Patient-Centric Histology: Efficient and Effective Workflow

PRESENTED BY OLGA KOCHAR, M.S., CSSGB
DIRECTOR OF LABORATORY AND TRANSFUSION SERVICES, THE GEORGE WASHINGTON UNIVERSITY HOSPITAL
FACULTY, SCHOOL OF MEDICINE AND HEALTH SCIENCES, THE GEORGE WASHINGTON UNIVERSITY WASHINGTON DC
OLGA.KOCHAR@GWU-HOSPITAL.COM

Workflow Analysis: Objectives

Upon completion of this webinar, participants will be able to:
- Outline the need to improve patient safety
- Analyze major risk factors for patient safety in the histology laboratory
- Discuss possibilities for mitigation or elimination of these risk factors
- Identify and improve the key metrics in your histology laboratory based on best practices
- Analyze existing laboratory process and identify areas of improvement

Disclaimer

The following document was distributed as a handout for the 2016 Laboratory Webinar Series and is designed to enhance the sessions you have attended. NSH makes no representations to the factual correctness of any information contained herein. All of the content comprising this handout is the exclusive property of the presenter and the National Society for Histotechnology. It may not be copied, reproduced, distributed, displayed or transmitted without the consent of the presenter or the National Society for Histotechnology.
What is Workflow?

Workflow Analysis NSH Histology Leader Webinars March 23rd 2016

From DAKO “Immunohistochemistry Guide”

Workflow Analysis: Process

Six Pillars of Process Management

- VOC
- Process
- Measurement
- Roles and responsibilities
- Process review
- Linking and leveraging

Process Management

Histology Process: Considerations

- Is this how you measure your process?
  - Cost-benefit analysis?
  - Regulatory Compliance?
  - Organizational needs?
  - Pathologists preference?
  - This how we always did it...

- How about our patient?
Histology: Food for Thought…

- 98K patients die from medical error-related issues
- 440K patients die if you include documentation, communication and overall EMR records
- Up to 8% of tissue slides are contaminated
- One study showed that 100% of stainers examined were contaminated...
- Patient Safety and Risk Mitigation: CAP, CMS, CLIA, State Organizations

Histology: Vulnerability Points

- Batch processing of containers
- Manual cassette printing
- Grossing/Embedding multiple specimens at the same time
- Carry-over in tissue processors or errors in processing (sequence of solutions, etc.)
- Batch printing of slides (wrong slide can be picked up)
- Manually labeled slides (Mislabeled slides or hard to read)
- Waterbath contaminants
- Microtomy challenges: depleted tissue, microtomy artifacts
- Pulling wrong block for IHC
- Dilution errors
- Wrong reagent/Wring control/Wrong unstained slide used
- Over labeling Slides (Mislabeled Slides)

Histology: Vulnerability Points

- Based on one of the studies, average lab helps 93 patients per day
- Each patient is “touched” at least 8 times: 1 specimen, 3 cassettes, 3 slides, one additional stain
- 744 possibilities for an error
Workflow Analysis: Process

- VOC – how to interpret the Voice of The Customer and link their wants/needs to the process goals and measures
- Who is your ultimate Customer?
- Process: map, analyze, streamline
- Measurement: data collection; data display; biases
- Roles and Responsibilities: WHO WHAT WHEN - different members of the team will drive process management, standardization and improvement
- Process Review: How to drive the process
- Linking and Leveraging: How to link all of the above activities to the strategic direction and goals of the Laboratory and align with the key desired results

Workflow Analysis: Process

- To improve the process, improve the efficiency and effectiveness of those steps that add value, and eliminate or minimize steps that do not add value
- By analyzing your "current state" you can determine which steps add value, as well as where and when defects occur

Workflow Analysis: Patient-Centric view

Process Evaluation and Stability - 3 main components:

I. Risk Assessment (RA)
   A. Collect Data
   B. Assess the frequency of occurrence of the error and the potential harm (impact) if an error when it does occur

II. Quality Control Plan (QCP)
   A. Design the control mechanisms in place for detecting, controlling or preventing errors
   B. Defines resulting QC and acceptability criteria

