Todays Speakers:

Kathy Good, Sr. Director Clinical Laboratory Operations
Cincinnati Children's Hospital Medical Center

Amy Marrs, Sr. Director of Quality
Children's Hospital Colorado

Adrienne Malta, Director Inspection Services,
College of American Pathologists

Cincinnati Children's
changing the outcome together

Presentation Agenda

1. Background and Inspection Goals

2. Inspection Timeline and Process

   - Inspection site preparations

   - Inspector pre-work

   - Inspection time!

3. Benefits and Challenges

4. Lessons Learned and recommendations for future success

5. CAP resources and tools to streamline inspections

Background Inspection Goals

Pandemic prohibited travel to conduct normal inspection processes.

Inspection team goals:
- Conduct a thorough inspection
- Maintain staff safety
- Encourage staff learning and inspection knowledge spread

Site team goals:
- Staff to interact confidently with the surveyors
- Demonstrate the exemplary care we provide

Inspection Timeline and Process

Discussions between Cincinnati and Colorado leadership teams lead to agreement to conduct a virtual inspection. Due to CLIA requirements, CAP instructed us that at least one inspector must go on site.

4 Week Process

Week 1 – Cincinnati team compiled documents requested for pre-view

Week 2 – Colorado team compiled documents requested

Week 3 – Shared materials and created a schedule for inspection

meetings, inspecting laboratory to review

Week 4 – On-line meetings, review of additional and follow up items,

on-site inspection

Cincinnati Children's Preparation

1. Prepare thorough documentation list to enable standards assessment.

2. Prepare team for "new" inspection model, including web site access and virtual teams processes.

3. Thorough review of documentation provided and timely request for additional documents.

4. Build knowledge within the laboratory team.

5. Conduct a thorough assessment for the Colorado team.

Colorado Children's goal:

1. Make a good 1ˢᵗ impression
2. Organized response and documentation
3. All requested materials went through the Quality Team
4. Provide all requested materials

Site Security

- Worked with the hospital IT security team to set up a secured SharePoint site used to share materials

Security cont.

- Documentation provided includes:

  - Policies & Procedures

  - Personnel files

  - Examples of reports, maintenance, logs, PT, QC, etc.

- HIPAA compliant to share information with inspectors

- Read-only access granted to inspection team during the inspection window

- Items added to the SharePoint site by the CHCO Quality Team

Presentation of Documentation and Materials

In the SharePoint:

- Created one folder for each laboratory section

- Within each section folder, created additional folders to sort documents by topic

Documents

	Name ⌄
📁	01. Quality Management Plan
📁	02. Proficiency Testing
📁	03. Competency Assessment
📁	04. Quality Control

Presentation of Documentation and Materials

Document Tracker

- All requested items were put into an Excel spreadsheet for each section

- Provided requested item, folder location and the associated document

Section: Lab General	Cincinnati Children's Hospital Medical Center	Inspector Name: Email:
	Children's Hospital Colorado	Manager: Email:
	Inspection Skype Meeting	Give Date and Time (include all time zones)
Document Requested	**Document Location - Folder**	**Documentation Provided**
Lab General Checklist:		
QM Plan w/ Metrics, Review, and action plan documentation for all depts.	Policies & Procedures; Quality Reports	QLT.001 Quality Management System (QM plan on page 44); Quality Reports for Oct 2018, Dec 2019, Feb 2020
Patient & Employee Satisfaction Surveys	Survey Documents	1-Patient and Employee Satisfaction Surveys; 2018 DPLM Customer Service Survey Results
Occurrence/Incident Management Process (w/ example)	Policies & Procedures; Event Investigations	QLT.203 Communication Escalation Policy QLT.204 Event, Recall and Notification Documentation and Investigation; Event Investigation Form - LN2 Event Investigation Form - T Cells Jan 2020

Cincinnati Children's
changing the outcome together

Presentation of Documentation and Materials

Spreadsheets used to:

- Provide an organized method of presenting requested documents
  - Ensures all materials are provided
  - Guide for inspectors to know where to locate answers
  - Included contact information for easy communication between lab section and inspectors

