytocin may also be used for induction or augmentation. The amount of oxytocin used for these purposes based on local data should also be added to the total need for oxytocin. In the absence of local data, the assumptions below can be used until accurate country-specific data are available.

All women expected to deliver in health facilities will need oxytocin for PPH prevention. According to scientific literature, 2.85% of hospital deliveries who received oxytocin to prevent PPH will develop PPH and will require oxytocin for treatment. Also, 6% of home deliveries who receive misoprostol for PPH prevention will end up with PPH and need oxytocin.[8]

While the forecasting guidance provided here is specifically to calculate the need for oxytocin for management of PPH, oxytocin is also used for other purposes. For example, on average, an estimated 9.6% of pregnancies per year are induced and may l require 10 IU of oxytocin. [9] In addition, up to 20% of pregnancies may require 10 IU of oxytocin for augmentation. Countries should take into account these other uses of oxytocin when preparing the forecast. The same logic used in forecasting the need of oxytocin for management of PPH will apply for these other uses.

Box 11. Summary of Data Needed for Forecasting Consumption of Oxytocin

- Total population
- Number of pregnant women (Population growth rate)
- Percentage of births that occur in health facilities
  - Number of pregnant women likely to be given oxytocin for the prevention of PPH
- Incidence of PPH after active management of the third stage of labor with oxytocin as prevention
  - Number of pregnant women that develop PPH that will be given oxytocin for the treatment of PPH
- Standard or average treatment regimen (i.e., the amount of oxytocin needed for each case for prevention, and treatment)
- Programmatic issues that may affect consumption (e.g., efforts to scale-up in use)

Table 9 describes potential sources of the data required for forecasting.

Table 9. Potential Sources of Data for Forecasting Consumption of Oxytocin using Morbidity Method

Data	Sources	Limitations
Forecasting		
Total population	Census data, DHS	--
Proportion of pregnant women	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually an underestimate
Proportion of pregnant women giving birth at health facilities who will be given oxytocin for the prevention of PPH	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	Not all pregnant women will be given oxytocin. Estimate compliance with the STGs.
Proportion of pregnant women giving birth at health facilities developing PPH	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	Not all pregnant women will be given oxytocin. Estimate compliance with the STGs
Proportion of pregnant women giving birth at home developing PPH	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	Not all pregnant women will be given oxytocin. Estimate compliance with the STGs.
Proportion of pregnant women giving birth at home and receiving misoprostol developing PPH	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	Not all pregnant women will be given oxytocin. Estimate compliance with the STGs.
Percentage of pregnancies in a year that are induced or augmented and will require oxytocin	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	Not all pregnant women will be given oxytocin. Estimate compliance with the STGs.
Dosage recommended	WHO or national MNCH guidelines	Providers may not always follow dosage recommended
STGs (actual prescribing practice versus ideal)	National essential medicine program, WHO, Ministry of Health, NMCP, surveys	Guidelines may propose different medicines for the same condition; parenteral treatment duration varies between patients depending on clinical evolution; STGs not always used by health providers
Programmatic changes	MNCH	Projected changes in consumption due to provider training or other efforts to increase use.

The forecasting formula involves adding the number of pregnant women likely to be given oxytocin X average quantity of oxytocin required for each case for prevention and the nmber of pregnant women likely to develop PPH and be given oxytocin X average quantity of oxytocin required for each episode for treatment (*in some cases, women who have received oxytocin to prevent PPH will still develop PPH, so may be administered twice*)

Forecasting Method using Morbidity Data

1. Estimate population that will need oxytocin for prevention
2. Estimate the target population that will need oxytocin for treatment
3. Calculate the amount of oxytocin needed for each case for prevention of PPH/establish standard or average prevention regimen
4. Calculate the amount of oxytocin needed for each case for the treatment of PPH/establish standard or average treatment regimen
5. Calculate the quantity of oxytocin needed for prevention and treatment for the forecast period

1. Estimate the target population who will need oxytocin for prevention

The target population for whom oxytocin should be used depends on the national MNCH guidelines. According to WHO, all women giving birth should be offered uterotonics, with oxytocin as the recommended first line for the prevention of PPH.[10] Oxytocin is needed at every level of the health care system where deliveries occur, from urban hospitals to rural maternity clinics.[11] The data on the population who will receive oxytocin can be obtained from facility records of women giving birth, or calculated from existing demographic data starting with the number of pregnant women. We suggest starting with the number of pregnant women as regardless of the outcome of the birth (live or stillbirth) women will receive oxytocin for prevention of PPH.

Several assumptions will then need to be applied as the calculations are continued. For example, if the forecast is meant to cover public sector facilities only, the percentage of births that occur in public sector facilities must be calculated by multiplying the number of births that occur in health facilities by the percentage of births that occur in public sector facilities. If this percentage cannot be found in health services data, data from DHS on care-seeking in public and private facilities can be used as a proxy.

Also, as mentioned previously, both oxytocin and misoprostol may be recommended for use for PPH. It may be the case that with introduction of misoprostol, the need for oxytocin at some levels of the system will decrease. These types of programmatic issues need to be considered in the forecast.

2. Estimate the target population that will need oxytocin for treatment

Oxytocin is also recommended for all deliveries that progress to PPH. This includes all women delivering at facilities that may have been given oxytocin for prevention, but still go on to develop PPH, women who have not received oxytocin for prevention of PPH, as well as women that deliver at home (and may have received misoprostol for prevention) and then present at health facilities for the treatment of PPH.

To obtain this number, calculate:

- Number of women who did not receive oxytocin but develop PPH and will be treated with oxytocin
- Number of women who received oxytocin and go on to develop PPH and require additional treatment with oxytocin

- Number of women who received misoprostol for home births and who go on develop PPH and will be treated with oxytocin
- Number of women who did not receive misoprostol for home births and who develop PPH and are likely to be treated with oxytocin

This information is not routinely collected in many health management information systems. When these data are unavailable, the number of PPH cases will need to be estimated based on available information (e.g., special studies, services data from a sample of facilities). Assumptions will then need to be applied; some of these are described below.

3. Calculate the amount of oxytocin needed for each case for prevention of PPH and establish standard or average prevention regimen

   This step depends on how each country addresses this issue in the national MNCH guidelines. Both oxytocin and misoprostol may be recommended for prevention of PPH at different levels within the health system. The national guidelines should be consulted to determine how to address this in the forecast.

   The recommended dosage for prevention is 10 IU of PPH intravenously (IV) or intramuscularly (IM). Therefore, 1 vial of 10 IU is needed to **prevent** each case of PPH, which is caused by uterine atony.

4. Calculate the amount of oxytocin needed for each case for the treatment of PPH and establish standard or average treatment regimen

   Just as with the previous step, calculation of the amount of oxytocin needed for each case of treatment of PPH depends on the content of the national MNCH guidelines. Average actual regimens versus ideal regimens should be considered in the calculation.

   The recommended dosage for treatment is 20 IU infusion or IM followed by 20 IU/l IV, with a maximum of 3 liters of IV fluids. Therefore, up to 7 vials IU may be needed to **treat** each case of PPH. In our calculations, we are using an average of 4 vials per case.

5. Calculate the quantity of oxytocin needed for prevention and treatment for the forecast period

   For this step, the forecast period must be defined. A two-year forecast that can be divided into two 12-month periods is recommended. If the forecast is meant to cover one year, then the amount of oxytocin required for prevention and treatment for one year should be estimated based on the previous steps. Therefore, the number of cases which will be given oxytocin for the prevention of PPH in a year should be multiplied by the amount needed per case. This should then be added to the number of cases which will be given oxytocin for the treatment of PPH in a year, multiplied by the amount needed per case.

Additional Products, Consumables, or Equipment Required

Oxytocin for prevention of PPH is given IM, while for treatment of PPH it is administered IV, therefore injection supplies are required including:

- IV infusion set
- Syringe
- Alcohol swabs

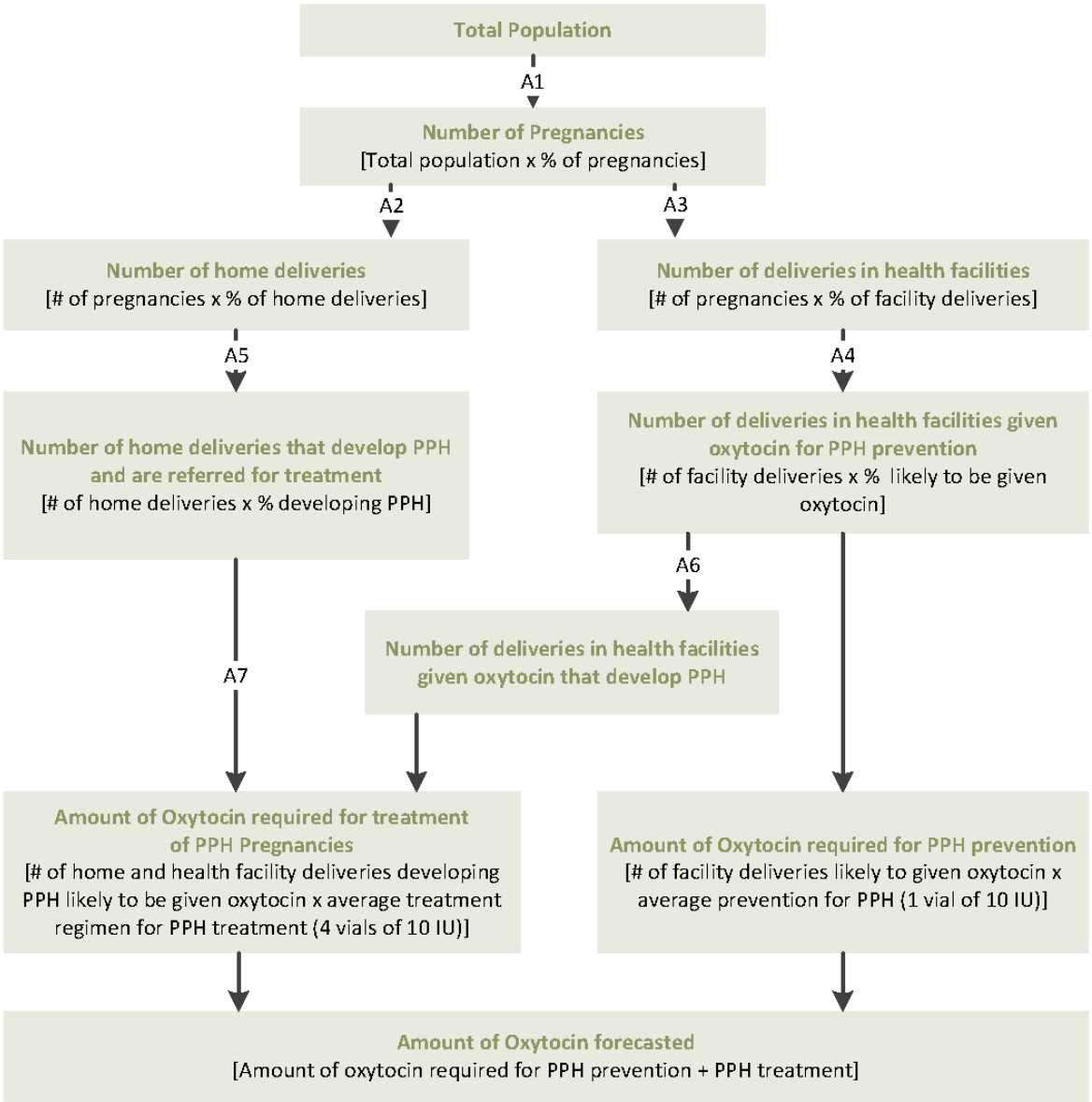
Product Availability

Oxytocin is produced by over 100 manufacturers around the globe.[12,13]

Forecasting Algorithm for Oxytocin

Figure 6 illustrates and example of the steps to follow when quantifying for oxytocin to prevent or treat PPH.

Figure 6. Sample algorithm for forecasting consumption of oxytocin



Assumptions for figure 6

A1	Percentage of population likely to become pregnant
A2	Percentage of pregnant women likely to deliver at home
A3	Percentage of pregnant women likely to deliver at health facilities
A4	Percentage of pregnant women delivering at health facilities likely to develop PPH and be given oxytocin
A5	Percentage of pregnant women delivering at home (with or without misoprostol) likely to develop PPH and be referred to a facility
A6	Percentage of women who received oxytocin for prevention and developed PPH
A7	Average treatment regimen for PPH treatment (e.g, 4 vials of 10 IU)

Once the adjusted amount of oxytocin is calculated, this is entered into a supply planning matrix which takes into account current pipelines, losses, price, and supplier lead times to determine the amount to be procured and delivered for each specific time period. Please see *Quantification of Health Commodities* for guidance on the supply planning step.

Box 12. Example of Country Forecast for Oxytocin based on Demographic Data

Country X recommends the use of oxytocin as first line for all facility births for the prevention of PPH at an average dose of 10 IU. The MNCH program estimates that compliance to this recommendation is 80%.

Of all facility births not receiving oxytocin, 20% develop PPH, but only 3% who are given oxytocin develop PPH.

Oxytocin is also recommended for the treatment of PPH at an average dose of 40 IU. About 30% of all pregnant women give birth at home and, on average, 20% develop PPH. Of these, about 90% are referred to health facilities and are given oxytocin for treatment.

Below are the data you have been given. Calculate the amount of oxytocin required by the program for the two-year forecast period.

Available data
Number of facility births per annum (from current year): 300,000
Percent increase in birth rate per year: 2%
From the data above, we can calculate:

	Input		Current year	Forecast year 1	Forecast year 2
No. of facility births	Pop. Growth rate	2%	300,000	306,000	312,120
No. of facility births given oxytocin for prevention	% compliance	80%	240,000	244,800	249,696
No. of facility births that did not receive oxytocin for prevention	% of facility births that did not receive oxytocin (not compliant)	20%	60,000	61,200	62,424
No. of facility births that did not receive oxytocin for prevention that develop PPH and require treatment	% of facility births that did not receive oxytocin and develop PPH	20%	12,000	12,240	12,484.80

(box 12 is continued on following page)

Box 12. Continued

	Input		Current year	Forecast year 1	Forecast year 2
No. of facility births that received oxytocin for prevention, but developed PPH and required treatment	% of facility births that received oxytocin and still developed PPH	3%	7,200	7,344	7,490.88
No. of home births	Pop. Growth rate	2%	128,571	131,142.42	133,765
No. of home births developing PPH	% of home births developing PPH	20%	25,714	26,228	26,753
No. of home births referred and treated for PPH	% of home births referred to facility for PPH treatment	90%	23,143	23,606	24,078
No. of patients requiring oxytocin for prevention	# of patients at health facility given oxytocin for prevention		240,000	244,800	249,696
No. of patients requiring oxytocin for treatment	total sum of facility births that require oxytocin for treatment		42,343	43,190	44,053
Total amount of oxytocin needed (vials) for prevention	# of vials needed per case for prevention (10IU)	1	240,000	244,800	249,696
Total amount of oxytocin needed (vials) for treatment	# of vials needed per case for treatment (40IU)	4	169,371	172,759	176,214
Total amount of oxytocin needed (vials)	total sum of vials needed (treatment + prevention)		409,371	417,559	425,910

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Section 2.3. Forecasting Algorithms for Newborn Health Products

Antenatal Corticosteroids

Product Description, Indications, and Considerations for Use

The administration of certain corticosteroid injections to women at risk of preterm birth causes a considerable reduction in the risk of complications of prematurity such as respiratory distress syndrome, intra-ventricular hemorrhage, and perinatal death.[1] The potential lives saved indicate a reduction in neonatal mortality by 31% and moderate to severe respiratory distress syndrome by 45%.[2] Research has shown that ACS show greatest effect when used between 31 weeks and 36 weeks gestation; and may be effective as early as 28 weeks.[2]

Betamethasone and dexamethasone are fluorinated glucocorticoid steroids that are administered as intramuscular injections to prevent these complications; the greatest effect is seen when there is a 24–48 hour time span between the first dose and birth. When birth takes place more than 7 days after treatment, there is no sign of benefit from the intervention.[3] The most challenging aspect of administering ACS is identifying pregnant women who are at risk for preterm birth 48 hours prior; timing and appropriate diagnosis are crucial for women who present bleeding, contractions, loss of fluid, or symptoms of pre-eclampsia/eclampsia.[4]

Both medicines have a long history of use, strong efficacy, and are safe to administer. Both medicines are on the WHO List of Priority Medicines for Mothers and Children. Dexamethasone is currently the preferred antenatal corticosteroid as it is as effective and significantly cheaper and more widely available than betamethasone. It is also on the WHO Essential Medicines List for multiple indications, including fetal maturation.[5,6] This depends on the regimen recommended in the national MNCH guidelines. Current global recommendations suggest 24 mg of dexamethasone administered in a 24-hour period, with either 6mg administered every 4 hours or 12mg every 12 hours.[7]

Looking at levels of care, ACS should be focused on national referral and district hospitals first. Expansion of use of ACS is not recommended beyond regional or district hospitals. The medicines should be administered by a trained health worker/skilled birth attendant, and are not recommended for home-based births.[8] Furthermore, recent studies of implementation of ACS in low- and middle-income countries[9] indicate that ACS should be used in settings that meet the following four conditions:

- Providers are able to accurately assess gestational age and determine risk of imminent preterm birth
- Adequate post-delivery care for preterm newborns is available, including thermal protection, adequate feeding support, prevention and management of infection, facilities for Kangaroo Mother Care, and resuscitation equipment
- Reliable, timely and appropriate identification and treatment of maternal infection
- Patient safety and compliance are monitored, including monitoring of mothers and newborns post discharge for complications and adverse events.[10]

Forecasting Considerations

Dexamethasone is typically available in 1 or 2-ml ampoules of 4mg/ml dexamethasone phosphate. Some producers label dexamethasone for 20°C–25°C storage while others allow a wider temperature storage range of 15°C–30°C. Labelling for dexamethasone sodium phosphate for injection typically also includes “protect from light” and statements on “protect from freezing” and “sensitive to heat.”[11] The recommended storage conditions have

implications for storage and distribution which should also be taken into account by the quantification team during forecasting.

Health workers in many settings face the challenge of estimating gestational age, which is an important factor for determining whether a woman is at risk of preterm delivery and hence the administration of dexamethasone. National treatment guidelines or services delivery protocols should indicate how estimation of gestational age should be handled in the local context at different levels of service delivery according to the level of provider available at each level.

The target population for dexamethasone is any woman who is considered preterm and has one of the four conditions (preterm labor, preterm pre-labor rupture of membranes, antepartum hemorrhage, severe preeclampsia) that increase her risk of preterm delivery. Service statistics in many settings do not include information on the number of women who have delivered at facilities and have presented with these conditions. An estimated 10% of births globally are preterm; however, this varies by country. For example, in Malawi the preterm birth rate is about 18%.[12]

Similarly, current coverage of dexamethasone for preterm birth varies widely with 90% coverage of indicated cases in high-income countries, compared with an estimated 10% coverage in middle/low income, high burden countries.[13] In the absence of any data, a global average can be used or proxy data from a neighboring country. The quantification team will need to decide on the best estimate to use.

Some countries may have both betamethasone and dexamethasone on their treatment guidelines and EML. In that case, program managers will need to decide whether both will continue to be made available or not. If both medicines continue to be made available, then the proportion that will be treated with betamethasone and the proportion that will be treated with dexamethasone will need to be calculated. The proportion likely to be treated with each product will depend on programmatic factors.

Finally, dexamethasone may be used for several indications. The quantification team should take into account the other indications listed in national standard treatment guidelines and on the national essential medicines lists during the forecasting exercise.

Box 13. Summary of Data Needed for Forecasting for ACS

- Target population
  - Number of facilities equipped to administer ACS
  - Number of women giving birth at facilities equipped to administer ACS
  - Number of pregnant women at risk of preterm birth
  - Proportion of women that will be given dexamethasone
- Standard or average treatment regimen (i.e., amount of dexamethasone needed for each case to prevent risks of preterm birth)
- Programmatic issues that may affect consumption (e.g., plans for scale-up, provider training)

Table 10 shows potential sources for the data needed for forecasting.

Table 10. Potential Sources of Data for Forecasting Consumption of Antenatal Corticosteroids using Morbidity Method

Data	Source	Limitations and Challenges
Forecasting		
Number of health facilities that meet conditions for use of dexamethasone	MoH	The information may not be readily available, and will need to be discussed with relevant program managers in MoH.
Number of pregnant women giving birth at facilities equipped to administer ACS	Service statistics	These data maybe not be readily available.
Proportion of pregnant women at risk for preterm birth	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually an underestimate
Dosage recommended	WHO or national MNCH guidelines	Providers may not always follow dosage recommended
STGs (actual prescribing practice versus ideal)	National essential medicine program, WHO, Ministry of Health, NMCP, surveys	Guidelines may propose both betamethasone and dexamethasone medicines for the same condition; parenteral treatment duration varies between patients depending on clinical evolution; STGs not always used by health providers
Programmatic issues	MNCH program	Scale up plans may not progress as quickly as anticipated

The forecasting formula involves multiplying the number of pregnant women at risk of preterm birth likely to be given dexamethasone by the average quantity of dexamethasone required for each case.

