Quantification of Health Commodities

RMNCH

Supplement *for* Forecasting Consumption *of* Select Reproductive, Maternal, Newborn, and Child Health Medical Products

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USAID
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In this version, one chapter on post-partum hemorrhage was updated with funding from the Gates Foundation. The remainder of the document remains the same as the 2022 version revised by the US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program and the current update by Management Sciences for Health

ABOUT THE USAID MTAPS PROGRAM

The United States Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to higher-performing health systems. MTaPS focuses on improving access to essential medical products and related services and on their appropriate use to ensure better health outcomes for all populations. The program brings expertise honed over decades of seminal pharmaceutical systems experience across more than 40 countries. The MTaPS approach builds sustainable gains in countries by including all actors in health care—government, civil society, the private sector, and academia. The program is implemented by a consortium of global and local partners and led by Management Sciences for Health (MSH), a global health nonprofit.

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TABLE OF CONTENTS

ACRONYMS

ACS	antenatal corticosteroids
ANC	antenatal care
CBR	crude birth rate
CHW	community health worker
CPR	contraceptive prevalence rate
CSO	Central Statistics Office
CSW	commercial sex worker
CYP	couple years of protection
DHS	Demographic and Health Survey
DT	dispersible tablet
EC	emergency contraception
ECP	emergency contraceptive pill
EML	essential medicines list
FP	family planning
HF	health facility
HMIS	health management information system
HSC	heat-stable carbetocin
IM	intramuscular
IV	intravenous
LMICs	low- and middle-income countries
MgSO4	magnesium sulfate
MICS	multiple indicator cluster survey
MNCH	maternal, newborn, and child health
MOH	Ministry of Health
NGO	nongovernmental organization
ORS	oral rehydration salts
PGR	population growth rate
PPH	postpartum hemorrhage
PSBI	possible serious bacterial infection
QAT	Quantification Analytics Tool
RH	reproductive health
RHS	reproductive health survey
RMNCH	reproductive, maternal, newborn, and child health
SAM	severe acute malnutrition
STG	standard treatment guideline
STI	sexually transmitted infection
TXA	tranexamic acid
UNCoLSC	United Nations Commission on Life-Saving Commodities
WHO	World Health Organization
WRA	women of reproductive age

SUMMARY

This updated forecasting supplement will assist technical experts and program managers when conducting quantification of needs for specific essential reproductive, maternal, newborn, and child health (RMNCH) medical products. The RMNCH forecasting supplement can be used with the main guide—*Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement,*[1] which provides general guidance on quantification. This supplement describes the steps in forecasting consumption of these medical products based on the morbidity/demographic method of forecasting. To complete quantification, users should refer to the main quantification guide for the supply planning phase. It builds on the document produced under the United Nations Commission on Life-Saving Commodities Supply Chain Technical Resource Team and includes updated guidance from the World Health Organization (WHO).

REFERENCE

1. John Snow, Inc. 2017. Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement. Arlington, Va.: John Snow, Inc.

INTRODUCTION

BACKGROUND

Increasing access to and appropriate use of RMNCH medical products could save the lives of more than six million women and children per year.[1] In 2012, the United Nations Commission on Life-Saving Commodities (UNCoLSC) for Women and Children, a part of the "Every Woman, Every Child" initiative, focused on a set of priority medical products for RMNCH with diverse characteristics. Some were new products in the process of being introduced at scale, while others have been in use for many years but are underused or unavailable when needed or in the recommended formulation. A major component of access is availability, and to ensure availability, accurate and timely estimates/quantifications of supply requirements are needed.

For the sake of discussions in this document, quantification is defined as the process involving both forecasting and supply planning. See the section "Key Concepts and Considerations in Quantification" for more details.

At the national level, results of quantifications are essential for budgeting, resource allocation and mobilization, and planning for procurement and supply chain operations. At the global level, donors and manufacturers can use the information to plan for resources, procurement, and production. In addition, aggregated estimates of future requirements can be used by donors, international procurement agents, and other agencies to negotiate framework agreements and unit prices.

This supplement (an update of the 2022 version) 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 the public sector, including where support is provided by nongovernmental organizations (NGOs), the methodology is also relevant for the private sector to forecast medical product needs if the morbidity method of forecasting is to be applied.

MEDICAL PRODUCTS IN THIS SUPPLEMENT

The priority medical products considered in this supplement fall into four categories: reproductive health (RH), maternal health, newborn health, and child health. The initial UNCoLSC list, which was utilized in the 2016 version of the forecasting supplement, has been expanded to include new medical products recently recommended by WHO and other essential medical products that were not considered by the UNCoLSC. While recognizing that diagnostic reagents, supplies, and equipment (e.g., blood pressure machines, respiratory rate timers, pulse oximeters) are important in the management of the conditions addressed in this supplement, they are not included in this forecasting guidance.

REPRODUCTIVE HEALTH PRODUCTS: FAMILY PLANNING AND PREVENTION OF SEXUALLY TRANSMITTED INFECTIONS

Emergency contraceptive pills, female condoms, and contraceptive implants are the three RH medical products included in this supplement. Other family planning (FP) medical products are sufficiently covered in other resources.[2]

MATERNAL HEALTH PRODUCTS

The three UNCoLSC maternal health medical products—oxytocin and misoprostol (for preventing or treating postpartum hemorrhage [PPH]) and magnesium sulfate (for eclampsia and severe pre-eclampsia in pregnancy)—are included. In addition, this supplement includes other newly recommended medical products: heat-stable carbetocin (HSC) (for prevention of PPH) and tranexamic acid (for management of PPH as an adjunct treatment), calcium gluconate (to treat toxicity of magnesium sulfate [$MgSO_4$]), antihypertensive medicines such as hydralazine and methyldopa (for management of severe hypertension in pregnancy), and calibrated drapes (for measuring the level of blood loss during and after delivery to determine PPH).

NEWBORN HEALTH PRODUCTS

The four groups of newborn health products included in this supplement are antenatal corticosteroids (ACS) (for reduction of the risk of respiratory distress syndrome in preterm births); chlorhexidine (for newborn cord care); antibiotics (for possible serious bacterial infection or very severe disease that could also affect the post-neonatal period); and resuscitation equipment (to assist breathing for babies with apnea or bradycardia [i.e., babies who are not breathing or not crying]).

CHILD HEALTH PRODUCTS

Three child health products included in this supplement are amoxicillin (to treat pneumonia) and oral rehydration salts (ORS) and zinc (to manage diarrhea).

Although a limited number of priority RMNCH health products, as listed above, are covered in this forecasting supplement, quantification teams need to use other complementary resources, also referenced in this document, to quantify any additional commodities needed for the management of the conditions addressed. Once they master the document, quantification teams can apply the principles and calculation steps to other products.

PURPOSE OF THIS SUPPLEMENT

This supplement was developed to assist those involved in quantification of RMNCH medical products using best practice morbidity/demographic-based forecasting methodologies, based on demographic; morbidity (prevalence, incidence); and service data, to improve the quality of national-level forecasts of life-saving RMNCH medical products. Logistics/consumption-based methodologies that use consumption data may also be used in triangulating forecasts, but they are not covered in this supplement. This document should be used in conjunction with *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement*[3] (hereafter referred to as *Quantification of Health Commodities)*.

A typical forecasting exercise should cover two to three years and be revised annually. It is also strongly recommended that annual forecasts be revised every six months in line with prevailing service uptake or consumption trends.

This supplement does not provide general guidance on managing RMNCH programs, nor does it offer programmatic guidance on selecting or administering the products used in a country. Though it indicates WHO's recommendations for the treatment of health conditions covered, quantification teams need to rely on local standard treatment guidelines (STGs) and actual practice in forecasting for the conditions.

The output from the forecasting process—a list of specific products with estimates of consumption quantities that are outlined in this document—should not be used directly for procurement. Supply planning must be carried out to determine scheduling and quantity of each product that should and can be procured to ensure optimal availability of the products. Once a forecast is prepared using this supplement, the quantification team should refer to the *Quantification of Health Commodities*[3] for guidance on how to conduct supply planning.

BASIC CONTENTS

This supplement is organized by health conditions and services, including:

1. Reproductive Health: Family Planning and Prevention of STIs
2. Prevention and Treatment of Postpartum Hemorrhage
3. Prevention and Treatment of Hypertensive Disorders in Pregnancy
4. Reduction of Risk of Respiratory Distress Syndrome in Preterm Births
5. Newborn Resuscitation and Essential Care around the Time of Birth
6. Newborn Cord Care
7. Treatment of Possible Serious Bacterial Infection (PSBI) or Very Severe Disease in Newborns and Young Infants (0–59 days)
8. Treatment of Pneumonia in Children 2–59 Months
9. Treatment of Diarrhea in Children under 5 Years

The supplement provides background on the description/definition of each health condition, its global and regional incidence, and the WHO-recommended medical products and dosages for its management. In addition, the supplement provides information and guidance on the medical products used for the management of the respective condition, including:

- Product characteristics and other forecasting considerations, including common presentations, indications, administration, storage conditions and requirements, and total shelf life
- Other supply chain aspects, including program-specific factors that need to be considered when forecasting needs
- Additional supplies, consumables, or equipment required to administer the medical products to be considered in quantification exercises
- Recommended level of use according to the latest WHO guidelines
- Types of data needed for forecasting and potential sources of those data
- A sample forecasting algorithm for the morbidity method using demographic/morbidity and/or service data with calculation steps and formulae
- A list of proxy data and respective sources that can be used when local data are not available
- An example of the application of the assumptions, steps, and calculation formulae for the forecast of the medical products

This supplement also includes definitions of quantification (i.e., forecasting and supply planning) and related concepts, descriptions of processes followed during quantification, types of data for forecasting, other general considerations for quantification, references, and an inventory of tools that can be applied in quantification.

HOW TO USE THIS SUPPLEMENT

This supplement is intended to help program managers, supply chain technical experts, and service providers use what they know about the products they manage and the programs they implement to estimate the quantities of products that will be needed to serve their programs' clients in a given time period.

Prior to a quantification exercise for any of the priority medical products, facilitators and technical staff should review the relevant sections of this document to inform data definition, collection, and exercise planning. The references/links included in the document can also be used as additional resources to capture more detailed and region/country-specific data useful for the quantification exercise.

During the quantification exercise, this supplement can serve as a reference to build assumptions and undertake the actual forecasting. The algorithms and examples provide standard processes and steps to calculate the quantities of each product expected to be consumed during the forecast period. However, the quantification teams will need to adapt the sample forecasting assumptions, algorithms, calculation steps, formulae, and examples to fit the local context and the scope of the forecast being undertaken.

The document can also be used to identify additional resources, such as general and program-specific quantification guides/manuals, that provide more detailed guidance on quantification processes and methodologies and tools and can be used to carry out the actual quantification of the medical product groups, including supply planning.

In addition, the WHO recommendations referred to in the guide may be used to advocate for revisions to national RMNCH treatment protocols.

KEY CONCEPTS AND CONSIDERATIONS IN QUANTIFICATION

The following definitions are provided to harmonize vocabulary used in this document. These definitions are consistent with those used in the *Quantification of Health Commodities.*[3]

Quantification is the process of estimating the quantities and costs of the products required for a specific health program (or service) and determining when orders should be placed and delivered to ensure optimal availability of the products. It answers the questions, "What will be required by the program? What quantity of each product is estimated to be consumed? What needs to be procured and at what quantity and cost? When should it be ordered, and when should it be delivered?"

The two main sub-processes of quantification are:

- **Forecasting**: The process of estimating **quantities** of products required to meet demand (*to be used/consumed)* during a particular time frame. It answers the question, "How much is needed, in quantities, to meet the health demand of a defined group or population during a specific period?"
- **Supply planning:** The process of estimating **quantities** and **total costs** of products required for procurement and determining order quantities and desired receipt dates of shipments. Supply plans require forecast quantities from the first subprocess (forecasting) and knowledge of lead times, system inventory requirements (such as minimum and maximum and desired stock levels), preferred order intervals, stock on hand, remaining shelf life of existing stock, stock on order (pending shipment quantities) and arrival dates, total shelf life, wastage rates, freight and logistics costs, available budget, warehouse space, and other factors. It is **the final output of the quantification and** answers the questions, "What needs to be procured? How much of each product can/needs to be procured? What is the total cost of acquiring products? When should orders be made, and when should products be received?"

For definitions of additional terms related to quantification, consult the glossary at the end of this document.

TYPES OF DATA FOR FORECASTING

Availability and quality of historical and projected data is critical for forecasting. Data needed for forecasting can generally be classified into four types.

1. Consumption data: Quantities of individual medical products dispensed to users or issued to lower supply chain levels (proxy consumption) in a specific time frame. Issue quantities from stores/warehouses are used as proxy data when data on dispensed quantities to users from health facilities (HFs) are not available.
2. Demographic data: Information on population size and projections disaggregated by age, gender, awareness about health services, physical access to health service, etc.
3. Morbidity data: Information on incidence and/or prevalence estimates by condition.
4. Services data: Number of cases diagnosed, treated, or served by condition or subcondition.

When such data are not available locally, informed assumptions shall be formulated based on research/survey data; similar countries' experiences; and 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.

The nature of some of these medical products suggests that they are not currently used or available in sufficient quantities to achieve their maximum health impact, suggesting that historical data, either service or consumption, would often underestimate the potential demand. Thus, demographic and morbidity (prevalence and incidence) data and assumptions tempered with realistic service capacity, service readiness and the need for emergency medications, coverage targets and supply chain performance measures such as allocation and distribution, and product expiration shall be used to develop forecasts for these products in most developing country settings.

There may be a need to account for data that are missing, unreliable, outdated, or incomplete. How severely accuracy is affected and how this influences decision will depend on the seriousness of the data gap and should be noted. Limitations require a closer review of the available data, assumptions, and results and an understanding of the deficiencies and risks—financial and other—of using such assumptions, data, and results.

Data and data sources required for forecasting the medical products considered in this supplement are detailed below and in each section of the document.

It is important to note that quantification teams need to consider potential interventions/factors affecting future changes in demand (e.g., scale up plans).

DATA FOR FORECASTING AND SOURCES

A number of data are required to forecast demands of the medical products included in this supplement. Table 1 summarizes the type of data required to conduct forecasting using the morbidity/demographic method that is common to many of the conditions/products considered in this supplement. Condition/product-specific data needs and potential sources are provided in the respective sections.

Table 1: Common data and potential sources for forecasting using morbidity/demographic method

NO	DATA	CONDITION/PRODUCT	SOURCE	NOTES
1	Total population per year	All conditions/products	National census and projections, Demographic and Health Survey (DHS), US Census Bureau International Programs Database, UN world population projections, special survey reports	May be outdated; may need to apply estimated annual growth rate to project to forecast years; may not be reported as needed
2	Proportion/number of women 15–59 years	Female condoms		
3	Proportion/number of sexually active women 15–59 years	Female condoms		
4	Proportion/number of women of reproductive age (WRA) (15–49 years) or married women of reproductive age*	Emergency contraceptive pills (ECPs), contraceptive implants		
5	Proportion/number of female commercial sex workers (CSWs)	Female condoms		
6	Proportion/number of pregnant women per year	Maternal health conditions: PPH and hypertensive disorders of pregnancy	DHS, health management information system (HMIS), national maternal morbidity and mortality surveys, special surveys, program strategic plans	DHS data may be outdated; HMIS data may not be complete; HMIS does not collect data from the private sector
7	Proportion/number of deliveries by level/ sector (e.g., home, public HFs, private HFs)			
8	Crude birth rate (CBR)	Single-use resuscitation device, possible severe bacterial infection (PSBI) or very severe disease, chlorhexidine di gluconate	DHS, HMIS, RMNCH program reports, national maternal morbidity and mortality surveys, special surveys, program strategic plans	
9	Proportion/number of live births by sector/level of care (births attended by sector): Community/home, public HFs, private HFs			
10	Proportion/number of children under 5 years	Pneumonia, diarrhea	National census and projections, DHS, US Census Bureau International Programs Database, UN world population projections	May be outdated; may need to apply estimated annual growth rate to project for forecast years
11	Types and number of public HFs in the country (e.g., regional, provincial, and district hospitals; health centers; health posts)	Resuscitation and suction devices, MgSO4, calcium gluconate	Program reports, Ministry of Health (MOH), regional health bureaus, district medical offices, strategic plans/program targets; WHO maintains a database of HFs from selected countries that can be found at https://data.humdata.org/dataset/health-facilities-in-sub-saharan-africa?force_layout=desktop	May be outdated and could be different depending on the source of information. Obtain information from higher- and lower-level sources and verify.
12	Interventions/factors affecting future changes in demand (e.g., scale up plans)	All conditions/products	Maternal, newborn, and child health (MNCH) program; HIV program; strategic plans	If strategies to increase awareness and health service seeking behavior are under way, the forecast should consider these; ensure that funding and appropriate human resources are available to support the program plans and are in place before increases in consumption are forecast

*The "married women of reproductive age group" should be used instead of the "all WRA group" in countries where extramarital relations are seen as nonpermissible for cultural or religious reasons.

FORECASTING METHODOLOGIES

In general, forecasting methods can be classified into two broad groups—the consumption method and the morbidity method. Table 2 provides a comparison of the two methods.

Table 2: Comparison of the forecasting methods

	CONSUMPTION METHOD	MORBIDITY METHOD
Definition	Forecast based on the past usage trend of individual products	Forecast based on past trends of cases served/treated coupled with rate of use of medical products per case as defined by STGs or actual prescribing practices
Data needs	Consumption data coupled with stock-out days	Demographic, morbidity, and service data coupled with regimens and dosages/usage rates

IMPORTANT NOTES:

- The morbidity method is sometimes referred as the demographic method when it is applied to conditions such as FP or when demographic data are applied to calculate estimated number of cases; however, the methodology is the same (i.e., considers estimated number of cases and average quantity of each product used to manage one case to calculate the estimated quantity of each medical product by condition/subcondition).
- If complete, recent, and accurate service data are available, morbidity-based forecasting can be carried out without the need for general demographic and prevalence/incidence data.

Selection of forecasting methods is mainly dependent on availability and quality of data required for the respective method; however, use of multiple methods and comparison of results is recommended to allow validation of results and further refining. For new programs where past consumption or service data are not available, or for programs with significant scale up and changes in management of conditions, it is more appropriate to use demographic and morbidity data (incidence and prevalence data) with program assumptions on service coverage. For mature programs where complete and reliable consumption and service data are available, it is advisable to use the consumption and morbidity methods based on service data to estimate needs, compare results of the two, and decide which to use.

Refer to Annex A for a description of each type of data and related forecasting methodology and to the *Quantification of Health Commodities*[3] for a detailed review of data types and the merits of different methodologies. For FP products, the sources of data, strengths, and challenges associated with each forecasting method are further discussed in the *Quantification of Health Commodities: Contraceptive Companion Guide*.[4]

QUANTIFICATION PROCESSES

Quantification should be carried out regularly in a timely and coordinated manner, following the recommended steps and processes described below and shown in figure 1, to increase the quality, reliability, and use of results. Timing of the quantification exercise should also be aligned with the national budget planning cycle to mobilize needed resources. The formation of program-specific coordination committees is recommended. The coordination committees should include program representatives and logistics officers from the public sector, implementing partners familiar with the products and plans, logistics and warehousing staff, procurement staff, clinicians, pharmacy unit staff, technical experts, and donors/funders.[5] Engaging stakeholders ensures better sharing of information and coordinated decision making. In addition, at least one member of the quantification team should be comfortable using Microsoft Excel or other software applications used to manage the forecasting data and calculations.

The quantification process involves the following major phases/steps, which need to be carried out sequentially:

Preparation: Proper planning and preparation is the first step in the quantification process. During this step, members of the coordination/quantification committee need to define the scope of the quantification exercise, including conditions and medical products to be considered, geographic area, time frame, data type and sources, and methods of quantification. Then they need to collect, organize, and assess the quality of the available data. Usually, a consultative workshop is conducted after analysis of the collected data to validate and refine the data and assumptions obtained during the preparation phase of quantification and/or add more data and assumptions as necessary before the forecasting step starts; the consultation can also be carried out at the end of the quantification exercise.

Forecasting: During this phase of quantification, the agreed forecast assumptions are used to develop estimated consumption/demand forecasts for each medical product. Electronic tools such as Quantimed®, the newly developed ***Quantification Analytics Tool (QAT)*** (both used for multiple product/condition groups), and Reality√® (used for forecasting FP medical products) are often used to carry out forecasting. The tools make it much easier to prepare forecasts by providing a structured and standardized way to organize and validate data and produce forecast results. The results of the forecasting step include a list of specific medical products with quantities needed for a specific time period. Some tools, such as Quantimed and QAT, can also be used to calculate quantity per case and cost per episode.

These two phases/steps of quantification, especially forecasting, are covered in detail in this supplement.

Figure 1, which is from *Quantification of Health Commodities,*[3] illustrates the steps in quantification (for another view of the quantification process, including the inputs and outputs for each step, refer to Annex B). Users of this supplement should refer to *Quantification of Health Commodities*[3] to prepare supply plans for each product.

Changes related to supply chain management, including shipment delivery times, wastages, unit costs of medical products, logistic costs, and actual consumption, happen continuously, and this requires commensurate realignment of medical product supplies. This requires frequent reviews and revisions of quantification as more data become available to either validate the assumptions that were made or revise them and adjust the forecast and supply plan as needed. We recommend that quantification exercises be carried out at least every year, with supply planning revisions at least every quarter. More frequent revisions of the forecast and supply plans are particularly important for new or emerging programs/products where historical data are weak and forecasts are heavily dependent on expert opinions.

STEPS IN QUANTIFICATION

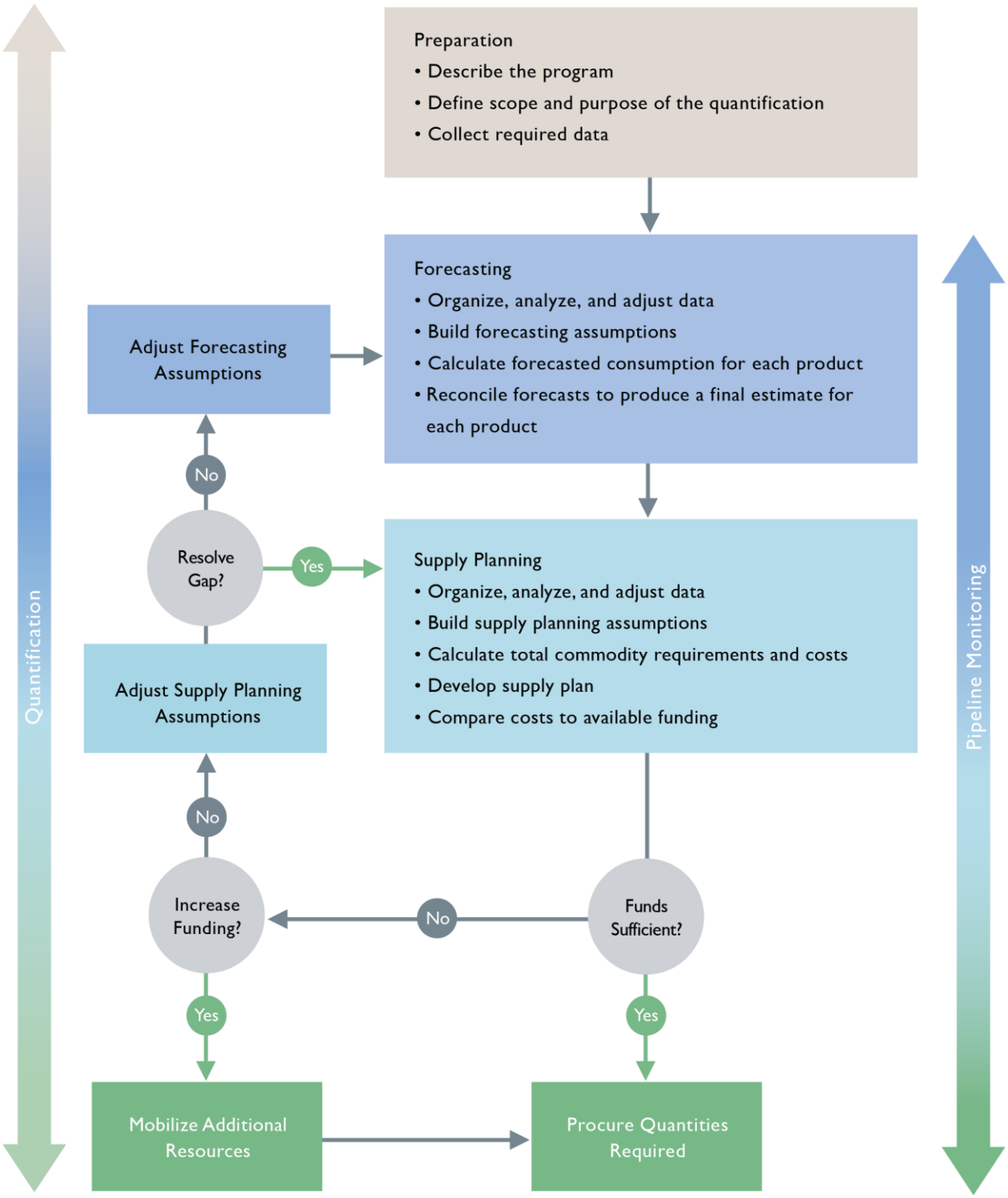

Figure 1: Steps in quantification[3]

OTHER GENERAL FORECASTING CONSIDERATIONS

FORECASTING REQUIREMENTS BY OTHER SECTORS

Although the primary focus of this supplement is the public sector, NGOs, social marketing programs, and even the private sector may get products from the public sector for free or with subsidies; in cases where countries are using the public platform as a single market approach to fund and procure products, including for use in the social marketing and/or private sectors, it is important to engage private-sector stakeholders and quantify for both the public and private sectors. Additionally, the private sector could use the guidance in this supplement to understand how the public sector quantifies and the gap that the private sector should fill.

PRODUCT (BRAND) MIX

If the same product appears in different forms in the country (e.g., different brands or formulations) such that the quantification team believes that programmatic efforts or other drivers of use might affect the rate of consumption of different brands or formulations, it might be necessary to separate the forecast by brand/formulation 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/formulations 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. Therefore, the quantification team may need to build separate assumptions about growth (or decline) by brand/formulation.

SOURCE MIX

Utilization of related services offered by the public, social marketing, and private sectors may differ significantly, and this can affect estimates. If more than one programmatic source (e.g., public sector, social marketing, private sector) provides these medical products in the country, it will likely be necessary to break out the estimated number of clients/cases (for the morbidity method) or estimated proportion of use of each medical product (for the consumption method) by source of products—at a minimum to specify the number of clients who will be served or cases that will be treated in each sector included in the forecasting exercise. If the public sector is the only program considered in the quantification, the quantification team only needs to 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. Note that the composition and needs of groups of clients who frequent different sources for their services may vary considerably.

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

AVAILABILITY

Most of the products considered in this supplement are included in WHO's Model List of Essential Medicines, including the WHO Model List of Essential Medicines for Children; they are also part of the national essential medicines lists (EMLs) of many low- and middle-income countries (LMICs). In addition, many of these products have WHO prequalified suppliers. For a full list of WHO prequalified products and supplies, refer to the WHO website. Quantification teams are advised to consider their national EMLs and list of products that are registered in the respective country when conducting quantification exercises. The possibility of obtaining waivers for importation should also be considered for products that are not registered.

PRICES

Unit prices of many of the products considered in this supplement are available from the UNICEF catalogue and UNFPA catalogue; they may also be available from MSH's International Medical Products Price Guide. These resources can be used if local data on prices are not available.

CONSIDERATIONS FOR MULTIUSE PRODUCTS

Some of the RMNCH medical products considered in this supplement are used to manage several conditions (e.g., amoxicillin can be used for pneumonia, PSBI, severe acute malnutrition [SAM], and otitis media). The quantification team should consider forecasting the needs for all relevant conditions to estimate the total needs of a specific medical product.

ENTRY OF PERCENTAGE VALUES

When calculations involve multiplications of a number by a percentage (%), users of the supplement should interpret the percentage as a fraction. There are two options for carrying out the calculations:

1. **Interpret the percentage as a fraction (e.g., 20% is actually 0.2) and in Excel,** the % sign after the percentage value interprets the value as a fraction (i.e., 50 x 20% = 10)
2. **Change the percentage value to a fraction before multiplying the percentage value** (i.e., change 20% to a fraction by dividing 20 by 100 = 0.2 and then multiply the fraction by the number; 50 x 0.2 = 10 [this can be the case when using a tool such as Quantimed that does not provide functionality to use the % sign with the percentage value])

PROXY DATA

Users of this supplement are provided with global and/or regional data when available that can be used as proxy data (e.g., on incidence of conditions). However, the use of proxy data is recommended only when it is not possible to find local data on the specific variable. In addition, it is important for users to refer to the sources of data provided as reference for proxy data since most of them have country- or region-specific data that can be used for the region or country under consideration instead of the global average. The proxy data provided in this document are from the pre-COVID-19 pandemic period and may not reflect the current context.

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1. REPRODUCTIVE HEALTH: FAMILY PLANNING AND PREVENTION OF STIS

INTRODUCTION

Contraceptive prevalence is defined as the percentage of women of reproductive age (15–49 years) who are currently using, or whose sexual partner is currently using, at least one method of contraception, regardless of the method used.[1] Globally, modern contraceptive method prevalence (i.e., the proportion of women of reproductive age who have their need for modern contraception methods satisfied) increased slightly, from 74% in 2000 to 76% in 2019.[2] However, significant differences exist in modern contraceptive prevalence rates across countries and regions. For example, the achievement is only 55% in sub-Saharan Africa and Western Asia and just 51% in Oceania (excluding Australia and New Zealand).[2]

The female condom, contraceptive implants, and ECP were classified by the "Every Woman, Every Child" movement as three underutilized RH products. Other resources, such as guides, manuals, and tools, exist for quantifying other more frequently used FP medical products, such as male condoms, injectables, intra-uterine devices, and oral contraceptives,[3] so the product-specific section below will focus only on ECPs, contraceptive implants, and female condoms.

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

EMERGENCY CONTRACEPTIVE PILLS

ECPs are oral contraceptives indicated for use to prevent pregnancy after unprotected or inadequately protected sex.[4] Most ECPs can be taken up to five days after unprotected intercourse. In general, ECPs are available in three types—levonorgestrel tablets, ulipristal acetate tablets, and mifepristone tablets. In developing countries, the levonorgestrel-only formulations are most widely available. This supplement covers the levonorgestrel-only formulations, although the methodology could also apply to the other types. ECPs can be important not only for couples who need contraceptive methods after no or incorrect use of contraceptives or after method failure[4] but also for women who experience sexual assault.[5] Regardless of their importance and efficacy, awareness continues to be an important barrier to uptake since ECP is one of the least known, least available, and least used modern FP methods in developing countries; most women have never heard of this safe and effective pill.[6]

The population that uses ECPs is likely a subset of the total population interested in using—or already using—a modern contraception method. In addition, ECPs may be offered via traditional and nontraditional outlets such as hospital emergency rooms, refugee and internally displaced persons camps, pharmacies, prisons, and schools where use/dispensing may not be completely or accurately reported. Access and availability can be influenced by many issues, including licensing and registration of products and whether clients can obtain the method without a prescription. Further, not every recent DHS has included ECP as a method. These factors make ECP difficult to forecast.

ECP demand forecasts should be realistically aligned with programmatic plans and capacity for introducing or expanding the provision of ECPs in a given sector, especially if ECP is well established in other sectors. For example, if the private sector plays an established role in providing ECPs, quantification teams should use caution in extrapolating private-sector demand for ECPs to the public sector, where the user profile may be significantly different.

FEMALE CONDOMS

Female condoms are barrier devices inserted inside the vagina before sexual intercourse to prevent unintended pregnancy and/or STIs. Female condoms do not require a prescription or clinician involvement beyond initial insertion training.

Women of all ages can use female condoms; however, they are 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; men who dislike the use of male condoms; women who cannot negotiate the use of male condoms; and people who are allergic to latex (most female condoms are made from polyurethane and synthetic latex, which have a lower incidence of allergic reactions).

Since male and female condoms prevent both pregnancy and transmission of STIs, including HIV, distinction by program and separate estimation and management by programs are common; however, this may hamper access to condoms. Conducting a coordinated quantification of requirements for FP and prevention of STIs is recommended. This will help each program avoid duplication, minimize overstocking and shortages, and plan for the transfer of products among programs if there are stock-outs/overstocks and potentials for expiry. It also allows sharing data and information for making better assumptions. An appropriate quantity of female condoms needs to be available to users regardless of their purpose.

A caution on using demographic data for forecasting both male and female condoms: the data will not reflect additional use of condoms for HIV and STI prevention if the user has already indicated the use of another contraceptive method.

CONTRACEPTIVE IMPLANTS

Contraceptive implants are a highly effective hormonal FP method used by WRA 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 (three–five years). Based on the 2015 WHO medical eligibility criteria for contraceptive use,[7] implants are suitable for nearly all women. Implant insertion and removal requires competency-based training.

Table 3: Summary of product characteristics: ECPs, female condoms, and contraceptive implants

PARAMETER	ECPS	FEMALE CONDOMS	CONTRACEPTIVE IMPLANTS
Protocol/usage rates/couple years of protection (CYP)[8]	▪ 1.5 mg levonorgestrel tablet – 1 blister of 1 tablet per case ▪ 0.75 mg levonorgestrel tablets – 1 blister of 2 tablets per case	▪ 1 condom per sexual intercourse ▪ CYP factor: 120 (120 female condoms per women per year)	▪ 1 contraceptive implant can serve for 3 to 5 years ▪ CYP ○ Levonorgestrel 75 mg/rod, 2-rod-5-year = 3.8 years ○ Levonorgestrel 75 mg/rod, 2-rod-3-year = 2.5 years ○ Etonogestrel 68 mg/rod, 1-rod-3-year = 2.5 years
Presentation	▪ 1 tablet of levonorgestrel 1.5 mg tablets ▪ 2 tablets of levonorgestrel 750 microgram (0.75 mg) tablets	▪ Latex sheath with inner retention ring, with or without fragrance, of 1 piece ▪ Nitrile sheath with inner retention ring, with or without fragrance, of 1 piece	▪ Levonorgestrel 75 mg/rod, 2-rod-5-year with disposable trocars ▪ Levonorgestrel 75 mg/rod, 2-rod-3-year with disposable trocars ▪ Etonogestrel 68 mg/rod, 1-rod-3-year with disposable trocars
Annual failure rate[9]	▪ Oral pills = 5.5% (3.5–7.3%)* ▪ Injectables = 1.7% (0.6–2.9%)*	▪ Condoms = 5.4% (2.3–8.7%)*	▪ Not applicable
Annual discontinuation rate[10]	▪ Not applicable because it is not considered a regular method	▪ 50%	▪ Levonorgestrel 75 mg/rod, 2-rod-5-year = 28% ▪ Levonorgestrel 75 mg/rod, 2-rod-3-year = 33% ▪ Etonogestrel 68 mg/rod, 1-rod-3-year = 42%
Administration	▪ Oral	▪ Intravaginal	▪ Subdermal
Storage condition[11]	▪ Do not store above 30°C, protect from light	▪ Store in well ventilated, dry conditions away from direct sources of heat, including sunlight ▪ Long-term average storage ▪ Do not store above 30°C	▪ Do not store above 30°C, protect from light
Additional supplies required for administration	▪ No additional supplies are required to administer ECPs or female condoms		▪ Insertion and removal procedures require instruments, expendable medical supplies, and infection prevention supplies
Level of use	▪ Can be self-administered by users after initial demonstration/advice by community health workers (CHWs) or HF staff		▪ Need to be administered at HF level or rarely by trained CHWs in home settings; 11% of surveyed countries indicated the use of CHWs to administer contraceptive implants[12]
Supply chain considerations	▪ Do not require cold chain ▪ Shelf life of 24–36 months	▪ Do not require cold chain ▪ Shelf life of 36–72 months	▪ Do not require cold chain ▪ Shelf life of 60 months

**Failure rates of short-acting modern methods are used in the calculation of ECP requirement*

REQUIRED DATA AND POTENTIAL SOURCES: MORBIDITY/DEMOGRAPHIC METHOD OF FORECASTING

A number of data points are required to forecast demand for ECPs, contraceptive implants, and female condoms. Table 4 summarizes the main data types and potential sources for this method of forecasting, in addition to the common data provided in the introduction of this supplement.

Table 4: Data and potential sources for forecasting ECPs, contraceptive implants, and female condoms using morbidity/demographic method

DATA	CONDITION/ PRODUCT	SOURCE	NOTES
Contraceptive prevalence rate by method, method mix	ECPs, contraceptive implants, female condoms	Family health surveys, DHS, reproductive health survey (RHS), national health surveys, performance monitoring for action	Survey data may be outdated; may need to apply estimated annual growth rate to project to forecast years
Short-term method specific failure rates	ECPs	DHS, special surveys, data from the Global Library of Women's Medicine	Survey data may be outdated; local data may not be available
Unmet needs for contraceptives	ECPs, contraceptive implants, female condoms	DHS, multiple indicator cluster survey (MICS), RHS, national health surveys, census data	Data quality is not always known; may be outdated
Incidence of rape	ECPs	DHS, national health surveys, census data	May be outdated; may need to apply estimated annual growth/reduction rate to project to forecast years
Proportion/number of women in need of ECPs or female condoms who are aware of the products	ECPs, contraceptive implants, female condoms	DHS, HMIS, special surveys; data from International Consortium for Emergency Contraception can be used in the absence of local data	DHS data may be outdated; HMIS data may not be complete; may need to apply estimated annual growth/reduction rate
Proportion/number of women who are aware of and have access to ECPs or female condoms (separately) by sector (public, social marketing, private): source mix	ECPs, female condoms	DHS, HMIS, special surveys; data from International Consortium for Emergency Contraception can be used in the absence of local data	
Method-specific discontinuation rates	Contraceptive implants	DHS; special surveys; Reality√: A planning and advocacy tool for strengthening FP programs, user's guide	May not reflect country-specific situation, survey data may be outdated
Annual failure rate	ECPs	DHS, special surveys, Contraceptive Failure Rates in the Developing World-2016	
CYP factor/usage rate per year	ECPs, contraceptive implants, female condoms	MEASURE Evaluation FPRH Family Planning and Reproductive Health Indicators Database	CYP is affected by counseling, age, intentions of the user, and availability of skilled providers for removal. The CYP factor for ECP is 20 doses, which may overestimate quantities needed if WRA use ECPs only for episodic, and not annual, protection. Usage rate of female condoms for prevention of STIs could be very different from CYP for prevention of pregnancy.
Product mix	ECPs, contraceptive implants, female condoms	MOH reports, logistics management information system records, facility records, DHS, MICS	Not always complete; data quality not always known; may be outdated or not collected; shipment information by product/brand is not a direct proxy for dispensed-to user information

Note:
All three methods of contraception dealt with here are available from multiple sectors—public, private/commercial, NGO, and social marketing. However, there are differences in relative availabilities. For example, ECPs are more likely to be found in the commercial sector, and implants and female condoms are more likely to be offered in the public and NGO sectors.[12] The contribution of the private sector is expected to grow further; in 2017, 94% of surveyed countries reported having policies that enable the private sector to provide contraceptive methods. This has increased significantly from 73% in 2015.[12]

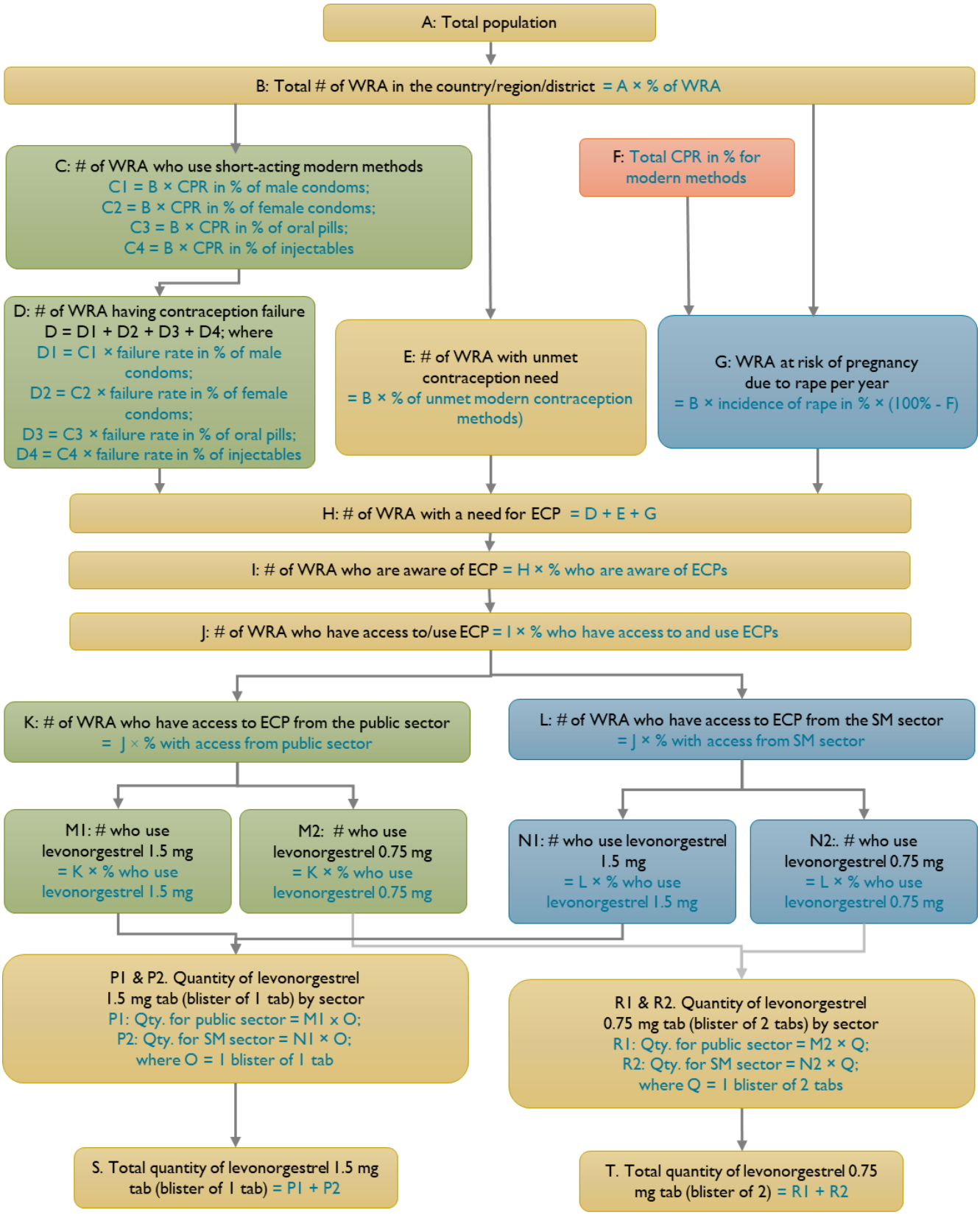

Figure 2: Forecasting algorithm for ECP based on morbidity/demographic method

IMPORTANT NOTES:

- WRA with unmet contraception need are not using another method and may choose to use ECPs if they have unprotected intercourse. In the sample algorithm, these women are included in the flow at "need for ECP" and filtered by awareness of and access to emergency contraception (EC). Some people might argue that women with an unmet need for contraception may not be able to access EC either. If agreement is reached on this based on local information, the quantification team may eliminate WRA with unmet need from the calculations.
- One episode per year is assumed for the calculation of H.

