Distribution Agreement

In presenting this thesis or dissertation as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby grant to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis or dissertation in whole or in part in all forms of media, now or hereafter known, including display on the world wide web. I understand that I may select some access restrictions as part of the online submission of this thesis or dissertation. I retain all ownership rights to the copyright of the thesis or dissertation. I also retain the right to use in future works (such as articles or books) all or part of this thesis or dissertation.

Signature:

_____ Date:_____

Heba Hayek

Key performance indicators for routine monitoring of pharmacy management at United Nations High Commissioner for Refugees (UNHCR) in Jordan

By

Heba Hayek

Degree to be awarded: Master of Public Health

Hubert Department of Global Health

Dabney P. Evans, PhD, MPH

Committee Chair

Aimee Summers, PhD, MHS

Committee Member

Lara S. Martin, MA, MPH

Committee Member

Key performance indicators for routine monitoring of pharmacy management at United Nations High Commissioner for Refugees (UNHCR) in Jordan

By

Heba Hayek, PhamD

Jordan University, 2012

Thesis Committee Chair: Dabney P. Evans, PhD, MPH

An abstract of a thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health, 2018.

Abstract

Key performance indicators for routine monitoring of pharmacy management at United Nations High Commissioner for Refugees (UNHCR) in Jordan

By: Heba Hayek

Background: Medicines and medical supplies comprise an essential building block for the delivery of healthcare services to disaster-affected and conflict-affected populations. Medicines and pharmacy systems in humanitarian settings are susceptible to mismanagement due to the sizable budgets allocated to medicines, complexity of pharmacy systems and involvement of multiple partners throughout the pharmacy management cycle of drug selection, procurement, distribution and use.

Objective: To research current pharmacy monitoring in humanitarian settings and develop key performance indicators that trigger alerts at early stages of pharmacy mismanagement that can be collected on a monthly basis by United Nations High Commissioner for Refugees (UNHCR) Public Health staff with no pharmacy background.

Methods: The project involved five main steps including: 1) a literature review for established indicators for pharmacy monitoring, key areas in pharmacy that require monitoring and methods to design routine monitoring systems; 2) identifying the key areas in pharmacy management related to this project that need to be monitored routinely; 3) defining criteria for the indicators to be collected; 4) developing indicators and selecting relevant established indicators based on the identified key areas and the defined criteria for the second and third steps; 5) developing guidance notes to aid the assessor in collecting the indicators and interpreting the results.

Results: Forty-four key performance indicators for monthly monitoring were compiled in the "PharMon Tool". The indicators cover the "distribution" and "use" steps of the pharmacy management cycle which includes pharmacy records, drug shortages, storage conditions, physical arrangement and rational drug use.

Conclusion: This project will help to improve routine pharmacy monitoring at UNHCR which may help to limit mismanagement, make the best use of resources, and ensure that pharmacy systems meet their goals in providing access to medicines, ensuring quality and safety of drugs and promoting rational drug use.

Key performance indicators for routine monitoring of pharmacy management at United Nations High Commissioner for Refugees (UNHCR) in Jordan

By

Heba Hayek, PharmD

Jordan University, 2012

Thesis Committee Chair: Dabney P. Evans, PhD, MPH

A thesis submitted to the Faculty of the Rollins School of Public Health of Emory University in partial fulfillment of the requirements for the degree of Master of Public Health, 2018.

Acknowledgements

First, I am grateful to the Centers for Disease Control and Prevention's (CDC) Emergency Response and Recovery Branch (ERRB) and Rollins School of Public Health (RSPH) for offering me the opportunity to work on this project with the United Nations High Commissioner for Refugees (UNHCR) through the Complex Humanitarian Emergencies (CHE) fellowship program.

Second, to Dr. Dabney Evans, your esteemed advice and support are greatly appreciated.

I would also like to express my special thanks of gratitude to Dr. Aimee Summers for her expert advice and supervision during this thesis project.

Also, I would like to thank Lara S. Martin for her generous support and the guidance she extended throughout the project.

To my mentor Dr. Ann Burton, a sincere thank you for your endless support. This project would not have been possible without your tremendous help and your extraordinary knowledge and experience. I only hope these simple lines convey the everlasting gratitude I feel.

To Mr. Javier Utande, thank you for sharing your knowledge and experience, and for meticulously reviewing the tool.

Additionally, special thanks to Dr. Aryeh Stein for reviewing the monitoring tool.

Last but not least, a heartfelt thank you to my mother and father. You are my pillars and your unconditional support, encouragement, and love are exemplary.

Acronyms

AMC: Average monthly consumption

EDL: Essential Drug List

FEFO: first-expiry first-out

MSF: Médecins Sans Frontières

MSH: Management Sciences for Health

UNHCR: United Nations High Commissioner for Refugees

WHO: World Health Organization

Table of Contents

Chapter 1: Introduction 1
I. Background 1
II. Problem statement 2
III. Purpose statement 3
IV. Objective 3
V. Significance statement 4
Chapter 2: Methods 9
Step 1: Literature Review 9
Step 2: Identification of key areas for pharmacy monitoring 10
Step 3: Defining criteria for indicators 11
Step 4: Developing and selecting indicators 11
Step 5: Developing guidance notes for each indicator 12
Chapter 3: Summary of Literature Review 13
Overview 13
I. Poor pharmacy management 13
II. Established indicators for pharmacy monitoring 16
III. Designing a system for routine pharmacy monitoring 18
IV. Key areas in pharmacy that need monitoring 20
Chapter 4: Results and Discussion 23
Overview 23
I. Key areas for pharmacy monitoring 23
II. Criteria for indicators 27
III. Developing and selecting indicators for the PharMon Tool 30
Chapter 5: Description of the PharMon Tool 35
Overview 35
I. Field reporting component 36
A. Physical inventory 36
B. Stock cards 43
C. Drug shortages 48
D. Triangulation of stock records at the pharmacy 51
E. Physical Arrangement 59

F. Temperature Control 61
G. UNHCR Essential Drug List 64
II. Self-reporting 65
A. Stock-outs 65
B. Rational drug use 66
Chapter 6: Conclusion 70
I. Summary 70
II. Framework for implementation 71
III. Pilot Plan 72
IV. Anticipated implementation challenges 73
V. Implications 74
Annex 1: **PharMon Tool** 75
Annex 2: **Physical Inventory Report Template** 121
Annex 3: **Stock Card Template** 122
References 123

Chapter 1: Introduction

I. Background

Disaster-affected and conflict-affected populations have the right to a dignified life and humanitarian assistance (Sphere, 2011). To support this, minimum standards have been set by humanitarian actors and described in the internationally recognized Sphere Handbook in four key sectors: water supply, sanitation and hygiene promotion; food security and nutrition; shelter, settlement and non-food items; and health action (Sphere, 2011). Health actions and standards in Sphere are based on the health system's six building blocks defined by the World Health Organization (WHO): leadership, human resources, drugs and medical supplies, health financing, health information management and service delivery (Sphere, 2011). All building blocks are required for the delivery of essential health services to the affected populations (Sphere, 2011). Essential health services include ensuring access and availability of essential drugs to the affected population (Sphere, 2011). Effective drug management systems are needed to fulfill this purpose (Sphere, 2011).

United Nations High Commissioner for Refugees (UNHCR) is one of the entities that provide support to disaster- and conflict-affected populations. The health of refugees and forcibly displaced persons is a key component of protection and a priority for UNHCR. The provision of health services by UNHCR to persons of concern is part of a larger public health response that aims to reduce excess morbidity and mortality. Among the health services provided by UNHCR is the access to essential medicines which are "medicines that satisfy the priority healthcare needs of the population" (WHO, 2017). To achieve this, UNHCR procures essential medications and distributes them to its implementing partners in each operation. UNHCR funds,

supervises and provides technical support to implementing partners to manage the drugs under comprehensive pharmacy systems that aim to provide access to needed medicines, ensure quality, efficacy and safety of medicines and promote rational drug (i.e. the patient receives the right treatment at the most effective cost) (UNHCR, 2006).

II. Problem statement

Pharmacy systems are susceptible to mismanagement (i.e. inadequate tracking of drug stocks, poor storage of drugs, irrational drug use). Pharmacy systems in humanitarian settings are at an even higher risk of mismanagement compared to non-humanitarian settings due to the sizable budget of medications and the complexity of systems (MSH, 2011). This is true for UNHCR where the budget allocated for the procurement of medicines and management of the drug stock accounts for a considerable amount of UNHCR's overall annual health budget. In addition, pharmacy systems at UNHCR are complex and involve several partners. The pharmaceutical activities are mainly carried out by UNHCR's implementing partners at country level with supervision from UNHCR. Several UNHCR operations have more than one implementing partner in the same country which further adds to the intricacy of the system. This multi-level involvement could potentially create gaps in the pharmacy systems putting them at risk of not meeting their intended goals in providing access to medicines, ensuring quality and safety of drugs, promoting rational drug use and making the best use of the resources. For example, such multi-level management requires an increased number of qualified pharmacy staff. Unqualified staff are unlikely to have sufficient knowledge to order medications based on needs, which could result in either overstock or under-stock of medications. This would fail to be the best

use of resources and may result in lack of access to essential medicines in terms of the pharmacy systems' intended goals.

Currently, UNHCR conducts in-depth assessments of pharmacy management on an ad-hoc basis. The duration of the assessments ranges from a few days to several weeks depending on the size and number of pharmacy facilities in each site. Previous in-depth assessments conducted by UNHCR revealed shortcomings in compliance with good pharmacy management that ensure availability and accessibility of essential medicines and ensure their correct use (UNHCR, 2015a; UNHCR, 2015b; UNHCR, 2015c). Good pharmacy management includes ordering medications and keeping track of stocks to avoid stockouts, overstock and expiration. It also includes proper storage and arrangement of medications as well as compliance with good dispensing practices to ensure rational drug use.

III. Purpose statement

There is an immense need for routine monthly monitoring, through the collection of key performance indicators, of pharmaceutical activities carried out by UNHCR's implementing partners in order to allow for early detection of pharmacy mismanagement and implement early corrective measures to ensure that the aims of pharmacy systems are met and to prevent the waste of resources.

IV. Objective

The objective of this special studies project was to research routine pharmacy monitoring and key performance indicators which can be collected, analyzed and reported on a monthly basis

in order to develop a tool for pharmacy monitoring in select areas of the pharmaceutical management cycle that will trigger alerts for ad-hoc, in-depth assessments in areas with identified shortcomings.

V. Significance statement

Routine monitoring of pharmaceutical activities is expected to enhance good pharmacy management by increasing the sense of accountability by the implementing partners and alerting the partners and UNHCR early when there is a problem, which would have a great clinical and public health impact. In addition, the design of the key performance indicators could trigger future discussions on the importance of the often-overlooked routine monitoring of pharmacy management in humanitarian settings.

VI. Definition of terms

Adjusted average monthly consumption—average monthly consumption (AMC) of a drug adjusted for stock outs; expected AMC if there were no stock outs.

Average monthly consumption (AMC)—consumption of a drug over a period of one month.

Basic unit—the smallest unit of the drug that can be dispensed (i.e. tablet, ampoule, bottle).

Bin card—a stock card that is physically kept with the stock (MSH, 2012b)

Cold chain—a temperature-controlled supply chain for pharmaceutical products that are temperature-sensitive (i.e. vaccines).

Consumption—the amount of drug consumed by a pharmacy facility in basic units. Consumption in pharmacies reflects the amount of a drug dispensed to patients while in

medical stores/warehouses consumption reflects the amount of drug distributed to pharmacies.

Cyclic stock counting—dividing the stock into groups where one group is counted every week or month, and physical counts are compared against stock counts from stock cards (MSH, 2012b).

Dispensing record—a record of the amount of drugs in basic units dispensed to patients by date at the pharmacy that is updated immediately upon dispensing any drug to a patient.

Distribution—the term distribution has two meanings in this context

- Distribution of drugs from a medical store/warehouse to pharmacies
- One of the four steps of the pharmaceutical management cycle and comes between procurement and use. This involves stock management after the drugs are procured and before they are dispensed and includes—in addition to distributing drugs from medical stores/warehouses to pharmacies—arranging the stock, maintaining the quality of the stock, and keeping track of the stock (Clark & Barraclough, 2010)

Dosage form—the physical form of the finished pharmaceutical product intended for use (i.e. tablet, syrup, ointment).

Essential drug list (EDL)—the list of drugs that are essential to treat the majority of the target population at costs affordable to the program (UNHCR,2006).

First-expiry first-out (FEFO)—consumption of the drugs that have the nearest expiry date the first.

First-in first-out (FIFO)— consumption of the drugs that were received first before the rest

Generic name—the scientific name of the drug. A generic name is also called an international nonproprietary name (INN).

Medical store—a facility for storing medical supplies and drugs. A medical store can also be called a medical warehouse.

Medical warehouse—a facility for storing medical supplies and drugs. A medical warehouse can also be called a medical store.

Minimum stock level—the minimum count of stock below which ordering to replenish the stock is required. Minimum stock level is different for each medication and is dependent on multiple variables including (MSH, 2012b).

Order schedule—a regular schedule for ordering medications (i.e. weekly, monthly). An order schedule is mainly dependent on the availability staffing and transportation (UNHCR, 2006)

Pallets—a flat structure used to hold stacks of boxes of drugs. Pallets can be wooden or plastic and prevent the direct contact of drug boxes with the floor

Pharmaceutical management cycle—a four-step cycle starting. First step is the selection of medications to be procured. Second step is the procurement of the selected medications. Third step is distribution which includes managing, arranging and tracking the stock. Fourth step is the use of medications which includes rational drug use and dispensing the medications to patients (Clark & Barraclough, 2010).

Physical inventory—the process of physically counting the available stock of each drug and comparing the physical count to the stock count from the stock card.

Proxy indicator—indirect measure that approximates or is indicative of a direct measure (MSH, 2012e).

Rational drug use—the patient receives the right medication for his medical condition, at the right dose for the right period of time at the most effective cost to himself and the society (UNHCR, 2006).

Routine Monitoring—refers to regular and feasible monitoring on a monthly basis in this context.

Shelf life—the length of time a drug where its usability is not affected (WHO, 2004).

Stock—the drugs stored at the pharmacy or the medical store/warehouse.

Stock card—a stock-keeping card that is used to track the stock balance where all movement of medications (issued and received) are recorded by date. Each drug has a separate stock card.

Stock count—the stock balance calculated using the stock card by adding the amount of received stock to the existing stock and subtracting the amount of stock issued. Stock count changes with every movement of the drug and should be updated immediately on the stock card.

Stock Management—arranging the stock, tracking the stock and maintaining the quality of the stock.

Stock status—estimates how long the drug will meet the needs of the consumption. Used to estimate overstock or understock (Clark & Barraclough, 2010).

Temperature log—the record of temperature monitoring in places where drugs are stored at the pharmacy or medical store/warehouse (i.e. room temperature, refrigerator temperature)

Chapter 2: Methods

The output of this special studies project is the pharmacy monitoring tool for UNHCR—the PharMon Tool—presented in Annex 1. The process for developing the PharMon Tool involved five main steps and are discussed in this chapter.

Step 1: Literature Review

Existing literature was reviewed for: established indicators for pharmacy monitoring, methods to design monitoring systems for pharmacies, key areas in the pharmacy management cycle that need to be monitored routinely, and reasons for poor pharmacy management. The latter was used indirectly to help in formulating the indicators and in identifying the key areas in pharmacy that require monitoring. PubMed and Embase were both searched using terms that included but were not limited to "pharmacy", "pharmaceutical", "drug", "medicine", "medication", "management", "monitoring", "evaluation", "assessment", "humanitarian", "low-resource", "resource-limited", "indicators", "routine", and "key performance indicators". This search resulted in only one relevant article (Trap et al, 2010). Based on previous knowledge about available guidelines and handbooks on the topic of interest, the search strategy was modified to include online search engines such as Google to search relevant guidelines by organizations that are not published in peer-reviewed journals. Twenty-eight documents were reviewed and based on relevance, nine documents from Management Sciences for Health (MSH); (Clark & Barraclough, 2010; MSH, na; MSH, 2011; MSH, 2012a; MSH, 2012b; MSH, 2012c; MSH, 2012; MSH, 2012e; MSH, 2012f; MSH, 2012g) and two documents from the World Health Organization (WHO) were included. In addition, five UNHCR pharmacy documents were

included: “UNHCR Drug Management Manual 2006”, “Medicine and Medical Supplies Management Standard Operation Procedures for UNHCR Uganda Health Programme” and pharmacy in-depth assessment field reports for three countries, two in Sub-Saharan Africa and one in the Middle East.

When reviewing indicators established for pharmacy monitoring and key areas for monitoring, we only focused on the third and fourth steps in the pharmacy management cycle, distribution and use. Any indicators that did not cover those two steps were excluded. Summary of the literature review is presented in Chapter 3 (Summary of Literature Review).

Step 2: Identification of key areas for pharmacy monitoring

Although the pharmacy management areas to be monitored could be generalizable to different settings, this project focused on humanitarian settings particularly settings in which UNHCR works. Thus, the three UNHCR in-depth assessment reports mentioned earlier were a main source for identifying the key areas in pharmacy management to be monitored. The reports were reviewed, and common findings were utilized for this purpose. In addition, the remainder of UNHCR, WHO and MSH references were reviewed for the same purpose. The “UNHCR Drug Management Manual 2006” was of particular importance for this process since it provides specific descriptions and guidance on how drugs should be managed throughout the pharmacy management cycle. All findings from other sources were compared with the UNHCR 2006 manual to avoid potential conflicts

or contradictions. Key areas identified for pharmacy monitoring are presented and discussed in Chapter 4 (Results and Discussion).

Step 3: Defining criteria for indicators

Criteria for the monitoring indicators were defined prior to selecting or developing the indicators. Criteria were derived from the literature taking into account three main points: the targeting of end-users of the monitoring indicators who may not have a pharmacy background, the suitability for monthly monitoring, and the context of pharmacy systems at UNHCR where implementing partners may not have computerized systems to manage the stock of drugs. The criteria are presented in Chapter 4 (Results and Discussion).

Step 4: Developing and selecting indicators

Indicators included in the PharMon Tool (Annex 1) were mainly newly developed, however a few were selected and adapted from established indicators. The reason for developing most of the indicators instead of using those already established was because the indicators for the PharMon Tool are intended to be collected by persons who may not have a pharmacy background. Based on the results of the literature review, no indicators were found to be previously established for our target end-users. Developing, selecting and adapting indicators for inclusion in the PharMon Tool involved three steps: identifying broad categories for monitoring based on the key areas identified in Step 3 of the Methods, identifying indicators needed to accomplish the objectives, then defining the type of each indicator. The results of this process are discussed in Chapter 4 (Results and Discussion).

Step 5: Developing guidance notes for each indicator

The last step in designing the PharMon Tool was to include guidance notes for each indicator for the assessors. This included: 1) the collection method, 2) the objective of the indicator, 3) how to interpret the data collected for each indicator and 4) suggested actions to be taken based on the data collected. The guidance listed is most likely intuitive for pharmacists but was developed to facilitate monitoring by non-pharmacists. The guidance notes for each indicator are discussed in detail in Chapter 5 (Description of the PharMon Tool).

Chapter 3: Summary of Literature Review

Overview

This section presents the findings of the literature review for the four main topics mentioned earlier in the methodology chapter. The topics are all interconnected and common findings among the four are only presented once under the most relevant one.

I. Poor pharmacy management

Poor pharmacy management results in resource wastage in several forms: expired medications, damaged stock and medicines that are never used (Clark & Barraclough, 2010). This results in failure to make the best use of medicines despite the large amount of money invested (Clark & Barraclough, 2010). According to Management Sciences for Health (MSH), medicines account on average for 30–50% of an overall health budget (Clark & Barraclough, 2010). Thus, medicines require a unique management system that ties together all components of the drug cycle: selection, procurement, distribution and use (see Figure 1) (Clark & Barraclough, 2010).

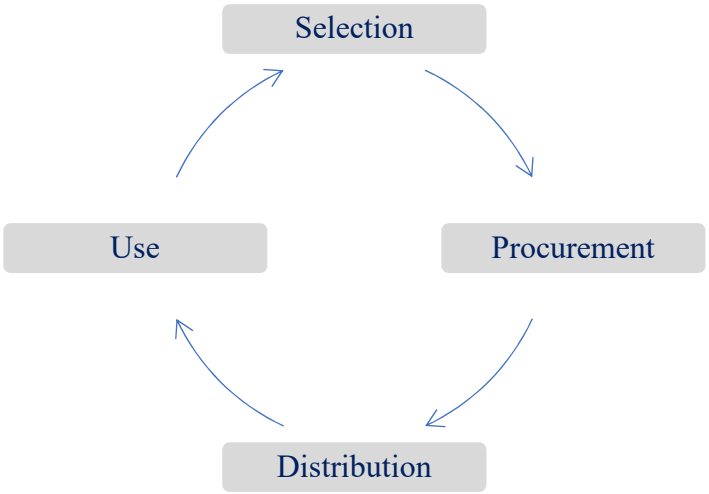


Figure 1: Pharmacy Management Cycle (Clark & Barraclough, 2010)

Within the pharmacy management cycle, there are nine pharmaceutical management functions (MSH, 2011):

1. policies and legislation; medicine regulatory systems, licensing processes selection
2. a pharmaceutical service supporting patient care and treatment, process of selecting medicines to be procured based on a predefined criteria
3. procurement; of medicines from suppliers
4. storage/distribution; a pharmaceutical service supporting patient care and treatment, storing and distributing medications according to standards
5. use; a pharmaceutical service supporting patient care and treatment, prescribing and dispensing medications
6. financing; component of the management support system of the pharmaceutical services
7. organizational management; component of the management support system of the pharmaceutical services, oversight of pharmaceutical activities
8. human resources management; component of the management support system of the pharmaceutical services, pharmacy staffing
9. information management; component of the management support system of the pharmaceutical services, provision of information to promote pharmaceutical care

Mismanagement can occur at any of these pharmaceutical management functions. The pharmaceutical management functions related to this project are: storage/distribution, use, organizational management, and information management.

One example of mismanagement in "storage/distribution" is poor auditing at storage sites resulting in stock-outs leading to the unavailability of needed drugs and/or overstock leading to over expenditure (MSH, 2011). Another example of "storage/distribution" mismanagement is poor inventory management which is manifested in wastage of financial resources, overstock of medications and/or shortages in medications (MSH, 2012b). Poor inventory management is usually the result of ad-hoc and subjective decisions on drugs' order frequency and quantity (MSH, 2012b). That is why stock records are core records in inventory management (MSH, 2012b). However, stock records are of little value if all information are not compiled and interpreted (MSH, 2012b).

Mismanagement in "use" can be reflected in irrational drug use resulting in compromised patient care and/or over expenditure (MSH, 2011). "Information mismanagement", begins with the lack of reliable and timely information (MSH, 2011). That is why Pharmacy Management Information Systems (PMIS) are necessary to present information for a few key indicators to improve accountability (MSH, 2012f). PMIS can be either manual or computerized and has four key components: record keeping documents, data compilation/aggregation tools, data reporting forms and feedback forms (MSH, 2012f).

Entities responsible for oversight may not be able to fulfill their role if there is no data available or if the data available is not interpretable or unreliable (MSH, 2011). The lack of oversight—regardless of the underlying cause—represents "organizational mismanagement" that could possibly facilitate mismanagement at different levels of the pharmaceutical management cycle including corruption and theft (MSH, 2011). In addition to "organizational mismanagement",

complexity of systems, involvement of multiple partners and sizable budgets render the pharmaceutical systems susceptible to mismanagement (MSH, 2011). Between 10% and 25% of global public health spending on medicines is for purposes other than the intended (WHO/GGM 2008) (MSH, 2011). In low-resource countries for example, shortage in qualified staff is one of the causes of pharmacy mismanagement and poor performance (MSH, 2011).

II. Established indicators for pharmacy monitoring

There are multiple established indicators for pharmacy monitoring. For example, MSH has a list of performance indicators and performance targets that cover several areas in pharmacy monitoring including overall performance, financing, procurement, quality assurance, central storage, delivery and storage at health facilities (MSH, 2012c). Management Sciences for Health has also developed an Inventory Management Assessment Tool (IMAT) consisting of four indicators to measure accuracy of record-keeping and effectiveness of monitoring stock levels (IMAT, n.d.). According to MSH, the implementation of IMAT at one site takes approximately half a day (IMAT, n.d.) which is impractical for routine monitoring.

The World Health Organization (WHO) designed indicators to assess drug use in health care facilities (WHO, 1992). Indicators are either core or complementary, covering three main areas in drug use: prescribing practices, patient care and facility-specific factors (WHO, 1992). The indicators are designed to be collected through drug use studies (WHO, 1992). Four types of designs that may be used for the studies are described; cross-sectional (basic), cross-sectional (comparative), supervision, and assessment impact of intervention (WHO, 1992). The type of

study design depends on the objective of the indicators used (WHO, 1992). The indicators are designed to be collected only through these planned studies and not on a routine basis.