Forecasting Method based on Morbidity Data

1. Calculate the target population (pregnant women at risk of preterm birth giving birth in equipped facilities) who will need dexamethasone
2. Calculate the amount of dexamethasone needed for each case for the prevention of complications of preterm birth/establish standard or average treatment regimen
3. Calculate the quantity of dexamethasone needed for the forecast period

1. Calculate the target population who will need dexamethasone to prevent preterm birth complications

The target population for which ACS should be used depends on the national MNCH guidelines, and other documentation that indicates at which facilities ACS can be administered. Any woman giving birth in facilities equipped to administer ACS, who is considered preterm and has one of the four conditions that increase her risk of preterm delivery should be administered an ACS.

The data on the number of pregnant women at risk for preterm delivery that will receive an ACS may be obtained from hospital records, national maternal morbidity data and mortality surveys, or non-routine research studies. Where this information is not readily available, estimate target population using the following data:

- Number of pregnant woman with one of the four conditions (preterm labor, preterm pre-labor rupture of membranes, antepartum hemorrhage, severe preeclampsia) that increase her risk of preterm delivery
- Number of pregnant women referred to hospitals
- Number of facility-based births
- Number of births in facilities that meet conditions for use
- Number of pregnant women
- Total female population

Depending on the scope of the forecast, assumptions will need to be applied as the calculations are made. For example, if the forecast is meant to cover only public sector facilities, the total number of facility-based births will need to be multiplied by the percentage of births that occur in public sector facilities. Also, the level of facility and whether all facilities at that level are equipped to administer ACS, will need to be taken into account as current international guidance recommends use only at facilities that meet the four conditions described above.

2. Calculate the amount of dexamethasone needed for each case for the prevention of complications due to preterm birth (establish standard or average treatment regimen)
   This depends on the regimen recommended in the national MNCH guidelines. Current global recommendations suggest 24 mg of dexamethasone administered in a 24-hour period, with either 6mg administered every 4 hours or 12mg every 12 hours.[14]

3. Calculate the quantity of dispensing units of dexamethasone needed for prevention and treatment for the forecast period
   This is calculated by multiplying the number of cases that will be given dexamethasone with the average amount required per case, to derive the number of ampoules needed. Since the most common formulation of dexamethasone may be 4 mg/ml in 1 ml ampoule, health providers might need to open and draw from two 1-ml ampoules in order to reach the 6mg dose. This would require discarding half of the second 4mg ampoule as the ampoules cannot be resealed.[15] If the preferred regimen is 12mg every 12 hours, three ampoules would be fully used for each administration.

Additional Products, Consumables, or Equipment Required

The use of dexamethasone requires injection supplies, including:

- Syringes
- Needles
- Alcohol swabs
- Sharps disposal

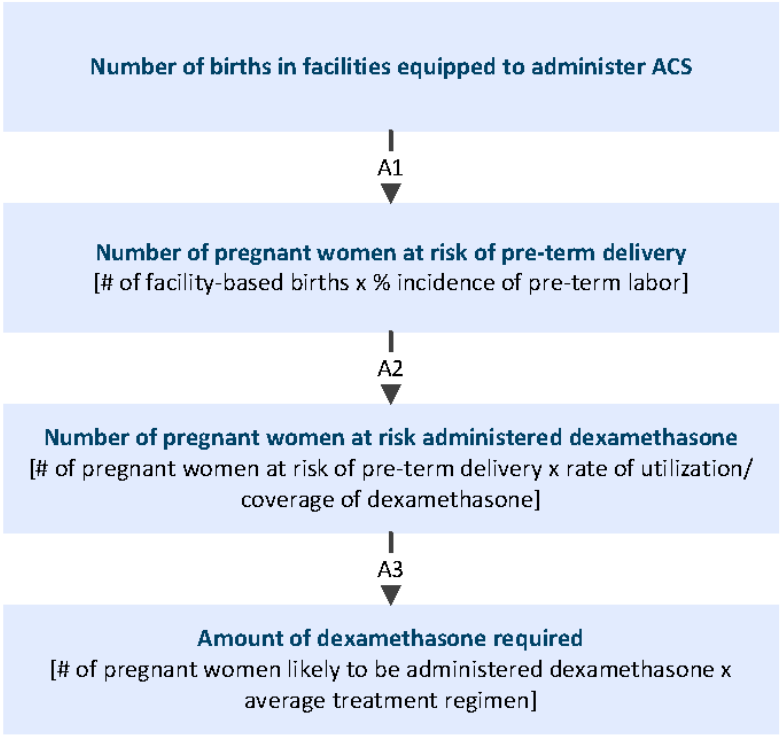
Product Availability

Dexamethasone sodium phosphate is available from many manufacturers globally and from suppliers including UNFPA and Mission Pharma.

Forecasting Algorithm for Antenatal Corticosteroids

Figure 7 illustrates an example of the steps to follow when forecasting needs for ACS for pregnant women at risk of preterm delivery including the data needed to reach each subsequent step.

Figure 7. Sample algorithm for forecasting consumption of antenatal corticosteroids



Assumptions for figure 7

A1	Incidence of preterm labor. In absence of country level data, proxy data from similar countries or global estimates, e.g., literature indicates that about 10% of all births are preterm (see assumptions).
A2	Percentage of pregnant women likely to be administered dexamethasone. Published literature suggests that only 10% of indicated cases of women in preterm labor in high burden and LMIC receive ACS (see assumptions).
A3	Average treatment regimen for dexamethasone

Once the amount of dexamethasone to be consumed is calculated, it is entered into a supply planning matrix which takes into account current stock on-hand or on order, losses; price and supplier lead times to determine the amount to be delivered for each specific time period. Please refer to *Quantification of Health Commodities* for guidance on the supply planning step.

Box 14. Example of country forecast for antenatal corticosteriods based on demographic data

Country *X*, which is located in Southern Africa and has a similar epidemiological profile to Malawi, recommends the use of dexamethasone for pregnant women at risk of preterm labor. Compliance to this recommendation is only about 10%; however, there are plans to scale up use down to the regional or district level, to 50% over 4 years through improved diagnosis of risk conditions, intensive training, supervision, and IEC and BCC campaigns.

Data available is as follows:

- ANC attendances: given below (ANC attendance in this example is a proxy for the # of facility based births down until the regional/district level facilities)
- Annual population growth % increase: 2%
- Recommended dosage: 4 intramuscular injections spaced 12 hours apart totaling 24 mg of active ingredient.
- Average number of ampoules administered per patient = 8 x 1 ml
- Dexamethasone is in boxes (packs) of 50 ampoules of 1 ml each

Assumptions:

- Each patient uses an average of 8 amps for a treatment episode
- Country X is similar to Malawi therefore we can use the incidence of preterm labor from Malawi which is 18% of all births
- Scale up estimated at 20% coverage of eligible births for forecast year 1; and 30% for forecast year 2

From the data above, we can calculate the quantity of dexamethasone required to meet program needs over the next 2 years.

	Inputs		Current year	Forecast year 1	Forecast year 2
Number of ANC attendances	Population growth rate	2%	180,000	183,600	187,272
Number of pregnant women at risk of preterm labor	Incidence of preterm labor	18%	32,400	33,048	33,709
Percentage of cases likely to be treated with dexamethasone	% compliance; plan to scale up to 50% in the next 4 years	10% increase per year	10%	20%	30%
Number of cases likely to be treated with dexamethasone			3,240	6,610	10,113
Amount of dexamethasone needed (ampoule)	# of ampoules needed per case	8	25,920	52,880	80,904

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Chlorhexidine

Product Description, Indications and Considerations for Use

Chlorhexidine digluconate 7.1% (also called chlorhexidine gluconate or just chlorhexidine) is an antiseptic used for newborn umbilical cord care and cleansing.

According to the 1998 WHO recommendations for care of the umbilical cord, clean and dry cord care practices are preferred. However, in settings where the risk of bacterial infection is high, use of an antiseptic such as chlorhexidine is acceptable.[1] As of July 2013, the WHO Model List of Essential Medicines for Children includes 7.1% chlorhexidine digluconate (delivering 4% chlorhexidine) for umbilical cord care.[2] In January 2014, the WHO published a new recommendation on umbilical cord care:

> "Daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) application to the umbilical cord stump during the first week of life is recommended for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1,000 live births). Clean, dry cord care is recommended for newborns born in health facilities and at home in low neonatal mortality settings. Use of chlorhexidine in these situations may be considered only to replace application of a harmful traditional substance, such as cow dung, to the cord stump." [3]

Chlorhexidine can be delivered through existing health services and initiatives such as antenatal and delivery care and postnatal care in the first days and week of life including essential newborn care. It can also be provided through health care providers working in public health facilities and communities (e.g., traditional birth attendants), and community health workers who have contact with pregnant women. In Nepal, chlorhexidine is delivered in facilities and through the government's existing cadre of Community Health Workers and Female Community Health Volunteers. Some other countries are opting to use chlorhexidine both at home births and facilities.

Chlorhexidine should be applied immediately after cutting the cord. If feasible, repeat application once daily through the first week of life or until the cord separates. It is most important that chlorhexidine be applied early; further benefits may be realized from multiple applications, including reduced localized infection. Ultimately, regular use of chlorhexidine may displace the use non-hygienic traditional applications.

Forecasting Considerations

The product has a long shelf-life in all climatic zones.[4] Chlorhexidine does not require cold chain and can therefore be stored at any level of the supply chain. The length of product shelf-life should be determined according to stability testing and in-country regulation. The application regimen (single application versus multiple applications) will be determined in countries based on what experts deem appropriate for the local context.[5]

There are two possible dosage forms of chlorhexidine—either an aqueous solution or a gel. Countries forecasting for two different formulations may make forecasting more complicated, but may be necessary if both formulations are used.

Chlorhexidine for umbilical cord care is often classified by national regulatory agencies as a medicine, increasing its regulatory hurdles. National regulatory pathways are yet to be —determined on a country-by-country basis. Therefore, the timeline for national level uptake should build in the time required to obtain national regulatory approval into account although WHO EML listing might facilitate country/regional level regulatory reviews.

Since chlorhexidine is a new product, the quantification team will need to develop and agree on assumptions about the factors and interventions that may affect future changes in demand for services and products, for example, population to be treated and scale-up goals.* Some of the considerations that will need to be defined include—

- Target population: All at home births versus all births (see national guidelines and determine actual clinical practice)
- Percentage of home births. For example, in Nepal, approximately 90% of births occur at home.
- Aqueous solution versus gel; single-day application versus multiple-day application. For example, which is more typically used during a single day application—3 g gel in a tube or 10 ml aqueous solution in a bottle, with some remaining volume. For multiple-day application, at least 20 g gel in tube or 30 ml aqueous solution in bottle could be considered.
- Product uptake: Percentage of deliveries that will actually use the product
- Scale-up plans: these will affect the target population to be treated. This assumption will also change over time. Phasing in a new product requires time and assumptions on the levels of coverage expected during the transition and implementation stage need to be made. The quantification team will need to agree upon assumptions about the expected levels of coverage that can be achieved as the product is introduced for this indication.

Box 15. Summary of Data Needed for Forecasting Consumption of Chlorhexidine

- Target population: Number of newborns delivered at home or all births (depending on MNCH guidelines) or target population likely to be treated with chlorhexidine
- Standard or average treatment regimen, i.e., chlorhexidine needed per treatment
- Programmatic issues that may affect consumption (e.g., scale-up in use)

Table 11 describes the potential sources to consult when looking for the data needed for forecasting.

* Scaling up of programs generally roll out much slower than expected and decisions on these factors must be made.

Table 11. Potential Sources of Data for Forecasting Consumption of Chlorhexidine using Morbidity Method

Data	Source	Limitations and Challenges
Forecasting		
Total female population	Census data, DHS	--
Proportion of pregnant women	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually an underestimate
Proportion of home deliveries	DHS, HMIS, National maternal morbidity and mortality surveys, special surveys, ANC records	Data usually underestimated
Percentage of women attending ANC	DHS, HMIS, special surveys, ANC records	Data usually underestimated
Percentage of births at home/facilities	DHS, HMIS, special surveys, ANC records	Data usually underestimated
Proportion of live births	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	Data usually underestimated
Dosage recommended	WHO or national MNCH guidelines	Providers may not always follow dosage recommended
STGs (actual prescribing practice versus ideal)	National essential medicine program, WHO, Ministry of Health, NMCP, surveys	STGs not always used by health providers
Interventions/factors affecting future changes in demand, e.g., scale up plans	MNCH	Scale up may take longer than planned

The forecasting formula involves multiplying the quantity of chlorhexidine for each case by the total projected number of cases.

Forecasting Method using Morbidity Data

1. Calculate the target population who will need chlorhexidine
2. Calculate the percent of births likely to receive chlorhexidine (e.g. pregnant women who seek care and receive chlorhexidine for home birth)
3. Calculate the amount of chlorhexidine needed per treatment/establish standard or average treatment regimen
4. Calculate the quantity of chlorhexidine needed for the forecast period

1. Calculate the target population that will need chlorhexidine

The target population for which chlorhexidine should be used depends on the national MNCH guidelines. This could be newborns delivered at home in settings with mortality greater than that of 30 neonatal deaths per 1,000 live births or all births, particularly those occurring at home or in lower level facilities.

To obtain the number of newborns delivered at home or at health facilities, find:

- Number of live births at home (preferred figure if data is available) or number of live births at facilities (depending on MNCH guidelines)
- Number of live births in country
- Number of pregnant women

- Total female population

Obtaining data on the number of home births may be the most challenging step in this process. This may be indirectly obtained through estimating the number of women attending antenatal care (ANC), adjusting for completeness of reported data and subtracting those women giving birth at a facility.

If there are programmatic efforts to increase the proportion of women given birth in facilities rather than at home, the quantification team should consider how these efforts might affect the proportion of deliveries occurring at home in future years.

2. Calculate the percent of births likely to receive chlorhexidine

Of those newborns needing chlorhexidine, what proportion will actually receive it? Estimates of care-seeking behavior, for instance the proportion of pregnant women that attend ANC, can be used to estimate the proportion of women who actually seek care and receive chlorhexidine for home birth, depending on the delivery mechanism of chlorhexidine adopted in countries.

Since chlorhexidine is currently being introduced in many settings, it is important to consider the expected scale-up rate. In most cases, introduction will proceed in phases. The quantification team will need to factor in scale-up plans during the forecasting exercise.

3. Calculate the amount of chlorhexidine needed per case

This depends on the national MNCH guidelines. The guidelines should include information regarding the recommended duration of treatment (e.g., one day or seven days) and formulation to be used (i.e., gel or aqueous solution). A 3 g tube of 7.1% chlorhexidine digluconate gel or a 10 ml bottle of aqueous chlorhexidine is sufficient for a single application. Larger volumes of gel and aqueous solution should be considered for multiple-day application.

4. Calculate the quantity of chlorhexidine needed

This is calculated by estimating the number of cases which will be treated with chlorhexidine.

# of newborns to be treated X # of tubes/bottles needed per case

Additional Products, Consumables, or Equipment Required

The use of chlorhexidine does not require any other products, consumables, or equipment.

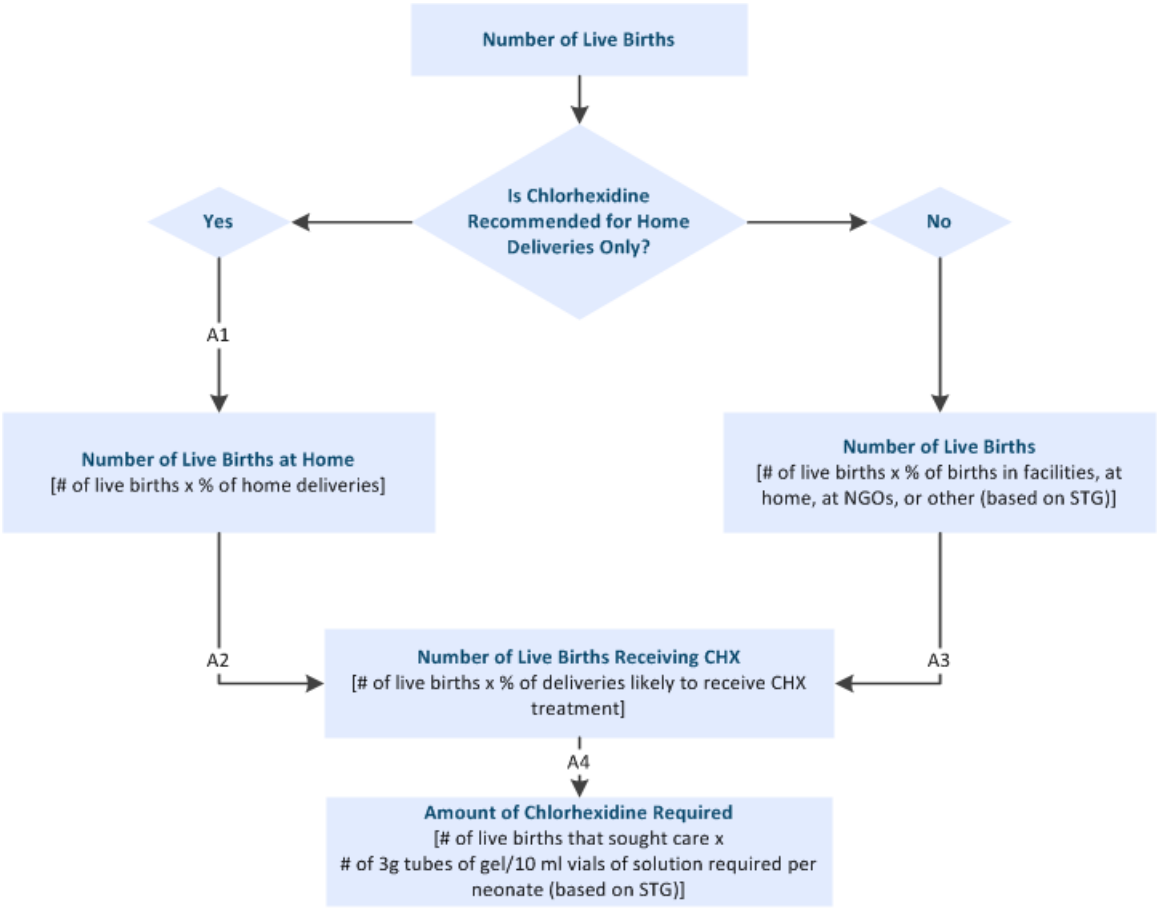
Product Availability

At present, there is limited availability of 7.1% chlorhexidine digluconate in the market. Some manufacturers are making chlorhexidine-based products (branded and generic) in concentrations ranging from less than 1% to 20%, but not the recommended 7.1%. The appropriate concentration of aqueous solution is available through the United Nations Children's Fund (UNICEF) Supply Division. Also, the appropriate concentration of gel is available from Lomus Pharmaceuticals, Pvt. Ltd. (Kathmandu, Nepal).[6,7] Further, local production of 7.1% chlorhexidine is being established in select countries in sub-Saharan African and South Asia, which could provide additional sources of product supply in the future.

Forecasting Algorithm for Chlorhexidine

Figure 8 illustrates the steps to follow when forecasting for chlorhexidine including the data needed to reach each subsequent step.

Figure 8. Sample algorithm for forecasting need for 7.1% chlorhexidine digluconate



Assumptions for figure 8

A1	Live births at home, %
A2	Percent likely to seek care/receive chlorhexidine
A3	Percent likely to seek care/receive chlorhexidine
A4	Average treatment regimen

Once the adjusted amount of chlorhexidine is calculated, this is entered into a supply planning matrix which takes into account current pipelines, losses, price, and supplier lead times to determine the amount to be procured and delivered for each specific time period. Please see *Quantification of Health Commodities* for guidance on the supply planning step.

Box 16. Example of country forecast for chlorhexidine 7% based on demographic data

Country *X* just updated its MNCH guidelines to include 7.1% chlorhexidine digluconate gel for all home births to be used as a single application immediately following birth. Chlorhexidine will be provided to community health workers for distribution to all women who give birth at home.

- The number of home births in the current year was estimated at 10,000
- Population growth rate: 2%
- Total amount of chlorhexidine required per neonate is 1 tube

Since the MNCH guidelines were only recently updated, Country *X* has set targets to increase use of chlorhexidine by 25% each year to achieve 100% coverage within four years. Calculate the chlorhexidine need for the next 2 years. The quantification team agreed that this is a reasonable target given current progress on training of health providers.