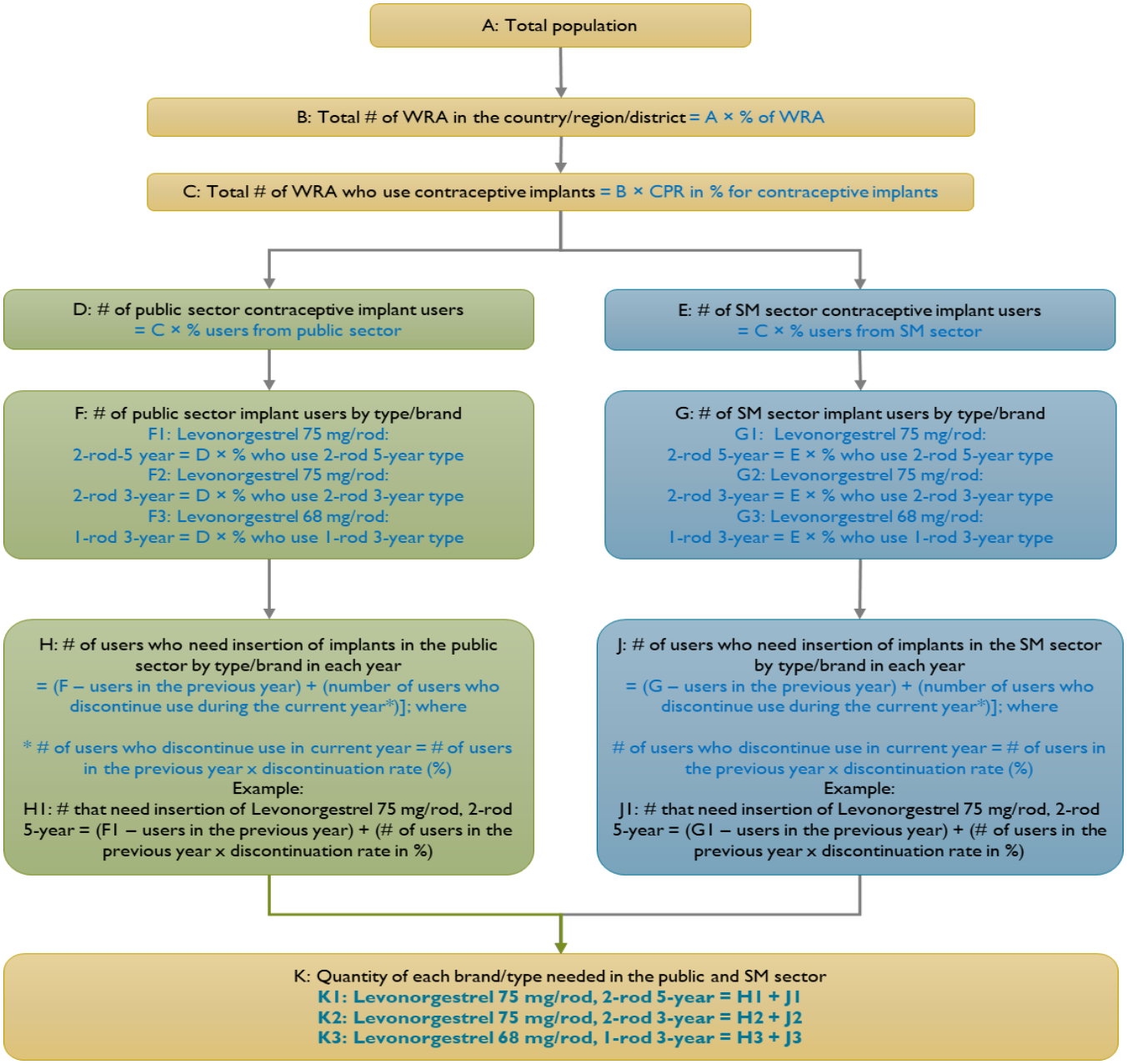

Figure 3: Forecasting algorithm for contraceptive implants based on morbidity/demographic method

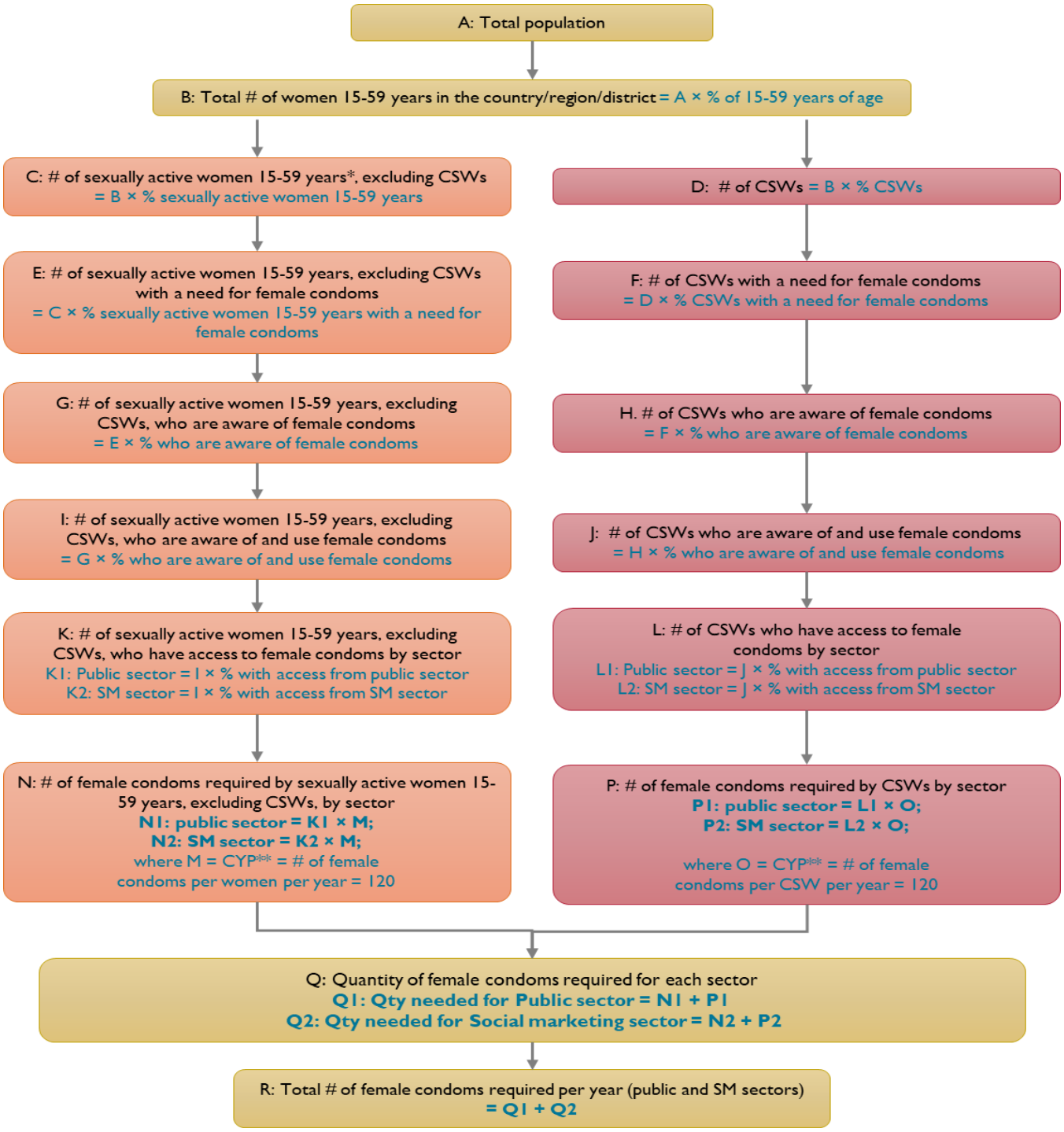

Figure 4: Forecasting algorithm for female condoms based on morbidity/demographic method

**Sexually active women are assumed to be 15–59 years of age.*
***CYP provided here is a global average for the general population mainly based on male condom use. The CYP rate for female condoms and especially for female CSW use could be significantly different.*

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

Table 5: Summary of proxy data and sources

	PARAMETER	VALUE
1	Usage rates (CYP factors)[8] ▪ ECPs	▪ 1 tablet of 1.5 mg levonorgestrel (blister): 1 blister per case per year ▪ 2 tablets of 0.75 mg levonorgestrel tablets (blister): 1 blister per case per year
	▪ Female condoms	▪ 120 condoms per women per year
	▪ Contraceptive implants	▪ Levonorgestrel 75 mg/rod, 2-rod-5-year = 3.8 years ▪ Levonorgestrel 75 mg/rod, 2-rod-3-year = 2.5 years ▪ Etonogestrel 68 mg/rod, 1 rod-3-year = 2.5 years
2	Discontinuation rates of contraceptive implants[9]	▪ Levonorgestrel 75 mg/rod, 2-rod-5-year = 28% ▪ Levonorgestrel 75 mg/rod, 2-rod-3-year = 33% ▪ Etonogestrel 68 mg/rod, 1-rod-3-year = 42%
3	Failure rates[10]	▪ Condoms = 5.4 % (2.3–8.7%) ▪ Injectables = 1.7% (0.6–2.9%) ▪ Oral pills = 5.5 % (3.5–7.3%)

IMPORTANT NOTES:

- 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.
- Quantification teams are advised to refer to the sources of data provided as references for the proxy data as most have country- or region-specific data that can be used for the region or country under consideration instead of the global average.

BOX 1. EXAMPLE OF COUNTRY FORECAST FOR ECPS BASED ON MORBIDITY/ DEMOGRAPHIC METHOD

Country X would like to estimate the quantities of ECPs to be consumed by clients of its public-sector reproductive health/FP program as well as a social marketing program over the next two years. The following data and assumptions were discussed and agreed to be used for the forecast. The quantification team has agreed to use global averages as proxy when local data are not available.

Available data and assumptions

- Total population as of current year (Central Statistics Office [CSO]: census): **20,000,000**
- Annual population growth rate (CSO): **2%**
- Percentage of WRA group (15–49 years) (based on census report): **25%**; estimated to remain the same during the quantification period
- Percentage of WRA with unmet need for contraception (DHS): **27%;** estimated to remain the same
- Percentage of WRA using a modern method of contraception): **44%**; the quantification team has estimated that contraceptive prevalence rate (CPR) for modern methods will increase by 1% annually (based on DHS and projections using current trends)
- Based on DHS data, trends, and program objectives, the quantification team has also estimated current CPR by method and annual increase in CPR of short-acting modern methods as follows:
  - Percentage of WRA using male condom (DHS): **2.70%; annual increase: 0.1%**
  - Percentage of WRA using female condom (DHS): **0.10%; annual increase: 0.01%**
  - Percentage of WRA using oral contraceptives (DHS): **10.00%; annual increase: 0.20%**
  - Percentage of WRA using injectables (DHS): **18.50%; annual increase: 0.30%**
- Method-specific failure rates: (proxy)
  - Condoms (male and female): **5.4%**
  - Oral pills: **5.5%**
  - Injectables: **1.7%**
- WRA at risk of pregnancy due to rape: **4%** (gender-based violence used as proxy)
- Percentage of WRA in need of ECPs who are aware of ECPs (DHS): **20%** (current year); it is estimated that it will increase to **21%** in year 1 and **22%** in year 2
- Estimated percentage of WRA who are aware of and have access to ECPs: **60%** (estimated based on DHS and expert opinion)
- Percentage of clients accessing ECPs by source (based on DHS):
  - Public sector: **35%**
  - Social marketing sector: **50%**
  - Private sector: **15%**
- Percentage of product (brand) mix and source mix (based on DHS); is assumed to be unchanged in the forecast period
  - Public sector:
    - Levonorgestrel 1.5 mg of 1 tab: 100%
  - Social marketing sector:
    - Levonorgestrel 1.5 mg of 1 tab: 65%
    - Levonorgestrel 0.75 mg of 2 tabs: 35%
- Episodic use: 1 episode per year and 1 dose per episode

Calculate the quantity of ECPs required over the next two years

Example: ECPs

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = population of the previous year + (population of the previous year x PGR) (annual population growth rate (PGR) is 2%)	**2%**	20,000,000	20,400,000	20,808,000
Total number of WRA (15–49 years) (B)	B = A x % of WRA	**25%**	5,000,000	5,100,000	5,202,000
CPR of male condoms (% of users out of WRA)	Annual increase in CPR: Male condoms	**0.10%**	**2.70%**	2.80%	2.90%
CPR of female condoms (% of users out of WRA)	Annual increase in CPR: Female condoms	**0.01%**	**0.10%**	0.11%	0.12%
CPR of oral pills (% of users out of WRA)	Annual increase in CPR: Oral pills	**0.20%**	**10.00%**	10.20%	10.40%
CPR of injectables (% of users out of WRA)	Annual increase in CPR: Injectables	**0.30%**	**18.50%**	18.80%	19.10%
Number of male condom users (C1)	C1 = WRA (B) x CPR of male condoms in %		135,000	142,800	150,858
Number of female condom users (C2)	C2 = WRA (B) x CPR of female condoms in %		5,000	5,610	6,242
Number of oral pill users (C3)	C3 = WRA (B) x CPR of oral pills in %		500,000	520,200	541,008
Number of injectable users (C4)	C4 = WRA (B) x CPR of injectables in %		925,000	958,800	993,582
Number of failures: Male condom users (D1)	D1= C1 x failure rate in %: Male condoms	**5.40%**	7,290	7,711	8,146
Number of failures: Female condom users (D2)	D2 = C2 x failure rate in %: Female condoms	**5.40%**	270	303	337
Number of failures: Oral pill users (D3)	D3 = C3 x failure rate in %: Oral pills	**5.50%**	27,500	28,611	29,755
Number of failures: Injectable users (D4)	D4 = C4 x failure rate in %: Injectables	**1.70%**	15,725	16,300	16,891
Number of WRA (15–49) with unmet contraception need (E)	E = B x % of WRA with unmet contraception need	**27%**	1,350,000	1,377,000	1,404,540
Total CPR of modern method of contraception (F)	F = Annual increase in CPR of 1%	**1%**	**44%**	**45%**	**46%**
WRA (15–49) at risk of pregnancy due to rape and in need of ECPs (G)	G = Incidence of rape x B x (100%-F): Incidence of rape (gender-based violence)	**4%**	112,000	112,200	112,363
Number of WRA (15–49) with a need for ECPs (H)	H = D1 + D2 + D3 + D4 + (E + G)		**1,512,785**	**1,542,125**	**1,572,033**
Number of WRA (15–49) who have a need for and are aware of ECPs (I)	I = % awareness x number in need of ECPs (H) (% increase in awareness of 1% per year)	**20%**	**302,557**	**323,846**	**345,847**
			20%	**21%**	**22%**
Number of WRA (15–49) who have a need for, are aware of, and have access to/use ECPs (J)	J = # that are aware (I) x % with access to ECPs	**60%**	**181,534**	**194,308**	**207,508**
Number of WRA (15–49) who have access to/use ECPs from the public sector (K)	K = J x % who use from public sector	**35%**	63,537	68,008	72,628
Number of WRA (15–49) who have access to/use ECPs from the social marketing sector (L)	L = J x % who use from social marketing sector	**50%**	90,767	97,154	103,754
Number of WRA (15–49) who use specific type/brand of ECP from the public sector (M)	M = K x % who use levonorgestrel 1.5 mg of 1 tab	**100%**	**63,537**	**68,008**	**72,628**
Number of WRA (15–49) who use specific type/brand of ECP from the social marketing sector (N)	N1: # using levonorgestrel 1.5 mg of 1 tab = L x % who use levonorgestrel 1.5 mg of 1 tab	**65%**	**58,999**	**63,150**	**67,440**
	N2: # using levonorgestrel 0.75 mg of 2 tabs = L x % who use levonorgestrel 0.75 mg of 2 tabs	**35%**	**31,768**	**34,004**	**36,314**
	P1: Quantity for the public sector = M x O;	**1**	**63,537**	**68,008**	**72,628**

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Quantity of levonorgestrel 1.5mg of 1 tab needed in the public and social marketing sectors (P)	where O = 1 blister of 1 tab				
	P2: Quantity for the social marketing sector = N1 x O; where O = 1 blister of 1 tab	1	58,999	63,150	67,440
Quantity of levonorgestrel 0.75 mg of 2 tabs needed in the social marketing sector (R)	R = N2 x Q; where Q = 1 blister of 2 tabs	1	31,768	34,004	36,314
Total quantity of levonorgestrel 1.5 mg of 1 tab needed in the public and social marketing sectors (S)	**S = P1 + P2**		122,536	131,158	140,068
Total quantity of levonorgestrel 0.75 mg of 2 tabs needed in the public and social marketing sectors (T)	**T = R**		31,768	34,004	36,314

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

BOX 2. EXAMPLE OF COUNTRY FORECAST FOR CONTRACEPTIVE IMPLANTS BASED ON MORBIDITY/DEMOGRAPHIC METHOD

Country X would like to estimate the quantities of contraceptive implants to be consumed by clients of its public-sector RH/FP program as well as a social marketing program over the next two years. The program has decided to use two types of contraceptive implants. Only the 2-rod-5-year implant is available in the public sector, while two types—2-rod-5-year implant and 1-rod-3-year implant—are available through the social marketing sector. The following data and assumptions were discussed and agreed to be used for the forecast. The quantification team has agreed to use global averages as proxy when local data are not available.

Available data and assumptions

- Total population as of current year (CSO: census): **20,000,000**
- Population growth rate (CSO): **2%**
- Percentage of WRA (15–49 years) (based on CSO projections): **25%**; estimated to remain the same
- Based on DHS data, trends, HMIS data, and program objectives, the quantification team estimates CPR for contraceptive implants is **3.5%** in the current year and is expected to grow by **3.7%** and **3.9%** in years 1 and 2, respectively.
- Percentage of clients accessing contraceptive implants by source (based on DHS):
  - Public sector: **83%**
  - Social marketing sector: **14%**
  - Private sector: 3%
- The following annual discontinuation rates were assumed for the two types of implants based on global data used as a proxy:
  - Levonorgestrel 75 mg/rod, 2-rod-5-year: **28%**
  - Etonogestrel 68 mg/rod, 1-rod-3-year: **42%**
- Brand (product) mix by sector (based on DHS, HMIS, and program objectives):
  - Public sector:
    - Levonorgestrel 75 mg/rod, 2-rod-5-year: **65%**
    - Etonogestrel 68 mg/rod, 1-rod-3-year: **35%**
  - Social marketing sector:
    - Levonorgestrel 75 mg/rod, 2-rod-5-year: **55%**
    - Etonogestrel 68 mg/rod, 1-rod-3-year: **45%**
- Episodic use: 1 insertion per new adopter

Calculate the quantities of contraceptive implants required over the next two years

Example: Contraceptive implants

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = population of the previous year + (population of the previous year x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total number of WRA (15–49 years) (B)	B = A x % of WRA out of the total population	25%	5,000,000	5,100,000	5,202,000
Total number of implant users (C)	C = B x CPR of implants in % (CPR of implants with annual increase of 0.20%)		175,000	188,700	202,878
		0.2%	3.50%	3.70%	3.90%
Number of implant users in the public sector (D)	D = C x % who use from public sector	83%	145,250	156,621	168,389
Number of implant users in the social marketing sector (E)	E = C x % who use from social marketing sector	14%	24,500	26,418	28,403

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Number of implant users by brand/type in the public sector (F)	F1: # using 2-rod-5-year implant in the public sector = D x % who use the product	65%	94,413	101,804	109,453
	F2: # using 1-rod-3-year implant in the public sector = D x % who use the product	35%	50,838	54,817	58,936
Number of implant users by brand/type in the social marketing sector (G)	G1: # using 2-rod-5-year implant in the social marketing sector = E x % who use product	55%	13,475	14,530	15,622
	G2: # using 1-rod-3-year implant in the social marketing sector = E x % who use the product	45%	11,025	11,888	12,781
Number of public-sector users who need insertion of implants each year (H)*	H1: Annual discontinuation rate: 2-rod-5-year - public sector	28%		33,827	36,154
	H2: Annual discontinuation rate: 1-rod-3-year - public sector	42%		25,332	27,142
Number of social marketing -sector users who need insertion of implants each year (J)*	J1: SM: Annual discontinuation rate: 2-rod-5-year - social marketing sector	28%		4,828	5,160
	J2: Annual discontinuation rate: 1-rod-3-year - social marketing sector	42%		6,523	6,996
*H & J: # of users who need insertion of implants by type/brand each year = (users in current year – users in the previous year) + (number of users that discontinue use during the current year) Number of users that discontinue use during the current year = total number of users in the previous year x discontinuation rate per year (%) Example: H1: # that need insertion of levonorgestrel 75 mg/rod, 2-rod 5-year in the public sector = (F1 – users in the previous year) + (# of users in the previous year x discontinuation rate in %)					
Total quantity of each type/brand of implant needed in the public and social marketing sectors (K)	**K1: Quantity of levonorgestrel 75 mg/rod, 2-rod-5-year: public and social marketing sectors (H1 + J1)**			**38,655**	**41,314**
	K2: Quantity of etonogestrel 68 mg/rod, 1 rod-3-year: public and social marketing sectors (H2 + J2)			**31,854**	**34,138**

Notes:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.
- In theory, the only implant clients who require a product in a given period are new adopters and clients who have reached the useful life of their implant and elect to have it removed and a new implant inserted. To convert the number of clients in a period to the quantity of products needed to serve them, you need to know the proportion of new users in the period and the proportion of users who have had implants inserted in the period who will have them removed and new ones inserted.
- There were two options provided for the calculation of implant insertions per year in the 2016 version of this document. In this version we have adapted option 2, which is more accurate and results in higher implant needs, to include slight modifications to the calculation of discontinuation rates. In the old version, the discontinuation rate for option 2 is calculated by taking the reciprocal of the CYP (1/CYP), while in this version we have used global data on the discontinuation rate by type of implant (see the proxy data for more detail). However, it is important to note that the global implant discontinuation averages by type of implant are not very different from the ones calculated using the reciprocal of the CYP. For example, the global discontinuation rate for etonogestrel 68 mg/rod, 1-rod-3-year implant is 42%, while the result of 1/CYP is (1/2.5 = 0.40 = 40%).

BOX 3. EXAMPLE OF COUNTRY FORECAST FOR FEMALE CONDOMS BASED ON MORBIDITY/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. Since it is difficult to separate the use for FP and prevention of STIs, it was agreed to forecast the requirements for the two programs together. The following data and assumptions were discussed and agreed to be used for the forecast. The quantification team has agreed to use global averages as proxy when local data are not available.

Available data and assumptions

- Total population as of current year (CSO census): **20,000,000**
- Population growth rate (CSO): **2%**
- Percentage of women aged 15–59 years (Based on CSO projections): **28%**; estimated to remain the same
- Percentage of sexually active women (DHS) (i.e., women 15–59 years excluding female CSWs) (DHS): **61%**
- Estimated proportion of female CSWs (local study): **0.3%** of women 15–59 years
- Percentage of sexually active women 15–59 years (excluding female CSWs) with a need for female condoms for prevention of pregnancy and/or STIs (percentage of women using female condom at last intercourse) (DHS): **0.25%**
- Percentage of female CSWs with a need for female condoms for prevention of pregnancy and/or STIs (local studies): **10%**
- Percentage of women in need and aware of female condoms (DHS):
  - Sexually active women 15–59 years (excluding female CSWs): **50%**
  - Female CSWs: **90%**
- Percentage of women who are aware and use/access female condoms (DHS, local studies, expert opinion):
  - Sexually active women 15–59 years (excluding female CSWs): **60%**
  - Female CSWs: **80%**
- Percentage of clients accessing female condoms by source:
  - Sexually active women 15–59 years (excluding female CSWs) (DHS): public sector (DHS): **25%;** social marketing sector: **45%**
  - Female CSWs: public sector: **35%**; social marketing sector: **55%** (from DHS, local studies)
- Quantity of female condoms used per woman per year (CYP factor)
  - Sexually active women 15–59 years (excluding female CSWs) (global average used as proxy): **120**
  - Female CSWs (local studies): **150**

Calculate the quantities of female condoms required over the next two years

Example: Female Condoms

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = population of the previous year + (population of the previous year x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total number of WRA (15–59 years) (B)	B = A x % women 15–59 years	28%	5,600,000	5,712,000	5,826,240
Number of sexually active women 15–59 years excluding CSWs (C)	C = B x % sexually active women 15–59 years	61%	3,416,000	3,484,320	3,554,006
Number of CSWs (D)	D = B x % CSWs	0.30%	16,800	17,136	17,479
Number of sexually active women 15–59 years (excluding CSWs) with a need for female condoms (E)	E = C x % sexually active women 15–59 years with a need for female condoms	0.25%	8,540	8,711	8,885

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Number of CSWs with a need for female condoms (F)	F = D x % CSWs with a need for female condoms	10%	1,680	1,714	1,748
Number of sexually active women 15–59 years excluding CSWs who are aware of female condoms (G)	G = E x % sexually active women 15–59 years aware of female condoms	50%	4,270	4,355	4,443
Number of CSW who are aware of female condoms, per year (H)	H = F x % CSWs aware of female condoms	90%	1,512	1,542	1,573
Number of sexually active women 15–59 years excluding CSWs who are aware of and use/have access to female condoms (I)	I = G x % sexually active women 15–59 years who use female condoms	60%	2,562	2,613	2,666
Number of CSW who are aware of and use/have access to female condoms (J)	J = H x % of CSWs who use female condoms	80%	1,210	1,234	1,258
Number of sexually active women 15–59 years excluding CSWs who have access to female condoms by sector (K)	K1 = I x % with access from the public sector	25%	641	653	666
	K2 = I x % with access from the social marketing sector	45%	1,153	1,176	1,199
Number of CSWs who have access to female condoms by sector (L)	L1 = J x % with access from the public sector	35%	423	432	440
	L2 = J x % with access from the social marketing sector	55%	665	679	692
Quantity of female condoms required by sexually active women 15–59 years excluding CSWs by sector (N)	M = CYP	120	215,208	219,512	223,902
	Public sector (N1) = M x K1		76,860	78,397	79,965
	Social marketing sector (N2) = M x K2		138,348	141,115	143,937
Quantity of female condoms to be used/required by CSWs by sector (P)	O = Average number of female condoms used per CSW per year	150	163,296	166,562	169,893
	Public sector (P1) = O x L1		63,504	64,774	66,070
	Social marketing sector (P2) = O x L2		99,792	101,788	103,824
Quantity of female condoms needed in the public sector per year (Q1)	Sum of public sector requirements (Q1) = N1 + P1		140,364	143,171	146,035
Quantity of female condoms needed in the social marketing sector per year (Q2)	Sum of social marketing sector requirements (Q2) = N2 + P2		238,140	242,903	247,761
Total quantity of female condoms needed in public and social marketing sectors per year (R)	**Sum of public and social marketing sector requirements (R) = Q1 + Q2**		**378,504**	**386,074**	**393,796**

Notes:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

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2. POSTPARTUM HEMORRHAGE: PREVENTION, DIAGNOSIS, AND TREATMENT

INTRODUCTION

Globally, obstetric hemorrhage is the leading cause of maternal mortality, accounting for 27% of all maternal deaths. Most of these deaths are due to PPH and occur in LMICs.[1]

PPH is commonly defined as a blood loss of 500 ml or more within 24 hours after birth.[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.[3] Therefore, all women are considered at risk, and prevention must be incorporated into care provided at every birth. WHO[2] affirms that the majority of PPH-associated complications and deaths could be avoided through the use of prophylactic uterotonics during the third stage of labor regardless of mode of birth (vaginal birth or caesarean section) or birth setting (hospital or community setting). Even with the provision of prophylaxis, women may develop PPH. A recently published Cochrane review estimates that 24% of pregnant women experience PPH without prophylaxis, and that prophylactic oxytocin given during the third stage of labor reduces the incidence by half to 12%.[4,] WHO also recommends treatment of PPH with a therapeutic uterotonic and intravenous tranexamic acid (TXA), supplemented by additional interventions based on the cause of the bleeding and the woman's clinical status.

With recent innovations and WHO recommendations, there are now more medication options to prevent and treat PPH. However, countries must determine the appropriate interventions for use at the community, primary, and referral levels. WHO[2] recommends oxytocin, HSC, misoprostol, ergometrine/methylergometrine, or oxytocin and ergometrine fixed-dose combination to manage PPH, but in settings where multiple options are available, WHO recommends the use of oxytocin. In settings where oxytocin is unavailable or its quality cannot be guaranteed, use of another effective uterotonic is recommended. The WHO CHAMPION trial, conducted across 10 countries between 2015 and 2018, found that HSC "was noninferior to oxytocin for the prevention of blood loss of at least 500 ml or the use of additional uterotonic agents."[5] WHO updated its recommendations for PPH treatment in 2017 to include TXA[6] and its recommendations for PPH prevention in 2018 to include HSC.[2], drawing on the CHAMPION trial and a 2018 Cochrane review[7].

Comprehensive management of PPH requires prompt detection and diagnosis. The use of calibrated drapes has been shown to substantially improve the early detection of PPH[8,9,10] and, when paired with the WHO first-response treatment bundle, as in the E-MOTIVE trial in Kenya, Nigeria, Tanzania, and South Africa, can lead to timely treatment and improved outcomes.[11]

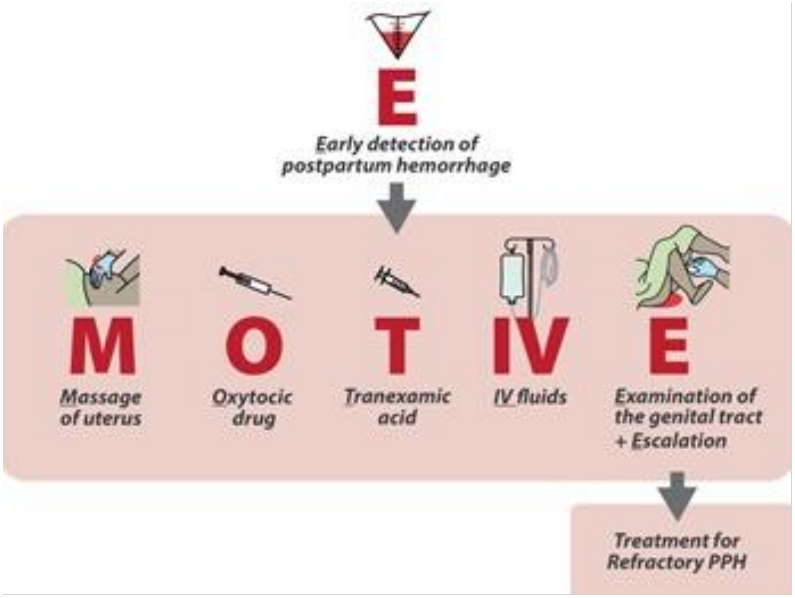

Figure 5: A diagram of the E-MOTIVE intervention

In 2023, WHO published new guidance on the assessment and treatment of PPH,[1] with two major recommendations:

1. "For all women giving birth, routine objective measurement of postpartum blood loss is recommended to improve the detection and prompt treatment of postpartum hemorrhage. Methods to objectively quantify blood loss, such as calibrated drapes for women having vaginal birth, can achieve this."

2. "A standardized and timely approach to the management of PPH, comprising an objective assessment of blood loss and use of a treatment bundle supported by an implementation strategy, is recommended for all women having a vaginal birth. The care bundle for the first-line treatment of PPH should include rapid institution of uterine massage, administration of an oxytocic agent and tranexamic acid, intravenous fluids, examination of the genital tract and escalation of care."

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

OXYTOCIN

Oxytocin is an injectable medicine that is recommended as the medicine of choice for prevention and treatment of PPH at HFs.[12] It is more effective and safer than misoprostol for both prevention and treatment of PPH.

MISOPROSTOL

Misoprostol is taken orally in tablet form for prevention and/or treatment of PPH and is recommended in settings where skilled health personnel are not present to administer injectable uterotonics (such as home births), where maintaining cold chain is difficult (such as in HFs where cold chain is not available), and where oxytocin is unavailable or its quality cannot be guaranteed. Advance distribution of misoprostol for self-administration has been adapted in some countries where country guidelines and policies allow.

HSC

Carbetocin is a long-acting synthetic analogue of oxytocin, and both heat-stable and non-heat stable formulations are available.[2] It is an injectable medicine. The use of the heat stable form (HSC) for prevention of PPH is recommended in settings where cost is comparable to other effective uterotonics and where oxytocin is unavailable or its quality cannot be guaranteed (including where it is difficult to maintain cold chain).[2]

TXA

TXA is an injectable coagulant and antifibrinolytic agent. Early use of intravenous TXA (within three hours of birth) in addition to standard care with uterotonics,[a] is recommended for women with clinically diagnosed PPH following vaginal birth or caesarean section as reinforced in the recently updated guidelines from WHO.[1]

CALIBRATED DRAPES

Calibrated drapes are medical devices, consisting of drapes with calibrated funnel-shaped blood collection pouches, used to objectively measure blood loss after vaginal childbirth, aiding in the early detection of PPH. The drapes are placed under the buttocks of the laboring woman and unrolled after the baby is born to capture blood in a calibrated pouch. The collection pouch is frequently marked at 50ml intervals and can include trigger marks at 300 ml and 500 ml to guide the timely detection and treatment of PPH.

Calibrated drapes are being manufactured in multiple countries in Africa and Asia including India, Kenya, Nigeria, and South Africa. There are no standard specifications for calibrated drapes, with variations seen in their design and the materials used, although target product profiles for drapes and blood loss measurement are currently being developed by UNICEF and the Concept Foundation. Given the importance of calibrated drapes for the detection and diagnosis of PPH, quality (e.g., materials used, non-leakage) must be considered as a key element of the selection criteria for procurement. To give an idea of the price of drapes, as the product is not yet included in UNICEF or UNFPA catalogues, it is estimated to be within the range of $0.50-$1, excluding shipment costs,[13] but actual prices will depend on the quotes and terms procurers are given.

Some calibrated drapes have detachable components, and there is some interest in exploring reusable components and materials. Currently, other blood loss measurement products exist in addition to calibrated drapes.[14] For example, a reusable drape with detachable disposable pouch or a reusable calibrated obstetric tray. The available evidence on postpartum blood loss measurement is largely from trials that used calibrated drapes, which this guidance focuses on.

[a] Should not be administered with oxytocin from the same iv bag, as mixing certain oxytocin and TXA products before administration may reduce the concentration of oxytocin, leading to under-dosing – further analysis is being conducted

IMPORTANT NOTES:

- Since the use of HSC for prevention of PPH and TXA for treatment of PPH administered together with uterotonics and the use of calibrated drapes for detection of PPH are recent recommendations by WHO,[2] the quantification team will need to develop and agree on assumptions for initial adoption/demand and about the factors and interventions that may affect future changes in demand for these products. This may also apply to misoprostol, not so new, but which may still be being scaled up in some settings. Introduction and scale up of new products is a long process; for example, medicines need to go through the process of registration, guidelines need to be updated and disseminated, training materials need to be updated, and health care workers need to be trained.
- Table 6 presents the key characteristics and health system considerations for each of the medicines. For more detailed information on oxytocin and misoprostol, refer to the chapter in the "Manual for procurement and supply of quality assured MNCH commodities."[15]
- Table 7 presents the key characteristics and health system considerations for calibrated drapes.
- In addition, uterine balloon tamponades[16] and nonpneumatic antishock garments can be used to control bleeding and stabilize women suffering from obstetric hemorrhage and shock in PPH cases and who are not responding to standard first line treatment. Country teams are advised to consider both in their quantifications according to national policy.

Table 6: Summary of product characteristics: Oxytocin, HSC, TXA, and Misoprostol

PARAMETER	OXYTOCIN	HSC	TXA	MISOPROSTOL
Prevention of PPH: Dosage	1 amp of 10 IU per case	1 amp of 100 mcg per case	**Not indicated**	400 mcg or 600 mcg per case (2–3 tabs of 200 mcg)
Treatment of PPH: Dosage	Up to 4 amp of 10 IU per case	**Not indicated**	1 amp of 1 g per case (as an adjunct treatment in addition to uterotonic)	800 mcg per case (4 tabs of 200 mcg)
Presentation	10 IU in 1 ml amp; 5 IU in 1 ml amp	100 mcg in 1 ml amp	1 g in 1 ampoule of 10 ml 500 mg in 1 ampoule of 5 ml	200 mcg oral tablets
Administration	IM or IV		IV*, simultaneously with uterotonics but not to be mixed in the same IV infusion bag as oxytocin due to potential reduction in concentration of oxytocin[18]	Orally for PPH prevention and treatment
Storage condition	Store at 2°C to 8°C (in cold chain)[17]	Store at or below 40°C for up to 6 months; or at or below 30°C for longer periods	Store at or below 25°C	Store at or below 25°C Must be packaged in double aluminum blisters; is sensitive to humidity
Additional supplies required for administration	IV infusion set (for IV only), syringes, needles, and alcohol swabs			
Level of use	HFs where appropriately skilled health personnel and infrastructure are present			Suitable for oral administration during home deliveries or in low-level HFs ~~w~~here there is no cold chain available
Supply chain considerations[19]	Requires functional cold chain Shelf life of 18–48 months Procure in 10 IU amp rather than 5 IU amp to minimize complexity and maximize efficiency, as unit costs are the same	Does not require cold chain Shelf life of 36 months	Does not require cold chain Shelf life of 36 months	Does not require cold chain Shelf life of 24 months In blisters of 3 tablets for prevention and blisters of 4 tablets for treatment
Additional comments[19]	Not indicated for postabortion care	Not indicated for treatment of PPH** or postabortion care. It is contra-indicated for labor induction or augmentation of labor	Not indicated for prevention of PPH, labor induction, augmentation of labor, or postabortion care	Contra-indicated for augmentation of labor

* There is ongoing work studying the efficacy of IM TXA for prevention of PPH. If found efficacious, IM TXA would then be suitable for deliveries in low-level HFs as well.
** A current study, expected to end in 2027, is evaluating the efficacy of HSC for treatment of PPH. Until the efficacy is confirmed, HSC should ONLY be used for PREVENTION of PPH.

