A Look Back on the COVID-19 Pandemic: What Happened & What We Learned



Partnership for Food Protection (PFP)

LABORATORY WORKGROUP

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Background

Human and animal food (HAF) regulatory laboratories comprise federal and state entities dedicated to evaluating the safety of food intended for consumption by both humans and animals. These laboratories play a crucial role in ensuring that the food we consume is free from various contaminants, including microbiological, chemical, radiochemical, filth, allergens, and more. Additionally, they verify that the food provided to animals is devoid of contaminants and nutritionally balanced.

Human and animal food testing laboratories are responsible for performing investigational, surveillance, and emergency response testing in collaboration with state and local regulatory programs. Their essential role involves identifying, containing, and preventing foodborne illnesses, contributing significantly to public health and safety.

Purpose/Executive Summary

The PFP Laboratory Science Workgroup formed a subgroup to explore the various experiences HAF laboratories encountered during the <u>COVID-19 (SARS-CoV-2) pandemic</u>. These experiences were not necessarily unique to these laboratories, as informal conversations with other laboratory groups found that many laboratories experienced similar situations. While we may never again experience a pandemic like COVID-19, the subgroup felt it prudent to capture the challenges laboratories faced during this pandemic and more importantly solutions devised to overcome these challenges.

Uncertainty of Laboratory Operations

Workload Disruption

In the beginning of the pandemic, it quickly became clear that many businesses and schools were either shutting down voluntarily or being mandated to shut down to stop the spread of COVID-19. This created an uncertainty in many of the HAF laboratories, as to whether workers would be deemed "essential workers" and required to continue working. The entities that were deemed essential differed by state. There was uncertainty over who could work in the laboratory and when. In laboratories that were mandated to close, there were questions about if required routine maintenance of specialized laboratory equipment and facilities could be continued, and if so, who could do this important task. Sample loads varied state-by-state, with the more traditional public health laboratories inundated with COVID testing samples. Many regulatory food laboratories, although essential and therefore operational, did not receive any samples because regulators were not in the field collecting them. The laboratory did not have much control over this, especially if firms decided not to permit visitors or local jurisdictions imposed movement bans. There was also a concern that curfews would be implemented, affecting the comings and goings of essential laboratory staff. While a curfew ban did not come to fruition, laboratories should consider in advance what documentation might be needed to allow essential staff to move freely outside of curfews.

Lesson/Solution Found



Staff identified alternative assignments for laboratory personnel, such as tasks related to revising Standard Operating Procedures (SOPs), deep cleaning the laboratory, inventorying, kit preparation, participating in online training events, and more. The stop-work for regulatory samples lasted several months during the height of the pandemic, but picked back up to normal levels even while the staffing levels remained a challenge for some laboratories. HAF laboratories may wish to explore the feasibility of partnering with clinical laboratories within their jurisdiction to cross-train and provide microbiologists for surge testing. Clinical Laboratory Improvement Amendments (CLIA) requirements would need to be considered for this activity.

Staff Shortages

There were many concerns about staffing: What would happen if staff tested positive for COVID, or if staff were pulled away to assist at state emergency operations centers or vaccination sites? Several states had difficulties with low staff volumes or staff being pulled to COVID testing efforts, responding to outbreaks, tracebacks, and other foodborne illness investigations as needed. Several staff vacated positions during the pandemic and low salaries have been a major barrier to filling those vacated positions.

Lesson/Solution Found

It is important to have good relationships with partners so that they can be notified of any delays or predicted ability to rebound testing capacities. Many laboratories used this pandemic as an opportunity to cross-train personnel; strengthen relationships with other states, academic medical centers, and hospitals to assist with testing capacity; and increase automation capabilities for sample preparation. Laboratories also learned to share resources across federal cooperative agreements through cross-training personnel. Some laboratories were able to hire student or temporary workers to perform low complexity or supportive tasks so permanent staff could focus on higher complexity tasks and testing. This redistribution of staff was easier for some laboratories than others and was especially difficult in the first few months of the pandemic. Some laboratories hired nurses to provide testing of staff that were ill to minimize transmission of disease within the laboratory.