	Inputs		Current year	Forecast year 1	Forecast year 2
Home births, *n*	Population growth rate	2%	10,200	10,404	10,612
Utilization rate, %	Targets to increase in utilization rate	25% increase every year	25%	50%	75%
Neonates receiving treatment with chlorhexidine, *n*	% of neonates that will receive chlorhexidine	25% increase every year	2,550	5,202	7,959
Forecasted amount of chlorhexidine required (tubes)	Total amount of chlorhexidine required per neonate	1	2,550	5,202	7,959

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Antibiotics for possible severe bacterial infection in newborns

Product Description, Indications, and Considerations for Use

WHO guidelines currently recommend managing newborns and young infants under two months of age with suspected bacterial sepsis with 7–10 days of parenteral antibiotics: ampicillin (or penicillin) and gentamicin as first-line treatment,[1] and ceftriaxone as second-line therapy.[2] Integrated management of neonatal and childhood illness recommends that frontline health workers at health centers identify possible severe bacterial infection (PSBI), provide the first dose of parenteral antibiotics, and refer to hospitals for assessment and management. The WHO-recommended antibiotics are listed on its *Essential Medicines List for Children*.[3]

In settings where laboratory studies are available, clinicians can rule out newborn sepsis within 48-–72 hours and stop antibiotic therapy if appropriate. However, in settings where clinicians do not have access to laboratory investigations, they must empirically provide a full course of 7–10 days of parenteral antibiotics to all cases of PSBI to ensure optimal life-saving treatment. While WHO recommends that first-level facilities provide the first dose of injectable antibiotic and then refer to hospital; in many settings, referral to hospital is not possible for the majority of cases or families refuse hospital referral. In these situations, WHO recommends that a health worker trained on how to administer the antibiotics treat the patient with injectable ampicillin, or a comparable penicillin such as procaine benzylpenicillin (PBP) (recommended by WHO only in situations with trained health workers where hospital care is not possible), and gentamicin for at least 5 days.[4]

These current recommendations for newborns for whom referral is not possible are expected to be revised in 2015, based on expert review of new evidence from three large trials in Africa [5]and Asia of simplified antibiotic regimens.[6] It is expected that the new guidelines will recommend simplified antibiotic regimen(s) that include fewer injections of gentamicin combined with oral amoxicillin, which would be feasible for first-level facility health care workers to administer and would likely be more acceptable to families than the current WHO-recommended regimen. The three simplified regimens studied in the trials are as follows:

- Regimen A—gentamicin injection once daily and oral amoxicillin three times daily for 7 days (7 injections total; 7 gentamicin injections)
- Regimen B—gentamicin and PBP injections once daily for 2 days, followed by 5 days of oral amoxicillin (4 injections total, 2 gentamicin injections)
- Regimen C—gentamicin injection once daily and oral amoxicillin three times a day for 2 days, followed by 5 days of oral amoxicillin (2 injections total, 2 gentamicin injections)

Based on this evidence, high dose amoxicillin (80-100mg/kg/day divided BID) will likely be included in recommended treatment options when hospitalization is not possible. Some ‘early adopter’ countries have developed and are implementing outpatient oral antibiotics for newborn PSBI. The WHO guidelines will likely provide two regimen options when referral to hospital is not possible: regimen A (above): 7 days of gentamicin + amoxicillin OR Regimen C (above): 2 days of gentamicin + amoxicillin, followed by 5 days of amoxicillin. It is likely that most countries will choose the latter for feasibility and acceptability considerations.

Until the updated guidelines are made available, most countries will be following the current WHO recommendations. As such, the forecasting considerations and sample algorithm in Figure 9 below are only based on the current recommended therapies and will be revised as

soon as the updated guidelines are published with detailed guidance on dosage for different newborn weight bands.

Forecasting Considerations

- Cold chain is not required for any injectable antibiotics, since they are stored as a dry powder. However, once reconstituted, PBP and ceftriaxone must be refrigerated and used within a very short time.* Also, PBP and ceftriaxone powders must be reconstituted with sterile water.

- Gentamicin is frequently available in 20 mg/2 ml and 80 mg/2 ml presentations. The pediatric presentation of gentamicin (20 mg/2 ml) is preferable as the accuracy of dosing improves using the pediatric presentation

- Penicillin (benzylpenicillin, ampicillin, or PBP) and gentamicin are used as first-line therapy in newborns at risk of bacterial infection. Ceftriaxone is delivered alone as a second-line therapy.[7]

- At first-level health facility, at least five days treatment should be given with injectable gentamicin and injectable penicillin. Procaine benzyl penicillin is preferred as it is a once a day dosing. At referral level facilities, the injectables are continued for 7-10 days.[8]

Box 17. Summary of Data Needed for Forecasting for Injectable Antibiotics

- Total population
- Number of births
- Number of newborns
  - Expected number of PSBI cases requiring treatment with an injectable antibiotic
  - Proportion of cases accepting hospitalization and the proportion treated at first level facilities.
- Treatment regimen as per national guidelines based on current WHO recommendations:
  - Hospital-based regimen: 7-10 days of ampicillin or benzylpencillin intravenously and gentamicin intravenously with ceftriaxone intravenously as second line treatment
  - First-level facility based regimen: procaine benzyl penicillin intramuscularly (preferred as it is once daily) and gentamicin injection intramuscularly once daily for at least 5 days
- Standard or average treatment regimen, i.e., amount of procaine benzylpenicillin or ampicillin or benzylpenicillin, gentamicin, and ceftriaxone needed for each case of PSBI as per the dosage in guidelines
- Expected projected changes in consumption (potential losses or scale-up in use)

The forecasting formula involves:

Number of newborns with PSBI multiplied by the average quantity of injectable antibiotic required for each case.

* The manufacturers state up to 10 days if stored in a refrigerator http://www.gene.com/download/pdf/rocephin_prescribing.pdf

Forecasting Method using Morbidity Data

1. Calculate the target population that will need antibiotics for treating PSBI
2. Calculate the amount of antibiotic needed for each case/establish standard or average treatment regimen
3. Calculate the quantity of antibiotic needed for PSBI for the forecast period
4. Adjust for programmatic changes

1. Calculate the target population that will need antibiotic for PSBI

The target population for which antibiotics should be used is newborns and infants at risk of bacterial infection. The treatment of neonatal sepsis should be at all levels of the health system[9] according to WHO and country recommendations, but preferably at the referral level by a trained health worker.

The data on the incidence of PSBI (number of newborns that should receive an injectable antibiotic) can be obtained from national morbidity and mortality surveys or can be estimated at 10% (range of 7-14% in study settings) of all newborns according to surveillance data from the Simplified Antibiotic Therapy Trial (SATT) in Bangladesh or SATT Pakistan and African Neonatal Sepsis Trial (AFRINEST) (as yet unpublished).[10]

The data on the proportion of newborns who are hospitalized or whose caregivers refuse hospitalization and are treated at facility level should be available through country data or estimates. In the absence of such data, rates from the literature could be used although this will vary from country to country and setting to setting. In Pakistan, for example, 50% of families in urban sites and 70–90% of families in semi-rural sites refused hospital care for sick newborns, [11] averaging 70% refusing hospital referral.[12]

2. Calculate the amount of antibiotic needed for each case of PSBI according to the standard or average treatment regimen

This depends on the national MNCH guidelines. The current WHO recommendations for hospital level treatment are 7–10 days of injectable ampicillin or benzylpencillin and gentamicin. First-level facility recommendations are first dose of injectable antibiotic before referral to the hospital, but where referral is not possible, 5 days of treatment with an injectable penicillin and injectable gentamicin should be provided at first level facilities. These recommendations will be reviewed and likely revised by WHO in 2015 as a result of the new evidence and these forecasting algorithms will then be updated accordingly.

Standard treatments can be developed as average actual treatments or ideal treatment. Average regimens are based on observed or reported practices and are more likely to predict what will actually happen whereas ideal regimens describe what should happen if prescribers follow the ideal guidelines. If one treatment regimen is viewed as ideal but another is commonly used, include both regimens in the guidelines for quantification. A combination approach should be used as inaccuracies may unfold, should the forecast not reflect reality.

Table 12. Formulation, Presentation, and Dosage of Antibiotics

Antibiotic	Formulation	Dose
Ampicillin	powder for injections 250 mg vial	IV 50 mg/kg every 12 hours for first week of life, every 8 hours in 2-4 weeks of life[1]
Benzylpencillin	powder for injections 600 mg (or 1,000,000 IU)	IV 50,000 U/kg every 12 hours for first week of life, every 6 hours in 2-4 weeks of life and older[1]
PBP	powder for injection: 1 g (= 1 mill IU) 3 g (= 3 mill IU) in vial	IM 50,000 U/kg once a day [2]
Gentamicin	liquid injection: 10 mg/ml in 2 ml ampoule; 40 mg (as sulfate)/ml in 2 ml ampoule	IM or IV first week of life low birth weight 3 mg/kg per day or normal birth weight 5 mg/kg/day Second to fourth weeks of life, 7.5 mg/kg for at least 7–10 days[1]
Ceftriaxone (second-line treatment)	powder for injection 250 mg and 1 g	IV 50 mg/kg once daily for all newborns younger than 1 week and less than or equal to 2 kg or 75 mg/kg once daily for ten days (for infants more than one week and greater than 2 kg)[2].

3. Calculate the quantity of injectable antibiotic needed for the forecast period

This is calculated by multiplying the number of cases that will be given each antibiotic for the treatment of PSBI with the amount needed per case.

Note: When calculating the number of gentamicin ampoules, keep in consideration that ampoules are not reusable once opened.

4. Adjust for programmatic changes

This adjustment can be made before or after converting the number of episodes to products. If the number of episodes is expected to change, these adjustments can be made when estimating the number of episodes.

As international guidance is updated, some countries may decide to revise national MNCH guidelines to reflect the changes. These countries will then need to decide what antibiotics will continue to be made available, and at what levels of the health system. If multiple antibiotics will continue to be made available, then the proportion that will be treated with each will need to be calculated. Likewise, if the implementation of changes to national MNCH guidelines is gradual or phased, this should also be taken into consideration during forecasting. For forecasting and budgetary purposes, adding a percentage for uncertainties in demand to avoid stock-outs might be sensible.

Table 13. Potential Sources of Data for Forecasting Consumption of Injectable Antibiotics using Morbidity Method

Data	Source	Limitations and Challenges
Forecasting		
Total population	Census data, DHS	--
Number of births	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually underestimated
Proportion of facility births	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually underestimated
Proportion of home deliveries	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually underestimated
Proportion of live births	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data usually underestimated
# of newborns at risk of developing bacterial infection/sepsis	HMIS, national maternal morbidity and mortality surveys, special surveys	Survey data usually underestimated
Proportion of newborns referred for newborn sepsis	HMIS, national maternal morbidity and mortality surveys, special surveys	Survey data usually underestimated
Proportion of live births developing neonatal sepsis/ incidence of neonatal sepsis	HMIS, national maternal morbidity and mortality surveys, special surveys	Survey data usually underestimated
Dosage recommended	WHO or national MNCH guidelines	Providers may not always follow dosage recommended
STGs (actual prescribing practice versus ideal)	National essential medicine program, WHO, MoH, NMCP, surveys	Guidelines may propose different medicines for the same condition; parenteral treatment duration varies between patients depending on clinical evolution; STGs not always used by health providers
Programmatic factors		
Interventions/factors affecting future changes in demand, e.g., scale-up plans	MNCH	Scale up may take longer than planned

Additional Products, Consumables, or Equipment Required

The use of injectable antibiotics requires injection supplies per treatment episode, including:

- 2–3 ml syringe and 23 gauge needle
- Butterfly needle or IV cannula
- IV infusion and drip set
- Alcohol swab
- Sterile water 10 ml vials/ampoules
- Sharps disposal

These should be included in the forecasting and supply planning process in addition to the injectable antibiotics.

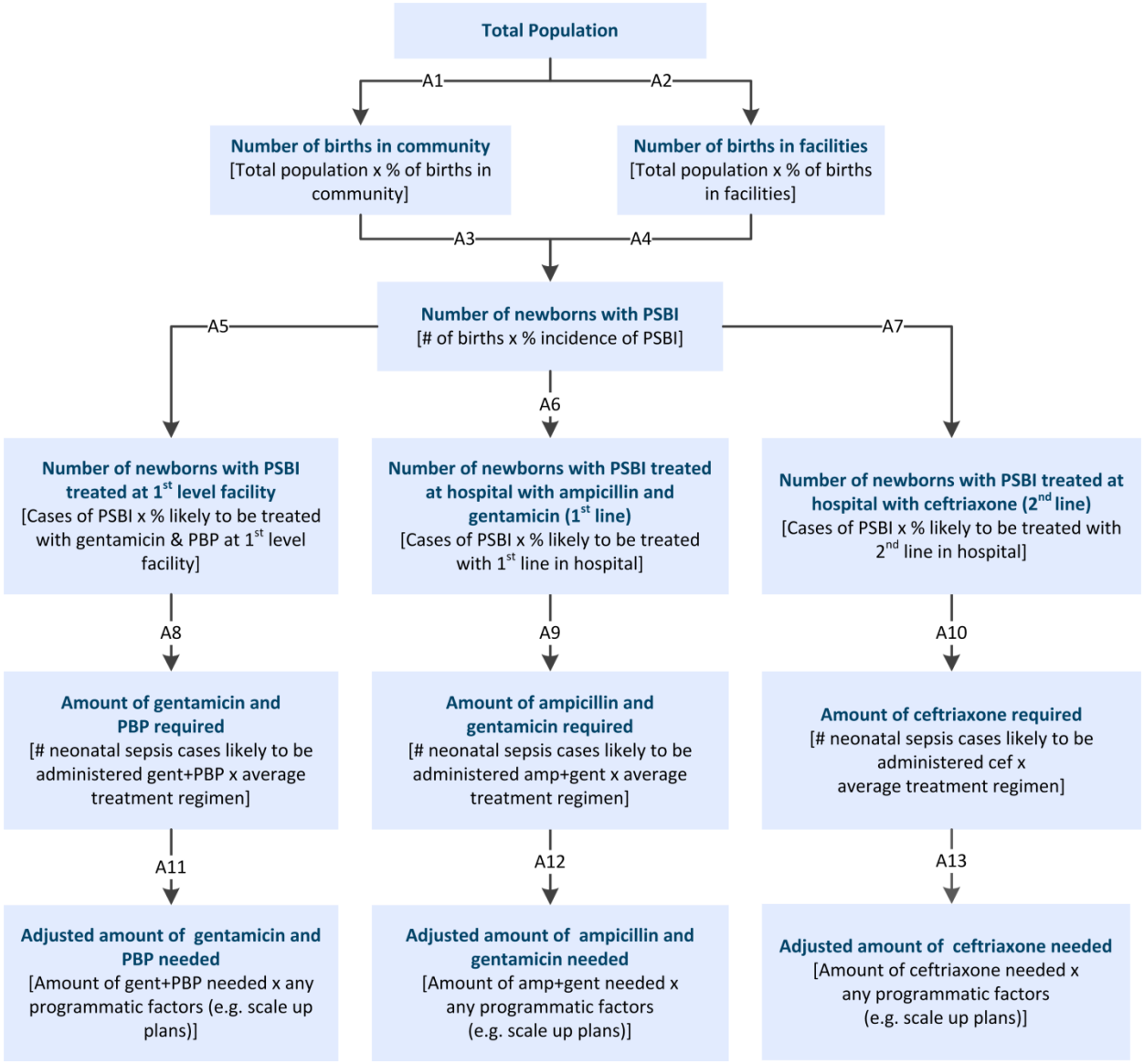
Product Availability

There are over 50 different companies throughout Asia and South Asia, Europe, the Middle East, and North America that manufacture these injectable antibiotics. The products are often not readily available or subject to stock-outs in weaker health systems. Manufacturers have cited insufficient demand as a reason for low supply of PBP in some cases. Countries should, but often do not, specify the pediatric presentation in their tender specification, e.g., gentamicin 20 mg/2 ml ampoules rather than 80 mg/2 ml ampoules.

Forecasting Algorithm for Injectable Antibiotics

Figure 9 illustrates the steps to follow when quantifying for antibiotics for neonatal sepsis including assumptions and the data needed to reach each subsequent step. Once the amount of antibiotic required to meet program needs is calculated, this is entered into a supply planning matrix which takes into account current pipelines, losses; price and supplier lead times to determine the amount to be delivered for each specific time period. Please refer to *Quantification of Health Commodities* for guidance on the supply planning step.

Figure 9. Forecasting algorithm for antibiotics for PSBI



Assumptions for figure 9

A1	Births in community, %
A2	Births in facilities, %
A3	Incidence of PSBI in community. In absence of country level data, proxy data from similar countries or global estimates, e.g., published literature indicates that PSBI occurs in approximately 10% of births
A4	Incidence of PSBI in facility. In absence of country level data, proxy data from similar countries or global estimates, e.g., published literature indicates that PSBI occurs in approximately 10% of births
A5	PSBI cases refusing referral likely to be treated in a first-level facility, % [†]
A6	PSBI cases likely to be treated at hospital and given first-line treatment, %

[†] This regimen would change to include oral amoxicillin if the WHO guidelines are adapted according to the evidence

A7	PSBI cases likely to be treated at hospital and given second-line treatment, %
A8	Average treatment regimen of gentamicin and PBP (based on average birth weight)
A9	Average treatment regimen for each of ampicillin and gentamicin (based on average birth weight)
A10	Average treatment regimen for each of ceftriaxone (based on average birth weight)
A11	Rate of expected programmatic change at first-level facility level, e.g., scale-up
A12	Rate of expected programmatic change at hospital level, e.g., scale-up (first-line treatment)
A13	Rate of expected programmatic change at hospital level, e.g., scale-up (second-line treatment)

Box 18. Example of forecasting using the current WHO recommended injectable antibiotics

Country X recommends the use of ampicillin and gentamicin for first-line treatment of neonatal sepsis for 10 days at a referral hospital or, for those that cannot be hospitalized, treatment at a health facility with 5 days of IM gentamicin and PBP*. The incidence of neonatal sepsis in the population is estimated to be 10% of all live births. It is estimated that only 50% of these cases are actually seen in formal health facilities. Thirty percent of cases presented at health facilities are referred to hospitals.

Data available is as follows:

- Total population: 10,000,000 (current year)
- Annual increase: 2%
- Birth rate: 2%
- PSBI: 10% of newborns
- Total cases seen at health facilities: 50%
- Cases treated in health center: 70%
- Cases referred to hospitals: 30%
- Sepsis cases needing 2nd line in hospitals: 10%

Ampicillin (500 mg vials) packed in boxes of 50 vials each
Gentamicin 20 mg/2ml amps packed in boxes of 100 amps each
PBP (1 million U vials) packed in boxes of 50 vials each
Ceftriaxone 250 mg packed on boxes of 50 vials each

Assumptions:

- Average weight of a newborn: 3.4 kg
- Average number of 500 mg vials of ampicillin administered per patient in hospital = 20
  (3.4 kg x 50 mg = 170 mg every 8 hours (2 vials per day)
- Average number of amps of gentamicin 20 mg/2 ml administered per patient in hospital = 20
  (3.4 kg x 7.5 mg/kg = 25.5 mg per day i.e., 2 ampoules of 20 mg/2 ml x 10 days)
- Average number of amps of gentamicin administered per patient in health center = 10
  (3.4 kg x 7.5 mg/kg = 25.5 mg per day i.e., 2 ampoules of 20 mg/2 ml x 5 days)
- Average number of 1 million unit vials of PBP administered per patient in health center = 1,
  (3.4kg x 50,000 U = 170,000 U per day. One million unit vial contains 5 doses)
- Average number of 250 mg ceftriaxone vials administered per patient in hospital = 20
  (3.4 kg x 75 mg/kg= 255 mg or 2 x 250 mg vials per day)

From the data above, we can calculate the quantity of injectable antibiotics required to meet program needs over the next 2 years.

* This regimen would change to include oral amoxicillin if the WHO guidelines are adapted according to the evidence

(box 18 continued on following page)

Box 18. Continued

	Input		Current year	Forecast year 1	Forecast year 2
Population	Pop. Growth rate	2%	10,000,000	10,200,000	10,404,000
Number of births	Birth rate	2%	200,000	204,000	208,080
Number of cases of PSBI among newborns	PSBI rate	10%	20,000	20,400	20,808
Number of cases of PSBI treated	% of total cases treated	50%	10,000	10,200	10,404
Number of cases treated in first- level health facilities with gentamicin and PBP	% of total cases treated in health facilities	70%	7,000	7,140	7,282
Number of cases treated in hospitals with ampicillin and gentamicin	% of total cases treated in hospitals	30%	3,000	3,060	3,121
Number of cases likely to be treated in hospital with the second line (ceftriaxone)	% treated with 2nd line	10%	300	306	312
Amount of PBP needed (vials)	# of vials needed per case, on average	1	7,000	7,140	7,282
Amount of ampicillin needed (vials)	# of vials needed per case in hospital, on average	20	60,000	61,200	62,420
Amount of gentamicin needed (ampoules) (hospital + facility)	# of amps needed per case in hospital and in facility, on average	20, 10	130,000	132,600	135,240
Amount of ceftriaxone needed (vials)	# of vials needed per case, on average	20	6,000	6,120	6,240

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Neonatal Resuscitation Commodities

PATH developed a national-level quantification tool for neonatal resuscitation commodities. It was designed to provide estimates of product quantities for planning and cost simulations and can be used at a national, regional, district, or health facility level. The majority of the commodities are reusable and the lifespan of each product will vary depending on the manufacturer, the amount of use at a health facility, and how the products are cleaned and stored.

The tool is set up to provide initial estimated needs for neonatal resuscitation commodities for a one-year period. It is advisable that the tool be adjusted in future years to accommodate for the average lifespan of each commodity at each level of the system. It is also advisable that some reserves are stocked at the central level and at the health facility level to cover additional needs, breakages, and losses. Additional stock should be based on a county's usual recommended stock quantity.

Given that multiple algorithms are needed to calculate the needs for these commodities, a user-friendly Excel document was created to allow countries to easily enter the corresponding data needed to use these algorithms. The tool is available online at: http://www.path.org/publications/detail.php?i=2401

The following text describes each section of the tool as well as the rationale for the algorithms.

Product Description, Indications, and Considerations for Use

Neonatal resuscitation commodities are used for clinical as well as pre- and in-service training purposes for newborn asphyxia. In this document, clinical resuscitation devices include newborn resuscitation bag and masks, and suction bulbs, while training commodities include pre- and in-service training manikins. Furthermore, the suction bulbs are available as single-use or multiuse, so there are a variety of considerations when forecasting these commodities.