Table 7: Summary of product characteristics: Calibrated drapes

PARAMETER	CALIBRATED DRAPES
Recommended uses	• Objective measurement of blood loss after delivery to determine PPH
Components/features	• Single-piece drape - Blood collection pouch often marked at 50ml intervals that can include trigger marks at 300 mL and 500 mL - Straps, ties, or adhesive to keep drape in place
Administration	• Placed under buttocks of the laboring woman in a delivery bed in a health facility and unrolled after the baby is born
Storage condition	• Clean, dry, able to withstand ambient temperatures - no cold chain storge required
Additional supplies required for administration	• Delivery bed, IV fluids, safe delivery supplies, disinfectants • Uterotonics and tranexamic acid if PPH is diagnosed
Level of use	• Delivery suite in health centers or hospitals
Other supply chain considerations	• Rate of wastage/damage • Proper disposal through standard biohazard disposal procedures • Shelf life of calibrated drapes is typically a minimum of 2 years under standard storage conditions

IMPORTANT NOTES:

- Quantification teams are advised to consider several factors in selecting the appropriate regimens/medicine for the appropriate level of use. Such factors include national treatment policies, cold chain availability, consistency and capacity, training and qualifications of health care workers available at each level of care, and availability of equipment. For example, misoprostol oral tablets would be the best choice for community-level or lower-level HFs where cold chain capacity is not available or is not consistently functional, where appropriately skilled health personnel and equipment are not present, and/or inpatient care is not possible. On the other hand, oxytocin is preferred at hospitals where cold chain capacity is usually adequate, trained professionals and equipment are available, and inpatient care is possible. HSC can be used at HFs where trained professionals and equipment are available, but where cold chain is not available or is not consistently functional. More details on consideration for selection of regimens/medicines by level of care is available from "Uses of Medicines for Prevention and Treatment of Post-partum Hemorrhage and Other Obstetric Purposes."[19]

REQUIRED DATA AND POTENTIAL SOURCES: MORBIDITY METHOD OF FORECASTING

A number of data points are required to forecast demands of medicines and supplies recommended for the prevention, diagnosis, and treatment of PPH. Table 8 summarizes the main data types and potential sources for the morbidity method of forecasting of uterotonics, TXA, and calibrated drapes, in addition to the relevant common data on population, proportion of pregnant women, and proportion of deliveries by level and sector provided in the introduction of Table 1 of this supplement.

Table 8: Data and potential sources for forecasting of uterotonics, TXA, and calibrated drapes using morbidity method

DATA	FOR USE IN CALCULATION OF		SOURCE	NOTES
	MEDICINES	DRAPES		
Miscarriage rate[17]*	X	X	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data may be outdated; HMIS data may not be complete; may need to apply estimated annual growth/reduction rate
Proportion/number of public HF and home deliveries (separately) that are provided uterotonics for prevention of PPH	X			
Proportion/number of public HF and home deliveries (separately) that are not provided uterotonics for prevention of PPH**	X			
Proportion/number of public HF vaginal deliveries***		X		
Proportion/number of public HF vaginal deliveries that are provided calibrated drapes for diagnosis of PPH		X		
Incidence/number of PPH among deliveries without prevention by level of care (incidence without prevention)	X			
Incidence/number of PPH among deliveries with prevention of PPH by level of care (incidence after prevention)	X			
Proportion/number of women with PPH with prevention of PPH that seek care from the public health facilities	X			
Proportion/number of women with PPH without prevention of PPH that seek care from the public health facilities	X			
Type and respective proportion of regimens/medicines given for prevention and/or treatment of PPH in the public health sector	X		HMIS, national maternal morbidity and mortality surveys, special surveys; national STG, WHO STG	HMIS data may not be complete; actual practice may be different from STGs; need to consider expert opinion and program/ strategic plans
Type and respective proportion of calibrated drapes used for diagnosis of PPH in the public health facilities		X		
Quantity of each medicine (specific formulation and dosage) used for the prevention and/or treatment of PPH per case	X		National STG, WHO STG, expert opinion, programmatic/strategic plans	Guidelines may be outdated; may not include new WHO recommendations; actual practice may be different from STGs, consider the actual practice if guidelines are relatively old and not followed

**Miscarriage rate is the percentage of pregnancies lost within the first 28 weeks of gestation.*

***There could be many reasons for not providing prevention doses, including noncompliance to treatment recommendations, unavailability of products, and refusal by pregnant women. Quantification teams may reduce the percentage of home deliveries that are not provided with uterotonics for prevention of PPH. It could be 0% if there is clear indication that the proportion given uterotonics is close to 100%.*
**** Calibrated drapes are used only in vaginal deliveries and not for cesarean section deliveries.*

CALCULATION ALGORITHMS TO FORECAST MEDICINES FOR PREVENTION AND TREATMENT OF PPH AND DEVICES FOR DIAGNOSIS OF PPH

Conventional morbidity method calculations are applied to forecast medicines for prevention and treatment of PPH as well as single-use (disposable) calibrated drapes. Figures 6 to 8 below provide the algorithms that can be followed to calculate the forecast requirements.

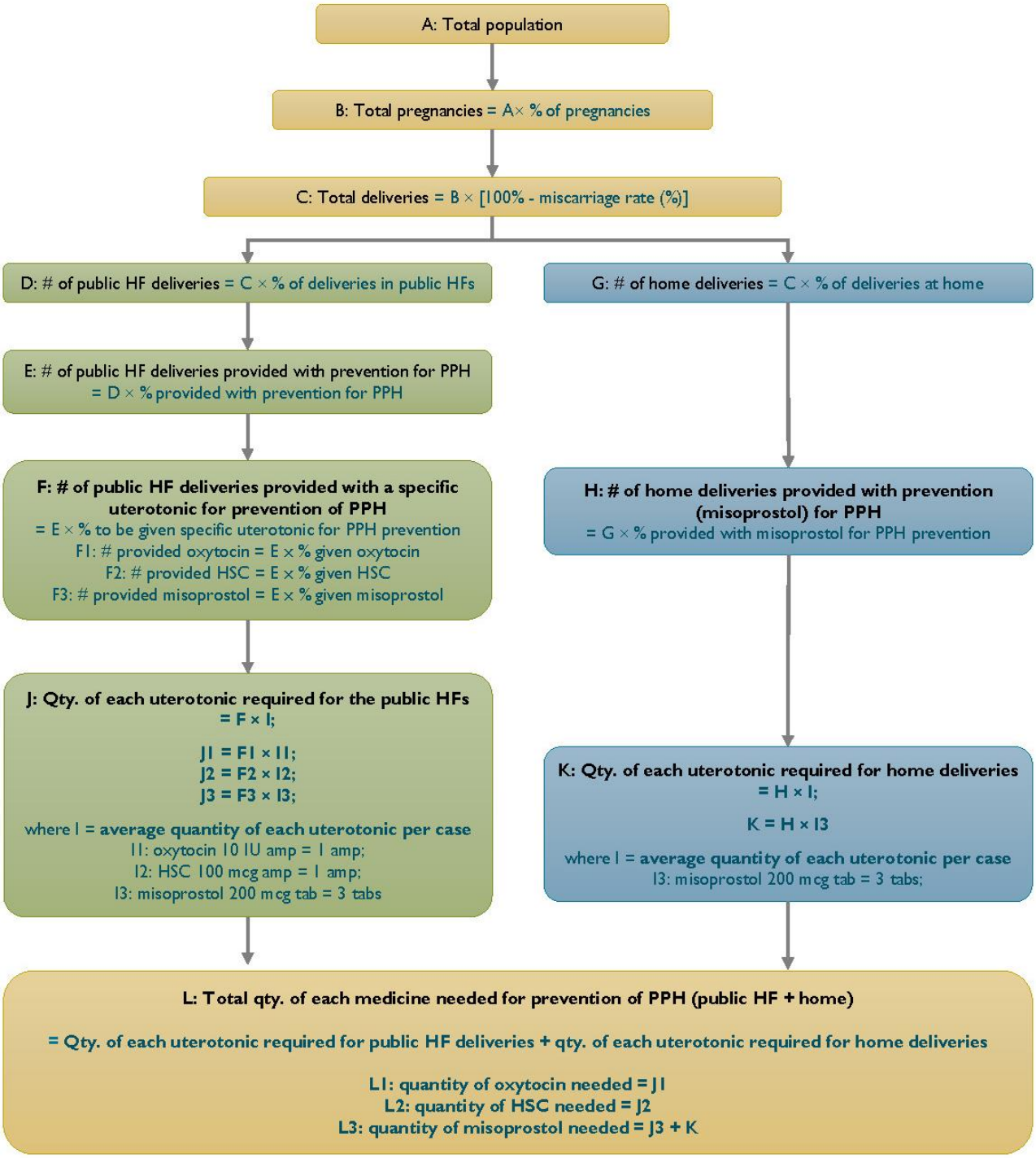

Figure 6: Forecasting algorithm for medicines used for prevention of PPH based on morbidity method

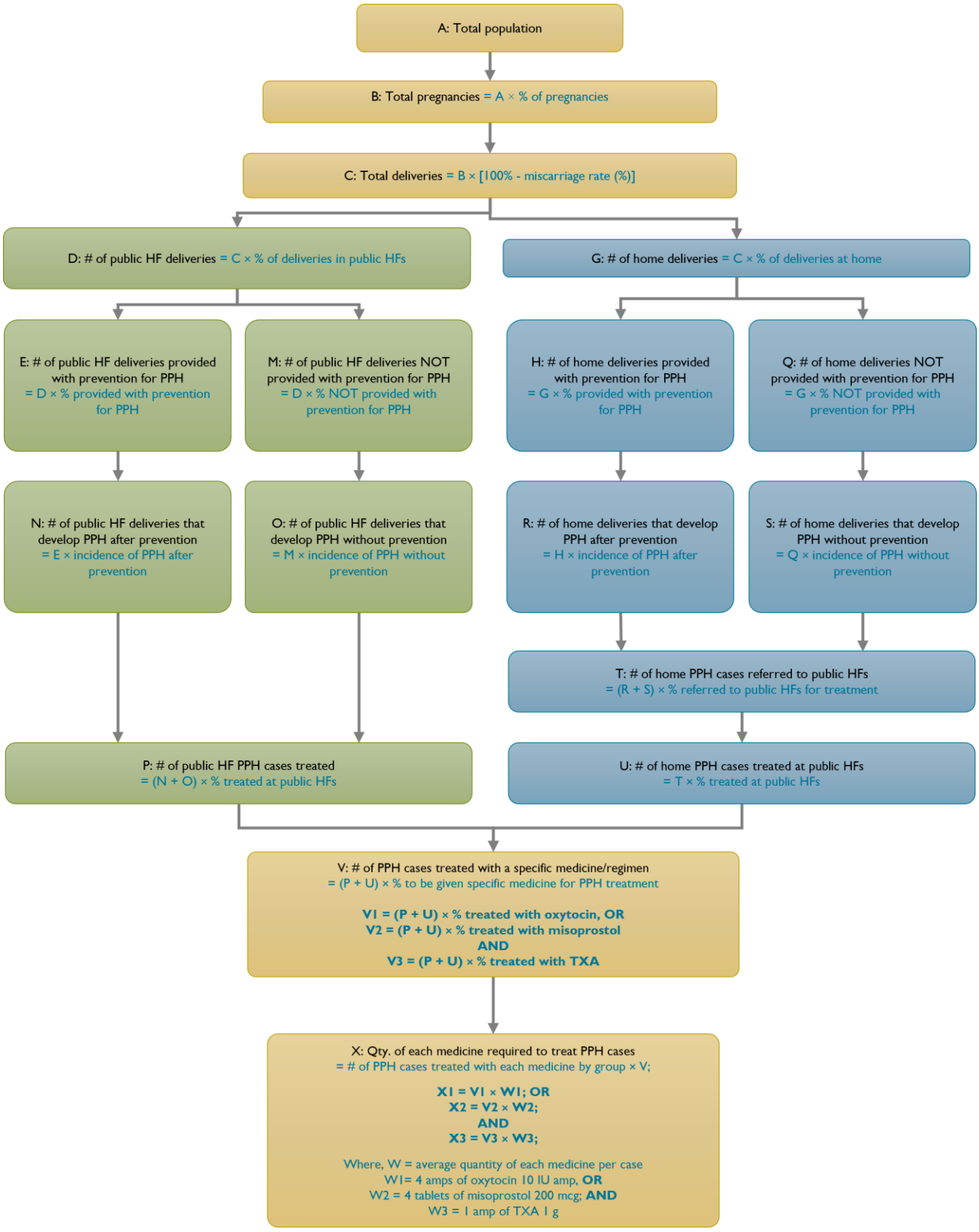

Figure 7: Forecasting algorithm for medicines used for treatment of PPH based on morbidity method

IMPORTANT NOTES:

- To get the total requirements of each medicine for both prevention and treatment of PPH, add the requirement for prevention and treatment (i.e., L [from figure 6] + X [from figure 7]). For example, oxytocin 10 IU amp = L1 + X1.
- Assumptions need to be made on how much HSC will be used compared to oxytocin for PPH prevention. One approach is to estimate the number of women giving birth in the health facilities without cold chain equipment and use this to determine the proportion and quantity of HSC to be used.
- While the forecasting guidance provided here is specifically to calculate the need for management of PPH, the products are also used for other purposes. For example, on average, an estimated 9.6% of pregnancies per year are induced and may require oxytocin or misoprostol.[20]
- In addition, up to 20% of pregnancies may require oxytocin for augmentation of labor. Countries should take these and other uses of the products into account when preparing forecasts. The same logic used in forecasting the need for management of PPH will apply for these other uses as well.
- Similarly, TXA is used for non-PPH conditions such as prevention of bleeding after trauma. The quantity calculated here should be added to whatever is needed for other uses.
- While these algorithms provide an approach to estimate projected needs of medical products to diagnose, prevent and treat PPH, they are based on the assumption that the products that will be procured, distributed, and used are quality assured to ensure optimal patient outcomes and efficient resource use. Without quality assurance, achieving similar positive patient outcomes and resource efficiency will not be possible.

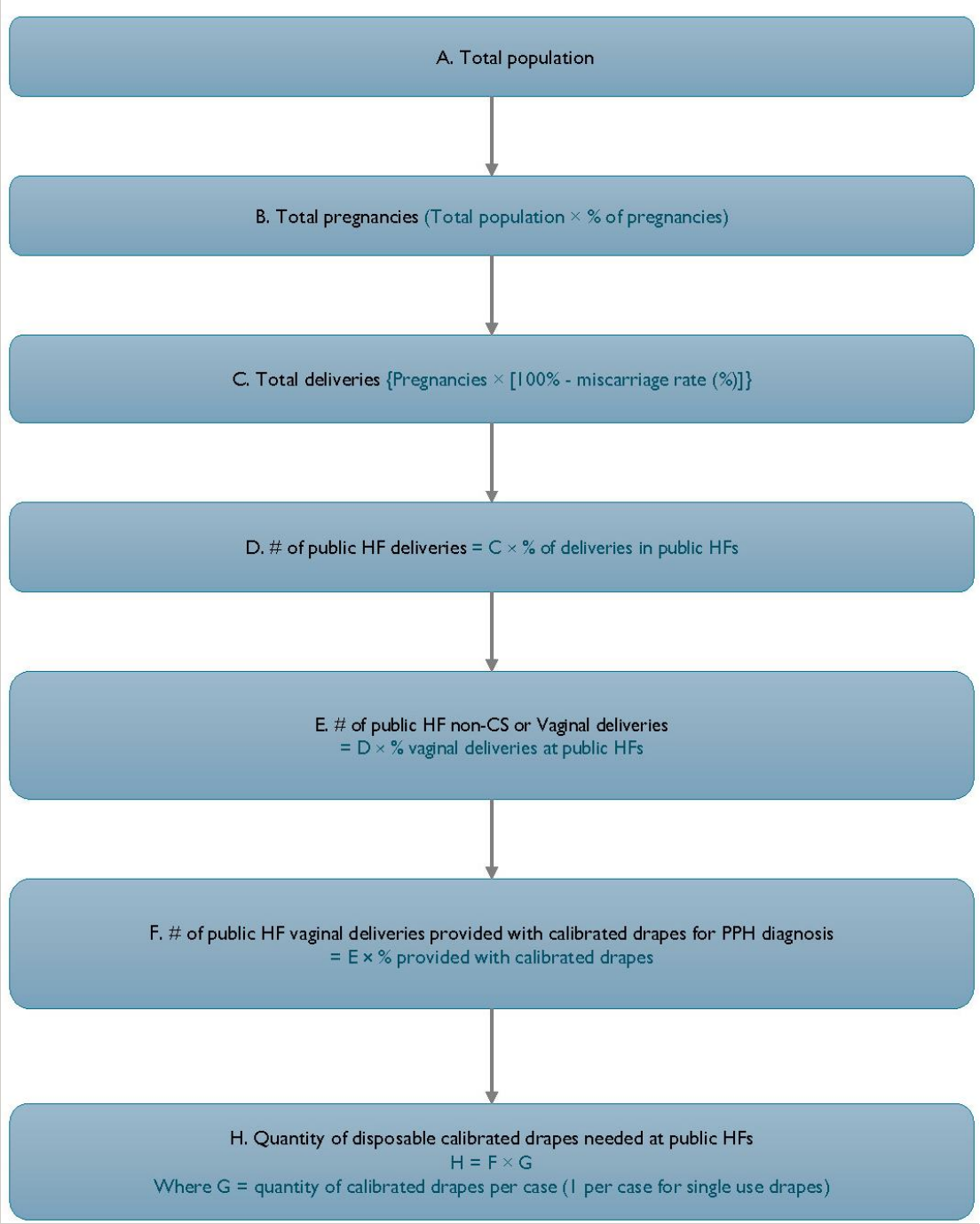

Figure 8: Forecasting algorithm for single-use calibrated drapes used for diagnosis of PPH based on morbidity method[b]

[b] If reusable devices are used in a country, the forecast will be based on the daily number of facility deliveries, the time required to disinfect each reusable tray, and the device's lifespan.

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

Table 9: Average quantity of medicines per case

	MEDICINE	DOSAGE	QUANTITY PER CASE
A	Oxytocin 10 IU per ampoule	Prevention: 10 IU Treatment: Up to 40 IU	1 ampoule Up to 4 ampoules
B	Misoprostol 200 mcg tablet	Prevention: 600 mcg Treatment: 800 mcg	3 tablets 4 tablets
C	HSC 100 mcg in 1 ml amp	Prevention: 100 mcg	1 ampoule
D	TXA 1 g in 1 ampoule of 10 ml	Treatment: 1 g	1 ampoule

Table 10: Summary of incidence rates

	PARAMETER	VALUE
A	Miscarriage rate (%)[21]	10%–15%
B	Incidence of PPH in pregnant women who have received prophylaxis	5%
C	Incidence of PPH in pregnant women without prophylaxis[4]	10%
D	Vaginal delivery rate Cesarean section rate (%)[22]	95–85% (5–15%)

IMPORTANT NOTE:

- Quantification teams are advised to consult the provided reference for the proxy data as many contain country- or region-specific information that can be applied to the specific region or country under consideration, rather than relying on global averages.
- It is possible that with the increased use of drapes, there may be a resultant increase or reduction in the number of diagnosed cases of PPH depending on whether there is currently an overestimation or underestimation based on current empiric practices. For example, in the E-MOTIVE trial, PPH detection was less in the intervention group (8.5%) with use of drapes than in the control group (16.7%)[11].
- In some cases, repeated doses may need to be administered to achieve clinical outcomes – quantification teams are advised to use local experience to inform the forecast as appropriate.

EXAMPLES

BOX 4. EXAMPLE OF COUNTRY FORECAST FOR PREVENTION AND TREATMENT OF PPH

Country X recommends the use of **oxytocin** OR **HSC** for prevention of PPH for facility deliveries, and **oxytocin** AND **tranexamic acid (TXA)** for treatment of PPH cases identified or referred to its HFs. In country X, m**isoprostol** is recommended for prevention of PPH for home deliveries only. CHWs are recommended to refer cases of PPH to HFs.

Available data and assumptions

- Total population as of current year (CSO census): **20,000,000**
- Population growth rate per year: **2%**
- % of pregnant women out of total population: **4%**
- Miscarriage rate: **10%**
- % of deliveries in public HFs: **50%**, with annual **increase of 4 percentage points** (54% in year 1 and 58% in year 2)
- % of home deliveries: **45%**, with annual **reduction of 4 percentage points** (41% in year 1 and 37% in year 2)
- % of home deliveries provided with prevention for PPH in the current year is estimated to be **30%**; expected to grow to **35%** and **40%** in years 1 and 2, respectively
- Compliance to the PPH prevention recommendations for HF births (use of oxytocin OR HSC) in the current year is estimated to be **80%**; expected to grow to **85%** and **90%** in years 1 and 2, respectively
- In the current year, **60%** and **40%** of the HF deliveries are estimated to be given preventive oxytocin and HSC, respectively. The country plans to increase the HF level use of HSC by **10%** points annually and reduce that of oxytocin for prevention of PPH by the same magnitude.
- Compliance to the PPH prevention recommendations for home births (use of misoprostol) in the current year is estimated to be **30%**; expected to grow to **35%** and **40%** in years 1 and 2, respectively
- Incidence of PPH in women who were not given uterotonics for prevention of PPH is **24%** (global average)
- Incidence of PPH in women who were given uterotonics for prevention of PPH is **12%** (global average)
- Referral of home deliveries with PPH: **85%**
- Compliance to PPH treatment recommendations (use of oxytocin AND TXA) in the current year is estimated to be **96%**; expected to grow to **98%** and **100%** in years 1 and 2, respectively
- Available formulations:
    - Oxytocin: 10 IU ampoule
    - HSC: 100 microgram ampoule
    - Misoprostol: 200 micrograms tablet
    - Tranexamic acid: 1 gram ampoule

- Dosage recommendations per one women/case (from the national STG)
    - Oxytocin for prevention of PPH: 10 IU (1 ampoule)
    - HSC for prevention of PPH: 100 mcg (1 ampoule)
    - Misoprostol for prevention of PPH: 600 micrograms (3 tablets)
    - Oxytocin for treatment of PPH: 40 IU (4 ampoules)
    - Tranexamic acid for treatment of PPH: 1 gram (1 ampoule)

Calculate the quantities of oxytocin 10 IU ampoules, misoprostol 200 microgram tablets, HSC 100 mcg ampoules and TXA ampoules required by the program (in the public health sector) for the two-year forecast period.

Example: Prevention of PPH

PARAMETER	INPUT		CURRENT YEAR*	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year* population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total pregnancies (B)	B = A x % of pregnant women out of total population	4%	800,000	816,000	832,320
Total deliveries (C)	C = B x (100 % - miscarriage rate in %) (miscarriage rate of 10%)	10%	720,000	734,400	749,088
Number of public HF deliveries (D)	D = C x % of deliveries in public HFs		360,000	396,576	434,471
	(annual increase in compliance of 4%)	4%	50%	54%	58%
Number of public HF deliveries provided with prevention for PPH (E)	E = D x % compliance	5%	288,000	337,090	391,024
	(annual increase in compliance of 5%)		80%	85%	90%
Number of public HF deliveries given oxytocin for prevention of PPH (F1)	F1 = E x % of deliveries given oxytocin (annual decrease of 10%)	-10%	172,800	168,545	156,410
			60%	50%	40%
Number of public HF deliveries given HSC for prevention of PPH (F2)	F2 = E x % of deliveries given HSC (annual increase of 10%)	10%	115,200	168,545	234,614
			40%	50%	60%
Number of home deliveries (G)	G = C x % of home deliveries		324,000	301,104	277,163
	(annual decrease of 4%)	-4%	45%	41%	37%
Number of home deliveries provided with misoprostol for prevention of PPH (H)	H = G x % compliance		97,200	105,386	110,865
	(annual increase in compliance of 5%)	5%	30%	35%	40%
Quantity of oxytocin 10 IU ampoules needed for prevention of PPH (J1)	J1 = F1 x I1; where I1: # of ampoules needed per case for prevention = 1 x 10 IU = 1 ampoule of 10 IU	1	172,800	168,545	156,410
Quantity of HSC 100 mcg ampoules needed for prevention of PPH (J2)	J2 = F2 x I2; where I2: # of ampoules needed per case for prevention = 1 x 100 mcg = 1 ampoule of 100 mcg	1	115,200	168,545	234,614
Quantity of misoprostol 200 mcg tablet needed for prevention of PPH (K)	K = H x I3; where I3: # of tablets needed per case for prevention = 3 x 200 mcg = 3 tablets of 200 mcg	3	291,600	316,159	332,595
Total quantity of oxytocin 10 IU ampoules needed for prevention of PPH (L1)	**L1 = J1**		**172,800**	**168,545**	**156,410**
Total quantity of HSC 100 mcg ampoules needed for prevention of PPH (L2)	**L2 = J2**		**115,200**	**168,545**	**234,614**
Total quantity of misoprostol 200 mcg tablet needed for prevention of PPH (L3)	**L3 = K**		**291,600**	**316,159**	**332,595**

*For the population for the current year, insert the total population from our respective source, and population figures for forecast year 1 and forecast year 2 are calculated based on the previous year population and the annual PGR. For example, the population for forecast year 1 is calculated by multiplying the population in the current year (i.e., the previous year to forecast year 1) by the annual PGR.

Example: Treatment of PPH

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Number of public HF deliveries NOT provided with prevention for PPH (M)	M = D x % of facility deliveries that do NOT receive prevention (annual reduction in noncompliance of 5%)	-5%	72,000 20%	59,486 15%	43,447 10%
Number of public HF deliveries that develop PPH after prevention (N)	N = E x % of deliveries that develop PPH after prevention (incidence of PPH after prevention)	12%	34,560	40,451	46,923
Number of public HF deliveries that develop PPH without prevention (O)	O = M x % of deliveries that develop PPH without prevention (incidence of PPH without prevention of 10%)	24%	17,280	14,277	10,427
Number of public HF PPH cases treated (P)	P = (N + O) x % compliance (annual increase in compliance of 2%)	2%	49,766 96%	53,633 98%	57,350 100%
Number of home deliveries NOT provided with prevention for PPH (Q)	Q = G x % of home deliveries that do NOT receive prevention (annual reduction in noncompliance of 5%)	-5%	226,800 70%	195,718 65%	166,298 60%
Number of home deliveries that develop PPH after prevention (R)	R = H x % of deliveries that develop PPH after prevention (incidence of PPH after prevention of 5%)	12%	11,664	12,646	13,304
Number of home deliveries that develop PPH without prevention (S)	S = Q x % of deliveries that develop PPH without prevention (incidence of PPH without prevention)	24%	54,432	46,972	39,911
Number of home PPH cases referred to public HFs (T)	T = (R + S) x % of home PPH cases referred to public HFs	85%	56,182	50,676	45,233
Number of home PPH cases treated at public HFs (U)	U = T x % compliance (annual increase in compliance of 2%)	2%	53,934 96%	49,662 98%	45,233 100%
Number of PPH cases given oxytocin for treatment (V1)	V1 = (P+U) x % given oxytocin	100%	103,701	103,295	102,583
Number of PPH cases given TXA for treatment (V2)	V2 = (P+U) x % given TXA	100%	103,701	103,295	102,583

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Quantity of oxytocin 10 IU ampoules needed for treatment of PPH cases (X1)	X1 = V1 x W1; where W1: # of ampoules needed per case for treatment = 4 ampoules	4	414,803	413,181	410,332
Quantity of TXA 1g ampoules needed for treatment of PPH cases (X2)	X2 = V2 x W2; where W2: # of ampoules needed per case for treatment = 1 ampoule	1	103,701	103,295	102,583

Total Quantities for PPH

PARAMETER	INPUT	CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total quantity of oxytocin 10 IU ampoules needed for PPH (Y1)	Y1 = L1+X1	587,603	581,726	566,742
Total quantity of HSC 100 mcg ampoules needed for PPH (Y2)	Y2 = L2	115,200	168,545	234,614
Total quantity of misoprostol 200 mcg tablets needed for PPH (Y3)	Y3 = L3	291,600	316,159	332,595
Total quantity of TXA 1 g ampoules needed for PPH (Y4)	Y4 = X2	103,701	103,295	102,583

IMPORTANT NOTES:

- Quantities of the same product needed for prevention and treatment are added to obtain the total need of each medicine for PPH management.
- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

BOX 5. EXAMPLE OF COUNTRY FORECAST FOR CALIBRATED DRAPES

Country X recommends the use of single-use (disposable) calibrated drapes for diagnosis of PPH for health facility deliveries.

Available data and assumptions

- Total population as of current year (CSO census): 20,000,000
- Population growth rate per year: **2%**
- % of pregnant women out of total population: **4%**
- Miscarriage rate: **10%**
- % of deliveries in public HFs: **50%,** with annual increase of 4 percentage points (**54%** in year 1 and **58%** in year 2)
- % of vaginal deliveries in the public HFs is assumed to be **90%** in the current year with expected annual 2% points decrease (**88%** in year 1 and **86%** in year 2). Meaning, cesarean section deliveries at the public HFs are estimated at **10%** in the current year with estimated annual increase by 2% points.
- Compliance to the use of disposable calibrated drapes for diagnosis of PPH among women giving birth at public health facilities in the current year is estimated to be **40%**; expected to grow to **60%** and **80%** in years 1 and 2, respectively (i.e., annual increase of 20% points per year)
- Available presentation of drapes:
    - Single-use (disposable) calibrated drapes calibrated at 300ml and 500ml
- One drape is used per woman delivering

Calculate the quantities of single-use (disposable) calibrated drapes required by the program (in the public health sector) for the two-year forecast period.

Example: Single-use (disposable) calibrated drapes to diagnose PPH

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total pregnancies (B)	B = A x % of pregnant women out of total population	4%	800,000	816,000	832,320
Total deliveries (C)	C = B x (100 % - miscarriage rate in %) (miscarriage rate of 10%)	10%	720,000	734,400	749,088
Number of public HF deliveries (D)	D = C x % of deliveries in public HFs (estimated annual increase in public facility delivery of 4%)	4%	360,000 50%	396,576 54%	434,471 58%
Number of public HF vaginal deliveries (E)	E = D x % of vaginal deliveries in the public HFs (estimated annual reduction in public HF vaginal deliveries of 2%)	2%	324,000 90%	348,987 88%	373,645 86%
Number of public HF deliveries provided with calibrated drapes for PPH diagnosis (F)	F = E x % compliance (estimated annual increase in usage of 20%)	20%	129,600 40%	209,392 60%	298,916 80%

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Quantity of disposable calibrated drapes needed for diagnosis of PPH (H)	H = F x G; where G: # of Disposable Calibrated Drapes needed per case for diagnosis of PPH = 1 Disposable Calibrated Drape	1	**129,600**	**209,392**	**298,916**

Note: This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

The increase in usage of drapes may not increase in a linear fashion, i.e., the same percentage increase each year. Countries will need to review this as part of the forecast review.

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3. PREVENTION AND TREATMENT OF HYPERTENSIVE DISORDERS IN PREGNANCY

INTRODUCTION

Hypertensive disorders in pregnancy are an important, common, and treatable cause of severe morbidity, long-term disability, and death among both pregnant women and their babies and account for approximately 14% of all maternal deaths worldwide.[1]

Globally, about 10% of all pregnancies are affected by hypertensive disorders of pregnancy (i.e., gestational hypertension, chronic hypertension, pre-eclampsia, eclampsia).[2]

In 2018, WHO updated its recommendations on antihypertensive medicines for severe hypertension in pregnancy based on important new evidence. Accordingly, the following two major recommendations were issued:[2]

1. All pregnant women with severe hypertension should be treated with antihypertensive medicines.
2. The drug of choice and route of administration should be based primarily on the prescribing clinician's experience with the particular medicine, its cost, and its local availability, while ensuring that the medication has no adverse fetal effects.

Hypertensive disorders of pregnancy, pre-eclampsia, and eclampsia stand out as major causes of maternal and neonatal mortality and morbidity.[2] Generally, the onset of a new episode of hypertension during pregnancy (with persistent diastolic blood pressure >90 mm Hg) and the occurrence of proteinuria (>0.3 g/24 h) is used as the criteria for identifying pre-eclampsia.[2] When severe hypertension, substantial proteinuria, or substantial maternal organ dysfunction occur, pre-eclampsia is classified as severe.[2] Eclampsia is characterized by generalized seizures in women with pre-eclampsia, given that the seizures are not attributable to other causes, such as epilepsy.[2]

Pre-eclampsia is present in 4.6% (2–8%) of pregnancies, and it usually becomes apparent in the second half of pregnancy. About 26% of pre-eclampsia cases develop to severe pre-eclampsia.[2,3]

The incidence of eclampsia in pre-eclamptic pregnancies after treatment with $MgSO_4$ was found to be 0.8%, while 1.9% of those given placebo developed eclampsia,[4] showing that prophylaxis with $MgSO_4$ reduces the risk of eclampsia in women with pre-eclampsia by more than 50%. The incidence of eclampsia in the general pregnant population without prophylaxis is 0.5%.[5]

The 2011 WHO recommendations on using magnesium sulfate, an anticonvulsant, for prevention and treatment of eclampsia[2] still apply and include:

1. Use $MgSO_4$ for prevention and treatment of eclampsia in women with severe pre-eclampsia in preference to other anticonvulsants. Capacity for clinical assessment of women and administration of calcium gluconate are essential components of the package of services for the delivery of magnesium sulfate.
2. Use the full intravenous (IV) or intramuscular (IM) magnesium sulfate regimens to prevent and treat eclampsia. HFs using magnesium sulfate should have calcium gluconate available in case of magnesium sulfate toxicity.
3. For settings where it is not possible to administer the full magnesium sulfate regimen, administer loading dose and transfer to a higher-level HF immediately.

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

ANTIHYPERTENSIVES

Administration of antihypertensive medications can reduce the risk of maternal stroke or cerebrovascular events that occur with severe hypertension in pregnancy. They may also be used for treatment of other hypertensive disorders during pregnancy, including chronic (pre-existing) hypertension. If antihypertensive medication for acute treatment of severe hypertension cannot be used intravenously, oral treatment can be given.[6]

WHO recommends antihypertensive medications (hydralazine, labetalol, nifedipine immediate-release capsules, or methyldopa) for acute treatment of severe hypertension in pregnancy.[6]

Note: In this document, guidance is provided only on acute treatment of severe hypertension in pregnancy. Quantification teams need to factor in forecasts of the same or similar medicines for the treatment of chronic hypertension during and after pregnancy as needed and calculate the total requirements.

HYDRALAZINE

Hydralazine is a vasodilator that lowers blood pressure and allows blood to flow more easily through veins and arteries. For treatment of severe gestational hypertension, the injectable form of the medicine is recommended.

METHYLDOPA

Methyldopa is an oral antihypertensive medicine that stimulates central alpha-adrenergic receptors, resulting in a decreased sympathetic outflow to the heart, kidneys, and peripheral vasculature.

LABETALOL

Labetalol lowers blood pressure by decreasing systemic vascular resistance by α1-blockade and at the same time counteracts the reflex tachycardia from vasodilation through its β-blocker effect. Both oral and injectable formulations are recommended for the treatment of severe gestational hypertension.

NIFEDIPINE

Nifedipine is a calcium channel blocker that inhibits cardiac and vascular smooth muscle contraction, thereby dilating main coronary and systemic arteries. Immediate-release nifedipine capsules are recommended for the treatment of severe gestational hypertension. The immediate release formulations are not widely available in the global market, and calcium channel blockers are not included in the most recent WHO recommendations for use of antihypertensive drugs for nonsevere hypertension in pregnancy because they are reported to probably increase the risk of developing proteinuria and/or pre-eclampsia.[7]

Table 11: Summary of product characteristics: Antihypertensives

PARAMETER	HYDRALAZINE	LABETALOL	METHYLDOPA	NIFEDIPINE
Acute treatment of severe hypertension in pregnancy: Dosage	▪ 5 mg IV slowly, repeat every 5 minutes or 12.5 mg IM every two hours until the blood pressure goal has been achieved ▪ The maximum dose is 20 mg per 24 hours ▪ Assume 3 days of treatment as an average	▪ **IV:** 10 mg IV, if response is inadequate after 10 minutes, administer 20 mg. The dose can be doubled to 40 mg and then 80 mg with 10-minute intervals between each increased dose until blood pressure is lowered below threshold. The maximum total dose is 300 mg. ▪ **Oral:** 200 mg, repeat dose after one hour until the treatment goal is achieved ▪ The maximum daily dose is 1,200 mg ▪ Assume 3 days of treatment as an average	▪ 750 mg orally, repeat dose after 3 hours until the treatment goal is achieved ▪ The maximum dose is 3 g in 24 hours ▪ Assume 3 days of treatment as an average	▪ 5–10 mg orally, repeat dose after 30 minutes if response is inadequate until optimal blood pressure is reached ▪ The maximum total dose is 30 mg in the acute treatment phase of 90 minutes ▪ Assume 3 days of treatment as an average
Presentation	▪ Hydralazine HCl 20 mg powder for injection in 2 ml vials	▪ Labetalol HCl IV solution 20 mg/4 ml ampoule ▪ Labetalol HCl 200 mg tablet	▪ Methyldopa 250 mg tablet	▪ Nifedipine immediate release 5 mg, 10 mg capsules
Administration	▪ IV	▪ IV, Oral	▪ Oral	▪ Oral
Storage condition	▪ Store at 20°C to 25°C	▪ **Tablets:** Store between 2°C and 30°C; protect from light and excessive moisture ▪ **Injections:** Store between 20°C and 25°C; do not freeze; protect from light	▪ Store between 20°C and 25°C; protect from light	▪ **Immediate-release capsule:** Store between 15°C and 25°C; prevent from freezing; protect from light and moisture
Additional supplies required for administration	▪ IV infusion set (for IV only), syringes, needles, and alcohol swabs, 5% dextrose in water solution, normal saline solution			▪ None[6]
Level of use	▪ Every HF in which births are attended by qualified professionals who can monitor hypertension of pregnant women			
Supply chain considerations	▪ Do not require cold chain ▪ Some antihypertensive products, such as labetalol and nifedipine immediate-release capsules, may not be widely available in the market, especially for developing countries ▪ Shelf lives of these formulations range from 36 to 60 months			

MAGNESIUM SULFATE ($MGSO_4$)

$MgSO_4$ is an injectable anticonvulsant. It is recognized by WHO as the safest, most effective, and lowest-cost medicine for treating pre-eclampsia and eclampsia.[8]

$MgSO_4$ is a lifesaving drug and should be available in all health care facilities throughout the health system, but there are often stock-outs. In addition to issues related to availability, there are various sociocultural and policy-based issues hindering its use: health care service 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 for the patient. Current practices and plans to increase use of magnesium sulfate should be considered during forecasting.

For more detailed information on $MgSO_4$, refer to the chapter in the manual for procurement and supply of quality-assured MNCH commodities.[8]

Note: $MgSO_4$ is a lifesaving medicine and should be available in all HFs where antenatal care (ANC) is provided for pregnancies or deliveries are attended. The quantification team needs to consider forecasting requirements of MgSO4 based on allocations for each type of HF, especially when there are lower-level HFs that need to provide the first dose of MgSO4 and refer to higher-level HFs for full treatment and or when the quantity of $MgSO_4$ forecasted is too small to allow distribution of adequate quantities of the medicine to each HF where the medicine is needed. For details on such methodology of forecasting, see the algorithm (figure 9) and associated example below.

CALCIUM GLUCONATE

Calcium gluconate is an injectable that is used as an antidote to reverse the adverse effects of $MgSO_4$. There is a less than 1.3% (0–8.2%) chance of adverse effect from administration of $MgSO_4$ that may affect breathing. Even though the risk is minimal, calcium gluconate is a lifesaving drug and should be available in all health care facilities throughout the health system where $MgSO_4$ is administered.

Note: The estimated number of cases with toxicity from magnesium sulfate, and therefore the forecasted demand for calcium gluconate ampoules, could generally be too small if calculated using the morbidity method; thus, the forecasting of calcium gluconate demands a different methodology. Given this, allocation by type of HF depending on the average number of ANC services/deliveries applied to forecast initial demand for distribution is recommended. For details on such methodology of forecasting, see the algorithm (figure 10) and associated example below.

For both $MgSO_4$ and calcium gluconate, this methodology of allocation would probably result in over-quantification/forecast but ensures that each facility has a minimum stock. To minimize wastage, it is important to implement a number of approaches, including procurement for multiyear use at once, procuring products with long shelf lives, continuous reporting and assessment of availability and stock levels at HFs, and rotation of stock as needed depending on shelf life and consumption rate.

