



# Integration of Oxytocin into the Cold Chain of the Expanded Programme on Immunization: Case of Mali

December 2014



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## **Integration of Oxytocin into the Cold Chain of the Expanded Programme on Immunization: Case of Mali**

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December 2014



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## **Key Words**

maternal health, oxytocin, cold chain, quality

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## ACRONYMS AND ABBREVIATIONS

AMTSL	active management of third stage of labor
ASACO	Association de Santé Communautaire (Community Health Association)
CHC	community health center
CHW	community health worker
DNS	National Health Directorate
DPM	Department of Pharmacy and Medicine
DRC	Dépôt Répartiteur de Cercle (health district)
DV	Dépôt de Vente
EPI	Expanded Programme on Immunization
HCR	health center of reference
INN	international nonproprietary name
IS	Immunization Section
MHTRT	Maternal Health Technical Resource Team
MOH	Ministry of Health
NHD	National Health Directorate
PDDSS	Plan Décennal de Développement Sanitaire et Social (Ten-Year Plan for Health and Social Development)
PPH	postpartum hemorrhage
PPM	Pharmacie Populaire du Mali (Central Medical Store)
PPMc	Pharmacie Populaire du Mali central purchasing
PPMr	Regional store of the Pharmacie Populaire du Mali
PRODESS	Programme Quinquennal de Développement Sanitaire et Social (Five-Year Program for Health and Social Development)
RH	reproductive health
RHD	Reproductive Health Division
SDADME	Schéma Directeur d'Approvisionnement et de Distribution des Médicaments Essentiels (Manual for the Master Plan for the Supply and Distribution of Essential Medicines)
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
UN	United Nations
UNICEF	United Nations Children's Fund
USAID	US Agency for International Development
WHO	World Health Organization

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## EXECUTIVE SUMMARY

Postpartum hemorrhage (PPH) still remains one of the major causes of maternal mortality, accounting for 35% of all maternal deaths. The World Health Organization (WHO) has recommended oxytocin as the most effective medicine for the prevention and treatment of PPH, particularly for facility-based births. Most countries include oxytocin on their essential medicines lists (EML) as the medicine of choice for prevention and treatment of PPH. In most countries, several oxytocin products are registered. Despite this positive policy framework for oxytocin use, supply chain barriers that limit access to the medicine still persist in many countries. The factors that contribute to this lack of availability include inadequate forecasting of requirements, weak information systems, and poor distribution systems. Another major challenge is maintaining proper storage conditions throughout the supply chain. Oxytocin requires storage at between 2 and 8 °C, with possible excursions to room temperature for brief time periods. However, the distribution systems in many countries do not allow for cold storage.

In practice, in countries where the average temperature is above 30 °C and where adequate infrastructure for cold chain management is often lacking, maintaining the required storage conditions for oxytocin is a challenge. As a result, oxytocin is often provided by service delivery points outside of a temperature-controlled cold chain, compromising its effectiveness and shelf life. In response to this challenge, the Maternal Health Technical Resource Team of the United Nations Commission on Life-Saving Commodities has been exploring strategies to increase access to quality oxytocin, including advocating for the integration of oxytocin into the existing cold chain for the Expanded Programme on Immunization (EPI). In most countries, EPI cold chains are highly effective in reaching even the lowest levels of the health system. However, they are managed vertically, separately from other essential commodities. One of the barriers to integrating other products into the EPI cold chain is the perception at the country level that this is not permitted. However, some countries, such as Mali, have already attempted integration in some areas of the country and have experiences that may be useful.

The main objective of this activity was to document how oxytocin is currently distributed in Mali so that the experience may be used as a case study to inform how the integration of oxytocin into the EPI cold chain may be achieved.

The specific objectives were to:

- Map the distribution of oxytocin in Mali from the central level to the service delivery level
- Document how the cold chain is maintained
- Identify at what points along the supply chain oxytocin is currently integrated into the EPI cold chain
- Determine what steps were taken to allow this integration

- Document any challenges encountered in the integration process and the actions taken to address them

The methodology consisted of reviewing existing documents describing the supply chain in Mali and interviewing key informants at the central level, at key points along the supply chain, and at service delivery points where oxytocin is stored with vaccines.

## **Results**

The supply chain for oxytocin and other essential medicines in Mali is completely separate from the one for vaccines. The Central Medical Store (Pharmacie Populaire du Mali [PPM]) procures oxytocin annually and distributes it to its regional warehouses (PPMr) on a monthly basis. The PPMr's customers are the health districts (DRCs) and regional hospitals (HCRs), which place orders quarterly. The DRC distributes to HCRs and community health centers (CHCs), which order on a monthly basis, except for the HCRs and CHCs in Bamako, which order monthly from the PPM. The procurement of vaccines is done semi-annually by the Immunization Section (IS) in the National Health Directorate, with technical assistance from the United Nations Children's Fund (UNICEF). Vaccines are kept in cold rooms in the IS warehouse and are distributed to IS regional units, which requisition quarterly. HCRs requisition and receive vaccines monthly and distribute them to CHCs, which also requisition monthly.

The cold chain for oxytocin is maintained at the storage place throughout the distribution chain, despite some cases when oxytocin is stored at room temperature. The PPM warehouses are equipped with cold rooms, while DRCs, HCRs, and CHCs have either freezers or refrigerators, for which the temperature is generally monitored. But maintenance of the cold chain during transport is uncertain because no device for temperature control is used during distribution.

The integration of oxytocin into the EPI cold chain has occurred at the CHC level as a result of a combination of circumstances: recommendations of maternal health program supervisors to keep oxytocin between 2 °C and 8 °C, and the fact that most of the CHCs have only one refrigerator given by the IS. It is the responsibility of CHCs to figure out how to keep oxytocin cool. Such integration, which has been more or less successful, was done without any guidance to or supervision by the health care facilities. At present, there is no integration of oxytocin into the EPI cold chain—either official or at central, regional, and district (DRC and HCR) levels.

## **Recommendations**

- The Department of Pharmacy and Medicine (DPM) should work with the IS to provide a framework for the integration of oxytocin into the EPI cold chain. Since integration of oxytocin has already occurred in some health facilities, DPM and IS should formalize the option of using the EPI cold chain to keep oxytocin cool in settings that have only one refrigerator.

- In conjunction with the IS, DPM, , should develop a procedure for managing oxytocin in the EPI cold chain, and thus standardize the option of integrating oxytocin into the EPI cold chain in cases where a facility has only one refrigerator.
- DPM should also develop standard operating procedures for managing the cold chain and ensure that these procedures are implemented. This is because the Manual for the Master Plan for the Supply and Distribution of Essential Medicines (Schéma Directeur d'Approvisionnement et de Distribution des Médicaments Essentiels [SDADME]) and the manual of standard operating procedures for the management of logistics information for essential medicines and supplies for health programs do not mention the management of a cold chain. Moreover, personnel managing essential medicines are not trained in the management of a cold chain, and have even less knowledge on the management of oxytocin in the EPI cold chain.
- Supervision by the DPM should be enhanced and regular. Despite the dissemination and implementation of the SDADME manual and the manual of standard operating procedures for the management of logistics information for essential medicines and supplies for health programs, there are still cases of oxytocin and essential medicines supplied by the informal system, regardless of the quality and effectiveness of these products or the potential dangers of their use. Regular supervision will help improve compliance with the SDADME standards.

## INTRODUCTION

Postpartum hemorrhage (PPH) remains a leading cause of maternal mortality and accounts for 35% of all maternal deaths.<sup>1</sup> The World Health Organization (WHO) recommends that oxytocin be used as the first-line therapy to both effectively prevent and treat PPH and save lives. Pursuant to this recommendation, several countries have selected oxytocin as the medicine of choice for the prevention and treatment of PPH. In most countries, oxytocin is registered and listed on the national list of essential medicines. Despite this favorable policy framework for the use of oxytocin, barriers in the supply chain of many countries exist that limit access to the medication. A multi-country study conducted in 2012 showed that the continuous availability of oxytocin at service delivery points is a problem.<sup>2</sup> Factors contributing to the lack of availability include inadequate forecasting, weak information systems, and inefficient distribution systems. Another major challenge is maintaining the cold chain throughout the supply chain. Oxytocin requires storage at 2 to 8 °C, with storage at room temperature for short periods of time (up to four weeks). However, current distribution systems for essential medicines in many countries do not allow for cold storage. Similarly, warehouses at lower levels of the distribution system and at services delivery points do not have the infrastructure or equipment to maintain cold storage.

