Ecumenical Pharmaceutical Network
Réseau Pharmaceutique Œcuménique

STANDARD OPERATING PROCEDURES

"HOW TO" MANUAL

For

Drug Supply Organizations
And
Church Health Institutions

Ecumenical Pharmaceutical Network

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Table of Contents

INTRODUCTION

The Ecumenical Pharmaceutical Network (EPN) is a Christian, not for profit, independent organization committed to the provision of quality pharmaceutical services as a means to achieving global goals and targets on health and access to medicines.

This manual is intended to be a resource for DSOs and CHIs to build capacity for developing and implementing SOPs for their operations in a participatory manner.

The first chapter of the manual deals with definitions and benefits of SOPs. The second chapter covers the SOP process. This includes identifying an area within pharmaceutical management for SOP development, mapping out the processes of operations, writing the SOPs and implementing the SOPs. The third chapter discusses the formats for presenting an SOP. Chapter four provides an overview of the operational principles for good procurement practice. The issues that anyone involved in procurement needs to address are discussed.

There are activities at the end of each chapter that will allow the users of the manual to develop the skills needed to develop SOPs.

This manual was prepared by Mr. Charles Allotey of Health Access Network (HAN). Mr. Allotey is a Pharmacist by training and has been involved with EPN activities for a very long time.

Abbreviations used

CHI	Church Health Institution
DSO	Drug Supply Organization
EPN	Ecumenical Pharmaceutical Network
HAN	Health Access Network
SOP	Standard Operating Procedure
WHO	World Health Organization

CHAPTER 1: OVERVIEW STANDARD OPERATING PROCEDURES

1. OBJECTIVES

- Identify what constitutes an SOP
- Understand the purpose of an SOP
- Appreciate the importance of SOPs
- Differentiate between guidelines and SOPs

In any enterprise, successful managers recognize that most people naturally desire to do a good job, and they seek to channel the efforts of workers in ways that will bring benefit to the enterprise. The manager's role is to create an environment that encourages high performance, and standardized systems must exist to ensure that consistent work is done to achieve that performance.

The development and use of SOPs are an integral part of a successful quality system as these SOPs provide individuals with the information to perform a job properly, and facilitate consistency in the quality and integrity of a product or end-result.

The SOP development process is also an excellent way for managers, workers, and technical advisers to work together towards the achievement of the organizational goals. SOPs, when well-written provide direction, improve communication, reduce training time and improve work consistency.

This document is designed to provide guidance to Drug Supply Organizations (DSO) and health institutions in the preparation and use of an SOP within their health care setting.

2. DEFINITION OF TERMS

During the process of compiling SOPs, the difference between varied documents (policy, guidelines, procedures, regulations, rules) may become blurred. For instance, often the distinction between policy and procedure does not seem so clear. We will attempt to define certain words that we encounter when we write SOPs. This will clarify in our minds what endeavour we are undertaking.

Policy – A guiding principle or course of action adopted toward an objective or objectives. Describes the general principle that will guide behaviour or a definite course or method of action to guide and determine present and future decisions.

Guideline – A statement, indication, guide or outline of policy by which to determine a current or future course of action.

Procedure – Prescribes specific ways of undertaking specific activities, that which regulates the formal steps into an action. It provides a series of steps followed in a particular order.

Regulation – A rule or order prescribed by an authority, to regulate conduct.

Rule – A principle set up by an authority, prescribing or directing action or forbearance.

3. WHAT ARE SOPS?

The term "SOP" is sometimes used synonymously with terms such as protocols, instructions, and worksheets. There are different definitions for SOPs depending on the area where it is being applied. Below are a few definitions:

1. A written document that describes in detail, step-by-step, how a procedure should be done.
2. A management process that describes chronological steps to follow and decisions to make in carrying out a task or function.
3. A written document which details an operation, analysis, or action whose mechanisms are prescribed thoroughly and which is commonly accepted as the method for performing certain routine or repetitive tasks.
4. A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness.
5. An authorized, written procedure giving instructions for performing operations not necessarily specific to a given product but of a more general nature (WHO 40th Report 2006).
6. A standard operating procedure specifies in writing what should be done, when, where and by whom.

What is common to all the definitions irrespective of area of operation is that:

- It is applied to a task or function or operation or procedure being undertaken
- It provides the details (chronological steps) of how the task should be carried out
- It is an official written document

4. PURPOSE

The purpose of an SOP is simply to ensure that essential job tasks are performed correctly, consistently, and in conformance with internally approved procedures. SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with organizational policies and in some instances government regulation.

If not written correctly, SOPs are of limited value. In addition, the best written SOPs will fail if they are not followed. Therefore, the use of SOPs needs to be reviewed and re-enforced by management, preferably the direct supervisor. Current copies of the SOPs also need to be readily accessible for reference in the work areas of those individuals actually performing the activity, either in hard copy or electronic format, otherwise SOPs serve little purpose.

5. BENEFITS

SOPs have several benefits to an organization where it is developed and used. Listed below are some of the benefits of an SOP

1. **Improved productivity and performance**
   SOPs help to assure the quality and consistency of drug supply activities. People need consistency to achieve top performance. Studies suggest that up to 40% of operational inefficiencies can be attributed to employees' failure to fulfil their job responsibilities. Doing jobs the same way every time rather than asking how the job has to be done every day, improves productivity and performance.
2. **Improved quality of products and services**
   The development and use of SOPs minimizes variation and promotes quality through consistent implementation of a process or procedure within the organization, even if there are temporary or permanent personnel changes.

3. **Cooperation among staff**

   SOPs provide an opportunity to fully utilize the expertise of all members of a department or team. People tend to be supportive of the things they help create. Involving employees in developing SOPs can help assure the final product is more complete, useful and accepted. The SOP also helps senior managers to delegate responsibilities, and among staff it assists in clarifying the roles of staff with respect to specific tasks.