Trap et al. developed an indicator-based tool to systematically assess and report on good pharmacy practice (GPP). The tool consists of a set of indicators, an indicator and survey manual, a data collection sheet, and a Microsoft Excel data collection and analysis tool (Trap et al., 2010). The authors defined five components of pharmacy cycle for assessment: system, storage, services, dispensing and rational drug use (Trap et al., 2010). In total, 34 indicators were developed using 5 references (Trap et al., 2010). The first component, "system", included 5 indicators to assess availability and use of a prescribing recording system, degree of computerization, implementation of stock management and re-order system (Trap et al., 2010). The second component, "storage", included 7 indicators to assess the presence of pests, cleanliness of dispensing and storage area, pharmacy hygiene, storage conditions, system and practices (Trap et al., 2010). The third component, "services", included 6 indicators to assess prescription load, opening hours, staff availability and qualifications, availability of services, tests and health promotion activities (Trap et al., 2010). The fourth component, "dispensing", included 8 indicators to assess information available to the dispenser, product range, dispensing time, packaging material, dispensing equipment, dispensing procedure and contact with prescriber (Trap et al., 2010). The fifth component, "rational drug use", included 8 indicators to assess information available to the dispenser, product range, dispensing time, packaging material, dispensing equipment, dispensing procedure and contact with prescriber (Trap et al., 2010). A scoring system was assigned for each indicator; scores were compared against a defined standard (Trap et al., 2010).

The tool was tested in Ethiopia, Zimbabwe and Uganda, and was found to be simple and easy to use and allowed inter- and intracountry comparisons (Trap et al., 2010). However, the applicability of the tool for use in developed countries was questionable (Trap et al., 2010). Further research was found to be needed to design indicators to measure patient care and patient satisfaction (Trap et al., 2010). Some of the indicators require a professional pharmacy background to be collected (Trap et al., 2010).

III. Designing a system for routine pharmacy monitoring

Monitoring is the continuous and ongoing reviewing of program activities (MSH, 2012c). Monitoring should be a key component of everyday pharmaceutical activities (MSH, 2012c). To track the performance of pharmacy programs, it is essential for monitoring to be systematic and ongoing (MSH, 2012c). However, pharmacy monitoring is often performed casually with no clear objectives and targets, and the findings do not help in enhancing the system's performance (MSH, 2012c). The design of a feasible pharmacy monitoring system requires identifying key monitoring questions and indicators, keeping the data collection to a minimum, keeping the monitoring procedure practical, applying the "KISS" principle; keep it simple and straightforward, and standardizing the monitoring process to allow for comparison over time and between facilities (MSH, 2012c). Common pitfalls in designing pharmacy monitoring systems include: failing to identify key areas to be monitored, trying to achieve too many objectives, designing a complex and impractical system, and designing indicators that could result in wrong or subjective conclusions (MSH, 2012c). The methods for pharmacy monitoring vary and could be either formal or informal and include: supervisory visits, routine reporting, sentinel reporting or reporting through special studies (MSH, 2012c). For routine reporting, it

is crucial to identify key data and information in the pharmaceutical management cycle to be monitored and to only collect data that can be acted upon to avoid overdesign which could lead to under-implementation and system failure (MSH, 2012c). Indicators for routine monitoring should be selective and proxy to make collection more practical (MSH, 2012f). Proxy indicators are likely to produce accurate results and save time and money if designed properly (MSH, 2012f). Indicators for routine monitoring do not necessarily need to be representative (MSH, 2012f).

Routine reporting could be supplemented by sentinel reporting which differs from the former in terms of frequency, site of monitoring, or level of detail (MSH, 2012c). Special studies could provide an additional layer of data through qualitative approaches such as in-depth interviews, observations and key-informant interviews (MSH, 2012c). For example, a special studies approach could be applied to explore patients' adherence to treatment and prescribers' adherence to standard treatment protocols.

In-depth assessments of pharmacy systems are not conducted routinely. In-depth assessments of pharmacy systems need to be structured (MSH, 2012e). Otherwise, the assessment would be the subjective opinion of the assessor (MSH, 2012e). In-depth assessments could be comprehensive, exploring all aspects of the system, or could be limited to a selected area of interest (MSH, 2012e). As in-depth assessments are not conducted routinely, the timeframe for the assessment and the qualitative and quantitative data for collection need to be defined prior to the start of the assessment (MSH, 2012e). Qualitative data in assessments have several merits: provision of information that cannot be collected using quantitative data and the

provision of the same findings as quantitative data but in a less time-consuming manner (MSH, 2012e).

IV. Key areas in pharmacy that need monitoring

According to the "UNHCR Drug Management Manual 2006", several aspects in pharmacy management need to be monitored. These include: drug quality, procurement process, performance and qualifications of suppliers, order status, temperature, cold-chain, selected products, potential theft, inventory records, safety stock, stock level, minimum and maximum stock levels, expiry of medications, storage conditions, rational drug use, received orders, inventory records versus physical counts, and stock records versus dispensing records and prescriptions (UNHCR, 2006). Selected products are drugs that are fast moving, chronically in short supply, expensive, therapeutically important, or in high demand by patients (UNHCR, 2006). Potential theft by health staff is described as either petty theft "leakage" for personal use by the staff or his/her family, systematic diversion into illicit markets, multiple prescriptions to the same patient or to ghost patients, and systematic over-ordering of drugs for use in private practices (UNHCR, 2006).

The Standard Operations Procedures (SOP) for UNHCR Uganda Health Program highlights several practices that need to be in place to maintain a good pharmacy management system. Pharmacy staff in-charge or preparing orders of medications should know how to calculate the adjusted average monthly consumption (UNHCR, 2015d). In addition, to avoid stock-outs and shortages in supply, a procurement calendar and an order schedule should be in place (UNHCR, 2015d). Also, in health facilities, pharmacies should maintain stock cards while other wards

should keep a record of what they dispense (UNHCR, 2015d). Stock cards at medical stores should be updated immediately with each drug movement in or out (UNHCR, 2015d). Furthermore, there should be a system for the organization of stock at medical stores and pharmacies (UNHCR, 2015d).

The in-depth pharmacy assessments conducted by UNHCR in three countries all had common findings on pharmacy mismanagement by the implementing partners. The findings included: frequent stock-outs, overstock, orders of medications that are not related to needs, discrepancies in stock balances between different stock records (i.e. stock cards), lack of updating the stock records, lack of conducting physical inventory as recommended and lack of routine reporting to UNHCR on stock levels (UNHCR, 2015a; UNHCR, 2015b; UNHCR, 2015c). The areas for pharmacy monitoring described by MSH are compatible with those described by UNHCR and include: medicine use at the health facilities, stock-outs (MSH, 2011; MSH IMAT, n.d.), security breaches (MSH, 2012g), performance of suppliers, storage conditions (MSH, 2012a), tracer medications (MSH, 2012c), and temperature control (MSH, 2012a; MSH, 2012c).

The assessment tool by Trap et al. was designed and implemented in developing countries (Trap et al., 2010). It focused on several pharmaceutical aspects: archiving of prescriptions, components of the prescription, availability of a stock management system (i.e. computerized system, stock cards), stock levels, orders of medications, storage conditions (i.e. cleanliness, protection from sunlight, protection from pests), dispensing medications according to First-Expiry First-Out (FEFO) principle, tracking of expired medications, temperature monitoring and control, staffing and working hours, qualifications of pharmacy staff, availability of drug

references, dispensing time, packaging of drugs, labeling of drugs, and rational drug prescribing (Trap et al., 2010).

Chapter 4: Results and Discussion

Overview

This chapter discusses in detail the three steps taken to develop the PharMon Tool following the literature review: identifying key areas in pharmacy to be monitored, defining criteria for the monitoring of key performance indicators and developing and selecting the indicators. All of these results were informed by the results of the literature search which is discussed in Chapter 3 (Summary of Literature Review).

I. Key areas for pharmacy monitoring

The first step in designing the PharMon Tool was selecting the key areas needed for routine monitoring. Management Sciences for Health, WHO, UNHCR Drug Management Manual and UNHCR in-depth assessment reports were used for this purpose. Findings of the literature review were evaluated, and the areas that fall under the "distribution" and the "use" steps in the pharmaceutical management cycle were selected:

- **Stock-outs**

  Stock-outs and drug shortages as an area for monitoring were mentioned and included in most of the references reviewed (MSH, 2011; MSH IMAT, n.d.; UNHCR, 2006; UNHCR, 2015a; UNHCR, 2015b; UNHCR, 2015c; UNHCR, 2015d). Stock-outs and drug shortages are common indicators of poor quantification of medications (UNHCR, 2006). It is important to ensure that essential medications are in stock at all times, thus the routine monitoring of stock-outs and drug shortages is recommended and highly justifiable.

- **Temperature control**

  Temperature control of pharmaceuticals was a common area for monitoring among all reviewed references (MSH, 2012a; MSH, 2012c; Trap et al., 2010; UNHCR, 2006; UNHCR, 2015a; UNHCR, 2015b; UNHCR, 2015c). Controlling temperature does not only refer to protection from heat but also to protection from humidity and sunlight (UNHCR, 2006). Heat, humidity and direct sunlight can damage certain drugs such as creams, ointments and suppositories, making them therapeutically ineffective (UNHCR, 2006). Thus, routine temperature monitoring is necessary. Monitoring should be conducted at both the storage facility and where cold-chain medications are stored, whether in a refrigerator or cooler-boxes (UNHCR, 2006).

- **Orders in relation to needs**

  This is a critical area to monitor, as orders of medications that are not related to needs—whether over-ordering or under-ordering— are considered an indicator of poor pharmacy management that could lead to drug shortages or overstock and waste of resources (Clark & Barraclough, 2010; Trap et al., 2010; UNHCR, 2006).

- **Prescribing practices**

  Prescribing practices fall under rational drug use. The most common monitored prescribing practices are completion of the prescription components, polypharmacy (multiple or over-prescription) of antibiotics and injectables (UNHCR, 2006; UNHCR, 2015b, UNHCR, 2015c; WHO, 1992). Evidence exists on the

improvement of prescribing practices and accordingly on improvement of rational drug use by monitoring these aspects (MSH, 2012c).

- **Stock records**

  Monitoring of stock records is required as the lack of or their inaccuracy are among the main indications of poor pharmacy management (MSH, 2012b; MSH, 2012c; MSH IMAT, n.d.; Trap et al., 2010; UNHCR, 2006; UNHCR, 2015a; UNHCR, 2015b; UNHCR, 2015c; UNHCR, 2015d). Stock records are of little value if the information is not compiled and interpreted (MSH, 2012b). Thus, it is important to triangulate the information from the different records in the monitoring process by looking to see if the stock and physical counts match, and by looking if stock cards and dispensing records and/or prescriptions match (UNHCR, 2006).

- **Potential theft**

  UNHCR gives this aspect a focus and recognizes the different types of potential theft (UNHCR, 2006). Although there is no straightforward mechanism to monitor this, potential theft could be monitored by looking at unexplained over-ordering of medications, unjustified discrepancies between the stock records, and prescriptions to ghost patients (UNHCR, 2006; UNHCR, 2015a). Also, Management Sciences for Health describes the three most common types of theft: slow and sustained leakages, large scale robberies and diverting shipments before they reach their destination (MSH, 2012g).

- **Storage conditions**

  Storage conditions include temperature, light, cleanliness, protection against pests, and protection against fire (UNHCR, 2006). These aspects are frequently included under monitoring of pharmacy to prevent degradation of medications (MSF, 2016; MSH, 2012a; Trap et al., 2010; UNHCR, 2006; UNHCR, 2015b; UNHCR, 2015c).

- **Availability of essential medicines**

  Monitoring of the availability of essential medications is recommended by UNHCR and WHO (UNHCR, 2006; WHO, 1992). One of the main functions of pharmacy management is to ensure permanent stock of essential drugs (MSF, 2016; UNHCR, 2006). Monitoring the availability of essential medications is crucial as they contribute towards disease prevention and control (UNHCR, 2006).

- **Selected products** (tracer/index medications)

  Monitoring selected drugs has been proposed as a mechanism to avoid drug shortages or to protect against theft (MSH, 2012c; UNHCR, 2006). Selected products have general common characteristics that might vary according to the objective of the monitoring. For monitoring against theft, it is recommended to select products that are expensive (i.e. anti-malarials), fast moving, continuously low in stock, therapeutically important (i.e. anti-bacterials), or easy to mask or hide. (UNHCR, 2006). As for monitoring to prevent stock-outs and shortages, the main characteristic of selected drugs is therapeutic importance (MSH, 2012c).

- **Rational drug use**

  Irrational drug use has three main types; irrational prescribing (i.e. prescribing medications that are not needed, or polypharmacy), irrational dispensing (i.e. dispensing a wrong drug, strength, or amount), and factors/practices that negatively impact patient adherence, such as inadequate instructions of language barriers (UNHCR, 2006). This area in pharmacy management is commonly recommended for monitoring to promote rational drug use (MSH, 2012c; Trap et al., 2010, UNHCR, 2006; WHO, 1992).

II. Criteria for indicators

Defining the criteria for the monitoring indicators was the second main step in designing The PharMon Tool (Annex 1). Five necessary criteria were determined:

1. **Simple**

   According to MSH, overdesign and under-implementation are the two major causes of failure of routine reporting systems (MSH, 2012c). Thus, simplicity is a key feature in the design of indicators for routine monitoring, especially when implemented in low-resource humanitarian settings. Indicators need to be simple enough so they can all be collected in approximately an hour on a monthly basis in a pharmacy or a medical warehouse. In addition, indicators should be simple enough for collection by public health staff with no pharmacy background. Indicators need to be simple enough to be collected using the manual stock records since not all UNHCR operations—depending on the context—have computerized systems for pharmacy management or at least not with an analytic function.

2. **Standard**

One of the key principles of monitoring systems according to MSH is to allow for comparison of performance between different facilities with similar programs and to allow for comparison over time (MSH, 2012c). Accordingly, indicators need to be standardized. This is of particular importance in our settings of interest where the assessors have varying levels of pharmacy knowledge. Lack of standardization of indicators will result in subjective monitoring practices and recommendations.

Standardization does not only apply to the indicators but also to their methods of collection and the interpretation of their results. In addition, it is crucial to have clear, unambiguous standard definitions of key pharmaceutical terms used in the indicators to ensure uniform understanding among assessors who do not have a pharmacy background and to avoid subjectivity in interpretations.

3. **Flexible**

This is the only one of the five criteria not extracted from existing literature. It was based on the author's previous knowledge about the pharmacy system at UNHCR and the need for flexibility in monitoring indicators. Some indicators are designed on index/tracer medications, which are a small number of representative pharmaceuticals that are therapeutically important and ideally should be available in the pharmacy at all times. Tracer medications vary between countries based on the country-specific population health profile. Also, index/tracer medications could vary between different health facilities within the same country depending the level of

health services provided. Thus, indicators should be flexible enough to account for this variability without affecting the quality of the indicator.

4. **Proxy**

   Proxy indicators are approximate measures of direct indicators and are less time consuming and more practical to collect on a routine basis compared to direct measures (MSH, 2012f). It is preferred to collect proxy indicators on a regular basis instead of collecting direct measures infrequently. This makes proxy indicators appropriate for routine monitoring and accordingly to this project, as the objective of the PharMon Tool is to generate alerts of pharmacy-related issues and not fully assess the pharmacy management and practices.

5. **Selective**

   Selectiveness of the indicators to be collected is a key feature in monitoring systems (MSH, 2012c). In PharMon tool, the indicators do not cover all aspects of the pharmacy management cycle but rather are designed on selected key areas that are deemed the most important and are indicative of pharmacy management in the cycle. (see Figure 1). For the purpose of this project, we designed key indicators around the "distribution" step in the pharmacy management cycle and the "use" step to a lesser extent. The first step "selection" was not included because it is carried out centrally at UNHCR and our objective with the indicators is to monitor the pharmacy activities at the level of UNHCR's implementing partners. The second step "procurement" has also been excluded for the same reason mentioned above, although the procurement

is carried out by the implementing partners in few operations. However, the indicators were designed to be applicable to all contexts where UNHCR operates. Any needed country-specific adaptions (i.e. addition of certain indicators) will be addressed at country level after the pilot.

III. Developing and selecting indicators for the PharMon Tool

Construction and selection of indicators was the third step in designing the PharMon Tool (Annex 1). After identifying the areas to be monitored and defining the characteristics of the indicators, the following steps were taken:

1. Designing the outline of the PharMon Tool

- *Pharmaceutical categories to be monitored*

  Eight pharmaceutical categories have been included based on the previously discussed key areas for pharmacy monitoring (stock-outs, temperature control, orders in relation to needs, prescribing practices, stock records, potential theft, storage conditions, availability of essential medicines, selected products, and rational drug use). Stock records were divided into two sections, "physical inventory" and "stock cards". Potential theft was translated into the "Triangulation of stock records" category. One category to monitor issues relating to UNHCR's essential drug list was added. Other categories remained the same. The final eight categories are:

  - Physical inventory
  - Stock cards

- Drug shortages
- Triangulation of stock records
- Temperature control
- Physical arrangement
- UNHCR Essential Drug List
- Rational drug use

Every category and the indicators under each are discussed in detail in Chapter 5.

- *Field reporting and self-reporting*

  The initial planning and outlining of indicators in the PharMon Tool were intended for collection in the field at pharmacies and medical warehouses by UNHCR Public Health staff. However, since one of the pharmaceutical categories to be monitored is rational drug use, "self-reporting" by pharmacy staff was added for that category. This is because these indicators are time-consuming to collect since a representative number of prescriptions need to be reviewed. Thus, they are not feasible for collection by UNHCR staff on a monthly basis in the field. Self-monitoring by pharmacy staff of rational drug use was implemented in rural Java where indicators were designed on the number of prescribed drugs, percentage of prescribed antibiotics and percentage of prescribed injectables (MSH, 2012c). An evaluation two years after the implementation of the self-monitoring showed a substantial improvement in rational drug use in rural Java (MSH, 2012c).

Field reporting forms the bulk of the PharMon Tool and pharmaceutical categories to be monitored fall under the "distribution" step of the pharmacy management cycle. As discussed earlier, the first two steps of the pharmacy management cycle, "selection" and "procurement", are not included in the monitoring indicators as the objective of this tool is to monitor the pharmaceutical activities carried out by UNHCR's implementing partners, and the first two steps are primarily carried out by UNHCR. The fourth step "use" is only included under the "self-reporting" component. The rationale for this is provided in the discussion of that section.

2. **Selecting relevant existing and established indicators for inclusion in the PharMon Tool**

To prevent duplication of efforts, some established, relevant monitoring indicators were selected and adapted for inclusion in the PharMon Tool (as discussed previously in Chapter 2: Methods) with slight modification of wording afterwards. The selected indicators and their sources are listed below:

- *Average number of drugs per encounter* (WHO, 1992)—included under self-reporting on rational drug use
- *Percentage of encounters with an antibiotic prescribed* (WHO, 1992)—included under self-reporting on rational drug use
- *Percentage of encounters with an injectable prescribed* (WHO, 1992)—included under self-reporting on rational drug use

- *Are medicines stored on shelves?* (Trap et al., 2010)
- *Are shelves labeled?* (Trap et al., 2010)
- *Is there a refrigerator? Is its temperature regularly recorded?* (MSH, 2012d)

3. **Developing indicators for the PharMon Tool**

The indicators under each pharmaceutical category were divided into core and complementary indicators. As described by MSH, core indicators are those that need to be collected routinely for monitoring purposes, whereas complementary indicators are considered sentinel indicators to be collected in special circumstances (MSH, 2012c). The WHO has applied this principle in its "Selected Drug Use Indicators" where there are core and complementary indicators to investigate the drug use in health facilities (WHO, 1992).

Core indicators in the PharMon Tool (Annex 1) are simpler than complementary indicators in terms of design and data collection. Core indicators need to be collected on a monthly basis while complimentary indicators are sentinel indicators to be collected when alerts are generated from the core indicators under the same pharmaceutical category. They can also be collected whenever the assessor has time, or at certain facilities/sites with ongoing issues in pharmaceutical management according to the core indicators or in-depth assessments. Lack of alerts from core indicators is not necessarily indicative of proper pharmacy management.

Identification of all possible aspects of pharmacy mismanagement is only possible through in-depth assessments.

In addition, the majority of the constructed indicators are binomial rather than numerical to ease data collection and make it more practical for routine monitoring by non-pharmacists.

Chapter 5: Description of the PharMon Tool

Overview

This chapter discusses all components of the PharMon Tool and the indicators under each in the same order they appear in the tool. This chapter also discusses the last step in designing the PharMon Tool, developing guidance notes for each indicator. Each indicator is supplemented with an objective, collection method, results, interpretation of results, actions that need to be taken based on results, and any notes that the assessor might need. It is worth mentioning that it is not possible to cover every potential scenario of the results, thus the interpretations and actions listed cover general situations. In uncommon situations, the actions to be taken could be subject to the judgement of the assessor or with consultation of UNHCR staff.

As discussed in Chapter 4 (Results and Discussion), the indicators designed for routine monitoring of pharmacy management in humanitarian settings are divided into two main categories: field reporting and self-reporting. The field reporting component forms the bulk of the monitoring indicators and is categorized according to key areas that need monitoring. Each category has at least one core indicator, and the majority of the categories are supplemented by complementary indicators. The self-reporting component is also categorized according to key areas and each category has only one core indicator to be reported on a monthly basis to UNHCR by the implementing partner.

Note: the numbering of the indicators listed below is continuous and is same as the numbering in the PharMon Tool (Annex 1).

I. Field reporting component

A. **Physical inventory**

There are 2 core indicators and 3 complementary indicators under "physical inventory". Accordingly, a maximum of 2 alerts can be generated from this section. Any alert should trigger further investigations that start with the collection of the 3 complementary indicators.

Core indicators:

1. ***Is there a report for the most recent physical inventory?***

   Physical inventory is one of the essential activities in pharmacy management for stock tracking. Physical inventory is a monitoring technique to determine the physical stock and to compare it to the theoretical stock written on the stock cards (UNHCR, 2006). The comparison aims to identify discrepancies between the actual physical stock and the theoretical stock (UNHCR, 2006).

   This indicator aims to assess if physical inventory is conducted. It does not however measure if physical inventory is conducted correctly or if it is conducted according to the recommended frequency.

   This indicator is collected through retrospective document review. For documentation purposes and as a data quality check, the assessor needs to take a picture of the report and upload it onto the tablet used for data collection. Asking the in-charge whether physical inventory was conducted is insufficient.

Even if the in-charge states that physical inventory was conducted but there is no report available, it should not be considered conducted.

If there is no physical inventory report, a physical inventory should be planned and conducted within 3 days of the visit for pharmacies and within 2 weeks for medical warehouses. During physical inventory, no movement of drugs should take place (UNHCR, 2006). That is why physical inventories should always be planned in advance. A larger timeframe to conduct the physical inventory is given for medical warehouses compared with pharmacies due to the size of their operations. Medical warehouses distribute medications to pharmacies, and it should be guaranteed that medical pharmacies have adequate stock levels during the physical inventory of the medical warehouses since there will be no drug movement throughout the activity. Two weeks should generally be sufficient to distribute adequate amounts of drugs to the pharmacies before conducting the physical inventory.

2. ***Date of the physical inventory report***

   Physical inventory should be conducted according to recommended frequencies. It should be conducted at the end of each month in pharmacies and biannually at medical warehouses according to UNHCR recommendations (UNHCR, 2006).

This indicator aims to assess if physical inventory is conducted according to the recommended frequency. However, this indicator does not measure whether the physical inventory is conducted correctly or not. The date of the physical inventory should be documented on the report (UNHCR, 2006). Thus, this indicator is collected through retrospective document review. For pharmacies, no action is needed if the date of the report is within one month of the date of the visit. Otherwise, a physical inventory should be planned and conducted within 3 days from the date of the visit. For medical warehouses, no action is needed if the date of the report is within 6 months of the date of the visit. Otherwise, a physical inventory should be planned and conducted within 2 weeks from the date of the visit.

Complementary indicators:

3. ***Components of the physical inventory report***

   This indicator aims to assess if all required components are included in the physical inventory report. Because there might be variances between different references in the components of the physical inventory report, the following are based on the "UNHCR Drug Management Manual 2006":

   - Date of inventory: the date of the physical inventory should always be documented for two reasons. First, to monitor the frequency of the physical inventory. Second, without the date, it would not be possible to extract the theoretical stock from the stock card and compare it with the actual stock.

- Health center: this refers to the name of the facility and whether it is a pharmacy or a medical warehouse where the physical inventory was conducted. Physical inventory reports should always be submitted to both UNHCR and senior management at the implementing partner level for review. The review will not be possible if the facility/location is unknown.
- Drug name (generic): the generic name is the scientific name of the drug
- Strength: the strength of the drug should always be documented. Many drugs have more than one strength, so it is essential to differentiate the different strengths being counted.
- Dosage form: the dosage form is the pharmaceutical form of the drug (i.e. tablets, syrup, suspension, cream). Many drugs have more than one dosage form and it is essential to differentiate the dosage forms being counted
- Basic unit: the basic unit is the smallest unit of the drug that can be counted and should not be confused with the dosage form. For example, the dosage form of an antibiotic could be a syrup or a suspension, while the basic unit would be a bottle. It is important to know the basic unit because the counts documented on the physical inventory report are in basic units.

Note: some physical inventory forms have one column named "Item" for "Drug name", "Strength", "Dosage form" and "Basic unit".

- Batch number: the same drug could have more than one batch number. It is important to know the different batches available for each drug and the count of each batch for recall purposes. In addition, costs could differ slightly

among different batches. In such a case, calculating the cost of the stock would be dependent on the number of basic units available from each batch.

