Inspecting Virtually: The Next Best Thing to Being There!

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Overview

Loyola Medicine – Regional Laboratory Services

• Background and Inspection Goals
• Inspection Timeline and Process
• Inspection
  • Inspection preparation
  • Inspection
  • Summation
• Benefits and Challenges
• CAP resources and tools to streamline inspections
• Lessons Learned and recommendations for future success
Learning Objectives

Upon completion of this webinar, participants will be able to:

• Identify available resources to plan for a virtual CAP inspection
• Maximize the accessibility of document control systems to facilitate a transparent and efficient inspection process
• Discuss strategies of inspectors to organize tasks to enable a thorough and focused audit of laboratory operations
• Recount several challenges and advantages of inspecting virtually
• Foster collaborative relationships between inspection teams and virtually inspected laboratories
Late last year, the laboratory at Loyola Medicine, a 550 bed, academic medical center inspected a similarly sized academic medical center.

The site inspected had multiple physical locations and an extensive activity menu.

Due to rising COVID-19 cases and institutional restrictions for traveling and visitors, both sites and CAP agreed to a completely virtual inspection.
Background

Total Number of inspectors – 14 with 2 not pictured as they were completely virtual inspectors. 5 of our inspectors were first time inspectors.
Inspection Goals

- Conduct a fair and thorough inspection following the "Read, Observe, Ask, Discover" inspection methodology
- Encourage an environment of continuous improvement
- Engage with our peers to learn and share ideas for quality and workflow improvement
CAP Resources and Tools

- Utilize Virtual Inspection Process Overview Document
  - Details the requirements of virtual inspections
    - Digital Requirements
    - Highlights that the inspection team will still perform a thorough review of the laboratory while not actually going on site.
  - Details the overview of the inspection planning and requirements from both teams on the day of inspection.

- Utilize the Inspection Planning and Tracking Tool
  - Can aid the inspecting team in structuring the document review process.
  - Can serve as a “To Do List” and ensure that all documents that were requested are reviewed.

- Utilize the section specific Inspection Tip Sheets – Great tool for 1st time inspectors!
  - Tailored to each specific section and can ensure that inspectors are focusing on the elements for that particular section.
Inspection Preparation

- Selecting inspectors
  - *Skill level – mix of experience and new inspectors*
  - *Meet with prospective inspectors to give an overview of expectations, goals, and workflow*

- CAP inspector training
  - *Inspection Team Member Training*
  - *Performing Virtual Inspections: Being the CAP’s ‘Eyes and Ears’ from Home*
  - *Review of Section-Specific Tip Sheets*
  - *Utilize the resources available from CAP Accreditation Resources*
Inspection Preparation

• Digital experience:
  • Technical challenges – having enough microphones, webcams, computers available
  • Inspection site had access to iPads for giving tours. This provided great visual capabilities but was shaky and had connection issues as well.
    • This allowed for the inspector to be able to engage and ask questions about their workspace and workflow directly with their team
  • Lesson learned: Add digital platform training for users less familiar with these platforms
    • Recommend testing audio/visual components ahead of time

• Record management:
  • Having scanned records made the inspection process substantially easier for both teams. This takes more time during preparation but makes inspection workflow much smoother.
Inspection Preparation

- Preparing content packages for each inspector:
  - Provide CAP inspector resources including tip sheets
  - Include all relevant items provided by CAP: activity menu, equipment lists, past inspection information, and proficiency testing, etc.
  - For the virtual inspection: also needed to include Inspection Planning and Tracking Tool excel sheet which guides request lists by CAP Number and Checklist.
    - We modified the Document Request sheet from CAP tailored to each department.
    - Used past deficiencies and other provided information to guide areas of focus for document sampling.
    - Added specimen tracers to cover key testing components from pre-analytical to post analytical testing.

<table>
<thead>
<tr>
<th>Heme Tracer 1: CBC</th>
<th>Select a sample from May 15th 2020 with a critical value. Show instrument maintenance for this month, QC, temperature records, Final report with critical call documentation, competency records for performing tech.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heme Tracer 1: Coag</td>
<td>Select a sample from January 16th 2021. Show instrument maintenance for this month, QC, temperature records, Final report with critical call documentation, competency records for performing tech.</td>
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Inspection Preparation

• After providing inspection packets to inspectors – hold an inspection prep meeting with each inspector regardless of their level of inspection experience
  • Virtual/modified inspections are new for all
  • New inspectors can really benefit from talking through their section specific tip sheets
    • Focus on areas that are common citations in their section-specific checklist and the All Common checklist.
  • Confirm their comfort level with the technology platforms that will be used
  • Discuss the overall timelines for their part of the inspection and if they will need to share a leader from the institution with another member of our inspection team.
# Inspection Preparation