III. Quality Assessment (QA)
   A. Designed to measure (and to monitor) the effectiveness of the Quality Control Plan you implemented
   B. Brainstorm if need be and adjust accordingly
Workflow Analysis: Risk Assessment

- Identify the RISKs (sources of potential failures and errors) associated with the test system
- Risk Assessment Components (as defined by CMS)
  - specimen
  - test system
  - reagent
  - environment
  - testing personnel

Workflow Analysis: Risk Assessment Components

Risk Assessment Components (as defined by CMS)
- Specimen
  - Patient preparation, collection, labelling, storage preservation, cold ischemic time, transportation, processing, acceptability
- Test System
  - Inadequate sampling, bar code readers, function checks, built-in controls, external controls, temperature monitors/controllers, software/hardware, transmission of data to LIS, result reporting
- Reagent
  - Shipping/receiving, storage, expiration dates, preparation, validation
- Environment
  - Temperature, airflow/ventilation, light intensity, humidity, altitude, dust, water, utilities, space
- Testing Personnel
  - Training, competency, education, experience, staffing

Workflow Analysis: Risk Matrix

Severity of harm (Impact)

<table>
<thead>
<tr>
<th>Probability of Harming</th>
<th>Severe</th>
<th>High</th>
<th>Moderate</th>
<th>Low</th>
<th>Negligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>&gt;6</td>
<td>6-3</td>
<td>3-1</td>
<td>1-0.5</td>
<td>&lt;0.5</td>
</tr>
<tr>
<td>Probable</td>
<td>&gt;6</td>
<td>6-3</td>
<td>3-1</td>
<td>1-0.5</td>
<td>&lt;0.5</td>
</tr>
<tr>
<td>Occasional</td>
<td>&gt;6</td>
<td>6-3</td>
<td>3-1</td>
<td>1-0.5</td>
<td>&lt;0.5</td>
</tr>
<tr>
<td>Rare</td>
<td>&gt;6</td>
<td>6-3</td>
<td>3-1</td>
<td>1-0.5</td>
<td>&lt;0.5</td>
</tr>
<tr>
<td>Infrequent</td>
<td>&gt;6</td>
<td>6-3</td>
<td>3-1</td>
<td>1-0.5</td>
<td>&lt;0.5</td>
</tr>
</tbody>
</table>
Workflow Analysis: Risk Matrix Examples

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Frequency of Occurrence</th>
<th>Specificity of Harm</th>
<th>Measures to control risk</th>
<th>Relevant SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Identification</td>
<td>Occasional</td>
<td>Minor - Critical</td>
<td>Patient identification criteria defined; acceptability defined; competency assessment performed</td>
<td>SOP 0000</td>
</tr>
<tr>
<td>Collectors/Container</td>
<td>Occasional</td>
<td>Major - Critical</td>
<td>Collection and container criteria defined; acceptability defined; competency assessment performed</td>
<td>SOP 0000</td>
</tr>
<tr>
<td>Transport</td>
<td>Occasional</td>
<td>Minor - Critical</td>
<td>Transport criteria defined per source; acceptability defined; competency assessment performed</td>
<td>SOP 0000</td>
</tr>
<tr>
<td>Storage</td>
<td>Occasional</td>
<td>Minor - Critical</td>
<td>Storage criteria defined per source; acceptability defined; competency assessment performed</td>
<td>SOP 0000</td>
</tr>
</tbody>
</table>

Workflow Analysis: Risk Matrix Examples

<table>
<thead>
<tr>
<th>Test Results</th>
<th>Frequency of Occurrence</th>
<th>Severity of Harm</th>
<th>Measures to control risk</th>
<th>Relevant SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission of results</td>
<td>Unlikely</td>
<td>Negligible - Minor</td>
<td>Periodic review of returned results; customer feedback</td>
<td>SOP 0000</td>
</tr>
<tr>
<td>Received results</td>
<td>Occasional - Frequent</td>
<td>Negligible - Minor</td>
<td>Review of all (per patient) returned results ensuring to ID and Appropriate investigation for all reporting errors</td>
<td>SOP 0000</td>
</tr>
<tr>
<td>Clinician feedback</td>
<td>Occasional</td>
<td>Minor - Critical</td>
<td>Appropriate investigation for all clinician feedback, issues, complaints</td>
<td>SOP 0000</td>
</tr>
</tbody>
</table>
Workflow Analysis: Monitoring