Laboratory leadership met with laboratory customers (e.g., regulatory programs served by the laboratory, other regulatory programs, fee for service customers, grantors, etc.) to prioritize testing needs, method development requests, and determine if changes were needed to manage complaint and/or outbreak samples in a timely manner. While these meetings were conducted in-person in early March 2020 at the onset of the pandemic, meetings transitioned to virtual a few weeks later once the scale and severity of the pandemic was better understood. The laboratory had to determine what could and could not be done; for what could not be done, contingency plans or MOUs with other labs that could subcontract or do the testing as fee for service were discussed.

Laboratories may need to think outside of the box and offer unique benefits to retain current staff or attract new personnel. One HAF laboratory allowed two full-time employees to move to part-time to



retain them. APHL fielded a workforce survey in 2022 that provided rich information on current workforce challenges and shed light on recruitment and retention strategies. Several workforce-related tools can be found on APHL's website at <u>APHL Publications Search</u>.

Postponed Proficiency Samples

Many of the HAF laboratories routinely participate in externally offered proficiency testing programs to support ISO 17025 accreditation. Given the combined challenges of disruptions in the supply chain and courier services, laboratory staffing shortages, and shifts in laboratory workload during the pandemic, laboratories were sometimes faced with postponed proficiency samples, which had a negative impact on their ability to ensure quality laboratory results.

FDA's Moffett Proficiency Testing Laboratory staffing levels were reduced during the height of the pandemic and there were three proficiency testing events cancelled – the June 2020 Vitamins and the Fiscal Year 2020 June FERN Chemistry and Microbiology events. For the raw milk proficiency testing event, Moffett was not able to offer a Charm flunixin test in the scheme due to a shortage in the test kit availability. For the 2020 Food PT, the powdered infant formula portion of the event was canceled due to the Moffett laboratory's capacity limitations. During the pandemic, the Moffett Center was tasked with creating media for COVID testing, as well as conducting proficiency testing for COVID assays in partnership with FDA's Center for Veterinary Medicine; this contributed to the need to cancel the scheduled proficiency testing events described above.

Lesson/Solution Found

Laboratories considered alternative pathways for meeting the ISO/IEC 17025 requirement to maintain or assess technical competency. In-depth internet searches were done to look for other proficiency test providers, or, if no proficiency test was found, customers were asked if they were willing to accept test results that may not fully meet the ISO/IEC 17025 accreditation requirements. Some laboratories skipped participation in Moffett PT events or requested extensions for testing or submitting results – these extensions were mostly granted unless the extension would significantly delay the results of reports. Internal proficiency tests are also an option and can still meet ISO/IEC 17025 requirements.

Inadequacy of Large-Scale Emergency Preparedness

Many laboratories felt they were not as prepared for a pandemic of COVID's scale as they had originally believed. Laboratory Continuity of Operations Plans (COOP) did not cover many of the situations encountered during the pandemic. While the laboratory was its own entity, its autonomy to make decisions depended on the state structure as well as the scale of the emergency or event. Decision-making abilities depended on resources requested (e.g., money or personnel vs. day-to-day operations). As COOP planning became more granular, such as determining which staff to send home or keep in the laboratory, the laboratory director generally had more autonomy to make those decisions.

Lesson/Solution Found



One laboratory mentioned that participation in a FERN exercise around emergency planning resulted in an updated COOP that could be used during the pandemic response. Many laboratories learned that the COOP is *a* plan, not *the* plan. It is helpful to establish a COOP prior to a pandemic situation, whether an agency would be deemed essential, and revise the COOP accordingly. It is important to ensure that people with the authority to make decisions are included in emergency response plan development. APHL created model guidelines to assist laboratories in developing a COOP plan, which can be found on APHL's website at https://www.aphl.org/aboutAPHL/publications/Documents/APHL-PHPR-2021-COOP-Guidelines.zip.