4. **Facilitating training**

   SOPs are useful tools for training staff, especially new members. Having complete step-by-step instructions helps trainers ensure that nothing is missed and provides a reference resource for trainees. For employees filling in on jobs they do not perform on a regular basis, an SOP can be an excellent reference document on how a task is done.

5. **Safety and legal protection**

   SOPs minimize opportunities for miscommunication and can address safety concerns. Correct and consistent use of SOPs can help keep employees safe at work and may provide some legal protection from national regulatory agencies.

6. **Evaluation**

   SOPs provide a contribution to the audit process. Having SOPs can encourage regular evaluation of work activity and continuous improvement in how things are done.

Activity 1.1.: Reviewing SOPs

Review the samples of SOPs available. Determine whether they meet the requirements of an SOP. Give reasons for your answer.

CHAPTER 2: THE SOP PROCESS

1. OBJECTIVES

- Understand the need for preparation
- Identify the pharmaceutical management processes
- Map processes for SOP development
- Write SOPs

2. SOP PREPARATION

The SOP development process is critical to successful implementation of SOPs. For an organization, developing a set of SOPs can be a time consuming process, but a little time spent in the beginning to organize the effort can help reduce frustration with the process and make the effort more efficient and effective. The development should be an inclusive process that considers the input of everyone with an interest in the procedure's success.

Managers who write procedures without input from workers or technical advisers run the risk of upsetting workers and producing a poorly written SOP. Managers who enlist the talents of workers and technical advisers will increase buy-in and produce better SOPs. Most importantly, they will take advantage of an important opportunity to foster teamwork among workers, managers, and advisers.

In the preparatory phase, it is important to identify one individual within the organization with the skills and expertise in the particular area to lead the development process. Then select other people to form a team to support this individual to prepare the SOP.

Investing the time and energy to develop and implement effective SOPs must make bottom-line economic sense. This chapter will deal with identifying the areas of operation of concern where developing SOPs may be useful, prioritizing tasks and functions for SOP development, putting together a team to undertake the effort, and steps to write the SOP.

2.1. Selecting an area for SOP development

SOPs can be established for every task or function carried out in an organization. But due to the time consuming process involved, it is important that a thorough approach is used in identifying the area for SOP development. The selection should make business and economic sense so that the investment made in its preparation will yield the required dividends. You may need to come up with a decision-making matrix to guide you in the identification of the key area.

As a pharmaceutical service provider, in identifying the key area for SOP, the following questions should be asked:
1. Which area of the pharmaceutical operations is of concern to me? You need to go over the pharmaceutical management cycle to identify the area of concern.
   - Is it selection, procurement, distribution, use of medicines?
   - Is it management support?
2. In which of these areas are more controls desired or required?
3. In which of these areas will economic returns or impact on the operation be greatest?
4. Which areas are likely to yield some good successes early in the process so you can build momentum and excitement for the effort?

Overview of Pharmaceutical Management

Pharmaceutical management is defined as a set of practices aimed at ensuring the timely availability and appropriate use of safe, effective and quality medicines and related products, and services in any health setting.

It is important that we have an overview of what the pharmaceutical management system is about in order to develop SOPs for pharmaceutical services. In this overview, we will define all the various systems of the pharmaceutical management cycle.
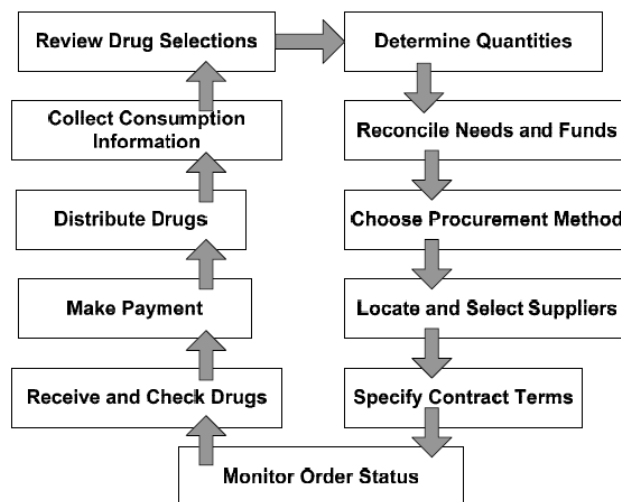
Selection
Selection is the process of establishing and using a limited list of essential medicines. It involves reviewing prevalent health problems; identifying the best clinical treatments; choosing medicines, dosages, dosage form, and special packaging needs; and deciding which medicines will be available at each level of health care.

Procurement
Procurement is the process of acquiring medicines and supplies, including those obtained by purchase and donation. An effective procurement process ensures the availability of the right medicines in the right quantities at reasonable prices, and at recognized standards of quality.

The Procurement Cycle

Review Drug Selections → Determine Quantities → Reconcile Needs and Funds → Choose Procurement Method → Locate and Select Suppliers → Specify Contract Terms → Monitor Order Status → Receive and Check Drugs → Make Payment → Distribute Drugs → Collect Consumption Information → Review Drug Selections

