INTRODUCTION

Preparing Standard Operating Procedures and Reports

Your Faculty

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Clinical Pathology
Case study

In the middle of performing a stat mononucleosis test for the ER, a medical technologist realized that the package insert was not in the box with the reagents he was using. His immediate reaction was to refer to the standard operating procedure manual (SOPM), but he remembered that procedure in SOPM listed is no longer used.

The supervisor posted, a memo noting that package insert must be used until the new procedure was written. The supervisor took out the insert but never put it back and she left for a two-week vacation.
Clinical Pathology Case study

- How could this situation be prevented?
  - Keep SOPs up to date
  - Proper oversight of lab operations

Anatomic Pathology Case study

A development technologist paid close attention to both existing and new Standard Operating Procedures (SOPs) as she prepared to implement a newly validated immunohistochemistry antibody.

Without accurate SOPs, she recognized that transitioning new tests or antibodies from the development area to clinical testing areas would be problematic.
SOPs?

• What is an SOP?
  – Approved procedures that aid and direct employees in completing their work
  – It trains staff members and requires their compliance.
  – Technical SOPs are finely detailed whereas general SOPs cover topics more broadly and may reference the technical SOPs.

SOPs?

• Why are they important?
  – Patient safety by standardization
    • Labs have to do business SAFELY by ensuring patient safety.
  – Efficiency will lower costs
  – Service quality = level of safety, cost, and efficiency
Course Objectives

- Summarize the CLSI Quality Management System (QMS) framework for the Laboratory
- Identify the components and delivery of an SOP
- Identify the components and delivery of a lab report
- Distinguish between properly and improperly written SOPs and lab reports

QMS

- What is a Quality Management System (QMS)?
  - A conceptual framework with 3 areas
    - Cultural
    - Structural
    - Functional
QMS

- **Cultural:** Committing to a vision of quality services
- **Structural:** Maintaining an appropriate scope of services, defined personnel roles and responsibilities, and design/implementation of the QMS
- **Functional:** Managing resources to meet the vision of quality services and assessing the effectiveness of the QMS

**Why is it important?**
- It gives the full benefit of sustained quality of service for customers while also meeting all regulatory and accreditation requirements.
Quality System Essentials (QSE)

- They are the 12 essential elements that comprise a quality management system.

Why are they important?

- They offer an elaborate division of your managerial responsibilities so that you do not have to spend as much time defining the organization of your lab.
Documents and Records

• Document Creation
  – Use a standardized format when creating documents.

• Document Control
  – A master index of all published documents along versioning and distribution information
  – A process to avoid versioning conflicts
  – A process for updating existing documents
  – Authorized versions in accessible locations

Documents and Records

• Document Review and Approval
  – All quality management system documents are reviewed and approved by the Laboratory Director or designated individual prior to implementation and distribution.

• Record Review and Approval
  – The director or other administrator reviews and approves the content and format of patient records.
Documents and Records

- Retention, Storage and Retrieval
  - A policy stating how long documents will be retained.
  - A policy stating all records will be stored securely and accessibly, for a designated period of time.

Knowledge Check

Kelly, a Histology tech, just drafted an SOP document on mailing slides to external labs. What should she do next?

Choose the best answer.
A. Start distributing the document to other lab personnel
B. E-mail it to external labs to get their feedback
C. Print it and place it near the mailing boxes
D. Ask the lab manager to review the document
Components of an SOP

- Title (Test Procedure)
- Clinical Significance
- Scope
- Purpose
- Summary and Explanation
- Min. Volume
- Reagent/Material
- Procedure Calculation
- Specimen
- Principle of the Test
- Instrument
- Interpretation
- Critical Range

Components of an SOP

- Guideline (suggested technique to complete task)
- Materials Required
- Quality Control
- Related Documents
- References
- Document History
- Document Check-in (Signature date + submission instructions)
- Reviewer Signature
- Approver Signature
- Release Date
- Comments
**Creating an SOP**

- Questions to ask yourself
  - **Why** do you do the procedure?
    - Policy states the intent or why we do the procedure
  - **What** is the workflow path of the procedure?
    - Process takes the policy or intent and puts it into action

**Creating an SOP**

- Should be written by the person most familiar with the process
  - e.g., Histology Tech writing the Acid Fast Stain SOP
- Templates
  - Content Management System
Creating an SOP

• Written in a scientific or straightforward manner
  – Specifically address each part of the procedure to avoid ambiguous interpretation
  – Brevity is key, concisely describe the critical steps of a procedure as well as the safety issues without getting too granular.

Creating an SOP

• Write in the present tense as if the procedure is happening in real time as the reader is using the document

• Alert the reader about potential safety risks prior to the step associated with the risk

• Use consistent terminology
Creating an SOP

- Avoid stating opinions or preferences, just the facts
- Include diagrams, tables, charts, and other visual media to help convey procedures

Review and Approval of SOPs

- Content expert approval
- Lab director must approve it as per Clinical Laboratory Improvement Amendments (CLIA) standards
- Comments go to the author so that they can revise the document and resubmit it if necessary
Keeping track of SOPs

• Document Control
  – Require an electronic or handwritten signature and date from the approver
  – Utilize a content management system or other electronic archival system

Keeping track of SOPs

• Document Control
  – Possible conflicting information by improper versioning?
    • Version documents electronically by way of a Content Management System
      – This prevents two different versions of a single document being used by your personnel at the same time
Keeping track of SOPs

• Document Control
  – Set up a regular review for the SOP e.g., annual SOP review
    • Set it and forget it!
  – Have an electronic system in place so that when an SOP is due for updating, it automatically alerts the author and/or approvers

Knowledge Check

Matching – Match the data with the proper SOP component.