- Expiry date: different batches of the same drug could have different expiry dates. It is important to document the different expiries to apply the first-expiry first-out (FEFO) principle and to track near expiry medications.
- Quantity counted: this refers to the actual stock counted in basic units
- Quantity on stock card: this column should be filled after filling the quantity counted column. The purpose of having it on the physical inventory report is to compare the actual and the theoretical stock.
- Difference: this refers to the difference between the actual and the theoretical stock. Ideally, there should be no difference or a small difference with a reasonable justification. It is worth mentioning that a difference of "0" for ALL drugs should always raise suspicion that the physical counts are being edited or falsified to match the stock counts or vice versa. The difference of "0" for all drugs is usually too good to be true.
- Justification: this should be filled whenever there is a difference between the quantity counted and the quantity on the stock card.
- Two signatures: for accuracy, physical inventory should be conducted separately by two staff (UNHCR, 2006). The quantities counted by each staff are then compared. Drugs with discrepancies in counts between the two staff should be counted again by both until the counts match. The two signatures on the physical inventory report are the signatures of the two staff conducting

the physical inventory. One signature indirectly indicates that the physical inventory is not conducted according to standards.

This indicator can only be collected through retrospective document review. Whenever the physical inventory report is incomplete, regardless of the number of incomplete components, a physical inventory should be planned and conducted within 1 week of date of visit for pharmacies and within 4 weeks for medical warehouses.

4. ***Number of drugs on the physical inventory form***:

   Each drug in the pharmacy or the medical warehouse should be counted during the physical inventory. This indicator aims to measure whether all drugs are physically counted by triangulating the number of drugs from the physical inventory report with the number of stock cards as each drug should have a stock card. This indicator is extracted from the findings of an in-depth assessment conducted by UNHCR (UNHCR, 2015a).

   If the number of stock cards does not match with the number of drugs on the physical inventory report, than the physical inventory is not conducted for all medications or not every drug has a stock card. In such a finding, physical inventory should be conducted, and stock cards should be updated within 3 days of the visit for pharmacies and within 2 weeks for medical warehouses.

In addition, the assessor might need to conduct further investigations by requesting the implementing partner to send a written justification for the discrepancy. The assessor can also compare the physical inventory report with the stock cards to see which medications are missing, document the name of the medications and make random checks on those medications during upcoming visits.

5. ***Is the physical inventory report filled on a standard form***?

In humanitarian settings, there is usually a high turnover rate of staff. Standard forms for routine activities are necessary to ensure completeness and uniformity and to avoid subjectivity in conducting the activities such as the physical inventory. This indicator has been developed based on the findings of an-depth assessment conducted by UNHCR (UNHCR, 2015a). It aims to assess the availability of a standard form for the physical inventory report. A suggested template for the physical inventory report is found in Annex 2. This indicator is collected through retrospective document review where the assessor looks to see whether a standard form was used or whether the report was filled on a blank piece of paper. If components are included but no standard was used, the next planned physical inventory should be conducted using a standard form. If not all components are included, a physical inventory should be planned within 2 weeks of the date of visit for pharmacies and within 4 weeks for medical warehouses. The findings on the inclusion of all components should already be available from

the first complementary indicator "Components of the physical inventory report" in this section.

B. **Stock cards**

There are 2 core indicators and 2 complementary indicators under this section. Accordingly, a maximum of 2 alerts could be generated from this section.

Core indicators:

6. ***Are there stock cards or bin cards***?

Stock cards are records that track every movement of the drug at the pharmacy or the medical warehouse, whether issued or received. Stock cards are the same as bin cards. The only difference is that stock cards are all stored in one location while bin cards are stored next to their drugs (Clark & Barraclough, 2010). Stock cards/bin cards are the principle records for controlling stock (MSF, 2016).

This indicator aims to measure if stock cards/bin cards are in place. However, it does not measure if the stock cards/bin cards are complete and are filled accurately.

This indicator is collected through retrospective document review. For documentation purposes and as a data quality check, the assessor needs to take a picture of one stock card or bin card and upload it onto the tablet used for data collection. If stock cards or bin cards are not in place, stock cards or bin cards need to be created for all drugs within 3 days of the date of visit for pharmacies and within 2 weeks for medical warehouses.

7. ***Are the counts recorded in basic units***?

As discussed earlier, a basic unit is the smallest unit of the drug that can be counted. When comparing counts from different records (i.e. physical inventory report, stock cards), basic units are always used. It is very important to record counts in basic units on stock cards (UNHCR, 2006). The rationale behind this is that the same drug can have more than one packing size. For example, a drug with a tablet basic unit could have a packing size of 30 tablets per box, or 28 tablets per box, or even 1000 tablets per box if the drug is produced for mass procurement. In addition, drugs are not always dispensed to patients in their full packing size. Some patients may be prescribed a medication for a short duration that does not add up to the full packing size of the drug. Accordingly, it is only possible to record what is dispensed, "Quantity issued", on the stock card in terms of basic unit.

This indicator aims to assess if reporting in basic units is in place. It is an indirect measure of correct recording of stock counts according to standards. However, it does not necessarily indicate that the figures recorded are accurate. Complete accuracy of stock counts is dependent on the accuracy of both "Quantities issued" and "Quantities received". This indicator can be collected through retrospective document review. Any stock card can be reviewed by the assessor to see if the counts are in basic units (i.e. box, pack). If counts are not recorded in basic units, stock cards need to be updated for all drugs within 3 days of the visit for pharmacies and within 2 weeks for medical warehouses.

Complementary indicators:

8. ***Components of the stock card or bin card***

This indicator measures if all required components of stock cards/bin cards are included. Because each agency or health facility has its own stock card formatting (Clark, & Barraclough, 2010), the components listed below are based on the "UNHCR Drug Management Manual 2006". A template for a stock card can be found in Annex 3.

- Drug name (generic): the generic name is the scientific name of the drug
- Strength: the strength of the drug should always be documented. Many drugs have more than one strength, so it is essential to differentiate between the different strengths being counted.
- Dosage form: the dosage form is the pharmaceutical form of the drug (i.e. tablets, syrup, suspension, cream). Many drugs have more than one dosage form and it is essential to differentiate the dosage forms being counted
- Basic unit: the basic unit is the smallest unit of the drug that can be counted and should not be confused with the dosage form. For example, the dosage form of an antibiotic could be a syrup or a suspension, while the basic unit would be a bottle. It is important to know the basic unit because the counts documented on the physical inventory report are in basic units.
- Minimum stock level or the minimum stock threshold: the stock level below which ordering is required to replenish the stock. Ideally, minimum stock levels should never be reached. Minimum stock levels are different for each drug and could be different at each facility for the same drug. Minimum

stock levels are dependent on the consumption rate, order frequency, available storage space, and lead time for orders. Since stock balance is only available on the stock cards, minimum stock levels should be listed as a reminder for the in-charge to know when orders are required to avoid stock-outs.

- Batch number: the same drug could have more than one batch number. It is important to know the different batches available for each drug and the count of each batch for recall purposes. In addition, costs could slightly differ among different batches. In such a case, calculating the cost of the stock would be dependent on the number of basic units available from each batch.
- Expiry date: different batches of the same drug could have different expiry dates. It is important to document the different expiries to apply the first-expiry first-out (FEFO) principle and to track near expiry medications.
- Date: the date of any drug movement should be listed next to the corresponding quantities received or issued on that date.
- Received from: this refers to the name of the facility which the drugs were received from
- Quantity received (IN): the quantity in basic units that were received on a specific date from a specific facility
- Issued to (OUT): the facility or entity (i.e. patients) to whom the drugs were issued
- Quantity issued (OUT): the quantity in basic units that were issued on a specific date to a specific entity

- Stock balance: the stock available at the end of the day on a specific date based on what is issued and what is received (i.e. the stock balance on 15/06/2018 is the stock balance on 14/06/2018 plus the quantity received on 15/06/2018 minus the quantity issued on 15/06/2018)
- Remarks: this is not a mandatory field but could be filled whenever the in-charge has notes about the stock balance (i.e. donation, expired or nearly expired medication, any other comments)
- Signature: this refers to the signature of the person recording the stock balance on a specific date.

It is worth noting that stock cards could be electronic, where stock balance is calculated automatically based on the starting stock balance, quantities issued, and quantities received. In this case, it is important to make sure that any data entry can be tracked by date, time and username of the person that made the entry. Otherwise, there would be a high risk of editing and falsifying the stock records possibly to match the physical counts. Components would still be the same with the exception of the signature which is replaced in this case by the username of the person making data entries into the system.

This indicator can only be collected through retrospective document review. Whenever all components are not included in the stock card, stock cards should be updated within 1 week of date of visit for pharmacies and within 4 weeks for medical warehouses.

9. ***How many stock cards or bin cards are there?***

Each drug in the pharmacy or the medical warehouse should have a stock card (Clark, & Barraclough, 2010). This indicator aims to measure whether all drugs have stock cards by triangulating the number of stock cards with the number of drugs from the physical inventory report obtained from indicator number 4; "*Number of drugs on the physical inventory form*".

If the number of stock cards does not match the number of drugs on the physical inventory report, than the physical inventory is not conducted for all medications or not every drug has a stock card. In such a finding, physical inventory should be conducted, and stock cards should be updated within 3 days of the visit for pharmacies and within 2 weeks for medical warehouses.

C. **Drug shortages**

There are 2 core indicators and one complementary indicator under this category. A total of 11 alerts can be generated from this category; 10 from the first core indicator and one from the second.

Core indicators

10. ***Are the following essential medications available?***

This indicator aims to measure the availability of 10 selected essential medications. The list of selected medications to be monitored could vary between countries and between facilities within the same country. The selection of medications within a country is dependent on the health profile of the persons

of concern. For example, malaria medications are only available in countries where malaria is endemic. As for the selection of medications within the health facility, it is dependent on the level of services provided.

Regardless of the site, medications selected for this indicator need to be therapeutically important and ones that the pharmacy or the medical warehouse should always have in stock (MSH, 2012c). In other words, stock-outs of these medications could potentially result in huge negative health consequences to the patients that need them. The list in Annex 1 is a suggestion that can be adapted at country level.

This indicator is collected through observation by asking the in-charge in the pharmacy or the medical warehouse to physically show the assessor where the drugs are stored on the shelves or the pallets. If a drug is not found, the assessor needs to review the stock card or the bin card of that drug to see how many days that drug has been out of stock. This would help investigate the reasons behind the stock-out. If a stock card or a bin card is not available, reasons for that should be looked at as well.

There is no standard action in case of stock-outs. It is recommended that the assessor informs the UNHCR pharmacy focal point in his/her country immediately. Details on the roles of the pharmacy focal point are provided in

Chapter 6 (Conclusion) under the framework for implementation. Actions to be taken will be dependent on the reason behind the stock-out.

In addition, whenever one or more of the selected essential medications is/are found to be out of stock, it is likely that other medications are also out of stock. Thus, it is highly recommended in this case to complete the complementary indicator for this section.

11. ***Is there an order schedule?***

Medications should be re-ordered on a regular order schedule (UNHCR, 2006). The presence of an order schedule is an indirect measure of avoiding drug shortages. Pharmacies usually order medications from the medical warehouses on a weekly, biweekly or monthly basis depending on the consumption rate and the available space. Medical warehouses usually order medications on an annual or biannual basis.

This indicator aims to measure the presence of a regular schedule for ordering medications. The assessor can collect this indicator by asking the in-charge to show him/her the order schedule. If not available, an order schedule needs to be developed within one week from the date of the visit for both pharmacies and medical warehouses. The order schedule needs to be shared with UNHCR directly afterwards.

Complementary indicator

12. ***Are essential medications available?***

As per UNHCR's Essential Drugs List (EDL) policy, all medications at the implementing partners' pharmacies and medical warehouses are essential. This indicator aims to measure if all medications that should be available are in stock. To collect this indicator, the assessor needs to take the procurement list with them to the visit. The procurement list is the list of medications that have been procured centrally by UNHCR and distributed to the implementing partners. Procurement usually occurs on an annual basis. Thus, any medication on the procurement list should be available in the pharmacy or the medical warehouse. It is worth mentioning that the procurement list could vary from one implementing partner to another in the same country.

There is no standard action in case of stock-outs. It is recommended that the assessor informs the UNHCR pharmacy focal point in his/her country immediately. Actions to be taken will be dependent on the reason behind the stock-out and the urgency of the situation.

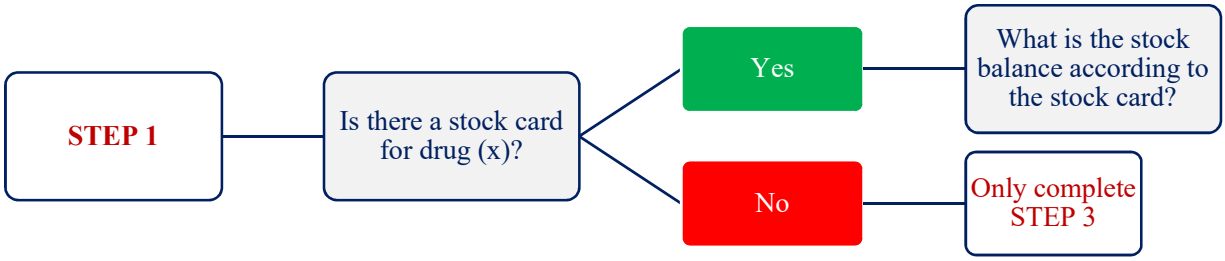
D. Triangulation of stock records at the pharmacy

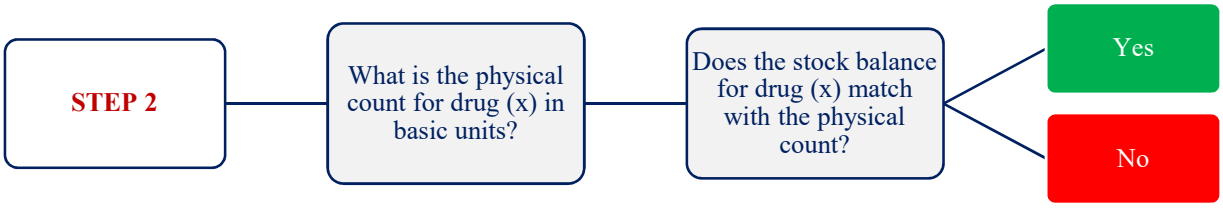
There are multiple records at the level of the pharmacy that can provide data directly or indirectly on the stock of the drugs. These records include but are not limited to: physical inventory reports, stock cards, dispensing records and prescriptions. Physical inventory reports and stock cards represent the actual stocks and theoretical stocks respectively.

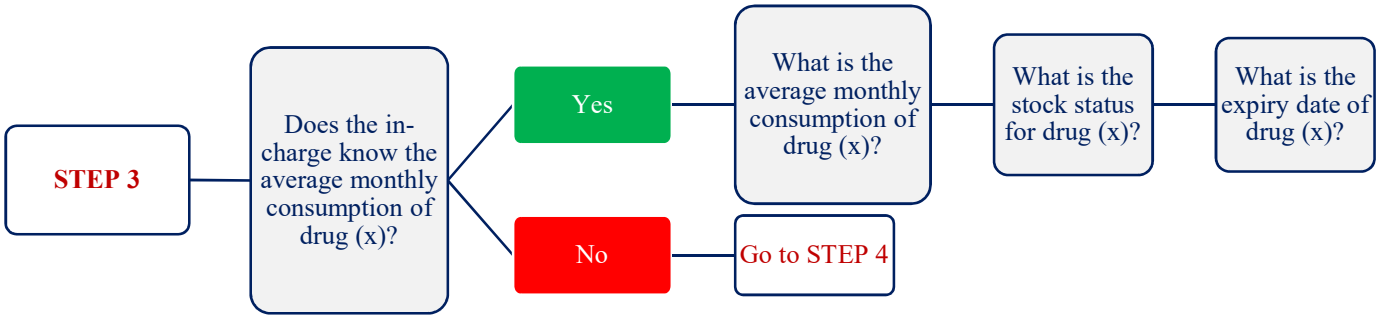
Actual stocks and theoretical stocks should match or have small discrepancies that are reasonably justified (UNHCR, 2006). In addition to providing the theoretical stocks, the stock cards can also provide data on drug movements, whether received or issued on specific dates. Most of the drug movements out of the pharmacy are to patients. In rare occasions, drugs are moved out of a pharmacy to another pharmacy or back to the medical warehouse. Thus, it is expected that drug movements to patients according to the stock card match with the dispensing records on specific dates (UNHCR, 2006). Dispensing records are records for documenting the amount of drug in basic units that is dispensed to patients by date. No drug should be dispensed without a prescription to UNHCR's implementing partners. Thus, whenever there is dispensation of a drug on a specific date according to the dispensing record, a prescription should be available on that same date.

This section aims to triangulate the data available from the different resources of drug records. To facilitate the date collection for this section, a list of drugs suitable for this section will be created that can later be adapted at country level based on the context. Suitable drugs for this section are drugs that are expensive and thus are considered attractive pharmaceutical items. In addition, it is preferred that drugs are easily physically counted and have low drug movement such as the drugs with basic units that are easy to count and drugs that are uncommonly prescribed, respectively. For example, narcotics are suitable for this section. The tablet that will be used for data collection will be automated to select one medication randomly form the list.

The following diagram (Figure 2) summarizes the four steps of this section:


STEP 1
Is there a stock card for drug (x)?
Yes
No
What is the stock balance according to the stock card?
Only complete STEP 3


STEP 2
What is the physical count for drug (x) in basic units?
Does the stock balance for drug (x) match with the physical count?
Yes
No


STEP 3
Does the in-charge know the average monthly consumption of drug (x)?
Yes
No
What is the average monthly consumption of drug (x)?
Go to STEP 4
What is the stock status for drug (x)?
What is the expiry date of drug (x)?

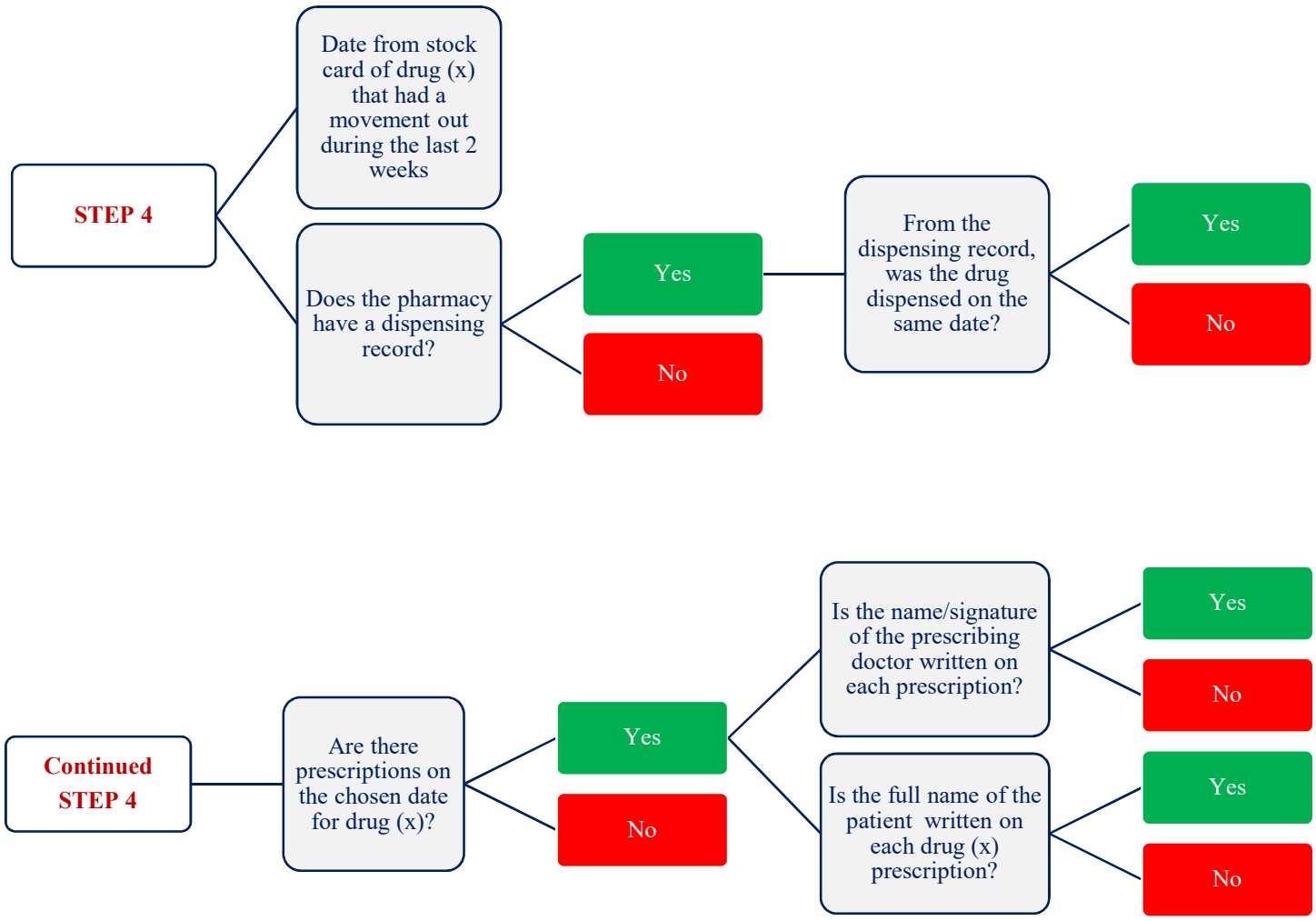


Figure 2: Steps for completing "Triangulation of stock records at the pharmacy" indicators

STEP 1

Core indicators

13. ***Is there a stock card for drug (x)?***

14. ***What is the stock balance according to the stock card?***

The two indicators aim to assess the stock balance of the selected drug to be compared with the physical count of the same drug in Step 2. Both indicators can be collected through retrospective document review of the stock card of the selected drug.

STEP 2

Core indicators

15. ***What is the physical count for drug (x) in basic units?***

16. ***Does the stock balance for drug (x) match with the physical count?***

This step is dependent on the previous step. If the stock card of the selected drug is not available there would be no point of collecting the two indicators under this step. The stock balance from the stock card and the physical count are expected to match or have small discrepancies that are reasonably justified. According to MSH, conducting an unannounced physical count is one of the security measures in pharmacy monitoring that could potentially reveal leakage of medications (MSH, 2012g). However, this is not the only reason for discrepancies between actual and theoretical stocks. For example, stock cards in pharmacies are sometimes updated at the end of the working day. If the drug was dispensed on the date of the visit, and the stock card was not yet updated

for that date, then there would be a discrepancy between the stock balance and the physical count. This could be identified through the dispensing record for that date.

Stock counts and physical counts are expected to match or have small discrepancies with reasonable justifications. Whenever there are big and unjustified discrepancies, it is recommended to conduct an in-depth assessment as quickly as possible. Any delay

STEP 3

Core indicators

17. ***Does the in-charge know the average monthly consumption of drug (x)?***
18. ***What is the average monthly consumption of drug (x)?***
19. ***What is the stock status of drug (x)?***
20. ***What is the expiry date of drug (x)?***

This step indirectly assesses the qualifications of the in-charge of the pharmacy. Each in-charge should have knowledge on how to quantify medications for ordering (UNHCR, 2015d). Average monthly consumption (AMC) of medications is needed for consumption-based quantification to be evidence-based and is also needed to assess the stock status of the medication, which is the duration that the available stock would cover the demands based on the consumption (Clark & Barraclough, 2010). Stock status can be used to assess drug shortages by triangulating it with the order schedule. For example, if the

stock of the selected drug is adequate for 15 days based on the consumption, and the next order is scheduled after that date (i.e. after 3 weeks or more), then it is anticipated that there will be drug shortage or stock-out. In addition, stock status in this step is also triangulated with the expiry date to assess overstock (Clark & Barraclough, 2010). For example, if the expiry date of the selected drug is 5 months from the date of the visit and the stock is sufficient for 7 months from the date of the visit based on the average monthly consumption, there is an anticipated overstock that could expire before its use.

STEP 4

Core indicators

21. ***Write the date you randomly chose (dd/mm/yy) from the stock card that has a movement out during the last two weeks***
22. ***Does the pharmacy have a dispensing record?***
23. ***From the dispensing record, was drug (x) dispensed on the date you chose in question 21?***
24. ***Are there prescriptions on the chosen date for drug (x)?***
25. ***Is the full name of the patient written on each drug (x) prescription?***
26. ***Is the name/signature of the prescribing doctor written on each prescription?***

This step aims to triangulate the stock card with the dispensing record and the dispensing record with the prescriptions. Comparison of the three records is one of the pharmacy monitoring techniques (UNHCR, 2006). As discussed earlier, most of the movement out, "Quantity issued", in pharmacies is to patients. Any

drug that is recorded on the stock card as issued to patients should be recorded on the dispensing record on the corresponding date and should also have a prescription for the same date. In addition, this indicator assesses possible falsification of prescriptions by looking at certain components that should always be complete such as the full name of the patient and the name/signature of the prescribing doctor. One of the theft types in pharmacies is writing prescriptions to ghost patients (UNHCR, 2006). Lack of these two components in the prescription, especially for attractive drugs such as narcotics, should raise suspicion and trigger further investigations.

Note: for random selection of a date from the stock card during the last two weeks prior to the visit, the assessor needs to count the number of all days that had a "movement out" during the last two weeks and enter that number into the tablet used for data collection. The tablet will be designed to randomly select a number between 1 and the number of days counted (the number of days counted will be 14 or less). Starting at the first date to have movement out in the past two weeks, count each date that has a number out until you reach the date of the number randomly generated by the tablet. That is the date you will use for this step. For example, if there are 5 days with movement out for a certain drug in the two weeks prior to the assessment and the tablet randomly chooses the number 3, you would choose the third day that has movement out as the random date to use.