Supply chain systems for the Expanded Programme on Immunization (EPI) developed in the 1980s were designed at a time when vaccines were among a handful of essential health products that required a cold chain. At that time, vaccines were in the minority of essential health products requiring a cold chain at most health facilities. Due to the global initiatives advocating increased vaccine coverage, and recognizing that the national supply chains of most countries were weak, the supply chain systems put in place in countries to support the EPI in the 1980s tended to operate in a vertical mode, in other words, independent of supply chains for other health products. As a result, over the years, the perception has grown that the cold chain for vaccines controlled by the EPI should be used exclusively for vaccines, and despite the absence of a policy statement or official recommendation from the WHO or the UNICEF. In fact, the original guidelines for the cold chain developed by the WHO in the 1980s were entitled “The logistics and cold chain for primary health care.” This guidance document does not exclude the possibility of storing other temperature-sensitive health products in the cold chain for vaccines.<sup>3,4</sup>

In countries where the average temperature is above 30 °C and where adequate infrastructure for the cold chain is often lacking, keeping oxytocin properly cooled is a challenge. As a result, oxytocin is largely provided at the service-delivery level outside of temperature-controlled cold chain, thereby compromising its effectiveness and shelf life.

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<sup>1</sup> WHO and UNICEF. *Countdown to 2015 Maternal, Newborn, and Child Survival: Building a Future for Women and Children: The 2012 Report*. Geneva, Switzerland: WHO Press; 2012.

<sup>2</sup> Smith J, Currie S, Perri J, Bluestone J, Cannon T. *National Programs for the Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: A Global Survey*. Washington, DC: Maternal and Child Health Integrated Program; 2012; [http://www.mchip.net/sites/default/files/2012%20Progress%20Report\\_Full%20Report.pdf](http://www.mchip.net/sites/default/files/2012%20Progress%20Report_Full%20Report.pdf).

<sup>3</sup> WHO. *Logistics and Cold Chain for Primary Health Care: Guidelines*. Modules 1 to 25. Immunization Vaccines and Biologicals Department. WHO/EPI/LOG/84/modules 1 to 25; <http://apps.who.int/iris/handle/10665/59388>.

<sup>4</sup> WHO. *Immunization in Practice: A Practical Guide for Health Staff*. Geneva, Switzerland: Expanded Programme on Immunization; 2004.

In recognition of this challenge, the Maternal Health Technical Resource Team (MHTRT) of the United Nations (UN) Commission on Life-Saving Commodities has been exploring strategies to increase access to quality oxytocin, including advocating for its integration into the existing cold chain for the EPI. One of the barriers to integrating other products into the EPI cold chain is the perception at the country level that this is not permitted. To address this perception, the MHTRT in close collaboration with WHO and UNICEF developed a joint statement that affirms that countries may choose to integrate other products, specifically oxytocin, into the EPI cold chain to ensure access to quality products. Now the question is how to operationalize integration at the country level.

Prompted by maternal health programs, some countries, such as Mali, have attempted the integration of oxytocin into the EPI cold chain in some areas, and potentially have experiences that will help address the question. The purpose of this case study is to document the extent to which integration has occurred in Mali, and from this experience, derive lessons that may be shared with other countries interested in pursuing integration.

## **Objectives**

The objective of this activity was to document how oxytocin is distributed in Mali so that this experience may be used as a case study to inform how integration of oxytocin into the EPI cold chain may be achieved.

The specific objectives were to:

- Map the distribution of oxytocin in Mali from the central level to the point of service delivery
- Document how the cold chain is maintained
- Define at what points along the supply chain oxytocin is currently integrated into the EPI cold chain
- Determine what steps were taken to facilitate integration
- Document any challenges encountered in the integration process and the actions taken to address them

## BACKGROUND

### General Information on Mali<sup>5</sup>

Mali is a landlocked country located in the heart of West Africa. It covers an area of 1,241,248 square kilometers. It shares 7,420 kilometers of border with seven neighboring countries: Algeria to the north, Côte d'Ivoire and Guinea to the south, Burkina Faso to the southeast, Niger to the east, Senegal to the west, and Mauritania to the northwest.

Administratively, the country is divided into eight administrative regions (Kayes, Koulikoro, Sikasso, Segou, Mopti, Gao, Timbuktu, and Kidal) and the District of Bamako (the capital of the country), which has the rank of region. The regions are subdivided into 49 prefectures in which are distributed the 289 sub-prefectures and 703 municipalities. Bamako District is divided into six urban municipalities.

Mali has had a health sector policy since 1990 and a population policy since 1991. A Ten-Year Plan for Health and Social Development (Plan Décennal de Développement Sanitaire et Social [PDDSS]) covering the period 1998 to 2007, and extended to 2011, was adopted for the implementation of the health sector policy. This plan is the framework guiding all partners in the health and social sectors. Since March 1999, the Five-Year Program for Health and Social Development (Programme Quinquennal de Développement Sanitaire et Social [PRODESS]) has served as the basis for interventions by the Ministry of Health (MOH) for the Malian population, which are implemented with the support of partners and civil society. The PDDSS and PRODESS are considered the main tools for the implementation of the country's health component.

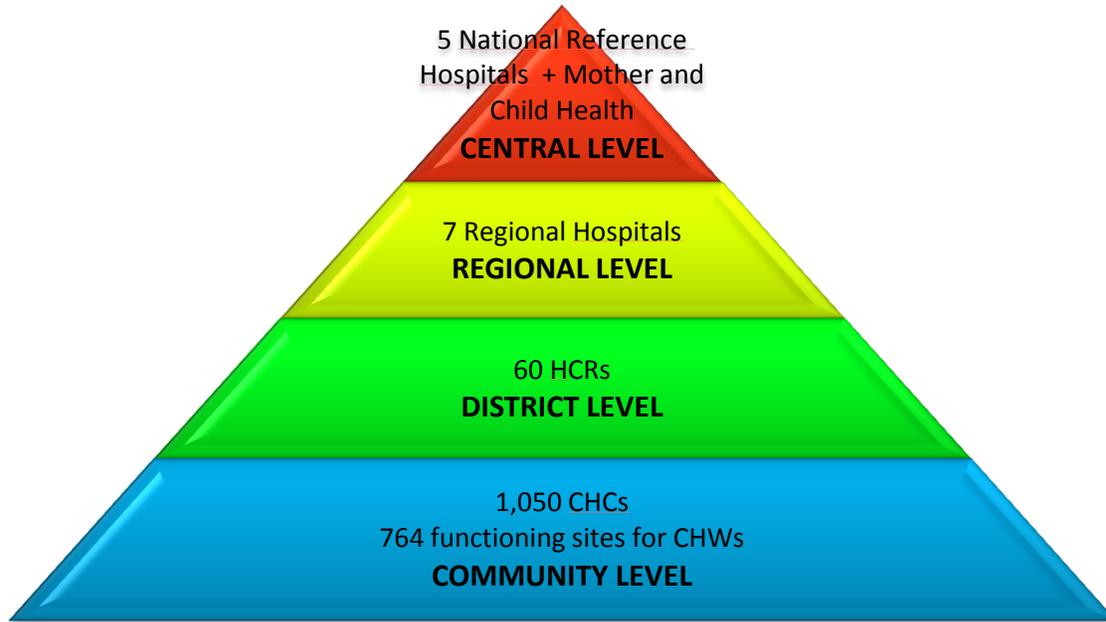
In the pharmaceutical area, Mali adopted a National Pharmaceutical Policy document in 1999. It was revised in 2009 and included a new overall objective: to ensure equitable access to quality essential medicines by people and to promote their rational use. The Manual for the Master Plan for the Supply and Distribution of Essential Medicines (Schéma Directeur d'Approvisionnement et de Distribution des Médicaments Essentiels [SDADME]), developed in 1995 and revised in 2010, describes the management procedures for essential medicines and the tools for strengthening the management capacity of the different actors.

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<sup>5</sup> This section is drawn from :

- Diarra A, Diarra S, Konaré A, Kouamé C, Haidara Diallo F, Diallo Y, Sangaré A, Diarra M, Coulibaly Y, Sangho F. 2013 *Rapport d'évaluation du système de gestion logistique des médicaments essentiels du Mali*. Présenté à l'Agence des États-Unis pour le Développement International par le Programme des Systèmes pour l'amélioration de l'accès aux produits et services pharmaceutiques (SIAPS). Arlington, VA: Management Sciences for Health.
- Ministère de la Santé, Direction de la Pharmacie et du Médicament, République du Mali, and WHO. Évaluation du secteur Pharmaceutique au Mali. Bamako; 2003.
- Ministère de la Santé, Direction de la Pharmacie et du Médicament and WHO. Surveillance et évaluation du secteur pharmaceutique national du Mali. Bamako; 2003.
- Institut National de Recherche en Santé Publique. Les comptes nationaux de la santé du Mali, 1999-2004. Bamako; 2006.
- <https://www.cia.gov/library/publications/the-world-factbook/>

The healthcare system in Mali is composed of public, private, and community sectors. The public sector provides the bulk of outpatient and inpatient care through health facilities organized in a pyramid scheme at three levels: central, regional, and peripheral, as shown in figure 1.



**Figure 1. Health system structure in Mali**

The peripheral level has 60 health centers of reference (HCRs), of which six are in the district of Bamako. There are also 1,050 community health centers (CHCs), structures that serve as the first point of contact for the population. According to guidance in the Health Act (Act No. 02-049 of 22 July 2002), CHCs are considered to be private, nonprofit health institutions, created and managed by the Community Health Association (Association de Santé Communautaire [ASACO]).

