

Standard Operating Procedures (Sops)

3rd year

Laboratory management and quality assurance MLS-QUAL-323

30/12/2018

Us. Fatimaalzahra Ahmed

Learning objectives

- By the end of this lecture you will be able to:
 - Define SOPs
 - Determine the criteria of good SOP
 - Identify standardized format
 - Discuss procedure of preparation of SOP
 - Define job aids

What is an SOP?

- SOPs are also documents, and contain written step-by-step instructions that laboratory staff should meticulously follow when performing a procedure.
- A laboratory will have many SOPs, one for each procedure conducted in the laboratory

- **Written SOPs ensure the following:**
 - Consistency—everyone should perform the tests exactly the same way so that the same result can be expected from all staff.
 - Consistency enables people who use laboratory results to observe changes in a particular patient's results over time.
 - If different laboratories use the same SOPs, comparisons of their results can be made; it should be emphasized that all laboratory staff must follow the SOPs exactly.

- Accuracy—following written procedures helps laboratory staff produce more accurate results than relying on memory alone because they will not forget steps in the process.
- Quality—consistent (reliable) and accurate results are primary goals of the laboratory, and could be considered as the definition of quality in the laboratory.

Criteria of good SOP

- **A good SOP should be:**
 - Detailed, clear and concise, so that staff not normally performing the procedure will be able to do so by following the sop—all necessary details (e.g. Ambient temperature requirements and precise timing instructions) should be included;
 - Easily understood by new personnel or students in training;
 - Reviewed and approved by the laboratory management—approval is indicated by a signature and a date (this is important to ensure that the procedures being used for testing in the laboratory are those that are up to date and appropriate);
 - Updated on a regular basis.

Standardized format

- It is a good idea to standardize the formats of SOPs so staff can easily recognize the flow of the information.
- Headers are a very important part of the format.
- Complete standardized header—typically the standardized header would appear on the first page of each SOP.
- The standardized form makes it easy for staff to quickly note the pertinent information.

Preparing SOPs

- There are a few things to keep in mind when preparing an SOP.
 - Firstly, it is important to assess the scientific validity of the procedure.
 - Then, when writing the procedure, include all steps and details explaining how to properly perform the procedure.
 - The SOP should refer to any relevant procedures that may be written separately, such as instructions for sample collection or quality control.
 - Finally, a mechanism should be established for keeping SOPs updated.

- SOPs should include the following information:
 - Title—name of test;
 - Purpose—include information about the test (why it is important, how it is used, and whether it is intended for screening, to diagnose, or to follow treatment and if it is to be used for public health surveillance);
 - Instructions—detailed information for the entire testing process, including pre-examination, examination and post-examination phases;
 - Name of the person preparing the SOP;
 - Signatures of approving officials and dates of approval—it is necessary to follow the laboratory's quality policy and regulatory requirements.

- Examination instructions should address the actual step-by-step laboratory procedures to follow and the quality control procedures needed to ensure accuracy and reliability.
- Post-examination instructions should provide information on reporting the results, including the unit of measurement to be used, the normal (reference) range, ranges that are life-threatening (sometimes called “panic values”) and instructions for how to deal with an urgent report. They should also include references to the published sources of the procedures, including published evidence that the procedures are scientifically valid.

Manufacturer's instructions

- The instructions that manufacturers provide in their product inserts tell how to perform the test, but do not include other important information that is specific to laboratory policy, such as how to record results, algorithms outlining the sequence of testing and safety practices.
- The manufacturer's instructions may describe recommended quality control procedures for the test, but the recommendations may not be as comprehensive as protocols that a laboratory has put into place.
- **Do not rely solely on manufacturer product inserts for SOPs.** Use information from these inserts, but develop SOPs specific to your laboratory.

What is a job aid?

- **A job aid** is a shortened version of an SOP.
- It is designed for use directly at the testing site.
- It should be placed in a visible location, and serves as a reminder of the steps that need to be completed.
- The job aid and the SOP must include the same instructions.
- If a job aid is distributed to sources outside the laboratory, ensure that the information illustrated matches that which is instructed in the SOP.

- External laboratory assessors often check to see if job aids and SOPs are in accordance.
- Job aids supplement—not replace—the SOP. They do not include all the details that are provided in the SOP

Summary