- Develop a “Post-Implementation Monitoring Process” that will allow you to know when a process is in need of review/revision
- This monitoring process may include the periodic review and monitoring of the following (just a few examples; please cover all stages of the process as in any other Quality Review):
  - Specimen collection/transportation, etc. protocols
  - Staff training
  - Competency assessment
  - Proficiency testing
  - Quality Control/Instrument function results
  - Unexpected Errors
  - Laboratory error investigation/remediation
  - Complaint investigation/remediation

Workflow Analysis: Data Collection

- What are the most important steps in your workflow?
- Accurate data – report what you see and measure, no biases of what you think your process is...
- Start with analyzes of the distribution of samples over time (goal is to identify overall workload patterns to assess whether resources are appropriately matched to needs, and whether turnaround time or other performance indicators can be improved)

Workflow Analysis: Interviews and Observations

- An opportunity for staff to participate in analyzing workflow and improving performance
- Build a multi-departmental group to look at all pre-analytical challenges your clients might be faced with
- Identifies issues that would not be readily apparent from data collection alone (statistics are dry)
- Helpful in understanding of pre-analytical limitations
- Helps identify where you need to work on standardization the most
Note areas of batch processing (not only TAT delays, but possible area of errors/mislabeling)
Mark examples of physical bottlenecks: getting up and loading specimens into the stainer or moving the rack from the stainer to the coverslipper (try to identify and quantify)
Same for non-physical bottlenecks: case assignment, manual verification
Not always possible to eliminate all bottlenecks, but we might be able to mitigate their impact through new technology, alternative processing modes, and workflow redesign
Again, patient safety focus especially if utilization of technology is possible...
Workflow Analysis: Current State
- Understand “as is” process
- Be true with yourself
- Goals are to identify sources of delay; re-work due to errors; duplicate efforts; unnecessary steps; cycle time and handoffs
- Develop an understanding of What is it? Why use it? Who needs it?

Workflow Analysis: Waste of Motion
- Outline your ideal workflow or process
- Design your new to-be process as close to your “ideal process” as possible based on the “current state”
- Avoid identified traps and non-value add activities
- Listen to your customers (Voice of the Customer)
- “Listen” to your business (Voice of the Business, including Risk Mitigation)
- What do you want to improve? What is most important?
- Multi-disciplinary approach
Workflow Analysis: Conclusions

- Quality is Everything!!!
- It is not enough to put a perfect solution in place – it has to be maintained over time (buy-in from everyone)
- Continue to monitor key measures
- Continue to review work methods and procedures
- Take appropriate actions when problems occur
- Set stretch goals and continuously improve
- Process Owner has an ongoing accountability for monitoring the process
- Re-evaluate your process any time major changes occur: new staff, new equipment, new workflow, new tests, etc.

Workflow Analysis: References and Materials

- "LEAN for Practitioners (Healthcare) by Oriel STAT A Matrix, 2015 (some of the schematics used are from this publication)
- "Using LEAN Principles to Improve Quality, Patient Safety, and Workflow in Histology and Anatomic Pathology" by Serrano, Leo FACHE, and others
- "Improving Patient Safety Through Quality Assurance" by Stephen S. Raab, MD
- "Transforming Histology Operations with Workflow Optimization and Automated Systems" by Leo Serrano
- "The benefits of continuous workflow" by Matthias Hoogland
- The Err is Human: Building a Safer Health System

Workflow Analysis: Questions?

Olga Kochar, MS, CSSGB
Olga.Kochar@gwu-hospital.com
Thank you to all of my colleagues who over the years taught me everything I know, I appreciate all of you!