Complementary indicator

27. ***After field visit, verify if each patient received drug (x) on that date***

This complementary indicator aims to verify if the drug was dispensed to the designated patient as recorded on the prescription. The phone number could be obtained from the health facility if available. If unavailable, the phone number of the patient could be obtained from UNHCR records where contact information is usually stored. Each person of concern registered with UNHCR has an ID number. The ID number can be obtained from the health facility or by searching the UNHCR platform "proGres" using the full name of the patient. If the patient did not receive the medication, an investigation with the pharmacy staff and prescribing physicians should take place.

E. Physical Arrangement

This section covers few yet essential aspects of the physical arrangement of the pharmacy or the warehouse. There are 4 core indicators under this section all of which are easy to collect through observation.

Core indicators

28. ***Are there shelves and/or pallets?***

Every pharmacy and medical warehouse should have shelves and/or pallets for appropriate storage of medications (UNHCR, 2006). This indicator aims to assess the presence of shelves and/or pallets through observation. If no shelves/pallets are available, they should be placed within 2 weeks from the date

of the visit if the structure and the space of the pharmacy or the medical warehouse allows. If not, action to be taken will be dependent on the context.

29. ***Are there any medication boxes on the floor?***

No medication boxes should be put directly on the floor (MSF, 2016; UNHCR, 2006). This indicator is collected through direct observation and aims to indirectly measure if the available shelves and/or pallets are sufficient for storing all the medications in the pharmacy or the medical warehouse.

The action to be taken depends on the reason for placing boxes on the floor. If the reason is lack of pallets/shelves, they should be placed within two weeks of the date of visit.

30. ***Is there a label on the shelves/pallets for each medication?***

Each medication should have a designated spot on the shelves or pallets and the spot should be labeled with the medication's name (MSF, 2016). Labels ease finding the medications in the pharmacy, reduce dispensing error, and indicate stock-outs when the space of shelf behind a label is empty (MSF, 2016). This indicator aims to assess if the labels are in place through direct observation. If shelves/pallets are not labeled, labels should be created and put in place within 3 days from the date of the visit for both pharmacies and medical warehouses.

31. ***Are medications stored in a clean, ventilated and free of pests area?***

This indicator aims to assess the overall level of cleanliness and ventilation of the storage area through observation. For example, the assessor could look to see if there are windows or air vents that allow circulation, and if the windows have screens that keep out the insects and pests (UNHCR, 2006). Actions to be taken will be dependent on the context.

F. Temperature Control

Monitoring of temperature in pharmacies and medical warehouses is essential to ensure that the temperature stays within an acceptable range, as many drugs get spoiled in the heat and become therapeutically useless (UNHCR, 2006). Monitoring the temperature of the cold-chain medications is even more important (UNHCR, 2006). The 8 core indicators under this section all look at temperature control of medications including cold-chain medications.

Core indicators

32. ***Is there a temperature record for the pharmacy?***

The terms temperature record and temperature log can be used interchangeably. This indicator aims to assess if temperature monitoring is in place and is collected through retrospective document review. If there is no temperature monitoring in place, a thermometer should be placed in the hottest spot in the pharmacy or the medical warehouse and a temperature record should be created and updated daily as of the next day following the visit.

33. ***Is the temperature kept below 30°C according to the temperature record on the day of the visit?***

According to WHO, normal storage conditions refer to storage in dry, ventilated areas in temperatures between 15° and 25°C, or up to 30°C, depending on the climate. In this indicator, the upper limit is used to account for the climatic conditions in the different sites. This indicator aims to assess whether the temperature is within the acceptable range through retrospective document review. The action to be taken will be dependent on the context. For example, air conditioning should be considered whenever possible.

34. ***Is there a refrigerator?***

Cold-chain medications are usually stored in a refrigerator. Cooler-boxes are used whenever refrigerators are unavailable. This indicator aims to assess the availability of the usual storage mechanism for storing cold-chain medications through observation. A refrigerator should be placed whenever the context allows (i.e. when there is electrical power).

35. ***Does the pharmacy/medical warehouse have cooler-boxes?***

Cooler-boxes should be available at pharmacies and medical warehouses whether there are refrigerators or not. If no refrigerators are available, the cooler-boxes are considered the primary mechanism for storing cold-chain medications. If refrigerators are available, cooler-boxes are considered the alternative and the backup plan for storing the cold-chain medications in case of refrigerator failure

(i.e. power cut-off). This is based on findings and recommendations of an in-depth assessment conducted by UNHCR (UNHCR, 2015b). This indicator is collected through observation. If cooler-boxes are not available, they (or insulated coolers) need to be in place within 3 days from the date of the visit.

36. ***Is there a temperature record for the refrigerator/cooler-boxes?***

In principle, this indicator is the same as the first indicator under this section but is specific to the refrigerator and is collected through retrospective document review. Temperature monitoring of medications requiring cool storage is essential to ensure they retain their therapeutic effectiveness (MSH, 2012d). If there is no temperature monitoring, a temperature record should be created and updated daily as of the next day following the visit.

37. ***What is the range of refrigerator/cooler-box temperature according to the temperature record on the day of the visit?***

Items that require cool storage need to be stored at temperatures between 2° and 8°C (UNHCR, 2006). This indicator aims to assess whether the temperature is within the acceptable range through retrospective document review. The action to be taken will depend on the underlying reason (i.e. refrigerator requires maintenance, number of ice-packs needs to be increased to correspond to the number and size of the cooler-boxes).

38. ***Are there enough cooler-boxes to store the cold-chain medications?***

This indicator can be collected through key-informant interview by asking the in-charge if the cooler-boxes available are adequate for storing the cold-chain medications. It is difficult to collect this indicator through observation as the findings will be subjective and might vary according to the judgment of the assessor. If no enough cooler-boxes are available, an adequate number should be made available within 3 days of the date of the visit.

39. ***Are there enough ice-packs per each available cooler-box?***

This indicator aims to assess if there is a sufficient number of ice-packs that correspond in size and number to the available cooler-boxes through observation. If the number is insufficient, an adequate number of ice-packs should be made available within 3 days from the date of the visit.

G. UNHCR Essential Drug List

The UNHCR Essential Drug List (EDL) is a list of essential medications that is based on the WHO list of essential medications and is updated every two years. Any medication available at the level of the implementing partner is from the UNHCR EDL. Although the EDL covers most of the common diseases, some patients are expected to require medications considered essential to their medical condition that are unavailable on the UNHCR EDL. Some UNHCR operations have implemented the system of Exceptional Approval of Medications where cases that require medications not on UNHCR's EDL are submitted to and reviewed by the Health Unit at UNHCR for approval.

40. ***If a patient has a prescription with a drug that is unavailable at the pharmacy, what are the action/s taken by the pharmacy?***

The indicator under this section aims to assess how the implementing partners in the different operations deal with patients who are prescribed medications that are not on the UNHCR EDL. There is no standard action to be taken based on the findings. Any action to be taken will depend on the context and needs to be discussed centrally at UNHCR. This indicator helps assess an area of the pharmacy management that might be overlooked in certain operations.

II. Self-reporting

There are four indicators under the self-reporting component. One indicator is about stock-outs and the remaining are on rational drug use. All should be reported by the implementing partner to UNHCR on a monthly basis.

A. **Stock-outs**

1. ***Were there stock-outs of the following medications during the last month?***

This indicator is the same as the first indicator under "Drug shortages" in the "Field reporting" component *"Are the following essential medications available?",* but instead of looking if selected essential medications are available on the day of the visit, the implementing partner is requested to report whether the selected essential medications were out of stock during the reporting period the previous month. There are two reasons for adding this indicator under "Self-reporting". First, it is important to know if the selected essential drugs that

are therapeutically important and should always be in stock were out of stock at any time and not just at the day of the visit. Second, if for any reason the assessor was not able to complete the "Field reporting" component for a certain month, the data on stock-outs of the selected essential medications would be available through this indicator keeping in mind that stock-outs are a major concern and a challenge in humanitarian settings that could result in drastic effects.

There is no standard action in case of stock-outs. Actions to be taken will be dependent on the reason behind the stock-out. However, an urgent monitoring visit to the health facility that reported stock-outs is highly recommended. It is also recommended to ask the implementing partner to send a report on stock-outs for all medications in the procurement list.

B. **Rational drug use**

As discussed earlier, monitoring of rational drug use is only included under self-reporting. The three indicators were all selected from WHO's "How to investigate drug use in health facilities" (WHO, 1992).

2. ***Average number of drugs per encounter***

   This indicator aims to assess polypharmacy. To collect this indicator, the in-charge at the implementing partner's site needs to review 30 randomly selected encounters (patient's visits) from the registry, count the number of drugs for each encounter, add up the total number of drugs prescribed and then divide by 30 to calculate the average (WHO, 1992).

For random selection of the 30 encounters, the in-charge needs to count the number of total encounters for the reporting period from the registry. A random number generator is needed for this process to generate 30 random numbers between 1 and the total number of encounters. The random number generator will differ according to the resources available in the reporting health facility. Random number generation can be done using Excel "=RAND( )" function or using paper-based random number tables.

There is no standard for this indicator. There is significant variation between countries according to treatment guidelines and morbidity patterns (WHO, 1992). There could also be a considerable variation among the different health facilities within the same country depending on the level of health services provided. Trends can be compared between the different health facilities and over time for the same health facility. However, the average number of drugs per encounter is 1.3–2.2 drugs/patient according to the results of earlier drug use studies (WHO, 1992).

3. ***Percentage of encounters with antibiotics prescribed***

   This indicator aims to assess rational prescribing of antibiotics. The same encounters randomly selected for the previous indicator are used for this indicator as well. To collect this indicator, the in-charge needs to count the number of encounters with one or more antibiotics prescribed, divide by 30 and

multiply by 100%. It does not matter if the patient didn't receive the antibiotic as the indicator is assessing prescribing practices (WHO, 1992).

There is no standard for this indicator. There is significant variation between countries according to treatment guidelines and morbidity patterns (WHO, 1992). There could also be a considerable variation among the different health facilities within the same country depending on the level of health services provided. Trends can be compared between the different health facilities and over time for the same health facility. However, the average percentage of encounters with an antibiotic prescribed is ≈20–40%/ according to the results of earlier drug use studies (WHO, 1992).

4. ***Percentage of encounters with injectables prescribed***

   This indicator aims to assess rational prescribing of injectables. The same encounters randomly selected from the first indicator are used for this indicator as well. To collect this indicator, the in-charge needs to count the number of encounters with one or more injectables prescribed, divide by 30 and multiply by 100%. It does not matter if the patient didn't receive the injectable as the indicator is assessing prescribing practices (WHO, 1992).

   There is no standard for this indicator. There is significant variation between countries according to treatment guidelines and morbidity patterns (WHO, 1992). There could also be a considerable variation among different health facilities within the same country depending on the level of health services

provided. Trends can be compared between the different health facilities and over time for the same health facility. An acceptable range can be identified at country level according to the level of services provided.

Chapter 6: Conclusion

I. Summary

Drugs comprise a fundamental unit of health systems (Sphere, 2011). Their management requires efficient pharmacy systems. The management of pharmacy systems is more prone to malpractice in humanitarian settings (MSH, 2011). Thus, monitoring of pharmacy should be a key component of routine activities in such settings (MSH, 2012c). This applies to facilities supported by the United Nations High Commissioner for Refugees providing health services—including essential medicines—to refugees and forcibly displaced populations through its implementing partners. The implementing partners are mainly responsible for the "distribution" and "use" steps of the pharmacy management cycle. The oversight by UNHCR of those two steps is essential to avoid the waste of resources and ensure that pharmacy systems function properly. Thus, it was identified that there is a need for tailored monitoring that: 1) allows for collection of key performance indicators on a monthly basis by UNHCR Public Health staff who may not have a pharmacy background and 2) detects pharmacy mismanagement practices at early stages.

This project consisted of five main steps: 1) review of existing literature, 2) identifying key areas in pharmacy to be monitored specific to humanitarian settings and UNHCR, 3) defining criteria for indicators that help meet the objective of the project in routine monthly monitoring by non-pharmacists, 4) developing and selecting key performance indicators and 5) developing guidance notes on each indicator to aid the target end-users in data collection and interpretation of results. The project yielded a monitoring tool—the PharMon Tool (Annex 1)—consisting of 44 key performance indicators. Forty indicators to be collected in the field by UNHCR for each

pharmacy facility operated by implementing partners and four to be self-reported by the implementing partner to UNHCR on a monthly basis.

The utilization of the PharMon Tool requires a well-constructed framework for implementation. An ideal framework has been proposed and is discussed below. However, this framework may need modifications in the future based on the outcomes of a pilot plan which is also discussed below along with the implementation challenges.

II. Framework for implementation

In each country where UNHCR operates, a pharmacy focal person will be designated from UNHCR. This focal person is not necessarily the one conducting the "Field reporting" component on a monthly basis but is rather the person that the assessors should report to with their findings each month and should come to if clarifications on the PharMon Tool are needed. A focal person from each UNHCR implementing partner will also be designated for pharmacy-related communications. In some countries, UNHCR has more than one implementing partner, and each implementing partner may run health activities in multiple health facilities. In those facilities, each pharmacy or medical warehouse is run by at least 1–2 staff, one of which is in charge of the facility. Thus, it is important to streamline and standardize communications with the implementing partner. The findings of the visits will be reported by the UNHCR pharmacy focal person to the implementing partner's focal person on a monthly basis. The implementing partner focal person is also responsible for reporting to UNHCR the "Self-reporting" component each month.

The "Self-reporting" component will be reported on either an Excel template or on a web portal designed for this purpose. Data from the "Field reporting" component will be collected on tablets that will automate suggested actions as described in Annex 1 for each indicator. The findings will either be incorporated into the UNHCR Health Information System (HIS) report or displayed on a web-portal designed for this purpose. The UNHCR's HIS web-portal could potentially be utilized. The different options will be reviewed during the pilot phase. Whenever an action is recommended by UNHCR, a timeframe for the completion of the action will be specified. The implementing partner's pharmacy focal person is requested to confirm in writing to UNHCR when the action has been completed. The UNHCR pharmacy focal person is responsible for following-up with the implementing partner whenever there is delay in reporting the status of the action. Most of the actions will be confirmed in writing and followed-up during the next monitoring visit whereas others will require the implementing partner to share a specified report that confirms the action was taken. The actions listed in Annex 1 list the reports that need to be shared. If no report is requested, a written confirmation should suffice.

III. Pilot Plan

The piloting is planned to take place at UNHCR's implementing partner's facilities in Jordan in September 2018. The first step will be consulting with UNHCR Information Technology (IT) staff to program the tablets that will be used for data collection. The next step is to train five non-pharmacist public health staff at UNHCR Jordan on the monitoring tool during the second and third week of September. Initially, the monitoring tool will be piloted at one medical warehouse and 4 pharmacies. Simultaneously, in-depth assessments will be conducted by a UNHCR pharmacist at each of the sites. Results from the in-depth assessments and from the

routine monitoring tool will be compared to measure concordance among issues assessed. A focus group discussion will be conducted afterwards with the 5 non-pharmacist assessors to receive feedback on the time needed to complete the indicators, ease of data collection, and interpretation of findings. Indicators will be adjusted based on the feedback received.

IV. Anticipated implementation challenges

The core indicators are expected to take less than an hour to collect. However, it is anticipated that alerts will be generated from the core indicators triggering the need to collect some complementary indicators and triggering further in-depth assessments and investigations. This process might be time-consuming especially for UNHCR Public Health staff that cover sites with multiple health facilities operated by the same implementing partner. These staff might not have enough time every month to conduct monitoring visits to all of the health facilities in the site they're covering which could lead to under-implementation of routine monitoring. To mitigate this, the development of pharmacy training materials targeting UNHCR Public Health staff and the implementing partners is under discussion. Conducting trainings will raise awareness among UNHCR staff on the importance of pharmacy management monitoring and will attempt to build the pharmacy monitoring into their routine duties and responsibilities.

Another challenge could be the identification of a UNHCR pharmacy focal person in each country. The person would need high-level trainings on pharmacy management in order to be able to make recommendations and communicate with the UNHCR staff and with the implementing partners regarding findings of the monitoring visits.

In addition, data collection in the field will be done using tablets. Moving the PharMon Tool into its electronic version on tablets may pose some challenges and will require consultations with Information Technology experts to design a user-friendly application that allows smooth movement between indicators and automatically skips certain dependent indicators based on the results of other relevant indicators (i.e. if there is no physical inventory report, the tablet should be automated to skip questions on the date of the report and the components of the report).

Lastly, adherence of the implementing partners with self-reporting on a monthly basis is a likely challenge, especially at the initial phases of the implementation and in the case of staff turnover. Trainings, orientations and continuous follow-up by UNHCR are needed to avoid noncompliance with monthly reporting.

V. Implications

The PharMon Tool is designed to be expandable to countries where UNHCR operates other than Jordan after the pilot phase. Routine monitoring through the PharMon Tool is expected to limit mismanagement by UNHCR's implementing partners, make the best use of resources, and ensure that pharmacy systems meet their goals in providing access to medicines, ensuring quality and safety of drugs, and promoting rational drug use.

Annex 1: PharMon Tool

I. Field Reporting by UNHCR Public Health staff

PHYSICAL INVENTORY

Note: physical inventory is the process of physically counting the available stock of each drug and comparing the physical count to the stock count from the stock card

Core Indicators

1. Is there a report for the most recent physical inventory?

Yes ☐ No ☐

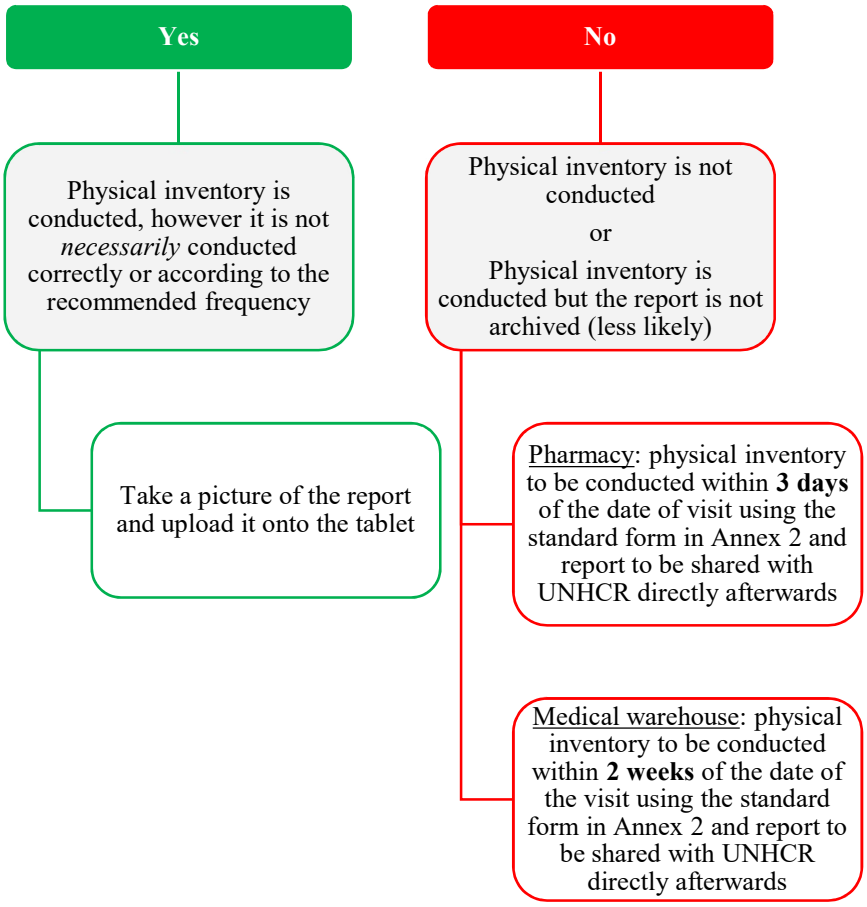
Note: answer yes only if you see the report

Objective: to assess if physical inventory is done

Collection method: ***retrospective document review****; ask the in-charge to show you the physical inventory report*

Results: Yes → ✓

No → ✘



If yes, please go to Question 2

If no, please go to the following section (Stock cards)

---

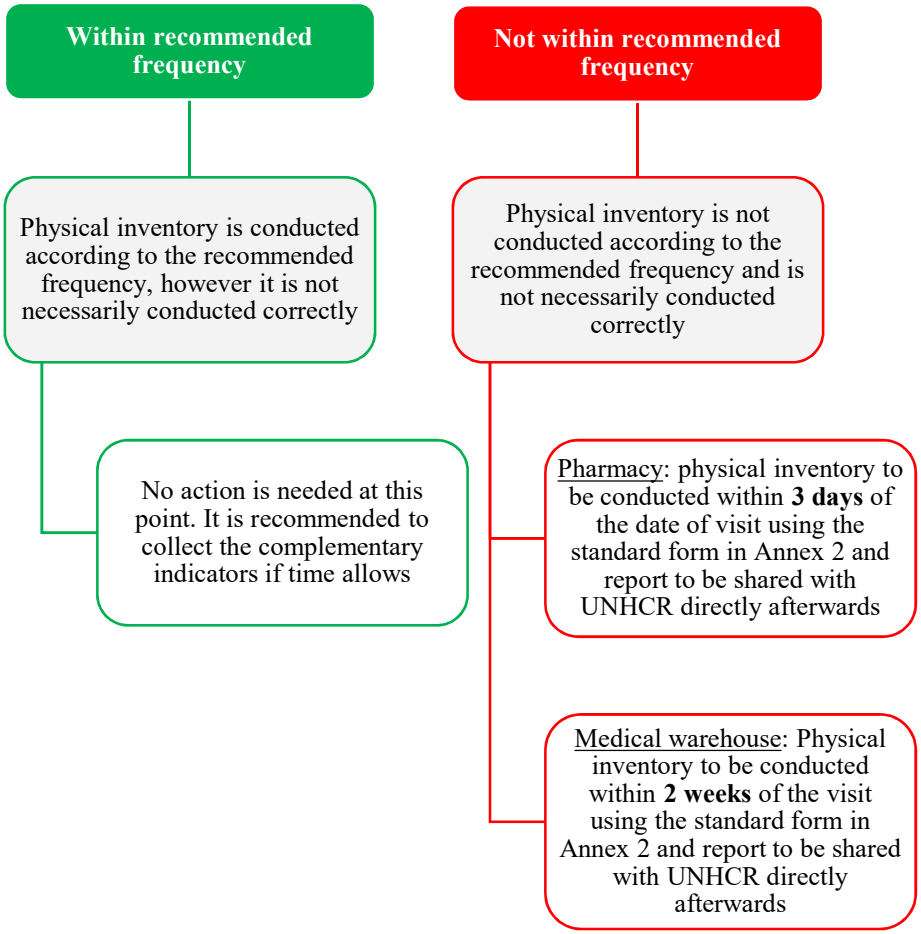
2. Please write the date of the report: dd/mm/year

Note: only write the date if you read it on the report

Objective: to assess if physical inventory is done according to recommended frequency

Collection method: retrospective document review; look to see of the date is written on the physical inventory report

Results:
***Pharmacy**: within one month of date of visit → ✓*
more than one month ago → ✘
***Medical warehouse**: within 6 months of date of visit → ✓*
more than 6 months ago → ✘



Complementary Indicators

3. Components of the physical inventory report:

Date of inventory	Yes ☐	No ☐
Health center	Yes ☐	No ☐
Drug name (generic)	Yes ☐	No ☐
Strength	Yes ☐	No ☐
Dosage form	Yes ☐	No ☐
Basic unit	Yes ☐	No ☐
Batch number	Yes ☐	No ☐
Expiry date	Yes ☐	No ☐
Quantity counted	Yes ☐	No ☐
Quantity on stock card	Yes ☐	No ☐
Difference	Yes ☐	No ☐
Justification	Yes ☐	No ☐
Two signatures	Yes ☐	No ☐

Note: Each of the "drug name", "batch number", "expiry date", "quantity counted", "quantity in stock card", "difference", and "justification" represent a ***column*** *on the physical inventory report*

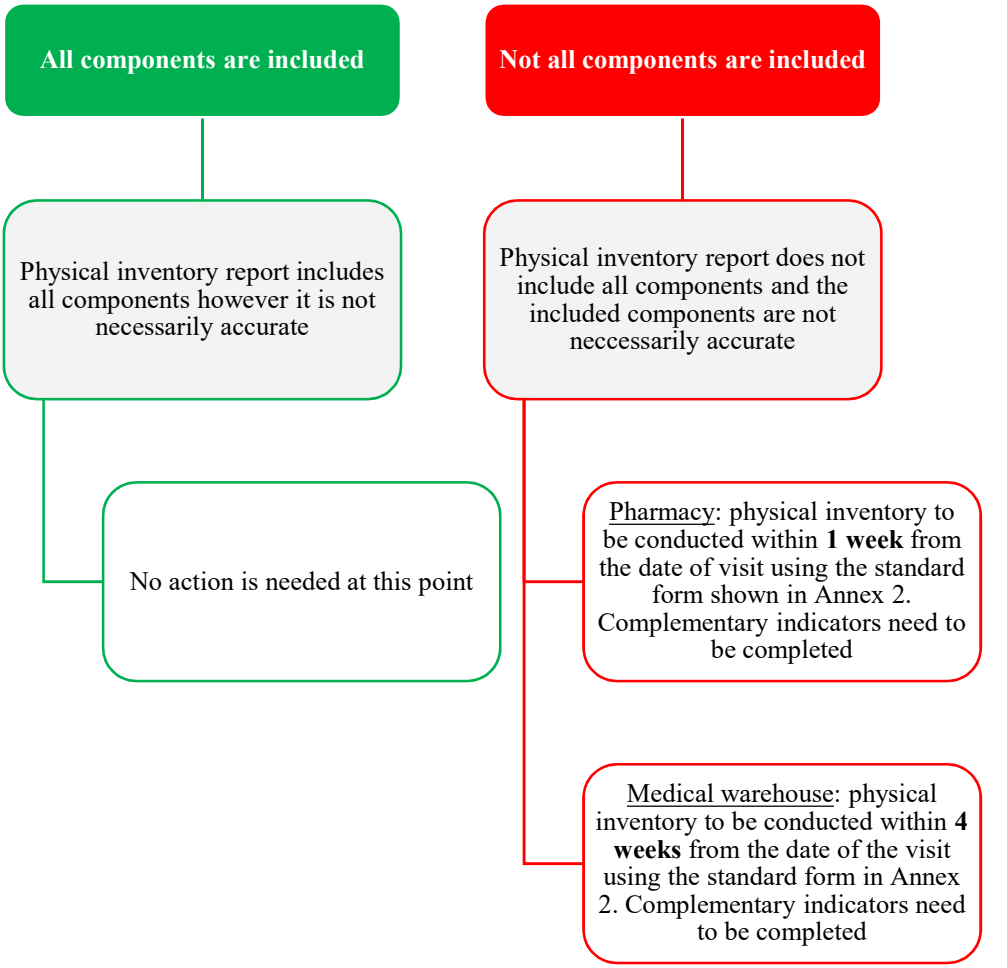
Objective: to assess if the components of the physical inventory report are complete

Collection method: retrospective document review; review the physical inventory report to see the components present

Results:
For each component

Yes → ✓

No → ✘



It is highly recommended to pay close attention to the "difference" column. If the difference is "0" for all items, this should raise suspicion. A difference of "0" is usually too good to be true. It is likely that the physical count is being edited to match the stock count according to the stock cards. You can monitor the difference during the next visit. For pharmacies, if the difference is "0" for 2-3 consecutive visits, a more in-depth assessment should be conducted. For medical warehouses, a difference of "0" should trigger a more in-depth assessment from the first visit. Slight differences are always expected due to human error or discarded medications (i.e. broken ampoules), that is why a difference of "0" for ALL items is highly suspicious.

