Policies and Procedures:

It’s not OUR fault that nurses won’t read our SOPs!

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Speaker Financial Disclosure Information

- Grant/Research Support: None
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- Board/Committee/Advisory Board Membership: None
- Stocks/Bonds: None
- Honorarium/Expenses: None
- Intellectual Property/Royalty Income: None

Sentara Healthcare

Elevate your career.
Objectives

Participant will be able to:

Upon completion, the attendees should be able to:
- Describe a process for writing effective and efficient P&Ps
- Compile and analyze a Process Map
- Create documents that
  - are easy for the intended audience to understand and follow as instructed
  - consistently produce an expected outcome

Why do POCT Operators avoid SOPs?

- Too Busy
- Don’t know how to find them
- Difficult to retrieve
- Don’t understand them
- Too technical
- Easy to skip over details
- Don’t need a procedure

Is this SOP written for the audience?

1. Quality Control Procedure
   1. Quality Control Procedure
   2. Quality Control Procedure
   3. Quality Control Procedure
   4. Quality Control Procedure
   5. Quality Control Procedure
   6. Quality Control Procedure

   The purpose of this paper is to define and analyze the relationship between the P&Ps and the intended audience. The documentation and analysis are based on the intended audience.

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How Can You Help?

• Write to your audience
• Say what you do, and do what you say
• Design the SOP to avoid error

Document Hierarchy

- Policies
- Procedures
- Job Aids
- Forms

Document Differentiation

1. Policy
   - High level expectation mandated by a regulatory requirement or self-imposed requirement
   - The “what” and “why”

2. Process
   - Sequence of activities
   - Inputs into outputs
   - Describe operations of a workflow
   - The “how it happens”
Document Differentiation 2.

- **Procedure**
  - Step-by-step required actions to perform activities in a process
  - The "how to do"
  - Steps in column one; supplemental guidance in column two
  - Job aids referenced within action steps
  - Adherence to required actions = policy compliance

Document Differentiation 3.

- **Job Aids** ("More Tools")
  - Tools needed in the workplace to effectively carry out the procedure and work in the process
  - Condenses procedure information into a shorter format for rapid access
  - Instructions, lists, quick reference materials
  - Written, graphical, combination
  - Subject to document control
    - Should connect to the related procedure

Document Differentiation 4.

- **Forms**
  - Records - what was done
  - NOTE1: Documents are created by planning what needs to be done; Records are created when something is done.
  - NOTE2: Documents can be revised; records should never be revised.
11 Steps: Simplify Work Process

1. Map the current process
2. Identify requirements the process must meet
3. Evaluate the process for risk and effectiveness
4. Modify the process to reduce risk and improve effectiveness
5. Assess document needs
   • Policy, Process, Procedure, Job Aid, Form

Process Map

• What is a process map?
  • A process map is a tool/technique used to illustrate the steps of a process in sequence
  • Swim Lane Chart
• Benefits of a Swim lane chart
  • Identify who is responsible
  • Identify hand-offs
  • More detailed workflow

Process Map Template

• Organizes the process map by roles
• Indicates process states and transitions

<table>
<thead>
<tr>
<th>Patient</th>
<th>Assessment</th>
<th>Application</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>Transition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse</td>
<td></td>
<td></td>
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<tr>
<td>LPN</td>
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<td></td>
</tr>
</tbody>
</table>
Process Evaluation

• Flow
  o bottlenecks
  o duplication
  o redundancies
  o excessive hand-offs
• Complexity
  o detail
  o necessity of steps
• Risk (patient, employee, quality, financial)
  o likelihood of error
  o severity of error if occurs
  o likelihood of catching the error
• Compliance with requirements

Modify Process

• Remove any unnecessary steps
• Consider alternate workflows to address bottlenecks
• Balance complexity with level of knowledge and skills of the individuals
• Address areas of risk:
  o Avoid areas of risk – remove cause of risk
  o Decrease risk – add checks into the process
  o Bring attention to unavoidable risk – Stop gaps in the computer system, signs, job aids, etc.
  o Poka Yolk (mistake proof)
• Ensure compliance with regulatory and accreditation requirements
• Develop & assess process monitors

11 Steps: Simplify the Procedure

6. Create needed documents
7. Obtain appropriate reviews and approvals
8. Educate/Train
9. Implement
10. Maintain Document Control
11. Develop methods to monitor the document for compliance
Format the procedure effectively

- Title
  - Brief, unique, descriptive
  - Unique identifier
- Two columns for novice-to-expert application
  - "Required Action Steps" for all
  - "Supplemental Guidance" when further information is needed
- Three columns for multi-actor procedure
- Sequential action steps written as clear, concise phrases beginning with an action word and written in the order needed

Format the procedure effectively

- Required headings: equipment, reagents/supplies, action steps
- Cautions and notes and limitations placed before the step to which they apply
- Job aids referenced with related action steps
- Related documents
- Clear instructions reduce the risk of error

Terms to Convey Compliance Expectations

- **Shall**
  Individual must follow the directive exactly and in all situations. STOP if the directive cannot be met.

- **Should**
  Directive is highly recommended, but there may be extenuating circumstances that make the action inappropriate for the situation at hand. Consult with manager before choosing not to perform the action.