- Multiuse neonatal resuscitation commodities
  - Resuscitation bag and masks (sizes 1 and 0)
  - Reusable suction bulbs
  - Training manikins

- Single-use neonatal resuscitation devices
  - Single-use suction bulbs

The option for either type of suction bulb has been included here so that a country may choose their preferred device (reusable or single-use). A reusable suction bulb is one that can be opened, cleaned, and disinfected. If opting for a single-use suction bulb, it is imperative that enough are on hand at every facility, as these types of suction bulbs should not be reused to avoid the spread of infection.

Definitions and specifications for each commodity are provided in the Definitions section below.

Quantification Methods

The numbers shown in the tool are based on findings in Uganda and Tanzania and are for example purposes. Each health facility may have a different type and number of rooms so it is important for each country to assess and average the number of rooms per facility type and change the numbers in the tool accordingly. For example, it was estimated in Uganda and Tanzania that a regional hospital has 10 rooms; (four (4) delivery areas, two (2) theatres, one (1) emergency area, one (1) neonatal, and two (2) neonatal intensive care units (NICUs), whereas a provincial hospital has nine (9) rooms, a district hospital has seven (7), health center has three (3), and a health post has one (1). These are averages that are used at a national level in order to model for the entire country.

See the definitions section for a definition of each type of room/area.

The health facility levels that receive neonatal resuscitation commodities will depend on the country MNCH guidelines and policy, although they are likely to be placed where there are skilled birth attendants who have been trained on the use of newborn resuscitation devices.

Target Population

The target population for which the clinical neonatal resuscitation commodities should be used depends on a country's MNCH guidelines and policy. Typically, the commodities should be made available in health facility rooms or areas where a newborn may need resuscitation and where there is at least one skilled birth attendant at the facility, and also where resuscitation training may occur. In some settings, this may be at hospital level only, whereas in others it may include a range of facility levels including health centers and possibly health posts.

The target population for the neonatal training manikins also depends on a country's MNCH guidelines and policy. Oftentimes, manikins are placed within nursing and medical schools for nursing students and clinical officers in pre-service training. The manikins may also be placed within health facilities for training students and for in-service practice for health care workers. Some policies may require that the manikins for in-service training be placed at each hospital, whereas others may require them at the health center level(s), and sometimes at the health post level where health care workers can practice and receive supervision.

Summary of Data/Information/Considerations Needed for Neonatal Resuscitation Commodity Forecasting

- Number and types of health facilities in country (i.e., regional, provincial, district hospitals; health center; health post.) **(required)**
- Number and types of rooms in each type of health facility where a newborn may require resuscitation (i.e., delivery rooms/wards theaters, emergency areas, neonatal wards, NICU/special care) **(optional)**
- Number of each resuscitation commodity needed per room for each health facility type **(optional)**
- Number of training manikins per health facility type **(optional)**
- Number of births per year **(required)***
- Percentage of births attended by a skilled birth attendant **(required)***
- Percentage of babies estimated to need single-use suction bulb **(optional)***

- Number of nursing and medical schools **(required)**
- Average number of students per class **(required)**
- Number of students per manikin **(optional)**

*Numerical value needed only if procuring single-use suction bulbs.

Forecasting Method using Service Capacity Data

The method proposed in this algorithm is different than the methods proposed in other algorithms because of the nature of neonatal resuscitation commodities. As some commodities may be used multiple times, a morbidity-based approach is not appropriate.

Because of the variety of neonatal resuscitation commodities (e.g., clinical; single use, reusable and training; pre-service, in-service), the method for forecasting will be different for each type of commodity.

Also, the number of cases that require use of these commodities may be small, but because timely access to the devices is required to save the life of the newborn, it is critical that it be available. For these reasons, the forecasting method presented here is based on the number of rooms in each health facility where the devicesneed to be present.

The numbers shown throughout this document are provided for example purposes only and each country should be assessed. For ease of use, the examples are color coded as follows:

YELLOW cells	REQUIRED to be completed for the quantities and costs for the neonatal resuscitation commodities to be automatically calculated. REQUIRED to be completed in accordance with country information that is generally accessible through the Ministry of Health (MoH). The numbers shown in the examples are provided for demonstration purposes only.
ORANGE cells	OPTIONAL. The estimated statistics in these cells are based upon assumptions collected from global implementers and trainers from the Helping Babies Breathe (HBB) partnership and public health care workers from the MoHs in Uganda and Tanzania. It is recommended that these are adjusted based on individual country situations and need. For information on how each of these current numbers was reached, please see the Assumptions section below.
BLUE cells	FORMULAS that calculate totals and other allocations. They are locked and cannot be changed without the password. Changing the formulas is not recommended.

The following steps should be followed:

Step 1. Health facility information

a. Enter the number of each level of health facility to be quantified in the “Number of health facilities in country” row. These are the health facilities that will receive the **clinical** resuscitation devices (bag and masks and reusable suction bulbs), and **in-service training** commodities (training manikin) (table 16, row 1a).
b. Enter the average number of rooms in each type of health facility to receive the clinical resuscitation devices (table 16, row 1b).

Step 1 a-b example

Considerations	Regional hospital	Provincial hospital	District hospital	Health center	Health post
1a: Number of health facilities in country	4	38	115	465	0
1b: Average number of labor wards per facility	4	2	2	1	0
1b: Average number of theatres per facility	2	2	2	0	0
1b: Average number of emergency areas per facility	1	1	1	1	0
1b: Average number of neonatal wards per facility	1	2	1	0	0
1b: Average number of ICU/special care per facility	2	2	1	1	0
Total number of rooms per facility type	10	9	7	3	0

Step 2. Multiuse device information

a. Determine the number of resuscitation bags and masks (sizes 0 and 1) and the number of reusable suction bulbs to be placed in each room (see rows 2a).
b. Determine the number of training manikins per health facility (see row 2b).

Step 2 a-b example

Considerations	Regional hospital	Provincial hospital	District hospital	Health center	Health post
2a: Number of resuscitation bags per room	3	2	2	2	0
2a: Number of resuscitation masks size 0 per room	3	2	2	2	0
2a: Number of resuscitation masks size 1 per room	3	2	2	2	0
2a: Number of reusable suction bulbsper room*	3	2	2	2	0
2b: Number of training manikin sets per health facility (post-service)	3	3	3	1	0

c. The number of health facilities is multiplied by the number of rooms in each type of facility to receive the total number of rooms.

Example: In the example shown below, there are 4 regional hospitals in the country and each hospital has 10 rooms, so the answer received is 40 (see cell 2c).

d. By type of health facility, multiply the answer above (40) by the number of clinical multiuse devices required per room. Do this for the resuscitation bag and masks and the multiuse suction bulbs.

Example: In the example shown below, there should be 3 resuscitation bag and masks per room, so the answer is 120 (40 x 3) (see cell 2d and 2e).

e. By type of health facility, multiply the number of facilities by the number of training manikins required per facility.

Example: In the example shown below, there are 4 regional hospitals that each need 3 manikins, so the answer is 12 (see cell 2f).

Step 2 c-e example (regional hospitals)

Type of unit/room	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Bag & masks (sizes 0 and 1)	Multiuse suction device	Training manikin (in-service)
Regional hospitals	4					12
Delivery rooms/wards		4	16	48	48	n/a
Theaters		2	8	24	24	n/a
Emergency areas		1	4	12	12	n/a
Neonatal wards		1	4	12	12	n/a
NICU/special care units		2	8	24	24	n/a
Total		10	2c: 40	2d: 120	2e: 120	2f: 12

f. Repeat the above steps for each type of health facility to be quantified.

Step 2 f example (other health facilities)

Type of unit/room	Number of facilities	Estimated number of rooms in facility	Total number of rooms in country	Bag & masks (sizes 0 and 1)	Multiuse suction device	Training manikin (in-service)
Provincial hospitals	38					114
Delivery rooms/wards		2	76	152	152	n/a
Theaters		2	76	152	152	n/a
Emergency areas		1	38	76	76	n/a
Neonatal wards		2	76	152	152	n/a
NICU/special care units		2	76	152	152	n/a
Total		9	342	684	684	114
District hospitals	115					345
Delivery rooms/wards		2	230	460	460	n/a
Theaters		2	230	460	460	n/a
Emergency areas		1	115	230	230	n/a
Neonatal wards		1	115	230	230	n/a
NICU/special care units		1	115	230	230	n/a
Total		7	805	1,610	1,610	345
Health centers	465					465
Delivery rooms/wards		1	465	930	930	n/a
Theaters		0	0	0	0	n/a
Emergency areas		1	465	930	930	n/a
Neonatal wards		0	0	0	0	n/a
NICU/special care units		1	465	930	930	n/a
Total		3	1,395	2,790	2,790	465

g. Add the total of each type of health facility for the total number of commodities needed for the country.

Step 2 g example (other health facilities)

	Total number of rooms	Bag & masks (sizes 0 and 1)	Multiuse suction device	Pre-service training manikin
Total number of commodities needed	2,582	5,204	5,204	936

Step 3. Single-use device information

This section should ONLY be completed if single-use suction bulbs are being procured rather than reusable suction bulbs. If single-use suction bulbs are selected, ensure that the number of reusable suction bulbs in step 2 is changed to zero (0) so that the device is not calculated twice. If procuring single-use suction bulbs, complete the yellow cells and change the orange cells as necessary, as in the example below.

a. Enter the number of births per year (see 3a).
b. Enter the percentage of births attended by a skilled birth attendant (see 3b).
c. The number of births is multiplied by the percentage of skilled birth attendants (see 3c).
d. Enter the percentage of newborns estimated to need a single-use suction bulb (see 3d).
e. The total number of births attended by a skilled birth attendant is multiplied by the percentage of babies estimated to need a single-use suction blub for the TOTAL number of single-use suction bulbs (see 3e).

Step 3 (a-e) Example

3a: Number of births per year	1,786,815
3b: Percentage of births attended by a skilled birth attendant	51%
3c: Total number of births attended by a skilled birth attendant	911,276
3d: Percentage of babies estimated to need a single-use suction bulb	10%
3e: Total number of one-time use suction bulbs	91,128

Step 4: Pre-service training device information

a. Enter the number of nursing and medical schools being quantified for pre-service neonatal training manikins.
b. Enter the average number of students per class
c. The number of schools is multiplied by the number of students for the total number of students
d. Enter the number of students per manikin
e. The total number of students is divided by the number of students per manikin for the TOTAL number of training manikins required

Step 4 (a-e) Example

4a: Number of nursing and medical schools	26
4b: Average number of students per class	52
4c: Total number of students	1,352
4d: Number of students per manikin	6
4e: Total number of training manikins required	225

Information, Assumptions, and Proxy Data Needed to Quantify

Definitions

Term	Definition	Source
Devices	**Multi- and single-use neonatal resuscitation and related training commodities**	
Self-inflating neonatal resuscitation bag with masks	A collection of sterile devices designed for performing cardiopulmonary resuscitation (CPR), which typically includes airway tubes, a CPR face mask or masks of various sizes, and a manual resuscitation bag. Self-inflating, hand operated and portable resuscitator (bag and mask) with a bag size between 200 ml and 320 ml, and two masks, size 1 for term babies and small infants under 5kgs and size 0 for preterm and low-birth-weight babies, with a pressure limiting valve so that airway pressure does not exceed 4 – 4.5kPa (40-45cmH30) and can generate an airway pressure of at least 3kPa (=30cmH20)Intake valve with nipple for o2 tubing, material shall be polycarbonate/polysulfone or any other material fulfilling the ISO biomaterial standards and USP Class VI. Resuscitator can be totally disassembled and easy to clean and disinfect. All parts are manufactured from high-strength, long-life materials.	WHO Draft Technical Specifications of Life-Saving Commodities.
Masks	Size 1 (for term babies), round type, diameter 45-55 mm and size 0 (for preterm and low-birth-weight babies), round type, diameter 45–55mm.Translucent.	WHO Draft Technical Specifications of Life-Saving Commodities.
Suction bulbs, reusable	A portable, hand-held, manual suction device designed to enable an adult to gently suction and clear excessive mucus from the nasal passages of an infant or child to facilitate easier breathing. The top part can be opened and the device can be subjected to boiling (high-level disinfection) and sterilization including autoclaving. May be translucent.	WHO Draft Technical Specifications of Life-Saving Commodities.
Suction bulbs, single-use	A portable, hand-held, manual suction device designed to enable an adult to gently suction and clear excessive mucus from the nasal passages of an infant or child to facilitate easier breathing.	WHO Draft Technical Specifications of Life-Saving Commodities.
Training manikin	A specially constructed doll with simulated respiratory and cardiovascular functions designed to demonstrate and teach resuscitation techniques that include mouth-to-mouth resuscitation and heart compressions (cardiopulmonary resuscitation/CPR) and sometimes manual pulse registration.	WHO Draft Technical Specifications of Life-Saving Commodities.
Health facilities	The health facilities have been defined per WHO's framework (regional hospital, provincial hospital, district hospital, health center, health post), although countries may differ.	WHO website; Medical devices, country data. Available at http://www.who.int/medical_devices/countries/en/.
Regional hospital	Tertiary-level hospital: Highly specialized staff and technical equipment. For example, cardiology, intensive care unit, and specialized imaging units; clinical services highly differentiated by function; could have teaching activities; size ranges from 300 to 1,500 beds. Alternative terms commonly found in the literature include national hospital; central hospital; academic, teaching, or university hospital.	Hensher M, Price M, Adomakoh S. Referral hospitals. In: Jamison DT, Breman JG, Measham AR, et al., eds. *Disease Control Priorities in Developing Countries.* Washington, DC: World Bank; 2006:1230–1239. Available from: http://www.ncbi.nlm.nih.gov/

Term	Definition	Source
		books/NBK11
Provincial hospital	Secondary-level hospital: Highly differentiated by function with 5 to 10 clinical specialties; size ranges from 200 to 800 beds. Alternative terms commonly found in the literature include regional hospital, provincial hospital (or equivalent administrative area such as county), and general hospital.	Hensher M, Price M, Adomakoh S. Referral hospitals. In: Jamison DT, Breman JG, Measham AR, et al., eds. *Disease Control Priorities in Developing Countries.* Washington, DC: World Bank; 2006:1230–1239. Available from: http://www.ncbi.nlm.nih.gov/books/NBK11
District hospital	Primary-level hospital: Few specialties; mainly internal medicine, obstetrics and gynecology, pediatrics, and general surgery, or just general practice; limited laboratory services available for general but not specialized pathological analysis. Alternative terms commonly found in the literature include district hospital, rural hospital, community hospital, and general hospital.	Hensher M, Price M, Adomakoh S. Referral hospitals. In: Jamison DT, Breman JG, Measham AR, et al., eds. *Disease Control Priorities in Developing Countries.* Washington, DC: World Bank; 2006:1230–1239. Available at http://www.ncbi.nlm.nih.gov/books/NBK11
Health center	Lower-level health facilities: Some countries may have one level of health center, whereas others are known to have more (Uganda, for example, has four). Each level and each country will usually differ from whether they have in-patient services, theaters, etc.	WHO website; Medical devices; country data. Available at http://www.who.int/medical_devices/countries/en/.
Health post	Lowest-level health facilities: Also referred to as dispensaries. Health centers do not usually have in-patient services, although there may be skilled birth attendants working at a facility.	WHO Medical devices; country data. Available at http://www.who.int/medical_devices/countries/en/.
Room type	**The type of rooms/areas shown are main areas where a newborn may be present and may need resuscitation devices. Two rows have been listed as "Other" for countries to complete should they have additional rooms/areas.**	
Delivery room/ward	Area dedicated to providing care and treatment for mother and baby during and/or after the childbearing process.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoH in Uganda and Tanzania.
Theater	A room in which surgical operations (such as cesarean section) are performed.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoH in Uganda and Tanzania.
Emergency area	Typically a department of a hospital that provides immediate treatment for acute illnesses and trauma. ***Note***: in Uganda and Tanzania, each hospital visited had an emergency area where a mother may give birth or a mother and/or newborn may need assistance. Examples include the reproductive health unit where mothers may arrive with newborns after	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoHs in Uganda and

Term	Definition	Source
	giving birth at home or an area near the reception where a mother might give birth when there is not enough time to get to the delivery room.	Tanzania.
Neonatal ward	Area provided for babies who need some medical treatment or who are not well enough to be cared for at their mother's bedside.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoH in Uganda and Tanzania.
NICU/special care unit	Area provided for babies with serious problems including premature and low-weight babies.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoHs in Uganda and Tanzania.
Other		
Skilled health personnel	Nurses, doctors, and midwives can all be categorized as skilled birth attendants.	WHO website; WHO Indicator and Measurement Registry, version 1.7.0. Available at http://apps.who.int/gho/indicatorregistry/App_Main/browse_indicators.aspx.
Pre-service training	Training activities which take place before a person takes up a job which requires specific training (i.e., before a person 'enters service').	Page on pre-service education. WHO website. Available at http://www.emro.who.int/child-health/IMCI-preservice-training/what-is-it.
In-service training	Training of persons already employed (e.g., health providers already working in the public or private sector).	Page on pre-service education. WHO website. Available at http://www.emro.who.int/child-health/IMCI-preservice-training/what-is-it.

Note: Each country may have different terms for the rooms for newborns. In some countries, the name of a ward/area may change between facilities. The names used in this tool may be changed according to country terms. Other terms may include, but are not limited to, kangaroo room, laying-in room, and recovery room.

Forecasting Assumptions

Variables	Assumptions	Source
Step 1: Health facility information		
Number of health facilities in country	This information is usually available at the MoH, although it is also important to understand the country policies around what resuscitation commodities are approved for use in the country as well as where the skilled birth attendants are located. The WHO maintains country information, which can be found at: http://www.who.int/medical_devices/countries/en/. Although this information can be helpful, it is imperative to also know country policy and practices when supplying neonatal resuscitation commodities.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoHs in Uganda and Tanzania.
Number and types of rooms per health facility	Each facility may be different, but the number of rooms shown in the examples are the averages for Tanzania and Uganda. The quantifiers complete these numbers for the country they are quantifying. If, however, this information is not readily available, the numbers shown on the quantification tool can be used as a BASIC GUIDELINE. An "Other" column has been added for countries that need to include an additional level of health facility. For example, in Uganda, health centers four, three, and two require newborn resuscitation devices and would use the "Health center," "Health post," and "Other" columns.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoHs in Uganda and Tanzania.
Step 2: Multiuse device information		
Number of reusable clinical devices per room	The reusable clinical devices (resuscitation bag and mask and reusable suction bulb) are quantified per ROOM or area where a newborn may need resuscitation (delivery, theater, emergency, neonatal, intensive care unit [NICU]/special care unit, etc.). A MINIMUM of two resuscitation bag and masks (sizes 0 and 1) and two resuable suction bulbs need to be available at any time in EVERY ROOM where a newborn might be. Because of the higher number of births at regional hospitals in Uganda and Tanzania, it was concluded that AT LEAST three resuscitation bag and masks and three reusable suction bulbs be quantified per room in these countries. For health facilities with high numbers of births, more may be required. It should be noted that in some hospitals, a room may also be referred to as an area or cubicle. Note that if selecting a reusable suction bulb, Step 3 may be skipped. If, however, selecting a single-use suction bulb, go to Step 3 and ensure that the number of reusable suction bulbs has been changed to zero (0) in Step 2 so that suction bulbs are not double ordered.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers and the MoHs in Uganda and Tanzania.
Number of training manikins per health facility (in-service)	The reusable commodities for in-service training (training manikins) are quantified per HEALTH FACILITY for health care workers to use for practice and for students in the facility. This section is for those countries requiring a training manikin in health facilities for students and for staff to practice their skills. The optional numbers shown in the	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers and the

Variables	Assumptions	Source
	quantification tool are three for hospitals and one for health centers. The reason for recommending three per hospital is due to the high number of students in these facilities. Health centers are shown with one manikin because oftentimes students are at this level too, and practice and supervision is provided for the health care workers and students. Health posts are shown with zero manikins, although a country should quantify if a training manikin is required at this level. It is recommended from interviews and in-country visits that there are not more than six students per manikin. It is assumed that there is only one class per school as there is typically only one practice lab in a school. These numbers should be changed according to country practice, policy, and budget.	MoH in Uganda and Tanzania.
Step 3: Single-use device information	**The single-use devices for clinical use have been quantified per national demographics, as these devices should be used only once and need to be calculated per NEWBORN attended by a skilled birth attendant.**	
Single-use suction bulbs per newborn	It would be difficult to quantify the single-use suction bulbs per room as information is oftentimes not available regarding the number of babies per room (delivery, theater, NICU, etc.), and this would be difficult to model for a national-level quantification tool. The quantification for single-use suction bulbs is based upon the number of births per year multiplied by the percentage of births attended by a skilled birth assistant. This information is usually found at the MoH. The percentage of babies estimated to need a suction device should be based on WHO guidelines on when to use a suction device, which are as follows:	WHO. *Guidelines on Basic Newborn Resuscitation*. Geneva:WHO; 2012. Available at http://www.who.int/maternal_child_adolescent/documents/basic_newborn_resuscitation/en/.
	• In neonates born through clear amniotic fluid who do not start breathing after thorough drying and rubbing the back 2 to 3 times, suctioning of the mouth and nose should not be done routinely before initiating positive pressure ventilation. Suctioning should be done only if the mouth or nose is full of secretions.	
	• In neonates born through meconium-stained amniotic fluid who do not start breathing on their own, suctioning of the mouth and nose should be done before initiating positive-pressure ventilation.	
	• In settings where mechanical equipment to generate negative pressure for suctioning is not available and a newly born baby requires suctioning, a bulb syringe (single-use or easy to clean and sterilize) is preferable to a mucous extractor with a trap in which the provider generates suction by aspiration.	
	Given that 5% to 10% of newborns require some degree of resuscitation, and that health care workers in Uganda and Tanzania who were following WHO	Wall SN, Lee ACC, Niermeyer S, et al. Neonatal resuscitation

Variables	Assumptions	Source
	suctioning guidelines estimated that 10% of babies needed suctioning at birth, the cell has been prefilled to reflect the 10% estimate. It is highly recommended, however, that a country maintains records on the number of babies requiring suctioning and that suctioning is done per current WHO and HBB guidelines.	in low-resource settings: what, who, and how to overcome challenges to scale-up? Int J Gynaecol Obstet. 2009 October;107(Suppl 1): S47–S64. doi:10.1016/j.ijgo.2009.07.013. Available at http://www.sciencedirect.com/science/article/pii/S0020729209003609
Step 4: Training device (pre-service) information	**This section should be completed if quantifying training manikins for nursing and medical schools.**	
Number of training manikins (pre-service) per number of students	The reusable commodities for pre-service training have been quantified per number of STUDENTS. This section should be completed if quantifying training manikins for nursing and medical schools. The number of nursing and medical schools along with the average number of students per class are often available at the MoH or the Ministry of Education. Various stakeholders from the HBB partnership and from the MoHs in Uganda and Tanzania agreed that it is ideal to not have more than six students per manikin for practicing purposes. This number should be changed according to country policy, practice, and budget.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoH in Uganda and Tanzania.
Number of students per manikin	The number of nursing and medical schools along with the average number of students per class are often available at the MoH or the Ministry of Education. Various stakeholders from the HBB partnership and from the MoH in Uganda and Tanzania agreed that it is ideal to not have more than six students per manikin for practicing purposes. This number should be changed according to country policy, practice, and budget.	Established through interviews and meetings with global implementers/trainers from the HBB partnership, health care workers, and the MoH in Uganda and Tanzania.