4. Please write the number of drugs on the physical inventory form:

Note: This indicator is linked to Question number 9 under "Stock cards". You need to complete both to meet the objective of the indicators

Objective: to assess if the number of drugs on the physical inventory report matches the number of drugs with a stock card (collected from another indicator)

Collection method: retrospective document review; count the drugs on the physical inventory report

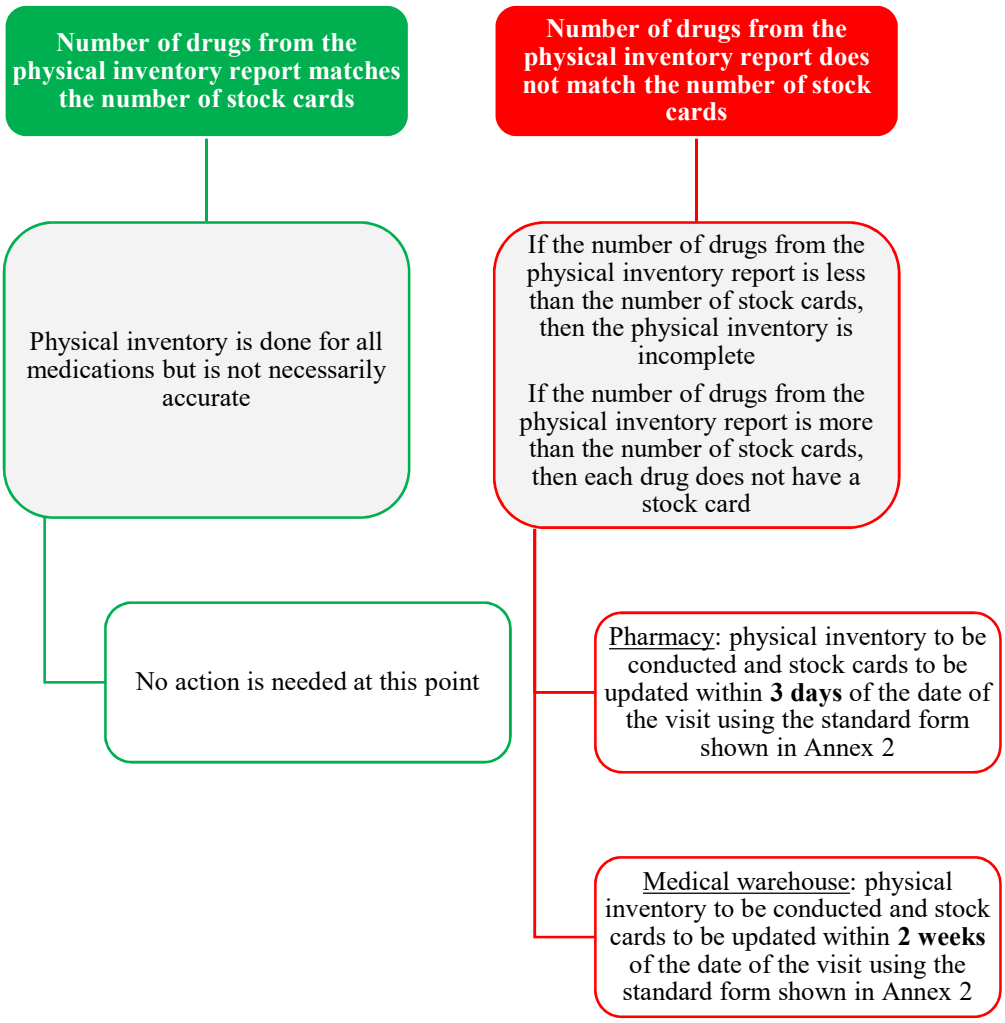
Results:

Number of drugs from the physical inventory report matches with number of stock cards → ✓

Number of drugs from physical inventory report does not match with number of stock cards → ✘

If # on physical inventory < # of stock cards ⇨ *physical inventory is incomplete*

If # on physical inventory > # of stock cards ⇨ *not every drug has a stock card*



In addition, further investigation is needed:
1. Request the implementing partner to send a written justification for the discrepancy
2. Compare the physical inventory report with the stock cards to see which medications are missing
3. Document the name of the medications and make random checks on those medications during upcoming visits

5. Is the physical inventory report filled on a standard form?

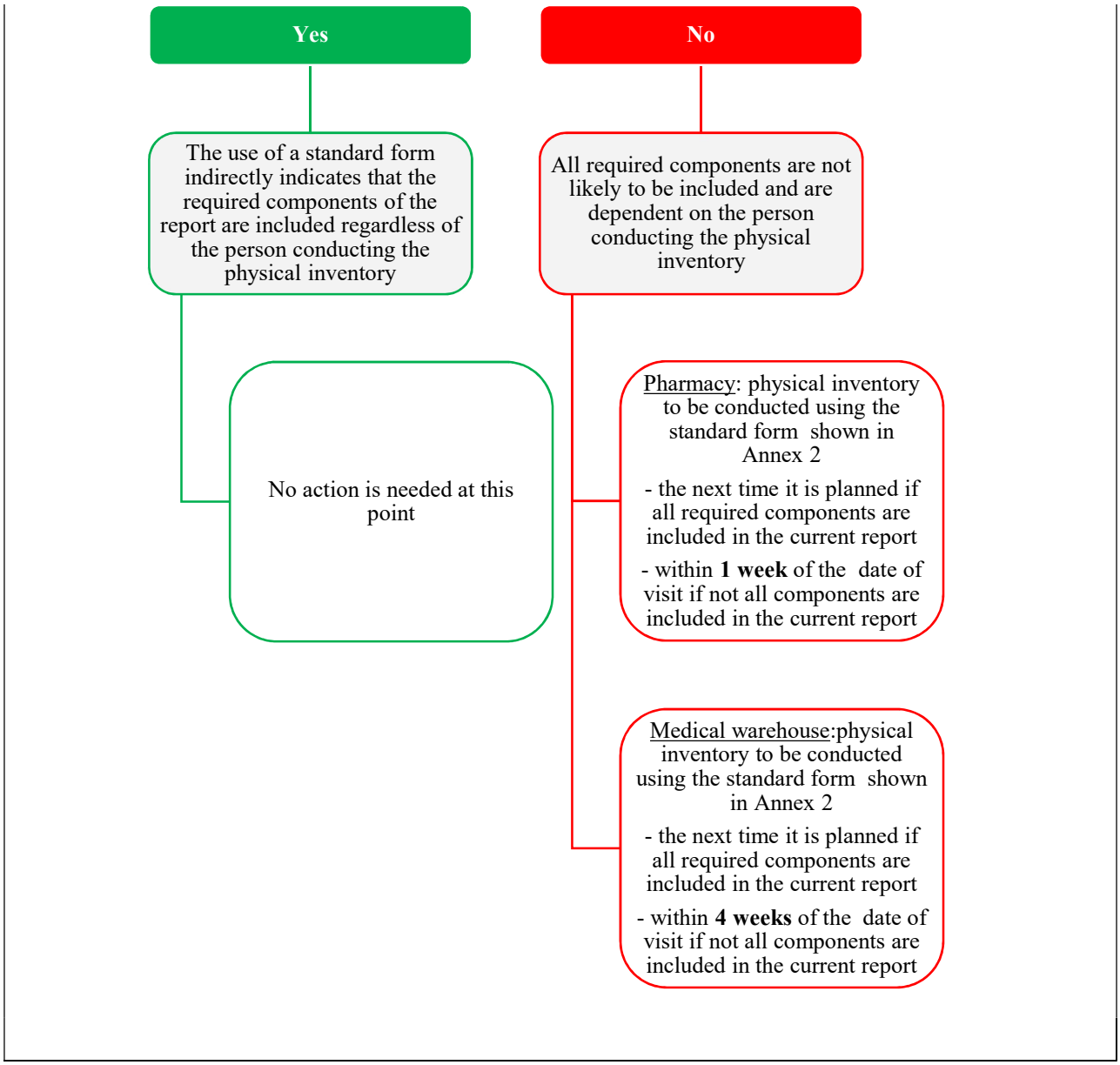
Yes ☐ No ☐

Objective: to assess if the components included in the physical inventory report are standardized over time and among staff conducting physical inventory.

Collection method: retrospective document review; look at the physical inventory report to see if it is filled on a standard form

Results:

Yes → ✓
No → ✗


Yes
No
The use of a standard form indirectly indicates that the required components of the report are included regardless of the person conducting the physical inventory
All required components are not likely to be included and are dependent on the person conducting the physical inventory
No action is needed at this point
Pharmacy: physical inventory to be conducted using the standard form shown in Annex 2
- the next time it is planned if all required components are included in the current report
- within 1 week of the date of visit if not all components are included in the current report
Medical warehouse:physical inventory to be conducted using the standard form shown in Annex 2
- the next time it is planned if all required components are included in the current report
- within 4 weeks of the date of visit if not all components are included in the current report

STOCK CARDS

Note: a stock card is a tool for tracking the stock balance where all movement of medications (in and out) are recorded by date. Each drug has a separate stock card.

Core Indicators

6. Are there stock cards or bin cards?

Yes ☐ No ☐

Note: answer yes only if you see the stock cards or bin cards

Stock card: a stock-keeping card that is used to track the stock balance where all movement of medications (issued and received) are recorded by date. Each drug has a separate stock card.

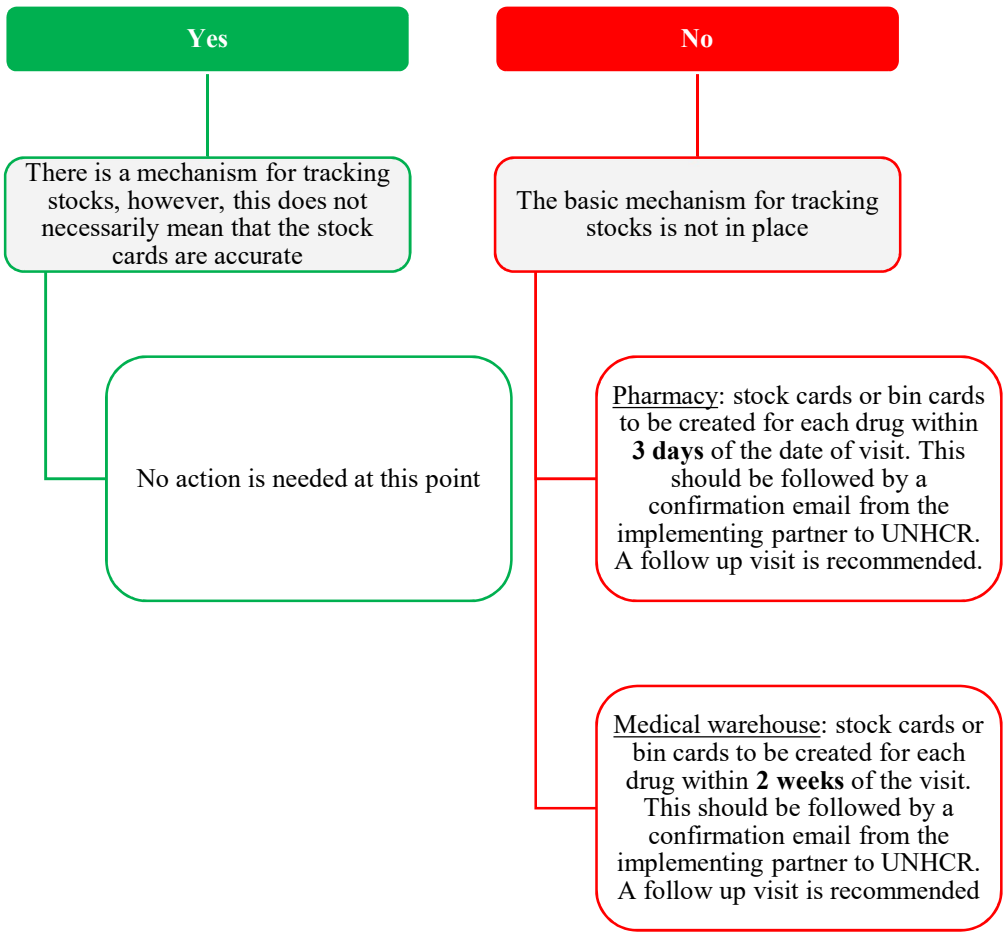
Bin card: a stock card that is physically kept with the stock (MSH, 2012b)

Objective: to assess if stock cards are in place

Collection method: retrospective document review

Results: Yes → ✓

No → ✖



If yes, please go to Question 7

If no, please go to the following section (Drug shortages)

---

7. Are the counts recorded in basic units on the stock card or bin card?

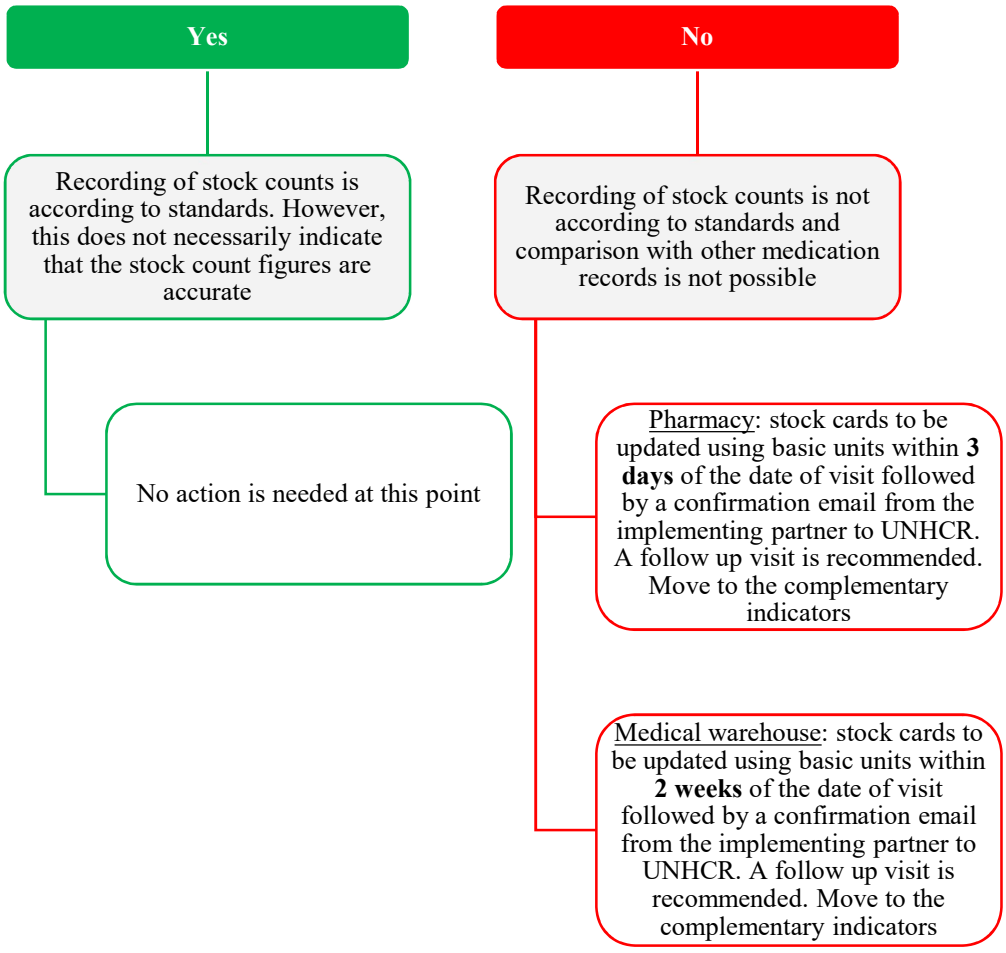
Yes ☐ No ☐

Note: basic unit is the smallest unit of the drug that can be dispensed (i.e. tablet, ampoule, bottle). If stock counts are not recorded in basic units, there is a high risk of recording and counting errors. For example, the same drug could have two different packing sizes (box of 30 tablets and box of 28 tablets), so recording the stock count as number of boxes would result in incorrect total number of tablets. All pharmaceutical calculations and activities are carried out using the basic unit (i.e. quantification, physical inventory, dispensing, ...). It is essential to have the stock count as a basic unit on the stock card to allow comparison with other medication records.

Objective: to assess if accurate recording of stock counts is in place

Collection method: retrospective document review

Results: Yes → ✓
No → ✘



Complementary Indicators

8. Components of the stock card or bin card:

Drug name (generic)	Yes ☐	No ☐
Drug strength	Yes ☐	No ☐
Basic unit	Yes ☐	No ☐
Drug dosage form	Yes ☐	No ☐
Expiry date	Yes ☐	No ☐
Batch number	Yes ☐	No ☐
Minimum stock level	Yes ☐	No ☐
Date	Yes ☐	No ☐
Received from	Yes ☐	No ☐

Quantity received (IN)	Yes ☐	No ☐
Issued to	Yes ☐	No ☐
Quantity issued (OUT)	Yes ☐	No ☐
Stock balance	Yes ☐	No ☐
Remarks	Yes ☐	No ☐
Signature	Yes ☐	No ☐

Objective: to assess if the components of the stock card are included

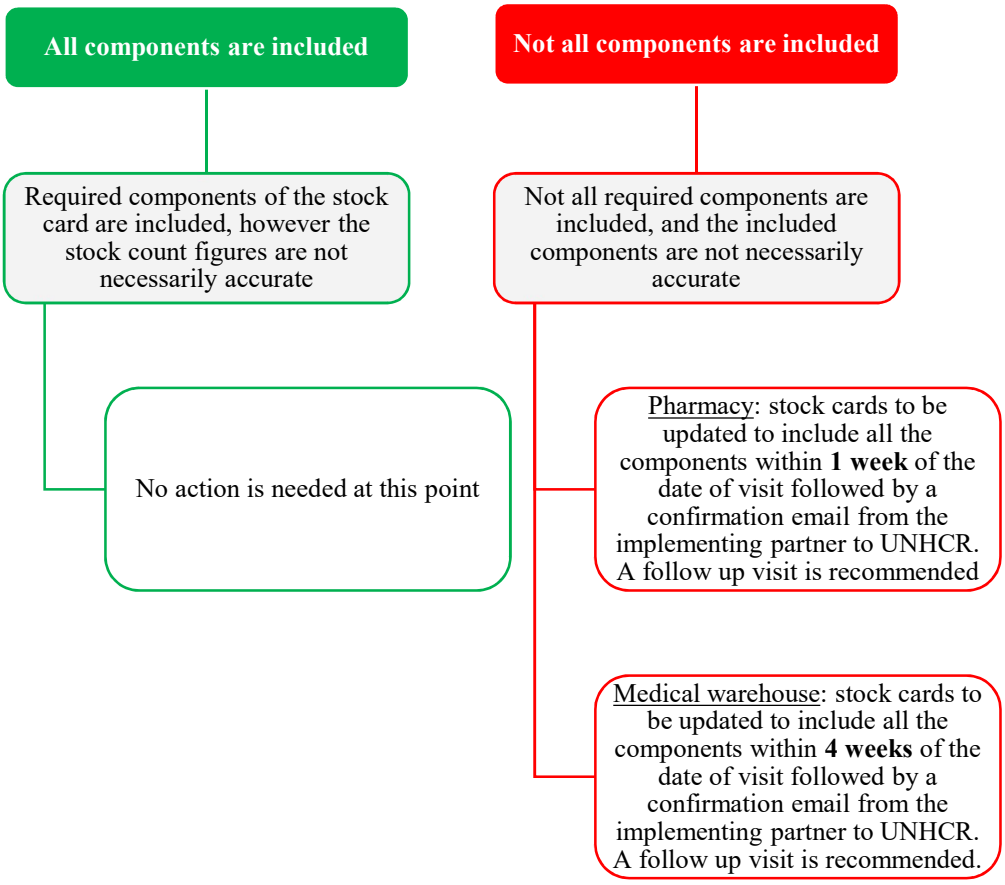
Collection method: retrospective document review; choose one stock card randomly and review it to see the components present

Results:

For each component

Yes → ✓

No → ✘



9. How many stock cards or bin cards are there?

Note: This indicator is linked to Question number 4 under "Physical Inventory". You need to complete both to meet the objective of the indicator

Objective: to assess if the number stock cards matches the number of drugs on the physical inventory report (collected from another indicator)

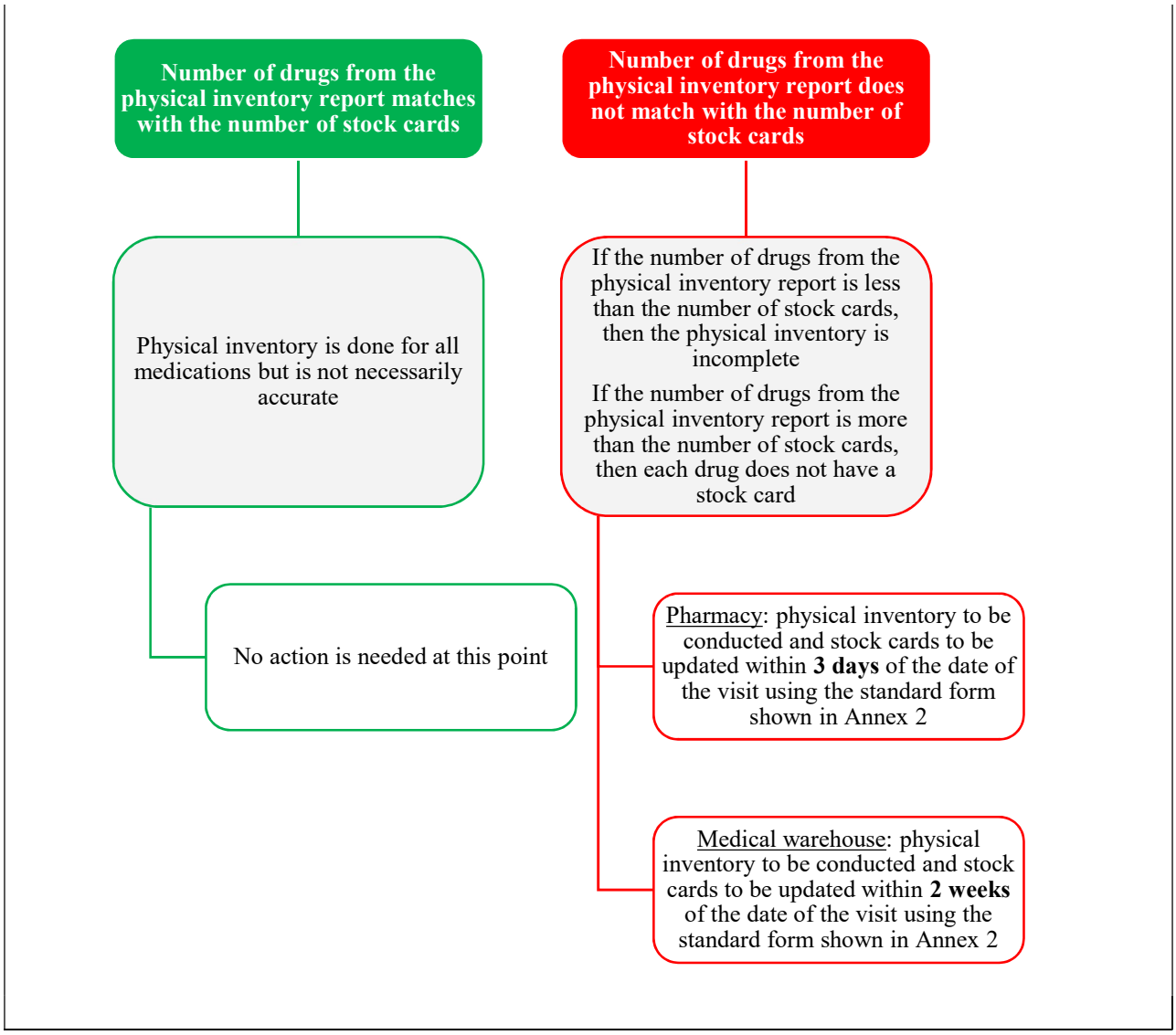
Collection method: retrospective document review; please count the stock cards or ask the in-charge to do so

Results: Yes → ✓

No → ✘

If # on physical inventory < # of stock cards ⇨ *physical inventory is incomplete*

If # on physical inventory > # of stock cards ⇨ *not every drug has a stock card*


Number of drugs from the physical inventory report matches with the number of stock cards
Number of drugs from the physical inventory report does not match with the number of stock cards
Physical inventory is done for all medications but is not necessarily accurate
If the number of drugs from the physical inventory report is less than the number of stock cards, then the physical inventory is incomplete
If the number of drugs from the physical inventory report is more than the number of stock cards, then each drug does not have a stock card
No action is needed at this point
Pharmacy: physical inventory to be conducted and stock cards to be updated within 3 days of the date of the visit using the standard form shown in Annex 2
Medical warehouse: physical inventory to be conducted and stock cards to be updated within 2 weeks of the date of the visit using the standard form shown in Annex 2

DRUG SHORTAGES

Note: this section gives an indication of actual and/or potential stock-outs and/or shortages.