Distribution
A *distribution system* ensures a continuous flow of supplies from a central point to the end-user facilities. It is composed of four major elements: the system's design (degree of centralization, push versus pull ordering, geographic or population coverage, number of different levels); an information system (inventory control, records and forms, consumption reports, information flow); appropriate storage (locations, building design, materials handling systems, and order picking systems); and delivery (collection versus delivery, choice of transport, vehicle procurement, vehicle maintenance, routing, and scheduling of deliveries).
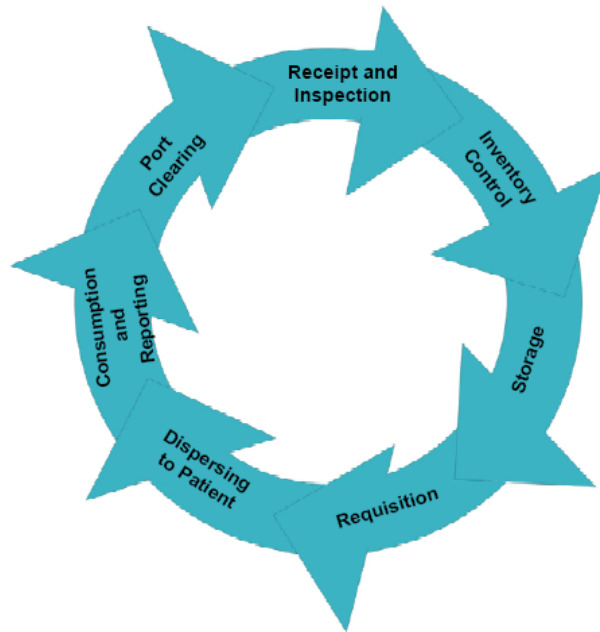
Use

The Conference of Experts on the Rational Use of Drugs, convened by the World Health Organization (WHO) in Nairobi in 1985, defined rational use as follows: "the rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community."
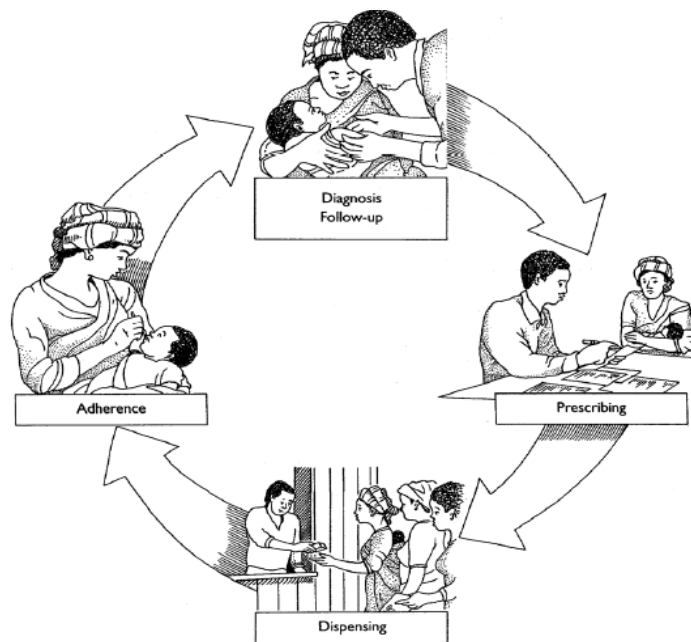
Management Support

Management support is located at the centre of the pharmaceutical management cycle, which represents its central, crucial nature as the engine that drives the other components of the cycle. Effective management support is required during all activities in the cycle and at all organizational levels, from the national level down to where the medicines are prescribed and dispensed to patients.

Management support includes various subcomponents:
- Organization and management
- Financing and sustainability
- Information management
- Human resources management

Source: Management Sciences for Health

Within the pharmaceutical management cycle, there are sub systems in each major area. After selecting a major area, say, procurement, you need to identify the one or two areas for development of SOPs.

In selecting the tasks for an SOP, you need to first and foremost determine the goal of preparing this SOP. SOPs work best when they are designed to achieve specific results. After you have defined the objective for developing an SOP, you need to identify which stage(s) in the procurement cycle limit performance, i.e. the bottlenecks. This is done by finding out tasks in the procurement cycle where a lot of delays are encountered when carrying out the activities. Delays in the process imply you are not utilizing efficiently the resources available to you. Other questions you need to ask to help you select tasks for an SOP are:
- Which tasks impede productivity?
- Which tasks in the cycle require improvement?

The area(s) with bottlenecks are the areas for which an SOP will be most beneficial.

After identifying the tasks for SOPs, some of them can be grouped together and prioritized for SOP development. For example in the procurement cycle you can group some of the tasks together into 4 main areas:
- Requirement (determining quantities, reconciling needs with funds)
- Purchasing (choosing procurement method, locating and selecting suppliers, specifying contract terms, monitoring order status)
- Goods receipt (receiving and checking drugs)
- Accounting (making payment)

The SOPs can then be developed for whichever task(s) we deem to be the priority area(s).

2.2. Mapping all the processes or functions that you have selected for an SOP

Process mapping is a logical step-by-step representation of business activities showing key inputs/outputs. So in this process, we will learn how to represent our pharmaceutical activities in a process map. Before we embark on the process mapping, we need to understand some terms so that we can make a good representation of our activities.

System: it is a network of interdependent components (items, people, or processes) that work together to accomplish the aim of the system. It shows relationships.

Process: a process is defined as a set of causes and conditions that repeatedly come together in a sequence of steps to transform inputs into outcomes. This implies that any process has a beginning and an end linked by various sequence of steps.

Within every process, there are roles that are played by those involved. These are:

Workers: Persons who participate in the transformation of inputs to outcomes

Suppliers: Persons or entities (e.g., other processes) that   provide an input to the process

Customers: Persons or entities that receive or use the outcomes of the process

Owner: Person(s) whose approval is needed to make fundamental changes to the process

There is a model for showing the boundary of a process which is known as the SIPOC (Suppliers, Inputs, Process, Outcomes, Customers) boundary form. This is used in mapping the processes in an operation.

SUPPLIERS	INPUTS	DESCRIPTION OF THE PROCESS	OUTCOMES	CUSTOMERS
		PROCESS NAME: PROCESS OWNER: KEY STEPS IN THE PROCESS: 1. 2. 3. LAST		

*Source: Institute of Healthcare Improvement*

To map the processes pictorially, you use a flow diagram. The basic steps and symbols for a flow diagram are given below.