Proxy Data

Data	Limitations and Challenges	Source
Number and type of health facilities where a skilled birth attendant is present and trained in newborn resuscitation	WHO data can be helpful for the number of health facilities in a country, but it does not indicate which levels of health facilities have skilled birth attendants who are trained on the use of neonatal resuscitation commodities. WHO country information can be found at http://www.who.int/medical_devices/countries/en/.	DHS, National MNCH guidelines and policy, and WHO
Type and average number of rooms per health facility where a newborn may be present	Health facilities differ so it is important to gather information from enough facilities to identify the average number of rooms per type of facility and the average number of births per room. Some hospitals may have high numbers of births and their main delivery room(s) and/or theatre(s) may need extra resuscitation bag and masks and suction bulbs. The full range of rooms/areas where a newborn may be present may be overlooked. What one person considers four delivery rooms could be conceived by another as one delivery area. **Large health facilities that are outliers may need to be considered separately and included in the final procurement numbers.**	MNCH program staff, health care workers at each level of the health care system
Number of clinical reusable resuscitation commodities per room	MNCH guidelines may propose a lesser amount of commodities that is needed. Life span of the multiuse commodities is unknown at this time. The quantification tool is for a country's initial supply, but monitoring and consumption data should be performed in order to know when/how much to order for future requirements.	MNCH guidelines and policy and health care workers at each level of the health care system.
Number of training manikins per health facility for in-service training		MNCH guidelines, Ministry of Education guidelines, and health facilities
Number of births per year		DHS
Percentage of births attended by a skilled birth attendant		DHS
Percentage of newborns estimated to need a single-use suction device	The number of newborns suctioned is not typically available.	DHS, MNCH guidelines and policy, health care workers, and WHO guidelines
Number of nursing and medical schools requiring training manikins for pre-service training		DHS and the Ministry of Education
Average number of students per class in nursing and medical schools		DHS and the Ministry of Education

Challenges

- Resuscitation commodities are not systematically included in country essential device lists.
- There are often no guidelines and policy at the central level.
- Health care workers need training to operate these commodities.
- There is a lack of consumption data for commodities.
- Health management information systems do not include data on the number of newborns that needed suctioning

Product-Specific Considerations

- Life span of these commodities may vary greatly depending on the quality, amount of time they are used, and how they are cleaned.
- Quality failures occur relatively frequently, including valves, leakages, and mask seals due to quality of materials, mechanical failure during operation, dust particles, and cleaning procedures.
- Commodity types, costs, and quality can vary greatly. The selection of commodities should be influenced by the settings in which they will be used and the amount of usage they will receive. Attention to quality is imperative.
- Single-use suction devices are commonly reused increasing the risk of the spread of infection.

Program-Specific Considerations

- During visits to Uganda and Tanzania, health care workers reported preferring the reusable suction device over the single-use suction device.
- Country policy and guidelines are imperative for neonatal resuscitation commodities to know which levels of the health system should receive the commodities.
- There is little to no consensus on whether neonatal resuscitation commodities should be available wherever a baby is born or whether they should only be provided to those facilities with skilled birth attendants.
- Training is required for the use of these commodities so only those facilities that have skilled birth attendants need to be quantified.
- The document is designed to develop initial estimated needs for neonatal resuscitation commodities for a one-year period. It is advisable that the tool be adjusted in future years to accommodate for the average life span of each device, which will be based on the quality of the product, how often it is used, and how the product is cleaned. It is also advisable that some reserves are stocked at the central level and at the health facility level to cover additional needs, for example, to cover breakages or losses.

Product Availability

In 2011, PATH conducted an “Evaluation of manual neonatal bulb suction devices for use in low-resource settings.” In this global inventory of neonatal suction bulb devices, 34 devices were procured, all of which were labeled specifically for infant use, and 20 representative devices were tested. The report is currently in draft form but is expected to be made available in 2015.

In May 2010, PATH produced Version 3 of its field guide, “Practical selection of neonatal resuscitators.” PATH conducted a bench and user assessment of the performance and functionality, safety during use and reuse, ease of assembly and disassembly, and construction of many devices. Particular attention was given to reusable, silicone bag-and-mask devices costing less than 30 US dollars each. The features and performance of the devices were compared in order to guide procurement decisions, with the expectation that demand from developing countries could be driven to high-quality and affordable devices. The guide can be found at: http://www.path.org/publications/detail.php?i=1565.

For further information on newborn resuscitation, refer to the Helping Babies Breathe partnership website at: http://www.helpingbabiesbreathe.org/.

Section 2.4. Forecasting Algorithms for Child Health Products

Amoxicillin

Product Description, Indications, and Considerations for Use

Amoxicillin is a broad-spectrum antibiotic recommended for the treatment of suspected pneumonia in children under five. WHO guidelines have recently been updated to recommend amoxicillin rather than co-trimoxazole for the treatment of childhood pneumonia.[1,2,3]

The recommended product specifications are for amoxicillin 250 mg dispersible tablets (DTs) in blister packs of 10. Some countries are currently using amoxicillin 125 mg DTs in blister packs of 10 because they work better with their current treatment guidelines and avoid health care workers or care givers' need to split tablets, however with the current WHO dosage recommendations for pneumonia, no age band is given a dose under 250mg tablets. The products selected should support the STGs and avoid the need to split tablets, as any manipulation before consumption introduces potential contamination and sub-optimal dosing.

Amoxicillin is available in a variety of strengths and formulations; however it is important to ensure that pediatric products are procured to promote use and adherence by infants and young children. The recommended product is the dispersible table (DT). UNICEF defines dispersible tablets as "uncoated or film-coated tablets that can be dispersed in liquid before administration giving a homogenous dispersion."[4] DTs can be dissolved in water or a small amount of breast milk and usually disintegrate within a minute or so. While capsules and tablets are available more widely, dispersible tablets are preferable because they can be given to infants and young children and are simple to dispense. The tablets are also smaller in volume and weight and tend to have a longer shelf life than syrups, which make them more suitable for distribution to lower levels of the supply chain. However, due to their enhanced dissolvability, they are more sensitive to moisture and humidity than regular tablets, and therefore require specific packaging, typically aluminum/polyvinyl chloride blisters or aluminum strips to ensure stability and efficacy. Large bottles of loose dispersible tablets should be avoided to reduce manipulation and possible degradation.

Forecasting Considerations

To align with the most current WHO guidelines for treatment of childhood pneumonia,[5] amoxicillin 250 mg dispersible should be purchased in blister packs of 10 or 20 tablets for both product protection and ease of dispensing as a full course of treatment. The product packaging options that exist in the market are as follows;

- a patient pack of 1 x 10 blisters of 250mg Amoxicillin DT (for under one year olds),
- a patient pack of 2 x 10 blisters of 250mg Amoxicillin DT (for 2 – 5 year olds)
- and a multi-dispensing pack of 10 x 10 blisters of 250mg Amoxicillin DT (flexible dispensing pack that can be used by health workers to dispense to multiple patients of both age groups using dispensing envelopes).

As patient packs are more expensive than the multi-dispensing pack, many programs are opting for the 10 x 10 multi-dispensing pack. However, limited use of amoxicillin DTs to date means that few countries include amoxicillin DTs in their STGs and EMLs and therefore there may be few or no registered suppliers. If DTs are not well known in the health system, health care workers may need to be trained to explain and demonstrate how to dissolve

dispersible tablets in a small amount of water or breast milk to caregivers and this demonstration may require additional materials.

Note: Amoxicillin is a product that can be used for many indications. For children, amoxicillin may also be recommended for treatment of neonatal sepsis, malnutrition, ear infections as well as other infections; amoxicillin DTs could also be used in adult populations but ideally the 250 mg DTs will be reserved for pediatric use. Therefore, this does not ensure that a forecast only for pediatric pneumonia will be sufficient. If this product is in short supply in facilities or for other indications, forecasts for pediatric pneumonia, however accurate, will be undermined by use of this product for other types of needs unless the demand for all conditions is considered in total.

Quantification teams may find the following programmatic assumptions relevant for estimating the number of cases of childhood pneumonia and the quantity of antibiotics required to treat them:

- All children under five with suspected pneumonia should receive antibiotics
- Current estimates of pneumonia incidence rates in low- and middle-income countries range from 0.11–0.51 episodes of pneumonia/child/year; the average is 0.22 episodes/child/year. The Child Health Epidemiology Reference Group has provided updated estimates for many countries.[*6]
- DHS and other surveys provide estimates of the percent of children who seek care for pneumonia, and where children and their caregivers seek care by type of facility
- Recent evidence indicates that estimates of antibiotic treatment coverage provided in DHS may actually underestimate this figure as the denominator includes children with other conditions who might not actually require antibiotics.[7] Unfortunately, there is no better data source available at this time; this information should be consulted but validated with experts familiar with the local context.

WHO has recently revised their guidelines for treatment of childhood pneumonia at health facilities differentiating the dose based on where care is received. There are three age/weight bands for facilities, combining the two previous categories of “pneumonia” (fast breathing) and “severe pneumonia” (chest indrawing) under a single classification of “pneumonia” to simplify treatment with oral amoxicillin. The guidelines for treatment of fast breathing pneumonia by community health workers (CHWs) have not changed and remain as two age-bands.

Current WHO guidelines for treatment of childhood pneumonia:

Amoxicillin 250 mg dispersible tablets	CHW (fast breathing pneumonia)	2– 12 months (4–<10 kg)	1 tablet 2x per day for 5 days	10 tablets
		1 to 5 years (10–19 kg)	2 tablets 2x per day for 5 days	20 tablets
	Health Facility (fast breathing and chest in- drawing (severe pneumonia)	2– 12 months (4–<10 kg)	1 tablet 2x per day for 5 days	10 tablets
		12 months to 3 years (10-<14kg)	2 tablets 2x per day for 5 days	20 tablets
		3 to 5 years (14–19 kg)	3 tablets 2x per day for 5 days	30 tablets

* Epidemiology and etiology of childhood pneumonia in 2010: estimates of incidence, severe morbidity, mortality, underlying risk factors and causative pathogens for 192 countries

Box 19. Summary of Data Needed for Forecasting for Amoxicillin for Treatment of Childhood Pneumonia

- Target population
  - Number of children under age five by age or weight band (per STGs)
  - Pneumonia incidence in children under age five (estimated number of episodes/child/year)
  - % of children (or their caregivers) who will seek care or treatment in either public sector, by source (family or CHW), or private sector
- Standard treatment guidelines for treatment of pneumonia (including referral doses if included as part of CHW treatment algorithms)
- Programmatic changes that would affect consumption of amoxicillin (increase in service provision, i.e., CHWs authorized to dispense antibiotics for treatment of childhood pneumonia)
- Scope of quantification – types of facilities, sectors (public, private, NGO)

Table 14 shows potential sources of these data. All data and assumptions that are used in the process of forecasting should be documented. This makes it possible for others to review and also to update/revise data and assumptions if better information becomes available.

Table 14. Potential Sources of Data for Forecasting Consumption of Amoxicillin using Morbidity Method

Data	Source	Limitation
Quantification		
Total population	National census data	May be older; may need to apply estimated annual growth rate to project to forecast years
Population age 5 and under; including breakouts by age bands	Census data, DHS, MICS	Age bands may not be precise; will have to make assumptions to match numbers with STGs; if STGs are by weight band will have to make assumptions about ages of children
Incidence of pneumonia	Clinical survey data or research studies; Child Health Epidemiology Reference Group estimates	Using estimates of incidence of pneumonia is more precise but since much diagnosis is done symptomatically it is likely that additional children will be treated with antibiotics
Proportion of children (caregivers) seeking care by sector/type of facility	DHS, MICS, HMIS, special surveys	This data may not be current and may not reflect recent changes that would affect care-seeking (i.e. introduction of iCCM)
Dosage recommended	National STGs, WHO if not available	Providers may not always follow dosage recommended
STGs	National essential medicine program, WHO, MoH, surveys	Guidelines may propose different medicines for the same condition; STGs not always used by health providers
Programmatic changes	Child Health, IMCI	Projected changes may not be known or it may be difficult to estimate their impact

The forecasting formula involves estimating the number of children under five with suspected pneumonia and then determining how many of those will seek treatment and receive antibiotics from which source.

> # of children with suspected pneumonia in an age/weight band who are expected to receive treatment multiplied by # of tablets of dispersible amoxicillin in a course of treatment for that age/weight band.

If the guidelines also include a referral dose of amoxicillin for cases of severe pneumonia, whereby a CHW classifies a child as severe and refers him or her to a health facility, the referral dose can be included in the forecast. This will require an estimate of the percentage of cases seen by CHWs that are referred and STGs for the referral dose. These estimates of tablets needed for referrals would be added to the quantities needed for full courses of treatment.

Forecasting Method Using Morbidity Data

1. Calculate the target population that will receive pediatric dispersible amoxicillin tablets for suspected pneumonia.
   This is done in two steps:
   a. Calculate the estimated number of children under five who will fall sick with suspected pneumonia during the forecast period (generally annual estimates)
   b. Calculate the target population that will receive treatment with amoxicillin by source (facility or CHW)
2. Adjust for programmatic changes including treatment targets, demand generation activities, or service delivery, for example expansion of iCCM
3. Estimate the number of children with suspected pneumonia in each age/weight band per the STGs
4. Calculate the number of tablets of amoxicillin needed for each case for the treatment of pneumonia by age or weight band (per STGs)
5. Calculate the quantity of amoxicillin dispersible tablets needed for treatment of suspected pneumonia for the forecast period

1a. Calculate the estimated number of children under five who will fall sick with suspected pneumonia during the forecast period (generally annual estimates)

According to WHO, children under five with suspected pneumonia should receive antibiotics promptly in order to avoid progression to more severe illness and, potentially, death. Amoxicillin is therefore needed wherever children may be taken to receive care, with the greatest need likely in primary health care facilities and with CHWs, in countries where iCCM has been implemented and CHWs are authorized to dispense antibiotics. In the absence of robust consumption or services data, estimates of morbidity and care seeking will be needed to estimate the quantities required.

> Number of children under five in geographic area under consideration multiplied by the estimated incidence of pneumonia for children under age 5 in that area (generally provided as an estimate of episodes/child/year for the full age group (Pneumonia incidence in low- and middle-income countries is currently estimated to be 0.11–0.51 episodes pneumonia/child/year; average 0.22 episodes/child/year.[4])

Note on incidence: using incidence for pneumonia rather than acute respiratory infections (ARI) is preferable as pneumonia is the condition that requires treatment with an antibiotic. The reality though is that since diagnosis is done symptomatically, it is likely that children who do not have pneumonia are also treated. DHS and MICS surveys

provide estimates of two-week prevalence of ARI based on caregiver recall. While this data is useful for other reasons, it is not the preferred input for a forecast for amoxicillin as it requires a calculation to convert to annual prevalence and then annual incidence and the data itself is affected by the season of when the two-week survey was conducted. If it is necessary to do this calculation, WHO provides guidance on appropriate conversion methodology in Appendix R of the 1994 publication *Household survey manual: diarrhoea and acute respiratory infections.*[8,9]

1b Calculate the target population that will receive treatment with amoxicillin

While step 1a should provide a good estimate of the number of children that would need treatment for pneumonia, the reality is that because not all children are brought for care it is unlikely that 100% of the population in need will receive treatment. That means that if a forecast concludes with all children who would be ill with pneumonia, it will overestimate the demand for medicine. Further, depending on the scope of the quantification, it is important to consider where children would be receiving care. For instance, if the forecast is only for public sector facilities, information about where people in the population seek care is critical. And, if new WHO guidelines have been adopted that differentiate treatment guidelines by source of care, additional data will be needed on the percentage of care-seeking by type of facility or health care worker. Therefore, it is important to adjust this figure based on data for the local context:

- Percentage of children (caregivers) who seek care for symptoms of ARI/pneumonia
- Percentage of children (caregivers) who seek care by source
  - Private sector (may be further broken down to include clinics, pharmacies, etc.)
  - Public sector (may be further broken down by hospitals, health centers, CHWs, etc.)
  - Do not seek care

These assumptions will be applied to the estimates of cases of pneumonia to determine the numbers of children who will be seeking care at each type of facility.

A forecasting algorithm (figure 10) is a good way to visualize this process, think through assumptions, and help identify where decisions need to be made regarding specific assumptions.

DHS and MICS surveys may also include estimates of antibiotic treatment coverage rates. However, this should be used carefully, as recent evidence indicates that these estimates of antibiotic treatment coverage may be underestimates as the denominator includes children with other conditions who might not actually require antibiotics.[10] Unfortunately, there is no better data source available yet; this information should be consulted as a reference point, but validated with experts familiar with the local context, if it seems useful to the forecast.

2. Adjust for programmatic changes including treatment targets, demand generation activities, or service delivery

While historical data can be useful to inform a forecast based on the amounts and methods by which a product has been distributed in the past, it may be necessary to make adjustments based on assumptions of program changes that are happening or will happen in the span of the forecast. Given the emphasis on increasing treatment for childhood pneumonia there may be efforts that would increase demand. For example, in countries where CHWs are not authorized to dispense amoxicillin there may be effort to change that policy for integrated community case management of pneumonia in children under age 5. If this change has been authorized but not yet implemented, it should be factored into the forecast. This will require assumptions about the rate of roll out and

would need to take into account a realistic timeline for training CHWs and equipping them with the knowledge and skills to manage these products.

Several countries may have already identified coverage targets for scale-up of amoxicillin through national scale-up plans for child essential medicines or as part of global initiatives.[11] For example, the Global Action Plan for the Prevention and Control of Pneumonia and Diarrhea (GAPPD)[12] set ambitious targets of 90% access to appropriate pneumonia and diarrhea case management (with 80% coverage in every district). Using this target, it is possible to estimate the quantities needed to reach this level of treatment coverage. However, these goals are understandably ambitious and the forecast should consider the starting point of treatment coverage and realistic time frames for achieving these targets. If the forecast is for two years and starting coverage rates are 20%, it is unlikely that an increase to 90% in two years (or maybe even five) is realistic, unless there is significant investment in scale up, demand generation, and increasing treatment availability.

Depending at what level these assumptions are made, adjustments to the estimates made in Step 1b may be required, or overall adjustments to the number of children receiving treatment may be needed. For example, if there was a policy change to start allowing CHWs to treat children classified with pneumonia with antibiotics, the quantification team would need to estimate the percentage that would start to receive treatment from CHWs and how that would affect current care-seeking. That is, it might reduce the number of children who receive care at health facilities but may also increase the total percentage who seek care and reduce the percentage that do not. If a pilot has been conducted, it may be possible to extrapolate data from the pilot experience to inform these estimates. Otherwise, consult with program experts to help inform these assumptions. The potentially large number of assumptions in the final calculation underscores the need to frequently review and revise forecasts as more data becomes available—to either validate the assumptions that were made or revise them and make adjustments to the supply plan as needed.