Core Indicators

10. Are the following medications available?

1. Amoxicillin 500mg

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

2. Oral rehydration solution

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

3. Insulin

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

4. Salbutamol

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

5. Glibenclamide

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

6. Diazepam

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

7. Ciprofloxacin

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

8. Simvastatin

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

9. Atenolol/bisoprolol/metoprolol

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

10. Paracetamol

Yes ☐ No ☐

If no, does it have a stock card or a bin card?

Yes ☐ No ☐

If yes, how many days has it been out of stock during the last month according to the stock card?

Answer:

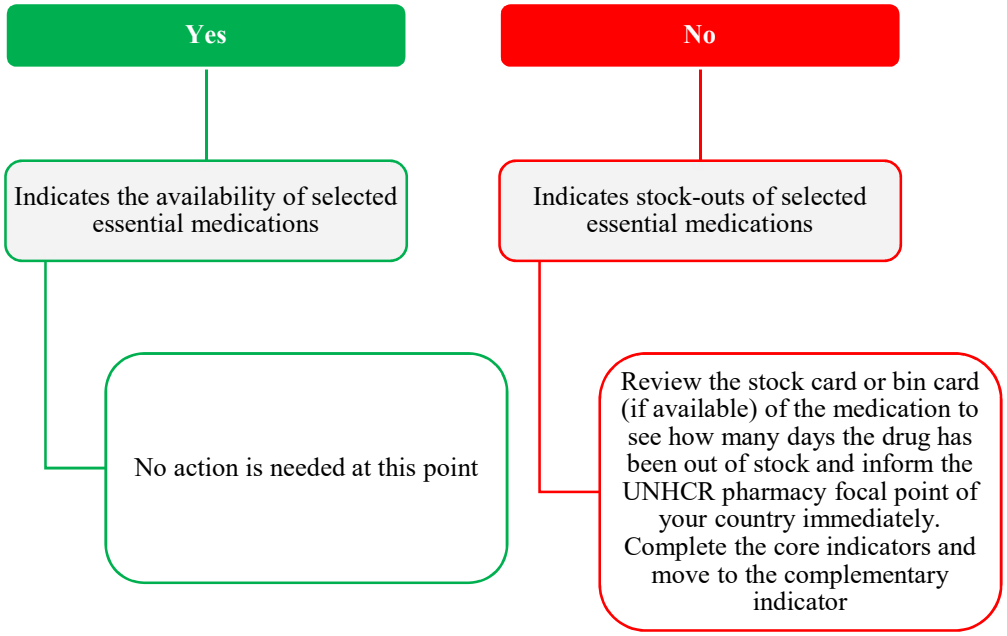
Note: The list of medications can be adapted at country level. The strength needs to be listed at country level according to what is available. It is recommended to include "tracer/index medications"; that are therapeutically important and should be available at all times. The medications listed above are suggestions.

Objective: to assess if critical medications are available

Collection method: observation; only answer yes if you see the medication. You can ask the in-charge to direct you or show you where the medications are located

Results: Yes → ✓

No → ✘



11. Is there an order schedule?

Yes ☐ No ☐

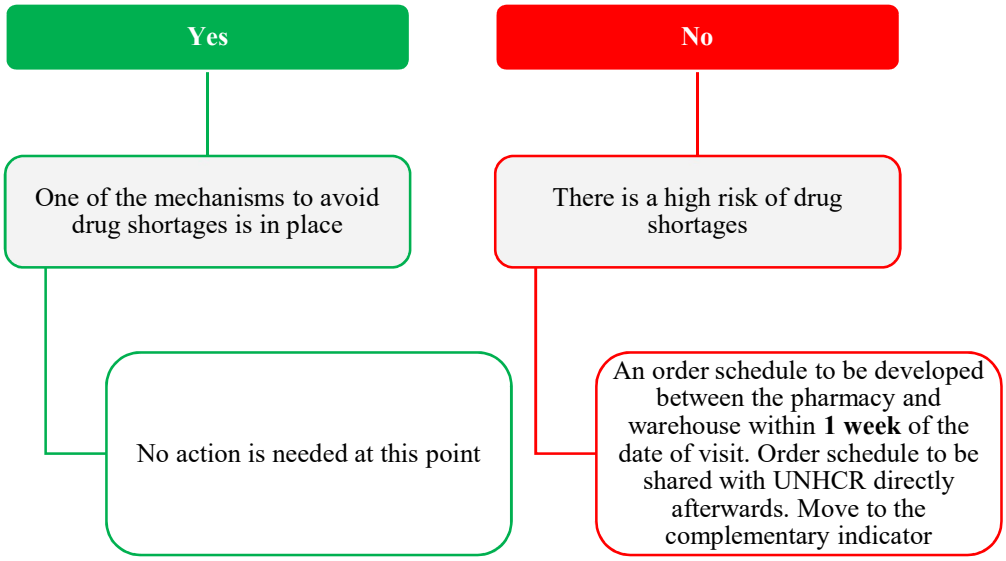
Note: an order schedule is a regular schedule for ordering medications. There is no rule, but medical warehouses usually order medications on an annual or biannual basis, whereas pharmacies usually order on a biweekly or monthly basis.

Objective: to assess if measures are in place to avoid drug shortages and stock-outs

Collection method: key-informant interview/observation; ask the in-charge if there is a defined time-period for ordering medications (i.e. weekly, biweekly, monthly, ...). The order schedule needs to be written and documented.

Results: Yes → ✓

No → ✘



Complementary Indicator

12. Are essential medications available?

Drug Yes ☐ No ☐

Drug Yes ☐ No ☐

Drug Yes ☐ No ☐

Drug Yes ☐ No ☐

…

Note: in order to collect this indicator, you need to take the procurement list with you to the monitoring visit. The procurement list is a list of all medications that were procured by UNHCR and distributed to the implementing partner. It is country specific and is available at UNHCR level.

Alternatively, the list could also be customized and automated on the tablets at country level.

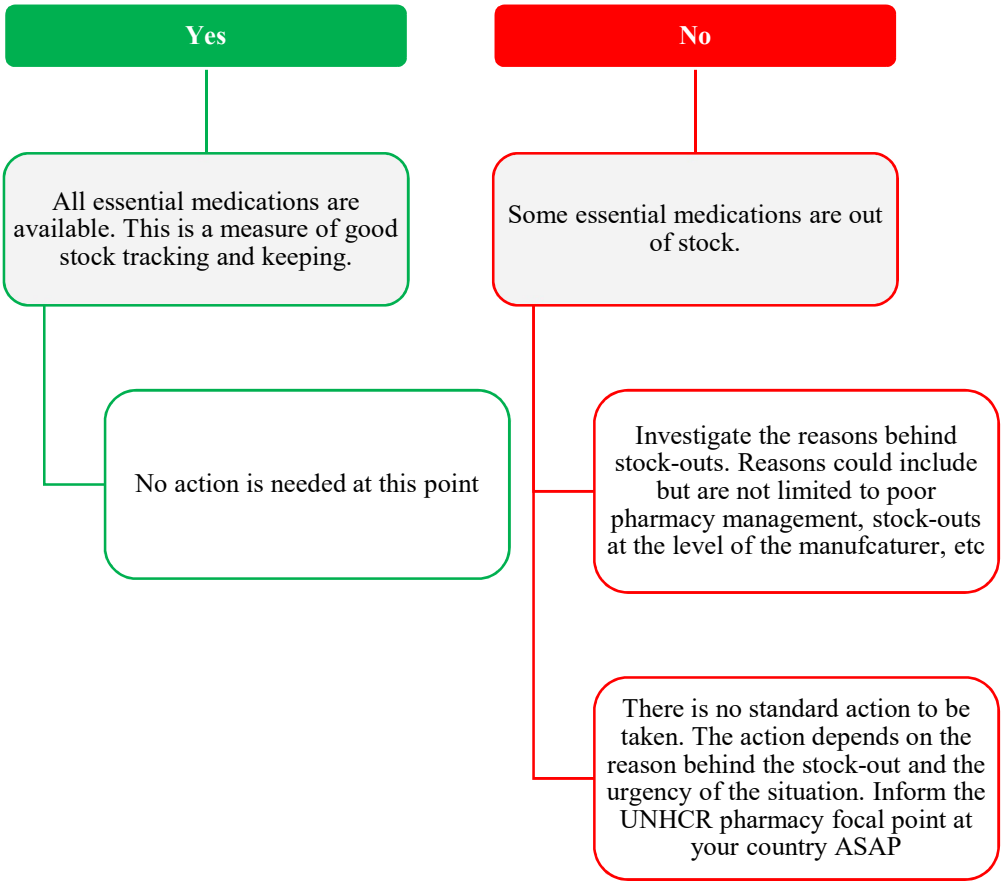
It is highly recommended to collect this indicator when there is suspicion of drug shortages (i.e. complaints from beneficiaries) or when selected essential medications (from the first core indicator) are found to be out of stock

Objective: to assess if all essential medications are available and compare the medications that are available with the medications that should be available according to the procurement list

Collection method: observation; only answer yes if you see the medication. You can ask the in-charge to direct you or show you where the medications are located

Results: Yes → ✓

No → ✘



TRIANGULATION OF STOCK RECORDS AT PHARMACY

***Note**: this section is only applicable to pharmacies and is one of the most important monitoring sections.*

Drugs can be adapted at country level.

To facilitate data collection for this section, drugs selected to be monitored in this section need to be attractive drugs (i.e. expensive) and drugs that are not commonly prescribed and dispensed to patients

The tablet will be automated to randomly select one of the drugs that are suitable for this indictor

Insulin

Ciprofloxacin eye drop

Gabapentin

Morphine

Salbutamol

Beclomethasone

Core Indicators

STEP 1

13. Is there a stock card for drug (x)?

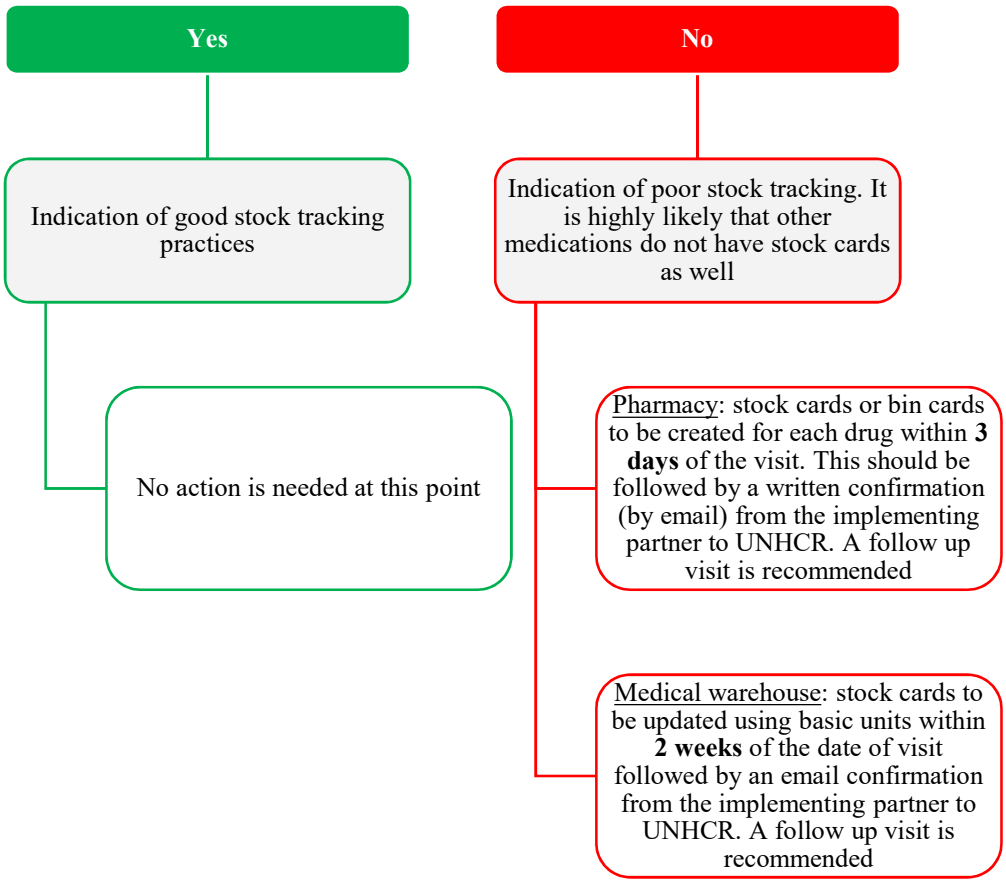
Yes ☐ No ☐

Objective: to compare the stock balance on the stock card to the physical count

Collection method: retrospective document review; ask the in-charge to show you the stock card for drug (x)

Results: Yes → ✓

No → ✘



If yes, go to Question 14

If no, only complete Step 3 of this section

14. What is the stock balance according to the stock card?

Note: results are used in Question 16 of this section

Objective: to compare the stock balance on the stock card to the physical count

Collection method: retrospective document review; ask the in-charge to show you the stock card for drug (x)

Answer:

STEP 2

15. What is the physical count for drug (x) in basic units?

Note: results are used in Question 16 of this section

Objective: to compare the stock balance on the stock card to the physical count

Collection method: observation; count drug (x) in basic units

Answer:

16. Does the stock balance for drug (x) match with the physical count?

Yes ☐ No ☐

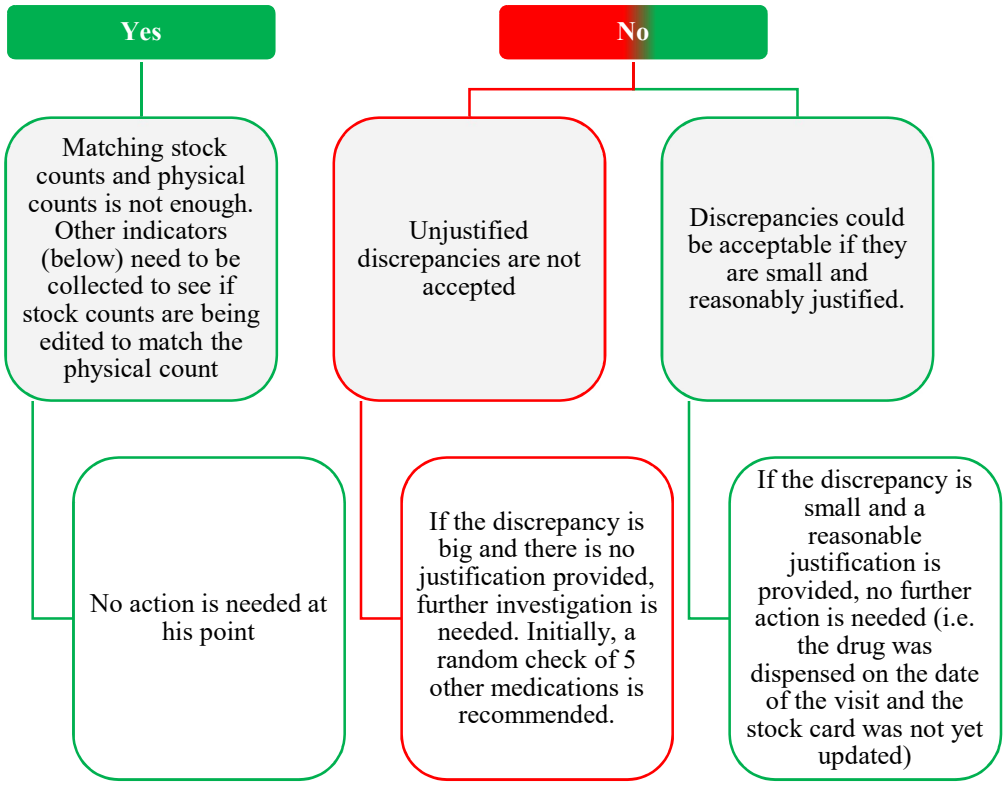
Objective: to assess if stock cards are accurate

Collection method: observation/retrospective document review; compare the stock balance on the stock card with the physical count

Results: Yes → ✓

No → ✘

*****the only acceptable explanation for "no" is that the drug was dispensed on the day of the visit and the stock card was not yet updated for the date of the visit. You can ask the in-charge to show you the dispensing record*



Stock counts and physical counts are expected to match or have small discrepancies with reasonable justifications.
Whenever there are big and unjustified discrepancies, it is recommended to conduct an in-depth assessment as quickly as possible. Any delay in the in-depth assessment could give enough time for the in-charge to edit and make changes to stock counts and physical counts.

If no, please ask the in-charge for justification

Brief justification:

Step 3

17. Does the in-charge know the average monthly consumption (AMC) of drug (x)?

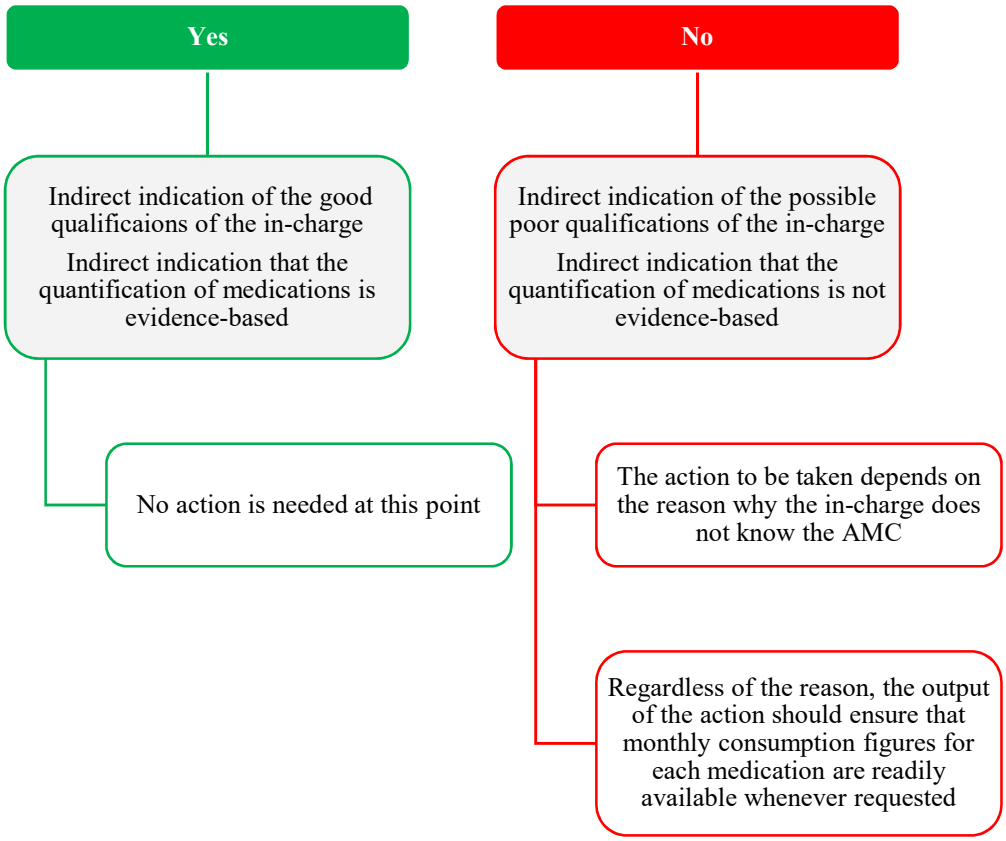
Yes ☐ No ☐

Note: if the in-charge doesn't know, there is a high chance that orders and quantification of drugs are being done arbitrarily indicating potential stock-outs and/or overstock.

Objective: to assess if quantification of drugs is evidence-based and is based on consumption figures. To assess the availability of data that helps in preventing shortages and/or overstock.

Collection method: key-informant interview; ask the in-charge if they know the average monthly consumption of drug (x). Only answer yes if the in-charge goes back to records to retrieve the figure. Do not answer yes if they speculate a number based on memory.

Results: Yes → ✓
No → ✘



If yes, please go to Question 18

If no, please go to Step 4

18. What is the average monthly consumption of drug (x)?

Objective: to calculate stock status in the following question

Collection method: retrospective document review; by the in-charge

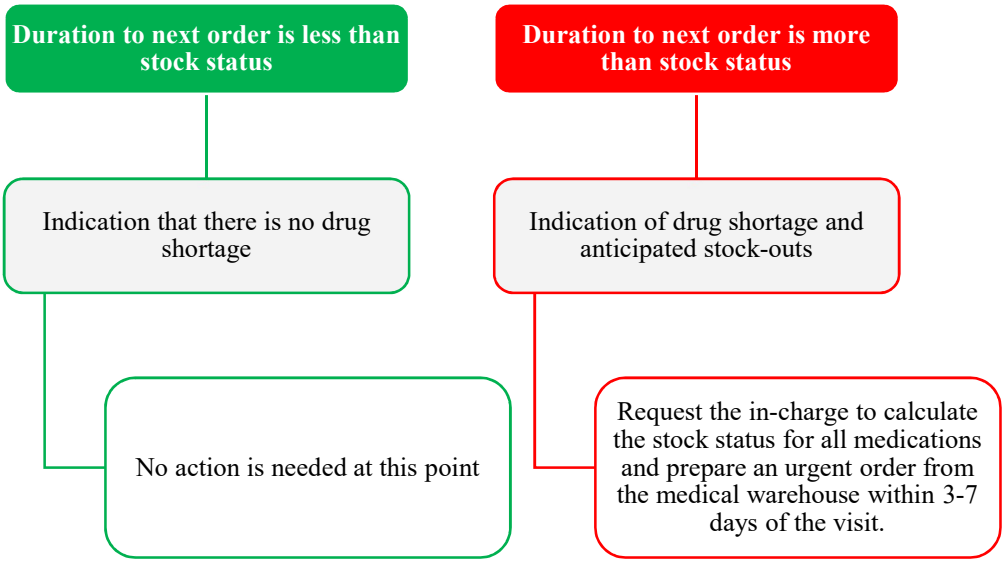
Answer:

19. What is the stock status of drug (x)?

Note: stock status estimates how long the drug will meet the needs of the consumption. Used to estimate overstock or understock

Objective: to assess if there is shortage

Collection method: calculation; for simplification, divide physical count (from Question 15) by the average monthly consumption (from Question 18); stock status= physical count/ AMC



20. What is the expiry date of drug (x)?

Expiry 1: mm/yy

Expiry 2: mm/yy

Expiry 3: mm/yy

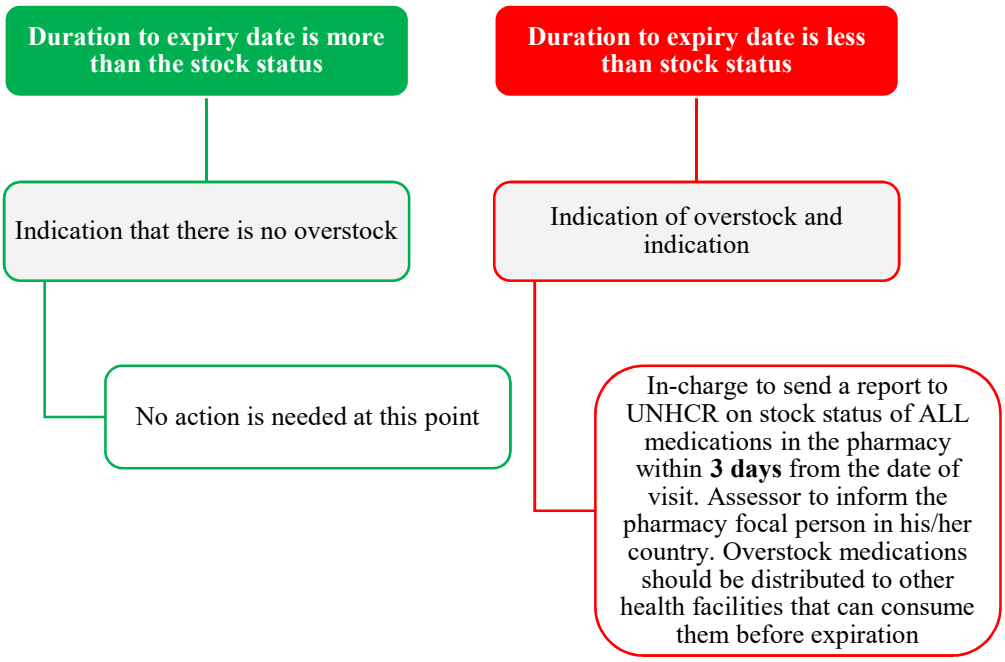
Note: if the drug has more than one expiry, the stock status for each expiry needs to be calculated. OR you could calculate the stock status for the nearest expiry

Objective: to assess if there is overstock; does the drug expire before it can be used

Collection method: observation

Results: if the stock status is more than the time until expiry, there is overstock

if the stock status is less than the time until expiry, there is no overstock



Step 4: from the stock card of drug (x), choose a random date during the last two weeks that has movement (OUT)

21. Write the date you randomly chose: dd/mm/yy

Method of random selection: count the number of days that have a movement out during the last two weeks "quantities issued" on the stock card. Enter this number on the tablet used for data collection in its designated space. The tablet will be designed to randomly select a number between 1 and the number of days counted (the number of days counted will be 14 or less). Starting at the first date to have movement out in the past two weeks, count each date that has a number out until you reach the number of days from the start of the previous two weeks that the tablet randomly selected. That is the date you will use for this step.