Inventory and Equipment Issues

Supply Chain

Challenges with ordering supplies continued for more than three years after the start of the pandemic. While some supply issues resolved over time, others persisted and new ones emerged. Delays in shipping samples and ordering or receiving supplies persisted even at the time of publication, due to industry labor shortages and a longer period of approval or renewal of state vendor contracts. Many multi-laboratory validation studies were delayed due to the supply and reagent shipment delays, potentially delaying implementation of new/improved technology in the laboratory. Laboratories noted difficulties in connecting with vendors' customer service personnel during the early part of the pandemic.

Lesson/Solution Found

Laboratories stressed the importance of talking with vendors, as well as sample collectors, and customers, to ensure everyone understood the causes of delayed testing. APHL worked with various suppliers to secure and distribute different product brands for its members. Laboratories checked with other laboratories to see if they had extra reagents or supplies. Laboratories also identified alternative methods, instruments, test kits and reagents that could be used and fast-tracked the evaluation of method performance to meet customer testing needs. In some cases, vendors reported that they lacked the resources to recertify their own products, which contributed to additional delays. Laboratories were more likely to keep expired testing supplies in case their use would be required for emergency testing needs; however, keeping expired testing supplies on hand and/or using such supplies may cause issues with accrediting bodies. One laboratory proactively wrote up a corrective action and used what they had on hand.

IT Equipment Shortages

As more laboratory workers transitioned to remote work and virtual meetings during the early part of the pandemic, many laboratories also faced a shortage of equipment that would make their remote work environment productive (e.g., computer monitors, headsets, and camera/microphone-enabled



laptops). State information technology (IT) departments also experienced COVID-related strain while trying to keep up with the dynamic needs of the laboratories and other agency divisions/bureaus they serve. Many employees decided to leave the workforce for several reasons, including the lack of childcare, mental well-being, and attrition. This became known as the "Great Resignation." The technical equipment left by the departing staff was often difficult to reassign to the incoming staff due to the logistical challenges of the pandemic and IT departments also working remotely.

Lesson/Solution Found

Some people used their personal devices for work purposes; however, this was on a volunteer-basis only. Others traded ill-equipped laptops with coworkers whose job duties did not require frequent Zoom calls or trainings. Laboratory management allowed employees to use vacant offices or conference rooms to perform work or to bring work home to avoid disturbing others. Some analysts were allowed to attend Zoom calls on their laptops at the laboratory benches while they were performing testing. In some cases, a state or agency had a surplus of old computers or equipment that were restored to service. Extra monitors or computers attached to laboratory instruments were used for this work when not used for testing.

Equipment Service Delays

At the beginning of the pandemic, laboratories also experienced delays in equipment maintenance services. Preventive maintenance, calibrations, and service calls for laboratory instruments were difficult to schedule and obtain in a timely manner. This meant that preventive maintenance and calibrations were not performed on schedule. There were several reasons for these delays, including late shipment of parts and hesitancy for both the laboratory and vendors about having visitors in the laboratory. Some laboratories faced questions regarding what health information could be asked of vendors or visitors coming into the laboratory.

Lesson/Solution Found

As the pandemic progressed, many of these issues resolved or eased. Vendors would often call ahead to determine if the laboratory will allow visitors and what health and safety precautions were required in the laboratory (e.g., wearing masks, being fully vaccinated). It is recommended to communicate these requirements before a vendor comes to the laboratory to avoid any confrontation or misunderstanding on-site.

Virtual Environment

ISO/IEC 17025 Assessments

The buzzword of the pandemic was "virtual" – anything that could be conducted virtually was done virtually. Many laboratories came due for their ISO/IEC 17025 accreditation audits during the pandemic.