3. Estimate the number of children with suspected pneumonia in each age/weight band per the STGs

Make an assumption of percentage of children in each age group that is then applied to the number of children seeking care by source. If data is not available it may be necessary to use data from a country that has a similar population structure. This will depend on the STGs in use in the setting where the forecast is conducted but the WHO guidelines are used as an example.[13]

- Percentage of children under age 5 by weight band per the STGs for pneumonia using WHO guidelines seen at health facilities:
  - 2 months–12 months (4–10 kgs), %
  - 1 year–3 years (10–<14 kgs), %
  - 3 years – 5 years (14-19 kgs), %

  Or seen by CHWs:
  - 2 months–12 months (4–<10 kgs), %
  - 1 year–5 years (10–19 kgs), %

4. Calculate the number of tablets of amoxicillin needed for each case for the treatment of pneumonia by age or weight band (per STGs)

Then, using the STGs, determine the number of tablets that will be needed for each age/weight group. For instance, the youngest age group requires 10 tablets of amoxicillin 250 mg DTs for a course of treatment and the older age group requires 30 tablets of amoxicillin 250 mg DTs. Amoxicillin 125 mg is not indicated for treatment of pneumonia

due to the large number of pills for older children to reach the optimal dosage, but may be appropriate for treatment of newborn sepsis.

Amoxicillin 250 mg dispersible tablets	CHW	2– 12 months (4–<10 kg)	1 tablet 2x per day for 5 days	10 tablets
		1 to 5 years (10–19 kg)	2 tablets 2x per day for 5 days	20 tablets
	Health Facility	2– 12 months (4–<10 kg)	1 tablet 2x per day for 5 days	10 tablets
		12 months to 3 years (10-<14kg)	2 tablets 2x per day for 5 days	20 tablets
		3 to 5 years (14–19 kg)	3 tablets 2x per day for 5 days	30 tablets

5. Calculate the quantity of amoxicillin dispersible tablets needed for treatment of suspected pneumonia for the forecast period

Multiply the population of children under 5 by the estimated pneumonia incidence rate to arrive at the estimated number of cases annually for the population.

Then multiply the estimated number of annual cases by the percentage seeking care by sector/channel and any programmatic change assumptions. From here, using the age/weight bands of the STGs (by type of care -facility/health care worker - if relevant), the numbers by source of care should be multiplied by the percentage of children that will fall in each age/weight band. This calculation will give you the number of children by source of care and by age/weight band. The numbers of children in each age/weight band and by channel would then be multiplied by the number of tablets in the respective course of treatment.

These quantities of tablets should be added together to provide a total quantity of amoxicillin tablets for the forecast period. Later, during supply planning, these may be converted into numbers of blister packs but at this stage it is preferable to keep in basic units (tablets). The program manager should be sure to include packaging size specifications to the procurement unit.

Additional Products, Consumables, or Equipment Required

To dissolve dispersible amoxicillin tablets to create a solution for infants and young children a small amount of clean water or breast milk may be used; additional supplies such as spoons and small cups may also be needed.

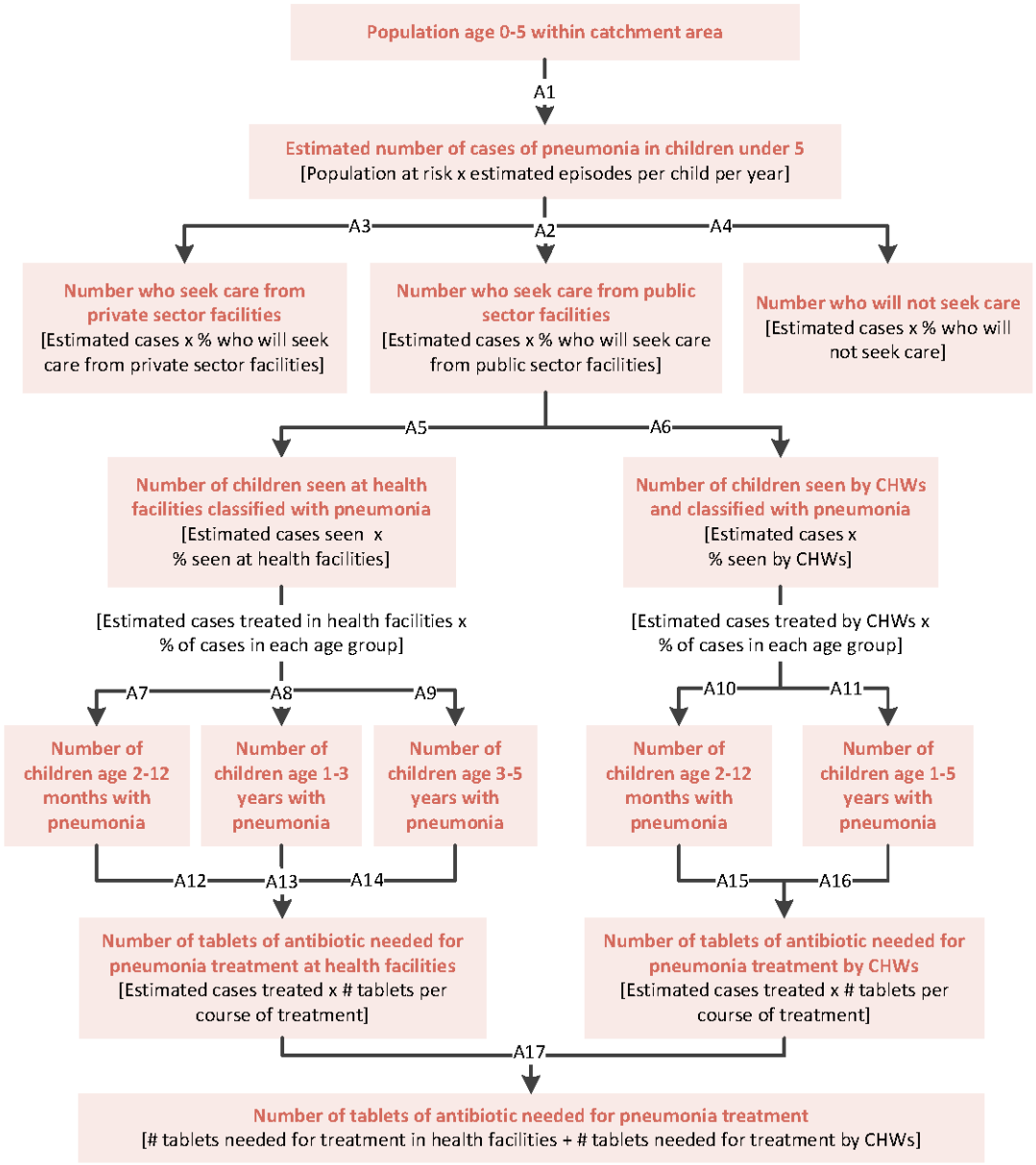
Product Availability

Amoxicillin dispersible tablets are produced by a number of suppliers in the international marketplace and efforts are underway to increase the number of quality assured suppliers. The UNICEF Supply Division catalogue currently includes several suppliers for amoxicillin dispersible tablets and this number will likely increase.[14] UNICEF's Supply Division and the Unit of Quality Assurance and Safety Medicines of WHO's Department of Essential Medicines and Health Products are in the process of establishing an Expert Review Panel (ERP) to provide evidence on quality products of amoxicillin DT from approved manufacturers for informed procurement decisions. Bioequivalence studies and supplier assessments are underway, and more information will be released once available.

Forecasting Algorithm for Amoxicillin

This is an example of how to set up a forecasting algorithm to estimate cases of pneumonia that will be treated and then convert that to tablets of amoxicillin using local STGs. This example broadly shows a breakdown of treatment estimates for the public sector, including CHWs in a country. However, countries/programs using this forecasting algorithm would have to adapt it depending on the scope of their quantification (private sector or public sector, different types of outlets/levels of a health system, geography, program, etc.) and local context. They would also need to make assumptions/adjustments to include estimates for what additional number of patients would be reached via scale-up efforts (or future expected coverage via additional channels). This example provides some ideas and suggested structure for the algorithm, but it will always be up to the quantification team with the local knowledge necessary to develop the assumptions they will use to build their forecast.

Figure 10. Sample algorithm for consumption of amoxicillin for treatment of children under 5 with suspected pneumonia in public sector (including CHWs)



Assumptions for figure 10

A1	Incidence of pneumonia in children under 5 (episodes/child/year)
A2	Children/care givers who seek care for ARI/pneumonia from the public sector, %
A3	Children/care givers who seek care for ARI/pneumonia from the private sector, %
A4	Children/care givers who do not seek care for ARI/pneumonia, %
A5	Children who will seek care at a facility for pneumonia, %
A6	Children who will seek care from a CHW for pneumonia, %
A7	Children in 2– 12 months age range with pneumonia treated in facility , %
A8	Children in 1-3 year age range with pneumonia treated in facility, %
A9	Children in 3-5 years age range with pneumonia treated in facility, %
A10	Children in 2–12 months age range with pneumonia, treated by CHW, %
A11	Children in 1– 5 years age range with pneumonia treated by CHW, %
A12	No. of tablets needed for course of treatment in facility children 2–12 months
A13	No. of tablets needed for course of treatment in facility children 1–3 years
A14	No.of tablets needed for course of treatment children in facility 3-5 years
A15	No. of tablets needed for course of treatment by CHW children 2–12 months
A16	No. of tablets needed for course of treatment by CHW children 1–5 years
A17	Total of tablets needed for treatment of children under 5 in the public sector

The figure above illustrates the steps to follow when quantifying for amoxicillin for the treatment of suspected pneumonia in children age five and under. This example is a forecast for public sector health facilities, and includes the two sets of STGs based on whether children are seen at health facilities or CHWs. The final result is the estimated annual need for amoxicillin for treatment of childhood pneumonia; however, this estimated need should not be used for procurement, because it does not take into consideration quantities of amoxicillin already in the supply chain, and quantities already on order. The estimated need will be used along with other data during the supply planning step to determine the quantity to order. If there is data available estimating the need for amoxicillin DTs for other conditions (newborn sepsis, malnutrition, others) it will be important to aggregate this demand and other relevant data for supply planning purposes (forecast consumption, stock on hand, funding) to ultimately guide procurement decisions and ensure supplies are sufficient for all indications/uses of amoxicillin.

Box 20. Example of country forecast for amoxicillin based on demographic data

Country *X* wants to know the amount of amoxicillin 250 mg dispersible tablets needed by their public sector facilities (including CHWs) to treat children under age 5 for pneumonia for the next two years.

Data available is as follows:

- Total population: 50 million (current year)
- Population growth rate: 3.29%
- Population under age 5: 5 million (current year)

* Assumption: % of children under age 5 remains constant at 10% annually

Population under 5 by age group
0–1 year = 33%
1–3 years = 37%
3-5 years= 30%

* Assumption: Data under age 1 group cannot be broken down to 2-12 months; the group working on forecasting decided to use the full number of children in that age group.

Incidence of pneumonia:
0.27 episodes of pneumonia/child/year
* CHERG estimates

STGs (varies by source of treatment):
STGs at Facilities:

2 months –12 months: one 250 mg tablet 2 times per day for 5 days = 10 x 250 mg tablets/course of treatment
1 year– 3 years: two 250 mg tablets 2 times per day for 5 days = 20 x 250 mg tablets/course of treatment
3 year– 5 years: three 250 mg tablets 2 times per day for 5 days = 30 x 250 mg tablets/course of treatment
STGs at CHW level
2 months –12 months: one 250 mg tablet 2 times per day for 5 days = 10 x 250 mg tablets/course of treatment
1 year– 5 years: two 250 mg tablets 2 times per day for 5 days = 20 x 250 mg tablets/course of treatment

Percentage seeking care for ARI/pneumonia (any source): 65%
Percentage seeking care from CHWs: 40%
Of those seeking care, percentage seeking care from CHWs: 30%

(box 20 continued on following page)

Box 20. Continued

	Input	Current Year	Forecast Year 1	Forecast Year 2
Total population		50,000,000	51,645,000	53,344,121
Under 5 population		5,000,000	5,164,500	5,334,412
Pneumonia				
Annual incidence (episodes/child/year)	*0.27*	1,350,000	1,394,415	1,440,291
% seeking care for ARI/pneumonia (from any source)	*65%*	877,500	906,370	936,189
% seeking care from public sector health facilities (of those seeking care)	*45%*	394,875	407,866	421,285
% seeking care from CHWs (of those seeking care)	*30%*	263,250	271,911	280,857
Amoxicillin - age breakdowns % treated at health facilities				
2–12 months	*33%*	130,309	134,596	139,024
1–3 years	*37%*	146,104	150,911	155,876
3–5 years	*30%*	118,463	122,360	126,386
Amoxicillin - age breakdowns % treated by CHWs				
2–12 months	*33%*	86,873	89,731	92,683
1–5 years	*67%*	176,378	182,180	188,174
Amoxicillin - tablets for treatment at health facilities				
2–12 months	*10*	1,303,088	1,345,959	1,390,241
1–3 years	*20*	2,922,075	3,018,211	3,117,510
3–5 years	*30*	3,553,875	3,670,797	3,791,567
Amoxicillin- tablets for treatment at CHWs				
2–12 months	*10*	868,725	897,306	926,827
1–5 years	*20*	3,527,550	3,643,606	3,763,481
Total tablets of amoxicillin		12,175,313	12,575,880	12,989,627

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Zinc and Oral Rehydration Salts

Product Description, Indications, and Considerations for Use

Diarrhea affects large numbers of children around the world and continues to be a leading cause of mortality in children under five, despite the availability of simple and inexpensive treatment. Death from acute diarrhea is most often caused by dehydration—the loss of a large amount of water and salt from the body. For cases of diarrhea in children under five, WHO guidelines recommend treatment with oral rehydration salts (ORS) and zinc to prevent and treat dehydration before it becomes severe.

ORS prevents dehydration and the need for intravenous therapy. Zinc decreases the duration and severity of diarrhea and the likelihood of future diarrhea episodes in the following 2–3 months by replacing zinc lost during the episode.[1, 2]

The recommended product specifications are for the low osmolarity formulation of ORS in 250 ml, 500 ml, or 1 L sachets, depending on local guidelines. While the 1 L sachet is the most common, it is frequently too much liquid for one child to consume in a day. Once mixed, any unused solution should be discarded within 24 hours; therefore smaller sachets may be more appropriate. Further, households may be more likely to have an existing jug or container to mix smaller quantities, which will help ensure the correct amount of liquid is used to create the solution.

ORS is available flavored and unflavored. Unflavored ORS tastes salty and most children report preferring flavored ORS and this increases acceptance. However, flavor selection should take into account locally acceptable tastes and be pretested with children. ORS requires access to clean water for mixing the solution. Health care workers may need to be trained to explain and demonstrate how to mix the ORS and demonstration may require additional materials, like jugs of the appropriate size, spoons, and cups.

The recommended product for zinc is a taste-masked dispersible tablet (DT). UNICEF defines dispersible tablets as “uncoated or film-coated tablets that can be dispersed in liquid before administration giving a homogenous dispersion.”[3] Dispersible tablets can be dissolved in water or a small amount of breast milk and usually disintegrate within a minute or so. Zinc has a strong metallic taste so tablets should be appropriately taste-masked to increase acceptability by children and encourage completion of a full course of treatment.

The recommended product specifications for zinc are 20 mg scored dispersible tablet in blister packs of 10. Some countries are currently using zinc 10 mg dispersible tablets in the blister packs because they avoid health care workers or caregivers’ need to split tablets for children under six months. Some countries are currently using zinc syrups; and so there may not be a need to change to dispersible tablets, especially in private sector outlets where consumer preference might be for syrups, driving that demand. However, dispersible zinc tablets are smaller in weight and bulk and tend to have a longer shelf life than syrups, which may make them more suitable for distribution in many settings, especially to lower levels of the health system.

It is strongly recommended that only one strength is selected so that health workers are not confused and the supply chain is not complicated unnecessarily by an additional product in the supply chain. The product selected should support the standard treatment guidelines (STGs) and where possible avoid the need to split tablets to prevent sub-optimal dosing through uneven breaking, as any manipulation before consumption introduces potential contamination and degradation caused by zinc’s sensitivity to humidity. This sensitivity also

requires enhanced packaging to ensure efficacy until the tablets are consumed by patients, typically aluminum/polyvinyl chloride (PVC) blisters or aluminum strips to ensure stability and efficacy.

Forecasting Considerations – ORS and Zinc

For both ORS and zinc, care-seeking limits treatment. All children with diarrhea should be treated with ORS and zinc but a large number of care givers do not seek treatment for mild symptoms, despite the fact that ORS is a well-known product and has been in use and available in many countries for years. For those who seek treatment, most are receiving suboptimal treatments (e.g., antibiotics and anti-diarrheal drugs).

Limited use of zinc to date means that few countries have robust demand for this product and will need to focus on demand generation and awareness-raising to increase uptake and use.

Interventions to improve demand of these products among caregivers and providers are being implemented by partners in selected countries as part of several global initiatives, namely the Diarrhea and Pneumonia Working Group for the UN Commission on Life-Saving Commodities for Women and Children. For providers, this may include supportive supervision and trainings to change practices such as overuse of antibiotics. For caregivers, this may include mass media, mid media (e.g., flyers, brochures, community events, billboards), and community mobilization to encourage them to seek treatment for their child's diarrhea and request the appropriate product from their provider.

In some countries ORS or zinc are available over the counter (OTC) and not subject to the same regulatory requirements as other medicines. Some countries are testing co-packaging of ORS and zinc to increase use of both products together. Depending on where the co-packaging will be done (locally or from the manufacturer), the eventual procurement quantities may need to be adjusted and would likely be based on estimate of the number of children who will receive treatment. Co-packaging the two products should be considered carefully as it may require additional registration depending on the country regulatory requirements. Additionally, it is important to ensure that co-packaged products have similar expiry dates to ensure the entire co-package is viable for a reasonable length of time given current consumption patterns and the length of the supply chain to intended recipients. Currently, most ORS has a shelf life of three years and most zinc tablets have a shelf life of two years; manufacturers are working on extending the shelf life of zinc to three years. Zinc syrups typically have one year shelf lives.

Another consideration is that many countries face challenges of having enough ORS stock on hand in anticipation of cholera outbreaks, based on seasonality or other patterns documented in the country. When large quantities are stocked, they tend to expire, so when orders are reduced and then cholera strikes, there is usually a shortage/stock-out. It may be necessary to include assumptions about cholera outbreaks and buffer stocks in anticipation of a potential outbreak.

Quantification teams may find the following programmatic assumptions relevant for estimating the number of cases of childhood diarrhea and the quantities of ORS and zinc required to treat them:

- All children under five with diarrhea should receive ORS and zinc together

- Current estimates of diarrhea incidence rates in low- and middle-income countries range from 2.1 to 5.6 episodes diarrhea/child/year; the average is 2.9 episodes/child/year, but incidence rates also vary by age (higher in children age two and under). The Child Health Epidemiology Reference Group has provided updated estimates for many countries.[4]

- It is important to note that many caregivers of children with mild cases of diarrhea never seek care or treat at home so these incidence rates should be understood as providing estimates of the upper-bounds of potential cases.

- DHS, MICS, and other surveys provide estimates of where children and their caregivers seek care – by type of facility and those not seeking care.

Current WHO guidelines for treatment of childhood (non-severe) diarrhea:

ORS	Low–osmolarity	less than 2 years	50–100ml after each loose stool
ORS	Low–osmolarity	2–5 years	100-200ml after each loose stool

Depending on the size of the sachet provided, it is recommended that children receive the number of packets equivalent to two liters of mixed solution. Once mixed the solution can only be used for 24 hours and then should be discarded.

Zinc	20 mg dispersible tablets	2 months–6 months	½ tablet 1x per day for 10–14days	5-7 tablets*
		6 months–5 years	1 tablets 1x per day for 10–14 days	10–14 tablets

* In reality healthcare workers may be instructed to dispense 10-14 tablets and caregivers asked to dispose of the split half tablet; local practices should inform this assumption.

Guidelines for treatment with zinc vary from 10 to 14 days.

Summary of Data Needed for Forecasting for ORS and Zinc

- Target population
    - No. of children under age five by age band (per STGs)
    - Diarrhea incidence in children under age five (estimated # of episodes/child/year)
    - Percentage of children (or their caregivers) who will seek care or treatment
- Standard treatment guidelines for treatment of diarrhea
- Programmatic changes that would affect consumption of ORS or zinc (increase in service provision, demand generation activities, a policy change to make zinc available as an over-the-counter medicine)
- Scope of quantification–types of facilities, sectors (public, private, NGO, etc.) that will be included

Potential data sources are listed in table 15. It is critical to document all data and assumptions that are used in the process of forecasting. This makes it possible for others to review and also to update/revise data and assumptions if better information becomes available.