22. Does the pharmacy have a dispensing record?

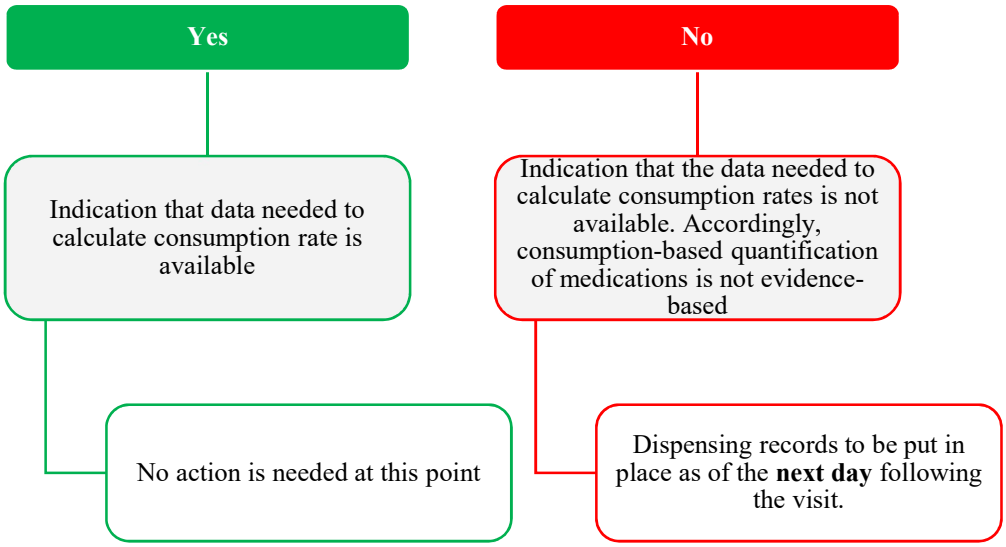
Yes ☐ No ☐

Objective: to assess if the pharmacy keeps track of medications dispensed. To assess if the information needed to calculate the average monthly consumption is available

Collection method:

Results: Yes → ✓

No → ✖



If yes, please go to Question 23

If no, please skip this section

---

23. From the dispensing record, was drug (x) dispensed on the date you chose in question 21?

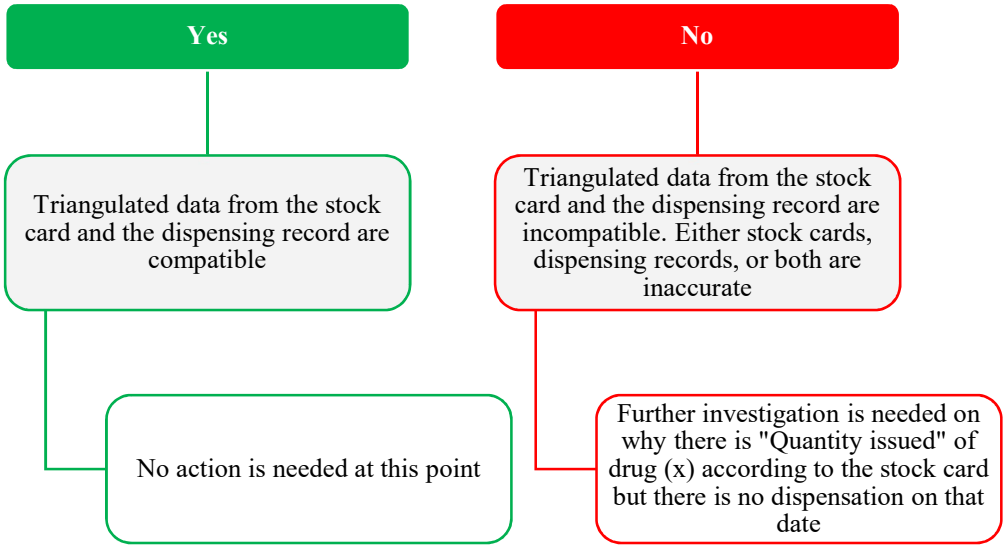
Yes ☐ No ☐

Objective: to assess if there was movement "out" as indicated on the stock card

Collection method: retrospective document review

Results: Yes → ✓

No → ✖



If yes, please go to Question 24

If no, please skip this section

---

24. Are there prescriptions on the chosen date for drug (x)?

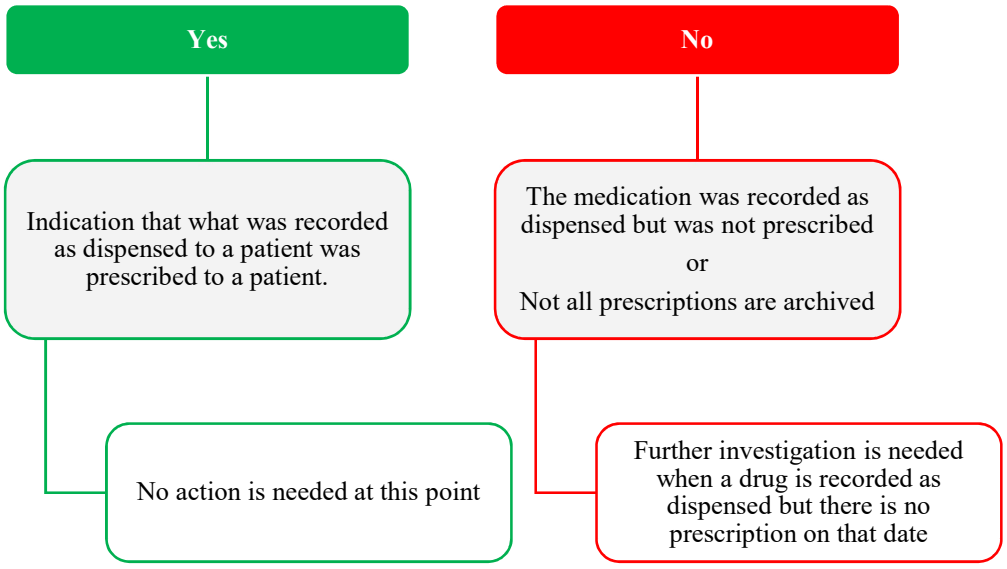
Yes ☐ No ☐

Objective: to assess if stock movement (OUT) is consistent with prescriptions

Collection method: retrospective document review; ask the in-charge to go through the prescriptions for that date and set aside each prescription that has drug (x)

Results: Yes → ✓

No → ✘



If yes, please go to Question 25

If no, please skip this section

---

25. Is the full name of the patient written on each drug (x) prescription?

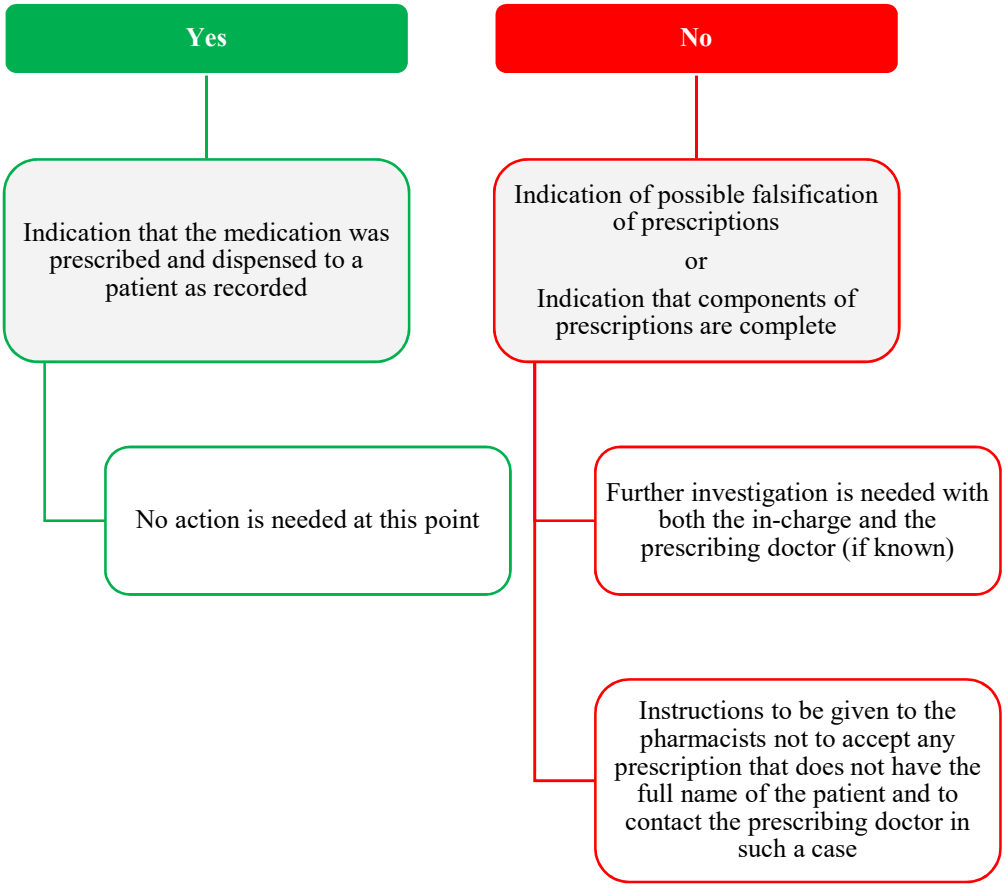
Yes ☐ No ☐

Objective: to assess potential falsification of prescriptions

Collection method: retrospective document review; review the prescriptions of drug (x) to see if the full name of the patient is written on each prescription

Results: Yes → ✓

No → ✘



26. Is the name/signature of the prescribing doctor written on each prescription?

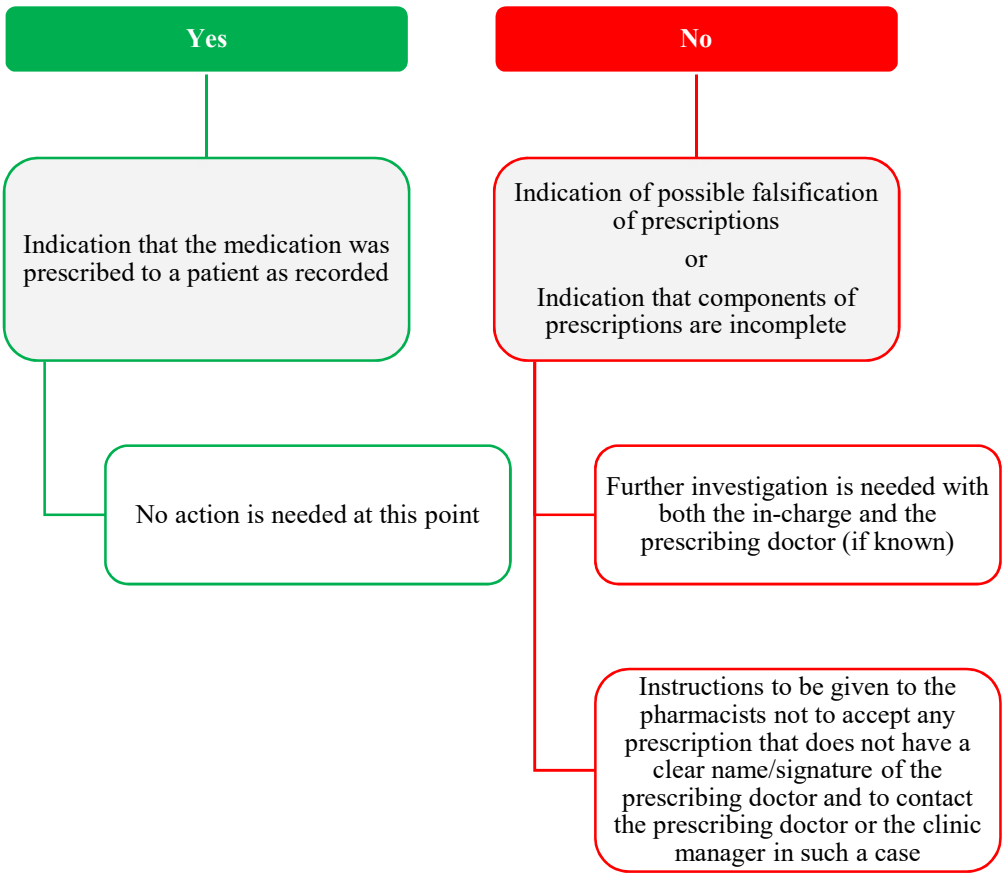
Yes ☐ No ☐

Objective: to assess potential falsification of prescriptions

Collection method: retrospective document review; review the prescriptions of drug (x) to see if the name of the prescribing doctor is written on the prescription

Results: Yes → ✓

No → ✘



Complementary Indicator

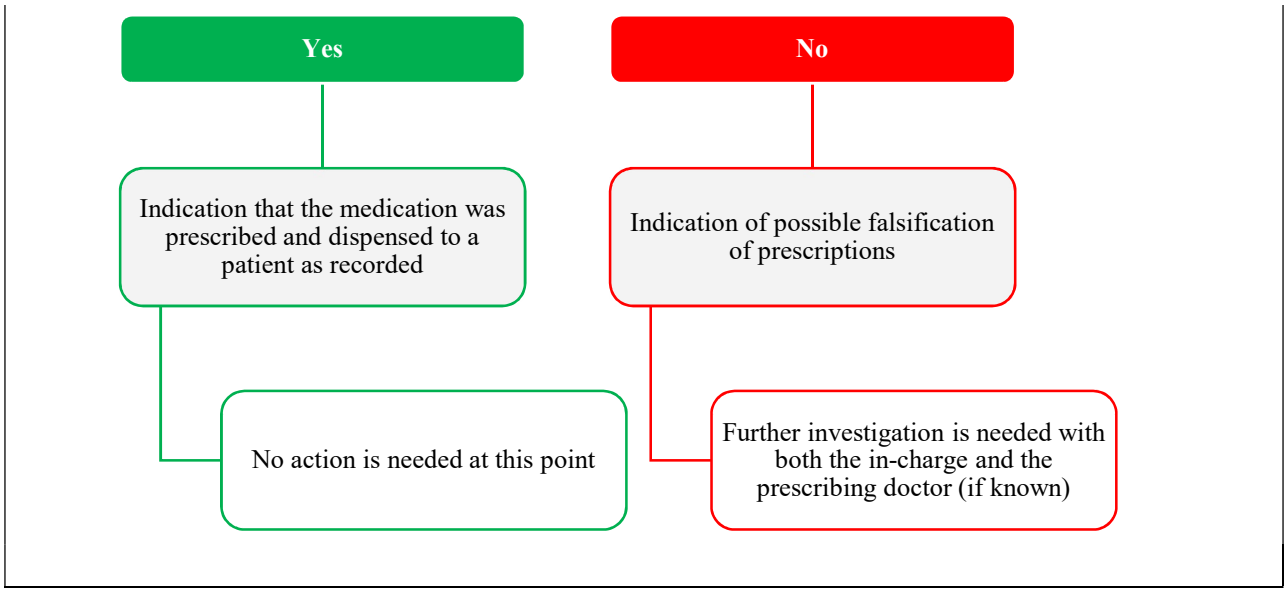
27. After field visit, verify if each patient received drug (x) on that date

Note: you can ask the health facility for the phone number of the patient if it is not available, you can ask for the UNHCR ID. If not available, make sure to document the full name of the patient. You can use the full name or the UNHCR ID to retrieve the contact information from proGres

Objective: to assess if the drug was actually dispensed to the patient

Collection method: phone-interview; contact the patient and ask if he/she received drug (x) and when.

Results: Yes → ✓
No → ✘


Yes
No
Indication that the medication was prescribed and dispensed to a patient as recorded
Indication of possible falsification of prescriptions
No action is needed at this point
Further investigation is needed with both the in-charge and the prescribing doctor (if known)

PHYSICAL ARRANGEMENT

Core Indicators

28. Are there shelves and/or pallets?

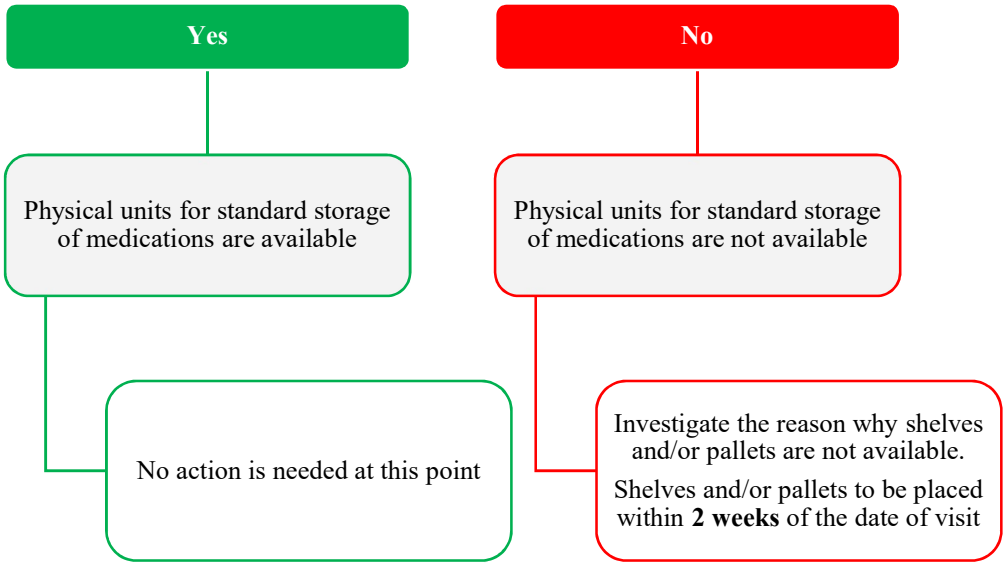
Yes ☐ No ☐

Note: pharmacies should have shelves and/or pallets

Objective: to assess the physical layout of the pharmacy

Collection method: observation

Results: Yes → ✓
No → ✘



29. Are there any medication boxes on the floor?

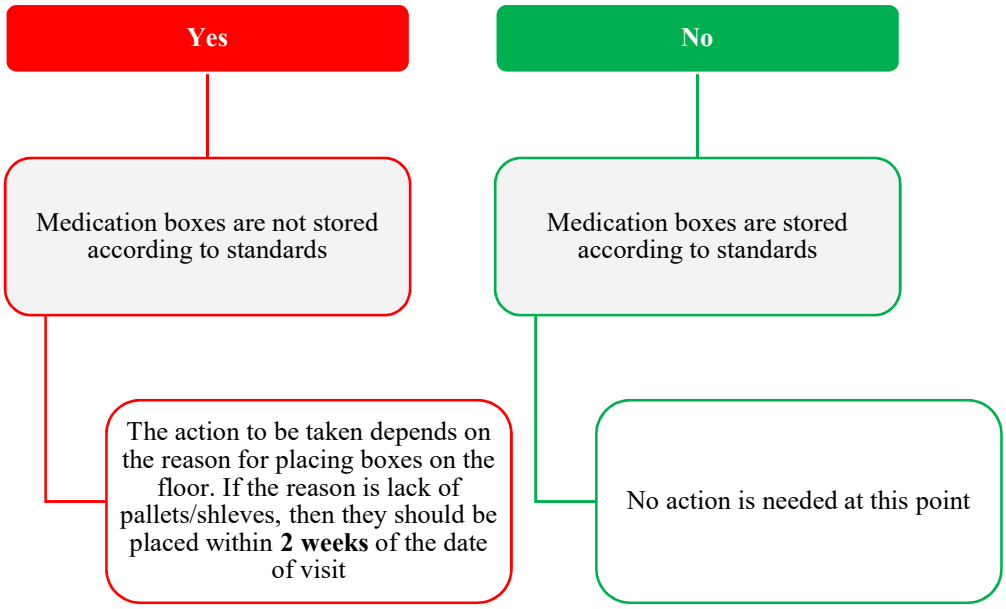
Yes ☐ No ☐

Note: no medications or medication boxes should be placed directly on the floor

Objective: to assess physical arrangement of medications

Collection method: observation

Results: Yes → ✘
No → ✓



30. Is there a label on the shelves/pallets for each medication?

Yes ☐ No ☐

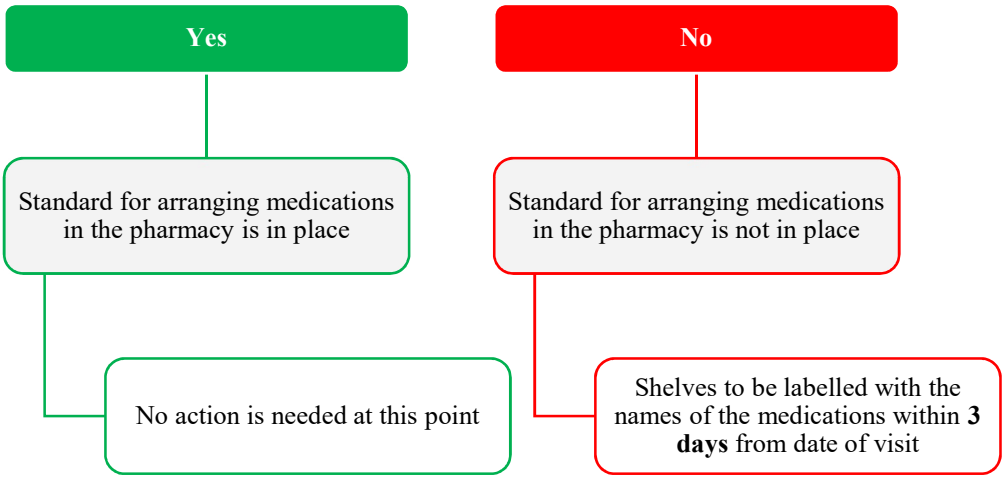
Note: each medication in the pharmacy should have a label on the shelf where the medication is located. Labels ease finding the medications in the pharmacy, reduce dispensing error, and indicate stock-outs when the space of shelf behind a label is empty.

Objective: to assess organization of medications on shelves

Collection method: observation

Results: Yes → ✓

No → ✘



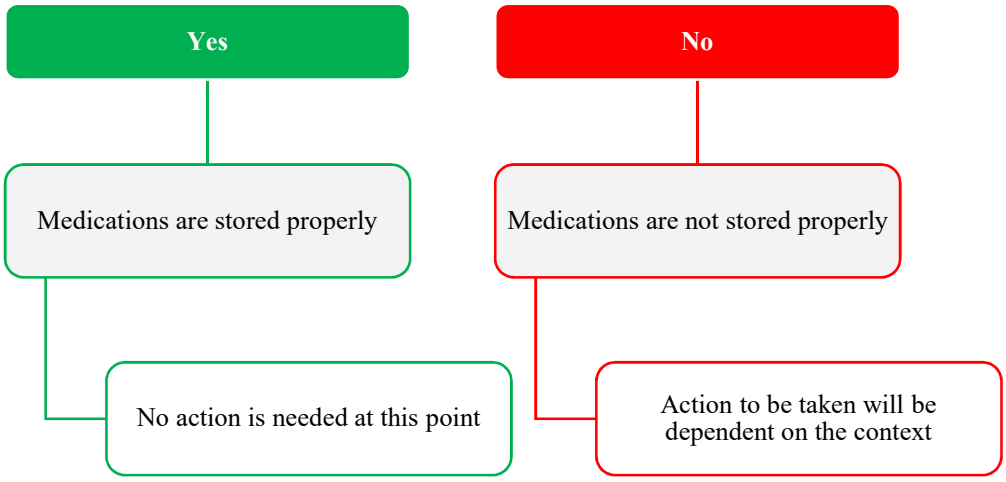
31. Are medications stored in a clean, ventilated, and free of pests area?