Lesson/Solution Found



Fortunately, many laboratories found their accrediting bodies to be accommodating and flexible in these unprecedented times. These assessments were largely conducted remotely, with effective planning being the key to success. It was crucial to communicate with the accrediting body so that the auditor and laboratory understood expectations ahead of the audit. Laboratories used their best audio-visual equipment to virtually walk the auditor through the laboratory space. Audit preparations largely remained the same, with the expectation of additional paperwork submission for documents and records that would normally be reviewed on-site. However, several laboratories noted that preparation prior to the audit was more time intensive as staff moved paper documentation into an electronic format. There was also a greater change of misplacing documentation as it moved from its usual place to scanning equipment. Some laboratories had multiple auditors conducting the virtual assessment for the various programs (e.g., microbiology and chemistry), which added to the confusion when pulling and scanning documentation. Converting laboratory records to an electronic format can assist in both virtual assessments and general ease of access for all assessments. Laboratories stressed the need for patience and planning for technical issues. One laboratory experienced a Wi-Fi connectivity issue during a virtual audit. Building Wi-Fi was not always strong enough in each lab room to support video connections. Laboratories should work with IT staff to have allowable backup equipment on hand and conduct dry runs or sound checks with the auditor at the start of each day. Allowable equipment will vary across laboratories. At least one laboratory was not allowed to use Wi-Fi hot spots due to perceived security issues.

NCMIS Audits

For laboratories participating in the FDA National Conference on Interstate Milk Shipments (NCIMS) Program, their laboratory audits have been delayed indefinitely (at the time of publication) due to travel restrictions.

Lesson/Solution Found

Laboratories suggested alternative assessment strategies to certify new dairy analysts, including having a Laboratory Evaluation Officer (LEO) from another state travel to the laboratory to provisionally certify new analysts. They also suggested identifying alternative dairy testing laboratories as part of a COOP.

Training Delivery and Information Sharing

Another shift occurred in training delivery and information sharing. Laboratories found that the virtual environment was not a suitable replacement for the priceless informal conversations that take place at meetings – conversing with current colleagues, networking with new people, and learning something new from those casual interactions. In the virtual environment, teams may still gather on virtual meeting platforms, but it can create an environment of anonymity that tends to result in quiet discussions. Additional challenges in the virtual environment included distractions and Wi-Fi connectivity issues.

Lesson/Solution Found

Resources were directed to virtual training opportunities, including those available from instrument vendors. While virtual trainings do not replace an in-person environment, key information can still be



delivered and creates the opportunity for employees who normally would not be allowed to travel. Virtual training best practices included starting with an icebreaker activity, using breakout rooms to facilitate small-group discussions, having a round-robin report out or exercise, and being sure to take short breaks every hour. Video calls may help with anonymity and some distractions but can put a strain on bandwidth causing call lag. Silence does not necessarily mean agreement, so it is important to engage participants in calls, meetings, and trainings to keep people connected.

Social Distancing Measures

Remote Work

Especially at the beginning of the pandemic, any work that could be conducted virtually was conducted virtually. Managers decided whose work duties made them eligible for remote work and who was needed in the laboratory. Most laboratory jobs are not suited for permanent remote work due to the need to access equipment and reagents, as well as the hesitancy to allow confidential materials to be taken outside the laboratory.

Lesson/Solution Learned

One laboratory suggested using the federal guidelines for remote work from the Office of Personnel Management as a tool for fairly determining who can and cannot work remotely. However, many quality assurance staff and upper management positions may have the ability to conduct their work duties from home. For those working remotely, they needed to be set up with a VPN or personal hotspot, access to a computer with a working microphone and camera, and an account with virtual meeting platform software (such as Zoom or Microsoft Teams).

