The traditional relationship between the laboratory and the organization’s infection control program has been as a source of analytic information and consultation. The laboratory provides reports of microbial isolates, antibiograms at both the individual pathogen level as well as for groups of organisms, trends in antibacterial resistance, an assessment of preanalytic error in the form of culture contamination rates, and other associated markers of infection in chemistry and hematology. These tasks are still relevant and vital; but the laboratory is also a unique environment and presents infection risks that differ from other healthcare settings. Infection risks are not new, it is our recognition and understanding of these risks that is evolving.

An organization’s Infection Preventionist (IP) can champion infection control awareness, risk assessment, and surveillance activities. The IP is the laboratory’s most important resource in understanding infection control concepts in a specialized environment. There is no expectation that the laboratory function in isolation or develop redundant systems for infection prevention when these capabilities already exist within the organization. The organization’s IP has specialized training and an elaborate skill set focused on infection risk and prevention processes; the IP is an asset to the laboratory and is integral to the laboratory’s success in designing, implementing, and monitoring prevention practices. The combination of laboratory and infection prevention leadership nucleates a powerful team.

Given its critical nature, the role of infection control cannot be underestimated. It is increasingly important for organizations to ensure that infection prevention and control principles are integrated throughout all systems and services, understand exposure risks present in the laboratory environment, and assess the implementation of infection prevention practices to align staff behaviors with prevention activities and goals.

Regardless of the specialty — surgery, pharmacy, acute care, or the clinical laboratory — infection control is one of the timeliest topics in healthcare. The potential for exposure to infectious material poses a significant risk to staff, patients, and visitors. Nowhere in a hospital is the potential for exposure more prevalent than in the clinical laboratory because of the concentration of blood, body fluid, tissues, and other patient specimens found there.
Opportunities for laboratory-acquired infections (LAIs) differ from those typically associated with healthcare-acquired infections (HAIs). The laboratory is a highly specialized with a high potential for contamination of the working environment; in this setting, exposure risks for laboratorians differ, and may be higher, than those common to the direct care staff and patients. The analytic processes of the clinical laboratory present unique transmission risks and exposure opportunities that necessitate an awareness and prevention approach targeted to the clinical laboratory environment. The laboratory is not an acute care setting and infection prevention practices optimized for patient care areas might not generate the same successful response in the core or satellite laboratories. The focus of this paper is on identifying risks, developing and implementing prevention practices, monitoring staff behaviors through process surveillance activities, and evaluating the success of infection control strategies in the clinical laboratory.

The emphasis on the laboratory environment is intentional; the processes used in the preanalytic and analytic phases of testing are only found in the laboratory. It is a remarkable setting unlike any other location in modern hospitals. Tasks performed in the laboratory and the places where this work is conducted are integrated into a common thread; each exist solely for the purpose of the other. The people, places, and things – the environment of the laboratory – contribute to infection risks in this setting and the challenges in preventing potential exposures.

The logical aim of laboratory biosafety is to prevent transmission of infections to laboratory personnel, patients, and visitors in and outside of the laboratory environment. Some of the basic environmental safety measures include pressure relationships, use of biological safety cabinets, and following standard precautions. But organizations must be aware that the type and frequency of infection varies with analytic processes and the numbers of employees in a laboratory. Infection control in the laboratory is not a “one size fits all” situation. The following historical trends illustrate this:

- Microbiological laboratories have a greater incidence of gastrointestinal infections compared to other analytic specialties, with *Shigella* and *Salmonella* species being among the most frequently reported LAIs [1,2]
- Reports suggest that infection with *Brucella* species is one of the more common LAIs [3]
- Pathology (anatomic) laboratories have traditionally experienced a greater risk of exposure to tuberculosis and other respiratory infections [2]
- Exposure to viral pathogens might surpass infection with bacterial pathogens [1,3]
- LAIs tend to occur more frequently in smaller laboratories, typically those with less than 20–25 employees [1]

While the literature regarding LAIs is limited, published reports highlight the traditional microbiology laboratory as the most common work environment associated with occupational exposure [1,4-5]. Selective propagation of microbial pathogens in the classic culture-based identification scheme introduces potential exposure risks at multiple steps in the process. The dynamic manipulation of specimens and cultures is a risk-prone work setting.

