# Virtual, blended inspections a sign of the times

## Valerie Neff Newitt

June 2021—As COVID-19 restrictions halted traditional laboratory inspections, virtual and blended inspections became the stand-ins, and early adopters say there's much to like and hold on to post-pandemic.

"The pandemic has forced us to rethink how we do everyday things," says Kathleen T. Good, MBA, BS, CLS, senior director of clinical laboratory operations at Cincinnati Children's Hospital Medical Center. Pioneering a new inspection model didn't appeal to her at first, she admits. "It was a practical matter. We wanted to meet our obligation to inspect Children's Hospital Colorado. We didn't want to bail out. And yet we had no one interested in traveling last summer, so we needed another way to make it happen."

Members of the CAP's Council on Accreditation began to explore options early on. "Traditional inspection, virtual inspection, and remote document review, often blended together, is essentially how we are tackling inspections as the pandemic lingers," says Richard M. Scanlan, MD, chair of the council and medical director of the laboratory, Oregon Health and Science University Hospital.

Bradford S. Collins, MD, medical director of the laboratories at Beaufort Memorial Hospital in South Carolina, was optimistic when he and his team prepared to conduct an inspection at Kershaw Health Medical Center, Camden, SC. "We thought a blended option potentially could be a way of identifying an easier, more thorough inspection, with less manpower."

Dr. Reineks

Edmunds Reineks, MD, PhD, D(ABCC), medical director and section head of point-of-care testing at the Cleveland Clinic, had five laboratories inspected by a CAP inspector using a blended inspection model. Up against an inspection deadline set to expire in March 2020, he says, "That was right when things fell apart. The CAP gave us a date extension, and yet we were already prepared for inspection. It felt as if we were in limbo. There was this underlying anxiety knowing something had to be done yet it wasn't happening. So when a hybrid option became available, we were well positioned for it and eager to do it."

Amy Marrs, MS, is associate director for quality and regulatory compliance at Children's Hospital Colorado where Good and her team used the new approach to inspection. Marrs and her colleagues were ready and wanted the inspection behind them. "We realized this pandemic could go on for an indefinite time, so we rolled up our sleeves and said, 'Let's try it.'"

That's what she and colleagues did, and Adrienne Malta, MBA, MT(ASCP), CAP director of inspection services, says others should too.

It all begins with understanding what virtual inspections are. "Facilities want to know how this works in their labs, and there is a lot of confusion about alternative ways to accomplish an inspection," Malta says.

All virtual models rely on video conferencing, digital file transfer, and live streaming. The live-streaming requirements for laboratories include two-way audio and video capabilities (sometimes in various laboratory areas), with Wi-Fi connectivity in each area; access to Skype, Microsoft Teams, Zoom, or GoToMeeting; and familiarity before the inspection with audio and screen-sharing functionalities. The remote interactive document

review can be accomplished by guest or read-only access to the laboratory's document management system, and file sharing via the CAP SharePoint site.

Blended traditional inspections consist of a modicum of remote document review followed by an on-site visit for the direct observation component of the inspection. Opening and summation conferences and executive interviews are completed using video or conference calls.

"Blended traditional inspections are the primary option for CLIA-regulated labs, allowing for much of the inspection to be done virtually and the rest on site," Malta says. "But blended inspections can provide for a detailed virtual review of documents and slides, usually a few days ahead of an on-site inspection by a limited group of inspectors who observe, do interviews, ask follow-up questions, and review documents that weren't available electronically." The accreditation decision is not made until after the on-site portion is completed, she says.

In contrast, virtual inspections are 90 to 100 percent virtual and useful primarily for international non-CLIA laboratories, or for laboratories in pockets of the United States where COVID-related restrictions might be in place, Malta says.

Laboratories participating in a virtual inspection must provide electronic access to their evidence of compliance with CAP checklist requirements, have reliable Wi-Fi connectivity in each laboratory area, and have a laptop, tablet, or smartphone, enabled with a camera, microphone, and speakers.

"A virtual inspection involves people taking cameras into the various areas of the lab so inspectors can virtually observe testing, talk with staff, make sure they're wearing PPE, ask questions, and follow some specimens through their processes to evaluate how things are working," Malta explains. At the end of that on-camera review, the lab receives an inspection summation report listing deficiencies, if any, to which it must respond within 30 days, and an accreditation decision is made immediately.

"Once they're accredited, CLIA-regulated labs still must undergo an on-site visit, usually four to six months later, because it is a requirement of our inspection process," Malta says. "It augments and validates what we saw on cameras and entails a walk-through to ensure the physical facilities are adequate. And because some labs may not have telepathology capabilities, we can look at slides at that time as well."

Laboratories not subject to the U.S. CLIA regulations will not have a mandatory on-site inspection unless the laboratory's compliance with CAP requirements could not be fully evaluated in the virtual inspection.