Work-from-Home Challenges

While many laboratory employees enjoyed the flexibility of working from home, it did (and continues to) produce its own unique challenges. There were reduced interactions with other staff. Quick conversations in the hall were now conducted via calls, online chats, or email – especially in chats and email, details or nuance can be lost. It was also important to ensure staff were working when not in the laboratory, and measuring productivity was also a challenge.

Lesson/Solution Learned

Managers should set expectations through telework agreements and establish regular weekly check-ins to monitor progress. Adapting management styles to a virtual work relationship can be difficult, so talking with other laboratories about their strategies and approaches can be helpful.

Safe Environment in the Laboratory

For those laboratory staff that were required to come into the laboratory, it was crucial to set up a safe working environment.

Lesson/Solution Learned



Social distancing measures were implemented throughout the laboratory, including setting visual markers to indicate six feet distances, staggering work or testing schedules, rearranging furniture to promote social distancing, installing plexiglass between cubicles, etc. At the beginning of the pandemic, many laboratories increased surface cleaning, although this decreased when the virus proved to have a more aerosolized transmission route. The laboratories also needed to balance the safety of their employees with the varying state mandates on mask and vaccine requirements. Many states dealt with difficult situations implementing these policies, including pushback from both employees and state governments.

Emotional Well-being of Employees

Health, Environmental, and Social Concerns

Laboratories faced many challenges during the COVID-19 pandemic, but one of the most impactful and longest-lasting challenges has been the toll on employees' emotional well-being. Being essential workers, many laboratory staff were concerned about their health and the health of their families as they came to work each day. There were many childcare challenges, which caused staff resignations as schools and daycares closed or went virtual. Some laboratories were also dealing with grief due to coworkers who succumbed to COVID. An increase in staff anxiety and other mental health issues put a strain on work relationships.

As was noted earlier, the many vacancies brought on by the "Great Resignation" left laboratorians feeling burnt out and fatigued. Many laboratories experienced delays in hiring due to the pandemic. Several laboratories were impacted by leadership retirements that were due to COVID concerns or the pandemic work environment; this left a gaps in institutional knowledge for the laboratory. Leadership retirements also led to more workload trickling down to lower-level staff; this increased workload, in turn, caused some staff to retire or leave.

There was also a sense of disconnection caused by the increasingly virtual and/or socially distant environment. There was a lack of interaction with laboratorians leaving or joining the laboratory. Many laboratorians mentioned "Zoom fatigue," with difficulty maintaining focus or forging collegial bonds in virtual meetings.

As impactful as COVID was during this time, it was not the only important event happening during the height of the pandemic. There were other significant events occurring, such as environmental (e.g., hurricanes and wildfires), and social injustice issues. The mental load of these events on top of the pandemic were incredibly detrimental to staff morale, and likely contributed to increased anxiety and fatigue.

Lesson/Solution Found

Laboratories offered some solutions to address employee emotional and mental well-being during these stressful times. It was important to listen to employee concerns and offer support and resources where available, such as the Employee Assistance Program (EAP) and encouraging the use of personal leave. Many found that establishing informal virtual get-togethers, such as luncheons or coffee chats, and

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showing appreciation to team members helped increase team morale. Not requiring video participation in virtual meetings can also help ease anxiety or "Zoom fatigue." In the wake of many COVID-facilitated retirements, it was important to have succession planning tools in place, such as those found in APHL's Knowledge Retention Toolkit, to capture key institutional knowledge for the laboratory and ease the transition for employees. In looking at the other impactful events that occurred during the pandemic, laboratories saw it as an opportunity to review and improve COOP.

Conclusion

While this document is not all encompassing, it serves to highlight the many situations laboratories faced during the COVID-19 pandemic and the innovative solutions implemented to overcome these challenges. The PFP Laboratory Science Workgroup wishes for the document to assist laboratories and others as they encounter similar situations in the future. For more information on the resources outlined in this document, please see the Resources Section on page XX. For more information about the PFP and the PFP Laboratory Science Workgroup, visit www.pfp-ifss.org.



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