Steps for flow diagram:
1. Define boundaries
2. Determine type of flow diagram
3. Show steps
4. Use action words (verbs)
5. Use basic symbols
6. Follow flow of decision points
7. Note missing knowledge
8. Review the diagram

Basic Symbols

You should use the generally accepted symbols for flowcharts, which are as follows:

Start/End	Action	Decision	Record or document
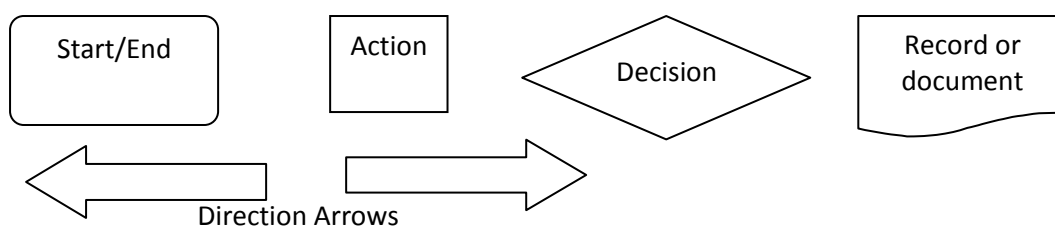
Direction Arrows

- A flattened oval represents a starting or ending point.
- A rectangle indicates the worker should perform an action of some sort.
- Unlabeled arrows between other symbols indicate the direction of the flow.
- Diamonds are the accepted symbol for a decision point. They must have two or more arrows leading away from them toward alternatives.
- Decision arrows lead away from a diamond and toward an appropriate action or follow-up decision. At least two alternatives must lead from each decision diamond. Many times they will be yes and no, but they also could involve three or more choices. For example, after taking a temperature, you might have several options to follow, depending on the results.
- A rectangle with a ragged bottom edge indicates that a record or notation should be written down. You might use this in an SOP to record how much cows were fed, or to note when a job is completed.

With this information we can map out the processes for all the tasks selected for SOP. The exercise at the end of the chapter will help the reader map out tasks in their DSO or hospital.

Activity 2.1: Identifying Areas for SOP Development
Use the activity sheets provided in the annex to determine which areas in your institution you need to select for SOP development.
1. What is the objective for undertaking the SOP development?
2. Identify key areas in the drug supply management process for SOP development (use worksheet 1).
3. Identify one or two key tasks within the area selected for SOP development (use worksheet 2).

Activity 2.2: SIPOC boundary
Use the SIPOC boundary form to map the processes you have identified for SOP development.

2.3. Writing the SOP

Standard Operating Procedures are instructions that should be understandable to everyone who uses them. Writers should always try to write procedures as simply as possible while communicating well. It should be written in a concise, step-by-step, easy-to-read format. The information presented should be unambiguous and not overly complicated. The active voice and present verb tense should be used. The term "you" should not be used, but implied. The document should not be wordy, redundant, or overly lengthy. Keep it simple and short. Information should be conveyed clearly and explicitly to remove any doubt as to what is required. Mark Twain once said he didn't have time to write a short story, so he wrote a long one instead. Writers tend to use long sentences and paragraphs because it is easier than thinking of the exact, most meaningful words. Procedure writers must use short, direct sentences so readers can quickly understand and memorize the steps in the procedure.

The level of detail to include in standard operating procedures is one of the most difficult decisions to make. Procedures definitely should include all steps that are essential and that should be performed the same way by all workers. Omitting any of these essential steps may lead to confusion for the reader or performance variation among different workers. On the other hand, procedures should not be so detailed that they are cumbersome and impractical for everyday use.

Highly detailed procedures cannot take the place of training. Recognizing this, procedure writers should not attempt to answer all possible questions that a worker might have. SOPs should complement and serve as a basis for introductory training. Excessive detail also is likely to cause resentment from experienced workers. They might feel that management is using the SOP to micromanage every aspect of their work performance. Procedure writers must ensure that they include enough detail to eliminate significant variation among workers.

Within different organizations, SOPs for the same task will be different depending on the SIPOC of each organization. However, the steps needed to write the SOPs will be the same. The following six steps will be useful and effective for writing SOPs for your institution.

Step 1. Name the SOP
The first step in writing an SOP is to give it a name. The naming should use descriptive action words; for example, purchasing for procurement, stock taking, etc. The name of the SOP should uniquely identify it from other SOP within the organization. The name is important for identification, filing and retrieval.

If you are developing SOPs for several different areas of your operation, give each area an identifying code, then number the SOPs within it, for example, code beginning with P for procurement SOP, if there are three different SOPs within Procurement, they can be identified as P-1, P-2, P-3. Within Distribution D-1, D-2, D-3 etc. This will make it easier to file the SOPs, refer to them in related SOPs, and for an employee to find a specific SOP for reference later.

Keep them filed in one or more notebooks accessible to the employees. Include the date the SOP took effect, any revision dates and the authors' names.

Step 2. Write a scope for the SOP
The second step is to define the scope of the SOP. We have already indicated that every process has a beginning and an end. The scope of the SOP indicates what is covered from the beginning to the end of the process. To define the scope, you need to answer these questions:

- Which specific operations or tasks within an operation will be covered?
- Which operations or tasks are not covered?
- Who is the SOP written for?

Using Stock Taking as an example, the scope will be: This Stock Taking SOP is for all staff working in the Store. The SOP starts with the preparation for stock taking and covers all procedures to the taking of needed action based on results of stock taking.

Step 3. Write main tasks description

In the third step of writing the SOP, you provide an overall description of the tasks involved in carrying out an operation. This will be based on the mapping exercise that was carried out. The information for writing out the task description will be found on the SIPOC boundary form.