A. Chemical hazards, safety SOPs
B. Safe handling of Chemicals
C. The content of this SOP applies to all allied health staff and other professionals who handle chemicals in the lab setting
D. The purpose of this SOP is to ensure that chemicals are safely handled and that risks are identified, with information shared on requirements for safe chemical handling

A. Title (Test Procedure)
B. Purpose
C. Related Documents
D. Scope
SOP Knowledge Check
Scenario – You are writing an SOP for Troponin tests. Which SOP components should be included? (select all that apply)

A. Clinical Significance
B. Related Documents
C. Summary and Explanation
D. Materials Required
E. Principle of the Test
F. Min. Volume
G. Interpretation
H. All of the above

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SOP Knowledge Check
Scenario – You are writing an SOP for complete blood count (CBC). Who should be involved with approving/reviewing this SOP? (multiple choice)

A. Safety and environmental committees
B. Lab Medical Director
C. Lab Medical Technologist
D. Hospital Director

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Standardized Lab Reports

• What is it?
  – Adopting best practices to ensure smooth lab reporting

• Why is it important?
  – Similar to SOPs, standardized lab reports ensure patient safety by clear communication of results between the lab and physician

INTRODUCTION

Lab Reports

Meets regulatory standards of CAP and CLIA

Increases efficiency

It has been found that 30% of pathology report information was incorrectly interpreted by surgeons, in part due to improperly formatted reports²
Elements of a Lab Report

- Historic data
- High results
- Low results
- Reference Ranges
- Critical Values
- Comments
- Collection Time
- Receipt Time
- Patient DOB and sex
- Recipient name
- Ordering provider and/or party
- Facility name and state license

Is your report easy to read and review?

- Communicate the findings only
- Reduce excessive verbiage
- Visual layout should be uncluttered
- Bold the critical result and follow with the reference range
Elements of a Lab Report

- Is your report easy to read and review?
  - Color code if possible
    - Try putting the critical results in red
  - Abbreviate long names
    - ACTH
    - PTH
    - CBC
    - CSF

Elements of a Lab Report

- Is your report easy to read and review?
  - Use diagnostic headings
    - Make the report patient-centered by emphasizing the most important findings
  - Use a consistent layout across all your lab reports
Elements of a Lab Report

• Is your report easy to read and review?
  – White space is OK
    • It improves readability
  – Use a proportional font such as Arial rather than a fixed-width font like Courier

Good or bad report?

Bone Marrow Pathology Report

Diagnosis – Bone Marrow Biopsy, Aspirate and Particle Preparation:
1. Reduced Trilineage Hematopoiesis
2. Acute Myeloid Leukemia, numerous blasts (73%) and eosinophilia (18%)

Microscopic Examination
Blasts 73%
Eos Myelo/Meta 15%
The blasts in the marrow were generally large
Good or bad report?

Bone Marrow Pathology Report

Acute Myeloid Leukemia

Diagnosis – Bone Marrow Biopsy, Aspirate and Particle Preparation:
1. Acute Myeloid Leukemia, numerous blasts (73%) and eosinophilia (18%)
2. Reduced Trilineage Hematopoiesis

Clinical History: A 30 year-old female without any significant past medical history, developed sinus pressure for 4 weeks. She then developed gingival hyperplasia and white blood cell count over 70x 10^9/L.

Microscopic Examination
Bone Marrow biopsy and aspirate were performed with the following abnormal differential counts:
Blasts 73%
Eos Myelo/Meta 15%

Lab Report management

- How can a lab report be accessed by those who need it?
  - Electronic or hard copy?
    - Hard copies must be sealed in confidence and physically mailed
    - Electronic transmission is faster and easier
INTRODUCTION

Lab Reports

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Case Study

- At Greenview General Hospital, a Medical Lab Tech is about to inaccurately post results for a blood test. It seems the chemistry instruments were not properly calibrated according to the Calibration of Chemistry Instruments SOP. Furthermore the result report was not formatted in a manner to highlight the abnormal results found and the physician did not properly convey the importance of the result.

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Case Study

- Is this the fault of the MLT alone or is there more to this picture?
- Who ensures that techs regularly follow SOPs?
- Where else did data become faulty in this case study?

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Best Practices

SUMMARY

• Quality Management System
  – Document Creation, Control, Review, Retention
• SOPs
  – Straight forward, reviewed/approved, up to date
• Lab Reports
  – Formatted for the best readability

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Conclusion

SUMMARY

• Clear communication!
  – Defined laboratory operations (QMS)
  – Pertinent SOPs
  – Readable lab reports

References


References


Congratulations

You have successful completed the online learning course:
Preparing Standard Operating Procedures and Reports

Credit is awarded upon successful completion of the post-test.
- Access the post-test by exiting the course and returning to the course content page.
- Click the link Post-Test to take the exam. You must score 80% in three attempts for credit to be awarded.

Interested in applying Lab Leadership best practices on the job?
- Please download from your Lab Management Tool Kit the performance support tools provided to help apply the skills learned in this course.
- Please join the lab leadership best practices discussion at the Lab Management University online Leadership Communities of Practice.
Think about it

_If you don’t have time to do it right you must have time to do it over._

-Unknown

Conclusion

“You get the best effort from others not by lighting a fire beneath them, but by building a fire within.” _Bob Nelson_

“Probably my best quality as a coach is that I ask a lot of challenging questions and let the person come up with the answer.” _Phil Dixon_

“Coaches have to watch for what they don’t want to see and listen to what they don’t want to hear.” _John Madden_