The regional level includes seven public hospitals. The central level consists of MOH, supported by the health programs. Health care at the central level is delivered at five national reference hospitals and at a hospital foundation (Hôpital Mère-Enfant le Luxembourg).

The private sector is largely concentrated in Bamako. Health facilities in this sector consist of a for-profit group and other nonprofits (CHCs, foundations, or religious congregations).

### **Distribution Chain for Essential Medicines<sup>3</sup>**

The overall objective of Mali's national pharmaceutical policy is to ensure that people have equitable access to quality essential medicines and to promote their rational use. Quality, safe, and effective essential medicines, which are accessible geographically and financially, and are rationally used, is likewise a specific objective of the PRODESS of MOH.

To better meet the objective of the pharmaceutical policy, the SDADME was established. It describes practical and functional measures that allow for the implementation of the essential medicines supply component of the health policy.

Supply to the pharmaceutical sector is provided by the Central Medical Store (Pharmacie Populaire du Mali [PPM]) and accredited private wholesalers. The national supply system consists of both the public and private sectors.

### **Public Sector**

At the central level, there is the PPM, which acts as the central procurement agency and is the preferred instrument of state procurement of essential medicines in international nonproprietary name (INN). It promotes the penetration of INN generic essential medicines in the private sector by importing blisters.

At the regional level, there are PPM regional stores (PPMr), except in Timbuktu, Gao, and Kidal. Regions are supplied through these PPM regional stores, using a requisition system. Regional hospitals and university hospital centers are supplied by the regional stores and PPM central purchasing (PPMc), respectively.

At the district level, the Dépôts Répartiteurs de Cercle (DRC) are supplied by the PPM regional stores using their own resources (i.e., the DRCs have vehicles for socio-medical services and funds generated from the sale of products). The pharmaceuticals are stored in the DRC until health centers come to purchase them. In the event of stock-outs at the PPMr, the DRCs can order from regional offices of accredited private wholesalers.

Regarding the supply to health districts and CHCs, the Dépôts de vente (DV) at public facilities (HCRs and CHCs) resupply from their DRC. DV of health centers use their own vehicles for resupply, and community health workers use their own motorcycles or bicycles, or hire public transport services. Community health workers (CHWs) resupply at the CHC-DV they report to administratively.

To fund the system, initial allocations of working capital were introduced, and a system of cost recovery was instituted. The system is nonprofit, so no profit is generated on the cost recovery; only the fixed and variable costs directly related to service provision are levied on the price of medicines (cf. Decree No. 036218 / P-RM May 30, 2003).

The public sector's essential medicines procurement system is a combined system of requisition from the central level to the CHCs and allocation between CHCs and CHWs.<sup>6</sup>

### **Private Sector**

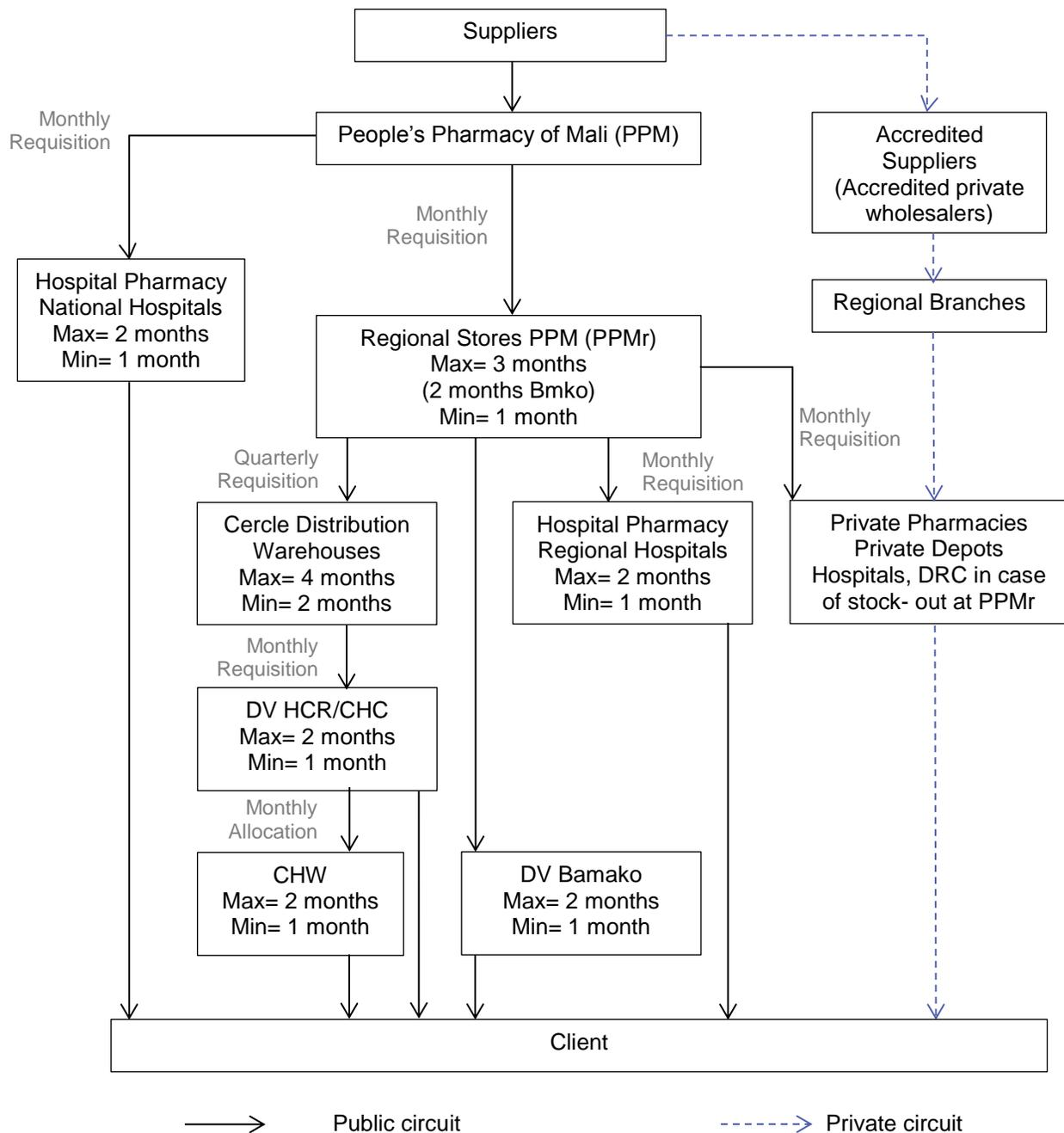
The distribution of medicines to patients is done from stores of importing establishments, commonly referred to as accredited private wholesalers, through regional offices, private

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<sup>6</sup> Ministère de la Santé, Direction de la Pharmacie et du Médicament, République du Mali. *Manuel de Procédures Opératoires Standard*. Bamako, Mali: USAID, SIAPS, and DPM; 2013.

pharmacies, private hospitals, and depots of denominational structures, foundations, and mutual societies.

The supply and distribution system for essential medicines in the public and private sectors in Mali is shown in figure 2.



**Figure 2. Supply and distribution chain for essential medicines in Mali<sup>4</sup>**

## Vaccine Distribution Chain of the Immunization Section

The Immunization Section (IS) in the National Health Directorate procures vaccines from international suppliers. UNICEF supports the IS in the procurement process, as the agency for the supply, procurement, and quality assurance of vaccines. The procurement system for vaccines is separate from that for essential medicines.

Procurement is done semi-annually at the national level. The regional level resupplies quarterly from the central level. HCRs replenish monthly from the regional level, and the CHCs also replenish at the HCR on a monthly basis. The IS has cold rooms at central and regional levels (currently a total of 11 cold rooms, except in the northern cities of Timbuktu, Gao, and Kidal). The HCRs have freezers and the CHCs have refrigerators for vaccine storage. CHCs support all expenses related to the maintenance of the cold chain.

During distribution from the central to regional levels, vaccines are either transported in refrigerated trucks or in insulated boxes. Temperature control devices and time of transport are used during distribution (Freeze-Tag, Map 3 million, and thermometer). The HCRs and CHCs use their own vehicles during replenishment (pick-up trucks, motorcycles) and store vaccines in insulated boxes, cold boxes, or vaccine carriers during transport.

Vaccines are provided for free throughout the system. This supply chain is shown in figure 3.