Table 12: Summary of product characteristics: Magnesium sulfate and calcium gluconate

PARAMETER	MAGNESIUM SULFATE	CALCIUM GLUCONATE
Prevention of eclampsia: Dosage*	▪ Pritchard regimen (IV/IM) ○ 44 ampoules of 1 g in 2 ml per case OR ○ 9 ampoules of 5 g in 10 ml per case ▪ Zuspan regimen (IV) ○ 28 ampoules of 1 g in 2 ml per case OR ○ 6 ampoules of 5 g in 10 ml per case *Assuming 1 ampoule for each dose given and not allowing any open ampoule to be kept for later administration. *Notes:* ○ Based on the country guidelines, first-level HFs may need to give loading dose and refer to hospitals to continue with the full treatment. ○ The above quantities per case are for cases without convulsion after the loading dose. ○ Table 17 provides details on calculation of quantity per case, including for those with convulsion after the loading dose.	▪ Not indicated
Treatment of eclampsia: Dosage	▪ The same as above	▪ Not indicated
Treatment of $MgSO_4$ toxicity, especially respiratory arrest	▪ Not applicable	▪ 1 g in 10 ml (10% solution) IV slowly over 3 minutes until respiration begins
Presentation	▪ The WHO recommended presentation is 50% weight/volume solution, which is equivalent to 0.5 g in 1 ml[9] ▪ Common presentations include 1 g in 2 ml (50%) ampoule and 5 g in 10 ml (50%) ampoule solutions for injection	▪ 100 mg/ml in 10 ml ampoule solution for injection
Administration	IM or IV	IV
Storage condition	▪ Store below 30°C[8] ▪ Do not freeze	▪ Store between 15°C and 30°C
Additional supplies required for administration	▪ IV infusion set (for IV only), 2% lidocaine solution (for IM only), syringes, needles, and alcohol swabs, calcium gluconate (antidote for magnesium sulfate toxicity)	▪ IV infusion set, syringes, needles, and alcohol swabs
Level of use	▪ Every HF in which births are attended by qualified professionals should monitor pre-eclampsia/eclampsia and administer magnesium sulfate ▪ More and more countries are recommending that lower-level HFs administer a loading dose and then refer when they identify a woman with severe pre-eclampsia or eclampsia	▪ Every HF with qualified professionals where magnesium sulfate is used for the prevention or treatment of eclampsia
Supply chain considerations	▪ Does not require cold chain ▪ Shelf life of 24–60 months ▪ 5 g in 10 ml ampoule is preferred to 1 g in 2 ml ampoule to reduce number of ampoules per case	▪ Does not require cold chain ▪ Shelf life of 36 months ▪ Assessment shall be made to decide the number of ampoules to be available at each HF by type and distribute accordingly ▪ Since the demand for this product could be too small, countries need to consider procurement of the product for multiyear use with long shelf lives to minimize expiries

REQUIRED DATA AND POTENTIAL SOURCES: MORBIDITY METHOD OF FORECASTING MAGNESIUM SULFATE, CALCIUM GLUCONATE, AND ANTIHYPERTENSIVES FOR SEVERE HYPERTENSION IN PREGNANCY

Several data points are required to forecast future demands of magnesium sulfate and calcium gluconate solutions as well as antihypertensives. Table 13 summarizes the main data types and potential sources for the morbidity method of forecasting (for both) and facility-based allocation (for calcium gluconate), in addition to the common data provided in the introduction of this supplement.

Table 13: Data and potential sources for forecasting of antihypertensive medicines for severe hypertension in pregnancy using morbidity method

DATA	SOURCE	NOTES
Proportion/number of pregnancies at public HFs with severe hypertension	HMIS, national maternal morbidity and mortality surveys, special surveys	HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; include those that are referred from community or the private sector
Proportion/number of pregnancies at public HFs with severe hypertension that are given antihypertensive medicines for treatment		
Proportion/number of pregnancies at public HFs with severe hypertension that are given specific antihypertensive medicines (hydralazine, methyldopa, labetalol, nifedipine)		
Quantity (formulations and dosages) of specific antihypertensive medicines (hydralazine injection, methyldopa tablets, labetalol, nifedipine) to be given for treatment of severe hypertension in pregnancy	National STG, WHO STG, expert opinion	Guidelines may be outdated; may not include new WHO recommendations; actual practice may be different from STGs, consider the actual practice if guidelines are relatively old and not followed; parenteral treatment duration varies between patients depending on clinical evolution

Table 14: Data and potential sources for forecasting of magnesium sulfate and calcium gluconate using morbidity method

DATA	SOURCE	NOTES
Incidence/number of severe pre-eclampsia (pregnancies with severe pre-eclampsia) by sector/level of care	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	Survey data may be outdated; HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; include those that are referred from community or the private sector
Proportion/number of pregnancies at public HFs with severe pre-eclampsia that are given $MgSO_4$ for prophylaxis of eclampsia		
Incidence/number of women with eclampsia among those with severe pre-eclampsia who have not received prophylaxis: home pregnancies, HF pregnancies (incidence of eclampsia without prophylaxis)		
Proportion/number of home pregnancies with eclampsia that are referred to public HFs for treatment		
Incidence/number of women with eclampsia among those with severe pre-eclampsia who have received prophylaxis (incidence of eclampsia after prophylaxis)		

DATA	SOURCE	NOTES
Proportion/number of eclampsia cases at public HFs that are given $MgSO_4$ for treatment by level of care (i.e., lower level where prereferral loading dose is given and higher-level HFs where capability for cesarean section is available and full treatment can be administered)		
Quantity of $MgSO_4$ used per one case (formulation and dosage of $MgSO_4$): for prophylaxis of eclampsia, when convulsion occurs after the loading dose, for treatment of eclampsia (separately)	National STG, WHO STG, expert opinion, programmatic/strategic plans	Guidelines may be outdated; may not include new WHO recommendations; use expert opinion if the practice is different from what the guidelines prescribe
Proportion/number of cases that develop $MgSO_4$ toxicity after prophylaxis and treatment	HMIS, national maternal morbidity and mortality surveys, special surveys	HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; include those that are referred from community or the private sector
Proportion/number of cases with $MgSO_4$ toxicity that are treated with calcium gluconate		
Quantity of calcium gluconate to treat one case (formulation and dosage of calcium gluconate)	National STG, WHO STG, expert opinion	Guidelines may be outdated; may not include new WHO recommendations; actual practice may be different from STGs, consider the actual practice if guidelines are relatively old and not followed; parenteral treatment duration varies between patients depending on clinical evolution
Average number of calcium gluconate 100 mg/mL in 10 ml ampoules to be allocated by type of HF and for specific period	MNCH program; rapid assessment studies; MNCH strategic plans	Allocation should consider the number of births by facility type, qualifications of health professionals, and number of cases of magnesium toxicity per facility type

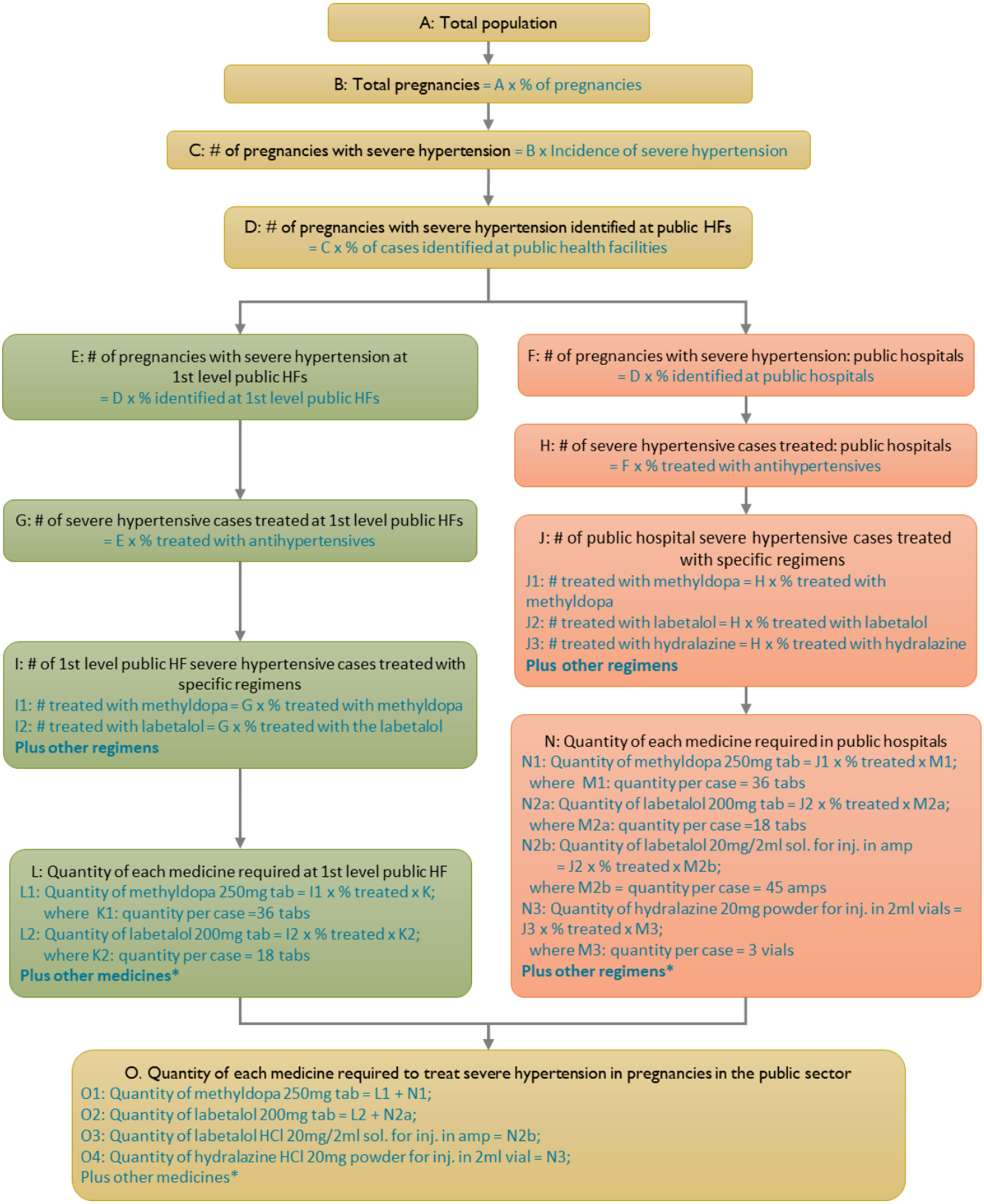

Figure 9: Forecasting algorithm for medicines used for acute treatment of severe hypertension in pregnancy based on morbidity method

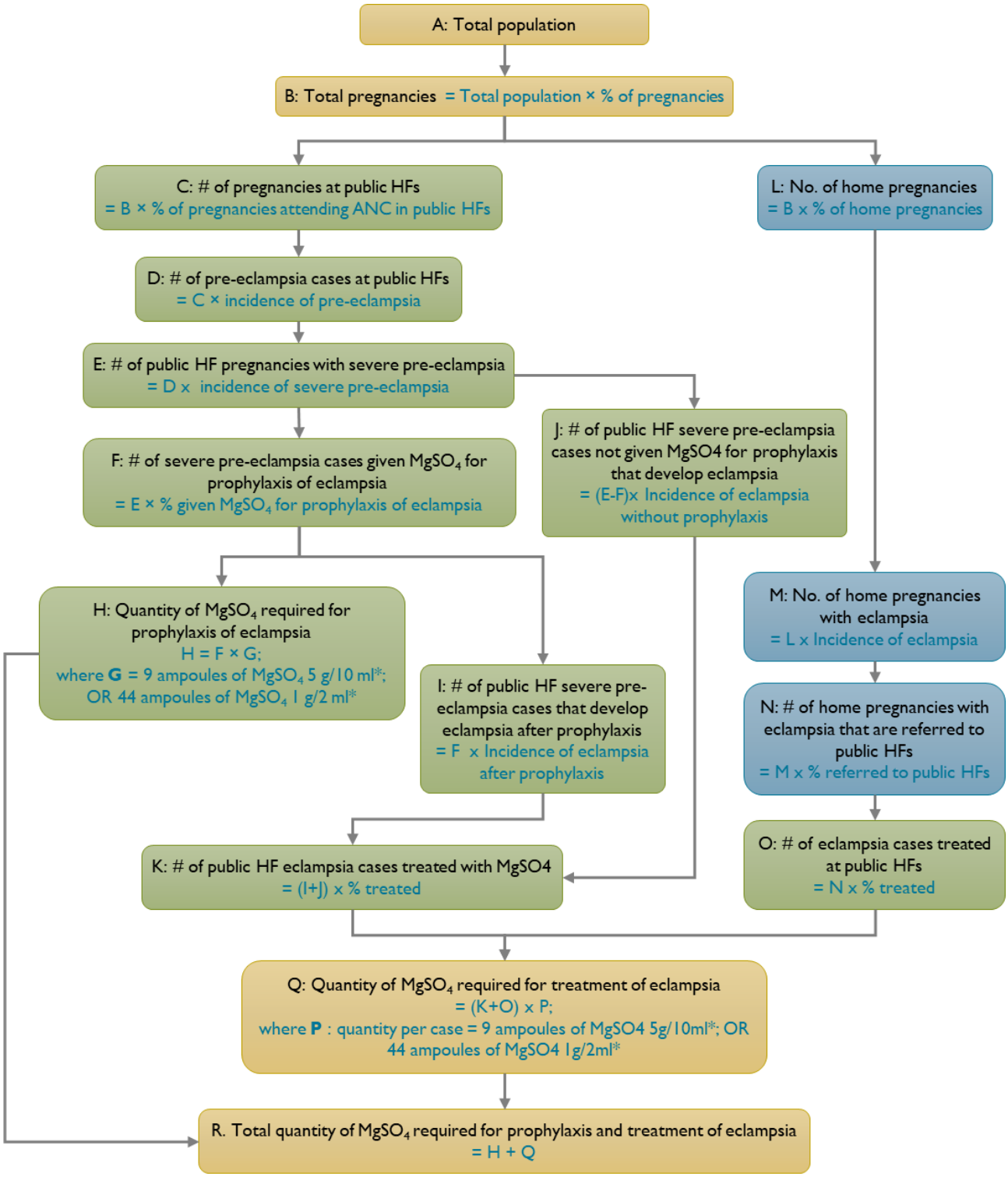

Figure 10: Forecasting algorithm for $MgSO_4$ used for prophylaxis and treatment of eclampsia based on morbidity method

*All cases are assumed to be given $MgSO_4$ only for the prevention or the treatment of eclampsia, according to WHO's recommendation, and no other anticonvulsants such as diazepam are used. Refer to table 11 for more option on regimen types and quantity per case.

IMPORTANT NOTE:

- $MgSO_4$ is a lifesaving medicine and should be available in all HFs where ANC is provided for pregnancies or deliveries are attended. The quantification team needs to consider forecasting requirements of $MgSO_4$ based on allocations for each type of HF, especially when there are lower-level HFs that need to provide the first dose of $MgSO_4$ and refer to higher-level HFs for full treatment or when the quantity of $MgSO_4$ forecasted is too small to allow distribution of adequate quantities of the medicine to each HF where the medicine is needed. See figure 11 for the allocation method.

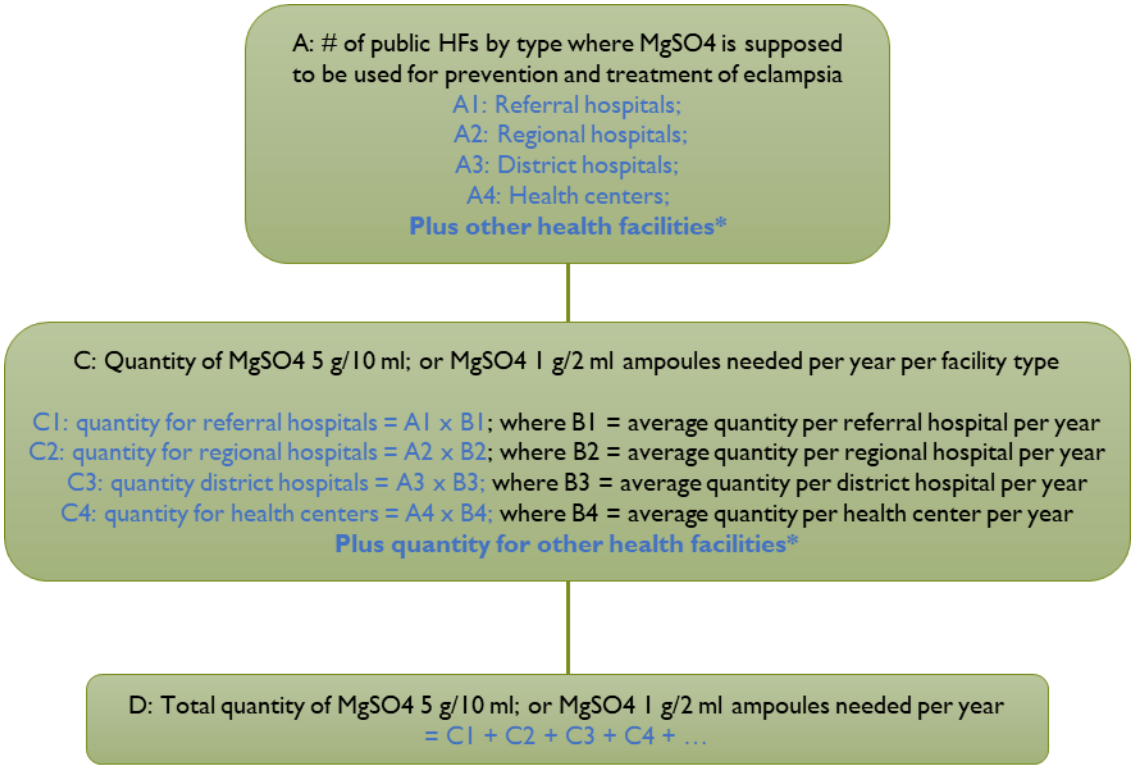

Figure 11: Forecasting algorithm for $MgSO_4$ used for prophylaxis and treatment of eclampsia based on allocations by facility type

*Consider other HF types, or subgroups of the ones indicated above, that are not included in the algorithm and quantities for each, as applicable, based on your local context.

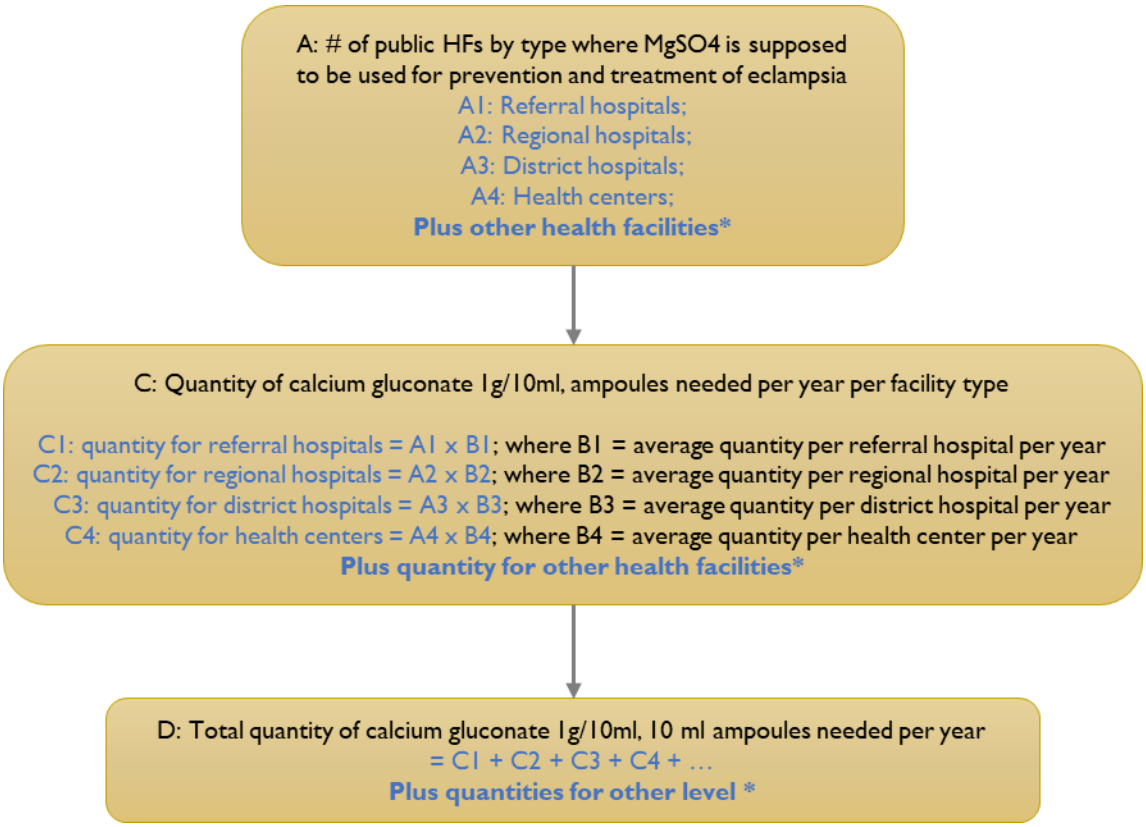

Figure 12: Forecasting algorithm for calcium gluconate used to treat toxicity of $MgSO_4$ based on allocations by facility type

*Consider other HF types, or subgroups of the ones indicated above, that are not included in the algorithm and quantities for each, as applicable, based on your local context.

Note: Applicable to both $MgSO_4$ and calcium gluconate

- To determine the average quantity of allocation per facility level per year, consider the incidence of cases by level; capacity to administer the products (e.g., health center may be allowed to administer the loading/prereferral dose of $MgSO_4$ only); and the minimum possible pack size for distribution to HFs.
- Quantification teams need to consider many factors, such as the actual usage rate, pack sizes, shelf life, and frequency of distribution, to decide whether to use the allocation method only or combine it with the morbidity method.
    - For example: Once $MgSO_4$ and calcium gluconate are distributed based on the allocation method for the first year of quantification, the morbidity method can be used to estimate actual demand and replenish what is used during each year of the remaining quantification years; expiry dates should be considered.
- Alternatively, the quantification team may use a combination of the two methods of forecasting, applying the allocation methods for the HFs where the number of cases is estimated to be low (such as health centers) and applying the morbidity method for those HF types that have relatively high incidence of cases, which allows for smooth distribution of the medicines considering the lowest distribution pack sizes.

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

1. Incidence of severe hypertension in pregnancy, pre-eclampsia, severe pre-eclampsia, and eclampsia and toxicity of $MgSO_4$.

Table 15: Summary of global incidence rates

	PARAMETER	VALUE
A	Incidence of pre-eclampsia[2,3]	4.6% (2–8%)
B	Incidence of severe pre-eclampsia among pregnancies with pre-eclampsia[4]	26%
C	Incidence of eclampsia in pre-eclamptic pregnancies without $MgSO_4$ prophylaxis[4]	1.9%
D	Incidence of eclampsia in pre-eclamptic pregnancies after $MgSO_4$ prophylaxis[4]	0.8%
E	Incidence of eclampsia in general pregnant population without prophylaxis[5]	0.5%
F	Incidence of severe hypertension in pregnant population[2,3,4]*	1.2%
G	Incidence of $MgSO_4$ toxicity (respiratory depression)[10]	1.3%

*For lack of readily available information on the incidence of severe hyperextension in pregnant women, the same incidence rate as that of severe pre-eclampsia is suggested by WHO experts to be used as proxy in the absence of local data (4.6% x 26% = 1.2%).

2. Dosage and average quantities per case by regimen type for **antihypertensives**

Note: This only considers severe hypertension during pregnancy, not control of moderate or chronic hypertension or hypertension of the postpartum period that needs treatment of a longer duration and assumes treatment duration of three days.

Table 16: Quantity of each antihypertension per case

	FORMULATIONS	QUANTITY PER CASE
A	Methyldopa 250 mg tablet	**36 tablets** (9 g)
B	Labetalol 200 mg tablet	**18 tablets** (3,600 mg)
C	Labetalol HCl 20 mg/2 ml solution in ampoule	**45 ampoules** (9 g)
D	Hydralazine HCl 20 mg powder for injection in 2 ml vial	**3 vial** (60 mg)

3. Dosage and average quantities per case by regimen type for **$MgSO_4$**

Table 17: Summary on calculations of number of ampoules per case by regimen type and strength

REGIMEN TYPE	DOSAGE	# OF 1 G/2 ML AMPOULES	# OF 5 G/10 ML AMPOULES
Pritchard	**Loading dose**		
	4 g	4 x 1 = 4	x 1 = 1
	2 injections of 5 g	2 x 5 = 10	2 x 1 = 2
	Maintenance dose		
	6 injections of 5 g every 4 hours for 24 hours	6 x 5 = 30	6 x 1 = 6
	Total for regimen without additional convulsion after the loading dose	44	9
	If convulsion occurs after loading dose, administer 2 g in 4 ml and continue with the maintenance dose	2 x 1 = 2	1 x 1 = 1
	Total for regimen with additional convulsion after the loading dose	46	10
Zuspan	**Loading dose**		
	4 g	4 x 1 = 4	1 x 1 = 1
	Maintenance dose		
	1 g every hour for 24 hours	24 x 1 = 24	5
	Total for regimen without additional convulsion after the loading dose	28	6

REGIMEN TYPE	DOSAGE	# OF 1 G/2 ML AMPOULES	# OF 5 G/10 ML AMPOULES
	If convulsion occurs after loading dose, administer 2 g in 4 ml and continue with the maintenance dose	2 x 1 = 2	1 x 1 = 1
	Total for regimen with additional convulsion after the loading dose	30	7

IMPORTANT NOTE:

- Quantification teams are advised to refer to the sources of data provided as a reference for proxy data as most have country- or region-specific data that can be used for the region or country under consideration instead of the global average.

BOX 6. EXAMPLE OF COUNTRY FORECAST FOR ANTIHYPERTENSIVES FOR SEVERE HYPERTENSION IN PREGNANCY BASED ON MORBIDITY METHOD

Country X's STG recommends the use of methyldopa oral tablet, hydralazine injection, and labetalol injection and tablet for acute treatment of severe hypertension in pregnancy. The guideline states that pregnancies with severe hypertension identified at hospitals should be given injectable antihypertensives preferably, but those at first-level HFs can be treated with oral antihypertensives without the need for referral.

Available data and assumptions:

- Total population as of current year (CSO census): **20,000,000**
- Percentage increase in population per year: **2%**
- Percentage of pregnant women out of total population: **4%**
- Percentage of pregnancies with severe hypertension: **1.3%** (based on HMIS reports)
- ANC attendance at public HFs: **81%** in the current year; expected to increase by 1.5 percentage points over the forecast period
- Percentage of case treated by level of public health care (based on HMIS reports):
  - First-level HFs: 70% and assumed to increase by 3 percentage points per year
  - Hospitals: 30% and assumed to decrease by 3 percentage points per year
- Compliance to treatment recommendations: (based on HMIS reports)
  - **80%** at first-level health public facilities with an increase of 2 percentage points per year
  - **90%** in public hospitals with an increase of 1 percentage point per year
- Percentage of cases treated with specific regimens, formulations by level of care, and quantity per case were agreed according to the table below. Based on the national STGs and expert opinion, the quantification team has agreed to forecast for 24 hour treatment per case and assumed each patient will need the maximum daily dose by average.

First-level HFs			
Regimen		**Formulations**	**Quantity per case**
Methyldopa	65%	Methyldopa 250 mg tablet	36 tablets (9 g)
Labetalol	35%	Labetalol 200 mg tablet	18 tablets (3,600 mg)

Hospitals				
Regimen		**Formulations**		**Quantity per case**
Methyldopa	10%	Methyldopa 250 mg tablet		36 tablets (9 g)
Labetalol	40%	Labetalol 200 mg tablet	15%	18 tablets (3,600 mg)
		Labetalol HCl 20 mg/2 ml solution in ampoule	85%	45 ampoules (9 g)
Hydralazine	50%	Hydralazine HCl 20 mg powder for injection in 2 ml vial		3 vial (60 mg)

Calculate the quantity of the recommended antihypertensives for acute treatment of severe hypertension in pregnancies in the public sector over the next two years.

Example: Severe hypertension in pregnancy

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total pregnancies (B)	B = A x % of pregnant women out of total population	4%	800,000	816,000	832,320
Number of pregnancies with severe hypertension (C)	C = B x incidence of severe hypertension in pregnant women	1.3%	10,400	10,608	10,820
Number of public HF pregnancies with severe hypertension (D)	D = C x % of pregnancies with severe hypertension identified in all public HFs (ANC attendance in public HFs) (annual increase of 1.5%)	1.5%	8,424 81.0%	8,752 82.5%	9,089 84.0%
Number of pregnancies with severe hypertension identified at first-level public HFs (E)	E = D x % of cases in first-level public HFs (annual increase of 3%)	3%	5,897 70%	6,389 73%	6,908 76%
Number of pregnancies with severe hypertension identified at public hospitals (F)	F = D x % of cases in public hospitals (annual decrease of 3%)	-3%	2,527 30%	2,363 27%	2,181 24%
Number of first-level public HF severe hypertension cases treated with antihypertensives (G)	G = E x % treated with antihypertensives (annual increase of 2%)	2%	**4,717** 80%	**5,111** **82%**	**5,526** **84%**
Number of public hospital severe hypertension cases treated with antihypertensives (H)	H = F x % treated with antihypertensives (annual increase of 1%)	1%	**2,274** 90%	**2,127** **91%**	**1,963** **92%**
Number of first-level public HF severe hypertensive cases treated with specific regimens of antihypertensives (I)	I1: # treated with methyldopa = G x % of treated with methyldopa	**65%**	3,066	3,322	3,592
	I2: # treated with labetalol = G x % of treated with labetalol	**35%**	1,651	1,789	1,934
Number of public hospital severe hypertensive cases treated with specific regimens of antihypertensives (J)	J1: # treated with methyldopa = H x % of treated with methyldopa	**10%**	227	213	196
	J2: # treated with labetalol = H x % of treated with labetalol	**40%**	910	851	785
	J3: # treated with hydralazine = H x % of treated with hydralazine	**50%**	1,137	1,063	982
Quantity of each medicine required to treat severe hypertension in pregnancy at first-level public HFs (L)	L1: Quantity of methyldopa 250 mg tab for first-level HFs **= I1 x % treated x K1**; where K1: quantity per case = **36 tabs**	**100%**	**36**	**110,388**	**119,596**	**129,310**
	L2: Quantity of labetalol 200 mg tab for first-level HFs = **I2 x % of treated x K2;** where K2: quantity per case = **18 tabs**	**100%**	**18**	**29,720**	**32,199**	**34,814**

PARAMETER	INPUT			CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Quantity of each medicine required to treat severe hypertension in pregnancy at public hospitals (N)	N1: Quantity of methyldopa 250 mg tab for hospitals = **J1 x % treated x M1;** where M1: quantity per case = **36 tabs**	**100%**	**36**	**8,188**	**7,656**	**7,068**
	N2a: Quantity of labetalol 200 mg tab for hospitals = **J2 x % of treated x M2a;** where M2a: quantity per case = **18 tabs**	**15%**	**18**	**2,456**	**2,297**	**2,120**
	N2b: Quantity of labetalol 20 mg/2 ml solution for injection in amp for hospitals = **J2 x % of treated x M2b;** where M2b: quantity per case = 45 amps	**85%**	**45**	**34,800**	**32,538**	**30,037**
	N3: Quantity of hydralazine 20 mg powder for injection in 2 ml vial for hospitals = **J3 x % of treated x M3;** where M3: quantity per case = **3 vials**	**100%**	**3**	**3,412**	**3,190**	**2,945**
Total quantity of each medicine required to treat severe hypertension in pregnancy in public health sector (O)	**O1: Quantity of methyldopa 250 mg tab = L1 + N1**			**118,576**	**127,252**	**136,378**
	O2: Quantity of labetalol 200 mg tab = L2 + N2a			**32,176**	**34,496**	**36,935**
	O3: Quantity of labetalol 20 mg/2 ml solution for injection in amp = N2b			**34,800**	**32,538**	**30,037**
	O4: Quantity of hydralazine 20 mg powder for injection in 2 ml vial = N3			**3,412**	**3,190**	**2,945**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

BOX 7. EXAMPLE OF COUNTRY FORECAST FOR MAGNESIUM SULFATE BASED ON MORBIDITY METHOD

Country X's STG recommends the use of $MgSO_4$ for the prevention and treatment of eclampsia. The STG recommends the use of $MgSO_4$ for pregnant women with severe pre-eclampsia in HFs to prevent eclampsia. Compliance to this recommendation is currently at 50%; however, there is a plan to scale up to 80% within the next three years. The guideline recommends treatment of cases that develop eclampsia with or without prophylaxis with the same regimen and dosage that is used for prevention. The Pritchard regimen is used in the country. The quantification team has agreed to use global averages as proxy when local data are not available.

Available data and assumptions:

- Total population as of current year (CSO census): **20,000,000**
- Percentage increase in population per year: **2%**
- Percentage of pregnant women out of total population: **4%**
- Percentage of pregnancies with pre-eclampsia: **4.6%** (based on HMIS reports)
- Percentage of deliveries with severe pre-eclampsia out of pre-eclamptic cases: **26%** (proxy)
- ANC attendance at public HFs: **81%** in the current year; expected to increase by 2 percentage points per year
- Percentage of deliveries happening in the community: **45%**
- Compliance to prevention recommendations: 50% current year; assumed to increase to **60% and 70% in years 1 and 2, respectively**
- Currently only 50% of deliveries with severe pre-eclampsia are given $MgSO_4$ for prevention of eclampsia at public HFs, and there is a plan to scale this up to 80% in three years (i.e., **60% in year 1 and 70% in year 2**)
- Incidence of eclampsia after prophylaxis in severe pre-eclampsia cases: **0.8%** (proxy)
- Incidence of eclampsia in severe pre-eclampsia cases without prophylaxis: **1.9%** (proxy)
- Incidence of eclampsia in pregnant population (among those that deliver in the community without prophylaxis): **0.5%** (proxy)
- Percentage of eclamptic cases identified by CHWs and referred to public HFs is only 30% in the current year, but there is a plan to increase it to 45% in three years (i.e., **35% in year 1 and 40% in year 2)**
- Recommended formulation and quantity per case (both prevention and treatment): **9 ampoules of 5 g/10 ml $MgSO_4$** (STG)
- Compliance to treatment recommendations: **95%** current year and was assumed to remain the same (HMIS)

Calculate the quantity of $MgSO_4$ required for prevention and treatment of eclampsia in the public sector over the next two years.

Example: Prevention of eclampsia

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total number of pregnancies (B)	B = A x % of pregnant women out of total population	4%	800,000	816,000	832,320
Number of public HF pregnancies (C)	C = B x % of pregnancies in public HFs		648,000	677,280	707,472
	(ANC attendance) (annual increase of 2%)	2%	81%	83%	85%
Number of pre-eclampsia cases in public HFs (D)	D = C x incidence of severe pre-eclampsia	4.6%	29,808	31,155	32,544
Number of severe pre-eclampsia cases in public HFs (E)	E = D x incidence of severe pre-eclampsia in pre-eclamptic cases	26.0%	7,750	8,100	8,461
Number of severe pre-eclampsia cases in public HFs provided with MgSO4 for prevention of eclampsia (F)	F = E x % given $MgSO_4$ for prophylaxis	10.0%	3,875	4,860	5,923
	(% increase per year of 10%)		50%	60%	70%
Quantity of MgSO4 5 g/10 ml ampoules required for the prevention of eclampsia (H)	**H = F x G; where G: Quantity per case (without convulsion after loading dose) = 9 amps**	**9**	**34,875**	**43,741**	**53,307**

Example: Treatment of eclampsia

PARAMETER			CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Number of public HF severe pre-eclamptic cases that develop eclampsia after prophylaxis (I)	I = F x % of pregnancies given $MgSO_4$ for prevention that still develop eclampsia (incidence after prophylaxis)	0.8%	31	39	47
Number of public HF severe pre-eclamptic cases not provided $MgSO_4$ that develop eclampsia (J)	J = (E-F) x % of pre-eclamptic cases that develop eclampsia without prevention (incidence without prophylaxis)	1.9%	74	62	48
Number of public HF eclampsia cases treated with $MgSO_4$ (K)	K = (I + J) x % of cases treated (compliance to treatment recommendations)	95.0%	99	95	91
Number of home pregnancies (L)	L = B x % of home pregnancies not attending ANC services at HFs	45.0%	360,000	367,200	374,544
Number of home pregnancies with eclampsia (M)	M = L x incidence of eclampsia in pregnant women without prophylaxis	0.5%	1,800	1,836	1,873
Number of home pregnancies with eclampsia that are referred to public HFs for treatment (N)	N = M x % of referral to public HFs for treatment;	5.0%	540	643	749
	(increase per year of 5%)		30%	35%	40%
Number of referred eclampsia cases given $MgSO_4$ at public HFs for treatment of eclampsia (O)	O = N x % of cases treated; (% compliance to treatment recommendations)	95.0%	513	610	712
Quantity of $MgSO_4$ 5 g/10 ml ampoules required for treatment of eclampsia (Q)	**Q= (K+O) x P; where P: quantity of $MgSO_4$ 5 g/10 ml amp per case = 9 amps**	**9**	**5,512**	**6,353**	**7,222**

Total for prevention and treatment of eclampsia

Total quantity of $MgSO_4$ 5 g/10 ml ampoules required for the prevention and treatment of eclampsia (R)	**R = H + Q**	**40,387**	**50,094**	**60,529**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

BOX 8. EXAMPLE OF COUNTRY FORECAST FOR $MGSO_4$ BASED ON ALLOCATION BY HF TYPE

The maternal and child health guidelines of the country state that $MgSO_4$ is used for prevention and treatment of eclampsia. The country has three levels of hospitals—national, regional, and district hospitals—plus health centers.

As a strategy to increase the use of $MgSO_4$ and appropriate management of pre-eclampsia/eclampsia, the MOH wanted to allocate $MgSO_4$ to each facility to make the product available where it can potentially be needed, including health centers where a prereferral dose should be given before a woman is referred to a hospital for full treatment. The Pritchard regimen is used in the country, and a 5 g/10 ml $MgSO_4$ ampoule is the recommended formulation.

Available data and assumptions:

- Type and number of HFs where $MgSO_4$ is expected to be used per year
  - National hospitals: 5
  - Regional hospitals: 10
  - District hospitals: 80
  - Health centers: 500

  (The number of hospitals is expected to remain the same over the forecast year)
- Average quantity of 5 g/10 ml $MgSO_4$ ampoule required (allocated) per year per facility type
  - National hospitals: 450 ampoules per year (considering 50 cases per year, 9 ampoules per case)
  - Regional hospitals: 450 ampoules per year (considering 50 cases per year, 9 ampoules per case)
  - District hospitals: 900 ampoules per year (considering 100 cases per year, 9 ampoules per case)
  - Health centers: 150 ampoules per year (considering 50 cases of referral per year, 3 ampoules per case)

Notes:

- Based on HMIS, it was found that most of the deliveries with complications happen at district hospitals
- The lowest distribution pack size was assumed to be 10 ampules

Calculate the quantity of MgSO4 sulphate 5g/10ml, ampoule required for distribution to all facilities in the public sector.

Example: $MgSO_4$ using allocation by facility

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
# of public HFs where $MgSO_4$ is supposed to be used by type (A)	The number of public HFs by type is assumed to remain the same over the forecast period				
# of national hospitals (A1)			5	5	5
# of regional hospitals (A2)			10	10	10
# of district hospitals (A3)			80	80	80
# of health centers (A4)			500	500	500
Quantity of $MgSO_4$ 5 g/10 ml amp needed per year per facility type (C)					
National hospitals (C1)	**C1 = A1 x B1**; where B1 = average quantity per national hospital per year	**450**	**2,250**	**2,250**	**2,250**
Regional hospitals (C2)	**C2 = A2 x B2**; where B2 = average quantity per regional hospital per year	**450**	**4,500**	**4,500**	**4,500**
District hospitals (C3)	**C3 = A3 x B3**; where B3 = average quantity per district hospital per year	**900**	**72,000**	**72,000**	**72,000**
Health centers (C4)	**C4 = A4 x B4**; where B4 = average quantity per health center per year	**150**	**75,000**	**75,000**	**75,000**
Total quantity of $MgSO_4$ 5 g/10 ml amp needed per year (D)	**D = C1 + C2 + C3 + C4**		**153,750**	**153,750**	**153,750**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

BOX 9. EXAMPLE OF COUNTRY FORECAST FOR CALCIUM GLUCONATE BASED ON ALLOCATION BY HF TYPE

Country X recommends the use of calcium gluconate injection for treatment of toxicity due to $MgSO_4$. The maternal and child health guidelines of the country state that all heath facilities where $MgSO_4$ is used for prophylaxis and treatment of eclampsia need to maintain calcium gluconate injections to treat potential toxicity due to $MgSO_4$ administration. The management of eclampsia, both prevention and treatment, is expected to be carried out at hospitals, and health centers are expected to administer a prereferral dose before a woman is referred to a hospital for full treatment. The country has three levels of hospitals—national, regional, and district—plus health centers. Since the quantity of calcium gluconate forecasted based on the morbidity method is too low to make effective distribution of the product to all facilities where it may be needed, the quantification team has agreed to use allocation by facility to estimate requirements.