Independent of analytic specialty, reports of specific accidents indicate that laboratory infections are caused by five types of events: splashes and spills, needle-stick injuries, skin cuts and abrasions (often associated with compromised personal protection equipment), animal bites/scratches, and mouth-pipetting. And, unfortunately, exposures are linked to non-compliance with established biosafety requirements. [5]
Leadership, infrastructure, and effective bio-risk management activities are the foundation of infection prevention and control in the laboratory setting. In that light, understanding and controlling exposure risks in the laboratory can be structured across the following elements:

- Participate in the organization-wide risk management process to identify exposure risks to staff and the secondary community
- Align laboratory prevention and control practices with the organization’s overarching goals; the laboratory is compliant with, and integral to, the organization’s efforts
- Hospital-based laboratories have an excellent resource in the organization’s Infection Preventionist (IP); the IP has training and tools to guide the laboratory
- Understand that exposure risk is independent of test complexity; do not overlook potential exposure risks in waived test systems
- Integrate risk mitigation and prevention processes into every element of laboratory service, begin with initial training for new employees and follow through to competency assessment activities
- Have an ongoing process to monitor staff compliance with established prevention practices in the laboratory

At a basic level, laboratory infection control requires a systematic approach to identify and characterize exposure risks, develop and implement prevention practices, and monitor staff compliance. A risk-mitigate-monitor mantra oversimplifies the effort but is a meaningful starting point for laboratories to develop a proactive system of infection prevention so that they can be ready for emerging infections and new risks. The organization’s IP team is an excellent partner for the laboratory, as they often have access to alerts about emerging infectious agents and can help the lab identify potentially affected areas, collaboratively plan mitigation strategies, and assist with implementation, monitoring prevention processes and setting goals for improved compliance.
The Joint Commission encourages organizations to follow a hierarchical approach to ensuring that organizations develop compliant infection prevention and control policies, procedures, and processes starting by ensuring compliance with rules and regulations through implementation of applicable evidence based guidelines to ensure best practices.

The hierarchy is summarized in the following sequence:

- **Rules and Regulations**: Common sources of regulations would include Occupation Safety and Health Administration (OSHA), the Food and Drug Administration (FDA), and other local, state, and federal regulations

- **Condition of Participation (CoP) and/or Conditions for Coverage (CfC)**: Program-specific guidance contained in the State Operations Manual (SOM) appendix to the Centers for Medicare and Medicaid Services (CMS) and the Clinical Laboratory Improvement Amendments (CLIA); for example, CLIA Conditions for Systems in the Laboratory General, Preanalytic, Analytic, and Postanalytic domains

- **Manufacturers’ Instructions for Use**: Specific instrumentations using a product or device as required by the manufacturer’s label to safeguard the quality, function, safety, and longevity of the product or device

- **Evidence-Based Guidelines**: Many related to infection prevention and control are based on Centers for Disease Control and Prevention (CDC) recommendations and guidelines. The Joint Commission standards require compliance with CDC and/or World Health Organization Hand Hygiene guidelines, CDC Isolation and Standard Precautions guidelines. Others may be required by state or federal regulations, referred to by manufacturers or chosen by organizations.