You will have to include the number of people required for the task, their skill levels, the equipment and supplies (this may be information from other processes that is needed as input) required, any personal protective or safety equipment required, and a description of the expected outcome or result. Using the stock taking example, a task description will be:

- Stock taking will be carried out in the store where the pharmaceutical products are kept
- Two people undertake the task, one of them from the finance/accounts office
- Supplies needed include: current pricing information, computer print-out of availability, worksheet
- Clean overcoats/aprons should be worn
- The expectation is that the physical count of all pharmaceutical products in the store will be taken and the needed adjustments and updates made.
- Stock taking includes the following steps:
  - Prepare for the stock taking
  - Assign staff to conduct stock taking
  - Organize the storeroom
  - Count the usable products
  - Update the stock keeping records
  - Take the needed action

Step 4. Describing each task

Step four involves describing each task in detail and writing the protocols (steps and procedures involved in this task or process).

In this step you should include the following:
Specific order in which activities are done
- Timing sequences and times allowed
- Materials or tools used and how they are used
- Safety or health considerations
- References to other associated SOPs

At this stage you need to define terms and concepts when needed. Also if there are any health and safety warnings, they should be placed prominently in the SOP.

In this stage, you need to keep the following information at the back of your mind when writing the protocols.
- People can't remember more than 10 or 12 steps, so they tend to have difficulty with long SOPs.

- If your SOP goes beyond 10 steps, either break it into logical sub-task SOPs, or write a second shortened form of the SOP for use at the job site, listing only the main steps, not the detailed explanations of the steps.
- Use the highly detailed form of the SOP for training and reference.
- Abbreviated versions of SOPs for use at the work site make excellent reminder aids for employees and help ensure that important items are not missed.

Step 5. Get everybody on Board

Step five is a critical stage for achieving success. It is important to make the SOP development a participatory one. Successful SOP development and implementation typically requires that all people who are affected by the SOP are involved in a team-based SOP development and problem solving process. You need to actively identify those to be affected by the SOP and get them involved in the process.

To achieve that:
- Ask several experienced employees to be involved in drafting the initial SOP.
- Have trained employees check the written procedures against actual practices before implementation. Make revisions if necessary.
- Talk with all employees to gain agreement that procedures and expectations are appropriate and achievable.
- Inform everyone about the written SOP.
- Train them on the SOPs' contents and tell them where they can find it for future reference.

Step 6. SOP Review and Approval

The final step for the SOP development is to set up a system to monitor the SOP regularly. The minute you write and implement an SOP, it is already time to evaluate and update it.

Even new SOPs frequently need to be tweaked once or twice before they operate smoothly. SOPs should be reviewed (that is, validated) by one or more individuals with appropriate training and experience with the process. It is therefore very important to set up a system to review and incorporate changes when and where necessary.

Provide each worker who performs the procedure with a copy of the draft SOP. Ask them to review and suggest changes that are easier to understand, more accurate, or will improve performance. Assure the workers that their input is important and will be used. Also provide your technical advisers with a copy of the SOP draft. Ask them to suggest any changes that will make it clearer and more effective. Revise the procedure as necessary to incorporate input from both technical advisers and workers.

SOPs need to remain current to be useful. Employees should be able to report needed changes to their supervisor any time they see an opportunity, problem, or concern. Whenever procedures are changed, SOPs should be updated and re-approved.

For procedures to be effective, they must perform in the workplace. There is only one way to be absolutely certain that a procedure is well written and performs as expected. Have someone test the procedure by performing each step exactly as it is described while the procedure writer watches. Have a person not familiar with the work follow the procedure. Any steps that cause confusion or hesitation for the test worker should be revised.

The finalized SOPs should be approved in accordance with the institution's management arrangements. Generally the immediate supervisor and the institution's quality assurance officer should review and approve each SOP. Signature approval indicates that an SOP has been both

reviewed and approved by management. After the final draft has been prepared, the SOP should be posted in the appropriate locations and staff trained and retrained as necessary to follow the SOP exactly. SOPs should also be systematically reviewed on a periodic basis, e.g. every 1-2 years, to ensure that the policies and procedures remain current and appropriate, or to determine whether the SOPs are even needed.
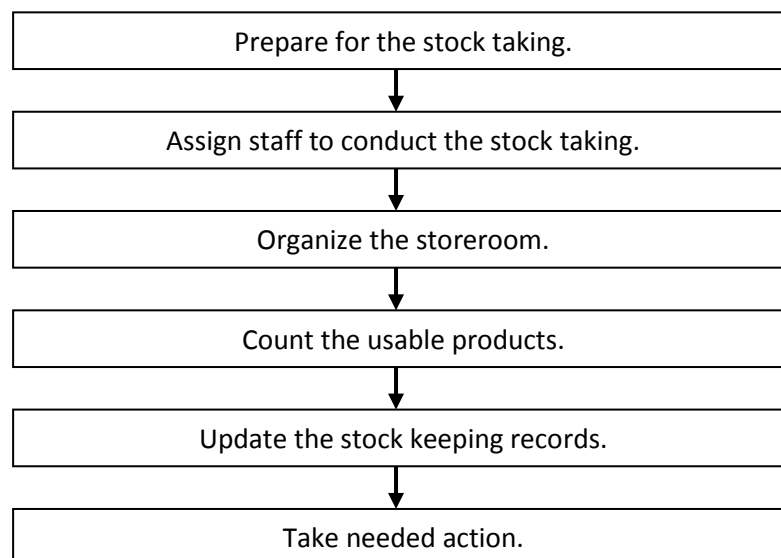
Activity 2.3.: SOP development Exercise
A drug supply organization in Ghana has gone through participatory processes of developing an SOP for storage at its warehouse. The following gives some information on what they came up with during the exercise.
- Stock taking was one of the main tasks under storage identified as a priority for SOP development
- The stock taking tasks were mapped as indicated below
- The following instructions were written in order to put in an appropriate SOP format:

Mapping for Stocktaking

Stock taking SOP

```
┌─────────────────────────────────────────────┐
│         Prepare for the stock taking.        │
└─────────────────────────────────────────────┘
                      │
                      ▼
┌─────────────────────────────────────────────┐
│     Assign staff to conduct the stock taking.│
└─────────────────────────────────────────────┘
                      │
                      ▼
┌─────────────────────────────────────────────┐
│             Organize the storeroom.          │
└─────────────────────────────────────────────┘
                      │
                      ▼
┌─────────────────────────────────────────────┐
│            Count the usable products.        │
└─────────────────────────────────────────────┘
                      │
                      ▼
┌─────────────────────────────────────────────┐
│        Update the stock keeping records.     │
└─────────────────────────────────────────────┘
                      │
                      ▼
┌─────────────────────────────────────────────┐
│              Take needed action.             │
└─────────────────────────────────────────────┘
```

1. Prepare for the stocktaking.
   - Schedule the day and time when stock taking will be done.
2. Assign staff to conduct the stock taking.
3. Organize the storeroom.
   - Arrange products according to FEFO.
   - Make sure open cartons, boxes are visible.
   - Separate damaged or expired products.
4. Count the usable products.
   - Count products according to their dispensing units.
   - If you have a bottle that contains individual capsules or tablets, estimate the quantity. If a bottle of 1,000 capsules is 2/3 full, then estimate 650 or 700 capsules. If you have a one litre bottle of syrup that is ½ full, then estimate 0.5 litres.
   - Update the stock keeping records (The stock keeping record is the Tally Card).

- Write the date the stock taking is done and the word "Stock taking" in the Issued/Received column of the tally card.
- Write the quantity of the product that you count during stock taking.
- The Stock on Hand quantity listed on the Tally Card should match the quantity that you have counted.

5. Take action based on the results of the stock taking.
   - If the number of products counted during stocktaking does not match the quantity listed on the Tally Card, update the Tally Card balance by adding or subtracting the excess or missing quantities in the appropriate column in the Tally Card.
   - If expired or damaged products are found, dispose of them following established procedures. Subtract the quantity from the Tally Card balance and update the current balance.

For either of the above, the cause of the problem should also be identified and corrected.

Adjustments

When conducting stock taking, there may be differences between the number of products that are counted and the balance that is recorded on the Tally Card (the procedure for updating the Tally Card is described above). If the stocktaking count shows that the balance recorded on the Tally Card is higher or lower than the quantity of products that were counted, then an adjustment needs to be made on the Tally Card.

If the physical count at stock taking was more than the recorded stock on hand balance, then a positive adjustment is made. If the physical counts at stock taking was less than the recorded balance, or if expired products were found, then a negative adjustment is made.

Some adjustments are required because of mathematical errors that were made on the Tally Card. Other adjustments signal that a loss has occurred, either though product expiry, damage or theft. One method for evaluating the effectiveness of stores operations is to monitor losses and adjustments as a percentage of total stock managed. An adjustment of more than 5% of the total stock quantity managed is a signal that there are problems that need to be corrected. Losses of any level due to theft should be fully investigated.

All losses, including those that are identified during stock taking, are reported on the Stock Valuation Form. The Stock Valuation Form tracks both the quantities and value of products lost.

Questions

1. Comment on the work done by the DSO.
2. Based on your knowledge of SOP development, what will you have done differently?

CHAPTER 3: PRESENTATION OF SOPS

1. OBJECTIVES

Participants will:
1. Know the different formats in which SOPs can be presented
2. Make a rational choice for selecting a format
3. Use one of the formats for presenting the SOP

SOPs should be organized to ensure ease of use and efficiency in use, and should be specific to the organization which develops it. There is no one "correct" format and internal formatting will vary with each organization and with the type of SOP being written. Where possible, break the information into a series of logical steps to avoid a long list. The level of detail provided in the SOP may differ based on, e.g., whether the process is critical, the frequency of that procedure being followed, the number of people who will use the SOP, and where training is not routinely available.

2. SOP FORMATS

There are many ways of presenting an SOP; the basic formats are as follows:
- Simple Steps
- Hierarchical Steps
- Graphic
- Flowcharts

2.1. Simple steps SOP or checklist

These are easy to write and follow, and work well for short, simple, straight forward tasks. It is used in processes that are fairly repetitive with very limited decision making.
The advantages are:
- Easy to write
- Easy to follow
- Logical flow

The disadvantages are
- Lack of detail
- Tends to get long if detail is included
- Keeps all steps at same level
- Does not handle decisions well

2.2. Hierarchical steps SOP

This is an extension of the simple steps format; this format works better for tasks that require additional detail or sub-steps within each primary step. The hierarchical steps format allows the use of easy-to-read steps for experienced users while including more detailed sub-steps as well. Experienced users may only refer to the sub-steps when they need to, while beginners will use the detailed sub-steps to help them learn the procedure.
Advantages
- Easy to write
- Easy to follow
- Logical flow

- Handles details very well
- Allows different levels of steps

Disadvantages
- Does not handle decisions well

2.3.   Graphic SOP

This is a graphic version of the two previous formats. It works well for tasks where activities must be done in a specific order and where an easy to follow reminder at the job site is useful. The graphic format breaks long processes into shorter sub-processes that consist of only a few steps. Workers can learn several short sub-processes more easily than learning one long procedure.

Advantages
- Easy to write
- Easy to follow
- Logical flow
- Handles long procedures well

Disadvantages
- Does not handle decisions well

2.4.   Flowchart

Flowcharts are simply a graphic way to present the logical steps in a decision-making process. A flowchart provides an easy-to-follow mechanism for walking a worker through a series of logical decisions and the steps that should be taken as a result.