<table>
<thead>
<tr>
<th>Documents Requested</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Training and competency</strong></td>
<td></td>
</tr>
<tr>
<td>Records of degree/transcript and work history</td>
<td>* Will request specific users</td>
</tr>
<tr>
<td>Written protocol of activities and nature of supervision for each non-pathologists</td>
<td>Please provide policy</td>
</tr>
<tr>
<td>performing gross examinations</td>
<td></td>
</tr>
<tr>
<td>Assessment by a pathologist of non-pathologists assisting with gross examination</td>
<td>Provide on example for a recently hired employee</td>
</tr>
<tr>
<td>Training documents for:</td>
<td>Embedding, microtomy, tissue processing, IHC (with examples for the same</td>
</tr>
<tr>
<td>Competency documents for:</td>
<td>specific users requested above)</td>
</tr>
<tr>
<td>Quality</td>
<td></td>
</tr>
<tr>
<td>Notification of methodology changes</td>
<td>If any methodology changes occurred</td>
</tr>
<tr>
<td>Records of daily review of histologic slide quality</td>
<td>Nov 2020, May 2021</td>
</tr>
<tr>
<td>IF QC records</td>
<td>Nov 2020, May 2021</td>
</tr>
<tr>
<td>IHC QC records</td>
<td>Nov 2020, May 2021</td>
</tr>
<tr>
<td>Examples of failed QC with troubleshooting</td>
<td>If any available</td>
</tr>
<tr>
<td>Statistical records and annual summary</td>
<td>2020</td>
</tr>
<tr>
<td>Records of retrospective review and evidence of corrected reports, if applicable</td>
<td>If any available</td>
</tr>
<tr>
<td>HER2, ER, PgR proficiency testing records</td>
<td>PM-B 2020, PM-A 2021</td>
</tr>
</tbody>
</table>

PLEASE NOTE - Document Request must be for sampling purposes only.
## Inspection Preparation

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<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PLEASE NOTE - Document Request must be for sampling purposes only.</strong></td>
<td><strong>Equipment</strong></td>
</tr>
<tr>
<td>Microscope maintenance</td>
<td>Annual for 2020</td>
</tr>
<tr>
<td>Check NIST thermometer standard</td>
<td>Most recent certificates</td>
</tr>
<tr>
<td>Temperatures logs for completion, appropriate ranges, corrective actions and monthly review</td>
<td>Autopsy, histology: Nov 2020, May 2021</td>
</tr>
<tr>
<td>Instrument/equipment maintenance logs and repair records</td>
<td>Nov 2020, May 2021</td>
</tr>
<tr>
<td>Cryostat decontamination records</td>
<td>Nov 2020, May 2021</td>
</tr>
<tr>
<td>Microwave reproducibility and ventilation checks</td>
<td>Most recent records</td>
</tr>
<tr>
<td>Sampling of EM calibration records</td>
<td>Most recent calibration</td>
</tr>
<tr>
<td>Pipette Verification</td>
<td>2020, 2021 records</td>
</tr>
<tr>
<td>Bench maintenance: Microtomy</td>
<td>Nov 2020, May 2021</td>
</tr>
<tr>
<td>Chemical fume hood maintenance</td>
<td>2020, 2021 records</td>
</tr>
<tr>
<td>Chemical monitoring records for Xylene, Formaldehyde</td>
<td>2020, 2021 records</td>
</tr>
<tr>
<td>Waterbath temperatures</td>
<td>Nov 2020, May 2021</td>
</tr>
<tr>
<td>Oven temperature checks</td>
<td>Nov 2020, May 2021</td>
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</tbody>
</table>
Inspection Preparation

• Scheduling
  • Setting schedules guided by CAP recommendations for time spent inspecting is key.

<table>
<thead>
<tr>
<th></th>
<th>Limited Service Laboratory</th>
<th>“Full” Service Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>General/Administrative</td>
<td>2-3 hours</td>
<td>3-4 hours</td>
</tr>
<tr>
<td>Proficiency Testing</td>
<td>1 hour</td>
<td>1.5 hours</td>
</tr>
<tr>
<td>Core Lab</td>
<td>3 hours</td>
<td>4-5 hours</td>
</tr>
<tr>
<td>POC</td>
<td>1 hour</td>
<td>2 hours</td>
</tr>
<tr>
<td>TRM</td>
<td>1 hour (limited)</td>
<td>3-4 hours (full with ID)</td>
</tr>
<tr>
<td>MIC</td>
<td>1 hour (limited)</td>
<td>3-4 hours (full with ID/Sens, possibly)</td>
</tr>
<tr>
<td>Blood Gas</td>
<td>1 hour</td>
<td>1.5 hours</td>
</tr>
<tr>
<td>Personnel files and competency</td>
<td>1 hour</td>
<td>2 hours</td>
</tr>
<tr>
<td>ANP/CYP</td>
<td>0.5 (FS only)</td>
<td>2 hours</td>
</tr>
</tbody>
</table>

• Lessons learned:
  • Specify time in schedule for document review vs. video meetings and schedule team members away from lab so that inspectors don’t feel like they have to “multi-task” their regular job responsibilities with inspector responsibilities.
Inspection Preparation