The forecasting formula is:

Number of children with diarrhea in an age band who will receive treatment multiplied by the number of ORS sachets and zinc dispersible tablets in a course of treatment for that age band

Table 15. Potential Sources of Data for Forecasting Consumption of Oral Rehydration Salts and Zinc using Morbidity Method

Data	Source	Limitation
Quantification		
Total population	National census data	Data may be older/outdated; may need to apply estimated annual growth rate to project to forecast years
Population age 5 and under; including breakouts by age bands	Census data, DHS	Age bands may not be precise; will have to make assumptions to match numbers with age groups STGs; if STGs are by weight band will have to make assumptions about ages of children
Incidence of diarrhea	Survey data; CHERG estimates	
Proportion of children (caregivers) seeking care by sector/type of facility	DHS, MICS, HMIS, special surveys	This data may not be current and may not reflect recent changes that would affect care-seeking (i.e. introduction of zinc as over the counter or provided through iCCM)
Dosage recommended	National Standard Treatment guidelines; WHO guidelines if not available	Providers may not always follow dosage recommended
STGs	National essential medicine program, WHO, Ministry of Health, surveys	Guidelines may propose different medicines for the same condition; STGs not always used by health providers
Programmatic changes	Child Health, IMCI/iCCM Programs, others	Projected changes may not be known or it may be difficult to estimate their impact

Forecasting Method using Morbidity Data

1. Calculate the target population that will receive ORS and zinc for diarrhea. This is done in two steps:
    a. Calculate the estimated number of children under five who will fall sick with diarrhea during the forecast period (generally annual estimates)
    b. Estimate the number of children with diarrhea in each age band per STGs
2. Adjust for programmatic changes including treatment targets, demand generation activities, or service delivery
3. Calculate the number of sachets of ORS and tablets of zinc needed for each case for the treatment of diarrhea by age band (per national STGs)
4. Calculate the quantity of ORS sachets and zinc tablets needed for treatment of diarrhea for the forecast period

1. Calculate the target population who will receive ORS and zinc for diarrhea

1a. Calculate the estimated number of children under five who will fall sick with diarrhea during the forecast period (generally annual estimates)

According to WHO, children under five with diarrhea should receive ORS and zinc together upon the first signs of diarrhea in order to avoid progression to more severe illness and, potentially, death. ORS and zinc are therefore needed wherever children may be taken to receive care, with the greatest need likely in primary health care facilities, drug shops, and with CHWs, in countries where iCCM has been implemented. In the absence of robust consumption or services data, estimates of morbidity and care seeking will be needed to estimate the quantities required.

- Number of children under five in geographic area under consideration
- Percentage of children under 5 by age or weight band per the STGs for diarrhea*;* Using WHO guidelines:
  - ORS
    - All children under age 5
  - Zinc
    - 2–6 months, %
    - 6–59 months, %
- Estimated incidence of diarrhea for children under age 5 in that area (generally provided as an estimate of episodes/child/year). The Child Health Epidemiology Reference Group has recently published updated estimates of diarrhea incidence for many low and middle income countries.[5] Diarrhea incidence is highest in children age two and under so it may be possible to break out incidence by age band.
  - Diarrhea incidence in low and middle income countries ranges from 2. – 5.6 episodes diarrhea/child/year; average around 2.9 episodes/child/year

As noted earlier, these estimates tend to represent the upper-bounds as many cases are mild and caregivers will treat at home or not seek care. The local context is important and there may be surveys of diarrhea and care-seeking done locally that will provide better estimates of incidence.

Note on incidence: DHS and MICS surveys provide estimates of 2-week prevalence of diarrhea based on caregiver recall. While this data is useful for other reasons, it is not the preferred input to a forecast for diarrhea as it requires a calculation to convert to annual prevalence and then annual incidence and the data itself is affected by the season of when the two-week survey was conducted. If it is necessary to do this calculation, WHO provides guidance on appropriate conversion methodology in Appendix R of the 1994 publication *Household survey manual: diarrhea and acute respiratory infections.*[6] [7]

1b. Calculate the target population that will receive treatment for diarrhea

While step 1a should provide a good estimate of the number of children that would need treatment for diarrhea, the reality is that due to care seeking behavior is unlikely that 100% of the population in need will receive treatment. That means that if a forecast concludes with all children who would be ill with diarrhea it will overestimate the demand for medicine. Further, depending on the scope of the quantification, it is important to consider where children would be receiving care. For instance, if the forecast is only for public sector facilities, information about where people in the population seek care is critical. Therefore, it is important to adjust this figure based on data for the local context:

- Percentage of children (caregivers) who seek care for symptoms of diarrhea
- Percentage of children (caregivers) who seek care by source

- Private sector (may be further broken down to include clinics, pharmacies, shops, etc.)
- Public sector (may be further broken down by hospitals, health centers, CHWs, etc.)
- Do not seek care

These assumptions will be applied to the estimates of cases of diarrhea to determine the numbers of children who will be seeking care at each type of facility.

A forecasting algorithm (Figure 11) is a good way to visualize this process, think through assumptions, and help identify where decisions need to be made regarding specific assumptions. While many of the inputs for zinc and diarrhea are the same given the different age bands used in most STGs it may be helpful to have two forecasting trees, one for each product.

2. Adjust for programmatic changes including treatment targets, demand generation activities, or service delivery

While historical data can be useful to inform a forecast based on the amounts and methods by which a product has been distributed in the past, it may be necessary to make adjustments based on assumptions of program changes that are happening or will happen in the span of the forecast. Given the emphasis on increasing treatment for diarrhea to improve child survival outcomes there may be efforts underway locally that would increase demand. For example, in countries where ORS is available widely but zinc is not, there may be effort to change that policy so that zinc can be sold as an over the counter product alongside ORS. There may also be demand generation activities underway to increase caregiver and provider awareness of the efficacy of ORS and zinc and to increase care-seeking behavior and use of these two products. This will require assumptions about the rate of increase and would need to take into account a realistic timeline for seeing the effects of these efforts.

Several countries may have already identified coverage targets for scale-up for zinc and ORS through national scale-up plans for child essential medicines or as part of global Initiatives.[8] For example, the Global Action Plan for the Prevention and Control of Pneumonia and Diarrhea (GAPPD)[9] set ambitious targets of 90% access to appropriate pneumonia and diarrhea case management (with 80% coverage in every district). Using this target it is possible to estimate the quantities of ORS and zinc needed to reach this level of treatment coverage. However, these goals are understandably ambitious and the forecast should consider the starting point of treatment use and demand and set realistic time frames for achieving these targets. If the forecast is for two years and starting usage/coverage rates for ORS are 40% and 10% for zinc it is unlikely that an increase to 90% in two years is realistic, unless there is significant investment in scale up, demand generation, and increasing treatment availability.

Depending at what level these assumptions are made these may require adjustments to the estimates made in Step 1b or may require overall adjustments to the number of children receiving treatment. For example, if there was a policy change to start allowing zinc to be sold over the counter, you would need to estimate the % that would start to receive treatment from shops and how that would affect current care-seeking. That is, it might reduce the number of children who receive care at health facilities but may also increase the percentage that seek care at all (reducing the % that do not seek care). If a pilot has been conducted, it may be possible to extrapolate data on that to inform these estimates. Otherwise, it will be important to consult with program experts to help inform these assumptions. This underscores the need to frequently review and revise forecasts

as more data becomes available – to either validate the assumptions that were made or revise them and make adjustments to the supply plan as needed.

3. Calculate the number of sachets of ORS and tablets of zinc needed for each case for the treatment of diarrhea by age or weight band (per STGs)

Using the STGs, determine the units of each product that will be needed for each age group. For instance, using the WHO recommended STGs we see that the youngest age group requires 5-7 tablets of zinc 20mg dispersible tablets for a course of treatment and the older age group requires 10-14 tablets of zinc 20mg dispersible tablets. In practice though, providers that split tablets may dispose of the other half tab and may actually require 10-14 tablets. This will depend on how the health workers have been trained to dispense and the course of treatment adjusted accordingly.

Zinc	20 mg dispersible tablets	2 months–6 months	½ tablet 1x per day for 10-14 days	5–7 tablets
		6 months–5 years	1 tablet 1x per day for 10-14 days	10–14 tablets

Depending on the size of the sachet provided, it is recommended that children receive the number of packets equivalent to two liters of mixed solution for a course of treatment[10]: one is used each day

ORS	Low-osmolarity	< 2 years	50–100 ml after each loose stool
ORS	Low-osmolarity	2–5 years	100–200 ml after each loose stool

4. Calculate the quantity of ORS sachets and zinc tablets needed for treatment of diarrhea for the forecast period

First, multiply the population of interest (children under 5 by age band, per the STGs) by the estimated diarrhea incidence (age-specific, if available) to arrive at the estimated number of cases in each age band annually for the population.

Numbers representing both age bands (or however many age bands are included in the STGs) would then be multiplied by the % seeking care by sector/channel and/or any programmatic change assumptions. The estimates of number of children in each age band and by channel would then be multiplied by the number of sachets or tablets in the respective course of treatment for each product.

The quantities of product needed per age band should be totaled to give the total quantity required across all age bands.

Additional Products, Consumables, or Equipment Required

To dissolve dispersible zinc tablets to create a solution for infants and young children a small amount of clean water or breast milk may be used so spoons or small cups may be needed. ORS requires clean water to create the solution for drinking. If health workers demonstrate how to mix and give to children, they will need an appropriate sized jug or container (depending on size of ORS sachet), spoons, and cups as will the caregiver to mix the ORS in their home.

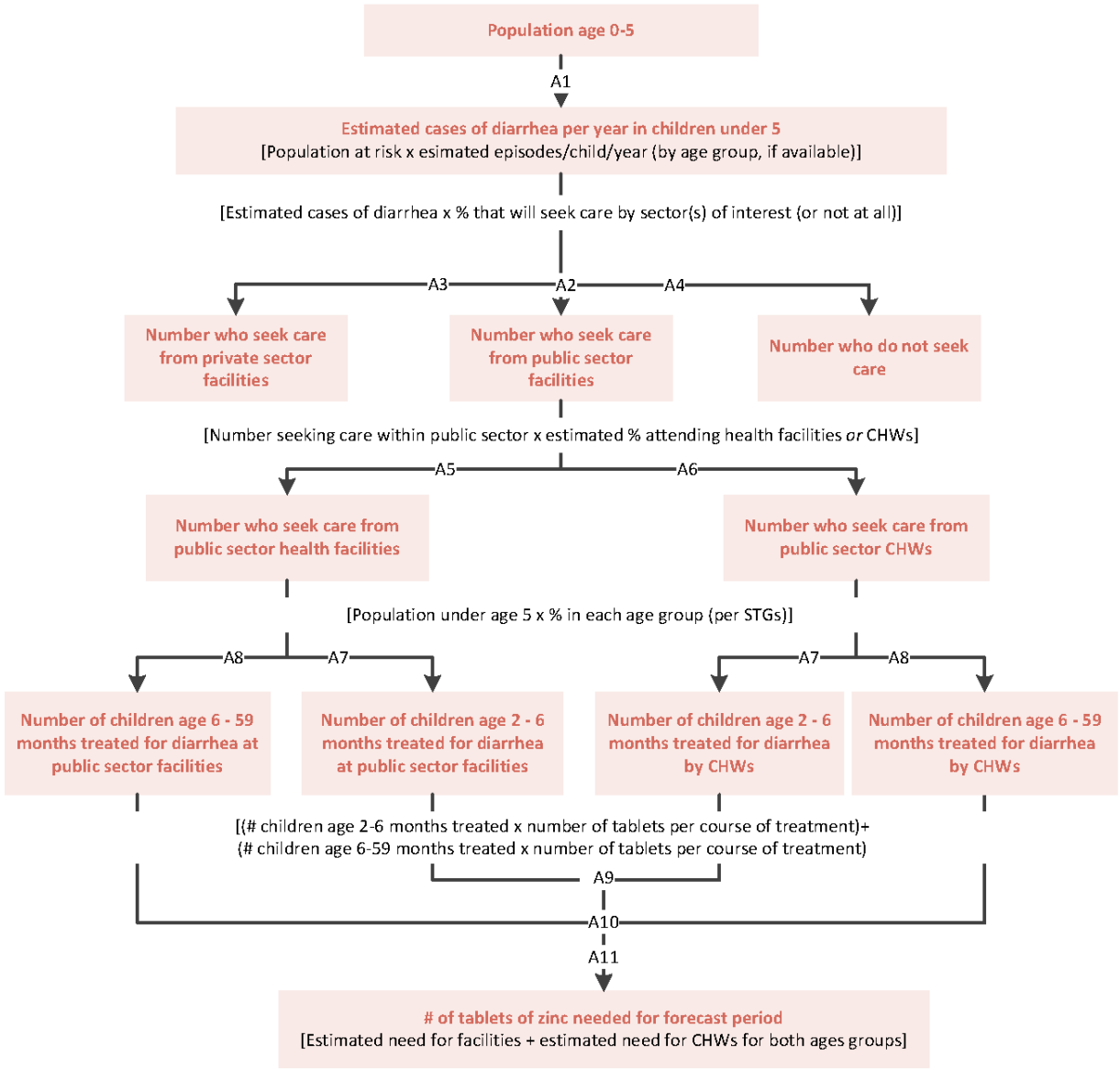
Product Availability

There are many suppliers of ORS and zinc tablets. There are currently two WHO-prequalified suppliers of zinc 20 mg dispersible tablets and many local manufacturers who are producing quality zinc and ORS products. For a complete udpated list please also see the list of zinc manufacturers maintained on the Zinc Task Force website– http://www.zinctaskforce.org/supply-commodities/ and the WHO List of Prequalified Medicinal Products - http://apps.who.int/prequal/

Forecasting Algorithm for Zinc

This algorithm is meant to be an example only of how to set up a forecasting tree to estimate cases of diarrhea that will be treated and then convert that to sachets of ORS or tablets of zinc using local STGs. This example is set up to broadly show a breakdown of treatment estimates for public and private sectors. However, countries/programs using this would have to adapt it depending on the scope of their quantification (private sector or public sector, different types of outlets/levels of a health system, geography, program, etc.) and local context—and make assumptions/adjustments to include estimates for what additional number of patients would be reached via scale up efforts (or future expected coverage via additional channels). The point of this example is to provide some ideas and possible algorithm structure, but it will always be up to the quantification team with the local knowledge to develop the assumptions they will use to build their forecast. The major audience of this guide will use it for quantification in the public sector; however the same principles apply to the private sector although the process is much more complicated given the different sectors of the private sector, especially considering that treatment of diarrhea can be available in numerous types of private outlets. An approximate % of potential users would still be required for each type of outlet to be able to estimate the need for ORS and zinc for the private sector. Additionally there are many other variables in the private sector affecting consumer choice, such as branding.

Figure 11. Sample forecasting algorithm for zinc tablets for treatment of diarrhea in children under 5 in the public sector (including CHWs)



Assumptions for figure 11

A1	Incidence of diarrhea in children under 5 (episodes/child/year)
A2	Children/care givers who seek care for diarrhea from the public sector, %
A3	Children/care givers who seek care for diarrhea from the private sector, %
A4	Children/care givers who do not seek care for diarrhea, %
A5	Children with diarrhea/care givers who will seek care from a public sector facility, %
A6	Children with diarrhea who will seek care from a public sector CHW, %
A7	Children 2–6 months with diarrhea, %
A8	Children 6–59 months with diarrhea, %
A9	No. of tablets needed for course of treatment for children 2-6 months
A10	No. of tablets needed for course of treatment for children 6-59 months
A11	Total number of tablets

The figure above illustrates the steps to follow when quantifying for zinc for the treatment of diarrhea in children age five and under. This example is looking at the forecast for public sector health facilities, breaking out patients seen at health facility level and by CHWs. It could be modified to include/exclude other sectors or types of facilities as needed, though it is worth checking assumptions on what products private sector service providers are dispensing as they may be different formulation the public sector.

The steps would be similar to forecast for ORS; the changes would be in the age groups, per STGs and in the number of sachets per course of treatment. The final result is the estimated annual need for ORS and zinc for childhood diarrhea in the public sector; however, this estimated need should not be used for procurement, because it does not take into consideration quantities already in the supply chain, and quantities already on order. The estimated need will be used along with other data during the supply planning step to determine the quantity to order and on what schedule.

Box 21. Example of country forecast for ORS and zinc

Country *X* wants to know the amount of zinc 20 mg dispersible tablets and ORS sachets needed by their public sector CCM program for CHWs to treat children under age 5 for diarrhea for the next two years.

Data available is as follows:

Total population: 50 million (current year)
- Population growth rate: 3.29%
- Population under age 5: 5 million (current year)*

* Assumption: % of children under age 5 remains constant at 10% annually

Incidence of diarrhea—2.9 episodes of diarrhea/child/year*
* CHERG estimates

Population under 5 by age group, likely to have diarrhea
- 0–6 months = 10%*
- 6 months to 5 years = 90%

* This is not half of the percentage in the 0-1 year group, due to lower incidence of diarrhea in the 0 to 6 month age group for children whose mothers exclusively breastfeed; additionally, data was not available to break out the group under 2 months for zinc treatment so the quantification committee decided to use the same assumption for 0-6 months

STGs – zinc 20 mg dispersible tablets
- 2–6 months—1/2 tablet 1 time per day for 10 days = 5 tablets/course of treatment
- 6 months–5 years—1 tablet 1 time per day for 10 days = 10 tablets/course of treatment

STGs–ORS 1 L sachets
0–5 years—all children receive 2 sachets

Percentage seeking care for diarrhea (any source): 55%
Percentage seeking care from CHWs: 40%
Percentage of cases seriously dehydrated requiring referral to a higher level facility: 8% (local estimate based on available service data)

(box 21 continued on following page)

Box 21. Continued

	Input	Current Year	Forecast Year 1	Forecast Year 2
Total Population		50,000,000	51,645,000	53,344,121
Under 5 years Population		5,000,000	5,164,500	5,334,412
Diarrhea				
Annual incidence (episodes/child/year)	2.9	14,500,000	14,977,050	15,469,795
Patients seeking/obtaining care (from any source), %	55%	7,975,000	8,237,378	8,508,387
Patients seeking/obtaining care from CHWs, %	40%	3,190,000	3,294,951	3,403,355
Percentage of severe cases (Number of cases referred)	8%	255,200	263,596	272,268
Patients with some or no dehydration (Number of cases treated)	92%	2,934,800	3,031,355	3,131,086
Zinc				
• Under 6 months	10%	293,480	303,135	313,109
• 6 months–5 years	90%	2,641,320	2,728,219	2,817,978
ORS				
• 0–5 years	100%	2,934,800	3,031,355	3,131,086
Zinc—tablets for treatment				
• 2–6 months	5	1,467,400	1,515,677	1,565,543
• 6 months–5 years	10	26,413,200	27,282,194	28,179,778
ORS—sachets for treatment				
• 0–5 years	2	5,869,600	6,062,710	6,262,173
Total tablets of zinc		27,880,600	28,797,872	29,745,322
Total sachets of ORS		5,869,600	6,062,710	6,262,173

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[4] Christa L Fischer Walker[1*], Jamie Perin[1], Martin J Aryee[2], Cynthia Boschi-Pinto[3] and Robert E Black[1] *Diarrhea incidence in low- and middle-income countries in 1990 and 2010: a systematic review* BMC Public Health 2012, 12:220 http://www.biomedcentral.com/1471-2458/12/220 - See Additional File **2** Diarrhea Incidence Rates for Included Countries for country specific data http://www.biomedcentral.com/1471-2458/12/220/additional

[5] Christa L Fischer Walker[1*], Jamie Perin[1], Martin J Aryee[2], Cynthia Boschi-Pinto[3] and Robert E Black[1] *Diarrhea incidence in low- and middle-income countries in 1990 and 2010: a systematic review* BMC Public Health 2012, 12:220 http://www.biomedcentral.com/1471-2458/12/220 - See Additional File **2** Diarrhea Incidence Rates for Included Countries for country specific data http://www.biomedcentral.com/1471-2458/12/220/additional

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[10] IMIC chart booklet 2008 http://whqlibdoc.who.int/publications/2008/9789241597289_eng.pdf and CHW chart booklet

SECTION 3: TOOLS AND RESOURCES FOR QUANTIFICATION

Several resources that can be consulted for guidance on forecasting and supply planning have been mentioned throughout the document. The table on the following page provides a description of additional tools and resources including their purpose and where they can be found.