Available data and assumptions:

- Type and number of HFs where $MgSO_4$ is expected to be used per year
  - National hospitals: 5
  - Regional hospitals: 10
  - District hospitals: 80
  - Health centers: 500

  (The number of hospitals and health centers is expected to remain the same over the forecast year)
- Average quantity of calcium gluconate 1 g/10 ml ampoule required (allocated) per year per facility type
  - National hospitals: 5 ampoules per year
  - Regional hospitals: 5 ampoules per year
  - District hospitals: 10 ampoules per year
  - Health centers: 5 ampoules per year

  (Based on the HMIS, it was found that most deliveries with complications happen at district hospitals)

Note: The lowest distribution pack size was assumed to be 5 ampules

Calculate the quantity of calcium gluconate 1 g/10 ml ampoules required for treatment of $MgSO_4$ toxicity in the public sector over the next two years.

Example: Calcium gluconate for $MgSO_4$ toxicity using allocation by facility

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
# of public HFs where $MgSO_4$ is supposed to be used by type (A)	The number of public HFs by type is assumed to remain the same over the forecast period				
# of national referral hospitals (A1)			5	5	5
# of regional hospitals (A2)			10	10	10
# of district hospitals (A3)			80	80	80
# of health centers (A4)			500	500	500
Quantity of calcium gluconate 1 g/10 ml amp required per year per facility type (C)					
National referral hospitals (C1)	C1 = A1 x B1; where B1 = average quantity per national referral hospital per year	5	25	25	25
Regional hospitals (C2)	C2 = A2 x B2; where B2 = average quantity per regional hospital per year	5	50	50	50
District hospitals (C3)	C3 = A3 x B3; where B3 = average quantity per district hospital per year	10	800	800	800
Health centers (C4)	C4 = A4 x B4; where B4 = average quantity per health center per year	5	2,500	2,500	2,500
Total quantity of calcium gluconate 1 g/10 ml amp required per year (D)	**D = C1 + C2 + C3 + C4**		**3,375**	**3,375**	**3,375**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

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4. REDUCTION OF RISK OF RESPIRATORY DISTRESS SYNDROME IN PRETERM BIRTHS

INTRODUCTION

Preterm birth (i.e., birth where the baby is born before the 37th week of gestation) is the leading global cause of perinatal and neonatal mortality and morbidity.[1] An estimated 10% (5–18%) of live births globally are preterm. Preterm infants are particularly vulnerable to complications due to lung immaturity, inability to maintain blood sugar, feeding difficulty, poor body temperature regulation, and high risk of infection.[2,3] Mortality and morbidity from preterm birth can be reduced through interventions delivered to the mother during pregnancy and to the preterm infant after birth.[3]

In 2015, WHO[1] recommended ACS therapy for women at risk of preterm birth from 24 to 34 weeks of gestation when the following conditions are met:

1. Gestational age assessment can be accurately undertaken
2. Preterm birth is considered imminent
3. There is no clinical evidence of maternal infection
4. Adequate childbirth care is available (including the capacity to recognize and safely manage preterm labor and birth)
5. The preterm newborn can receive adequate care if needed (including resuscitation, thermal care, feeding support, infection treatment, and safe oxygen use)

This treatment accelerates fetal lung development and reduces risk of respiratory distress syndrome, which is one of the most common life-threatening complications of prematurity.[4]

ACS should be administered when preterm birth is considered imminent (i.e., within seven days), and the greatest effect is seen when there is a 24- to 48-hour gap between first dose and birth. The accuracy of estimation of gestational age is crucial to reduce the probability of harm exceeding benefit.[5] Safety concerns exist for the use of ACS in LMICs, and strict adherence to WHO recommended criteria is essential. Studies have demonstrated an increased risk of neonatal deaths associated with inaccurate estimation of gestational age as well as an increased risk of maternal infections.[6]

Current coverage of use of ACS for preterm birth varies widely, with 90% coverage of indicated cases in high-income countries and an estimated 10% coverage in low- and middle-income, high-burden countries.[7]

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

DEXAMETHASONE AND BETAMETHASONE

Dexamethasone is currently the preferred ACS as it is as effective and significantly cheaper and more widely available than betamethasone.

Some countries may have both betamethasone and dexamethasone in their treatment guidelines and EML. In that case, program managers will need to decide whether both will continue to be made available. 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.

Table 18: Summary of product characteristics: dexamethasone and betamethasone

PARAMETER	DEXAMETHASONE	BETAMETHASONE
Improvement of fetal lung maturation: Dosage	▪ 24 mg of dexamethasone[8] ▪ 4 doses of 6 mg IM, 12 hours apart	▪ 2 doses of betamethasone 12 mg IM, 24 hours apart[8]
Presentation	▪ 4 mg/ml dexamethasone phosphate (as disodium salt) solution for injection in 1ml ampoule	▪ 6 mg/ml (3 mg/ml betamethasone sodium phosphate + 3 mg/ml betamethasone acetate) aqueous solution for injection in 1 ml vial
Administration	IM	
Storage condition	▪ Some manufacturers state 20°C–25°C storage while others allow a wider temperature storage range of 15°C–30°C ▪ Protect from light ▪ Do not freeze	
Additional supplies required for administration	▪ Syringes, needles, alcohol swabs, sharps containers	
Level of use	▪ Generally, it is recommended to use ACS at the hospital level; expansion of use of ACS to lower levels such as health centers is not recommended. ▪ The medicines should be administered by a trained health worker/skilled birth attendant and are not recommended for home-based births.[9] ▪ Recent studies of implementation of ACS in LMICs[10] indicate that these products should be used in HFs that meet the following conditions: ○ Providers who are able to accurately assess and determine gestational age and risk of imminent preterm birth ○ Adequate childbirth care is available, including reliable, timely, and appropriate identification and treatment of maternal infection, and patient safety and compliance are monitored, including postdischarge complications and adverse events[11] ○ Adequate postdelivery care for preterm newborns is available	
Supply chain considerations	▪ Do not require cold chain ▪ Shelf life of 36 months	

REQUIRED DATA AND POTENTIAL SOURCES: MORBIDITY METHOD OF FORECASTING

A number of data points are required to forecast ACS. Table 19 summarizes the main data types and potential sources for the morbidity method of forecasting, in addition to the common data provided in the introduction of this supplement.

Table 19. Data and potential sources for forecasting of ACS using morbidity method

DATA	SOURCE	NOTES
Incidence/number of preterm births (pregnant women at risk of preterm birth)	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys, national or WHO STGs	DHS data are usually outdated; HMIS data may be incomplete; may need to apply estimated annual growth/reduction rate; consider expert opinion; national STGs may not include new WHO recommendations.
Proportion/number of pregnant women at risk of preterm birth with access to public HFs that meet WHO's conditions for use of ACS		
Proportion/number of pregnant women at risk of preterm birth with access to appropriate public HFs who are treated with ACS to improve fetal lung maturation in public HFs		
Type and respective proportion of ACS given to improve fetal lung maturation of premature infants in public HFs		
Quantity of each medicine used to treat one case (formulations and dosage of the respective ACS)	National STG, WHO STG, expert opinion	Guidelines may be outdated; may not include new WHO recommendations; actual practice may be different from STGs, consider the actual practice if guidelines are relatively old and not followed; parenteral treatment duration varies between patients depending on clinical evolution

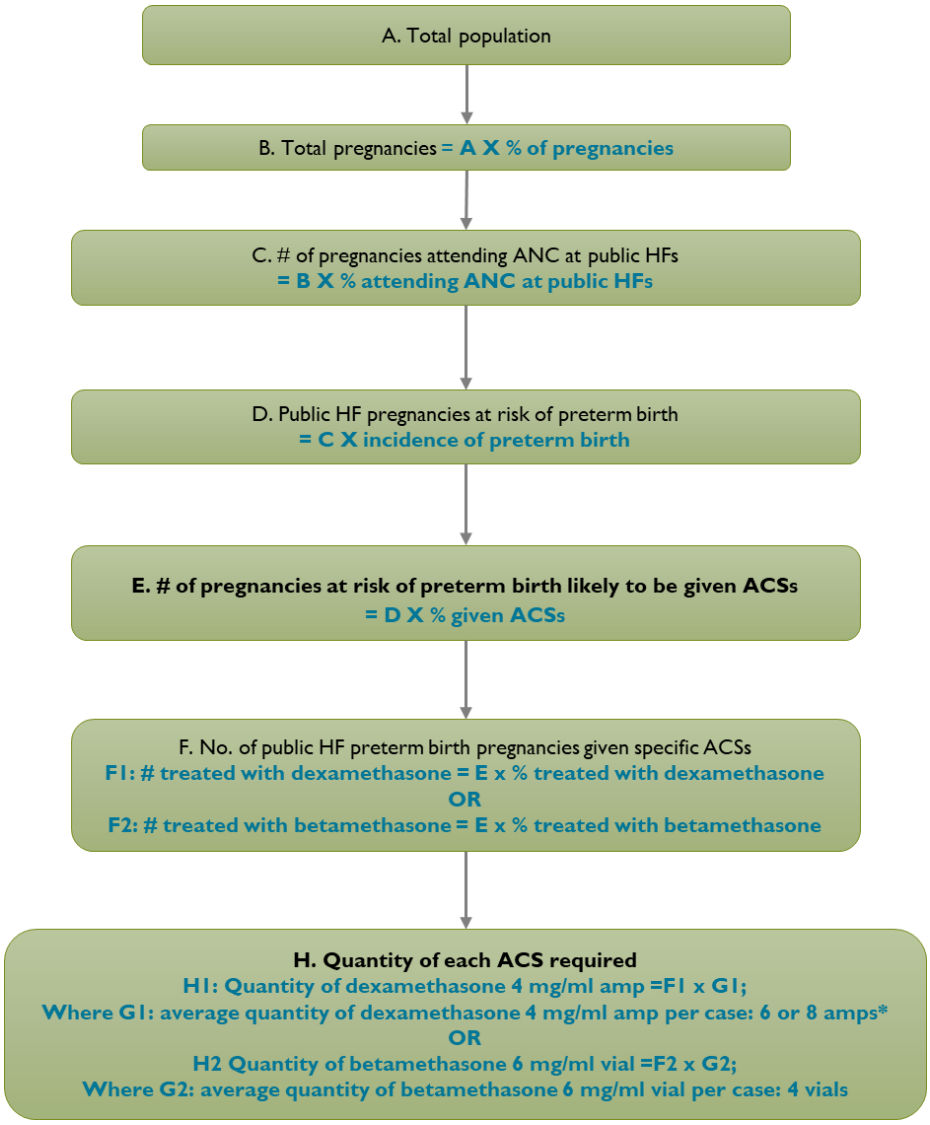

Figure 13: Forecasting algorithm for ACS based on morbidity method

IMPORTANT NOTES:

- *6 ampoules if no wastage is considered or 8 ampoules if 0.5 ml is wasted during administration of each dose.
- Quantification teams are advised to consider other indications of the ACSs. The total quantity of ACSs required is the sum of what is needed for improvement of fetal lung maturation, necrotizing endocarditis (NEC) and intracranial hemorrhage and other indications if and when the same formulations are used.

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

Table 20: Summary of proxy data and sources

	PARAMETER	VALUE
1	Average quantity per case: ▪ 4 mg dexamethasone phosphate (as disodium salt) solution for injection in 1 ml ampoule[8]	▪ 4 doses of 6 mg, 12 hours apart (6 or 8 ampoules)
2	Average quantity per case: ▪ 6 mg/ml (3 mg/ml betamethasone sodium phosphate + 3 mg/ml betamethasone acetate) aqueous solution for injection in 1 ml vial[8]	▪ 2 doses of 12 mg IM, 24 hours apart (4 ampoules)
3	Incidence of preterm birth[2,3]	▪ 10% (5–18%)

IMPORTANT NOTE:

- Quantification teams are advised to refer to the sources of data provided as a reference for proxy data as most have country- or region-specific data that can be used for the region or country under consideration instead of the global average.

BOX 10. EXAMPLE OF COUNTRY FORECAST FOR ANTENATAL CORTICOSTEROIDS BASED ON MORBIDITY METHOD

Country X, a Southern African country with a similar epidemiological profile to Malawi, recommends the use of dexamethasone injection for pregnant women at risk of preterm birth to reduce the risk of respiratory distress syndrome in preterm babies. Compliance to this recommendation is only about 15%; however, there are plans to scale up use to 45% over three years through improved ANC attendance, diagnosis of risk conditions, intensive training, supervision, and information, education and communication and behavior change communication campaigns. The guideline states the need for full adherence by HF staff to the criteria on administration of dexamethasone given the identified risks.

Available data and assumptions:

- Total population as of current year (CSO census): **20,000,000**
- Annual population growth % increase: 2%
- Pregnancy rate out of total population: 4%
- ANC attendance at public HFs: 80% in the current year and expected to grow to 83% in year 1 and 86% in year 2 (ANC attendance in this example is a proxy for # of facility-based births)
- Country X does not have complete data on the incidence of preterm birth in the country; therefore, the incidence of preterm birth from Malawi, which is 18% of all births, is taken as a proxy. This incidence rate is expected to remain the same throughout the forecast period.
- Currently, only 15% of preterm births at public HFs are estimated to be given ACS by HFs that are trained and capacitated to evaluate and support pregnancies that need ACS, but there is a plan to scale this up to 45% in three years (i.e., 25% in year 1 and 35% in year 2)
- The quantification team has agreed to quantify dexamethasone 4 mg/ml in 1 ml ampoule
- Recommended dosage from STGs: IM injections of dexamethasone spaced 12 hours apart totaling 24 mg (i.e., 6 ampoules per case)

Calculate the quantities of dexamethasone 4 mg/ml in 1 ml ampoule required by the program (in the public health sector) for the two-year forecast period.

Example: ACS

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = population of the previous year + (population of the previous year x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total pregnancies (B)	B = A x % of pregnant women out of total population	4%	800,000	816,000	832,320
Number of pregnant women receiving ANC services at public HFs who meet WHO's criteria (C)	C = B x % of pregnant women attending ANC services at public HFs (annual increase in ANC of 3%)	3%	640,000 80%	677,280 83%	715,795 86%
Public HF pregnancies at risk of preterm birth (D)	D = C x incidence of preterm birth (proxy from Malawi)	18%	115,200	121,910	128,843
Number of pregnant women at risk of preterm birth likely to be given ACS (E)	E = D x % attending or referred to public HFs that fulfill conditions for use of ACS (scale up annual increase of 10%)	10%	17,280 15%	30,478 25%	45,095 35%
Number of public HF preterm birth pregnancies treated with specific ACS regimen (F)	F = E x % treated with dexamethasone	100%	17,280	30,478	45,095
Quantity of dexamethasone 4 mg/ml amp (H)	**H = F x G; where G: Quantity of dexamethasone 4 mg/ml 1 ml amp per case = 6**	**6**	**103,680**	**182,866**	**270,571**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

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5. NEWBORN RESUSCITATION AND ESSENTIAL CARE AROUND THE TIME OF BIRTH

INTRODUCTION

Intrapartum-related hypoxic event is the failure of a newborn to establish and sustain breathing, leading to a decrease in oxygen perfusion to various organs. It kills around 700,000 newborns every year, accounting for 25% of all newborn deaths.[1] Additionally, there are an estimated 1.02 million intrapartum stillbirths every year, an unknown number of which may be live born but misclassified as fresh stillbirth.[2] In general, about 3–6% of all newborns (up to 6 million) require basic neonatal resuscitation.[3] A high number of neonatal deaths can be prevented through effective neonatal resuscitation and immediate care, including drying, keeping the baby warm, suctioning, stimulation as needed after assessment, and positive-pressure ventilation if the newborn has not established spontaneous respirations. However, poor quality of newborn care due to lack of availability of basic resuscitation equipment and poor resuscitation skills of health care providers remains a major bottleneck in reducing neonatal mortality in low-resource settings.[1]

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

In 2013, the WHO medical devices team, in collaboration with other international stakeholders, held a consultative meeting to develop technical specifications for neonatal resuscitation devices, specifically a resuscitation bag with masks, a suction machine, and single use and reusable suction devices.[1] Consequently, WHO produced the *WHO Technical Specifications of Neonatal Resuscitation Devices* in 2016.[1] The following summary of the technical specifications and health system considerations is based on this document.

Neonatal resuscitation medical products are used in clinical settings for newborns who have not established spontaneous and/or effective respiration as well as for pre- and in-service training. In this document, clinical resuscitation devices considered include self-inflating neonatal resuscitation bag and masks and single use and reusable suction devices. Medical products for training include pre- and in-service training manikins for which we provide the data required in this document, with potential sources but with no technical specifications or steps for calculations.

SELF-INFLATING NEONATAL RESUSCITATOR (REUSABLE) (RESUSCITATION BAG AND MASK)

Initiation of positive-pressure ventilation is recommended within one minute after birth if the baby has not started breathing after initial steps of resuscitation, thorough drying, and additional stimulation.[4] A self-inflating neonatal resuscitation bag with mask is the most standard basic neonatal ventilation device to ventilate a neonate with a body weight less than 5 kg because of its automatic re-expansion feature and simplicity of use.

SUCTION DEVICES (BULBS)

A suction device is a portable, hand-held device designed to provide gentle suction to clear excessive secretions from the mouth and nose of newborns if they are obstructing the baby's breathing or if the infant is having difficulty clearing secretions on their own. Both single-use and reusable suction devices are used in clinical settings. Single-use bulbs must be discarded after use, whereas reusable suction devices need to be precleaned, disassembled, cleaned, sterilized, reassembled, and properly stored before the next use.[1]

Table 21: Product characteristics: Reusable self-inflating resuscitators and suction devices

PARAMETER	NEONATAL SELF-INFLATING RESUSCITATOR (REUSABLE)	MULTIUSE MANUAL SUCTION DEVICES (BULBS)	SINGLE-USE MANUAL SUCTION DEVICES (BULBS)
Recommended uses	▪ Ventilation of a neonate without spontaneous or effective breathing	▪ Clearing airways of newborns' secretions (clear or meconium-stained) if either the mouth or nose is blocked with secretions. A neonate who does not start breathing after thorough drying and stimulation may require suctioning before ventilation.	
Components/features	▪ Mask (face mask sizes 0 and 1 for term and preterm newborns, respectively); ventilation bag with pressure relief valve[1]	▪ Manual/handheld and compressible bulb with a tip that can be inserted into the nares[1] ▪ Can be opened to be properly cleaned and disinfected[1]	Manual/handheld and compressible bulb with a tip that can be inserted into the nares[1]
Administration	▪ Mouth and nose	▪ Mouth first then nose	▪ Mouth first then nose
Storage condition	▪ Storage at -40◦C–+60◦C ▪ Avoid dust and exposure to insects, animals, chemicals, and direct sunlight		
Additional supplies required for administration	▪ Clean ambient air	▪ Clean ambient air	
Level of use	Can be used anywhere where appropriately skilled health personnel are present, including for home deliveries (for single-use suction bulbs)		
Other supply chain considerations	▪ Should be procured as a complete kit (face mask, ventilation bag with pressure relief valve) ▪ Clear instructions must be included for assembly, reassembly, cleaning, and disinfection ▪ Besides proper reprocessing and assembly, no other maintenance is required ▪ Life span may vary greatly depending on the quality, amount of time used, and how it is reprocessed	▪ Clear instructions must be included for assembly, reassembly, cleaning. and disinfection ▪ Besides proper reprocessing and assembly, no other maintenance is required ▪ Life span may vary greatly depending on the quality, amount of time used, and how it is reprocessed.	▪ Should be discarded after use

Further information on specifications and consideration can be found in the toolkit for procuring quality-assured, basic neonatal resuscitation medical products.[5] This toolkit is intended to help with the quantification of medical product needs, development of effective procurement plans, and writing specifications for national tenders. It provides information on where and how to procure quality-assured neonatal resuscitation medical products and addresses international shipping considerations.

REQUIRED DATA FOR FORECASTING AND POTENTIAL SOURCES

A number of data points are required to forecast future demands/needs of resuscitation devices. Table 22 summarizes the main types of data and potential sources for the morbidity method of forecasting in addition to the common data provided in the introduction of this supplement.

Table 22: Data and potential sources for forecasting of resuscitation devices and manikin

DATA	SOURCE	NOTES
Average number and types of rooms where a newborn may require resuscitation in each type of HF (i.e., delivery rooms/wards, theaters, emergency rooms, neonatal wards, neonatal ICUs/special care)	Program reports, MOH, regional health bureaus, guidelines, survey results, strategic plans/program targets. Obtain the information from higher- and lower-level sources and rectify.	Data may not be readily available or complete. Need to consult with experts and professionals at sample HFs.
Average number of each resuscitation medical product needed by room for each HF type	MOH, regional health bureaus, survey results, expert opinion	The average number of each reusable resuscitation device needed by room could be significantly different from one type of room to the other for the same facility type. Need to consult with experts and professionals at sample HFs.
Proportion/number of live births in public HFs with birth asphyxia per year	HMIS, RMNCH program reports, other survey reports, strategic plans/program targets	Country-specific data may not be available or may be incomplete; consult experts in the area. Use global data from similar counties if country-specific data are not available; refer to WHO resources indicated in this document.[3]
Proportion/number of births in public HFs that need suction devices to treat birth asphyxia per year		
Proportion/number of live birth asphyxia cases in public HFs that need suction devices and that are attended by skilled birth attendants	DHS, HMIS, RMNCH program reports, other survey reports, STG, strategic plans/program targets	DHS data may be outdated; HMIS data may not be complete or readily available; consult experts in the area
Proportion/number of birth asphyxia cases attended by skilled birth attendants that need single-use suction bulb	HMIS, RMNCH program reports, other survey reports, STG, strategic plans/program targets	
Average number of training manikins needed by HF type per year	MOH, regional health bureaus, district medical offices, expert opinion	Data may not be readily available; could differ from facility to facility; need to consider expert opinion
Number of midwifery, nursing, and medical schools	Ministry of Education, MOH, strategic plans/program targets	
Average number of students per class (per school) per year	Ministry of Education, MOH, strategic plans/program targets; school curriculums	Curriculum could differ from school to school depending on how many classrooms would be conducting resuscitation training at the same time in each school
Number of students per manikin	Surveys, expert opinion	Two learners per manikin is used in the Helping Babies Breathe initiative[6]

CALCULATIONS FOR REUSABLE RESUSCITATION DEVICES

The method proposed for the forecast of reusable resuscitation devices is different from the conventional morbidity method because quantities of products are not dependent on the number of cases. However, conventional morbidity method calculations are applied to forecast single-use suction bulbs. In addition, when the number of cases that need the medical products is too small, it may not be possible to distribute the small quantities based on the annual number of cases to all HFs where they are needed. Because timely access to the devices is required to save the lives of newborns, it is critical that these devices be available in all HFs. For these reasons, the forecasting method presented for reusable resuscitation devices discussed here is based on the number of rooms in HFs where the devices must be present.

PATH has developed a forecasting tool to estimate the need for reusable resuscitation devices, which is available at https://www.path.org/resources/quantification-tool-for-basic-neonatal-resuscitation-commodities-version-2/. The Microsoft Excel-based tool is designed to provide estimates of product quantities for planning and cost simulations and can be used at the national, regional, district, or HF level.

The forecasting tool is set up to provide initial estimated needs for neonatal resuscitation medical products for a one-year period. It is advised that the tool be adjusted in future years to accommodate for the average lifespan of each medical product at each level of the system. It is also advised that some reserves be stocked at all levels to cover additional needs, breakages, and losses. Procurement staff should consult with staff in labor units regarding additional quantities needed. It is necessary to have enough functional resuscitation equipment available in each unit to accommodate the number of patients who may need resuscitation, taking into consideration that equipment might be going through reprocessing and thus cannot be used at a given time. Estimated numbers will also have to consider malfunctioning equipment due to loss of parts or faulty reprocessing.

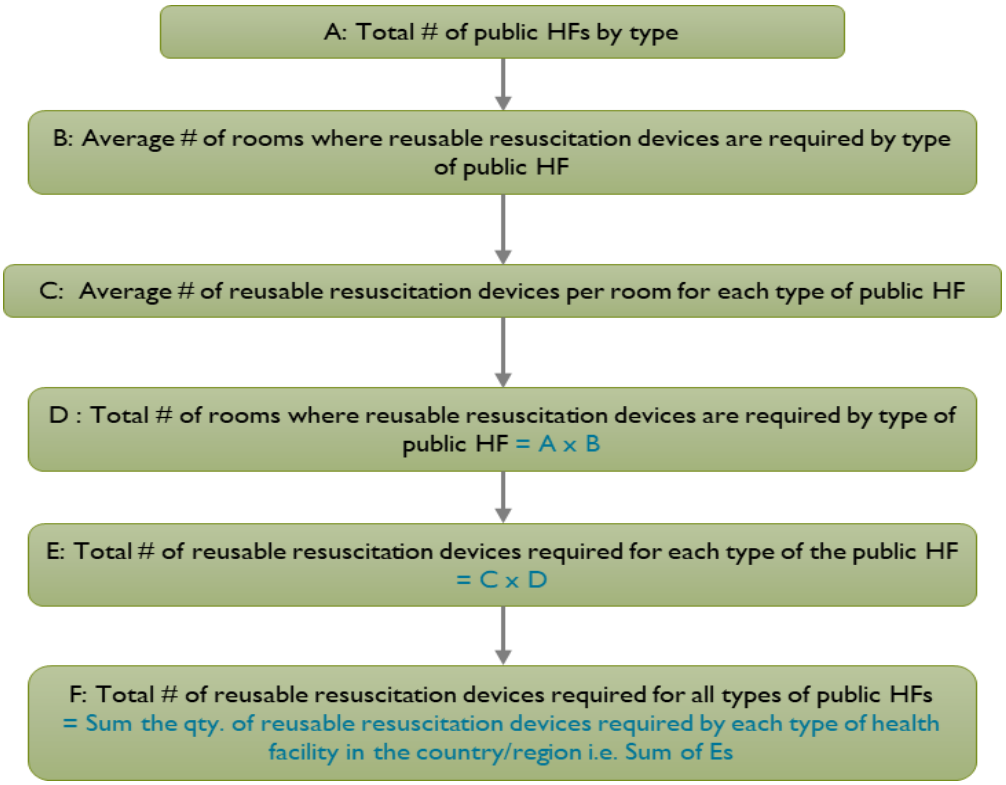

Figure 14: Forecasting algorithm for reusable resuscitation devices (bag and mask and multiuse suction device) based on allocation by facilities

IMPORTANT NOTES:

- The detailed steps for forecasting reusable devices are shown in https://www.path.org/resources/quantification-tool-for-basic-neonatal-resuscitation-commodities-version-2/.
- Steps A and B above are included under step 1 in that tool and step C is step 2; the rest of the steps described above are included under the results tab as calculation results.

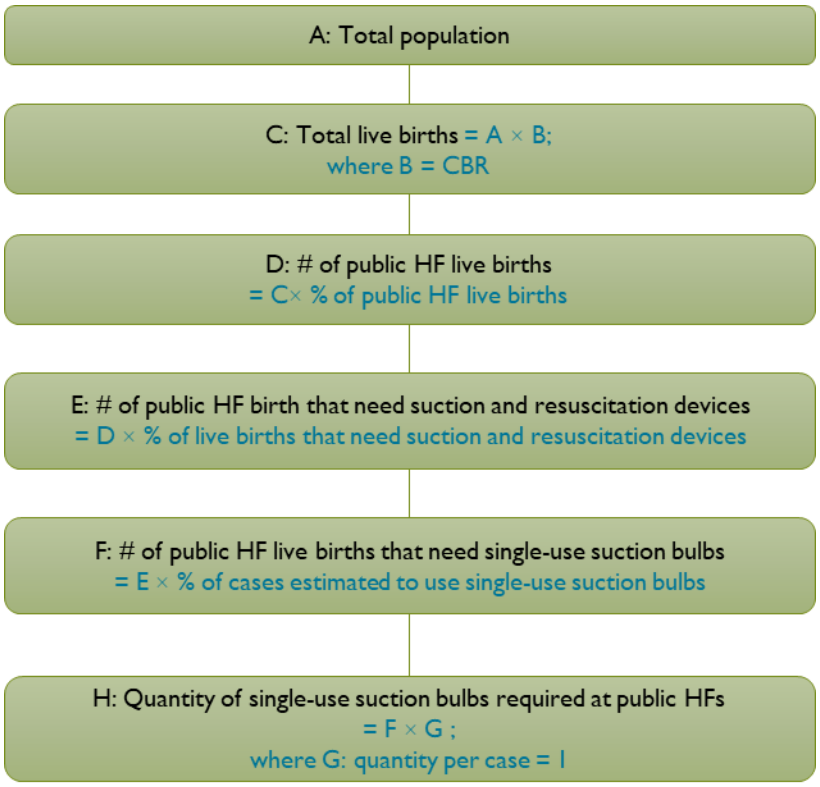

Figure 15: Forecasting algorithm for single use suction bulb (device) based on morbidity method

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

Table 23: Summary of proxy data and sources

	PARAMETER	VALUE
A	Incidence of newborns who need suction and/or basic neonatal resuscitation[3]	3%–6%

IMPORTANT NOTE:

- Quantification teams are advised to refer to the sources of data provided as a reference for proxy data as most have country- or region-specific data that can be used for the region or country under consideration instead of the global average.

BOX 11. EXAMPLE OF COUNTRY FORECAST FOR SINGLE-USE SUCTION DEVICE/BULB BASED ON MORBIDITY METHOD

Country X's STG recommends the use of single-use and reusable suction devices for newborns requiring suction. Not all HFs have the multiuse devices. In this country, rural health centers do not have reusable suction devices because they lack the proper training and infrastructure to clean and disinfect them; thus, single-use devices/bulbs are recommended at these HFs.

Available data and assumptions:

- Total population as of current year (CSO census): **20,000,000**
- Annual population growth % increase: 2%
- CBR: 35 live births per 1,000 population, based on DHS data
- Proportion of live births attended at public HFs: 50% in the current year; expected to increase by 5 percentage points per year
- Incidence of newborns who need suction: 3% based on data from HMIS
- % of deliveries/births at rural health centers (from HMIS): 35%; expected to remain the same during the forecast period

Calculate the quantity of single-use resuscitation bulbs required to meet program needs over the next two years.

Example: Single-use resuscitation device

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total number of live births (C)	C = (A/1000) × B; where B = CBR (# of live births per 1,000 population per year)	35	700,000	714,000	728,280
Number of public HF live births (D)	D = C x % of public HF live births (annual increase of 5%)		350,000	392,700	436,968
		5%	50%	55%	60%
Number of live births at public HFs that need suction or resuscitation devices (E)	E = D x % of live births that need suction or resuscitation devices	3%	10,500	11,781	13,109
Number of public HFs that need single-use suction device/bulb (F)	F = E x % of live births estimated to need/use single-use suction device	35%	3,675	4,123	4,588
Quantity of single-use suction bulbs required at public HFs (H)	**H = F x G; where G: Quantity of single-use suction bulb per case = 1**	**1**	**3,675**	**4,123**	**4,588**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

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6. NEWBORN CORD CARE

INTRODUCTION

The weeks following childbirth—the postnatal period—is a critical phase in the lives of infants and their mothers. Yet, this is the most neglected time for the provision of quality services, as the availability and quality of care are lower after childbirth when compared with before and during childbirth. The result is that most maternal and infant deaths occur during this time.[1]

Poor hygiene and lack of antiseptics during childbirth and in the first few days of life significantly increase the risk of deadly infections.[2] One of the causes of neonatal mortality and morbidity in the first week of life is infection of the umbilical cord stump. A freshly cut umbilical cord is an entry point for harmful microbes that can lead to sepsis and death. Ensuring proper cord care during birth and the first week of life, especially in settings with unsanitary conditions, is a crucial strategy to prevent sepsis in newborns.

In 2022, WHO released revised guidelines[3] on postnatal care for the prevention of neonatal infections that include an updated recommendation for umbilical cord care and use of chlorhexidine:

- Clean, dry cord care is recommended for newborns born in all settings
- Daily application of 4% chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) to the umbilical cord stump in the first week after birth is recommended only in settings where harmful traditional substances (e.g., animal dung) are commonly used on the cord

Countries need to determine whether the use of chlorhexidine is indicated and, if so, at what level based on the actual context and the most recent WHO recommendations.[3,4]

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

CHLORHEXIDINE DIGLUCONATE 7.1%

Chlorhexidine digluconate is an antiseptic with a broad spectrum of activity effective against gram-positive bacteria, gram-negative bacteria, and fungi. Chlorhexidine inactivates microorganisms with a broader spectrum and has a faster kill rate than antimicrobials (e.g., antibiotics, povidone-iodine).[5] The use of chlorhexidine digluconate 7.1% for umbilical cord care is part of the essential newborn care package but only in settings where harmful traditional substances are commonly used in the cord, according to 2022 WHO guidelines.[3]

Table 24: Summary of product characteristics: Chlorhexidine digluconate

PARAMETER	CHLORHEXIDINE DIGLUCONATE
Prevention of newborn cord infections: Dosage	Although a seven-day application is recommended by WHO, some counties use single-day regimens.[4] The global chlorhexidine working group[6] recommends the following regimens and corresponding pack sizes of products: ▪ Seven-day regimen (recommended by WHO) ○ 1 tube (10 g or 20 g) or 7 small tubes or sachets or 30 ml solution bottle ▪ Single-day regimen ○ 3 g gel tube or sachet or 10 ml solution bottle
Presentation	▪ Chlorhexidine digluconate 7.1% gel, 20 g tube ▪ Chlorhexidine digluconate 7.1% gel, 3 g sachet ▪ Chlorhexidine digluconate 7.1% aqueous solution, 10 ml or 30 ml bottle
Administration	Topical
Storage condition	Do not store above 30°C
Additional supplies required for administration	Water and soap for cleaning hands before application or use of gloves
Level of use	▪ Chlorhexidine digluconate can be used at the HF and/or community level (e.g., traditional birth attendants) and by CHWs who assist at delivery or have contact with pregnant/postpartum women.
Supply chain considerations	▪ None of the formulations require cold chain. ▪ Both gel and liquid formulations are available in the market, but there are more gel formulations than solution formulations. ▪ Labeling should indicate for external use only. ▪ Shelf life: 30 months for gel and 36 months for liquids.

For more information on the key characteristics and health system considerations, refer to the chapter in the manual for procurement and supply of quality-assured MNCH commodities.[7]

REQUIRED DATA AND POTENTIAL SOURCES: MORBIDITY METHOD OF FORECASTING

Several data points are required to forecast future demands for chlorhexidine preparations for newborn umbilical cord care. Table 25 summarizes the main data types and potential sources for the morbidity method of forecasting.

Table 25: Data and potential sources for forecasting of chlorhexidine digluconate for newborn umbilical cord using morbidity method

DATA	SOURCE	NOTES
Proportion/number of live births by level of care (home, public HFs) receiving chlorhexidine for umbilical care	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data are usually outdated; HMIS data may be incomplete; may need to apply estimated annual growth/reduction rate; consider expert opinion; national STGs may not include new WHO recommendations
Proportion/number of cases receiving single-day regimens vs multiday regimens (chlorhexidine)	HMIS, national maternal morbidity and mortality surveys, special surveys, national standard treatment guidelines (STGs), WHO STGs, expert opinion, programmatic/strategic plans	
Quantity of chlorhexidine digluconate per case (formulation and dosage)	National STGs, WHO STGs, expert opinion, programmatic/strategic plans	Guidelines may not include new WHO recommendations; use expert opinion if the practice is different from what the guidelines prescribe

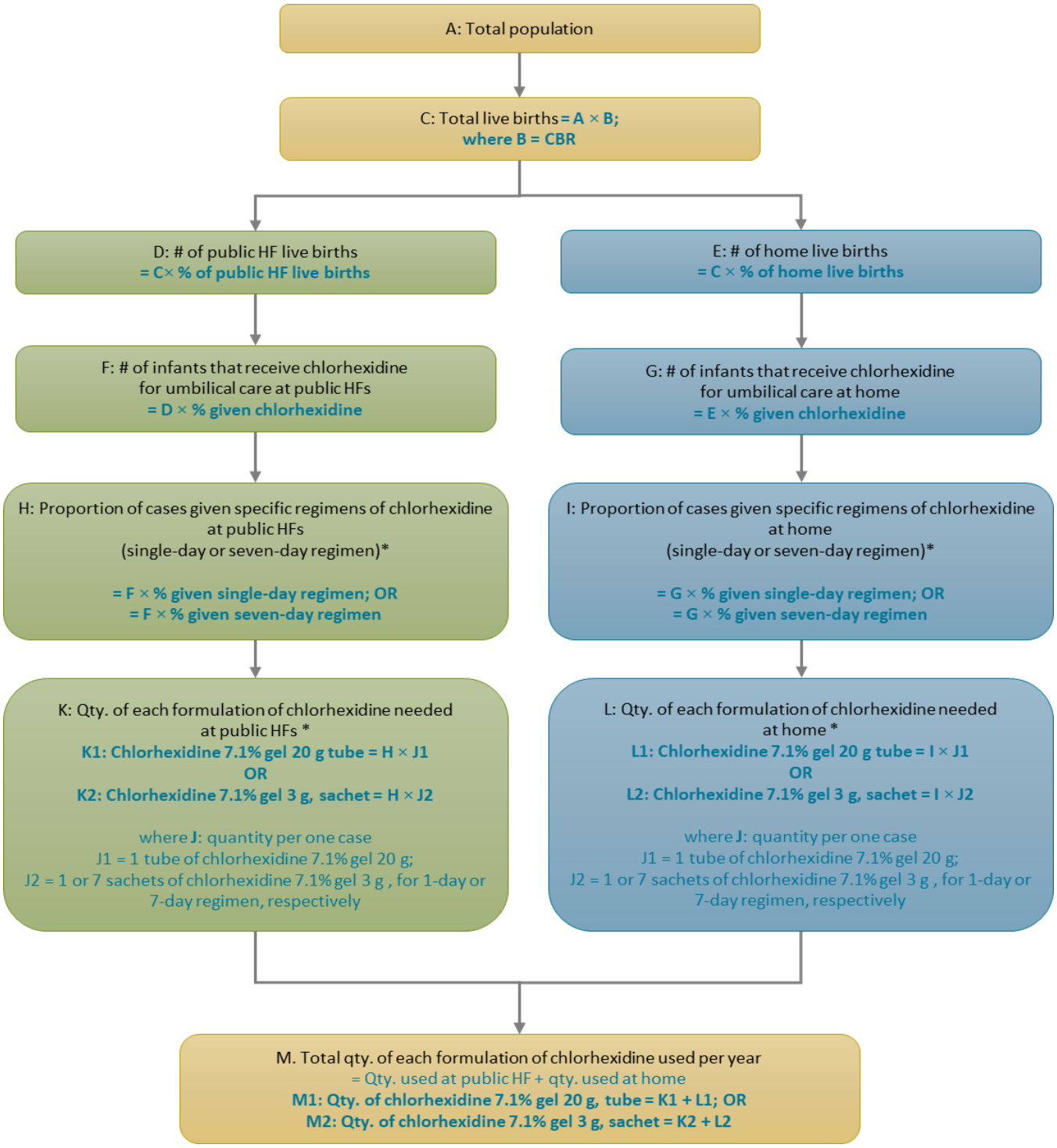

Figure 16: Forecasting algorithm for chlorhexidine digluconate used for infant cord care based on morbidity method

*The specific regimen and formulation should be selected to be used in the country, such as chlorhexidine digluconate 7.1% gel 20 g tube or chlorhexidine digluconate 7.1% gel 3 g sachet, assuming that only one formulation is selected for use per country.

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

Average quantity of each formulation by regimen and per case.

Table 26: Quantity per case by regimen and formulation[4]

	FORMULATION OF CHLORHEXIDINE DIGLUCONATE	QUANTITY FOR SEVEN-DAY USE	QUANTITY FOR SINGLE USE
A	7.1% gel, 20 g tube	1 tube	1 tube
B	7.1% gel, 3 g sachet	7 sachets	1 sachet
C	7.1% solution, 30 ml bottle	1 bottle	1 bottle
D	7.1% solution, 10 ml bottle	3 bottles	1 bottle

IMPORTANT NOTE:

- Quantification teams are advised to refer to the sources of data provided as a reference for proxy data as most have country- or region-specific data that can be used for the region or country under consideration instead of the global average.