For laboratories that want to learn about these new approaches, a starting point is the CAP's website, where a dedicated page (http://bit.ly/CAP-inspect-train) houses training guides, podcasts, tools, and tip sheets for inspectors and laboratories. CAP members can also view "Virtual CAP Inspections: Two Laboratories' Shared Perspectives" (http://bit.ly/CAP-virtual-inspect), a webinar presented by Good, Marrs, and Malta on strategies, tips, experiences, and lessons learned.

They and Dr. Reineks and Dr. Collins, having used these new inspection formats, share their experiences and offer their guidance:

• *IT/digital readiness.* Many documents must be available digitally, so laboratories with existing electronic document control systems are ahead of the game. For those with paper records, the advice is to start scanning. "Labs that still depend on paper systems necessarily will have to undertake a laborious process of scanning in documents and records. That's the major challenge," Marrs says. "It is particularly tough to gather personnel files in one place; there are often bits and pieces in the lab, in human resources, et cetera. It all must be gathered and scanned."

Coordination with IT is a necessity. "IT protocols are probably the most pivotal and crucial piece to get right," Dr. Collins says. Of the lab he inspected, he says, "At first we thought we could have them email files to us, but they were too large. Thankfully, we were able to pull our IT departments together to figure out how to have a review [via a Google app] of their documents in read-only format. Then each of our team leaders was able to review

specific policies and procedures. It wasn't reinventing the wheel, but it was certainly reconfiguring it."

• *Meeting of the minds.* Before an inspection, "it is important for an inspection team to have a conversation with a lab to find out if this is even feasible," Dr. Reineks says. "What do they have online? Do they have a good network? Do they have a mechanism for sharing documents or slides? And then there are logistics: Does the inspection team want access to documents on their own? Do they want to work with the other lab virtually in real time and ask for documents during a virtual conference?" It's also important, he says, to test platforms and make sure they work, and to make sure that labs and inspectors can hear and see each other and clearly view documents.

• *How it unfolds.* Because Cleveland Clinic had a robust electronic document control system in place, Dr. Reineks says policies and procedures, documentation of competency processes, validations, routine quality assessments, instrument comparisons, proficiency testing, and personnel files were already in digital format. "We sent documents that were requested. Next we had a virtual desktop inspection, conducted by several inspectors, one week. We met with them twice a day, before lunch and again at the end of the day," he says. "During these real-time interactions we were able to provide clarification as needed. The following week one CAP inspector came and visited facilities at our multiple campuses."

When Good and her team prepared to inspect Children's Hospital Colorado, they set up a proposed time frame of four weeks to allow for the gathering, scanning, and electronic sharing of documents in the SharePoint program, as well as a window of time for document review and virtual conferences, all followed by an on-site visit by one inspector.

"We didn't see any roadblocks that we couldn't circumvent," Marrs says. "The biggest concern we considered and strategized around was how to make that good first impression with inspectors in a virtual world. We wanted to set a tone of clarity and organization. When inspectors asked us a question, we wanted to have clear answers. That was our mindset."

The main challenges, she says, were getting the policies and procedures, personnel files, examples of reports, and maintenance logs, among other documents, scanned in and presented in a way that all were able to see them and answers to relevant questions could be provided. "All requested materials went through our quality team," she adds.

• *Managing time.* "It's a lengthy process," Marrs says. "Not only are you scanning and providing documents, you are also providing additional documents that the inspectors ask for along the way. In a traditional inspection, this all happens in the course of a day when you are running around like crazy. But still it was just one day. A hybrid inspection can stretch out over days and days."

Good says her inspection team tended to linger longer over documents. "Laboratorians are detail-oriented, meticulous folks," Good notes. "At first the inspection team felt they had to read every word in front of them in black and white. We had to remind people that if they take a week to look at every piece of paper, they'll get caught in the weeds. We urged them to spend about the same time reviewing documents virtually as they would have on site. Having people get stressed by the lengthy review process was our big surprise."

Dr. Collins favors a tighter time frame. "I think it's important not to drag this out. If it turns into a month-long inspection, you have defeated some of the benefits of this process." He expects the process to become more standardized, whereby digital documents would be shared two weeks in advance of a virtual meeting, followed by an on-site visit within a day or two. "It keeps things nice and condensed and tight. The process moves along and people don't grow weary of constant back and forth emails."

• *Luxury of flexibility.* Having documents available within one's own time frame was an advantage, Good says. "I could look at documents at 7 o'clock at night if I wanted," she says. "I could go through things at my leisure and take notes."

Dr. Collins says because documents could be reviewed in advance online, the on-site inspection his team

conducted was less hurried and more manageable. “We had reviewed more detail prior, and we provided a better inspection because of it.”

Dr. Reineks saw things similarly during the inspections of the Cleveland Clinic labs. “The inspectors didn’t feel the constraints of sitting in a conference room with someone handing them materials. They probably felt the luxury of being able to go through documents completely and think about the various elements in them,” he says.

• *Equally or more thorough.* The inspectors and inspectees agree that hybrid inspections are as thorough as traditional on-site inspections. “After the CAP inspectors completed our virtual document assessment,” Dr. Reineks says, “they commented that it may have been the most thorough document inspection they had ever done.”