Yes ☐ No ☐

Objective: to assess quality of storage area

Collection method: observation

Results: Yes → ✓
No → ✖



TEMPERATURE CONTROL

Core Indicators

32. Is there a temperature record?

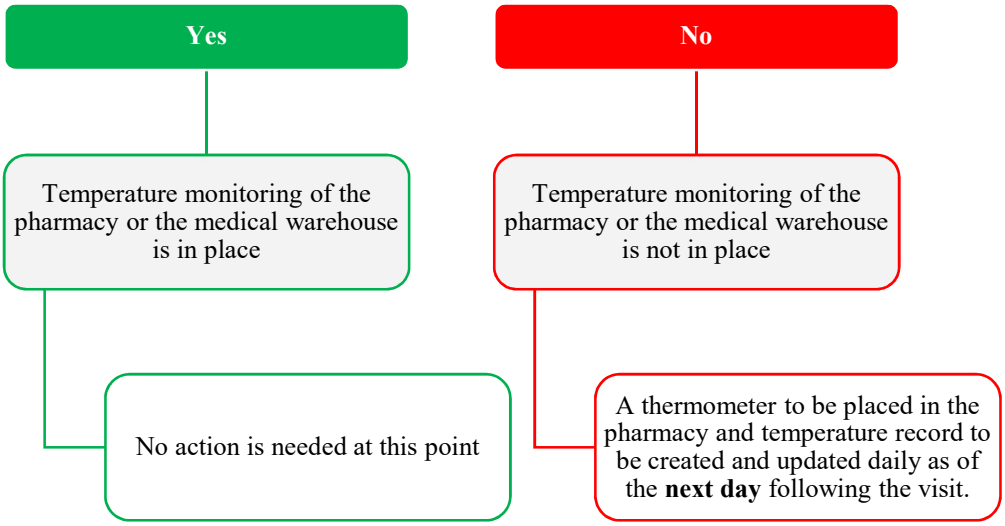
Yes ☐ No ☐

Note: a temperature log/record is the record of temperature monitoring in places where drugs are stored at the pharmacy or medical store/warehouse

Objective: to assess if basic quality control measures are in place

Collection method: observation

Results: Yes → ✓
No → ✗



If yes, please go to Question 33

If no, please go to Question 34

---

33. Is the temperature kept below 30ºC according to the temperature record on the day of the visit?

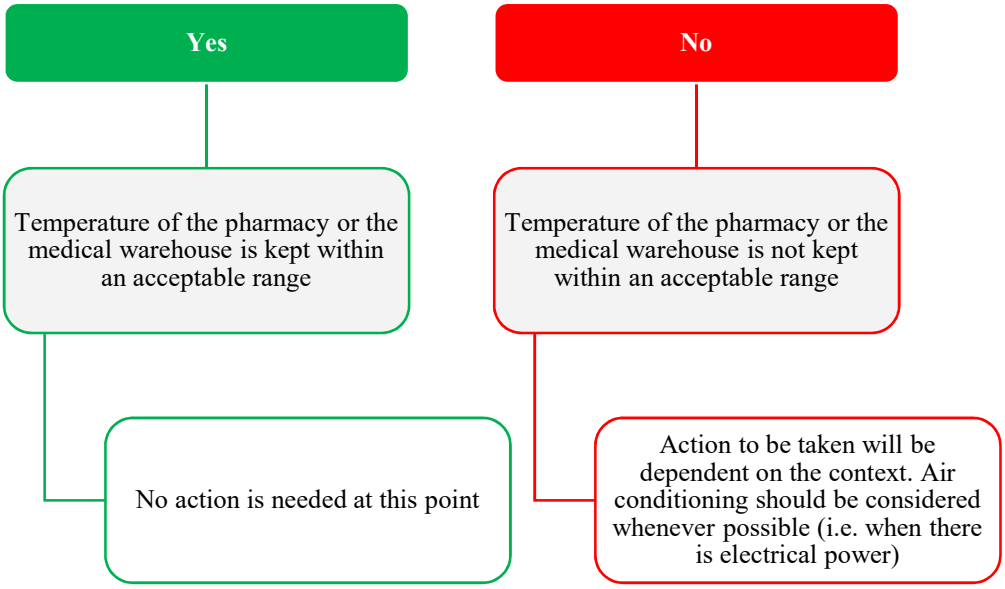
Yes ☐ No ☐

Objective: to assess if the storage temperature is acceptable

Collection method: retrospective document review

Results: Yes → ✓

No → ✘



34. Is there a refrigerator?

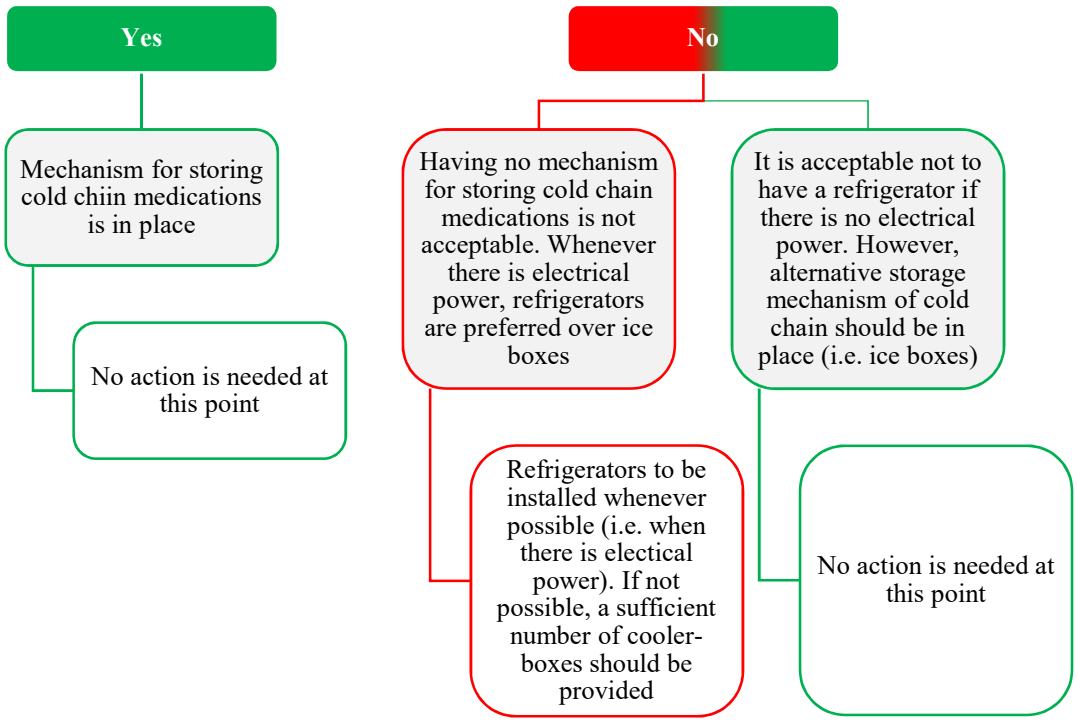
Yes ☐ No ☐

Objective: to assess how medications that require cool storage are stored

Collection method: observation

Results: Yes → ✓

No → ✘



35. Does the pharmacy/medical warehouse have cooler-boxes?

Yes ☐ No ☐

Objective:

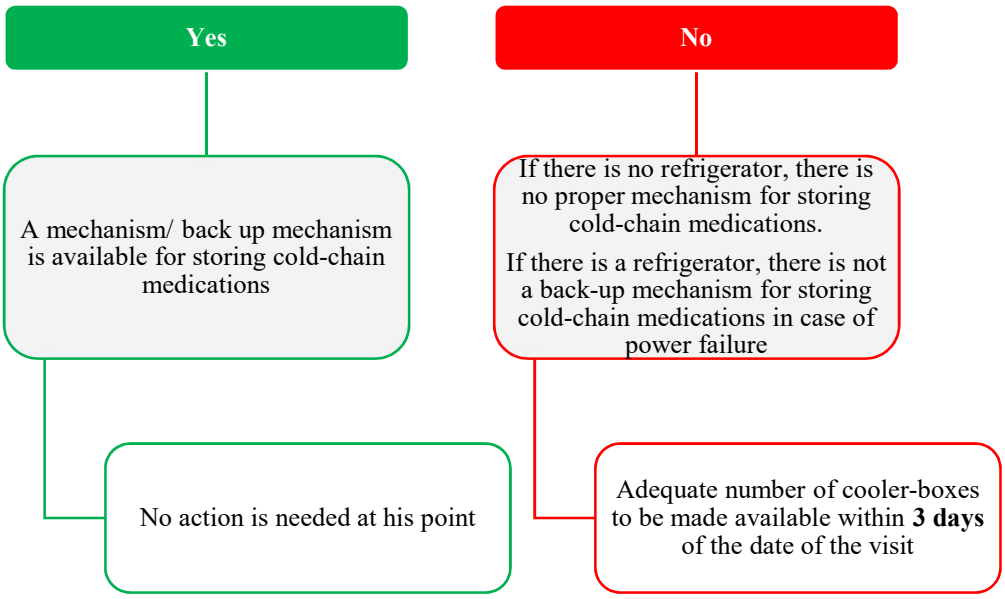
For sites that have no refrigerator or power: to assess if there is a proper cold storage mechanism

For sites that have a refrigerator: to assess if there is a contingency plan in case of power failure

Collection method: observation

Results: Yes → ✓

No → ✘



36. Is there a temperature record for the refrigerator or the cooler-box?

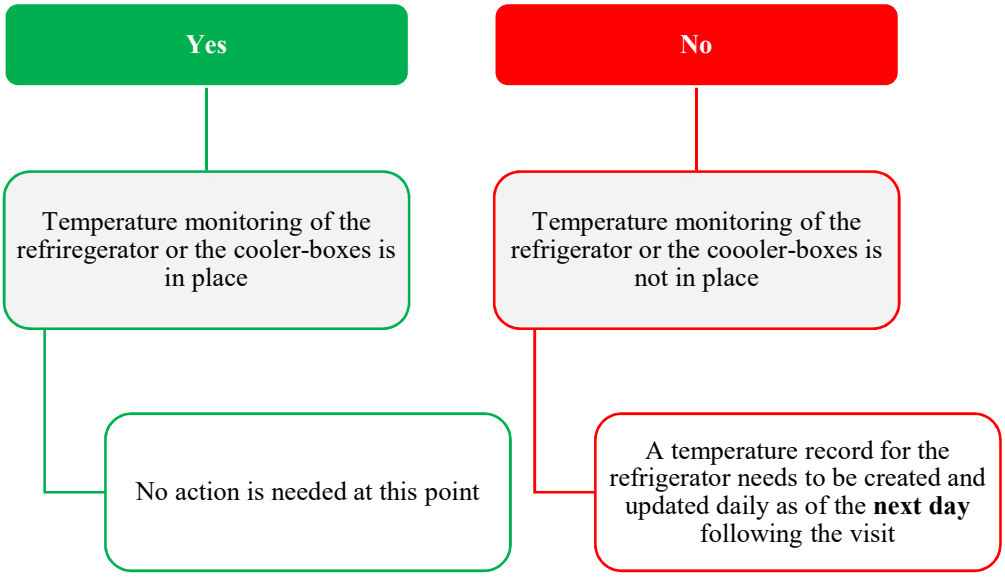
Yes ☐ No ☐

Objective: to assess if the temperature of the refrigerator is monitored

Collection method: observation

Results: Yes → ✓

No → ✘



37. What is the range of refrigerator/cooler-box temperature according to the temperature record on the day of the visit?

Minimum:

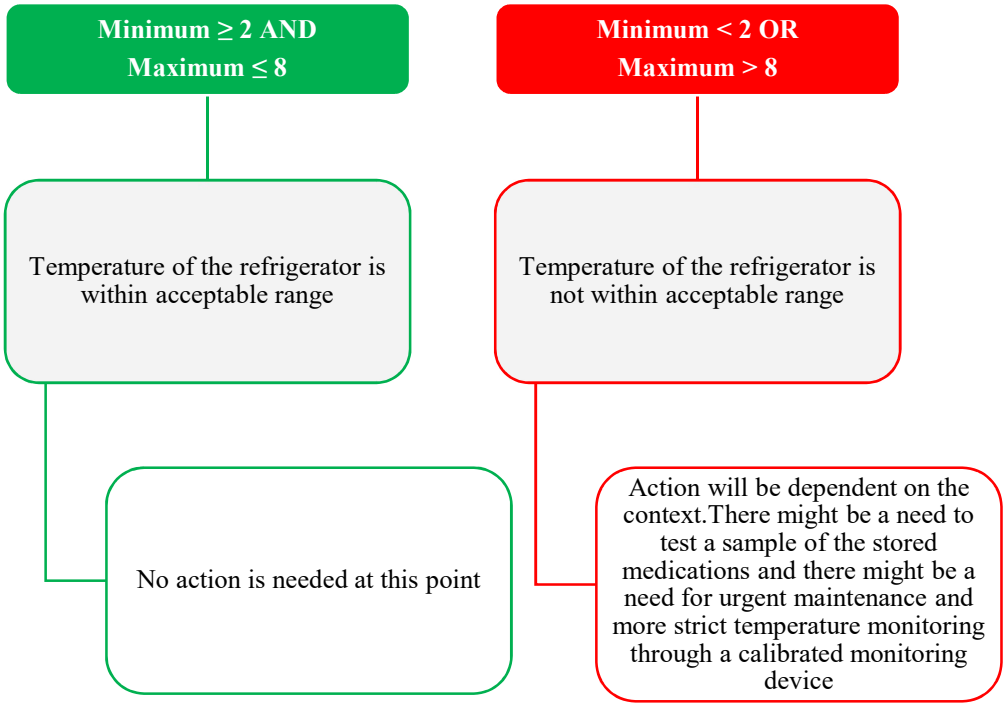
Maximum:

Objective: to assess if temperature range is acceptable

Collection method: retrospective document review

Results: Minimum → ≥ 2°C

Maximum → ≤ 8°C



38. Are there enough cooler-boxes to store the cold-chain medications?

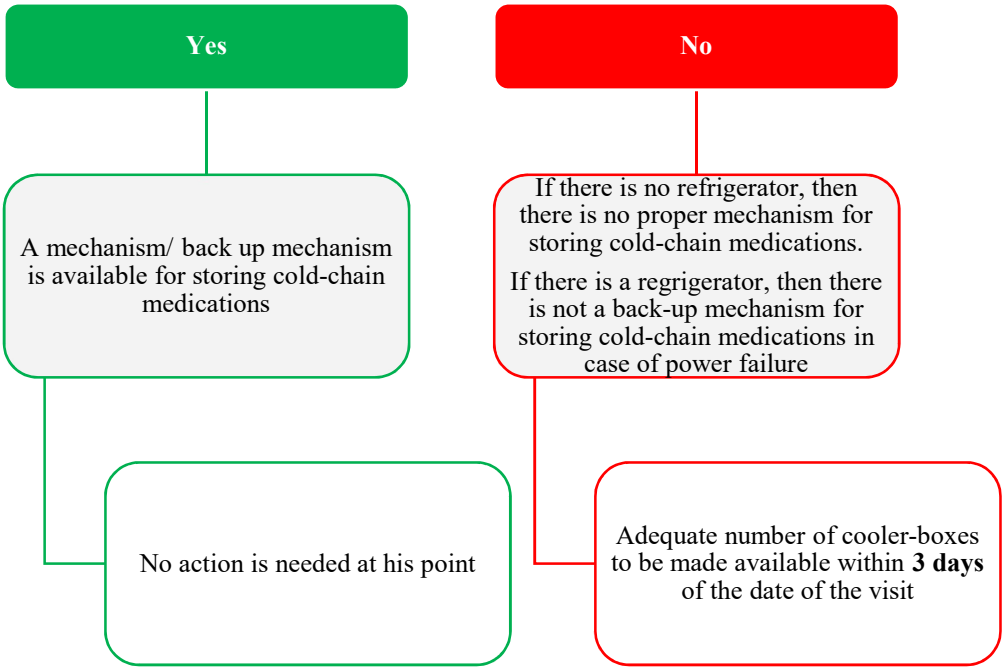
Yes ☐ No ☐

Objective: to assess if there are enough cooler-boxes to store cold-chain medications

Collection method: key-informant interview; ask the in-charge whether the cooler-boxes available are sufficient to store cold chain medications

Results: Yes → ✓

No → ✘



39. Are there enough ice-packs per each available cooler-box?

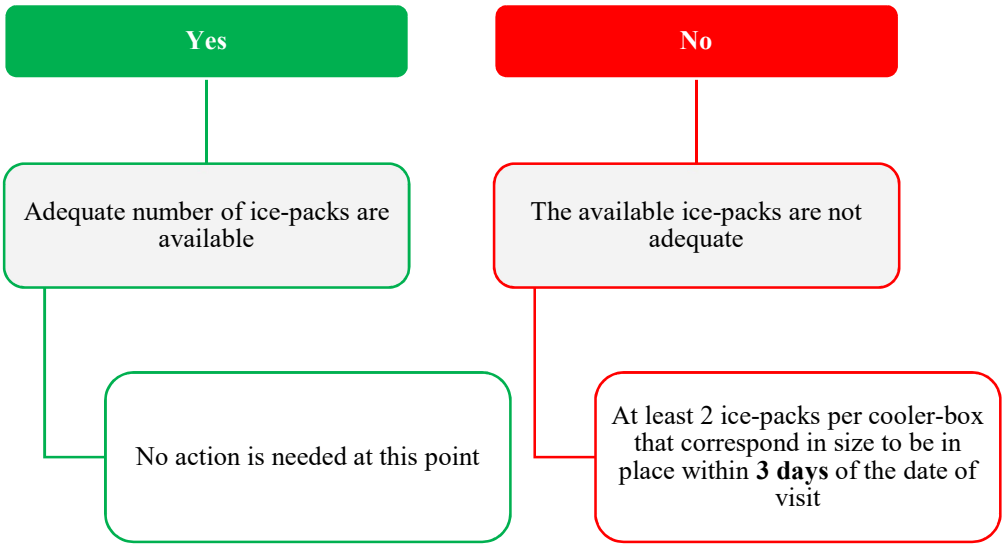
Yes ☐ No ☐

Objective: to assess if there are enough ice-packs per cooler-box

Collection method: observation

Results: Yes → ✓

No → ✘


Yes
No
Adequate number of ice-packs are available
The available ice-packs are not adequate
No action is needed at this point
At least 2 ice-packs per cooler-box that correspond in size to be in place within **3 days** of the date of visit

UNHCR EDL

40. If a patient has a prescription with a drug that is unavailable at the pharmacy, what are the action/s taken by the pharmacy?

Please select all that apply:

☐ The drug is usually available but is currently out of stock

☐ We tell the patient that the drug is not available

☐ We tell the patient to purchase the medication at his/her own expense

☐ We contact the prescribing physician to switch the drug to an available alternative

☐ We switch the medication to an available alternative without contacting the prescribing physician

☐ We give the patient a covering referral to obtain the medication from another health facility

☐ We procure or purchase the medication for the patient without approval from UNHCR

☐ We submit the case to UNHCR for exceptional approval of procurement or purchase

☐ Other: *please specify*

Objectives:

to monitor compliance with UNHCR EDL.
to assess adequacy of EDL.
to assess possible undertreatment of essential conditions

Collection method: key-informant interview; ask the question to the in-charge without mentioning the options. Mark the options based on their response. After the in-charge's initial response, you can use the unmarked options as a probe to gain more accurate information

II. Self- reporting by UNHCR's implementing partners

SELF-REPORTING		
Stock-outs		
1. Were there stock outs of the following medications during the last month?		
Amoxicillin	Yes ☐	No ☐
Oral rehydration solution	Yes ☐	No ☐
Insulin	Yes ☐	No ☐
Salbutamol	Yes ☐	No ☐
Glibenclamide	Yes ☐	No ☐
Diazepam	Yes ☐	No ☐
Ciprofloxacin	Yes ☐	No ☐
Simvastatin	Yes ☐	No ☐
Atenolol/bisoprolol/metoprolol	Yes ☐	No ☐
Paracetamol	Yes ☐	No ☐

Note: The list of medications can be adapted at country level. It is suggested to include "index and attractive medications"; therapeutically important medications that the pharmacy should never run out of or expensive medications

Objective: to assess if critical medications are available

Collection method: self-reporting by the implementing partner

Results: Yes → ✓

No → ✘

Rational Drug Use

2. Average number of drugs per encounter

Note: there is no specified standard for this indicator. An acceptable range is identified at country level according to the level of services provided and the season. However, average is 1.3-2.2 drugs/patient according to the results of earlier drug use studies (WHO, 1992)

Objective: to assess polypharmacy and monitor trend of polypharmacy over time

Collection method: self-reporting by implementing partner. Review 30 randomly selected encounters from the registry, count the number of drugs for each encounter, add up the total number of drugs prescribed and then divide by 30 to calculate the average.

Random selection method: count the number of total encounters for the reporting period from the registry. Use the random number generator to select 30 numbers between 1 and the total number of encounters. The random number generator will differ according to the resources available in the reporting health facility. Random number generation can be done using Excel "=RAND( )" function or using paper-based random number generators.

3. Percentage of encounters with an antibiotic prescribed

Note: there is no specified standard for this indicator. An acceptable range is identified at country level according to the level of services provided and the season. However, average is ≈20-40%/ according to the results of earlier drug use studies (WHO, 1992)

Objective: to assess rational prescribing of antibiotics

Collection method: self-reporting by implementing partner; same encounters used for the previous indicator are to be used for this indicator as well. Count the number of encounters with one or more antibiotics prescribed and then divide by 30 and multiply by 100%

4. Percentage of encounters with an injectable prescribed

Note: there is no specified standard for this indicator. An acceptable range is identified at country level according to the level of services provided.

Objective: to assess rational prescribing of injectable medications

Collection method: self-reporting by implementing partner; same encounters used for the previous indicator are to be used for this indicator as well. Count the number of encounters with one or more injectables prescribed and then divide by 30 and multiply by 100%

Physical Inventory Report Template

Date: _____ _____ _____
Day Month Year

Health Center: _____

Drug name (generic)	Strength	Dosage form	Basic unit	Batch number	Expiry date	Quantity counted	Quantity on stock card	Difference	Justification

Name/position: _____

Signature: _____

Name/position: _____

Signature: _____

Stock Card Template

Drug name (generic):	
Strength:	
Dosage form:	
Basic unit:	

Minimun stock level:	
Batch number:	
Expiry date:	

Day Month

Date	Quantity received	Received from	Quantity issued	Issued to	Balance	Remarks	Signature

References

Clark, M., & Barraclough, A. (2010). Managing medicine and health products. In *Health Systems in Action: An eHandbook for Leaders and Managers.* Medford, MA: Management Sciences for Health. Retrieved February 01, 2018, from http://www.msh.org/resources/health-systems-in-action-an-ehandbook-for-leaders-and-managers

Management Sciences for Health, (n.d.). Inventory Management Assessment Tool (IMAT)

Management Sciences for Health, (2011). Strengthening Pharmaceutical Systems (SPS). *Pharmaceuticals and the Public Interest: The Importance of Good Governance.* Arlington, VA: Management Sciences for Health

Management Sciences for Health, (2012a). Ensuring good dispensing practices. In *MDS-3: Managing access to medicines and health technologies*. Arlington, VA: Management Sciences for Health

Management Sciences for Health, (2012b). Inventory management. In *MDS-3: Managing access to medicines and health technologies*. Arlington, VA: Management Sciences for Health

Management Sciences for Health, (2012c). Monitoring and evaluation. In *MDS-3: Managing access to medicines and health technologies*. Arlington, VA: Management Sciences for Health

Management Sciences for Health, (2012d). Pharmaceutical management for health facilities. In *MDS-3: Managing access to medicines and health technologies*. Arlington, VA: Management Sciences for Health

Management Sciences for Health, (2012e). Pharmaceutical management information systems. In *MDS-3: Managing access to medicines and health technologies*. Arlington, VA: Management Sciences for Health

Management Sciences for Health, (2012f). Pharmaceutical supply systems assessment. In *MDS-3: Managing access to medicines and health technologies*. Arlington, VA: Management Sciences for Health

Management Sciences for Health, (2012g). Security management. In *MDS-3: Managing access to medicines and health technologies*. Arlington, VA: Management Sciences for Health

Médecins Sans Frontières (2016). Essential drugs – practical guidelines

World Health Organization, (1992). How to investigate drug use in health facilities, selected drug use indicators

Trap B, Hansen EH, Trap R, Kahsay A, Simoyi T, Oteba MO, Remedios V, Everard M, (2010). A new indicator based tool for assessing and reporting on good pharmacy practice. Southern Med Review.3; 2:4-11

World Health Organization, (2004). Management of drugs at health centre level. Training manual. Brazzaville.

World Health Organization (2017). Essential medicines. Retrieved from http://www.who.int/topics/essential_medicines/en/

United Nations High Commissioner for Refugees, (2006). UNHCR Drug management manual 2006. Policies, guidelines, UNHCR list of essential drugs

United Nations High Commissioner for Refugees (2015a). Field country report, unpublished. Middle East

United Nations High Commissioner for Refugees (2015b). Field country report, unpublished. Sub-Saharan Africa

United Nations High Commissioner for Refugees (2015c). Field country report, unpublished. Sub-Saharan Africa

United Nations High Commissioner for Refugees, (2015d). Medicine and medical supplies management standard operation procedures for UNHCR Uganda health programme. Uganda