In addition, the following websites contain data on the prices of products:

UNICEF Supply Catalogue
https://supply.unicef.org/unicef_b2c/app/displayApp/(layout=7.0-12_1_66_67_115&carea=%24ROOT)/.do?rf=y

UNFPA AccessRH Product Catalogue http://www.myaccessrh.org/products

International Drug Price Indicator Guide
http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English

Tools and Resources for Quantification

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
Country Commodity Manager (CCM)	UNFPA; Joseph Abraham jabraham@unfpa.org	Computerized quantitative health supplies management tool used for central warehouses. Country Commodity Manager (CCM), a software program that helps UNFPA Country Offices assess their reproductive health commodity requirements, stock positions and identify shortfalls. CCM also provides a mechanism to readily transmit each country's data to UNFPA headquarters from their country offices for use in generating global level reports for the purposes of planning, advocacy and resource mobilization.	Quantification Inventory Management	Software tool	UNFPA Country Offices	Software Visual basics based	Finalized	English French Russian Spanish	Has been used in many countries and adapted for many products and commodities
CHANNEL	UNFPA; Joseph Abraham jabraham@unfpa.org	Computerized quantitative health supplies management tool for warehouses and service delivery points. Can also be used for forecasting and procurement planning. It's been used in many countries	Quantification Inventory Management	software tool	MoH/SDPs	Software, visual basics based	Finalized	English French, Portu-guese, Russian, Spanish	Many focus countries under the UNFPA Global Program to Enhance RHCS(GPRHCS)
Quantification techniques	UNFPA; Kabir Ahmed kahmed@unfpa.org AND sarker@unfpa.org	Assist countries to strengthen their forecasting (and quantification) capacities and distribution to increase access to priority essential lifesaving maternal health medicines.			Govt counterparts and SDP staff	Word doc and Excel file	Being finalized	English	Planned for using/piloting in selected UNFPA focus countries

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
A Forecasting Guide for New and Underused Methods (NUMS) of Family Planning	JSI, PSI, IRH	This guide provides direction to programs that want to forecast for new and underused methods (NUMs) of family planning. It supports program managers and others involved in forecasting as they plan to (1) introduce a contraceptive technology for the first time in a country, and/or (2) position an underused method for scale up. It offers a framework for building rational assumptions to support accurate forecasting for NUMs or any family planning method where future demand is inherently difficult to predict. It also identifies common pitfalls in NUMs forecasting and recommends strategies to avoid them.	Quantification	Guide	Central level	http://www.k4health.org/toolkits/NUMs-forecasting-guide http://www.k4health.org/site...ds%201st%20Edition%202012.pdf	Finalized	English, French, Spanish	
Quantification of Health Commodities: Contraceptive Companion Guide; Forecasting Consumption of Contraceptive Supplies	USAID | DELIVER PROJECT	The companion guide will assist when conducting a quantification of commodity needs and costs for short-acting, long-acting, and permanent methods of contraception. The guide describes the steps in forecasting consumption of contraceptive supplies; after which, to complete the quantification, the users should refer to the main quantification guide for the supply planning step.	Quantification Procurement	Guide	Program managers, MoH staff	http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/QuantHealCommConCompGuid.pdf	Finalized	English	Various countries

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
Quantification of Health Commodities: Laboratory Commodities Companion Guide; Forecasting Consumption of Laboratory Commodities	USAID | DELIVER PROJECT	To supplement the general guide, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement,* by describing, in detail, the specific methodology for forecasting consumption of laboratory commodities as a critical step in the overall quantification process.		Guide	Program managers, MoH staff	http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/QuanHealCommLabo.pdf	Finalized	English	Various countries
Quantification of Health Commodities: ARV Companion Guide; Forecasting ARV Drugs Using the Morbidity Method	USAID | DELIVER PROJECT	To describe the process and the methods used for forecasting ARV drug needs. This is a guide to help program and product managers manually conduct forecasts of ARV drug requirements. Is helpful when a software application is not appropriate or available for use.	Quantification	Guide	Program managers, MoH staff	http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/ARVQuantGuide.pdf	Finalized	English	Various countries
Quantification of Health Commodities: HIV Test Kit Companion Guide; Forecasting Consumption of HIV Test Kits	USAID | DELIVER PROJECT	The variability in HIV testing procedures, the multiple purposes of testing, and the different types of HIV test kits available pose particular challenges in managing HIV test kit supply chains. The primary focus and purpose of this companion guide is to supplement the general guide on *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement* by describing in detail the specific methodology for forecasting consumption of HIV test kits as a critical step in the overall quantification process.	Quantification	Guide	Program managers, MoH staff	http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/QuanHealtCommoHIVtestkit.pdf	Finalized	English	Various countries

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
Quantification of Health Commodities: Community Case Management Companion Guide	JSI - Supply Chains for Community Case Management (SC4CCM) Project	This companion guide describes a forecasting methodology that can be used by countries, programs, and partners to develop credible demand forecasts for CCM products, with an emphasis on the specific needs of pediatric products required at the community level, and to guide planning for procurement and funding.		Guide	Program managers, MoH staff, others supporting forecasting and quantification for CCM programs	http://sc4ccm.jsi.com/files/2012/12/CCMQuantGuide.pdf	Finalized	English	Malawi, Rwanda, Ethiopia
Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement	USAID | DELIVER PROJECT	To assist in (1) estimating the total commodity needs and costs for successful implementation of national health program strategies and goals, (2) identifying the funding needs and gaps for procurement of the required commodities, and (3) planning procurements and shipment delivery schedules to be able to ensure a sustained and effective supply of health commodities; The step-by-step approach to quantification presented in this guide is complemented by a set of product-specific companion pieces that provide detailed instructions for forecasting consumption of ARV drugs, HIV test kits, antimalarial drugs, and lab supplies.	Quantification	Guide	MoH staff, program managers, technical advisors, warehouse managers, procurement officers, and service providers	http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/QuantHealthComm.pdf	Finalized	English	Various countries
Using Quantification to Support Introduction and Expansion of Long-Acting and Permanent Methods of Contraception	USAID | DELIVER PROJECT	To build capacity in quantification for long-acting and permanent methods of contraception—in order for family planning programs to be able to effectively respond to current and future demand for these methods.		Tech-nical brief	MoH staff, program managers, technical advisors, warehouse managers, procurement officers, and service providers	http://deliver.jsi.com/dlvr_content/resources/allpubs/logisticsbriefs/TechBriefQuantLongTermMethods.pdf	Finalized	English	Various countries

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
ProQ	DELIVER	ProQ is a software tool that quantifies HIV test requirements based on realistic forecast demand, assessment of existing supply chain capacity, and availability of resources for procurement; ProQ offers four methodologies for quantifying HIV tests for national programs, and the software lets you compare different forecasts. Methodologies can be adapted to specific country settings, and can be used in both data-poor and data-rich situations. You can use ProQ to forecast for national, local, or NGO programs. Guidance is provided for quantification in countries where a variety of HIV test kit brands exist and are used for various purposes. The quantification methodologies include logistics projections, morbidity/population projections, service statistic projections, and target projections.	Quantification	Software tool	MoH staff, program managers, technical advisors, procurement officers	http://deliver.jsi.com/dhome/resources/tools/softwaretools/proq	Finalized	English, French and Spanish	Various countries
Resources for a Health Commodity Quantification: A CD Toolkit	USAID | DELIVER PROJECT	This toolkit brings together many USAID | DELIVER PROJECT resources together for easy access. The toolkit includes an interactive graphic depicting the steps in the quantification process, a quantification guide, commodity specific companion pieces, and country reports.	Quantification and Policy	CD of re-sources	MoH staff, program managers, technical advisors, warehouse managers, procurement officers, and service providers	http://deliver.jsi.com/dhome/resources/tools	Finalized	English	Various countries

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
Manual for Quantification of Malaria Commodities	SIAPS, MSH	Designed to provide users, especially those at the malaria program level including program managers, procurement officers, warehouse managers, implementing partners, donor agencies and others, with practical steps and guidance on how to carry out national-level quantification of ACTs and RDTs	Quantification	Guide	Program managers, procurement officers, warehouse managers, implementing partners, donor agencies and others	Print and electronic	Guide/ manual	English	Finalized
Quantimed-Pharmaceutical Quantification and Cost Estimation Tool	SPS, MSH; Kyle Duarte kduarte@msh.org	Quantimed facilitates the calculation of pharmaceutical needs—volumes of medicines and medical supply items and costs—for general health services or specific health programs. Quantimed is designed to improve the accuracy of order planning and budgeting by providing a systematic approach to organizing and analyzing data. Quantimed facilitates the calculation of commodity needs using either a single method or a combination of any of the three primary quantification methods: past consumption, morbidity patterns, and proxy consumption. The program also includes an option for scaling up morbidity-based estimates, which is useful for growing programs.	Quantification	Software tool	Central, District, Regional	http://www.msh.org/projects/sps/Resources/Software-Tools/Quantimed.cfm	Finalized	English, French	Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Mozambique, Namibia, Nigeria, Rwanda, Tanzania, Uganda, Vietnam, Zambia, and Zimbabwe

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
PipeLine 5: *Software and manual*	USAID | DELIVER PROJECT	The Pipeline Monitoring and Procurement Planning System (PipeLine) is a software tool that helps program managers gather critical forecasting information, ensure that products arrive on time, maintain consistent stock levels at the program or national level, and prevent stockouts. The user guide and addendum provide basic information on how to use PipeLine 5. It complements and should be read in conjunction with the PipeLine 4.0 User's Guide.	Monitoring & Evaluation, Planning & Budgeting, Procurement, Quantification	Software tool	Central, District, Facility, Regional	http://deliver.jsi.com/dhome/resources/tools/softwaretools/pipeline	Finalized	English, Spanish	
Country Profile Part 2	Global Fund, WHO and other partners; Marlon.Banda@theglobalfund.org	Recommended for GF proposal in complementarity with the procurement plan and the GF-WHO Harmonized pharmaceutical country profile. It covers the specific PSM areas of pharmaceutical and health products for HIV, TB and malaria programs.	Planning & Budgeting, Policy, Pricing, Procurement, Quality Assurance, Quantification, Selection, Storage, Use	Word doc tool	Central	Country Profile Template Part 2 April2011.doc	Finalized	English	
Procurement Plan	Global Fund; Joseph.Serutoke@theglobalfund.org	When developing a proposal for the PSM plan, this part is for filling the information related to quantities and costs of pharmaceuticals and health products needed by the HIV, TB and malaria programs.	Procurement, Quality Assurance, Quantification, Selection	Word doc tool	Central	Procurement Plan_en (2).doc	Finalized	English, French	

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
Immunization Forecast Tool	UNICEF; mcho@unicef.org	For an annual forecasting exercise of immunization supplies. Input: programmatic needs of each vaccine, device and cold chain equipment, wastage rate, normal buffer stocks, estimated coverage rate, target, stock-out info, monthly delivery schedules, funding sources and so on. Output: A provisional plan is issued to countries which submitted forecasts.	Quantification	Excel sheet tool		http://www.unicef.org/supply...orecast_Tool_2012_English.xls	Finalized	English, French	
Stock Monitoring Tool	United Nations Development Programme (UNDP); sviatlana.kavaliova@undp.org	Stock monitoring spreadsheet at central level, using data of average monthly consumption, stock level, and expiries to calculate when quantities need to be reordered and when to initiate procurement process.	Inventory management, Quantification	Excel sheet tool	Central	Stock Monitoring Template.zip	Finalized	English	
CHAI - ARV Procurement Forecasting Tool	CHAI; camole@clintonhealthaccess.org	When forecasting adult and/or pediatric ARV in treatment programs and when looking to manage demand on a clinic level. Inputs: - Current patients on txt - Treatment targets - Distribution over regimens - Required security stock - Drug prices & shipping - Central stock inventory. Outputs: - Demand for each formulation over next 24 months, taking into account current stock - Total cost.	Quantification	Excel sheet tool	Central, District, Facility, Regional	CHAI Simple Tool_29July2011.zip	Finalized	English	

Title	Authors and Contact Persons	Purpose	Topics covered	Type	Intended Audience	Format and Location	Status	Language	Country experiences
FoCaMed	medICT; g.kaasschieter@medict.nl	When forecasting ARV requirements. Inputs: ARV treatment regimens and protocols; Expected number of patients per treatment protocol, incl. scaling up; ARV order pack sizes and prices; Lead times; ARV dispensing data of individual patients (monthly). Outputs: Forecasted monthly consumption (monthly basis); procurement plan; ARV monitoring statistics (monthly basis).	Quantification	Software tool	Central, District, Facility, Regional	http://www.medict.nl/Focamed/content_002.cfm	Finalized	English	
Resuscitation Commodities Quantification Tool	Path; Fay Venegas fvenegas@path.org	When forecasting resuscitation equipment requirements at tertiary, secondary, and primary health facilities in-country. Commodity requirements include bags, masks, and suction devices, and are quantified based on the estimated number of rooms in the hospital or health facility.	Quantification	Excel sheet tool	Central, District, Facility, Regional			English	

Glossary

Consumption data: Data on the quantity of product dispensed or used over a specified period of time; the rate at which items are dispensed to clients or patients; usually measured in terms of units consumed within a specific period.

Couple-Years of Protection: The estimated protection contraceptive methods provide during a one-year period, based upon the volume of all contraceptives sold or distributed free of charge to clients during that period. The CYP is calculated by multiplying the quantity of each method distributed to clients by a conversion factor, to yield an estimate of the duration of contraceptive protection provided per unit of that method.

Demographic data: Data based on the number and characteristics of the population that will desire, require or be offered a service for which commodities are required (these are not products that are required to treat a health condition or disease).

Forecasting: Forecasting answers the question: "How much is needed, in quantities, to meet the health demand of the population?" Forecasting is the process of estimating the quantities of products that will actually be dispensed or used to meet the health needs of the targeted population during a specific future period of time. Forecasting can be based on historical consumption (quantities dispensed or used), services, morbidity and/or demographic data, and assumptions about future demand, program plans, and performance. When historical data are unavailable or unreliable, assumptions will also be needed to estimate program performance and product consumption. The supply plan is the final output of the quantification, and details the total product quantities and costs required to fill the supply pipeline taking into account lead times, minimum and maximum stock levels, and desired arrival dates of shipments, in order to ensure optimal procurement and delivery schedules.

Lead time: The time between placement of an order for supplies and receipt of the supplies at the medical store (or dispensary, depending on the level).

Morbidity data: Data on the prevalence and the incidence of a disease or health condition in a given population.

Pipeline: The entire chain of storage facilities and transportation links through which supplies move from the manufacturer to the consumer, including the port facilities, central warehouse, regional warehouses, district warehouses, all service delivery points and transport vehicles.

Pipeline stock: Stock that is in transit at various stages of the purchasing and distribution cycles

Procurement data: Information on amounts of products procured in the recent past by the national government, NGOs, or amounts planned for upcoming procurement.

Procurement period: The period of time between an order to a supplier and the next scheduled order.

Quantification: Quantification answers the question, "How much should be procured and when should it be delivered?" Quantification includes both forecasting and supply planning. It is the process of estimating the quantities and costs of the products required for a specific health program (or service), and determining when the products should be delivered to

ensure an uninterrupted supply for the program. Quantification takes into account the expected demand for commodities, unit costs, existing stocks, stock already on order, expiries, lead time, minimum and maximum stock levels, and shipping costs. Using this information, the total commodity requirements and costs for the program are calculated and compared with the available financial resources to determine the final quantities to procure.

Services data: Data based on number of visits, number of services provided, or number of cases treated over a specified period of time.

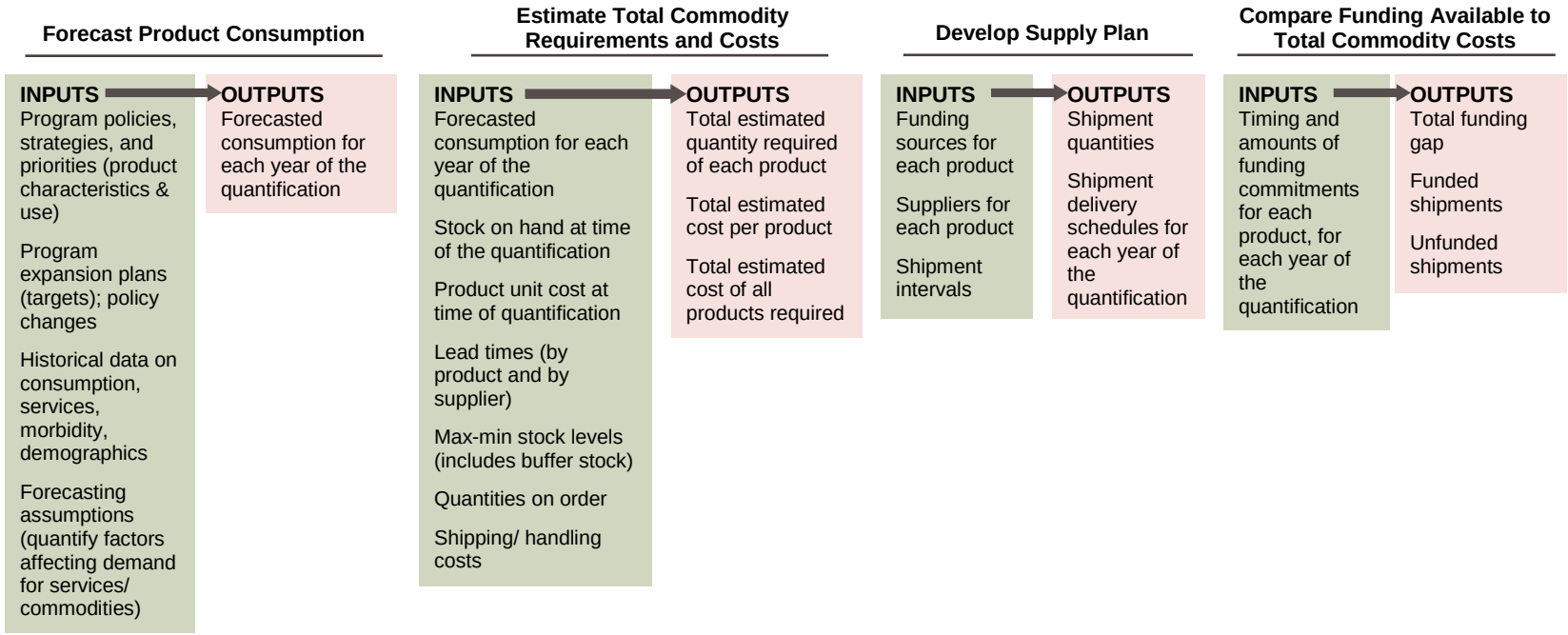
Stock on order: Any stocks that have been ordered but have not yet arrived; these stocks should be scheduled to arrive during the procurement period.

Stock on hand: The quantity of an item available for dispensing or distribution, including safety stock. It is also called working stock.

Supply planning: The supply plan is the final output of quantification, and details the total product quantities and costs required to fill the supply pipeline to ensure optimal procurement and delivery schedules, taking into account lead times, minimum and maximum stock levels, and desired arrival dates of shipments.

ANNEXES

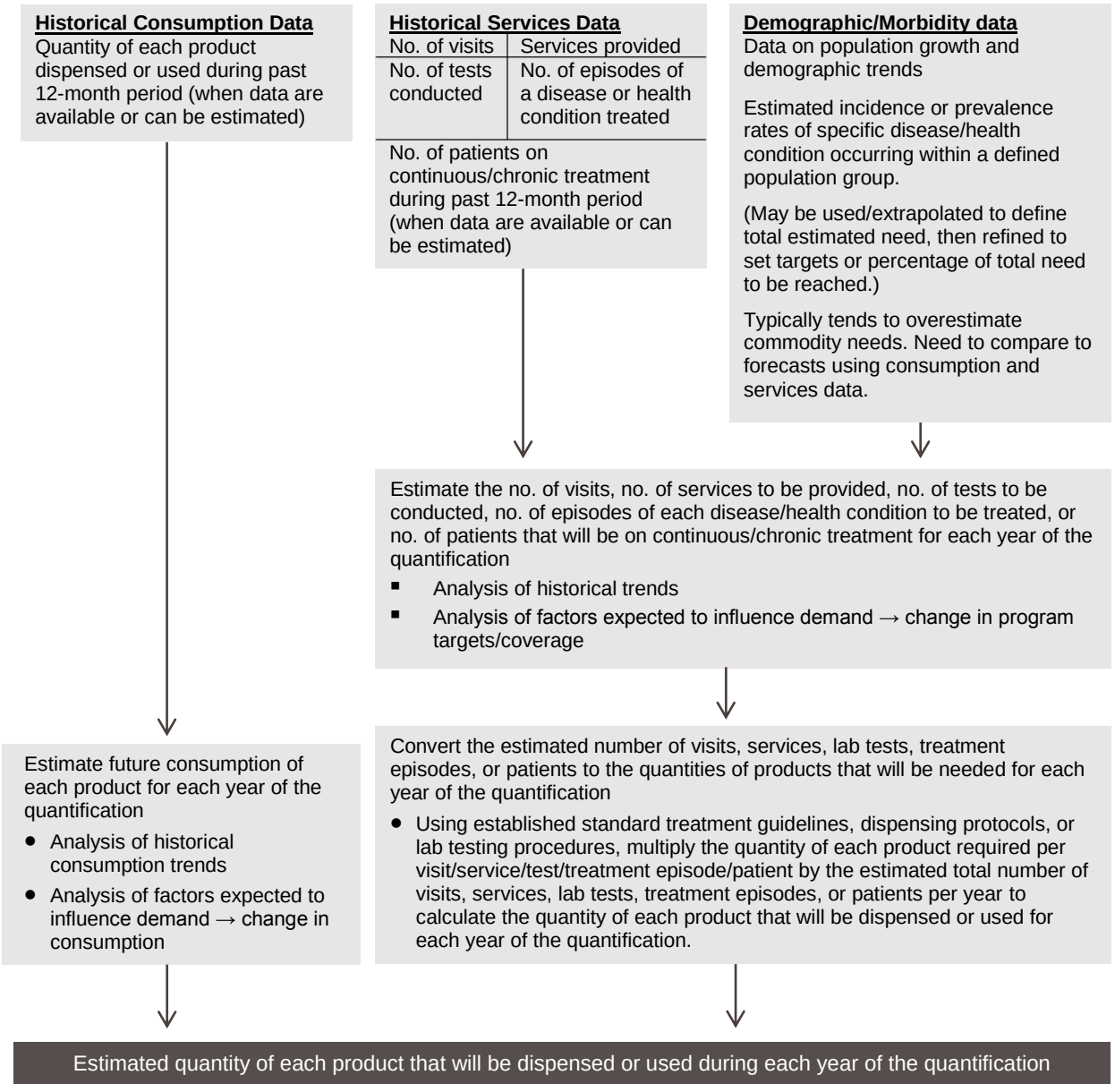
Annex A. Flow of Data in Quantification



Source: USAID | DELIVER PROJECT, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement*

Annex B: Types of Data Used for Forecasting Consumption of Health Commodities

Types of Data for Forecasting Consumption of Health Commodities



Source: USAID | DELIVER PROJECT, *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement*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