BOX 12. EXAMPLE OF COUNTRY FORECAST FOR CHLORHEXIDINE DIGLUCONATE BASED ON MORBIDITY METHOD

Country X just updated its MNCH guidelines to include 7.1% chlorhexidine digluconate gel for all home and HF births to be used as a seven-day application regimen following birth as applying harmful traditional substances is commonplace. Chlorhexidine will be provided to CHWs for distribution to all women who give birth at home, and it is also made available at all public HFs where deliveries happen. Chlorhexidine digluconate 20 g gel tube is recommended as the product of choice by the program.

Since the MNCH guidelines were only recently updated, the country has achieved provision of chlorhexidine to only 25% and 15% of live births at public HFs and home supported by CHWs, respectively. The country has set targets to increase use of chlorhexidine by 20% each year to achieve 80% coverage within the next three years at public HFs. The target for community-level use is 45% for the same period. The quantification team agreed that this is a reasonable target given current progress on training of health providers. Since local data on miscarriage and stillbirth rate are not available, the team has agreed to use global averages as proxy.

Available data and assumptions:

- Total population as of current year (CSO census): **20,000,000**
- Annual population growth % increase: **2%**
- CBR: 35 live births per 1,000 population
- Proportion of live births attended at public HFs: **50%** in the current year, expected to increase by 5 percentage points per year
- % of home deliveries/births: **45%**, expected to decrease by 5 percentage points per year
- Targets for provision of chlorhexidine digluconate for births at public HFs: **25%** in the current year, **45%** in year 1, and **65%** in year 2
- Targets for provision of chlorhexidine digluconate for births at home: **15%** in the current year, **25%** in year 1, and **35%** in year 2
- Recommended dosage from STGs: Once a day application of chlorhexidine digluconate gel for 7 days; thus, the quantification team assumed **1 tube of 20 g is adequate per case**.

Calculate the quantity of chlorhexidine digluconate 20 g gel tubes required by the program over the next two years.

Example: Chlorhexidine digluconate 7.1% gel

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total number of live births (C)	C = (A/1,000) × B; where B = CBR: # of live births per 1,000 population per year	35	700,000	714,000	728,280
Number of public HF live births (D)	D = C x % of public HF live births (annual increase of 5%)	5%	350,000 50%	392,700 55%	436,968 60%
Number of home live births (E)	E = C x % of home live births (annual decrease of 5%)	-5%	315,000 45%	285,600 40%	254,898 35%
Number of public HF live births provided with chlorhexidine for umbilical cord care (F)	F = D x % given chlorhexidine scale up (20% increase per year)	20%	87,500 25%	176,715 45%	284,029 65%
Number of home live births provided with chlorhexidine for umbilical cord care (G)	G = E x % given chlorhexidine scale up (10% increase per year)	10%	47,250 15%	71,400 25%	89,214 35%
Number of public HF live births given specific regimen of chlorhexidine (H)	H = F x % given 7-day regimen of chlorhexidine	100%	87,500	176,715	284,029
Number of home live births given specific regimen of chlorhexidine (I)	I = G x % given 7-day regimen of chlorhexidine	100%	47,250	71,400	89,214
Quantity of chlorhexidine digluconate 7.1% gel, 20 g tubes for public HF live births (K)	K = H x J, where J: quantity per case = 1 tube	1	87,500	176,715	284,029
Quantity of chlorhexidine digluconate 7.1% gel, 20 g tubes for home live births (L)	L = I x J, where J: quantity per case = 1 tube	1	47,250	71,400	89,214
Total quantity of chlorhexidine digluconate 7.1% gel, 20 g tubes required for public sector (M)	**M = K + L**		**134,750**	**248,115**	**373,244**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

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7. TREATMENT OF POSSIBLE SERIOUS BACTERIAL INFECTION (PSBI) OR VERY SEVERE DISEASE IN NEWBORNS AND YOUNG INFANTS (0–59 DAYS)

INTRODUCTION

Regardless of the significant progress in child survival over recent decades, improvements in neonatal survival remain slow.[1] About 2.8 million children die in the first month of life, with 98% of these deaths occurring in developing countries.[2] About 44% of all child deaths occur during the first month of life,[3] and of the neonatal deaths[4], around 30% are due to infections, including sepsis, pneumonia, and meningitis.[2,3] Approximately 10% of newborns develop signs of possible serious bacterial infection (PSBI) or very severe disease and require antibiotics.[5]

WHO recommends hospital-level treatment of sick young infants (birth–2 months) with PSBI or very severe disease where feasible as additional expertise, necessary medical products, procedures, and supportive care are available. Only cases of 7–59 day pneumonia with fast breathing as the only sign of illness should be treated at hospital- or lower-level health facilities as outpatients with oral amoxicillin twice a day . WHO recommends treatment of PSBI or very severe disease in infants under 2 months with a 10-day (or at least a 7-day) inpatient course of a combination of two injectable antibiotics—ampicillin plus gentamicin—as the preferred approach;[6,7] ceftriaxone injection alone is recommended as a second-line treatment option.[8] Existing evidence demonstrates that in resource-limited settings, many young infants with signs of severe infection do not receive the recommended inpatient treatment because such treatment is not accessible, acceptable, or affordable to families.[2]

Data on the proportion of newborns whose caregivers refuse hospitalization or do not have access to and are treated at primary-level HFs 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. For example, in Pakistan, only 24% of families accepted referral for hospital care for sick newborns.[9] The African Neonatal Sepsis Trial[10] and Simplified Antibiotic Therapy Trial[11] studies found that on average 80% refused hospital referral.[12,13,14] A body of research has been conducted over the past decade to inform the creation of an evidence-based guideline to offer outpatient treatment to young infants with PSBI or very severe disease when referral is not feasible. WHO published the guideline in 2015[2] with recommendations for the use of simplified regimens combining oral and intramuscular antibiotics that are easier to deliver at the outpatient level. In addition, two important documents—*WHO 2017 Operationalizing management of sick young infants with possible serious bacterial infection (PSBI) when referral is not feasible in the context of existing maternal, newborn, and child health programmes*[5] and Integrated management of childhood illness, Management of the sick young infant aged up to 2 months Chart booklet, 2019[6]—were published by WHO to guide the operationalization of the recommendations.

Quantification teams of countries that have not yet adopted the simplified regimens should refer to the 2016 RMNCH quantification supplement[15] for PSBI in addition to this supplement to ensure smooth phase-out of the old regimens and phase-in of the simplified regimens based on realistic timelines.

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

ANTIBIOTICS

Gentamicin solution for injection, ampicillin powder for injection, and ceftriaxone solution for injection are WHO-recommended injectable antibiotics for the treatment of PSBI or very severe diseases in newborns and children, including sepsis and severe pneumonia. Oral amoxicillin formulations are recommended for treatment of PSBI at the primary level of care in cases other than critical illness when referral is not possible.[2,6]

Further information on amoxicillin and gentamicin can be found in the manual for procurement and supply of quality-assured MNCH commodities.[16]

Table 27: Summary of recommended use and dosages by type of PSBI or very severe disease and age group[6,7]

PARAMETER	TREATMENT AT FIRST-LEVEL HFS/COMMUNITY[6]	TREATMENT AT HOSPITALS[7]
0–59-day PSBI or very severe disease cases with critical illness	***Referral to hospitals is preferred**; when referral is possible, first dose of gentamicin IM and ampicillin IM injections should be administered before referral to hospital* **If referral is not feasible:** ▪ **Gentamicin** (IM): 7.5 mg/kg per dose once a day for 7 days ***AND*** ▪ **Ampicillin** (IM): 50 mg/kg every 12 hours for 7 days	Administration of **gentamicin IV/IM** and **ampicillin IV/IM injections for 7–10 days** is recommended by WHO as the first-line treatment for any type of PSBI or very severe disease in young infants 0–59 days. **I) First-line treatment:** ▪ **Gentamicin IV/IM** First week of life: IM/IV: **5 mg/kg per dose once a day for 7–10 days** Weeks 2–4 of life: **IM/IV: 7.5 mg/kg once a day for 7–10 days** ***AND*** ▪ **Ampicillin IV/IM** First week of life: IM /IV: **50 mg/kg, every 12 hours for 7–10 days** Weeks 2–4 of life: IM /IV: **50 mg/kg, every 8 hours for 7–10 days** **II) Second-line treatment with ceftriaxone**: ▪ More than 2 kg weight at birth and weeks 2–4 of life: **IV/IM: 75 mg/kg once daily for 10 days** ▪ First week of life with less than or equal to 2 kg weight: **IV/IM: 50 mg/kg once daily for 10 days** Note: ▪ Gentamicin: dosage for low birth weight* infants is 3 to 4 mg/kg ▪ Ceftriaxone: dosage for low birth weight* infants is 50 mg/kg
0–59-day PSBI or very severe disease cases with clinical severe infection	***Referral to hospitals is preferred**; when referral is possible, first dose of gentamicin IM and ampicillin IM injections should be administered before referral to hospital* **If referral is not feasible:** ▪ **Gentamicin** (IM): 5–7.5 mg/kg per dose once a day for 7 days ***AND*** ▪ **Amoxicillin** (oral): 50 mg/kg every 12 hours for 7 days **Note**: ▪ Depending on local guidelines, **gentamicin** could be administered for two days to reduce the number of HF visits by the patient and the caretaker ▪ The gentamicin dosage for low birth weight* infants is 3 to 4 mg/kg	
0–6-day PSBI or very severe disease cases with fast breathing as the only sign of illness	***Referral to hospitals is preferred**; when referral is possible, the first dose of gentamicin IM and ampicillin IM injections should be administered before referral to hospital* **If referral is not feasible:** **Amoxicillin** (oral): 50 mg/kg every 12 hours for 7 days	

PARAMETER	TREATMENT AT FIRST-LEVEL HFS/COMMUNITY[6]	TREATMENT AT HOSPITALS[7]
7–59-day PSBI or very severe disease cases with fast breathing as the only sign of illness	***No need to refer to hospitals*** **Amoxicillin** (oral): 50 mg/kg every 12 hours for 7 days	**I) First-line treatment:** **Amoxicillin** (oral): 50 mg/kg every 12 hours for 7 days **II) Second-line treatment with ceftriaxone**: More than 2 kg weight at birth and weeks 2–4 of life: **IV/IM: 75 mg/kg once daily for 10 days**
Notes: **The country context and practice should be considered when determining route of administration, regimen and dosage, and formulation for treatment** ***Low birth weight is birth weight of 2 kg or less.**		

Table 28: Summary of product characteristics and other forecasting considerations

PARAMETER	GENTAMICIN	AMPICILLIN	CEFTRIAXONE	AMOXICILLIN
Presentations	**1) 40 mg/ml solution for injection, as sulfate salt, in 2 ml vials (80 mg)** 2) 20 mg/ml solution for injection, as sulfate salt, in 2 ml vials (40 mg) **3) 10 mg/ml solution for injection, as sulfate salt, in 2 ml vials (20 mg)***	1) 250 mg powder for injection, as sodium salt, in vials **2) 500 mg powder for injection, as sodium salt, in vials**	**1) 250 mg powder for injection, as sodium salt, per vial** 2) 500 mg powder for injection, as sodium salt, per vial	1) 125 mg dispersible and scored tablets, as trihydrate salt **2) 250 mg dispersible and scored tablets, as trihydrate salt** 3) 500 mg dispersible and scored tablets, as trihydrate salt 4) 250 mg/5 ml powder/suspension, as trihydrate salt, for oral use 5) 125 mg/5 ml powder/suspension, as trihydrate salt, for oral use
Administration	▪ IM and IV			▪ Oral
Storage condition	▪ Store intact vials at 20°C–25°C ▪ Protect from freezing		▪ Store intact vials at 15°C–25°C ▪ Protect from freezing	▪ **Dispersible tablet (DT)/tablet:** Do not store above 30°C. Best in blister presentation and not loose in pots ▪ **Oral powder for suspension**: Store dry powder at 20–25°C.
Additional supplies required for administration	▪ 1–3 ml syringe and 23-gauge needle ▪ Butterfly needle or IV cannula, IV infusion and drip set (for hospital only) ▪ Alcohol swab, sterile water 10 ml vials/ampoules, 1% lidocaine, sharps containers ▪ 5% dextrose in water solution, normal saline solution (for hospitals only) ▪ Antihistaminic, corticosteroids, and epinephrine may be required to treat anaphylactic reaction to penicillins			▪ Clean water, milk, cup, spoon, etc.
Level of use	▪ IM prereferral doses should be administered at lower-level HFs before referral to hospitals ▪ IV injection-only regimens should be used in hospital settings where comprehensive care can be provided ▪ The simplified regimens that include the use of intramuscular and oral formulations are to be used at lower-level HFs with qualified professionals who can identify signs of PSBI or very severe disease available and when referral is refused or is not possible			
Supply chain considerations	▪ None of the antibiotics require cold chain ▪ Most of these antibiotics have a shelf life of three years ▪ The country context and practice should be considered when determining regimen and dosage and formulation for treatment, quantification, and eventual procurement ▪ Selection and quantification of one formulation of each product considering other uses can help ensure economy of scale and reduce wastage			

IMPORTANT NOTES:

- *Gentamicin 10 mg/ml is ideal for IV administration in neonates but unsuitable for IM injection in the outpatient setting due to the large volume it would result in; not recommended for primary-level use.
- The bolded presentations of each product are the preferred ones considering ease of administration and wastage.

REQUIRED DATA AND POTENTIAL SOURCES: MORBIDITY METHOD OF FORECASTING

Several data points are required to forecast future demands of antibiotics for the treatment of PSBI or very severe disease. Table 29 summarizes the main data types and potential sources for the morbidity method of forecasting, in addition to the common data provided in the introduction of this supplement.

Table 29: Data and potential sources for forecasting of antibiotics for treatment of PSBI or very severe disease and pneumonia in young infants using the morbidity method

DATA	SOURCE	NOTES
Proportion/number of newborn and young infants (0–59 days) identified with symptoms of PSBI or very severe disease in the public sector by level of care (community, first-level HFs, hospitals)	DHS, HMIS, national maternal morbidity and mortality surveys, special surveys	DHS data may be outdated or may not be available at all; HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; consider expert opinion. Note: WHO recommends treatment of 0–6-day-old infants to be at hospitals (to be referred from community and first-level HFs)
Proportion/number of newborn and young infants (0–59 days) identified with symptoms of PSBI or very severe disease who are referred to higher-level HFs by level of care (community, first-level HFs)		
Proportion/number of newborn and young infants (0–59 days) identified with symptoms of PSBI or very severe disease who are treated by level of care (community, first-level HFs, hospitals)		
Proportion/number of newborn and young infants (0–59 day) PSBI or very severe disease cases given specific regimen of antibiotics by level of care (community, first-level HFs, hospitals)	HMIS, national maternal morbidity and mortality surveys, special surveys, National STG, WHO STG, expert opinion, programmatic/strategic plans	HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; consider expert opinion; national STGs may not include new WHO recommendations. Note: include regimens for infants with fast breathing as the only sign of illness
Quantity of each antibiotic (specific formulation and dosage) used for treatment of one PSBI or very severe disease case by level of care (community, first-level HFs, hospitals)	National STG, WHO STG, expert opinion, programmatic/strategic plans	Guidelines may be outdated; may not include new WHO recommendations; use expert opinion if the practice is different from what the guidelines prescribe

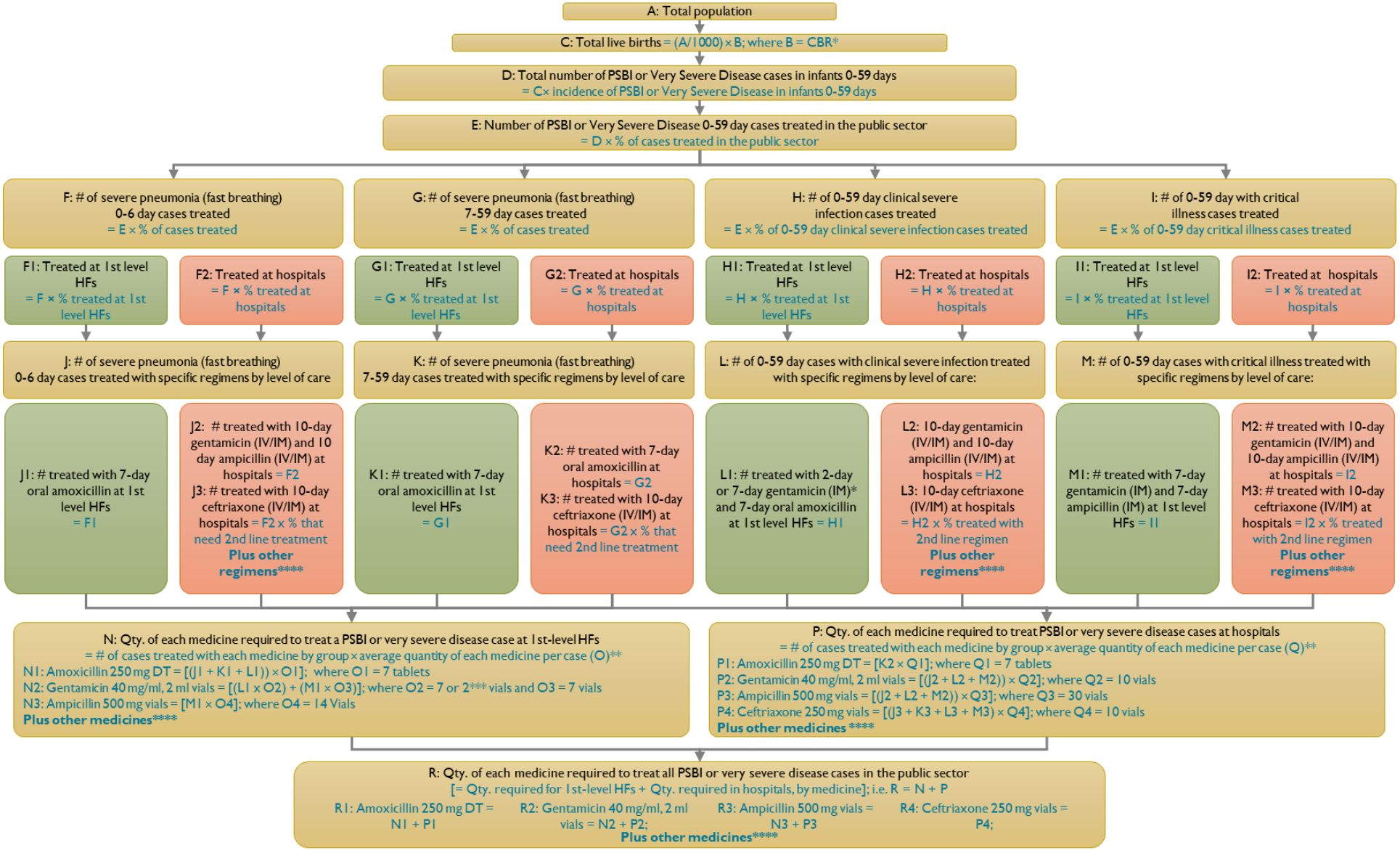

Figure 17: Forecasting algorithm for antibiotics used to treat PSBI or very severe disease in newborns based on morbidity method

CBR = number of live births per 1,000 population per year
***Average quantity of each medicine per case and by level of care is provided in table 30*
****2-day administration of gentamicin IM at first-level HFs is recommended in low HIV prevalence settings*
*****Please add any other regimens and/or medicines that are not included in the algorithm as applicable, based on your local guidelines and practices*

IMPORTANT NOTES:

- Prereferral doses of gentamicin and ampicillin IM should be given to each case that is referred from first-level HFs to hospitals. In the algorithm, the prereferral dose of such medicines is not specified as the quantity forecasted for hospital treatment of such cases includes quantities for full treatment. Country teams need to make sure that enough quantities of such medicines are distributed to lower-level HFs with the right supplies for IM administration.
- Ten-day treatment with injectable antibiotics is assumed at hospitals in this algorithm based on WHO's recommendation of 7–10 days of treatment. Quantification teams can decide the appropriate number of days for treatment within the provided limit.
- Quantification teams need to consider the proportion/number of cases identified at each level of care and the proportion/number of those cases that have access to hospital treatment in order to arrive at the proportion/number of cases treated at each level.

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

The following average quantities of each medicine per case can be used. In these calculations, the average weight of a newborn during treatment is assumed to be 3 kg, and the treatment is assumed to happen during the second to fourth week of life to estimate using the higher dosage.

Table 30: Average quantity of each antibiotic per case[6,7]

	MEDICINE	TREATMENT LEVEL	DOSAGE	QUANTITY PER CASE
A	Gentamicin 10 mg/ml solution for injection in 2 ml vials (20 mg)	Hospital	3 kg × 7.5 mg/kg = 22.5 mg (2 vials) once a day for 10 days	20 vials
B	Gentamicin 40 mg/ml solution for injection in 2 ml vials (80 mg)	Hospital	3 kg × 7.5 mg/kg = 22.5 mg (1 vial) once a day for 10 days	10 vials
		Lower-level HF	**Option 1:** 3 kg × 7.5 mg/kg = 22.5 mg (1 vial) once a day for 7 days	7 vials
			Option 2: 3 kg × 7.5 mg/kg = 22.5 mg (1 vial) once a day for 2 days	2 vials
C	Ampicillin 250 g powder for injection, vials	Hospital	3 kg × 50 mg/kg = 150 mg (1 vial) three times a day for 10 days	30 vials
		Lower-level HF	3 kg x 50 mg/kg =150 mg (1 vial) twice a day for 7 days	14 vials
D	Ampicillin 500 mg powder for injection, vials	Hospital	3 kg × 50 mg/kg = 150 mg (1 vial) three times a day for 10 days	30 vials
		Lower-level HF	3 kg x 50 mg/kg = 150 mg (1 vial) twice a day for 7 days	14 vials
E	Ampicillin 1 g powder for injection, vials	Hospital	3 kg × 50 mg/kg = 150 mg (1 vial) three times a day for 10 days	30 vials
		Lower-level HF	3 kg x 50 mg/kg =150 mg (1 vial) twice a day for 7 days	14 vials
F	Ceftriaxone 250 mg powder for injection, vials	Hospital	3 kg × 75 mg/kg = 225 mg (1 vial) once a day for 10 days	10 vials
G	Ceftriaxone 1 g powder for injection, vials	Hospital	3 kg × 75 mg/kg = 225 mg (1 vial) once a day for 10 days	10 vials
H	Amoxicillin 125 mg dispersible, scored tablets	Lower-level HF or hospital	3 kg × 50 mg/kg = 150 mg (1 tab) two times a day for 7 days	14 tablets
I	Amoxicillin 250 mg dispersible, scored tablets	Lower-level HF or hospital	3 kg × 50 mg/kg = 150 mg (0.5 tab) two times a day for 7 days	7 tablets
J	Amoxicillin 125 mg/5 ml powder/suspension, 100 ml bottle	Lower-level HF or hospital	3 kg × 50 mg/kg = 150 mg (6 ml) two times a day for 7 days	1 bottle
K	Amoxicillin 250 mg/5 ml powder/suspension, 100 ml bottle	Lower-level HF or hospital	3 kg × 50 mg/kg = 150 mg (3 ml) two times a day for 7 days	1 bottle

IMPORTANT NOTES:

- The guidance for hospital-level treatment of PSBI or very severe diseases in newborn and young infants (0–59 days old) is based on the Pocket book of hospital care for children, second edition, WHO, 2013, while the guidance for first-level HFs is based on Integrated management of childhood illness (IMCM), Management of the sick young infant aged up to 2 months Chart booklet, WHO, 2019. However, the latter is used for treatment of 7–59 day pneumonia cases presenting at the hospital level, assuming they will be treated using oral amoxicillin as outpatient cases.
- In general, use of 1 unit (ampule or vial) is assumed per administration/dose to avoid risk of contamination and confusion.

- Quantification teams may decide to use one vial for multiple patients or for the same patient for multiple administrations, which will result in smaller requirements, based on local guidelines and practices. Vials are preferred to ampoules in this case.

Table 31: Summary of incidence, refusal to referral, proportion, and failure rate by type

	PARAMETER	VALUE
A	Incidence of PSBI or very severe disease in young infants 0–59 days[5]	10%
B	% of PSBI or very severe disease cases that refuse referral or do not have access to hospital care*[12,13,14,17,18,19,20,21]	79% (total average)
	▪ Fast breathing 7–59 days	88%
	▪ Fast breathing 0–6 days	94%
	▪ Clinical severe infection	72%
	▪ Critical illness	25%
C	Average proportion of cases by type of PSBI or very severe disease and age group*[17,18,19,20,21]	
	▪ Fast breathing 7–59 days	42%
	▪ Fast breathing 0–6 days	13%
	▪ Clinical severe infection	38%
	▪ Critical illness	7%
D	Average proportion of treatment failure requiring second-line treatment (ceftriaxone)*[17,18,19,20]	6% (total average)
	▪ Fast breathing 7–59 days	4%
	▪ Fast breathing 0–6 days	7%
	▪ Clinical severe infection	6%
	▪ Critical illness	30%

*Both published and unpublished resources were used for the calculation of averages for B, C, and D. Unpublished studies are findings of implementation research: one site in DRC, one in Nigeria, two in Ethiopia, and two in India. This was provided by WHO experts.

Note: Due to significant differences of the above proxy value depending on the setting, quantification teams are recommended to refer to each study referenced above and use the most relevant data to their settings instead of taking the global (total) average.

BOX 13. EXAMPLE OF COUNTRY FORECAST OF ANTIBIOTICS TO TREAT PSBI OR VERY SEVERE DISEASE IN INFANTS 0–59 DAYS BASED ON MORBIDITY METHOD

Country X recommends the use of injectable and oral antibiotics for the treatment of PSBI in infants 0–59 days. The guideline states that referral of 0–59-day PSBI or very severe disease cases (except 7–59-day infants with fast breathing as the only sign of illness) to hospitals is the best option; however, if after counselling referral is refused or is not feasible, it recommends the use of intramuscular injectable antibiotics and/or oral amoxicillin to treat such cases at lower-level HFs.

Available data and assumptions:

- Total population as of current year (CSO census): **20,000,000**
- Annual population growth: 2%
- CBR: 32 live births per 1,000 population
- Incidence of PSBI or very severe disease in infants 0–59 days: 10% (proxy)
- 60% of the cases are assumed to be treated in the public sector, based on data from HMIS; the remaining 40% are estimated to use the private sector or not use any modern health services at all. The proportion treated in the public sector is expected to grow by 5 percentage points per year.
- Estimated proportions of PSBI or very severe disease cases treated by type for the forecasting (proxy)
  - 0–6 day infants with fast breathing as the only sign of illness = 13%
  - 7–59 day infants with fast breathing as the only sign of illness = 42%
  - 0–59 day infants with clinical severe symptoms = 38%
  - 0–59 day infants with critical illness = 7%
- It is estimated that about 94% of 0–6 day infants with fast-breathing pneumonia, 72% of 0–59 day clinical severe infection cases, and 25% of 0–59 day critical illness cases refuse referral and/or cannot access hospitals. Global average is used as a proxy because local data are not available.
- It is assumed that all cases are identified at first-level HFs and need referral for treatment at hospital levels (i.e., no new cases are identified and treated at hospital level).
- Hospital treatment cases were assumed to be provided second-line treatment (ceftriaxone) when treatment failure happens. Treatment failure rates were estimated at 7% for 0–6 day infants with fast breathing pneumonia, 6% for 0–59 day clinical severe infection cases, and 30% for 0–59 day critical illness cases treated at hospitals. Global average is used as a proxy because local data are not available.
- The average weight of an infant with PSBI or very severe disease is assumed to be **3 kg.**
- The following regimens are assumed, based on the national standard treatment guidelines, to be used by type of PSBI or very severe disease and level of care:
  - First-/primary-level HFs:
    - Infants with fast breathing: **oral amoxicillin** for **7 days**
    - Infants with clinical severe infection: **gentamicin IM and amoxicillin oral** for **7 days**
    - Infants with critical illness: **gentamicin IM and ampicillin IM** for **7 days**
  - Hospitals:
    - 7–59 day fast-breathing pneumonia cases as outpatients: **oral amoxicillin** for **7 days**
    - All PSBI or very severe disease cases, except 7–59 day fast breathing pneumonia cases: **gentamicin IV/IM and ampicillin IV/IM** for **10 days**
- The quantification team has selected and agreed to quantify the following formulations, and the quantity per case is also estimated by level of care based on the STG and expert opinion:
  - Gentamicin IM/IV: 40 mg/ml, 2 ml amp (hospital: 10 vials; first-level HF: 7 vials)
  - Ampicillin IV/IM: 250 mg vial (hospital: 30 vials; first-level HF: 14 vials)
  - Ceftriaxone IV/IM: 250 mg vials (hospital: 10 vials)
  - Amoxicillin 250 mg DT (first-level HFs and hospitals: 7 tablets)

Note: Since this is a national forecast, the quantity of gentamicin and ampicillin required to be given as the first dose before referral to hospitals does not need to be calculated separately and it is included in the hospital requirement.

Calculate the amount of antibiotics needed for the program in the next two years.

Example: Treatment of PSBI and very severe diseases in newborns and young infants less than 2 months of age

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total number of live births (C)	C = [(A/1,000) × CBR (B)]: CBR = # of live births per 1,000 population per year	32.00	640,000	652,800	665,856
Total number of total PSBI or very severe disease cases (D)	D = incidence of PSBI or very severe disease in infants (0–59 days)	10.0%	64,000	65,280	66,586
Number of PSBI or very severe disease cases treated in the public sector (E)	E = D x % of cases treated in the public sector		38,400	42,432	46,610
	(annual increase of 5%)	5%	60%	65%	70%
# of 0–6 day fast-breathing cases treated by level of care (F)	F = E x proportion of 0–6 day fast-breathing cases out of the total treated	13%	4,992	5,516	6,059
	F1: # of 0–6 day fast-breathing cases treated at first-level HFs = F x % treated at first-level public HFs	94%	4,692	5,185	5,696
	F2: # of 0–6 day fast-breathing cases treated at public hospitals = F x % treated at public hospitals	6%	300	331	364
# of 7–59 day fast-breathing cases treated by level of care (G)	G = E x proportion of 7–59 day fast-breathing cases out of the total treated	42%	16,128	17,821	19,576
	G1: # of 7-59 day fast-breathing cases treated at first-level HFs = G x % treated at first-level public HFs	100%	16,128	17,821	19,576
	G2: # of 7–59 day fast-breathing cases treated at hospitals = G x % treated at public hospitals	0%	-	-	-
# of 0–59 day clinical severe infection cases treated by level of care (H)	H = E x proportion of 0–59 day clinical severe infection cases out of the total treated	38%	14,592	16,124	17,712
	H1: # of 0–59 day clinical severe infection cases treated at first-level HFs = H x % treated at first-level public HFs	72%	10,506	11,609	12,752
	H2: # of 0–59 day clinical severe infection cases treated at public hospitals = H x % treated at public hospitals	28%	4,086	4,515	4,959
# of 0–59 day critical illness cases treated by level of care (I)	I = E x proportion of 0–59 day critical illness cases out of the total treated	7%	2,688	2,970	3,263
	I1: # of 0–59 day critical illness cases treated at first-level HFs = I x % treated at first-level public HFs	25%	672	743	816
	I2: # of 0–59 day critical illness cases treated at public hospitals = I x % treated at public hospitals	75%	2,016	2,228	2,447
	J1: 7-day amoxicillin oral: 0–6 day fast-breathing cases treated at first-level HFs = F1 x % treated with the regimen	100%	4,692	5,185	5,696

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Number of 0–6 day fast-breathing cases treated with specific regimen by level of care (J)	J2: 10-day gentamicin IV/IM and ampicillin IV/IM: 0–6 day fast-breathing cases treated at hospitals = F2 x % treated with the regimen	100%	300	331	364
	J3: 10-day ceftriaxone IV/IM: 0–6 day fast-breathing cases treated with second-line regimen at hospitals = F2 x % treated with the regimen	7%	21	23	25
Number of 7–59 day fast-breathing cases treated with specific regimen by level of care (K)	K1: 7-day amoxicillin oral: 7–59 day fast-breathing cases treated at first-level HFs = G1 x % treated with the regimen	100%	16,128	17,821	19,576
	K2: 7-day amoxicillin oral: 7–59 day fast-breathing cases treated at hospitals = G2 x % treated with the regimen	0%	-	-	-
	K3: 10-day ceftriaxone IV/IM: 0–6 day fast-breathing cases treated with second-line regimen at hospitals = G2 x % treated with the regimen	0%	-	-	-
Number of 0–59 day clinical severe infection cases treated with specific regimen by level of care (L)	L1: 7-day gentamicin IM and amoxicillin oral: 0–59 day clinical severe infection cases treated at first-level HFs = H1 x % treated with the regimen	100%	10,506	11,609	12,752
	L2: 10-day gentamicin IV/IM and ampicillin IV/IM: 0–59 day clinical severe infection cases treated at hospitals = H2 x % treated with the regimen	100%	4,086	4,515	4,959
	L3: 10-day ceftriaxone IV/IM: 0–59 day clinical severe infection cases treated with second-line regimen at hospitals = H2 x % treated with the regimen	6%	245	271	298
Number of 0–59 day critical illness cases treated with specific regimen by level of care (M)	M1: 7-day gentamicin IM and ampicillin IM: 0–59 day critical illness cases treated at first-level HFs = I1 x % treated with the regimen	100%	672	743	816
	M2: 10-day gentamicin IV/IM and ampicillin IV/IM: 0–59 day critical illness cases treated at hospitals = I2 x % treated with the regimen	100%	2,016	2,228	2,447
	M3: 10-day ceftriaxone IV/IM: 0–59 day critical illness cases treated with second-line regimen at hospitals = I2 x % treated with the regimen	30%	605	668	734
Quantity of amoxicillin 250 mg DT - first-level public HFs (N1)	N1= (J1 + K1 + L1) x O1; where O1: quantity of amoxicillin 250 mg DT per case = 7	7	219,287	242,312	266,171
Quantity of gentamicin 40 mg/ml, 2 ml vials - first-level public HFs (N2)	N2 = (L1 + M1) x Q2; where Q2: quantity of gentamicin 40 mg/ml 2 ml vials per case = 7	7	78,248	86,464	94,977
Quantity of ampicillin 250 mg vials - first-level public HFs (N3)	N3 = M1 x O4; where O4: quantity of ampicillin 250 mg vials per case = 14	14	9,408	10,396	11,419
Quantity of amoxicillin 250 mg DT - public hospitals (P1)	P1 = K2 x Q1; where quantity of amoxicillin 250 mg DT per case = 7	7	-	-	-
Quantity of gentamicin 40 mg/ml, 2 ml vials - public hospitals (P2)	P2 = (J2 + L2 + M2) x Q2; where quantity of gentamicin 40 mg/ml 2 ml vials per case = 10	10	64,013	70,734	77,699

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Quantity of ampicillin 250 mg vials - public hospitals (P3)	P3 = (J2 + L2 + M2) x Q3; where quantity of ampicillin 250 mg vials per case = 30	30	192,038	212,202	233,096
Quantity of ceftriaxone 250 mg vials - public hospitals (P4)	P4 = (J3 + K3 + L3 + M3) x Q4; where quantity of ceftriaxone 250 mg vials per case = 10	10	8,709	9,624	10,571
Total quantity of amoxicillin 250 mg DT (R1)	**R1 = N1 + P1**		**219,287**	**242,312**	**266,171**
Total quantity of gentamicin 40 mg/ml 2 ml vials (R2)	**R2 = N2 + P2**		**142,260**	**157,198**	**172,676**
Total quantity of ampicillin 250 mg vials (R3)	**R3 = N3 + P3**		**201,446**	**222,598**	**244,516**
Total quantity of ceftriaxone 250 mg vials (R4)	**R4 = P4**		**8,709**	**9,624**	**10,571**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

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8. TREATMENT OF PNEUMONIA IN CHILDREN 2–59 MONTHS

INTRODUCTION

Pneumonia is an acute respiratory infection that affects the lungs, resulting in limited oxygen intake and painful breathing.[1] Pneumonia can be caused by bacteria, virus, or fungus. The bacteria *Streptococcus pneumoniae* is the most common cause.[1] The number of pneumonia episodes in children under 5 in developing countries decreased from 178 million to 138 million (30%) between 2000 and 2015, while the number of associated deaths decreased from 1.7 million to 900,000 (22%) in the same time period.[2] Despite the significant reduction of pneumonia episodes and deaths, it is still the single largest cause of mortality in children under 5, accounting for 15% of total deaths in this age group.[1]

A recent systematic global analysis estimated that annual incidence of clinical pneumonia in children under 5 in developing countries has decreased from 329 episodes per 1,000 children in 2000 to 231 episodes per 1,000 children in 2015.[2] This systematic analysis[2] provided country estimates of the pneumonia incidence in 132 developing countries for 2015.

Pneumonia in children can be prevented with simple interventions and treated with low-cost, low-technology medication and care.[1] Pneumonia is classified as severe or nonsevere on the basis of clinical features.[3] Most cases of fast breathing and/or chest indrawing should be treated with oral antibiotics (amoxicillin) at a HF or at the community level by trained CHWs. Severe pneumonia, which is pneumonia with any general danger sign such as convulsions or vomiting, requires referral and injectable antibiotic therapy and additional supportive care, including oxygen.[1,3,4] Data show that the majority of childhood pneumonia deaths are due to severe pneumonia/severe disease; management of these cases requires early identification, prompt referral, and the availability of good-quality higher-level care. However, in many low-resource settings, referral is difficult and often does not take place. Based on this and a review of additional evidence, WHO has developed a simplified approach that could increase the number of children receiving correct treatment for pneumonia.[4]

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

AMOXICILLIN

Amoxicillin is a broad-spectrum oral penicillin antibiotic recommended for the treatment of suspected pneumonia in children under 5.[1] Most cases of pneumonia in children can be treated with oral amoxicillin.[5] Amoxicillin is also recommended for possible infections in all children with SAM.[3]

Amoxicillin 250mg DTs, in blister packs of 10, is the WHO-recommended formulation of oral amoxicillin for the treatment of nonsevere pneumonia at the community and HF levels. However, oral suspension forms of amoxicillin—250 mg/5 ml of 100 ml and 125 mg/5 ml of 100 ml—remain the most commonly used child formulations.[5]

Compared to oral suspension formations, amoxicillin DTs are cheaper, have logistical and supply chain advantages in terms of volume and weight, and make measuring the amount per dose more accurate.[5] The market for amoxicillin 250 mg DT is increasing steadily as more countries align their STGs with the latest WHO recommendations.