An example of the hierarchical approach can be applied to the use of personal protective equipment:

- **Rule and Regulations**: Applicable sources of rules and regulations include OSHA 1,2

- **CMS**: State operation manuals 3

- **Manufacturer Instructions**: May specify specific personal protective equipment that must be worn and when it is required

- **Evidence-Based guidelines**: CDC standard precautions address selection and use of personal protective equipment 4

### CHARACTERIZING LABORATORY EXPOSURE RISKS

In a clinical laboratory, the flow and accumulation of specimens directly impacts infection exposure risks. The large volume of specimens that aggregate in the laboratory contribute to a substantive concentration of potentially infectious materials in the pre-, post-, and analytic settings. Specimens collected in the hospital and its associated clinics are transported to the laboratory, massing in significant volume every workday. Knowing this concentrated risk exists in the laboratory, every work surface – especially high-touch and high-volume work areas – could become contaminated. The risk of exposure to bloodborne pathogens can be expanded by indirect or secondary transference, which includes hospital staff from outside the laboratory, that could potentially bring in and take out infectious material from work surfaces or transport vehicles such as pneumatic tube stations, coolers, and secondary carriers.

In the microbiology laboratory, exposure risk is influenced by the general workflow required to identify and characterize microbial agents. In a traditional approach to bacteriology, a swab plated on growth media leads to amplification, selection, and intentional propagation of suspected...
In such cases, pathogens are selected and concentrated in the workflow process. It is these procedural steps that emphasize the risks inherent to a traditional bacteriology work setting. Ultimately, specimens and microbiology culture media become waste products, making disposal from the laboratory a potential risk, often for environmental services employees.

These types of risks are unique to the laboratory, a specialized and nuanced environment where large concentrations of patient specimens are routinely concentrated, agitated (by handling and preanalytic preparation), and even selectively propagated as in the example of bacteriology. It is clearly a different environment with emphatic safety concerns that are not characteristic of the direct patient care settings. While there are certainly prevention strategies common to both laboratory and non-laboratory settings, such as hand hygiene, infection prevention processes in the core laboratory achieve a complexity proportional to the scope of services provided and their associated risks to staff, patients, and visitors.

Exposure risk is dynamic; a change in laboratory services, new procedures, revised processes, construction and renovation, emerging pathogens, handling and processing specimens, and implementing emergency operations can impact exposure risk in the laboratory environment. Similarly, introducing new products, even something as seemingly simple as adding a new surface disinfecting wipe in the point-of-care setting, can alter risk to staff and patients. To this end, exposure risk should be reviewed periodically to ensure a complete and timely assessment; infection control is not well served by a "one-and-done" mentality. Hospitals review their risk assessment annually, providing an excellent opportunity for the laboratory to further align its activities with the parent organization by participating in the organization's annual assessment process.

**PREVENTIVE PRACTICES**

Here are several criteria to consider when reviewing infection prevention practices in the clinical laboratory:

- Workflow, such as sample acquisition, handling and preparation, and the need for protective barriers when appropriate for risk-relevant procedures
- Review trafficking patterns for staff and specimen flow
- Inspect and maintain device safety mechanisms, such as pneumatic tube station access, interlocking lids and gaskets on centrifuges, cap-piercing sampling systems, special air pressure relationships, automated and robotic preanalytic lines, and using snap-caps that cover used sharps
- Ensure that hand hygiene facilities are readily accessible to all staff; create an awareness and understanding of when hand washing with antimicrobial soap is required instead of an alcohol-based hand rub
- Ensure that personal protection equipment (PPE) is appropriate for the task and available in usable condition, training is conducted on the proper use of personal protective equipment, including but not limited to masks, gloves, face shields and eye protection, and engineering controls (e.g., other physical barriers or equipment such as biological safety cabinets to protect from exposure) are available and appropriate to mount an escalated response appropriate to the assessed risk; these tasks requiring PPE or engineering controls should be part of an ongoing assessment to ensure staff compliance
- Implement policies and procedures to decontaminate work surfaces and achieve the appropriate level of disinfection for point-of-care (POC) devices
- In addition to regular cleaning and disinfecting, ensure that countertops, casement, flooring, and specimen handling areas are in a physical condition that allows them to be decontaminated in the event of spills or splashes
- Ensure potentially infectious waste is properly contained, removed from work areas, and processed in accordance with applicable laws and regulations
- The laboratory environment has a special air pressure relationship designed to minimize the spread of bioaerosols; the use of auxiliary fans can create secondary risks by disrupting airflow balance and distributing aerosolized material throughout a common air space. To this end, appropriate ventilation and air flow is a critical prevention process, especially in the microbiology laboratory. Create a consistent process to ensure pressure relationships are monitored and maintained
- Assign individuals who are trained and competent to provide oversight of the implantation of prevention practices to ensure that they are consistently followed and updated when necessary