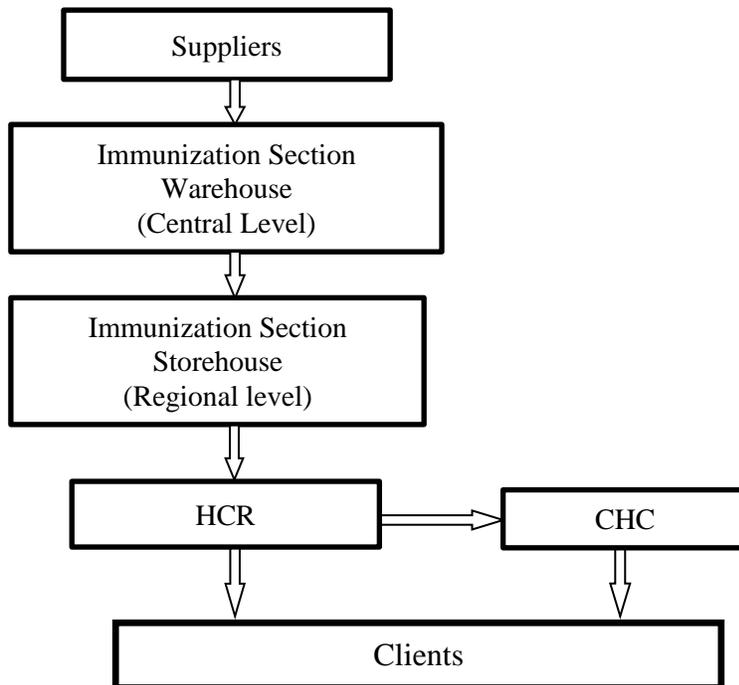


Figure 3. Supply chain for vaccines in Mali

## METHODOLOGY

To achieve the objectives of this study, three techniques were used to collect information. First, a review of documents describing the supply chain in Mali was conducted. Second, interviews with key informants at the central level were organized. Third, interviews with key informants were held at various critical points in the supply chain and at service delivery points where oxytocin is stored with vaccines.

The first step was to examine materials that describe the supply chain and cold chain of the IS. The study team reviewed reports describing the efforts of organizations that have worked to strengthen the supply chain in Mali to extract all relevant information. Standard operating procedures, other policy documents, and national guidance describing how the supply chain is supposed to work in Mali were also reviewed.

The study team then interviewed key personnel in MOH departments that are responsible for the management of the supply chain for oxytocin and the IS to understand how oxytocin is distributed throughout the system and to identify at what levels of the system oxytocin is integrated into the cold chain of the IS. Interviewees included key people from the Department of Pharmacy and Medicine (DPM), the National Health Directorate (DNS), PPM, chief of the IS, chief of the Reproductive Health Division (RHD), and other key informants.

Key informants at the regional level (regional director of health, regional pharmacist, head of IS, and head of the PPM regional store), at the district level (district medical officer, pharmacist district manager DRC/DV, midwife mistress, and the head of IS), and at the community level (doctor/chief nurse, DV manager, manager in charge of vaccinations/responsible for IS, midwife mistress /matron) were also interviewed.

The study team visited four health districts where oxytocin was reportedly integrated into the cold chain of the IS. This component of the study was done in the city of Bamako and two regions (Koulikoro and Sikasso), which were selected during conversations with officials in Bamako. In addition, two health districts in the city of Bamako (Commune I and Commune V) were visited. In each health district, visits were conducted to the PPM regional store, the DRC, HCR, and two CHCs, which were chosen at random. Key personnel were interviewed and the storage conditions for oxytocin and those of the IS were observed. These visits provided an opportunity to talk with key personnel about how the challenges to the integration of oxytocin into the cold chain of the IS had been overcome.

Semi-structured interview guides were developed (Annex B) as well as a tool for collecting data from the direct observation of storage spaces for oxytocin.

The study was limited to the public sector since it is currently the primary provider of both vaccines and maternal health services in Mali.

## RESULTS

### Central Level

The supply of oxytocin is obtained by the PPMc using different funding mechanisms: the PPMc's funds and funding from the MOH and its development partners through donations. Oxytocin is purchased from international manufacturers /suppliers (usually India or China) because there is no manufacturer in Mali.

The PPMc is responsible for the entire procurement process once the annual quantity of oxytocin needed is estimated by the DPM, in collaboration with the PPMc. Needs estimates for oxytocin are made for two types of distribution, namely, the "free system" and the "commercial system." The MOH has introduced a system of cost recovery in the public sector for pharmaceutical products to ensure their continuous availability. This is called "the commercial system." The MOH also funds the purchase and distribution of certain products that are provided free of charge to patients; these are commonly called "freebie" products. The Caesarean section kit is one of the free products; oxytocin is included in the kit. According to PPM officials, the estimated needs satisfy the demand because the PPM has never been out of stock for oxytocin.

The PPMc usually includes a section on the specifications for storage and transport of temperature-sensitive products, including oxytocin, in its tendering documents. Arrangements are made to maintain the cold chain for temperature-sensitive products and to minimize the waiting time for delivery of those products to the PPM stores. The international airport at Bamako Sénou, which is usually the port of entry for oxytocin in Mali, has cold rooms in which temperature-sensitive products are kept. Customs clearance procedures take up to one week. All temperature-sensitive products are kept in the cold rooms during this time.

The transport of temperature-sensitive products from the airport stores to the PPM is done using refrigerated trucks without a temperature control device. The PPM is in the process of equipping its trucks with such a device, with financial and technical support from its partners, specifically the United Nations Development Programme. Although the PPM regularly measures the temperature of its cold rooms (average temperature 5 °C), it has never checked or effectively controlled the temperature of the cold rooms at the airport.

Receipt of goods at the PPM is made in compliance with the standards of the SDADME. The PPM distributes oxytocin to its regional stores (PPMr) based on a monthly order placed by them. PPM is the sole supplier of the PPMr. The PPM uses refrigerated trucks for the delivery of temperature-sensitive products (active distribution), but the temperature is not monitored in the trucks. There is no specific schedule or deadlines for the submission of orders or for delivery.

No key informants interviewed at the central level were aware of any rules, regulations, or guidelines prohibiting or encouraging the storage or transport of oxytocin in the EPI cold chain, except for staff in the IS. However, they were not able to provide a copy of the document prohibiting it. They reported that during the training of vaccinators, the trainers insist that vaccines should not be kept in the same refrigerator as other products to prevent program errors.

There is currently no integration of oxytocin into the EPI cold chain at the central level.

## **Regional Level**

Two regions (Koulikoro and Sikasso) and the Bamako district were visited. While the Regional Health Directorates do not manage the distribution chain for essential medicines, they do ensure the implementation of and compliance with the SDADME.

The PPMr procures monthly from the PPM. It has a cold room in which all temperature-sensitive products are stored. There is no thermometer to monitor the temperature. Because the thermostat is set at between 5 °C and 6 °C, the manager assumes that the temperature is maintained within this range. The PPMr has a generator in case of power outages. Informants at the PPMr said that the PPM always meets their requests for oxytocin, unlike requests for other essential medicines, especially selected products required for hospital use.

The PPMr's customers are the health districts (DRC) and regional hospitals, which purchase quarterly. Distribution is usually passive, but one PPMr is doing active distribution (except for emergency orders) and uses coolers with ice packs for the transport of temperature-sensitive products, including oxytocin. No temperature control device is used during the transport of temperature-sensitive products. There is no timetable for submitting orders/requests or distribution.

No key informants interviewed at the regional level knew of any rules, regulations, or guidelines that prohibit or encourage the storage or transport of oxytocin in the EPI cold chain.

At present, there is no integration of oxytocin into the EPI cold chain at the regional level.

## **District Level**

The two DRCs visited obtain their resupply of oxytocin exclusively from the PPMr on a quarterly basis. Oxytocin is kept in a refrigerator but its temperature is not controlled. The DRC in Sikasso only recently acquired a refrigerator in February 2014; it does not have a thermometer to measure the temperature. The manager of the DRC visited in Koulikoro said that although they do have a functional thermometer, they do not monitor the temperature in the refrigerator. The manager said that last year they monitored the temperature for a while, and found that the maximum and minimum temperatures recorded were between 10 °C and 18 °C. He said that given the recommended storage conditions for oxytocin per the manufacturer's instructions on the box, which indicate storage below 25 °C, he thought that the storage conditions had been met. In addition to oxytocin, vitamin K1 and insulin are also stored in the refrigerator.

The DRC's customers are the HCRs and CHCs; they place resupply orders monthly. There is no timetable for submitting orders or delivery. CHCs must bring a cooler or a vaccine carrier with ice packs to the DRC for the transport of temperature-sensitive products; otherwise, the DRC does not deliver these products. However, according to the manager of a DRC, if the CHC is located nearby, he packs the secondary packaging of oxytocin with ice in a plastic bag. CHCs generally use motorbikes or public transportation for resupply.

At the HCRs visited, the exclusive provider of oxytocin is the DRC, except for the HCRs in Bamako district, which obtain supplies from the PPM. Among the four HCRs visited, three have a refrigerator in the sales depot (DV) and keep oxytocin in the refrigerators. However, one of these three HCR does not have a thermometer and as such not monitor the temperature of the refrigerator. In the HCR that has no refrigerator, oxytocin is stored at room temperature.

Delivery rooms usually requisition oxytocin from the DV and keep it in the refrigerator in the delivery room or in a vaccine carrier if there is no refrigerator in the delivery room. In the case of a vaccine carrier, ice packs are changed every day or as often as necessary. In general, there is no formal system of internal requisition. One DV manager said that when oxytocin ampoules are delivered to the maternity ward, it is recorded on a separate note. He holds on to the notes until the maternity ward is able to pay for all of the ampoules. Only then does the manager record the issue of the oxytocin ampoules on the daily consumption form and in the weekly consumption register, and finally, on the stock card. Meanwhile, he maintains a copy of the notes for his records.