 Advantages
- Easy to follow
- Logical flow
- Handles decisions very well

Disadvantages
- More difficult to write
- Does not handle details well

3. CHOICE OF FORMAT

The best SOP format is one that, given the situation, does the best job of accurately transmitting the necessary information and facilitating consistent implementation of the SOP. The primary considerations for choosing the best SOP formats are listed below.

3.1.   The scope and complexity of the SOP

Two factors determine what type of SOP to use. First, how many decisions will the user need to make during the procedure? Second, how many steps and sub-steps are in the procedure? Routine procedures that are short and require few decisions can be written using the **simple steps** format. Long procedures consisting of more than ten steps, with few decisions, should be written in **hierarchical steps** format or in a **graphic format**. Procedures that require many decisions should be in a flowchart.

3.2. The people who will use the SOP

How do they learn? If they are visual learners, perhaps a series of pictures or a flow chart will work best. Physical limitations, such as poor eyesight, may necessitate large clear print or big bright pictures and plenty of light. Can they read and understand another language if the information were translated?

3.3. How the SOP will be used

The purpose of an SOP is to give detailed directions so that any individual can do a job correctly, on time, every time. At the same time, any one SOP may have a number of different uses. Depending on the intended use at the time, the SOP may be written or presented differently to be more effective. An SOP that is part of a reference manual may contain large amounts of explanatory detail and even supporting background information so employees understand the importance behind certain SOP steps.

When using the same SOP in basic training, less detail may be desirable. The amount of detail should be tailored to the level of the training. For example, new trainees might be overwhelmed by large amounts of detail, so give them only the details they need to get the job done correctly.

For in-depth follow-up training or retraining, you may want the SOP to contain more detail and background information explaining why certain things are done or the biology behind certain practices. The same SOP used as an on-the-job reminder should be a bare-bones overview that is readily accessible at the work site, easy to see, and quick to review and understand.

Which Format to use?

Many decisions?	More than 10 steps?	Best SOP format
No	No	Simple Steps
No	Yes	Hierarchical or Graphic
Yes	No	Flowchart
Yes	Yes	Flowchart

Activity 3.1.: Writing an SOP
1. Using the SOP writing tool in the annex, select a procedure and write an SOP for the process.
2. Use at least two of the formats to present the SOP.

CHAPTER 4: HOW TO ENSURE GOOD PROCUREMENT PRACTICE (GPP)

1. OBJECTIVES

- Know the objectives of good procurement practice.
- Recognize the characteristics of a good pharmaceutical procurement system
- Identify areas in an institutional procurement system where improvement is needed

Pharmaceutical procurement occurs in many contexts: government medical stores, private pharmacies, NGO facilities and Mission hospitals. Irrespective of where it occurs, the intended goal has always been to make drug available to the population that needs them.

The World Health Organization working through the Interagency Pharmaceutical Coordination Group (IPC), which is made up of UNICEF, UNFPA, World Bank and WHO has published a book on the operational principles for Good Procurement Practice. This session will deal with the objectives and operational principles as presented in the book. We will use the principles as a standard checklist to assess our pharmaceutical procurement and identify areas where improvement is needed.

2. OBJECTIVES OF PHARMACEUTICAL PROCUREMENT

The objectives of the pharmaceutical procurement are based on many problems but the two key ones are that their funds for procurement are scarce and limited, and there is not a perfect market when it comes to pharmaceuticals.

The agreed strategic objectives for all pharmaceutical procurement irrespective of the context and management systems are:
1. Procure the most cost-effective drugs in the right quantities.
   This deals with selecting an essential drug list to ensure that only the most cost effective medicines are procured, and providing accurate estimates of the selected drugs to ensure continuous availability.
2. Select reliable suppliers of high-quality products.
   This involves selecting or pre-selecting reliable suppliers of high-quality pharmaceuticals and putting in place quality assurance programmes.
3. Ensure timely delivery.
   This objective deals with ensuring that procurement and distribution systems deliver pharmaceuticals to where they are needed in a timely manner.
4. Achieve the lowest possible cost for all drugs.
   This objective ensures that procurement and distribution systems achieve the lowest possible cost for pharmaceuticals, taking all possible costs (price, quality, overhead costs, and inventory costs) into consideration.

3. PRINCIPLES OF GOOD PROCUREMENT PRACTICES

To achieve the objectives, 12 operational principles have been grouped under four main headings.

3.1. Efficient and transparent management

3.1.1. Procurement functions and responsibilities

Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function.

Procurement management is to ensure that pharmaceutical procurement is carried out effectively, efficiently and in accordance with institution's policies and guidelines. Separation of functions reduces influence by special interests and corrupting tendencies, it also contributes to professionalism, accountability and efficiency in the procurement system.

Areas for improvement

The following functions in the procurement process could be separated:

- Drug selection
- Quantification of drug requirement
- Product specification
- Pre-selection of suppliers
- Adjudication of tenders

3.1.2. Transparency

Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.

When the pharmaceutical tender process is less transparent and even secretive, it tends to be perceived as corrupt or unfair. To attract the best suppliers and achieve the best prices, fairness and the perception of fairness are critical.

Areas for improvement

- Formal written procedures for tender processes
- Explicit criteria for making procurement decisions
- Bidders and health professionals should have access to information on successful suppliers and the prices for all winning contracts

3.1.3. Planning and monitoring

Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

In order to ensure that drugs are available where and when they are needed, drug procurement must be carefully planned.

Areas for improvement

- A functioning MIS is key in the planning and management of procurement
- Regular reporting on key procurement performance indicators
- Regular procurement audit

3.2. Drug selection and quantification

3.2.1. Essential drugs

Procurement should be limited to an essential drugs list or the local formulary list.
No institution can afford to purchase all the drugs available on the market within its budget. Resources are scarce and choices have to be made. An essential list or formulary defines which drugs will be regularly purchased.