Table 32: Product characteristics

PARAMETER	DESCRIPTION
Recommended uses and dosages by level of care[4]	
Community level by CHWs	▪ **Oral amoxicillin** is recommended by WHO for the treatment of **fast-breathing pneumonia** with no chest indrawing or no general danger signs at the community level by qualified CHWs without the need for referral to HFs. ○ Dosage: 40 mg/kg twice daily (80 mg/kg/day) for 5 days **Notes:** ▪ 3 days of treatment for low HIV prevalence settings (<1% in general populations) ▪ CHWs should refer children with chest-indrawing pneumonia or severe pneumonia (with danger signs) to appropriate HFs
First-level HFs	▪ **Oral amoxicillin** is recommended by WHO for the treatment of children with fast-breathing pneumonia or HIV-negative chest-indrawing pneumonia at first-level HFs without the need for referral to hospitals. ○ Dosage: 40 mg/kg twice daily (80 mg/kg/day) for 5 days **Notes:** ▪ 3 days of treatment for low HIV prevalence settings (<1% in general populations) ▪ HIV-positive children with chest-indrawing pneumonia or children with severe pneumonia (with danger signs) should be referred to hospitals for inpatient treatment with injectable antibiotics ▪ Empiric cotrimoxazole treatment is recommended for suspected Pneumocystis jirovecii (previously Pneumocystis carinii) pneumonia as an additional treatment for HIV-infected and HIV-exposed infants from 2 months to 1 year with chest-indrawing or severe pneumonia
Hospitals	▪ **Oral amoxicillin** is recommended by WHO for children 2–59 months with fast-breathing or HIV-negative chest-indrawing pneumonia. ○ Dosage: 40 mg/kg twice daily (80 mg/kg/day) for 5 days ▪ Children 2–59 months with severe pneumonia should be treated with parenteral **ampicillin** (or benzylpenicillin, when ampicillin is not available) and **gentamicin or ceftriaxone** as a first-line treatment. ○ Dosage: first-line treatment of HIV-negative children with severe pneumonia: — **Ampicillin**: 50 mg/kg IM/IV every 6 hours for at least for 5 days — **Gentamicin**: 7.5 mg/kg IM/IV once a day for at least for 5 days ○ Dosage: First-line treatment of HIV-positive children with chest-indrawing or severe pneumonia: — **Ampicillin**: 50 mg/kg IM/IV every 6 hours for at least for 5 days — **Gentamicin**: 7.5 mg/kg IM/IV or **ceftriaxone** 50mg/kg IM/IV once a day for at least 5 days ○ Dosage: Second-line treatment in HIV-positive children with chest-indrawing pneumonia or in non-HIV-positive or HIV-positive children with severe pneumonia — **Ceftriaxone** 80 mg/kg IM/IV once a day for at least 5 days
Presentations	▪ Amoxicillin (oral) ○ 125 mg dispersible and scored tablets, as trihydrate salt ○ **250 mg dispersible and scored tablets, as trihydrate salt** ○ 500 mg dispersible and scored tablets, as trihydrate salt ○ 250 mg/5ml powder/suspension, as trihydrate salt, for oral use ○ 125 mg/5ml powder/suspension, as trihydrate salt, for oral use **Note:** See the PSBI or very severe disease in infants 0–59 days chapter for information on injectable antibiotics
Administration	▪ Amoxicillin: oral **Note:** See the PSBI or very severe disease in infants 0–59 days chapter for information on injectable antibiotics

PARAMETER	DESCRIPTION
Storage condition	▪ Amoxicillin: ○ **DT/tablet: Do not store above 30°C.** ○ **Oral powder for suspension**: Store dry powder at 20–25°C **Note:** See the PSBI or very severe disease in infants 0–59 days chapter for information on injectable antibiotics
Additional supplies required for administration	▪ Clean water/boiled water, milk, juice, etc., to dissolve the dispersible tablets or powder for suspension; small cup; spoon ▪ Antihistamines, corticosteroids, and epinephrine may be required to treat anaphylactic reaction to penicillins
Level of use	▪ Fast-breathing pneumonia can be treated at the community or HF level by qualified CHWs or facility staff ▪ Chest-indrawing pneumonia can be treated at a lower-level HF by qualified staff ▪ Children with severe pneumonia (with or without HIV) and HIV-positive children with chest-indrawing pneumonia should be treated at hospitals with injections by qualified health professionals
Other supply chain considerations	▪ None of the antibiotics require cold chain ▪ Most of these antibiotics available in the market have a shelf life of 3 years ▪ While capsules and tablets of amoxicillin are available more widely, DTs 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, 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 DTs should be avoided to reduce manipulation and possible degradation. ▪ The products selected should support the national STGs and avoid the need to split tablets, as any manipulation before consumption introduces potential contamination and suboptimal dosing.

REQUIRED DATA AND POTENTIAL SOURCES: MORBIDITY METHOD OF FORECASTING

A number of data points are required to forecast demands for amoxicillin and other antibiotics for pneumonia. Table 33 summarizes the main data types and potential sources for the morbidity method of forecasting, in addition to the common data provided in the introduction of this supplement.

Table 33: Data and potential sources for forecasting of antibiotics for treatment of pneumonia using morbidity method

DATA	SOURCE	NOTES
Incidence of pneumonia in children under 5 (proportion/number of under-5 pneumonia cases)	DHS, HMIS, national child morbidity and mortality surveys, special surveys, expert opinion, programmatic/strategic plans	DHS data may be outdated or may not be available at all; HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; consider expert opinion
Proportion/number of children with pneumonia with access to health services (at community, public, and private facilities)		
Proportion/number of children with pneumonia by type (fast breathing, chest indrawing, and severe) identified in the public sector by level of care (community, first-level HFs, and hospitals)		
Proportion/number of children with chest-indrawing and severe pneumonia cases identified at and referred by community and first-level HFs to higher-level HFs		
Proportion/number of each type of pneumonia case treated at each level of public health care by age group (2–11m, 12–36m, 37–59m)		
Proportion/number of cases treated with specific antibiotic regimens by type of pneumonia	HMIS, special surveys, national STG, WHO STG, expert opinion, programmatic/strategic plans	HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; consider expert opinion; national STGs may not include new WHO recommendations.
Quantity (formulation and dosage) of each medicine used in each regimen to treat one case by age group	National STG, WHO STG, expert opinion	Guidelines may be outdated; may not include new WHO recommendations; actual practice may be different from STGs; consider the actual practice if guidelines are relatively old and not followed; parenteral treatment duration varies between patients depending on clinical evolution

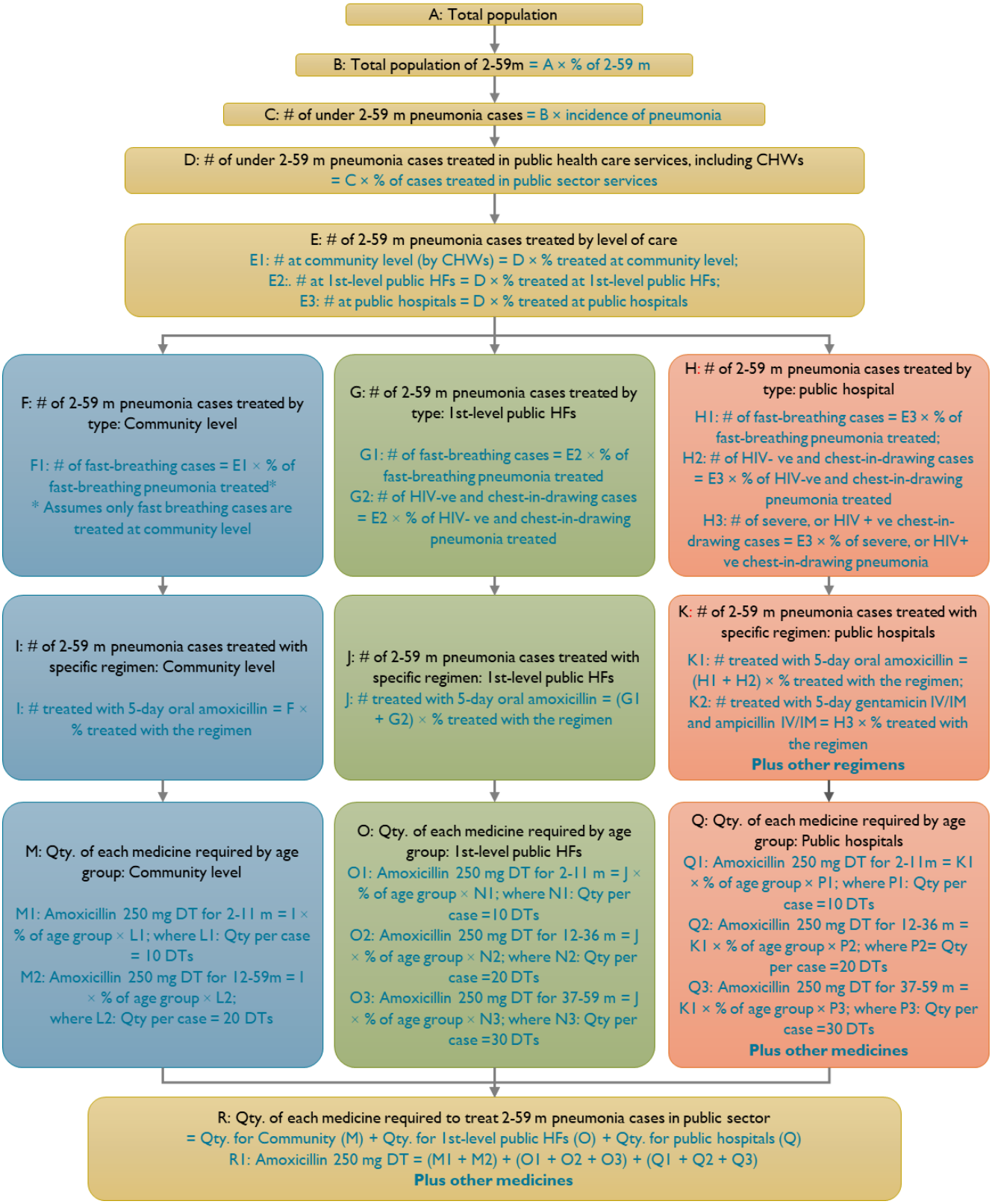

Figure 18: Forecasting algorithm for antibiotics used to treat pneumonia in children 2–59 months based on morbidity method

IMPORTANT NOTES:

- Quantification teams should consider several factors in determining the proportions of cases treated in the public sector and by level of care, including percentage of cases who do not seek care, percentage of cases who seek treatment from the private and other nonpublic sectors, types of pneumonia treated at each level of care, and referral from lower levels to higher levels of care.
- The total quantity of amoxicillin required is the sum of what is needed for PSBI or very severe disease in newborns, pneumonia, SAM, and other indications if and when the same formulations are used.
- In the algorithm above, a five-day oral amoxicillin regimen is used, assuming most of the countries using this supplement have HIV prevalence rates of >1%. In settings with low HIV prevalence, three days of oral amoxicillin is recommended for treatment of fast-breathing pneumonia without chest indrawing.
- Consider forecasting for the social marketing sector where applicable.
- Subdivide by health care level (e.g., community, first-level HFs, hospitals) where needed because programmatically the country may want to increase access by increasing case detection and treatment at lower levels. This may also go with task shifting so that more of the more complicated and severe cases are treated at higher levels. Targets could be set for each level.
- If there are no data or data need to be disaggregated by level of care (especially for the first level and hospital level), quantification teams can use the following simplified version of the algorithm (figure 19) to calculate needs. It is still important to disaggregate by the community and HF levels as the dosage recommendation for community-level treatment is different from that of HF treatments.

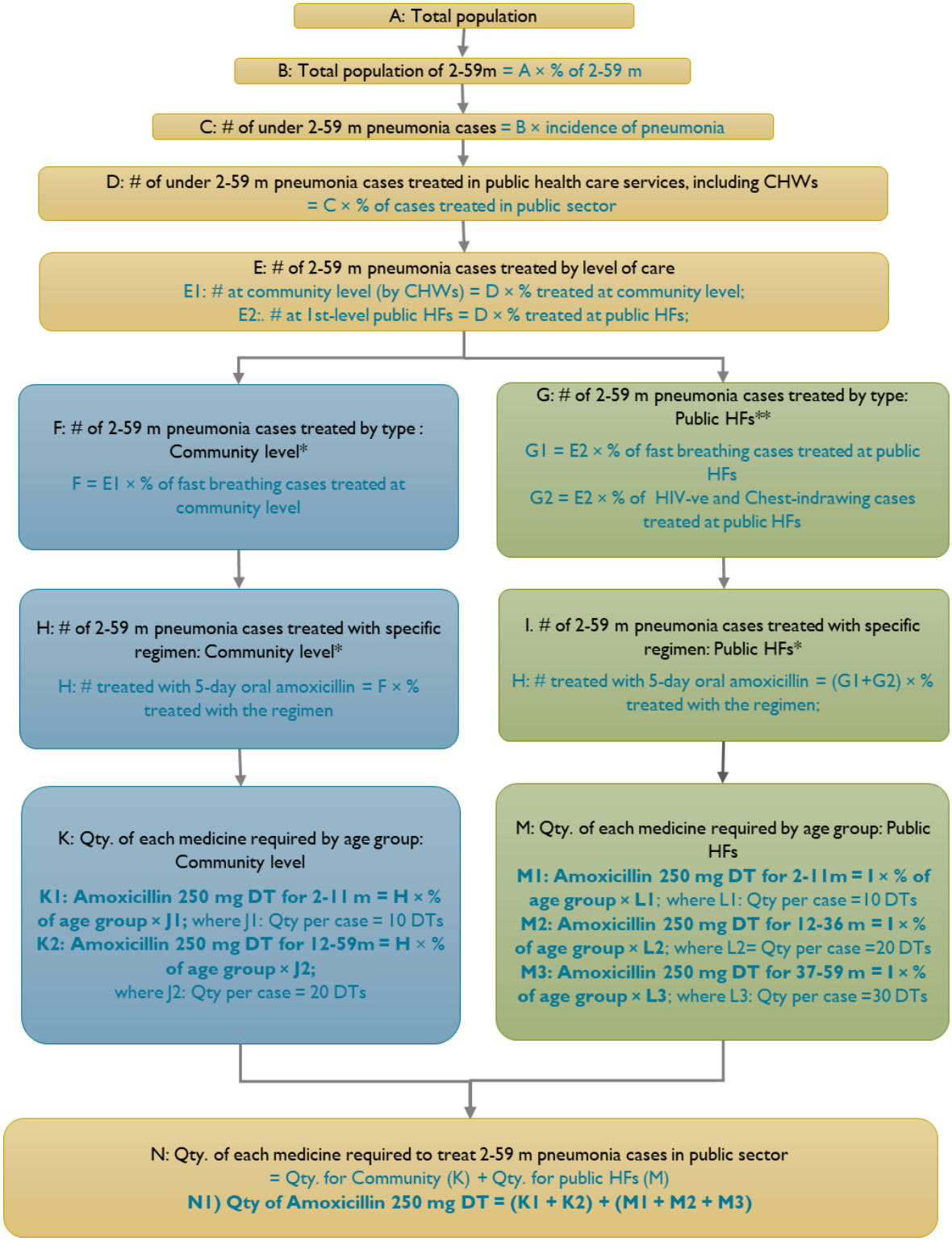

Figure 19: Forecasting algorithm for amoxicillin used to treat nonsevere pneumonia in children 2–59 months based on morbidity method (simplified version)

*Only fast-breathing cases are assumed to be treated at the community level with amoxicillin
**Fast-breathing and HIV-ve chest-indrawing cases are assumed to be treated at public HFs using amoxicillin

IMPORTANT NOTE:

- This algorithm only takes into account amoxicillin, which is used for outpatient treatment of nonsevere cases (fast-breathing pneumonia or HIV-negative chest-indrawing pneumonia cases) and no other antibiotics, such as injectables that are needed for the more severe cases covered in figure 18.

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

1. Use 231 episodes of pneumonia in 1,000 children (23.1%) for incidence of pneumonia in children 2–59 months.[2] The same reference has details for country-specific incidence of 136 LMICs.
2. Dosage and average quantities per case by age group

If local data are not available, the following average dosage and quantities of each medicine per case can be used for the respective age/weight group.[4]

Table 34: Community level: Fast-breathing pneumonia in children

AGE/WEIGHT	FORMULATIONS	DOSAGE	QUANTITY PER CASE
2–11m (4–<10 kg)	Amoxicillin 250mg DT OR Amoxicillin 250 mg/5 ml, 100 ml bottle	**1 DT twice a day for 5 days** OR 5 ml twice a day for 5 days	**10 DTs** OR 1 bottle
12–59m (10–19 kg)		**2 DT twice a day for 5 days** OR 10 ml twice a day for 5 days	**20 DTs** OR 1 bottle

Table 35: First-level HFs and hospitals: Any non-HIV-positive children with fast breathing and/or chest-indrawing pneumonia

AGE/WEIGHT	FORMULATION	DOSAGE	QUANTITY PER CASE
2–11m (4–<10 kg)	Amoxicillin 250 mg DT OR Amoxicillin 250 mg/5 ml, 100 ml bottle	1 DT twice a day for 5 days OR 5 ml twice a day for 5 days	10 DTs OR 1 bottle
12–36m (10–<14 kg)		2 DT twice a day for 5 days OR 10 ml twice a day for 5 days	20 DTs OR 1 bottle
37–59m (14–19 kg)		3 DT twice a day for 5 days OR 15 ml twice a day for 5 days	30 DTs OR 2 bottles

IMPORTANT NOTE:

- Quantification teams are advised to refer to the sources of data provided as a reference for proxy data as most have country- or region-specific data that can be used for the region or country under consideration instead of the global average.

BOX 14. EXAMPLE OF COUNTRY FORECAST OF ANTIBIOTICS TO TREAT PNEUMONIA IN CHILDREN 2–59 MONTHS BASED ON MORBIDITY METHOD

Country *X* has a generalized HIV prevalence of 2.5%. The national pediatric STG recommends the use of oral amoxicillin for 5 days for the treatment of fast-breathing-only and HIV-chest-indrawing pneumonia. Fast-breathing pneumonia cases without any other complications can be treated at all levels, including by trained CHWs. The CHWs are trained to screen and refer HIV-positive, chest-indrawing pneumonia and severe pneumonia cases to public HFs. HIV-negative chest-indrawing cases can be treated at first- or higher-level public HFs. The guideline states that all severe and/or HIV-positive chest-indrawing pneumonia case should be referred to hospitals for treatment with ampicillin (IV/IM) and gentamicin (IV/IM) injections as the first-line option. Cases that don't respond to first line treatment should be treated with ceftriaxone IV/IM. Incidence of pneumonia in children under 5 is not known in the country; thus, the quantification team has agreed to take global average as a proxy.

Available data and assumptions:

- Total **population**: **20,000,000** (current year)
- Annual population growth: **2.0%**
- Percentage of children 2–59m: **9%**
- Incidence of pneumonia in children 2–59m: **231 episodes per 1,000 children** (proxy)
- Percentage of pneumonia cases identified in the public sector, including at community level by CHWs, is estimated to increase by 5 percentage points per year (currently **60%**).
- Percentage of 2–59m pneumonia cases treated in the public sector by level of care
    - Hospitals = **15%,** expected to remain the same over the forecast period
    - First-level HFs = **65%,** expected to decrease by 3 percentage points per year
    - Community level (by CHWs) = **20%,** expected to increase by 3 percentage points per year
- Estimated proportions of pneumonia cases treated by level of care and type for the forecasting period based on HMIS data

	Community	First-level HFs	Hospitals
Fast breathing	100%	90%	10%
HIV-negative chest-indrawing	0%	10%	20%
Severe and/or HIV-positive chest-indrawing	0%	0%	70%

- Compliance to first-line treatment recommendations is estimated at 100% for all levels of care and is assumed to remain the same during the forecasting period.
- The following age groups and respective proportions were estimated based on HMIS data: 2–11m =3 3%, 12–36m = 37%, and 37–59m = 30%; these were assumed to be the same for all levels of care
- The following formulations and average quantities per case and age group were agreed by the quantification team, based on the STG and expert opinion:

	Level	Type of pneumonia	Formulations	Quantity per case by age group
1	Community	Fast breathing only	Amoxicillin 250 mg DT	2–11m: 10 tablets
				12–59m: 20 tablets
2	First-level public HFs and public hospitals	Fast breathing only and HIV-negative chest-indrawing	Amoxicillin 250 mg DT	2–11m: 10 tablets
				12–36m: 20 tablets
				37–59m: 30 tablets

Calculate the amount of amoxicillin 250 mg DT required in the public sector in the next two years.

Other medicines are needed for the treatment of pneumonia in children 2–59 months, including gentamicin inj. and ampicillin inj., but these are not shown in this example to keep it simple.

Example 1: Pneumonia in children 2–59 months

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total population of 2–59m (B)	B = A x % of population 2–59 months	9%	1,800,000	1,836,000	1,872,720
Number of total 2–59m pneumonia cases/episodes (C)	C = B x Incidence of pneumonia in children 2–59 months; where 231 episodes per 1,000 children	23.1%	415,800	424,116	432,598
Number of 2–59m pneumonia cases treated at public health care services, including by CHWs (D)	D = C x % of cases treated at public-sector heath care services (annual increase of 5%)		249,480	275,675	302,819
		5%	60%	65%	70%
Number of 2–59m pneumonia cases treated by level of public health care (E)	(E1) # treated in the community (by CHWs) = D x % treated at community (annual increase of 3%)		49,896	63,405	78,733
		3%	20%	23%	26%
	(E2) # treated in first-level public HFs = D x % treated at first-level HFs (annual decrease of 3%)		162,162	170,919	178,663
		-3%	65%	62%	59%
	(E3) # treated in public hospitals = D x % treated at public hospitals		37,422	41,351	45,423
		0%	15%	15%	15%
Number of 2–59m pneumonia cases treated at community level by type (F)	(F) # of fast-breathing cases treated at community (by CHWs) = E1 x % of fast-breathing cases	100%	49,896	63,405	78,733
Number of 2–59m pneumonia cases by type treated at first-level public HFs (G)	(G1) # of fast-breathing cases treated at first-level public HFs = E2 x % of fast-breathing cases	90%	145,946	153,827	160,797
	(G2) # HIV-negative and chest-indrawing cases treated at first-level public HFs = E2 x % HIV-negative chest-indrawing cases	10%	16,216	17,092	17,866
Number of 2–59m pneumonia cases by type treated at public hospitals (H)	(H1) # of fast-breathing cases treated at public hospitals = E3 x % of fast-breathing cases	10%	3,742	4,135	4,542
	(H2) # HIV-negative and chest-indrawing cases treated at public hospitals = E3 x % HIV-negative chest-indrawing cases	20%	7,484	8,270	9,085
	(H3) # of severe or HIV-positive chest-indrawing cases treated at public hospitals = E3 x % of severe or HIV-positive chest-indrawing cases	70%	26,195	28,946	31,796
Number of 2–59m pneumonia cases treated with specific regimen - Community/by CHWs (I)	(I) # of cases treated with 5-day amoxicillin oral (fast breathing) = F x % treated with the regimen	100%	49,896	63,405	78,733
Number of 2–59m pneumonia cases by type treated with specific regimen - first-level public HFs (J)	(J) # of cases treated with 5-day amoxicillin oral (fast breathing and HIV-negative chest-indrawing) = (G1 + G2) x % treated with the regimen	100%	162,162	170,919	178,663

PARAMETER	INPUT			CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Number of 2–59m pneumonia cases by type treated with specific regimen - public hospitals (K)	(K1) # of cases treated with 5-day amoxicillin oral (fast breathing and HIV-negative chest-indrawing) = (H1 + H2) x % treated with the regimen		100%	11,227	12,405	13,627
	(K2) # of cases treated with 5-day gentamicin IV/IM and ampicillin IV/IM (severe or HIV-positive chest-indrawing) = H3 x % treated with the regimen		100%	26,195	28,946	31,796
Quantity of amoxicillin 250 mg DT - community level (M)	(M1) Quantity for 2–11m cases = I x % of age group x L1; where, L1: quantity per case = 10 DTs	33%	10	164,657	209,238	259,819
	(M2) Quantity for 12–59m cases: I x % of age group x L2; where, L2: quantity per case = 20 DTs	67%	20	668,606	849,632	1,055,021
Quantity of amoxicillin 250 mg DT - first-level public HFs (O)	(O1) Quantity for 2–11m cases = J x % of age group x N1; where, N1: quantity per case = 10 DTs	33%	10	535,135	564,032	589,588
	(O2) Quantity for 12–36m cases = J x % of age group x N2; where, N2: quantity per case = 20 DTs	37%	20	1,199,999	1,264,799	1,322,107
	(O3) Quantity for 37–59m cases = J x % of age group x N3; where, N3: quantity per case = 30 DTs	30%	30	1,459,458	1,538,269	1,607,968
Quantity of amoxicillin 250 mg DT - public hospitals (Q)	(Q1) Quantity for 2–11m cases = K1 x % of age group x P1; where, P1: quantity per case = 10 DTs	33%	10	37,048	40,938	44,969
	(Q2) Quantity for 12–36m cases = K1 x % of age group x P2; where, P2: quantity per case = 20 DTs	37%	20	83,077	91,800	100,839
	(Q3) Quantity for 37–59m cases = K1 x % of age group x P3; where, P3: quantity per case = 30 DTs	30%	30	101,039	111,649	122,642
Total quantity of amoxicillin 250 mg DT for treatment of pneumonia in children 2–59m (R)	**R = (M1+M2) + (O1+O2+O3) + (Q1+Q2+Q3)**			**4,249,019**	**4,670,355**	**5,102,951**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

BOX 15. EXAMPLE OF COUNTRY FORECAST OF AMOXICILLIN TO TREAT PNEUMONIA IN CHILDREN 2–59 MONTHS BASED ON MORBIDITY METHOD (SIMPLIFIED VERSION)

Country *X* has a generalized HIV prevalence of 2.5%. The national pediatric STG recommends the use of oral amoxicillin for 5 days for the treatment of fast-breathing-only and HIV negative chest-indrawing pneumonia. Fast-breathing pneumonia cases without any other complications can be treated at all levels, including by trained CHWs. The CHWs are trained to screen and refer HIV-positive, chest-indrawing pneumonia, and severe pneumonia cases to public HFs. HIV-negative chest-indrawing cases can be treated at first- or higher-level public HFs.

Available data and assumptions:

- Total **population**: **20,000,000** (current year)
- Annual population growth: **2.0%**
- Percentage of children 2–59m: **9%**
- Incidence of pneumonia in children 2–59m: **231 episodes per 1,000 children** (proxy)
- Percentage of pneumonia cases identified in the public sector including at community level by CHWs is estimated to increase by 5 percentage points per year (currently **60%**).
- Percentage of 2–59m pneumonia cases treated in the public sector by level of care
  - Public HFs = **80%,** expected to decrease by 3 percentage points per year
  - Community level (by CHWs) = **20%,** expected to increase by 3 percentage points per year
- Estimated proportions of pneumonia cases treated by level of care and type for the forecasting period based on HMIS data

	Community	Public HFs
Fast breathing	100%	90%
HIV-negative chest-indrawing	0%	10%

- Compliance to first-line treatment recommendations is estimated at 100% for all levels of care and is assumed to remain the same during the forecasting period.
- The following age groups and respective proportions were estimated based on HMIS data: 2–11m = 33%, 12–36m = 37%, and 37–59m = 30%; these were assumed to be the same for all levels of care.
- The following formulations and average quantities per case and age group were agreed by the quantification team based on the STG and expert opinion:

	Level	Type of pneumonia	Formulations	Quantity per case by age group
1	Community	Fast-breathing only	Amoxicillin 250 mg DT	2–11m: 10 tablets
				12–59m: 20 tablets
2	Public HFs	Fast-breathing only and HIV-negative chest-indrawing	Amoxicillin 250 mg DT	2–11m: 10 tablets
				12–36m: 20 tablets
				37–59m: 30 tablets

Calculate the amount of amoxicillin 250 mg DT required in the public sector in the next two years using the simplified version of the algorithm (figure 19).

Other medicines are needed for the treatment of pneumonia in children 2–59 months, including gentamicin inj. and ampicillin inj., but these are not shown in this example to keep it simple.

Example 2: Pneumonia in children 2–59 months (simplified version)

PARAMETER	INPUT			CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)		2%	20,000,000	20,400,000	20,808,000
Total population of 2–59m (B)	B = A x % of population 2–59 months		9%	1,800,000	1,836,000	1,872,720
Number of total 2–59m pneumonia cases/episodes (C)	C = B x incidence of pneumonia in children 2–59 months; where 231 episodes per 1,000 children		23.1%	415,800	424,116	432,598
Number of 2–59m pneumonia cases treated at public health care services, including by CHWs (D)	D = C x % of cases treated at public-sector heath care services (annual increase of 5%)			249,480	275,675	302,819
			5%	60%	65%	70%
Number of 2–59m pneumonia cases treated by level of public health care (E)	(E1) # treated in the community (by CHWs) = D x % treated at community (annual increase of 3%)			49,896	63,405	78,733
			3%	20%	23%	26%
	(E2) # treated in public HFs = D x % treated at first-level HFs (annual decrease of 3%)			162,162	170,919	178,663
			-3%	65%	62%	59%
Number of 2–59m pneumonia cases treated by type at community level (F)	(F) # of fast-breathing cases treated at community (CHWs) = E1 x % of fast-breathing cases		100%	49,896	63,405	78,733
Number of 2–59m pneumonia cases by type treated at public HFs (G)	(G1) # of fast-breathing cases treated at public HFs = E2 x % of fast-breathing cases		90%	145,946	153,827	160,797
	(G2) # of HIV-negative and chest-indrawing cases treated at public HFs = E2 x % HIV-negative chest-indrawing cases		10%	16,216	17,092	17,866
Number of 2–59m pneumonia cases treated with specific regimen - community/by CHWs (H)	(H) # of cases treated with 5-day amoxicillin oral (fast breathing) = F x % treated with the regimen		100%	49,896	63,405	78,733
Number of 2–59m pneumonia cases by type treated with specific regimen - public HFs (I)	(I) # of cases treated with 5-day amoxicillin oral (fast breathing and HIV-negative chest indrawing) = (G1+G2) x % treated with the regimen		100%	162,162	170,919	178,663
Quantity of amoxicillin 250 mg DT - community level (K)	(K1) Quantity for 2–11m cases = H x % of age group x J1; where J1: quantity per case = 10 DTs	33%	10	164,657	209,238	259,819
	(K2) Quantity for 12–59m cases: H x % of age group x J2; where J2: quantity per case = 20 DTs	67%	20	668,606	849,632	1,055,021
Quantity of amoxicillin 250 mg DT - public HFs (M)	(M1) Quantity for 2–11m cases = I x % of age group x L1; where L1: quantity per case = 10 DTs	33%	10	535,135	564,032	589,588
	(M2) Quantity for 12–36m cases = I x % of age group x L2; where L2: quantity per case = 20 DTs	37%	20	1,199,999	1,264,799	1,322,107
	(M3) Quantity for 37–59m cases = I x % of age group x L3; where L3: quantity per case = 30 DTs	30%	30	1,459,458	1,538,269	1,607,968
Total quantity of amoxicillin 250 mg DT for treatment of pneumonia in children 2–59m (N)	**N = (K1+K2) + (M1+M2+M3)**			**4,027,855**	**4,425,969**	**4,834,503**

IMPORTANT NOTE:

- There are slight differences between the results for examples 1 and 2 due to differences in the assumptions made for the proportion of cases by type treated at public HFs.

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9. TREATMENT OF DIARRHEA IN CHILDREN UNDER 5 YEARS

INTRODUCTION

Diarrhea is the condition of passing three or more loose or liquid stools per day or more frequent passage than is normal for the individual.[1]

Diarrhea can last several days and lead to significant loss of water and electrolytes from the body, leading to death. Diarrhea is usually a symptom of an intestinal tract infection caused by bacteria, virus, or parasites, which are spread by feces-contaminated water. Rotavirus (virus) and *Escherichia coli* (bacteria) are the two most common causes of diarrhea in low-income countries.

There are three types of clinical diarrhea:[2]

1. Acute watery diarrhea (includes cholera) can be further classified into:
   A. Acute watery diarrhea with severe dehydration
   B. Acute watery diarrhea with some dehydration
   C. Acute watery diarrhea with no dehydration
2. Persistent diarrhea, with or without blood, begins acutely and lasts for ≥14 days. When there is some or severe dehydration, persistent diarrhea is classified as severe. The following guidelines are for children with persistent diarrhea who are not severely malnourished. Severely malnourished children with severe, persistent diarrhea require hospitalization and specific treatment.
   A. Severe persistent diarrhea: Lasts ≥14 days with signs of dehydration (severe or some dehydration) and requires hospital treatment
   B. Nonsevere persistent diarrhea: Lasts ≥14 days without signs of dehydration
3. Dysentery is acute diarrhea presenting with frequent loose stools mixed with blood. Shigella is the most common cause of dysentery. Nearly all dysentery cases require antibiotic treatment. Shigellosis can lead to death if not treated.

In general, severe diarrhea cases need hospitalization while nonsevere diarrhea cases can be treated at community or first-level HFs, including in the private sector.

Incidence of diarrhea among children under 5 decreased by 12.7% (10.6–14.8%) between 2000 and 2016 (from 2.0 per child-year to 1.75 per child-year) globally. The global average is 1.75 episodes per year (range: 1.52–2.02). There are huge disparities among world regions/countries when it comes to incidence of diarrhea, ranging from 0.13 (Australia) to 4.51 (tropical Latin America) episodes per child-year. Diarrhea is still one of the leading causes of mortality in children under 5.[3] In 2016, more than a quarter (27%) of diarrheal deaths occurred among children under 5, and about 90% of diarrheal deaths occurred in sub-Saharan Africa and South Asia.[3] Children who are malnourished or have compromised immunity, such as those with HIV, are most at risk of morbid diarrhea.[2]

Diarrhea is preventable and treatable. A significant proportion of diarrhea cases can be avoided by using safe drinking water, improved sanitation, hand washing with soap, exclusive breastfeeding, rotavirus vaccine, and improved nutrition. The three essential elements in the management of all children with diarrhea are rehydration therapy with low osmolarity ORS, zinc supplementation, and counselling for continued feeding and prevention.

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

PRODUCT CHARACTERISTICS AND OTHER FORECASTING CONSIDERATIONS

According to WHO,[4] children under 5 with diarrhea should receive ORS and zinc at the first signs of diarrhea to avoid progressing to more severe illness and, potentially, death. ORS and zinc are highly effective, affordable, and readily available products that could prevent death. Combined use of these products can reduce the chance of death in up to 93% of under-5 diarrhea cases.[5] However, a significant proportion of children with diarrhea do not receive ORS and zinc in sub-Saharan African countries; only about 33% and 5% of children experiencing diarrhea receive ORS and zinc, respectively.[6] In many countries, ORS and zinc are available over the counter, allowing significant proportions of cases to receive treatment from the private sector, such as drug shops. The private sector is a major source of care for diarrhea, accounting for up to an estimated 70% of care seeking in selected Asian countries and 12–46% across African countries.[7]

ORAL REHYDRATION SALTS

ORS is a combination of electrolytes and sugar used for replacement therapy of body fluids and electrolytes, especially during diarrhea. Low osmolarity ORS reduces stool output, vomiting, and the need for unscheduled intravenous therapy. The recommended product specifications are for the low osmolarity formulation of ORS in 200 ml, 500 ml, or 1 L sachets, depending on local guidelines. Once mixed, any unused solution should be discarded within 24 hours; therefore, smaller sachets may be more appropriate. It is recommended that children receive the equivalent to two liters of mixed solution.

ORS is available flavored and unflavored. Unflavored ORS tastes salty, and most children report preferring flavored ORS, which increases acceptance. However, selection of flavor should consider locally acceptable tastes.

ZINC

Zinc is an essential trace element necessary for normal human functioning. Zinc plays a critical role in metalloenzymes, polyribosomes, cell membranes, and cellular function, leading to the belief that it also plays a central role in cellular growth and the function of the immune system.[8] Zinc reduces the incidence of diarrhea in the two to three months following administration, reduces the duration of acute diarrhea, and reduces treatment failure or death due to diarrhea.[9]

The recommended product for zinc is a 20 mg scored, taste-masked, DT in blister packs of 10. DTs can be dissolved in water or a small amount of breast milk, usually disintegrating within a minute or two. Zinc has a strong metallic taste, so tablets should be appropriately masked to increase acceptability by children and encourage completion of a full course of treatment. Some countries are using zinc syrups; however, dispersible zinc tablets are smaller in weight and bulk and tend to have a longer shelf life than syrups, which makes them more suitable for distribution in many settings, especially to lower levels of the health system.

Co-packed ORS and zinc formulations are available in the market and listed on the WHO model EML 2019 to increase use of both products together.[10]

This section presents the key characteristics and health system considerations for each product. For more detailed information on ORS and zinc, refer to the chapter in the manual for procurement and supply of quality-assured MNCH commodities.[11]

Table 36: Product characteristics

PARAMETER	ORS	ZINC
Treatment of diarrhea: Dosage	ORS is recommended by WHO for the treatment of **diarrhea**, together with zinc, in children under 5 Dosage: ▪ **<24 months:** 50–100 ml after each loose stool for 2 days ▪ **24–59 months:** 100–200 ml after each loose stool for 2 days ▪ It is recommended that children receive the number of packets equivalent to two liters of mixed solution for a course of treatment: for example, this means 2 packets of ORS powder for dilution in 1 L per case	Zinc supplement is recommended by WHO for the treatment of **diarrhea,** together with ORS, in children under 5 Dosage: ▪ **2–6 months**: 10 mg once a day for 10–14 days ▪ **6–59 months:** 20 mg once a day for 10–14 days
	Note: *In addition to ORS and zinc, antibiotics and IV fluids are recommended to treat dysentery and persistent diarrhea with blood and dehydration, respectively, but they are not discussed in this supplement to keep it simple. Below are the recommended regimens and dosages for more complicated types of diarrhea.* [2]	
	Nonsevere diarrhea with blood Regimen: 2-day ORS (i.e., 2-1L sachets), 10-day zinc and **3-day ciprofloxacin or 5-day metronidazole**	**Severe diarrhea without blood** Regimen: 2-day ORS (i.e., 2-1L sachets), 10-day zinc, and **Ringer's solution stat**	**Severe diarrhea with blood** Regimen: 2-day ORS (i.e., 2-1L sachets), 10-day zinc, **3-day ceftriaxone or 5-day metronidazole, and Ringer's solution stat**
	Dosage and route of administration: [2] Ciprofloxacin: (10–20 mg/kg) 15 mg/kg 2 times a day for 3 days orally Metronidazole: 10 mg/kg 3 times a day for 5 days orally Ceftriaxone: 50–80 mg/kg per day for 3 days, IV or IM (for severely ill cases or as a second line-treatment) Ringer's solution: 70 ml/kg over 2.5 hours once, IV	
Presentations[10]	▪ ORS low osmolality, 10.2 g powder for oral dilution in 200 ml, sachet ▪ ORS low osmolality, 10.2 g powder for oral dilution in 500 ml, sachet ▪ ORS low osmolality, 20.5 g powder for oral dilution in 1,000 ml, sachet	▪ 20 mg dispersible and scored tablets, as sulfate salt
	▪ ORS flavored 4 x 10.2 g/0.5 L + zinc 20 mg 10 tablets, co-packed ▪ ORS flavored 2 x 20.5 g/1 L + zinc 20 mg 10 tablets, co-packed	
Administration	Oral	
Storage condition	Store below 25°C in a dry place	▪ Do not store above 30°C ▪ Protect from moisture and light
Additional supplies required for administration	▪ Clean/boiled water or milk to disperse the zinc DTs and ORS (water only) ▪ Jugs of the appropriate size, spoons, and cups	
Level of use	▪ Nonsevere diarrhea without blood can be treated at community or HF level by qualified CHWs or facility staff ▪ Severe diarrhea and diarrhea with blood can be treated at lower-level HF staff by qualified staff	
Supply chain considerations	Preparations have a shelf life of 36 months	Preparations have a shelf life of 36 to 48 months
	Notes: ▪ None of the products required for treatment of diarrhea require cold chain storage. ▪ It is strongly recommended that only one strength of zinc (preferably 20 mg) is selected so that health workers are not confused and the supply chain is not complicated unnecessarily by an additional product. The product selected should be in accordance with national STGs and, where possible, avoid the need to split tablets to prevent suboptimal dosing through uneven breaking of the tablet, as any manipulation before consumption introduces potential contamination and degradation caused by zinc's sensitivity to humidity.	

REQUIRED DATA AND POTENTIAL SOURCES: MORBIDITY METHOD OF FORECASTING

A number of data points are required to forecast demands of ORS and zinc. Table 37 summarizes the main data types and potential sources for the morbidity method of forecasting, in addition to the common data provided in the introduction of this supplement.