A midwife mistress said that the maternity ward used to requisition oxytocin from the DV using a stock movement notebook, but that this practice was abandoned because there was unexplained loss of oxytocin. According to the respondents, in some cases, midwives on duty reportedly procured from the informal sector, and brought ampoules of oxytocin to the delivery room. They stored them in the vaccine carrier in the delivery room. In response to these reports, and given the increased incidence of PPH, HCR management conducted investigations that revealed that midwives /matrons kept oxytocin in the pockets of their aprons. HCR management is working to resolve this problem.

Regarding EPI supervisors (responsible for IS at the HCR level), the RHD has not notified them of potential recommendations to integrate oxytocin into the cold chain for vaccines. However, during their supervision of CHCs, they found oxytocin with vaccines in the refrigerators. The CHCs explained that RHD supervisors recommended keeping oxytocin in the refrigerator. In general, the EPI supervisors do not require CHCs to remove oxytocin or other medicines from the refrigerator but try to ensure that there is clear separation between vaccines and other pharmaceuticals. Only one EPI supervisor mentioned asking for the removal of any products other than vaccines from the refrigerator. All EPI supervisors ensure that there is no food or drink in the refrigerator where vaccines are kept.

According to a medical officer of a HCR, there is always conflict during the week of vaccination campaigns because the quantity of vaccines kept at the CHCs is large. At these times, the EPI supervisors systematically remove any products, other than vaccines, from the CHC refrigerator.

An EPI supervisor said that based on his supervision experience, keeping other pharmaceuticals in the refrigerator where vaccines are kept does not in any way impact the cold chain that is maintained. The temperature range varies between 2 °C and 8 °C, depending on the CHC's temperature record sheets. For him, it is the management of the functioning of the refrigerator that will be a problem.

No key informants interviewed at the district level were aware of any rules, regulations, or guidelines prohibiting or encouraging the storage or transport of oxytocin in the EPI cold chain. However, all IS managers said that they give verbal instructions prohibiting the storage of other pharmaceutical products in the refrigerator where vaccines are kept. Yet, in practice, they do not enforce these verbal instructions because they are aware that refrigeration is required to maintain the quality and effectiveness of other products, and that the CHCs have financial constraints, making maintenance of two separate cold chains difficult.

There is currently no integration of oxytocin into the EPI cold chain at either the DRC or HCR levels.

## **Community Level**

CHCs were visited. Findings from each CHC are presented separately because oxytocin is managed slightly differently at each facility.

### **CHC #1**

This health center orders essential medicines monthly, usually from authorized private wholesalers. However, for oxytocin, the health center replenishes from the informal sector without respect for the cold chain. Receipt of pharmaceuticals is acknowledged a committee according to the SDADME. Oxytocin is kept at room temperature in the DV and there is no wall thermometer. “Keep cool” was written on the labelling of the boxes of oxytocin found in the DV on the day of the visit. The health center has two functioning refrigerators: one given by the IS for storing vaccines and one purchased by the ASACO for the laboratory

The person on duty in the maternity ward estimates the need for and requisitions oxytocin from the DV, and keeps it in the vaccine carrier that is in the delivery room. Ice packs in the vaccine carrier are changed every day. There is no form for the internal requisition of oxytocin. After a woman has given birth, the midwife or matron writes a prescription for the oxytocin used that will be paid for at the counter of the DV. The DV manager then records the oxytocin issued in the daily consumption form.

In response to recommendations made by reproductive health (RH) supervisors following their training on the active management of third stage of labor (AMTSL), the health center tried to keep oxytocin in the refrigerator with vaccines. However, because of unexplained losses of tetanus vaccines and oxytocin, this procedure was abandoned. According to the Chief Medical Officer at the health center, the reasons were that nobody was responsible for the management of oxytocin in the EPI cold chain, the refrigerator was in the common room, and the key to the refrigerator was available to all center personnel.

The EPI manager is responsible for vaccines and monitors the temperature of the refrigerator twice a day.

**CHC #2**

This health center orders from the PPM monthly, or from authorized private wholesalers. It usually replenishes oxytocin from authorized private wholesalers, who deliver the product directly to the health center without using any measures to maintain the cold chain. Receipt of pharmaceuticals is made in accordance with the standards of the SDADME. There is a refrigerator in the DV to store essential medicines requiring a cold chain. There is no thermometer and the temperature of the refrigerator in the DV is not monitored. Vaccines are kept in another refrigerator given by the IS.

The midwife on duty estimates and requisitions a few ampoules of oxytocin daily, which are kept in a vaccine carrier in the delivery room. Ice packs in the vaccine carrier are changed daily. There is no form for the internal requisition of oxytocin. The midwife writes a prescription for the woman who has given birth, which is presented at the counter of the DV for payment. The DV manager records the oxytocin issued on the daily consumption form.

**CHC #3**

This health center orders on a monthly basis from the DRC/DV and uses a vaccine carrier with ice packs to transport the oxytocin. Receipt is made in accordance with the standards of the SDADME. Following receipt, the DV manager gives all of the oxytocin to the EPI manager, who places it in the refrigerator with vaccines and notifies the midwife. The EPI manager is responsible for the refrigerator, but the health center's staff have access to it. The EPI manager monitors the temperature of the refrigerator twice daily.

The person on duty in the maternity ward removes some ampoules of oxytocin from the refrigerator to keep them in the vaccine carrier in the delivery room. Ice packs in the vaccine carrier are changed every day. There is no form for internal requisition of oxytocin. The midwife or matron writes a prescription for the woman who has given birth to pay for the oxytocin at the counter of the DV. The DV manager records the oxytocin issued on the daily consumption form.

According to respondents, oxytocin was integrated into the EPI cold chain in response to the recommendations of RH supervisors following their training on AMTSL. Since this health center has only one refrigerator given by the IS for vaccine storage, the oxytocin is kept in that refrigerator. EPI supervisors have not identified any problems when they find other pharmaceuticals in the refrigerator with the vaccines.

**CHC #4**

This health center generally orders essential medicines, including oxytocin, from the PPMr. This is easier because the PPMr was the only source of replenishment before the implementation of the SDADME. It occasionally orders from the DRC/DV. The PPMr does active delivery of oxytocin, which is transported in a cooler with ice packs. The DRC does not do active distribution; it requires the CHCs to bring a vaccine carrier for the transport of oxytocin. Receipt of pharmaceuticals is done according to the standards of the SDADME. The health center has only one refrigerator; oxytocin is kept with vaccines. The DV manager gives oxytocin to the EPI

manager who arranges it in the refrigerator. The EPI manager is the only staff person responsible for the refrigerator and all the products stored in it. She is also the only person at the health center with access to the refrigerator, whether to place or remove products. The EPI manager monitors the temperature of the refrigerator twice daily.

In response to the request of the person on duty in the maternity ward, the EPI manager provides some oxytocin when a woman arrives to give birth. (The EPI manager is always available as she lives within the walls of the health center.) There is no form for the internal requisition of oxytocin. The midwife or matron writes a prescription for the woman who gave birth to pay for the oxytocin used at the counter of the DV. The DV manager records the oxytocin issued on the daily consumption form.

According to respondents, oxytocin was kept at room temperature in the DV until about two years ago when a RH supervision visit took place. This was when RH supervisors recommended keeping oxytocin in the refrigerator. It has been kept in the refrigerator with vaccines since that time because the health center has only one refrigerator. EPI supervisors have not identified any problems when they find oxytocin in the refrigerator with the vaccines; they only ensure that vaccines are well separated from other products in the refrigerator.

The CHC provides oxytocin to a rural maternity, which uses a vaccine carrier with ice packs that are changed every day for transport and storage.

#### **CHC #5**

This health center usually orders oxytocin from an authorized private wholesaler who delivers the product without using a cold chain. It also occasionally orders from the DRC/DV. In this case, the CHC provides the vaccine carrier with ice packs for the transport of oxytocin. Receipt of the product is made according the SDADME. The DV manager gives the oxytocin to the midwife mistress, who puts it in the refrigerator. The center has two refrigerators: one for the health center that is functioning and one given by the IS that is not working.

Every morning, the midwife mistress checks the amount of oxytocin available in the delivery room and, if necessary, after estimation, takes oxytocin for the maternity ward from the refrigerator. Oxytocin is kept in a vaccine carrier in the delivery room, with ice packs that are changed every day. All personnel in the maternity ward have access to the refrigerator that is located in the office of the Chief Doctor of the health center. The EPI manager monitors the refrigerator temperature twice daily.

The DV manager records the oxytocin issued only after the midwife mistress has paid him the equivalent amount for all the oxytocin that he has given her.

According to the respondents, EPI supervisors prohibit keeping drinks or food in the refrigerator where the vaccines are kept, but have not identified problems when oxytocin is kept in the refrigerator, because of the recommendations of the RH supervisors.