Laboratories have progressively adopted prevention practices and many of these practices are habituated in daily routines. Be intentional when observing infection control activities, looking not just at prevention practices, but also the behaviors that drive their successful
implementation. For example, a lack of effective heating and cooling of the laboratory air space can propagate secondary responses that overcome established infection prevention practices, such as installing temporary cooling devices, removing laboratory coats, rolling up sleeves on over-garments, or avoiding glove use when the work setting is uncomfortably warm. Similarly, ill-fitted or incorrectly sized PPE might result in staff not using the equipment, or inappropriately modifying the PPE to achieve a more comfortable or convenient fit.

It is time to view the laboratory and relevant prevention practices from a fresh perspective. When touring the laboratory, responsible leaders at all levels must be trained and competent to critically observe practices across the full spectrum of pre-, post-, and analytic domains with a focus on risk and safety. As leaders observe laboratory activities, they might ask these questions:

- Is PPE available, sized correctly for staff, and used appropriately?
- Are staff aware of exposure risks and do prevention practices target these risks?
- Is the laboratory environment safe for staff, patients, and visitors?
- Does workflow create unnecessary exposure risk; does a lack of space or an irregular workflow encourage shortcuts or abbreviated biosafety measures?
- Are biological safety cabinets, physical barriers, and other special containment equipment available, properly maintained, and appropriate for the work being performed?
- Can work surfaces be cleaned and disinfected with the material available to staff?
- Is routine housekeeping being performed in the lab by staff who know and understand the laboratory specific hazards and the areas that they should not clean? How often are support areas, floors and high-touch surfaces cleaned?
- Is potentially infectious waste handled in accordance with regulations from “cradle to grave”?
- Are hand hygiene facilities readily accessible and do they encourage hand hygiene? Are sinks being used for handwashing (clean process) and dirty processes (e.g., specimen disposal)?
- When and where is alcohol-based hand rub (ABHR) used; has the supply of ABHR exceeded its expiration date? Is it dripping on the floor? Is it installed safely?
- Are staff following prevention practices required by laboratory policies, procedures, and established guidelines?
- Do staffing levels and training minimize overloaded and stressful work settings that might encourage shortcuts or disregard for safety measures?
- Are infection prevention activities in the laboratory consistent with the organization’s overall practices and goals?
- When laboratory items travel to other locations, such as carriers (totes), reusable transport containers, carts, mobile workstations, logbooks and clipboards, what cleaning and sanitation processes are in place to prevent cross transmission?

Laboratory infection prevention strategies can be viewed as practices designed to contain potential exposure in a specialized environment, restrain activities that enhance or propagate risks, and maintain processes to prevent exposure across all elements of laboratory services. To this last point, the contemporary laboratory is no longer exclusively defined by a physical structure but exists in a flexible and adaptive model that expands and contracts to best serve its targeted healthcare mission. The array of specimen collection areas (outpatient, inpatient, onsite, offsite, remote, specialized), POC testing, core analytics, specimen storage locations, and the transfer of specimens between and among clinical areas and laboratories each present exposure risks and opportunities for effective prevention practices.