Areas for improvement
- Is there an essential list or formulary for procurement (VEN Analysis)?
- Available mechanism to procure non formulary for special needs

3.2.2. Use of names

Procurement and tender documents should list drugs by their International Non-proprietary Name (INN), or generic name.
The INN is used to describe drugs on a procurement list or tender request

Areas for improvement
- Do you use INN when purchasing drugs or do you specify branded products?
- Do drugs supplied have INN labels on them, or only the brand name?

3.2.3. Order quantities

Order quantities should be based on a reliable estimate of actual need.
An accurate estimation of procurement requirement is needed to avoid stock outs and overstock of pharmaceuticals. An accurate estimate also gives confidence to suppliers to willingly offer lower competitive prices.

Areas for improvement
- Consumption-based method for estimation
- Morbidity-based method for estimation
- Adjusted – consumption-based method
- VEN Analysis for prioritization
- ABC analysis for prioritization

3.3. Financing and competition

3.3.1. Reliable financing

Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximize the use of financial resources.
In financing for pharmaceuticals, the most important considerations are the total funds available, adequate access to foreign exchange (if you are import pharmaceuticals) and the regularity with which funds are available. To be able to order drugs when needed and promptly pay for them requires that an efficient financial management system must be in place. Prompt payment increases supplier confidence in the procurement system and has an effect on prices and stock-outs.

Areas for improvement
- Revolving Drug Accounts
- Administrative cost for procurement
- Source of funding for procurement

3.3.2. Procurement quantities

Procurement should be effected in the largest possible quantities in order to achieve economies of scale.

Larger procurement volume makes favourable prices and contract terms more likely, by increasing suppliers' interest in bidding and by providing them with an incentive to offer a competitive price.

Areas for improvement
- Pooled procurement arrangement
- Estimated quantity tenders
- Negotiate prices for a list of essential drugs and institutions can procure as and when necessary

3.3.3. Competitive procurement methods

Procurement should be based on competitive procurement methods, except for very small or emergency orders.

There are four main methods for purchasing drugs. Three of them are competitive: restricted tenders, open tenders and competitive negotiations. The fourth method is direct negotiation with a single supplier. Since inducing supplier competition is a primary key to obtaining favourable pricing, we should use competitive methods for all but very small or emergency purchases.

Areas for improvement
- Number of bids per item
- Competitive or non competitive procurement for items
- Cost effective analysis for therapeutic category

3.3.4. Contracted items

Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.

Except in those systems where each health facility negotiates prices and purchases drugs individually, public pharmaceutical procurement systems are seen as purchasing groups. Normally, group purchasing achieves lower prices than would be available to the same group of health facilities if they purchased individually. These discounts are based on the fact that facilities which are part of the purchasing group will purchase contract items only from the selected contract supplier, as long as that supplier is able to perform. This is called sole-source commitment.

Areas for improvement
- Sole source commitment
- Group purchasing arrangements

3.4. Supplier selection and quality assurance

3.4.1. Prequalification of suppliers

Prospective suppliers should be pre-qualified, and selected suppliers should be monitored through a process which considers product quality, service reliability, delivery time and financial viability.

Pre- and post-qualification procedures help to eliminate substandard suppliers, if properly managed. Pre-qualification is the procedure of evaluating supplier capacity and reputation before bids are solicited for specific products. Post-qualification evaluates the suppliers after bids have been received.

Areas for improvement
- Restricted tender or open tender
- Process for evaluating new suppliers
- Monitoring of supplier performance
- Supplier ability to trace products

3.4.2. Quality assurance

Procurement procedures/systems should include all assurances that the drugs purchased are of high quality, according to international standards.

Four components make up an effective quality assurance system:
- Selecting reliable suppliers of quality drugs
- Using existing mechanisms, such as the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce
- Establishing a programme of product defect reporting
- Performing targeted quality control testing

Areas for improvement
- Bioequivalence of generic products
- Policy for changing old products with new ones
- Relationship with Drug Regulatory Authority
- Pre- and post-shipment policies and procedures
- Policy and procedures for product quality reporting
- Quality control testing of products

4. IMPLEMENTATION OF OPERATIONAL PRINCIPLES

The twelve operational principles for good pharmaceutical procurement practices aim to improve pharmaceutical procurement by organizations involved in drug supply.

The following should be taken into consideration when using these principles:
- The principles should be used in developing standard operation procedures
- The developed SOPs must be actively implemented and monitored
- Good drug procurement is only possible within a well-managed drug supply system
- The right purchasing and inventory control model should be chosen
- There is the need to build capacity for procurement

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ANNEXES

1. ANNEX 1: WORKSHEET 1

Worksheet 1 Key Activities in Drug Supply Management	Decision Making Criteria for selecting an area for SOP (1 is lowest and 5 is the highest)			
	Yield Greatest Economic Impact	Most Control Required	Good Early Success	Total Score
Selection				
Procurement				
Storage				
Distribution				
Use				
Management Support				

2. ANNEX 2 WORKSHEET 2

Area Selected	Main Processes	Criteria for Decision Making (Rate 1= lowest and 5 = highest)			
		Delays	Productivity impeded	Improvement needed	Total Score

3. ANNEX 3: SOP DEVELOPMENT TOOL

SOP DEVELOPMENT WORKSHEET	
SOP NAME:	
SOP Number:	Date Written:
Written By:	Date Effective:
Approved By:	Date Last Revised:
TASK DESCRIPTION	
Location work is done:	Number of people required:
	Skill level:
Equipment and supplies required:	
Personal protective and safety equipment required:	
Finished product or result expected:	
SCOPE OF THIS SOP	
Operations covered:	Workers covered:	Locations covered:
Specific skills, Training, Certifications, Licenses Required:		

SOP:	
Protocols (steps and procedures involved in this task or process)	