- Create a good 1st impression to inspectors

Section: Lab General	Cincinnati Children's Hospital Medical Center	Inspector Name: Email:
	Children's Hospital Colorado	Manager: Email:
	Inspection Skype Meeting	Give Date and Time (include all time zones)
Document Requested	**Document Location - Folder**	**Documentation Provided**
Lab General Checklist:		
QM Plan w/ Metrics, Review, and action plan documentation for all depts.	Policies & Procedures; Quality Reports	QLT.001 Quality Management System (QM plan on page 44); Quality Reports for Oct 2018, Dec 2019, Feb 2020
Patient & Employee Satisfaction Surveys	Survey Documents	1-Patient and Employee Satisfaction Surveys; 2018 DPLM Customer Service Survey Results
Occurrence/Incident Management Process (w/ example)	Policies & Procedures; Event Investigations	QLT.203 Communication Escalation Policy QLT.204 Event, Recall and Notification Documentation and Investigation; Event Investigation Form - LN2 Event Investigation Form - T Cells Jan 2020

Cincinnati Children's
changing the outcome together

Inspection Time!

Inspection schedule was created with inspectors and lab staff for:
- Opening meeting
- Section inspection meetings – initial 3-hour block
- Follow up inspection meetings as needed
- Summation

Denver Time (MT)	Monday 8/31/2020 Path A	Path B	Tuesday 9/1/2020 Path A	Path B	Wednesday 9/2/2020 Path A	Path B	Thursday 9/3/2020 Path A	Path B	Friday 9/4/2020 Path A	Path B	Cincinnati Time (ET)
7:00 AM			Lab General/ Quality (KG and DA) am, ht, sh, ty	Point of Care (Dr. Steele)	Follow-Up	PDL Meeting Requested Reschedule sh	Onsite Inspection				9:00 AM
7:30 AM	Opening Meeting										9:30 AM
8:00 AM								Follow-Up	Follow-Up	Follow-Up	10:00 AM
8:30 AM				Immuno							10:30 AM
9:00 AM	Heme/Coag /UA (Dr. Losos, Kristy Carnevale) gp	AP Scheduled (Dr. R, MT, & JH) sh		LIS am	Blood Bank (Dr. Kinney) ty				Summation Option B		11:00 AM
9:30 AM								Follow-Up			11:30 AM
10:00 AM											12:00 PM
10:30 AM											12:30 PM
11:00 AM			Micro / MM Scheduled (KR)	Flow Cytometry (Holly Bonar) ak		Chemistry (Dr. Losos, CT) sh		Follow-Up			1:00 PM
11:30 AM											1:30 PM
12:00 PM											2:00 PM
12:30 PM	Follow-Up	Biochemical Genetics (Dr. Nicole Weaver) ht			Follow-Up			Follow-Up			2:30 PM
1:00 PM											3:00 PM
1:30 PM											3:30 PM
2:00 PM	Follow-Up		Follow-Up	Follow-Up	Follow-Up	Follow-Up	Summation Option A				4:00 PM
2:30 PM											4:30 PM

On-line Meetings and Conversations

- Used hospital IT security approved applications for virtual meetings

- Meetings were held over Skype For Business

- Screens shared to display additional documentation

On-line Meetings and Conversations

Social Distancing

- Meetings were held in conference rooms to allow proper spacing
- CAP allowed 1 person for on-site inspection
  - Inspection limited to laboratory. Patient care areas including outpatient collection and point-of-care locations not included.
- Used Skype on laptops and cell phones to perform section walk-throughs and allow inspectors to see how processes are performed

Benefits	Challenges
• Time was not an issue • Document review prior to inspection help build team knowledge • No need to travel • Meets inspection obligation during the pandemic • Skype discussions helped to clarify and verify • On-site inspection had a list of items based upon findings from remote teammates	• Missed personal connection with staff • Lots of pre-work • Employee records • Requires a strong document control process • New process for experienced inspectors • Could be overwhelming for a smaller facility