Good agrees: “I’ll take it one step further and claim that there is a more thorough review of documents when done in advance online, compared with reviews done during stressful on-site inspections.” After the Children’s inspection in Colorado, her team did another hybrid inspection. “That lab expressed concern we were too thorough,” she laughs.

Marrs

• *The more, the better.* Being able to spread the work among a larger group of colleagues and use the effort to educate is the “big win,” Good says. “I was doing the general checklist and had someone with me who had never done the checklist before. So I let her ‘drive.’ She said, ‘Here are the questions I have based on the documents I’ve seen.’ As we talked through them, I could mentor her and make suggestions or point out fine points. There is a definite benefit to having others learn from the experience.”

Marrs, too, saw the upside of being able to bring in more people. “Usually when you are inspected you have a few point people. But in this format, when we were gathering our informational materials, we brought in new leads, new supervisors, and more staff to help support us and see how this all works. They had time to look and learn.”

Dr. Collins likes the collaboration: “The hybrid experience seems to drive a more consultative relationship between the peer lab inspection team and the labs being inspected.”

• *Less stress, less disruption.* Because document review takes place in advance of the hybrid and virtual inspections, on-site inspections often can be handled by one or two inspectors. “Their time on site can be shortened as well,” Dr. Reineks says. “The result is less disruption for the lab sending a team and for the lab being inspected. It also makes it more palatable for people to volunteer to do inspections if they are going to be away for only one day or night.”

Dr. Collins agrees that the new options are easier on the staff. “The number of people working in labs seems to get smaller even though volume goes up. Especially during COVID there have been issues with absences due to illness and increased testing coming in. We can’t spare as many people to go and do an inspection. These new options are less onerous.”

Says Malta: “Reducing size of the footprint of the on-site inspection team allows everyone to stay more focused. It’s better for everyone. It’s a win-win.”

Dr. Collins says he welcomes the opportunity to help fine-tune virtual inspections and remote document review. “When my team and I were on a lengthy ride home from an inspection, we brainstormed and made notes of recommendations,” he says. “We hope the CAP will take a strong role in standardizing this process—the way

policies and procedures are uploaded, within a specified time frame, to a shared website monitored by the CAP. We also would encourage the CAP to be available to offer clarifications that may come up before or during the online inspection process, rather than wait until the on-site inspection."

He and his team also believe that being able to review a laboratory's proficiency testing and its CAP checklist book, online and in advance, would be of great benefit to the inspection team. "It would be ideal if they were uploadable and viewable in read-only form," Dr. Collins says.

"It took a fair amount of work for my inspection team to coordinate our inspection because it was new to us. But with standardization it can go much quicker and more efficiently," he says. "The CAP can make the difference by embracing the new formats so they become the new norm after the pandemic."

Marrs and Good suggest that the CAP establish a standard virtual inspection process, complete with tools to allow documentation evidence to be tagged to a specific standard in question, a secure site for document submission and review, and smaller on-site inspection teams.

Such feedback has been instrumental in guiding the CAP to improve its inspection processes, Malta says. "We have been doing blended inspections since last summer. So last fall we did a survey of our labs and inspectors to find out how we can better support them." Secure file sharing was a key concern, she says.

"We realized labs do not have a standard way to share their records. They expressed concerns about access to and the security of their documents. We offered a SharePoint site as an interim step and began building more functionality into the system and adding more security around the process."

But SharePoint was always intended to be a temporary fix, Malta says. "We are implementing a more permanent solution, a standard platform. A lot of the feedback indicates this is something members want. We are in the process of making modifications to our 'organization profile' pages on the website, and building in a location for laboratories to upload documents during their reapplication process, giving them a significant amount of additional time to be able to get that done." Laboratories can continue to make updates to those documents for up to four months before their anniversary date, she says. "The pressure to upload so many documents in a relatively short time was a major cause of hesitancy. This should relieve some of that."

Phase-in of the improved organization profile functionality is set to begin in July. The CAP also plans to initiate an online deficiency response project downstream of the organization profile project.

What will remain of COVID-era inspections?

"I can't say we have that completely worked out at this point," Malta says. "But elements of the advance document review are likely to remain. It makes it easier to focus on the documentation, and then on-site time can be more purposeful. We've always tried to find a way to get inspectors out of the conference room, and this appears to be one effective solution."

The processes and feedback from laboratories about these new approaches will continue to be assessed, says Council on Accreditation chair Dr. Scanlan. "The pandemic has offered us a chance to critically evaluate program delivery, just as we critically evaluate the accreditation checklists year over year."

Dr. Reineks, for one, hopes the virtual and hybrid options are here to stay. "I don't know if hybrid and virtual inspections would have been feasible even 10 years ago," he says. "As times change we have to change with them, independent of the pandemic. I'm glad we now have this option."

Marrs hopes laboratories will get into the hybrid and virtual stride sooner rather than later.

"There's no way around this. We still need to do inspections during this pandemic. We still need to have that second pair of eyes looking at our policies and processes," she says. "We need to do it for accreditation. But even more important, we need to do it because we always come out a better lab on the other end."

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