

Beyond Compliance: The Impactful Role of Biosafety Controls and Good Laboratory Practices in a Biosafety Program

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Abstract

Biosafety is a critical aspect of laboratory medicine, defined as the application of principles and practices to prevent infections, as well as chemical and physical hazards, in the laboratory. To achieve optimal biosafety in clinical and research laboratories, it is essential to implement rules, regulations, and procedures for preventing hazards associated with laboratory work. This not only impacts the health of laboratory personnel but also significantly affects environmental health outside the laboratory. Hence, a structured biosafety program built on the principles of established evidence and guidelines functions to implement all the requisite protocols. The primary controls of biosafety and good laboratory practices and procedures (GLPPs) are two of the cardinal pillars of such a biosafety program, each providing its own courses of action for implementing biosafety in a stepwise methodology. The four primary controls of biosafety comprise engineering controls, standard operating procedures, personal protective equipment and leadership. Each of these controls play a pivotal role in ensuring biosafety and augmenting the effect of other controls. On the other hand, GLPPs comprise a set of procedures designed to enforce safety during laboratory tasks and are to be adopted by all laboratory personnel. GLPP aims to adopt a methodical and rigorous approach to laboratory work, thereby reducing errors and ensuring the accuracy of results. The authors provide an overview of the primary controls of biosafety and GLPPs in this article, emphasizing their importance in a laboratory biosafety program.

Keywords: *Biosafety, primary controls of biosafety, good laboratory practices and procedures, biorisk management, occupational health.*

INTRODUCTION

Biosafety is a critical aspect of laboratory medicine that has adopted a comprehensive approach to prevent infectious, chemical, and physical hazards in the laboratory [1]. It can only be ensured if all necessary precautions are in place, which can be accomplished by following the regulations and guidelines for reducing laboratory biohazards. This will not only safeguard the laboratory workforce but also mitigate risks to the environment outside the laboratory and to public health. This all-encompassing approach strengthens public trust and regulatory compliance [1, 2].

There are four primary biosafety controls, each of which is equally important. They comprise engineering controls, standard operating procedures, personal protective equipment and leadership. Each of these controls plays a pivotal role in ensuring biosafety and augmenting the effect of other controls [1, 3].

PRIMARY CONTROLS OF BIOSAFETY

The four primary controls of biosafety — engineering controls, standard operating procedures (SOPs), personal protective equipment (PPE), and leadership — cover and reflect different facets of safety implementation, which, when implemented together, produce a positive cumulative effect in curtailing the emergence and spread of biohazards. Through this comprehensive strategy of integrating and

correlating engineering operations with personal safety, documentation, and leadership, the risk of biohazards can be minimised [1, 4, 5].

Engineering controls encompass various specific construction measures suited to the safe performance of laboratory tasks. Furthermore, these may differ in relation to the containment level of the laboratory [6]. For instance, a clinical laboratory working with *Mycobacterium tuberculosis*, the pathogen that causes tuberculosis, requires a negative airflow system, whereby the outward flow of inside air containing aerosols generated during laboratory work is restricted [7].

Furthermore, PPE suited to the nature of precautions required while dealing with specific clinical samples or organisms further guards the safety of the laboratory personnel [8]. For example, when dealing with infectious agents, gloves and gowns provide protection from skin contact, and respirators, such as N95 masks, protect against airborne pathogens. For chemical laboratories, lab coats and safety goggles protect against corrosive materials. For high-containment labs, powered air-purifying respirators (PAPRs) and full-body coveralls protect from exposure to major biohazards. Such specific PPE selection offers adequate protection for laboratory workers, depending on the nature of the samples they are handling [8].

In addition, standardisation in the implementation of the primary biosafety controls can be achieved through appropriate documentation, where standard documents provide a means for the uniform replication of tasks by

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Received: February 18, 2025; Revised: April 08, 2025; Accepted: April 16, 2025
DOI: <https://doi.org/10.37184/jlnh.2959-1805.3.43>

laboratory workers [9]. For instance, autoclave SOPs establish standardised procedures for decontamination, while biosafety manuals identify specific safety procedures to follow when working with pathogens at various biosafety levels (BSLs). This type of documentation ensures laboratory operations are uniform and secure across multiple locations, minimising the risk of exposure to biological materials. Regular revision and updates of these documents make them even more efficient [9].

Leadership may also add to the safety of the workforce through encouraging vaccination, training and strict adherence to the SOPs. Furthermore, good leadership is essential for preserving the integrity of staff background checks, as well as for routine protocol evaluation and validation to adapt to changing biosafety risks [10, 11]. For example, leaders can plan vaccination drives and safety workshops to educate the public. They also enforce the integrity of background checks and routinely review and validate procedures to counteract changing biosafety threats. This forward-looking attitude promotes a safety culture and accountability, safeguarding both employees and the organisation against potential threats. Effective leadership establishes a precedent for prioritising safety, with employees following suit [10, 11].