Table 37. Data and potential sources for of ORS and zinc for treatment of diarrhea using the morbidity method

DATA	SOURCE	NOTES
Incidence/number of diarrhea cases in children under 5 years	DHS, HMIS, national child morbidity and mortality surveys, special surveys, program strategic plans, Child Health Epidemiology Reference Group estimates	Survey data may be outdated; HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; include those that are referred from community or the private sector; get data/estimate by age group if possible; Note: Many child diarrhea cases may be treated using home remedies or in the private sector.
Proportion/number of children with diarrhea who have access to modern health services by sector and level (at community, public facilities, and private facilities)		
Proportion/number of children with diarrhea by type (nonsevere and severe) identified by public health level of care (community level, first-level HFs, and hospitals)		
Proportion/number of children with diarrhea by type (nonsevere and severe) referred to higher-level HFs by level of care (from community and first-level HFs)		
Proportion/number of under-5 diarrhea cases by type (nonsevere, severe) treated by level of care (community, first-level HF, hospital) and by age group (0–5m, 6–59m)		
Proportion/number of under-5 diarrhea cases treated with specific regimens for each type of diarrhea (nonsevere, severe)	HMIS, national maternal morbidity and mortality surveys, special surveys, national STG, WHO STG, expert opinion, programmatic/strategic plans	HMIS data may not be complete; may need to apply estimated annual growth/reduction rate; consider expert opinion; national STGs may not include new WHO recommendations
Quantity of each medicine (specific formulation and dosage) used in each specific regimen for the treatment of one diarrhea case by type (severe, nonsevere), level of care, and age group	National STG, WHO STG, expert opinion	Guidelines may be outdated; may not include new WHO recommendations; actual practice may be different from STGs; consider the actual practice if guidelines are relatively old and not followed; parenteral treatment duration varies between patients depending on clinical evolution

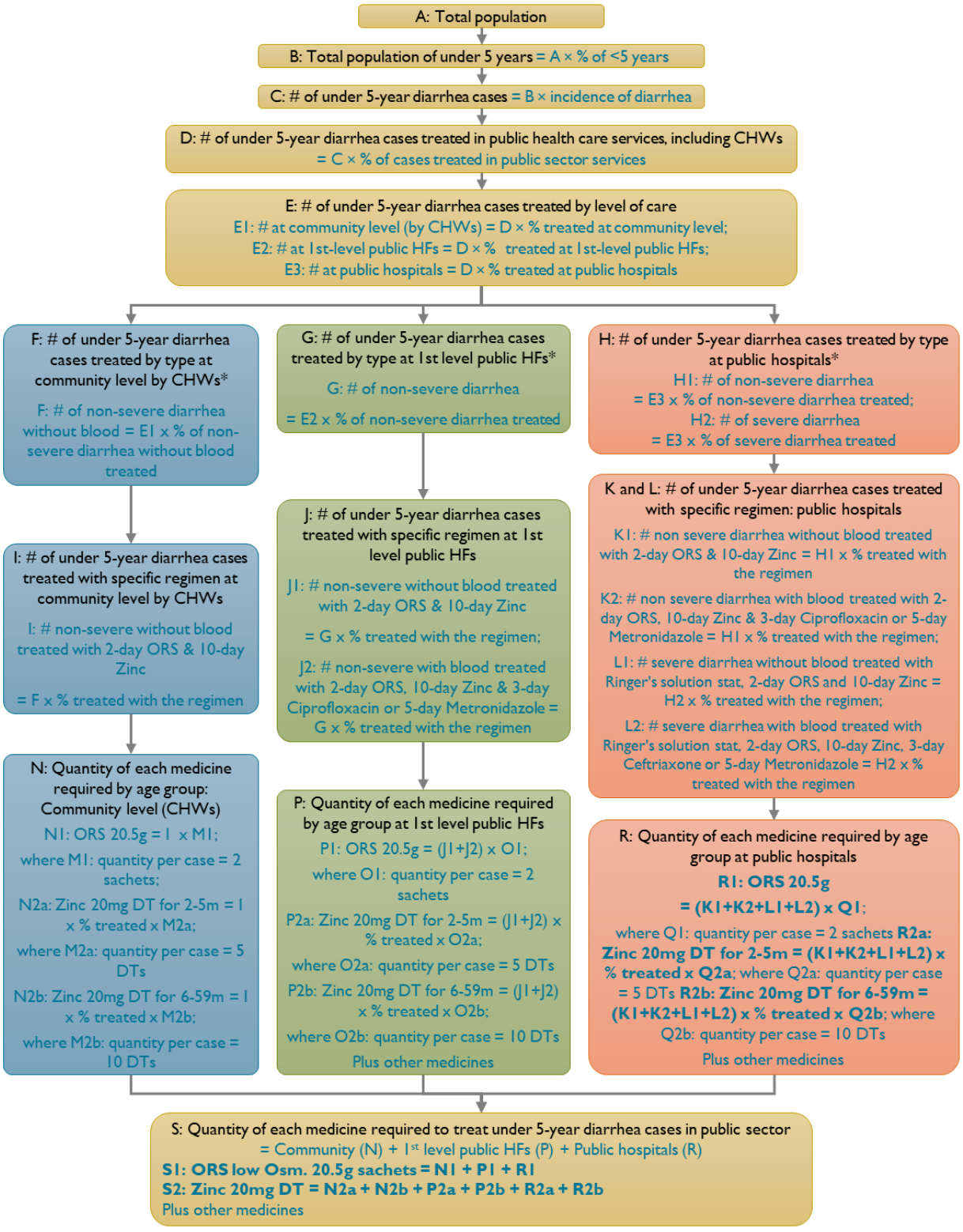

Figure 20: Forecasting algorithm for products used to treat diarrhea in children under 5 based on morbidity method

*Consider other medicines that are not included in the final calculation (e.g., metronidazole, ceftriaxone)

IMPORTANT NOTES:

- Quantification teams should consider several factors in determining the proportion of cases treated in the public sector and by level of care. These factors may include percentage of cases who do not seek care, percentage of cases who seek treatment from the private and other nonpublic sectors, types of diarrhea treated at each level of care, and referral from lower level to higher levels of cares.
- Consider forecasting for the social marketing sector where applicable.
- Subdivide by health care level (e.g., community, first-level HFs, hospitals) where needed because programmatically the country may want to increase access by increasing case detection and treatment at lower levels. This may also go with task shifting so that more of the more complicated and severe cases are treated at higher levels. Targets could be set for each level.
- If there are no data or data need to be disaggregated by level of care, quantification teams can use the following simplified version of the algorithm (figure 21) to calculate needs.

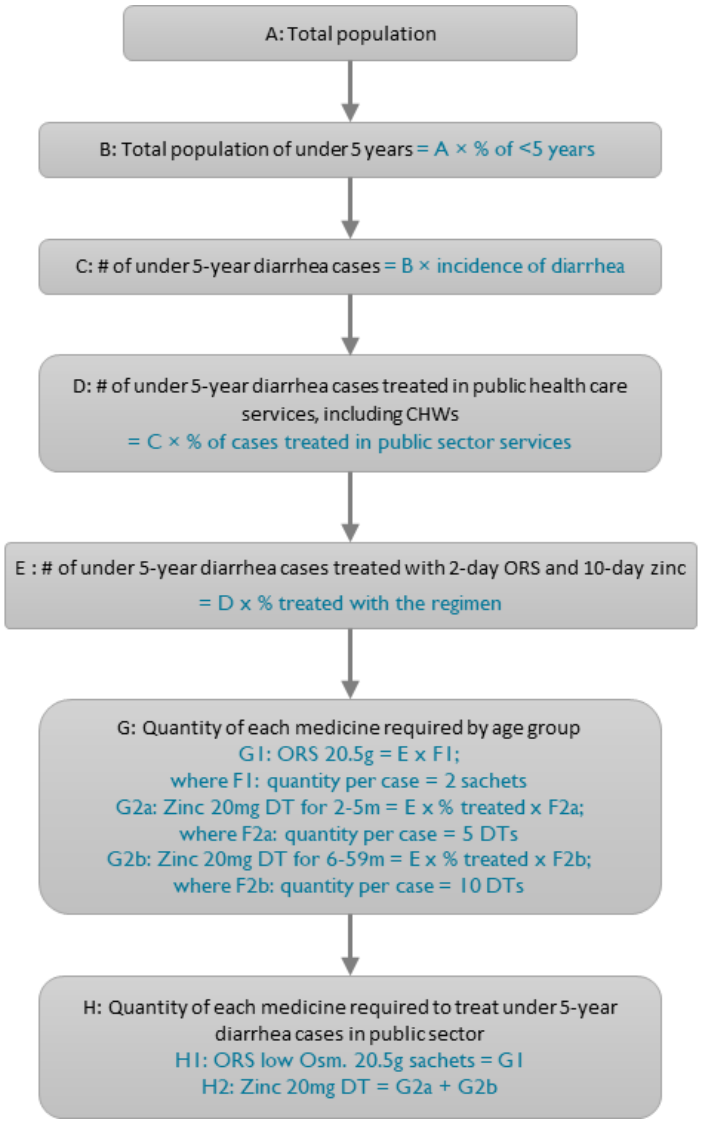

Figure 21: Forecasting algorithm for ORS and zinc used to treat diarrhea in children under 5 based on morbidity method (simplified version)

IMPORTANT NOTE:

- This algorithm only takes into account ORS and zinc and no other products such as antibiotics or fluids that may be needed for the more severe cases covered in figure 20.

PROXY DATA AND SOURCES

If local data are not available, quantification teams may use the following data as proxy.

1. Incidence of diarrhea in children under 5 years

Table 38: Global and regional estimates of diarrheal incidence per child year in 2016[3]

	REGION/SUBREGION	EPISODES PER CHILD-YEAR
I	Global	1.75 (1.52–2.02)
II	Sub-Saharan Africa	2.37 (2.06–2.74)
A	Central Sub-Saharan Africa	2.85 (2.41–3.34)
B	West Sub-Saharan Africa	2.43 (2.14–2.80)
C	East Sub-Saharan Africa	2.19 (1.90–2.54)
D	South Sub-Saharan Africa	2.04 (1.81–2.32)
III	South Asia	1.49 (1.29–1.72)
IV	South East Asia	1.60 (1.35–1.90)
V	Latin America and Caribbean	2.82 (2.50–3.18)
A	Tropical Latin America	4.51 (4.05–4.97)
B	Caribbean Latin America	2.30 (1.98–2.65)
C	Andean Latin America	2.32 (2.00–2.64)
D	Central Latin America	1.87 (1.62–2.18)

2. Dosage and average quantities per case by age group

Table 39: Dosage and average quantity per case

AGE/WEIGHT	FORMULATION	DOSAGE	QUANTITY PER CASE
2–5 m (4–<7 kg)	Zinc 20 mg DT	one-half tablet once a day for 10 days	5 tablets
	ORS 20.5 g low osmolality powder for dilution in 1 L sachet	100 ml after each loose stool for two days (2 liter)	2 sachets
	OR		OR
	ORS 10.2 g low osmolality powder for dilution in 0.5 L sachet		4 sachets
6–59 m (7–<19 kg)	Zinc 20 mg DT	1 tablet once a day for 10 days	10 tablets
	ORS 20.5 g low osmolality powder for dilution in 1 L sachet	100 ml after each loose stool for two days (2 liter)	2 sachets

IMPORTANT NOTE:

- Quantification teams are advised to refer to the sources of data provided as a reference for proxy data as most have country- or region-specific data that can be used for the region or country under consideration instead of the global average.

BOX 16. EXAMPLE OF COUNTRY FORECAST OF ORS AND ZINC TO TREAT DIARRHEA IN CHILDREN UNDER 5 BASED ON MORBIDITY METHOD

Country *X* is located in east Sub-Sahara Africa. The national pediatric STG recommends the use of oral ORS and zinc for all cases of diarrhea occurring in children under 5. The CHWs are trained to screen and treat or refer diarrhea cases. The guideline allows CHWs to treat nonsevere diarrhea without blood at the community level with ORS and zinc. The guideline also states that nonsevere diarrhea cases with blood should be referred to first-level public HFs, while all severe diarrhea cases identified at community or first-level HFs are expected to be referred to public hospitals. Incidence of diarrhea in children under 5 is not known in the country; thus, the quantification team has agreed to take regional average as a proxy.

Available data and assumptions:

- Total **population**: **20,000,000** (current year)
- Annual population growth: **2%**
- % of children under 5: **9%**
- Incidence of diarrhea in children under 5 in east Africa: **2.19 episodes per child-year** (proxy)
- % of diarrhea cases treated in the public sector including at community level by CHWs**:** is estimated to increase by 5 percentage points per year (currently **50%**).
- % of under 5-year diarrhea cases treated in the public sector by level of care
  - Hospitals = **15%,** expected to remain the same
  - First-level HFs = **65%,** expected to decrease by 3 percentage points per year
  - Community level (by CHWs) = **20%,** expected to increase by 3 percentage points per year
- Estimated proportions of diarrhea cases treated by level of care and type for the forecasting period based on HMIS data

	Community	First level HFs	Hospitals
Nonsevere diarrhea without blood	100%	90%	18%
Nonsevere diarrhea with blood	0%	10%	2%
Severe diarrhea without blood	0%	0%	72%
Severe diarrhea with blood	0%	0%	8%

- It is estimated that about 10% of nonsevere and severe diarrhea cases treated at each level have diarrhea with blood.
- Compliance to treatment recommendations was assumed to be 100% for all levels during the forecasting period.
- The following age groups and respective proportions were estimated based on HMIS data:
  - 0–5m = 10% and 6–59m = 90%; these were assumed to be the same for all levels of care.
- The following formulations and average quantities per case and age group were agreed by the quantification team:
  - ORS 20.5 g low osmolality 1 L sachet:
    - Under 5 years: 2 sachets
  - Zinc 20 mg DT
    - 2–5m: 5 tablets
    - 6–59m: 10 tablets

* **Calculate the total quantities of ORS 20.5 g low osmolality 1 L sachet and zinc 20 mg DT required for the program in the next two years.**

Note: Other medicines are needed for the treatment of diarrhea in children under 5, including ciprofloxacin and metronidazole at first-level HFs and injectable antibiotics and perfusions at the hospital level, but these are not shown in this example to keep it simple.

Example 1: Diarrhea in children under 5

PARAMETER	INPUT		CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)	2%	20,000,000	20,400,000	20,808,000
Total population under 5 (B)	B = A x % of population under 5	9%	1,800,000	1,836,000	1,872,720
Total number of under-5 diarrhea cases/episodes (C)	C = B x incidence of diarrhea in children (2.19 episodes per child) under 5	2.19	3,942,000	4,020,840	4,101,257
Number of under-5 diarrhea cases treated at public health care services, including CHWs (D)	D = C x % of cases treated in the public-sector heath care services (annual increase of 5%)		1,971,000	2,211,462	2,460,754
		5%	50%	55%	60%
Number of under-5 diarrhea cases treated by level of public health care (E)	E1: # treated in the community (by CHWs) = D x % treated at community (annual increase of 3%)		394,200	508,636	639,796
		3%	20%	23%	26%
	E2: # treated in first-level public HFs = D x % treated at first-level HFs (annual decrease of 3%)		1,281,150	1,371,106	1,451,845
		-3%	65%	62%	59%
	E3: # treated in public hospitals = D x % treated at public hospitals		295,650	331,719	369,113
		0%	15%	15%	15%
Number of under-5 diarrhea cases treated at community level by type (F)	F: # of non-severe diarrhea cases without blood treated in community (by CHWs) = E1 x % of non-severe diarrhea cases (without blood)	100%	394,200	508,636	639,796
Number of under-5 diarrhea cases treated at first-level public HFs by type (G)	G: # of non-severe diarrhea cases treated at first-level public HFs = E2 x % of non-severe diarrhea cases treated	100%	1,281,150	1,371,106	1,451,845
Number of under-5 diarrhea cases treated at public hospitals by type (H)	H1: # of non-severe diarrhea cases treated at public hospitals = E3 x % of non-severe diarrhea cases treated	20%	59,130	66,344	73,823
	H2: # of severe diarrhea cases treated at public hospitals = E3 x % of severe diarrhea cases treated	80%	236,520	265,375	295,290
Number of under-5 diarrhea cases treated with specific regimen - community/by CHWs (I)	I: # of cases non-severe without blood treated with 2-day ORS and 10-day zinc: = F x % treated with regimen	100%	394,200	508,636	639,796
Number of under-5 diarrhea cases by type treated with specific regimen - first-level public HFs (J)	J1: # of cases non-severe without blood treated with 2-day ORS and 10-day zinc: = G1 x % treated with regimen	90%	1,153,035	1,233,996	1,306,660
	J2: # of cases non-severe with blood treated with 2-day ORS, 10-day zinc and 3 days ciprofloxacin or 5 days metronidazole:: = G2 x treated with regimen	10%	128,115	137,111	145,184
Number of under-5 non-severe diarrhea cases by subtype treated with specific regimen - public hospitals (K)	K1: # of cases : non-severe without blood treated with 2-day ORS and 10-day zinc = H1 x % treated	90%	53,217	59,709	66,440
	K2: # of cases non-severe with blood treated with 2-day ORS, 10-day zinc, and 3-day ciprofloxacin or 5-day metronidazole oral: = H1x % treated	10%	5,913	6,634	7,382

PARAMETER	INPUT			CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Number of under-5 severe diarrhea cases by subtype treated with specific regimen - public hospitals (L)	L1: # cases severe without blood treated with Ringer's solution stat, 2-day ORS, and 10-day zinc: = H2 x % treated		90%	212,868	238,838	265,761
	L2: # cases severe with blood treated with Ringer's solution stat, 2-day ORS, 10-day zinc, and 3-day ceftriaxone or 5-day metronidazole: = H2 x % treated		10%	23,652	26,538	29,529
Quantity of ORS 20.5 g low osmolality 1 L sachet - community level (N1)	N1: Quantity for under 5 cases = 1 x % of age group x M1; where M1: quantity per case = 2 sachets	100%	2	788,400	1,017,273	1,279,592
Quantity of zinc 20mg DT - community level (N2)	N2a: Quantity for 2–5m cases = 1 x % of age group x M2a; where M2a: quantity per case = 5 DTs	10%	5	197,100	254,318	319,898
	N2b: Quantity for 6–59m cases = 1 x % of age group x M2b; where M2b: quantity per case = 10 DTs	90%	10	3,547,800	4,577,726	5,758,165
Quantity of ORS 20.5 g low osmolality 1 L sachet - first-level public HFs (P1)	P1: Quantity for under 5 cases = (J1+J2) x % of age group x O1; where O1: quantity per case = 2 sachets	100%	2	2,562,300	2,742,213	2,903,690
Quantity of zinc 20 mg DT - first-level public HFs (P2)	P2a: Quantity for 2–5m cases (10%) = (J1+J2) x % of age group x O2a; where O2a: quantity per case = 5 DTs	10%	5	640,575	685,553	725,922
	P2b: Quantity for 6–59m cases = (J1+J2) x % of age group x O2b; where O2b: quantity per case = 10 DTs	90%	10	11,530,350	12,339,958	13,066,604
Quantity of ORS 20.5 g low osmolality 1 L sachet- public hospitals (R1)	R1: Quantity for under 5 cases = (K1+K2+L1+L2) x % of age group x Q1; where Q1: quantity per case = 2 sachets	100%	2	591,300	663,439	738,226
Quantity of zinc 20 mg DT - public hospitals (R2)	R2a: Quantity for 2–5m case = (K1+K2+L1+L2) x % of age group x Q2a; where Q2a: quantity per case = 5 DTs	10%	5	147,825	165,860	184,557
	R2b: Quantity for 6–59m cases = (K1+K2+L1+L2) x % of age group x Q2b; where Q2b: quantity per case = 10 DTs	90%	10	2,660,850	2,985,474	3,322,018
Total quantity of ORS 20.5 g low osmolality 1 L sachet for treatment of diarrhea in children under 5 (S1)	**S1 = (N1+P1+R1)**			**3,942,000**	**4,422,924**	**4,921,508**
Total quantity of zinc 20 mg DT for treatment of diarrhea in children under 5 (S2)	**S2 = (N2a+N2b) + (P2a+P2b) + (R2a+R2b)**			**18,724,500**	**21,008,889**	**23,377,164**

Note:

- This is an example to show how the algorithm can be translated to calculations using an Excel tool. Quantification teams need to adapt the Excel tool and the examples provided to their context.

BOX 17. EXAMPLE OF COUNTRY FORECAST OF ORS AND ZINC TO TREAT DIARRHEA IN CHILDREN UNDER 5 BASED ON MORBIDITY METHOD (SIMPLIFIED VERSION)

Country *X* is located in east Sub-Sahara Africa. The national pediatric STG recommends the use of oral ORS and zinc for all cases of diarrhea occurring in children under 5. The CHWs are trained to screen and treat or refer diarrhea cases. The guideline allows CHWs to treat nonsevere diarrhea without blood at the community level with ORS and zinc. Incidence of diarrhea in children under 5 is not known in the country; thus, the quantification team has agreed to take regional average as a proxy.

Available data and assumptions:

- Total **population**: **20,000,000** (current year)
- Annual population growth: **2%**
- % of children under 5 years of age: **9%**
- Incidence of diarrhea in children under 5 in east Africa: **2.19 episodes per child-year** (proxy)
- % of diarrhea cases treated in the public sector including at community level by CHWs**:** is estimated to increase by 5 percentage points per year (currently **50%**).
- Compliance to treatment recommendations was assumed to be 100% for all levels during the forecasting period.
- The following age groups and respective proportions were estimated based on HMIS data:
  - 0–5m = 10% and 6–59m = 90%; these were assumed to be the same for all levels of care.
- The following formulations and average quantities per case and age group were agreed by the quantification team:
  - ORS 20.5 g low osmolality 1 L sachet:
    - Under 5: 2 sachets
  - Zinc 20 mg DT
    - 2–5m: 5 tablets
    - 6–59m: 10 tablets

* **Calculate the total quantities of ORS 20.5 g low osmolality 1 L sachet and zinc 20 mg DT** required for the program in the next two years using the simplified version of the algorithm.

Note: In this simplified example, there is no disaggregation by level of care.

Other medicines are needed for the treatment of diarrhea in children under 5, including ciprofloxacin and metronidazole at first-level HFs and injectable antibiotics and perfusions at the hospital level, but these are not shown in this example to keep it simple.

Example 2: Diarrhea in children under 5 (using the simplified version of the algorithm)

PARAMETER	INPUT			CURRENT YEAR	FORECAST YEAR 1	FORECAST YEAR 2
Total population (A)	A: Population = previous year population + (previous year population x PGR) (annual PGR is 2%)		2%	20,000,000	20,400,000	20,808,000
Total population under 5 (B)	B = A x % of population under 5		9%	1,800,000	1,836,000	1,872,720
Total number of under-5 diarrhea cases/episodes (C)	C = B x incidence of diarrhea in children (2.19 episodes per child) under 5		2.19	3,942,000	4,020,840	4,101,257
Number of under-5 diarrhea cases treated at public health care services, including CHWs (D)	D = C x % of cases treated in the public-sector heath care services (annual increase of 5%)		5%	1,971,000 50%	2,211,462 55%	2,460,754 60%
Number of under-5 diarrhea cases treated with specific regimen in public health care services (E)	E: # of cases treated with 2-day ORS and 10-day zinc = D x % treated with the regimen		100%	1,971,000	2,211,462	2,460,754
Quantity of ORS 20.5 g low osmolality 1 L sachet (G1)	G1: Quantity for under 5 cases = E x % of age group x F1; where F1: quantity per case = 2 sachets	100%	2	3,942,000	4,422,924	4,921,508
Quantity of zinc 20 mg DT (G2)	G2a: Quantity for 2–5m cases = E x % of age group x F2a; where F2a: quantity per case = 5 DTs	10%	5	985,500	1,105,731	1,230,377
	G2b: Quantity for 6–59m cases = E x % of age group x F2b; where F2b: quantity per case = 10 DTs	90%	10	17,739,000	19,903,158	22,146,787
Total quantity of ORS 20.5 g low osmolality 1 L sachet for treatment of diarrhea in children under 5 (H1)	**H1 = G1**			**3,942,000**	**4,422,924**	**4,921,508**
Total quantity of zinc 20 mg DT for treatment of diarrhea in children under 5 (H2)	**H2 = (G2a+G2b)**			**18,724,500**	**21,008,889**	**23,377,164**

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GLOSSARY

Consumption data are historical data on the actual quantities of a product that have been dispensed to patients or consumed at service delivery points within a specified period.

Consumption method of forecasting is a method that depends on the past usage trend of individual products to estimate future demand for the products.

Couple-Years of Protection (as a conversion factor) is the estimated amount/quantity of a contraception method necessary to protect one couple from pregnancy in one year.

Demographic data are data about the characteristics of the population that will desire, require, or be offered a service for which medical products are required (e.g., total population size, women of reproductive health group, children under five).

Emergency contraceptive pills are oral contraceptives indicated for use to prevent pregnancy after unprotected or inadequately protected sex.

Female condoms are barrier devices that are inserted inside the vagina before sexual intercourse to prevent unintended pregnancy and reduce STIs.

Forecasting is the process of estimating quantities of products required to meet demand (to be used/consumed) during a particular time frame. It answers the questions: "What is needed and how much is needed, in quantities, to meet the health demand of a defined group or population during a specific period?"

Forecasting period is the period for which demand of products is estimated.

Lead time is the period in months between finalization of the quantification and receipt of products at the medical store. This definition shall apply to lead time when it comes to procurement from international and national suppliers. However, the more commonly used definition is the period in months between placement of an order for products and receipt of the products at the medical store (or dispensary) and applies for distributions within the program, from higher level to lower level.

Manikin is a jointed model of the human body used for training on resuscitation techniques.

Morbidity data are data on the prevalence and incidence of diseases or health conditions in a given population.

Morbidity method of forecasting is a method that depends on past trend of cases served/treated coupled with rate of use of products per case to estimate future demand of the products.

Quantification is the process of estimating the quantities and costs of the products required for a specific health program (or service) and determining when orders should be placed and delivered to ensure optimal availability of products. It answers the questions, "What will be required by the program? What quantity of each product is estimated to be consumed? What needs to be procured and at what quantity and cost? When should it be ordered and when should it be delivered?"

Quantification period is the period for which procurement requirements are estimated.

Quantimed® is an access-based forecasting tool that can be used to estimate demands of wide range of health products using the consumption and/or morbidity/demographic methods of forecasting.

QAT is a modernized solution for country-led forecasting and supply planning leveraging from and enhancing Quantimed and Pipeline. QAT can be used to forecast and supply plan for any commodity using demographic, service, morbidity, and consumption forecasting data.

Reality√® is a forecasting tool that generates data for evidence-based advocacy and strategic planning in FP programs based on the morbidity/demographic method of forecasting.

Service data are historical program-level or facility-level data on the number of patient visits to facilities, the number of services provided, the number of disease (or fever) episodes, or the number of people who received a specific service or treatment within a given period.

Stock on hand is the quantity of an item available for dispensing or distribution. It is also called working stock.

Stock on order is the quantity of stock that has been ordered but not yet received and made available for distribution/use; this stock should be scheduled to arrive during the quantification/procurement period.

Supply planning is the process of estimating quantities and total costs of products required for procurement and includes determining order and arrival dates of shipments. It answers the questions: "What products need to be procured; how much of each product can/needs to be procured; what is the total cost of acquiring products; when should orders be made; and when should products be received?"

TOOLS AND RESOURCES FOR QUANTIFICATION

TITLE	AUTHORS: ORGANIZATION/ PROJECT	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; What to do when there is no trend data?	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 introduce a contraceptive technology for the first time in a country and/or 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	https://marketbookshelf.com/wp-content/uploads/2017/05/RH-supplies-_-A-Forecasting-Guide-for-New-and-Underused-Methods-1st-Edition.pdf	Finalized	English	
CHANNEL	UNFPA	Computerized quantitative health supplies management tool for warehouses and service delivery points. Can also be used for forecasting and procurement planning. It has been used in many countries	Quantification Inventory Management	Software tool	MOH/service delivery points	Not available	Finalized	English French, Portuguese, Russian, Spanish	Many focus countries under the UNFPA Global Program to Enhance RHCS (GPRHCS)
Country Commodity Manager (CCM)	UNFPA	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 and 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 (Visual basics based) with manual	UNFPA Country Offices	Manual is downloadable from (https://www.unfpa.org/publications/country-commodity-manager)	Finalized	English French Russian Spanish Arabic	Has been used in many countries and adapted for many medical products
Managing Access to Medicines and Health Technologies (MDS-3)	MSH	Chapter 20 provides details on quantification of health products with case studies and examples.	Quantification	Guide	Central, Regional, District, Facility	https://www.msh.org/resources/mds-3-managing-access-to-medicines-and-health-technologies	Finalized	English	Various countries

TITLE	AUTHORS: ORGANIZATION/ PROJECT	PURPOSE	TOPICS COVERED	TYPE	INTENDED AUDIENCE	FORMAT AND LOCATION	STATUS	LANGUAGE	COUNTRY EXPERIENCES
Manual for Procurement and Supply of Quality-Assured Maternal, Newborn and Child Health Commodities	Global Health Supply Chain program-Procurement Supply Management project	To assist procurement agencies and procurement specialists in establishing a quality assurance (QA) system for the procurement of maternal, newborn, and child health (MNCH) products.	Quality assurance in procurement Technical specifications for: Oxytocin, misoprostol, magnesium sulphate, gentamicin, chlorhexidine 7.1% amoxicillin, ORS, zinc	Technical manual	Procurement agencies	https://www.ghsupplychain.org/progress-increasing-access-quality-assured-life-saving-commodities	Finalized	English French Spanish	Various countries
PipeLine®	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 stock-outs. 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.	Supply planning	Software tool (Access based) and user's guide	Central, Regional, District, Facility	https://www.ghsupplychain.org/pipeline-monitoring-and-procurement-planning-system	Finalized	English, French, Portuguese, Spanish, Vietnamese	Various countries
QuanTB®	MSH	Developed for forecasting and supply planning of TB products but can be applied to other products too.	Quantification	Software tool and user's guide	Central, Regional, District, Facility	http://siapsprogram.org/tools-and-guidance/quantb/	Finalized	English, Chinese, French, Portuguese, Russian Spanish, Vietnamese	Various countries
Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement, Jan 2017	JSI	To assist in estimating the total commodity needs and costs for successful implementation of national health program strategies and goals; ; identifying the funding needs and gaps for procurement of the required commodities; and 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	https://www.jsi.com/resource/quantification-of-health-commodities-2017/	Finalized	English French	Various countries

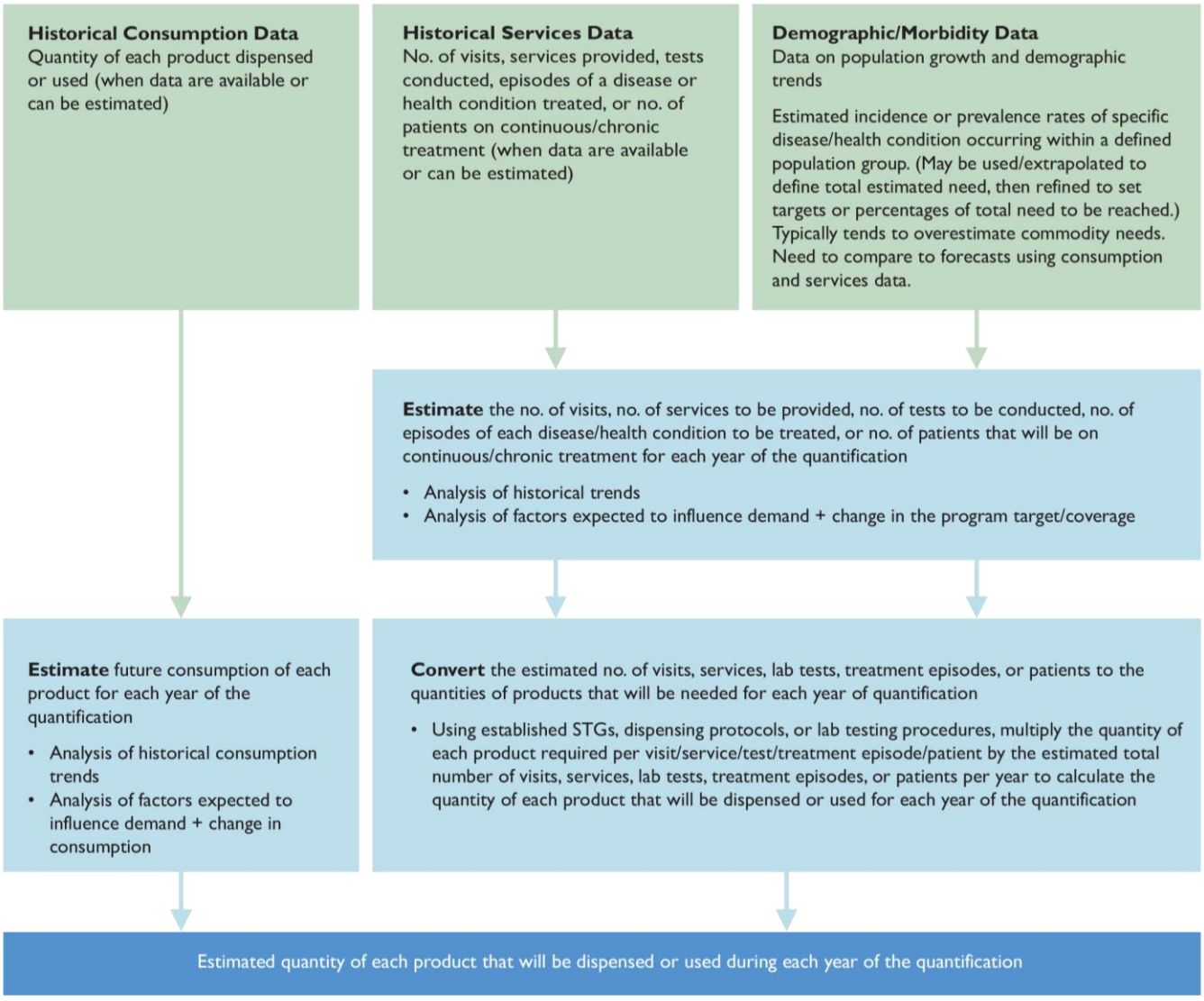
TITLE	AUTHORS: ORGANIZATION/ PROJECT	PURPOSE	TOPICS COVERED	TYPE	INTENDED AUDIENCE	FORMAT AND LOCATION	STATUS	LANGUAGE	COUNTRY EXPERIENCES
Quantification of Health Commodities: Community Case Management Companion Guide, Oct 2014	JSI - Supply Chains for Community Case Management (SC4CCM) Project	This 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.	Quantification	Guide	Program managers, MOH staff, others supporting forecasting and quantification for CCM programs	http://sc4ccm.jsi.com/wp-content/uploads/2016/07/CCMQuantGuide_2014-update.pdf	Finalized	English	Malawi, Rwanda, Ethiopia
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, users should refer to the main quantification guide for the supply planning step.	Quantification Procurement	Guide	Program managers, MOH staff	https://www.psmtoolbox.org/en/tool/quantification/reproductive-health/reproductive-health-products/quantification-of-health-commodities-contraceptive-companion-guide/ or here http://iaphl.org/wp-content/uploads/2016/05/Guide-for-Quantification-of-Contraceptives.pdf	Finalized	English	Various countries
Quantimed®- Pharmaceutical Quantification and Cost Estimation Tool	MSH	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.	Forecasting	Software tool (access based) and user's Manual	Central, District, Regional	http://siapsprogram.org/tools-and-guidance/quantimed/	Finalized	English, French, Portuguese, Spanish	Various countries

TITLE	AUTHORS: ORGANIZATION/ PROJECT	PURPOSE	TOPICS COVERED	TYPE	INTENDED AUDIENCE	FORMAT AND LOCATION	STATUS	LANGUAGE	COUNTRY EXPERIENCES
Quantification Analytics Tool (QAT)	GHSC-PSM	QAT is modernized solution for country-led forecasting and supply planning. QAT leverages new technologies, builds on existing tools, and enables program managers to forecast commodities, optimize procurement schedules, monitor stock status of products, and share data with external platforms and key stakeholders. QAT aims to shift traditional paradigms, improve planning, and contribute to end-to-end data visibility.	Forecasting and supply planning	Software Users manual Reports Reference sheet eLearning module	Program managers, MOH staff, implementing partners involved in quantification of any health commodity category at the national level	https://www.ghsupplychain.org/quantificationanalyticstool	Finalized	English, French, Portuguese, Spanish	Rolled out to over 25 countries
Reality√®	Engender Health, The Respond Project	Reality√ is an easy-to-use tool that generates data for evidence-based advocacy and strategic planning in FP programs. The tool can be used to set realistic FP goals and plan for service expansion to meet them; it can also provide data for advocacy by estimating program requirements for implementation, along with the health impact of achieving contraceptive goals.	Forecasting	Software tool with user's guide	Central, District, Regional	https://www.engenderhealth.org/pubs/family-planning/reality-check/	Finalized	English, French	Various countries
Quantification Tool for Basic Neonatal Resuscitation Commodities: Version 2	Path	When forecasting resuscitation equipment requirements at tertiary, secondary, and primary HFs in-country. Commodity requirements include bags, masks, and suction devices and are quantified based on the estimated number of rooms in the hospital or HF.	Forecasting	Excel sheet tool	Central, District, Facility, Regional	https://www.path.org/resources/quantification-tool-for-basic-neonatal-resuscitation-commodities-version-2/	Finalized	English	Various countries
Stock Monitoring Tool	United Nations Development Programme (UNDP)	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	https://www.psmtoolbox.org/en/tool/quantification/hiv-aids/medicines/stock-monitoring-tool/	Finalized	English	
Uses of Medicines for Prevention and Treatment of Post-partum Hemorrhage and Other Obstetric Purposes	USAID/ RHSC	To help program managers determine the most appropriate combination of medicines for prevention and treatment of PPH and other obstetric indications at community, primary, and referral levels.	Uterotonics and other medicines used for PPH- uses indication and characteristics and specific elements that may influence procurement and supply chain management decisions	Technical brief	Maternal health program managers	https://www.rhsupplies.org/uploads/tx_rhscpublications/Uses_of_Medicines_for_Prevention_and_Treatment_of_Post-partum_Hemorrhage_and_Other_Obstertric_Indications.pdf	Finalized	English	Various countries

TITLE	AUTHORS: ORGANIZATION/ PROJECT	PURPOSE	TOPICS COVERED	TYPE	INTENDED AUDIENCE	FORMAT AND LOCATION	STATUS	LANGUAGE	COUNTRY EXPERIENCES
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 for family planning programs to be able to effectively respond to current and future demand for these methods.	Quantification of permanent contraception methods	Technical brief	MoH staff, program managers, technical advisors, warehouse managers, procurement officers, and service providers	https://www.k4health.org/toolkits/permanent-methods/technical-brief-using-quantification-support-introduction-and-expansion	Finalized	English	Various countries

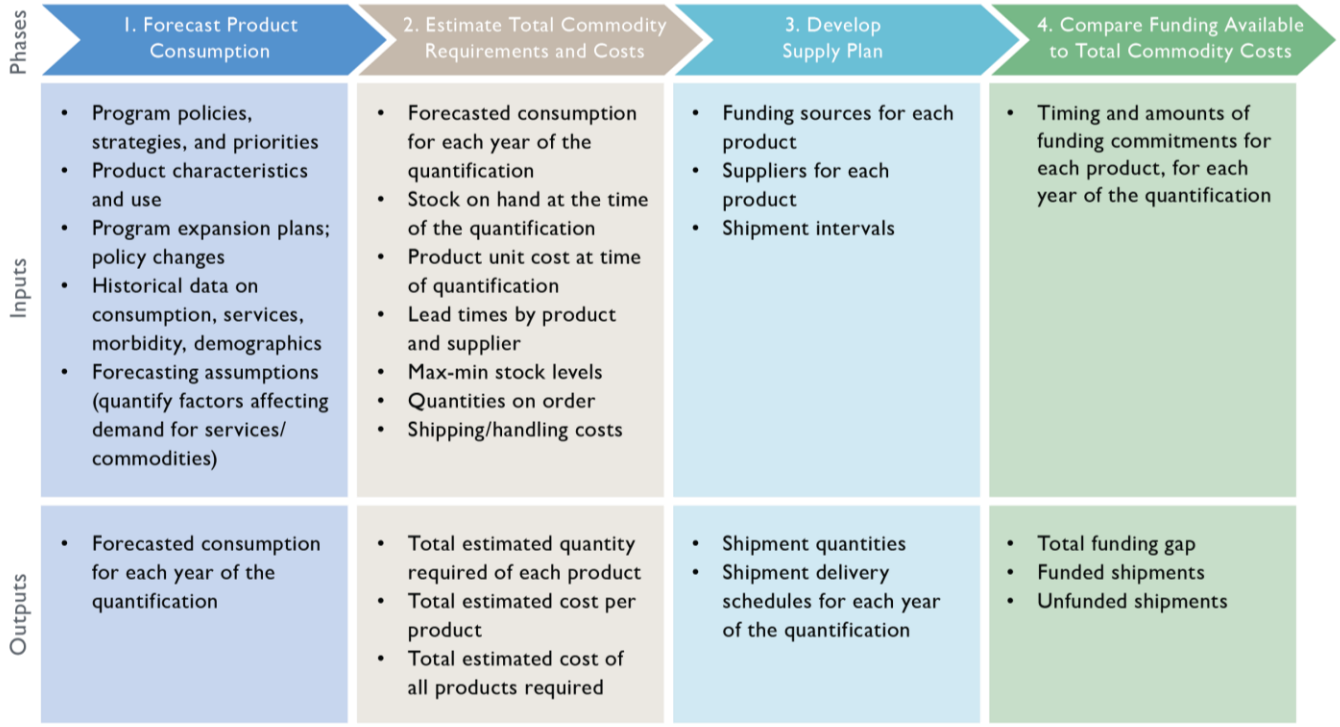
ANNEXES

ANNEX A. TYPES OF DATA FOR FORECASTING CONSUMPTIONS



Source: John Snow, Inc. 2017. Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement. Arlington, Va.: John Snow, Inc

ANNEX B. FLOW OF DATA IN QUANTIFICATION



Source: John Snow, Inc. 2017. Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement. Arlington, Va.: John Snow, Inc