**PROCESS SURVEILLANCE AND LABORATORY SUCCESS**

Process surveillance allows organizations to proactively monitor implementation of processes aimed at preventing exposure and subsequent disease rather than waiting for an exposure or infection to occur and then react with control measures. This type of surveillance consists of activities that assess staff compliance with infection prevention practices, identifying both successful implementation as well as opportunities to improve awareness and understanding. Process surveillance is the systematic evaluation of staff compliance with infection prevention practices (processes) implemented across the spectrum of laboratory services – from the core analytic work area to the POC environments. It is a series of data-driven metrics that yield an objective assessment of staff behaviors to recognize and apply prevention practices.
When determining process surveillance activities, the Centers for Disease Control and Prevention (CDC) Core Practices [7], Biosafety in Microbiological and Biomedical Laboratories [8], and hand hygiene [9] are excellent references for the hospital and clinical laboratory. Once again, partnering with the organization’s IP captures the skill set, training, and experience to develop an effective surveillance program for laboratory services.

Hand hygiene, while critically important throughout every healthcare organization, is but one element of infection prevention in the laboratory. An expanded view of process surveillance might include not just hand hygiene, but also consider PPE use, work practices, barrier protection (aerosol and splash shielding) when performing high-risk tasks or handling selected specimens, and the disposal of potentially infectious waste from laboratory work areas. Infection prevention in the laboratory is a highly integrated process and includes multiple layers of protection performed by many different staff members.

SUCCESSFUL PREVENTION PRACTICES

During the accreditation survey process, surveyors will ask staff about infection prevention processes and observe to see how these processes are implemented, including observing practices performed in the laboratory. Laboratory leadership can engage in the same approach – reviewing staff knowledge and competency during surveillance activities – to understand staff challenges and recognize further opportunities to improve infection prevention practices. The ask-and-watch approach is also an opportunity to engage staff through teaching and coaching.

Laboratories with mature process surveillance activities often include infection control practices in their performance improvement (PI) activities and both waived and non-waived competency assessments. These laboratories integrate their infection prevention practices across their service line to solidify the importance of infection control by including it in their competency assessment activities. This is another area where the IP staff can assist the laboratory in adopting organization-wide metrics and designing additional monitors if needed.

Infection control is also part of the POC setting and training should ensure staff understand potential exposure risks in the near-bedside testing environment. For example, CDC has identified a risk of transmission of bloodborne pathogens when glucose monitoring equipment is not disinfected after each use. [10] Because POC devices travel throughout a medical unit or hospital, cleaning and disinfection processes should be observed to ensure staff disinfect point-of-care devices and follow the manufacturer’s instructions for use (IFUs) when using a surface disinfectant. This provides a meaningful touchpoint with staff to enhance awareness and emphasis low-level disinfection; processes that extend beyond the POC testing environment to encompass other locations where disinfection products are used.
To summarize this section, ensure the organization’s IP team and all laboratory services are a cohesively integrated part of the laboratory’s and organization’s infection control activities. Think of infection control as a continuous teachable moment for laboratory staff to foster encouragement and coach corrective measures. Ensure that laboratory IC processes are aligned with the hospital’s overarching policies, processes, procedures, and goals, mutually supportive and accountable. And finally, make prevention processes intentional and monitor staff behaviors for compliance — as leaders of both the Laboratory and IP teams are responsible for ensuring implementation.

LABORATORY ACCREDITATION STANDARDS AND THE SURVEY PROCESS

The Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing presents infection control standards in the Infection Control (IC) chapter. Further IC compliance requirements are found with the National Patient Safety Goals (NPSG), Environment of Care (EC) and Quality System Assessment for Nonwaived Testing (QSA) chapters. The prefatory narratives for each of these chapters make clear the intent that infection control exist as a highly integrated process that requires well-designed, well-communicated, and focused approaches to achieve a successful outcome.

For many laboratorians, infection control was not part of the curriculum that ushered us into this profession and has not been a common theme of our continuing education and training. We find ourselves playing catch up with the rest of the healthcare system and are occasionally challenged by what we might perceive as an exclusive focus on the direct care setting. We have an opportunity to expand our role in the realm of infection control, better understand the environment in which we work, and ensure staff are aware and equipped in a setting that presents unique exposure risks.

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FOOTNOTES


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