- **May**
  Individual discretion or professional judgment is used to determine if the action is appropriate.
Procedure Example

**Procedure Example**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Division:</td>
<td>Example</td>
</tr>
<tr>
<td>Original Date:</td>
<td>Example</td>
</tr>
<tr>
<td>Version Date:</td>
<td>Example</td>
</tr>
</tbody>
</table>

Procedure: POC 1.12 Ultrasensitive Testing for C-reactive Protein

Description (Most Recent)

1. Place the test cassette on the test area.
2. Fill the test cassette with sample.
3. Insert the test cassette into the reader.
4. The results are displayed on the reader.

Procedure Example, 2 Column

**A. Required Action Steps: Chemistry and NIBS Testing**

- Required Action Steps
- Supplemental Guidance

- Required Action Steps
- Supplemental Guidance

Procedure Examples, 3 Column

<table>
<thead>
<tr>
<th>Required Action Steps</th>
<th>CAF Survey Testing</th>
<th>Supplemental Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prepare and perform testing according to the instructions using routine methods.</td>
<td>Performed by:</td>
<td>Specimen is to be handled in the same manner as patient specimens.</td>
</tr>
<tr>
<td>2. Ensure all personnel involved in testing have appropriate certification.</td>
<td></td>
<td>If CAF survey materials are used for an internal proficiency test, testing shall not be concluded until all required tests have been completed and a summary report of the results (CAF report) is generated.</td>
</tr>
<tr>
<td>3. Annotate documents handling equipment.</td>
<td>Laboratory Staff</td>
<td></td>
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<tr>
<td>4. Fill out computerized documents.</td>
<td>Medical Device</td>
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<tr>
<td>5. File all documents in appropriate location.</td>
<td>Laboratory Staff and Laboratory Manager</td>
<td>Signed documents (CAF Survey Submissions, Monthly QC summaries, etc.) are filed according to the type of document.</td>
</tr>
</tbody>
</table>
Result Interpretation

11. Read the results at 15 minutes through the device window.

12. If the result is off the scale, retest the sample in the test window if necessary.

13. Results read before or after 15 minutes may be inaccurate.

14. Recheck interpretations.

- T1 Positive: Any pink to purple Test Line (T1) along with a pink to purple Control Line (C) is a positive result of a 100% reading of the test sample.

- T1 Negative: No pink to purple Test Line (T1) along with a pink to purple Control Line (C) is a negative result, indicating no reading of the test sample.

- T2 Positive: Any pink to purple Test Line (T2) along with a pink to purple Control Line (C) is a positive result of a 100% reading of the test sample.

- T2 Negative: No pink to purple Test Line (T2) along with a pink to purple Control Line (C) is a negative result, indicating no reading of the test sample.

- T1 + T2 Positive: Any pink to purple Test Line (T1 and T2) along with a pink to purple Control Line (C) is a positive result of a 100% reading of the test sample.

- T1 + T2 Negative: No pink to purple Test Line (T1 and T2) along with a pink to purple Control Line (C) is a negative result, indicating no reading of the test sample.

Document Reviews

- Document Reviews:
  - Draft Review – experienced staff (accuracy)
  - Validation Review – inexperienced staff (effectiveness)
  - Approval Process (2 levels – Technical documents)
  - Prior to use of the document
  - Acknowledgement (Read & Sign) Process

Draft Review

- Preprint: To verify accuracy and completeness of the document.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Comments</th>
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<td>Are all steps defined and appropriate for the content?</td>
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<td>Are all steps necessary and properly completed in the right sequence?</td>
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<td>Are all materials measured and recorded accurately?</td>
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<td>Are all materials listed and recorded accurately?</td>
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<td>Are all of the material and equipment included in the procedure?</td>
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Validation Review

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<td>Is there sufficient guidance to perform the intended steps or record information, when applicable to the document, consistently with no variation?</td>
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<td>Are the formulas and calculations correct, explained, and accurate?</td>
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<td>Do all related documents provide consistent information and work well together?</td>
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Read & Acknowledgement

**Title:** [Title of Document(s)]

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<th>Signature</th>
<th>Date</th>
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Signing-off on the above document(s) indicates that the staff member has read and understood the document(s).

Are We There Yet?

- Action plan for implementation
  - Document management (load in system)
  - Training & assessment for existing employees
  - Incorporate into new employee orientation curriculum
  - Verification of implementation
- Observe performance to ensure that changes are translated into work practice
- Monitor and track outcomes
Document Maintenance

- Periodic Review Process
  - Review by designated staff
  - Revise as needed
  - Documentation
  - Control of Documents
- Printed copies

Review vs Revise

- Review
  - Designated and qualified personnel
  - Periodic as defined (biennial), or
    - Investigation (audit, NCE, RCA, PI)
  - Related processes are revised
  - Keep, Change, Retire
  - Document
- Revise
  - As needed

Standardization

1. Efficient way to achieve compliance
2. Reduces errors in point-of-care test programs
   - Each staff member performs test in the same way
3. Standardizing the following helps with consistent, high quality performance:
   - Format-placement, font type & style, margins, order of sections, numbering
   - Content-headings, abbreviations
Standardization

2.

- Eliminates need for different procedures and maintenance of multiple documents for the same test analyte
- Assures only current documents are available
- Organize for ease of retrieval
- Work with different departments to develop a process = one procedure/process for test facility

References


Questions?

Contact Information: lwyer@cox.net