## **CHC #6**

This health center often orders essential medicines from the informal sector, and sometimes from the DRC/DV or authorized private wholesalers. For about the past year, the DRC/DV has been the sole source of oxytocin, following an injunction by the ASACO. A vaccine carrier and ice packs are used to transport the product. According to respondents, the matrons previously bought the stock of oxytocin and kept it in the refrigerator at the health center. The health center has two refrigerators: one given by the IS (works with oil) and a solar-powered one purchased by the ASACO, which is used in case of failure of the refrigerator given by IS.

When it arrives at the health center, oxytocin is immediately put in the refrigerator until verification is done by the Reception Committee. The matron removes an average of five ampoules of oxytocin from the refrigerator, which are kept in the delivery room in a vaccine carrier. Ice packs in the vaccine carrier are changed daily, or as needed during periods of high heat. There is no form for internal requisition of oxytocin.

The DV manager records the oxytocin issued on the daily consumption form based on medical prescriptions written by the maternity ward for payment by the women who gave birth. The EPI manager is responsible for the refrigerator that is in the changing room, and monitors the temperature twice daily.

No key informant interviewed at the health center knew of any rules, regulations, or guidelines that prohibit or encourage the storage or transport of oxytocin in the EPI cold chain.

The integration of oxytocin into the EPI cold chain is effective at the CHCs as they usually have only one cold chain (refrigerator or freezer donated by the EPI). In general, the impetus for the integration of oxytocin into the EPI cold chain was the training of midwives and matrons in AMTSL, starting in 2009. Since that time, supervision visits conducted by the RHD from central and regional levels have recommended keeping the product in the cold chain. But it is up to each facility to determine how to keep oxytocin in the cold chain.

At the CHC level, the cold chain usually available is that of the EPI; as such, oxytocin is then naturally integrated. Although reluctant to store vaccines with other products, EPI supervisors concede that temperature-sensitive pharmaceutical products, including oxytocin, may be kept in the EPI refrigerator.

## **General Perceptions of the Feasibility of Integration**

All respondents at all levels were asked their opinion of the feasibility of integrating oxytocin into the EPI cold chain. A summary of the advantages and disadvantages to integration is as follows:

- Advantages:
  - Improved quality of oxytocin
    - Recommended storage temperature of the product is respected
    - Product quality/efficacy is conserved, thereby reducing the cases of PPH

- Improved cost-efficiency
  - Investment in additional infrastructure, equipment, and maintenance is reduced
- Improved efficiency and effectiveness of the supply chain
  - Compliance with the SDADME for oxytocin distribution is improved
  - Reduced risk of obtaining supplies from the informal system
- Disadvantages:
  - Quality and efficacy of vaccine products are compromised
    - Possible confusion of products if staff are not well trained
    - Temperature control is not maintained, with the more frequent opening of the refrigerator
  - Introduction of programmatic error
    - Possibility for confusion if personnel at the operational level are not trained
    - Need to develop joint procedures for the management of EPI and oxytocin to avoid confusion
    - Requires regular supervision
    - Roles and responsibilities of managers need to be defined

In addition to these points, some informants also expressed general concerns about the integration of oxytocin into the EPI cold chain, stating that the risks would need to be weighed against the potential benefits. Some of the specific concerns mentioned were:

- Challenge of coordination between the two programs (accountability)
- Personnel do not read the labels, which can be a source of programmatic errors
- There are no written management procedures for integrating oxytocin into the EPI cold chain.

## DISCUSSION

Integration of oxytocin into the EPI cold chain in Mali has occurred at lower levels of the health system only in response to specific instructions to providers to “keep oxytocin cold.” There has been no systematic or programmatic approach to integration, and there are conflicting opinions as to whether integration should be pursued. Some of the key problem areas identified by the assessment are as follows:

- 1) Unreliable cold chain for oxytocin and essential medicines, in general: The study team observed that the cold chain for the distribution of oxytocin was not always maintained, the temperature was not monitored during transport (no temperature control device was used), and the temperature was not always controlled at storage places. These results are unlike the EPI cold chain, which is controlled throughout the supply chain, from the point of entry to the user /beneficiary, by using devices for temperature control during transport.
- 2) Lack of guidelines and/or management procedures for the integration of oxytocin into the EPI cold chain: In the instances where oxytocin has been integrated into the EPI cold chain, this was the result of a combination of circumstances, including recommendations of RH supervisors to keep oxytocin stored at between 2 °C and 8 °C, and the fact that most CHCs have only one refrigerator provided by the IS. Integration was therefore done at the CHCs simply because the most important thing was to keep the product cold. CHCs that have a refrigerator in the DV have not integrated oxytocin into the EPI cold chain. Only the CHCs with one refrigerator had done integration, regardless of the origin of the refrigerator, whether donated by the IS or purchased by ASACO, and with varying degrees of success. Since it is the responsibility of health facilities to take the necessary actions to keep oxytocin cold, each CHC did things in its own way. Some CHCs have been very successful in the integration, although the internal requisition process lacks transparency and allows for unethical practices.
- 3) Training/orientation /refreshing training on the management of the cold chain: Unlike staff managing vaccines that have been trained in the management of the cold chain and the storage of vaccines in a refrigerator, personnel managing essential medicines are not trained or oriented to the management of a cold chain, and even less so on the management of oxytocin in the EPI cold chain. The SDADME manual and the manual of Standard Operating Procedures on the management of logistics information for essential medicines and supplies for health programs do not mention anything about managing a cold chain.
- 4) Non-compliance with the SDADME: supply is from the informal system. Despite the dissemination and implementation of the SDADME and the manual of Standard Operating Procedures for the management of logistics information for essential medicines and supplies for health programs, there are still cases of oxytocin and essential medicines supply from the informal sector, disregarding the quality and efficiency of the products that are not being controlled and thus the possible dangers of their use.

## CONCLUSIONS AND RECOMMENDATIONS

### Conclusions

The distribution chain for oxytocin and other essential medicines in Mali is completely separate from the one for vaccines. The PPMc procures oxytocin annually and distributes it to its regional warehouses (PPMr) on a monthly basis. PPMr customers are the health districts (DRC) and regional hospitals, which place orders quarterly. The DRCs distribute to HCRs and CHCs, which order on a monthly basis, except for HCRs and CHCs in Bamako district, which order monthly from the PPM. The procurement of vaccines is made semi-annually by the IS in the National Health Directorate, with the technical assistance from UNICEF. Vaccines are kept in cold rooms in the IS warehouse and are distributed to IS regional units, which requisition quarterly. HCRs requisition and receive vaccines monthly and distribute them to the CHCs, which also requisition monthly.

The cold chain for oxytocin is maintained at storage places throughout the distribution chain, although there are some cases where oxytocin is stored at room temperature. The PPM warehouses are equipped with cold rooms, while DRCs, HCRs, and CHCs have either freezers or refrigerators, with the temperature generally monitored. However, maintenance of the cold chain is doubtful during transport as no device for temperature control is used during distribution.

The integration of oxytocin into the EPI cold chain occurred at the CHC level as result of a combination of circumstances: the recommendations of RH supervisors to keep oxytocin stored at between 2 °C and 8 °C, and the fact that most of the CHCs have only one refrigerator provided by the IS. It is the responsibility of the CHCs to figure out how to keep oxytocin cool. Integration occurred at the few CHCs simply because the most important thing was to keep the product cold, and in a context where most CHCs have only one refrigerator (donation of the IS or not). This integration, which was more or less successful, was done without any guidance from or supervision of the health care facilities themselves.

### Recommendations

- In conjunction with the IS, DPM should provide a framework for the integration of oxytocin into the EPI cold chain. Since the integration of oxytocin has already occurred in some health facilities, DPM and IS should formalize the option of using the EPI cold chain to keep oxytocin cool in settings that have only one refrigerator.
- In conjunction with the IS, DPM should develop a procedure for managing oxytocin in the EPI cold chain, implement it, and thus standardize the option of integrating oxytocin into the EPI cold chain at the national level, and in circumstances where a facility has only one refrigerator.
- The DPM should also develop standard operating procedures for managing the cold chain and implement them.

- This is because the SDADME manual as well as the manual of standard operating procedures for the management of logistics information for essential medicines and supplies for health programs do not mention the management of the cold chain. personnel managing the essential medicines are not trained in the management of the cold chain and even less so on the management of oxytocin in the EPI cold chain.
- Supervision by the DPM should be enhanced and regularized. Despite the dissemination and implementation of the SDADME manual and the manual of standard operating procedures for the management of logistics information for essential medicines and supplies for health programs, there are still cases of oxytocin and essential medicines supplied by the informal sector, regardless of the quality and effectiveness of these products or the potential dangers of their use. Regular supervision will help improve compliance with the SDADME standards.

## ANNEX A. SCOPE OF WORK

### Case study on the integration of oxytocin into the cold chain of the Expanded Program on Immunization (EPI) in Mali

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#### 1. Context

Postpartum hemorrhage (PPH) is a leading cause of maternal mortality, accounting for 35% of all maternal deaths.<sup>7</sup> The World Health Organization (WHO) recommends that oxytocin, an injectable medicine, be used as the medicine of choice to both effectively prevent and treat bleeding in pregnant women after delivery and thus save lives. Pursuant to this recommendation, several countries have chosen oxytocin as the medicine of choice for the prevention and treatment of PPH. Oxytocin is a product sensitive to temperature and time. It loses its effectiveness if exposed to long periods of heat throughout the supply chain. For this reason, oxytocin must be kept in a cold chain and throughout the distribution process inasmuch as possible.