Lessons Learned

Technology

- Make sure both locations have compatible and secure technology to access materials and hold virtual inspections
- IT systems/Security may not allow access to all apps (Teams, Skype, Facetime, Zoom, etc.)
- Do a test run week before scheduled meetings to make sure everything works
- Multiple monitors can assist in locating additional documentation before presenting to inspectors

Lessons Learned

Communication
- Establish communication process
- Make sure everyone has each others email and phone numbers
- Set expected time-lines for communication
- Ensure timely response
- If unable to meet time-line, communicate alternate ETA
- Ask everyone to mute their lines if not speaking to reduce background noise
- Define who to contact for section information AND general information prior to meetings

Lessons Learned

Inspection Support
- Assigned roles to assist, including:
  - Scribe during inspection meetings
  - Single point of communication for major issues and questions
  - Technical support
  - Assistance with organizing requested document
  - Assistance with scanning or uploading documents
  - Recommend individual has access to PDF Writer program (Adobe, Acrobat, etc.) to flip and delete blank pages

Lessons Learned

General Expectations
- Inspection process is longer than usual 1–2-day inspection process
- Inspected lab has additional time to review requested documents before presenting to inspectors – identify potential problem areas ahead of time
- Inspector has additional time to review items and ask for additional documentation
- Make the best of the learning opportunities
- Expect technical difficulties… It will happen

Recommendations

1. CAP to establish a standard virtual inspection process
   - Standards response tool to allow documentation evidence to be tagged to the standard in question
   - Secure site for submission and subsequent review of documents
   - Local contacts to go on-site for required inspector presence
   - Consider smaller teams to go on-site if remote teams can review evidence prior to or at time of inspection
2. Use a document control tool that has an evidence room and secure on-line access outside of your hospital network
3. Be forgiving, this is new for everyone

New Tools and Resources

- **Inspection Planning and Document Tracking Tool**

- **SharePoint Site for Document Upload**

- **Online Courses**

- **Future Plans**

Inspection Planning & Document Tracking Tool

- **Multipurpose tool for inspectors and laboratories**
  - **Located in SharePoint Folder**
  - **Single point of reference**
    - **Inspection planning**
    - **Documents to upload**
    - **Document review findings**

Inspection Planning & Document Tracking Tool
continued

- **Multipurpose tool for inspectors and laboratories includes:**
  - **Example inspection schedule for inspection planning purposes**
  - **Recommended average time expectations for document review by checklists**

Inspection Planning & Document Tracking Tool
continued

- **Multipurpose tool for inspectors and laboratories**
  - ○ **Requested documents for laboratories to upload listed on each checklist page**
  - ○ **Provides space for inspectors to take notes**

SharePoint Site

- **Implemented in late December**
- **Provides secure location for laboratories to upload their files**
- **Allows CAP to share uploaded files securely with inspection team**
- **Temporary solution during the modified inspections process**

SharePoint Site

continued

Click link with laboratory Name

Will take you to the next page with folders for each laboratory section

SharePoint Site
continued

- **Within each section folder are additional folders for each document category where you can save your files**

Online Courses & Resources

- **For Inspectors and Laboratories**
  - **2020 Modified Inspection Processes** webpage
  - **Remote Review: How CAP Inspection Document Review Just Got Easier** podcast describing the CAP SharePoint site

- **For Inspectors**
  - ***Performing Virtual Inspections: Being the CAP's "Eyes and Ears" from Home*** supplemental training course
  - **Inspector Training and Tools** within e-LAB Solutions Suite

- **For Laboratories**
  - ***Navigating Your Virtual Inspection: Demonstrating CAP Accreditation Compliance in an Electronic World*** presentation

Future Plans

- **Modifications to Organization Profile for laboratories to upload their requested documents during reapplication**
  - o **Inspectors will be able to download inspector materials and view laboratory documents**
  - o **Implementation will replace SharePoint site later this year**

Contacts

Kathy Good

- **Kathleen.Good@cchmc.org**

Children's Hospital Colorado Quality Team (Amy Marrs)

- **DPLMQuality@childrenscolorado.org**

Adrienne Malta

- **Accred@cap.org**

College of American Pathologists