• Scheduling with inspection site
  • Plan time for virtual safety walkthrough – technology may be a challenge.
  • Discuss expectations for what will be provided for document review vs. in meetings.
    • What is available in policy manager and accreditation manager?
    • What will be scanned vs. shared via camera?
    • Pathology slide review – can telepathology be utilized?
    • Scheduling introductory meeting and summation
**Timeline**

- **2 months in advance**
  - Determine inspection date and type of inspection with inspection site
  - Begin recruiting team members

- **1 month in advance**
  - Schedule meeting with site leaders to discuss expectations, logistics, and accessibility
  - Schedule Introduction, Summation, interviews for each lab area, and leadership interviews with Team Leader
  - Discuss virtual walkthroughs and what technology barriers to expect
  - Have team members complete Inspector Team Member training and Performing Virtual Inspections: Being the CAP’s ‘Eyes and Ears’ from Home

- **2 weeks in advance**
  - Have team members perform document review and submit record requests using the Inspection Planning and Tracking Tool

- **2 days of inspection**
  - Conduct interviews to ask questions, observe practices, and complete the “discovery” phase of inspecting. Leave time for follow up interviews if needed, in case not all requested information is able to be provided.
  - Provide list of citations and recommendations to site leaders in “real-time” to allow for corrections.
  - Wrap up and hold Summation
Inspection

- **Virtual Inspection Challenges**
  - **Distractions:** It’s easy to be distracted by routine work when inspecting from your lab.
    - **Lessons learned:** Try to schedule quiet inspection space away from the lab, set out of offices messages, and treat the inspection time as if you are completely off-site.
  - **Missing “perks” of away inspections**
    - **Lessons learned:** Schedule a group meal (either virtually or socially distanced) so that the team is still able to bond and discuss the inspection.
  - **Virtual bottlenecks:** Different inspectors want to meet with the same leader at the same time
    - **Lessons learned:** Creating a schedule for all to follow helps alleviate any confusion.
Virtual Inspection Benefits

- *Time saved on traveling between sites and meetings.*
- *Allows for additional team members to sit in and learn the process of an inspection.*
- *Able to accommodate inspector schedule better – able to inspect on their own prior to the rest of the team if scheduling conflict doesn't allow inspectors to participate during main inspection days.*
- *More experienced inspectors have the opportunity learn a new way of inspecting.*
- *Allows for all involved to be socially distanced.*
Team Leader’s Role

1. Help inspectors remain on task and focused on their assignments
2. Assure coverage of work-related tasks to not distract/detract from inspection
3. Assure adequate training and preparation
4. Confirm accessibility to document control system or receipt of shared documents
Team Leader Interviews

Viewed as a major advantage to schedule virtual interviews with Directors, Institution Executive(s), and Chief Medical Officer

Scheduling Interviews with Directors, CMO, CEO/VP

*Suggest using leading, open-ended and engaging Interview Questions*

1. How did the laboratory respond to the early demands of the pandemic in providing key diagnostic services?

2. Describe a quality initiative led by the laboratory that has resulted in improvements in patient care.

*Compliment! Offer praise/accolades for lab staff*

*Communicate concerns regarding unresolved or serious deficiencies*

*End with a forward-looking statement – offer reassurance – i.e. guidance is available to help resolve/address issues*
Inspection Summation Conference

- Hold a pre-summation meeting to discuss findings – this is a great opportunity to have a group lunch/dinner
  - Discuss what worked well, what could be improved
  - What ideas inspectors will take back to their own labs
  - Discuss trends and items to highlight during the summation
  - **Check A-V connection and controls prior to live summation**

- Potential benefit of a virtual inspection: More frontline engagement – summation is more accessible to the lab being inspected as it can be joined from anywhere

- **Zoom etiquette is key:**
  - Microphones muted for non-speaking participants
  - Setting an agenda to prevent people from speaking over each other
  - Preparing for technical challenges
Team Leader’s Role (continued)

1. Wrap-up
2. Paperwork
   
   *Protecting PHI*
   
   *Discarding all documents*

3. Soliciting and providing feedback to CAP
   1. *Provided to inspectors during summation*
   2. *Collected and sent to CAP*
   4. *Remain auditable by CLIA*
## Plus/Delta of Virtual Inspections

### Safety - Social distancing
- A more planned process
- Increased document and personnel records review time for scrutiny
- Increased number of inspectors, particularly pathology residents and those not typically able to travel
- Accommodation of busy schedules

### Lack of spontaneity; reduced or inhibited interactions with lab staff
- Decreased opportunities for personal collaboration
- Increased time required to search/find evidence of compliance within policies and procedures
- Disruptions/distractions while multi-tasking with primary work
- Reduced visualization of operations
Thank You and Q&A

Thank you for joining our webinar. We hope this webinar will prove to be beneficial to you as you prepare for your virtual inspection experience.

We will now provide answers and feedback to your submitted questions.