Oxytocin is registered in most countries and is on the list of essential medicines (essential medicines). Despite this favorable policy framework for the use of oxytocin, in many countries, barriers in the supply chain exist that limit access to it. A multi-country study conducted in 2012 showed that the continuous availability of oxytocin at service delivery points is still a problem.<sup>8</sup> Factors contributing to the lack of availability include inadequate forecasting, weak information systems, and inefficient distribution systems. Another major challenge to accessing quality oxytocin is maintaining the cold storage conditions for the product throughout the supply chain. Oxytocin requires storage at 2 to 8 °C, with storage at room temperature for short periods of time. In many countries, distribution systems in place for essential medicines do not allow for cold storage. Similarly, many warehouses at lower levels of the health system and at service delivery points do not have the infrastructure or equipment to maintain cold storage.

The EPI's supply chain system, developed in the 1980s, was designed at a time when vaccines were among a handful of essential health products that required a cold chain. In fact, at that time and in most health facilities, vaccines were among the minority of essential health products requiring a cold chain. As a result, systems put in place in countries in the 1980s to support the EPI tended to operate in a vertical mode, thus independently of other supply chains for health products. Over the years, the perception has grown that the cold chain for vaccines administered by the EPI should be used exclusively for vaccines, and despite the absence of a policy statement or official recommendation of the WHO or UNICEF to this effect. Moreover, the original guidelines for the cold chain developed by the WHO in the 1980s were entitled "The logistics and cold chain for primary health care." This guidance does not exclude the possibility of storing other temperature-sensitive health products in the cold chain for vaccines.

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<sup>7</sup> WHO and UNICEF. *Countdown to 2015 Maternal, Newborn, and Child Survival: Building a Future for Women and Children: The 2012 Report*. Geneva, Switzerland: WHO Press; 2012.

<sup>8</sup> Smith J, Currie S, Perri J, Bluestone J, Cannon T. *National Programs for the Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: A Global Survey*. Washington, DC: Maternal and Child Health Integrated Program; 2012.

Mali conducted a pilot project on the use of oxytocin at community health centers (CHC) for the active management of third stage of labor (AMTSL). In response to the positive results, in 2012, the use of the product was extended on the national list of essential medicines at CHCs. The overall objective of the national medicines policy in Mali is to ensure equitable access to quality essential medicines and to promote their rational use.

## **2. Rationale for the study**

In countries where the average temperature is above 30 °C and where adequate infrastructure for the cold chain is often lacking, keeping oxytocin cool is a challenge. As a result, oxytocin is still largely delivered at the service delivery level outside a temperature-controlled cold chain, thereby compromising its effectiveness and use-life. To provide the patient with access to quality oxytocin, one option is to integrate it into the EPI cold chain.

Some countries, such as Mali, have attempted the integration of oxytocin into the EPI cold chain in some areas and have potentially already had experiences that will help address the challenges. The purpose of this activity is to document how the integration of oxytocin into the EPI cold chain is happening in Mali and how it was carried out. The issue is how to operationalize integration in other countries.

## **3. Objective**

The main objective of this activity is to document how oxytocin is distributed in Mali so that it may potentially be used as a case study to inform how integration of oxytocin into the EPI cold chain may be achieved.

### *Specific objectives*

- To map distribution of oxytocin in Mali from the central level to service delivery points.
- To document how the cold chain is maintained.
- To define at what points along the supply chain oxytocin is integrated into the EPI cold chain.
- To determine what steps were taken to facilitate this integration.
- To document any challenges encountered in the process of integration and the actions that were taken to address them.

## **4. Methodology**

To achieve these objectives, the study team will: review existing documents that describe the supply chain in Mali; and interview key informants at various key points in the supply chain and at the point of service delivery where oxytocin is stored with vaccines.

### a. Review of the literature

The first step is to review the literature that describes the supply chain and EPI cold chain in Mali. A number of organizations have worked to strengthen the supply chain in Mali

and reports describing their efforts are available. The study team will review reports to extract any information relevant to this activity. It will also review the standard operating procedures and other policy documents and national guidance that describe how the supply chain is supposed to work in Mali.

b. Interviews with key informants at the central level

The study team will interview key personnel in offices or departments of the Ministry of Health involved with supply chain management for oxytocin and the EPI cold chain. These include the Department of Pharmacy and Medicine (DPM), the Pharmacie Populaire du Mali (PPM), and the National Health Directorate (NHD). The purpose of these interviews is to understand how oxytocin is distributed throughout the system and to identify at what levels of the system oxytocin is integrated into the EPI cold chain.

Semi-structured interview guides will be developed.

Preliminary data collected in Mali indicate that integration has not been done in all areas of the country. During discussions, the study team will identify in which districts it has occurred, and will visit at least two districts to understand how integration is managed.

c. Field visits to at least two districts

The study team will visit at least two districts where oxytocin has been integrated into the EPI cold chain. In these districts, it will visit the regional store of the PPM, the district medical store, and two or three community health centers to interview the store keepers and maternal/child health personnel, and observe oxytocin and EPI storage conditions. These site visits will also provide an opportunity to discuss how challenges to integration have been overcome.

Semi-structured guides will be developed for these interviews as well as tools for data collection for direct observations.

The main steps for the data collection process are summarized in the table below:

<b>Method / Process</b>	<b>Activity</b>
Review existing documentation	Review the literature that describes the supply chain for health products and the EPI cold chain in Mali.
Interviews with key informants at the central level	Targeted personnel: <ul style="list-style-type: none"> <li>- Key personnel in the Directorate of Pharmacy and Medicine</li> <li>- Key personnel in the National Directorate of Health (NDH)</li> <li>- Key personnel in the Pharmacie Populaire du Mali</li> <li>- Head of the Immunization Section</li> <li>- Head of the Reproductive Health Division</li> <li>- Other key informants (to be determined by the NDH)</li> <li>- Nongovernmental organization partners</li> </ul>

<b>Method / Process</b>	<b>Activity</b>
	<ul style="list-style-type: none"> <li>- WHO</li> <li>- UNICEF</li> </ul>
Interviews with key informants at the regional level	Targeted personnel: <ul style="list-style-type: none"> <li>- Regional Director of Health</li> <li>- Regional Pharmacist</li> <li>- Regional manager responsible for the EPI</li> <li>- Head of the regional store of the PPM</li> </ul>
Interviews with key informants at the district level	Targeted personnel: <ul style="list-style-type: none"> <li>- District Medical Officer</li> <li>- District Pharmacist</li> <li>- Person responsible for the DRC/DV</li> <li>- EPI managers at the district level</li> </ul>
Field visits to at least two districts /community level	Targeted personnel: <ul style="list-style-type: none"> <li>- Community health center: doctor /nurse manager</li> <li>- Storekeeper (DV)</li> <li>- Person in charge of EPI at the CHC</li> <li>- Persons responsible for getting oxytocin from the EPI cold chain for use</li> <li>- Other key informants (to be determined by the Chief Doctor of the CHC)</li> </ul>

## 5. Tools

- Questionnaire, central level
- Questionnaire, regional level
- Questionnaire, district level
- Questionnaire, community level
- Data collection tool for direct observations

## 6. Proposed schedule of activities

<b>Activity</b>	<b>Apr</b>	<b>May</b>	<b>Jun</b>	<b>Jul</b>	<b>Aug</b>	<b>Sept</b>
Development of tools for data collection						
Coordination with SIAPS country team						
Data Collection						
Data Analysis						
Draft Report						
Final Report						
Case Study						

## ANNEX B. QUESTIONNAIRE

### Mali Oxytocin Case Study

Level	Informants
<b>Central</b>	Department of Pharmacy and Medicine (DPM-Direction de la Pharmacie et du Médicament) Central Medical Store (PPM- Pharmacie Populaire du Mali) Direction National de la Santé (DNS) <ul style="list-style-type: none"><li>• National EPI manager</li><li>• Maternal/neonatal/child health manager</li><li>• Other key informants (to be determined by the DNS)</li></ul> Nongovernmental organization partners working on PPH WHO UNICEF
<b>Region or intermediate level</b>	Regional health director Regional pharmacist EPI regional manager Regional warehouse manager
<b>Districts sanitaires Cercle/ Commune</b>	District chief doctor District pharmacist/medical store keepers (DRC/DV) Persons responsible for EPI at the district level
<b>Community level</b>	Community health center (CSCOM) doctor/chief nurse Community health center store keeper (DV) Persons responsible for EPI at the CSCOM level Persons responsible for getting oxytocin from the EPI cold chain for use Other key informants (to be determined by the district chief doctor)

### Questions for the Central Level

#### I. Procurement

- Does the MoH procure oxytocin?
  - o Does this satisfy the national need?
- Who else procures oxytocin?
- Is the oxytocin procured by the MoH from national or international manufacturers?
- Are there local manufacturers of oxytocin in Mali?
  - o Are the products they produce registered?
- Do the tender documents include specifications regarding storage?

- Do the tender documents specify that cold storage must be maintained during transport of the product to the central medical store?

## **II. Receipt of oxytocin from the supplier**

- If oxytocin is procured from an international manufacturer, what is the point of entry of the product?
- How long does the product typically await customs clearance before being shipped to the PPM?
- How is the product stored while it awaits clearance?
- Does the storage area have infrastructure for cold storage?
  - If so, how is the temperature monitored?

## **III. Storage at the PPM**

- How and where is oxytocin stored at the PPM?
- If not stored in special conditions: does the PPM monitor the temperature?
  - If the temperature is monitored and recorded, what is the average temperature of the warehouse?
  - Are there seasonal peaks in temperature, and if so, how high can the temperature in the oxytocin storage area go?
- If stored in special conditions, specify what these are.
- Is oxytocin stored with EPI supplies at the PPM?
- Where are vaccines stored at the central level?

## **IV. Distribution**

- Which facilities receive oxytocin from the PPM? Provide a diagram of the distribution chain for oxytocin to point of use.
- How is oxytocin transported from the PPM to the district level?
  - Is oxytocin integrated into the EPI cold chain?
- Is cold storage maintained throughout distribution?
  - If so, how?

## **V. General questions:**

- Do you know of any rules, regulations, or guidelines that would prohibit the storage and/or transport of oxytocin in the EPI cold chain?
- Do you know of any rules, regulations, or guidelines that would promote the storage and/or transport of oxytocin in the EPI cold chain?
- What are/would be the benefits of including oxytocin in the EPI cold chain from your perspective?

- What are/would be the disadvantages of including oxytocin in the EPI cold chain from your perspective?
- Do you know of facilities in which oxytocin is stored in the EPI cold chain?
  - o If yes:
    - Which facilities? (Where are they and at what level are they?)
    - How was the agreement reached? (Decided at the national level, district level, facility level?)
    - Ask the respondent to relate his/her understanding of the history of the agreement.

## **Questions for Regional, District and Facility Level**

### **I. Source of (including procurement) and storage at the regional and district medical stores**

- What is/are the source(s) of oxytocin – from where do you get oxytocin?
- How/where is oxytocin stored?
- If not stored in special conditions: is the temperature monitored?
  - o If temperature is monitored and recorded:
    - what is the average temperature of the warehouse?
    - what are the monthly temperature ranges (minimum and maximum) of the warehouse?
- If stored in special conditions, specify what these are.
- Where are vaccines stored at the regional level?
- Is oxytocin stored with EPI supplies at the regional store?
  - o If so, how was the decision made?
  - o Typically, how soon after receipt is the oxytocin stored in the EPI cold chain?
  - o How is the stock of oxytocin recorded?
  - o Who is responsible: the regional medical storekeeper or the regional EPI manager?
  - o What challenges have you faced in managing oxytocin in the EPI cold chain?
  - o Did you receive a specific orientation or training on how to manage oxytocin and vaccines in the EPI cold chain?
  - o Are there any concerns about the capacity of the cold chain?

### **II. Distribution**

- Which districts receive oxytocin from the regional medical store? Provide a diagram of the distribution chain for oxytocin to point of use.
- How is oxytocin transported from the regional level to the community health centers?
- Is cold storage maintained throughout distribution? If so, how?

### **III. District level**

- Where are vaccines stored at the district level?
- Is oxytocin stored with EPI supplies at the district store?
  - o If so, how was the decision made?
  - o Typically, how soon after receipt is the oxytocin stored in the EPI cold chain?
  - o How is the stock of oxytocin recorded?
  - o Who is responsible: the district medical storekeeper or the district EPI manager?
  - o What challenges have you faced in managing oxytocin in the EPI cold chain?
  - o Did you receive a specific orientation or training on how to manage oxytocin and vaccines in the EPI cold chain?
- What are/would be the benefits of including oxytocin in the EPI cold chain from your perspective?
- What are/would be the disadvantages of including oxytocin in the EPI cold chain from your perspective?

### **IV. Distribution**

- What facilities receive oxytocin from the district medical store? Provide a diagram of the distribution chain for oxytocin to point of use.
- How is oxytocin transported from the district level to the community health centers?
- Is cold storage maintained throughout distribution? If so, how?

### **V. Storage at the community health center**

- How is oxytocin stored?
- If not stored in special conditions: is the temperature monitored?
  - o If the temperature is monitored and recorded, what are the monthly average, and minimum and maximum temperatures of the warehouse?
- If stored in special conditions, specify what these are.
- Where are vaccines stored at the community health center?
- Is oxytocin stored with EPI supplies?
  - o If not, why not?
    - Are you opposed to or in favor of having oxytocin in the EPI cold chain – and why?
  - o If so, how was the decision made?
  - o Typically, how soon after receipt is the oxytocin stored in the EPI cold chain?
  - o How is the stock of oxytocin recorded?
  - o Who is responsible: the community health center storekeeper or the district EPI manager?
  - o Do you have any challenges/difficulties managing oxytocin in the EPI cold chain?

- Did you receive a specific orientation or training on how to manage oxytocin and vaccines in the EPI cold chain?
- Do you have any concerns about having oxytocin in the EPI cold chain?

### **Questions for EPI program**

- What is the point of entry of vaccines?
- How long do vaccines typically await clearance to be shipped to the place of storage?
- How are vaccines transported from the point of entry to the place of storage?
- Does EPI have its own warehouses or does it use those of the PPM?
- Where are vaccines stored at the central level? At the district level?
- How are vaccines distributed? Provide a diagram of the distribution chain for vaccines from the central level to the point of use.
- How are vaccines transported from the central level to the point of use?
- How is the cold chain maintained throughout the distribution?
- How is the temperature monitored throughout the distribution?
- What is the frequency of supply of vaccines in different structures?
- Do you know of facilities in which oxytocin is stored in the EPI cold chain?
  - Which facilities? (Where are they and at what level are they?)
  - How was the agreement reached? (Decided at the national level, district level, facility level?) Ask the respondents to tell us the story of how it all came to be.....
- What are the benefits/disadvantages of including oxytocin in the EPI cold chain from your perspective?

**Direct Observation Form**

**1) Information**

Date of survey: \_\_\_\_\_ / \_\_\_\_\_ / 2014

Region:

Health district:

**2) Facility/Site**

- 1) DV CSCOM (health center depot) / \_\_\_ /
- 2) Hospital pharmacy / \_\_\_ /
- 3) DV CSRef (referral health center depot) / \_\_\_ /
- 4) DRC (district distribution depot) / \_\_\_ /
- 5) PPM (Pharmacie Populaire du Mali/central medical store)/ \_\_\_ /

**3) Level of education of respondent**

- 1) 1-6 years / \_\_\_ /
- 2) 6-9 years / \_\_\_ /
- 3) 10-12 / \_\_\_ /
- 4) Over 12 years / \_\_\_ /

**4) Qualification of the head of the pharmacy (profile)**

- 1 = Pharmacist / \_\_\_ /
- 2 = No (please specify) / \_\_\_ /

**5) Qualification of the dispenser/provider (profile)**

- a = Pharmacy assistant ( / \_\_\_ /
- b = Senior health technician/\_\_\_ /
- c = Health technician / \_\_\_ /
- d = Medical assistant / \_\_\_ /
- e = Account/ \_\_\_ /
- f = Matron/\_\_\_ /
- g = Others

**6) Professional expérience**

- a : < 1 year /\_\_/
- b : 1 – 5 years /\_\_/
- c : 5 – 10 years /\_\_/
- d : > 10 years /\_\_/

**7) Specific storage conditions**

Medicines	Cold chain (2 to 8°C)		Observations
	Yes	No	
Oxytocin 5 or 10 UI injectable			

**8) Who calculates the needs estimation?**

- a. Pharmacist /\_\_/
- b. Manager /\_\_/
- c. Chef Doctor /\_\_/
- d. Account /\_\_/
- e. Others /\_\_/: Specify \_\_\_\_\_

**9) Storage conditions**

N°	Item	Yes	No
1	Verify these items upon receipt a) Date of expiry b) Packages are intact c) The lot number d) Compliance with the quantity on the delivery slip/form		
2	Is the oxytocin stored using the method of first expired, first out?		
3	Is the medicine storage space sufficient for volume of medicines manages?		
4	Is medicine storage place secure?		
5	Is medicine storage place clean?		
6	Is the storage area free of food?		
7	Is oxytocin protected from light?		
8	Is oxytocin protected from the sun?		
9	Are there functional refrigerators at the point of sale / use?		
10	Is there a thermometer to monitor the cold chain?		
11	The temperature of the cold chain is regularly recorded?		
12	Is there an alternative in case of failure of the cold chain?		
13	What are the means of transport used by your organization for supplying medicines: a) Vehicle b) Motorcycles c) Bicycle d) Transit e) Other		