All these controls can be combined to achieve maximum safety in the laboratory environment. For example, in a biosafety level 3 (BSL-3) laboratory, a negative airflow system is augmented by proper PPE comprising N95 masks, face shields/ goggles, protective gowns, etc., to guarantee adequate protection from circulating aerosols [7] (Table 1).

IMPLEMENTATION OF BIOSAFETY CONTROLS

The control of biological risks - whether at national or organisational levels - is well informed by conducting a risk assessment. Risk assessment refers to the stepwise process of evaluating the risks associated with working with a hazard(s) and determining whether risk control measures can help reduce those risks to acceptable levels [12]. Whereas, risk is defined as the probability that a hazard will cause injury as well as the severity of harm that may result from exposure to that hazard [13].

In laboratory biosafety, exposure refers to biological agents that have pathogenic properties and have the potential to harm humans or animals if they are exposed to them. The harm caused by biological agents can vary in nature, ranging from infection or injury to disease or outbreak in larger populations [1, 3]. It should also be noted that a hazard by itself is not necessarily a risk

Table 1: Primary controls of biosafety with examples.

Primary Control	Components/ Examples
Engineering	Door locks Directional air flow Interlocked doors Biosafety cabinet Autoclave HEPA filter
Personal Protective Equipment (PPE)	Gloves Eye protection Laboratory coat N95 mask Shoe covers Powered air-purifying respirator (PAPR)
Standard Operating Procedures (SOP)	Emergency evacuation Waste disposal Spill clean up Needle stick injury Bench disinfection Medical emergencies
Leadership	Training Vaccination SOP compliance Surveillance SOP evaluation/ validation Staff competency

to humans or animals. For instance, a vial of blood containing a biological agent, *Ebola virus*, is not itself a risk to the laboratory worker unless or until the worker comes into contact with the blood in the vial [14]. Hence, identifying a biological agent's pathogenic characteristics does not fully determine its risk.

Any facility that deals with biological agents has a duty to its employees and the general population to ensure that any work being conducted has been assessed for risk and that optimal risk control measures have been identified and implemented to ensure that the risk is within the required threshold. The purpose of a risk assessment is to gather, assess and use information on the identification of risks and their likelihood and consequences to support the choice, implementation, and monitoring of controls that will manage the risks [15]. The analysis of this data enables laboratory personnel to be more conscious of the biological risks. It promotes shared values, behavioural patterns, and awareness of the importance of biosafety, making laboratory personnel more likely to perform their work safely and thus maintaining a safe culture in the laboratory.

Risk assessments must always be performed in a standardised and systematic manner to ensure that they are repeatable and proportionate in the same situation. As a result, many organisations provide risk assessment templates, checklists, or questionnaires that offer step-by-step approaches to identify, evaluate and determine risks associated with potential hazards, before using

this information to identify appropriate risk control measures [16]. The various steps in the risk assessment process combine to form a risk assessment framework (Fig. 1).

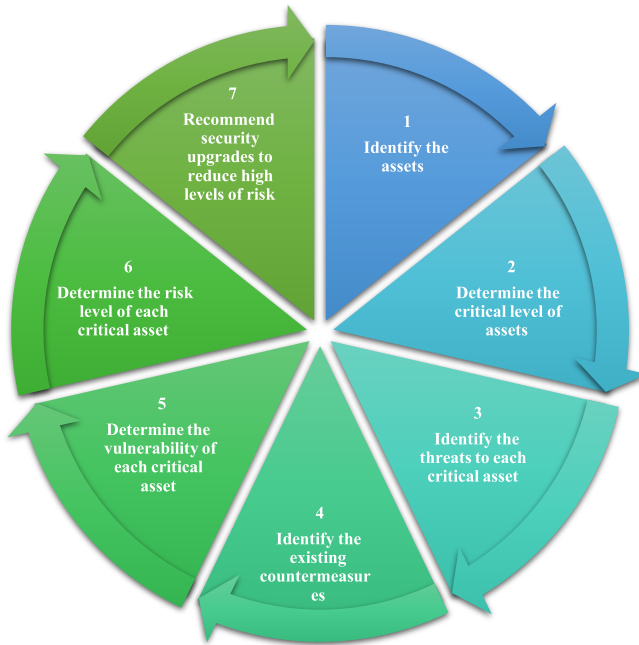


Fig. (1): Delineation of various processes in the Risk assessment framework.

GOOD LABORATORY PRACTICES AND PROCEDURES (GLPPS)

Good Laboratory Practices and Procedures (GLPPs) are a set of standards and guidelines for performing laboratory experiments to ensure or maintain the quality of laboratory research and testing [17-19].

GLPPs aim to promote the concept of a systematic and disciplined approach to laboratory work, thereby eliminating errors and ensuring accurate and consistent results. GLPPs address issues such as personnel training, equipment management, data collection and management, and quality assurance and control. They also stress the importance of SOPs, sampling and laboratory techniques and adherence to the required standards and regulations [20-23]. Therefore, the use of GLPPs assists laboratories in achieving a high level of quality, and thus their results can be trusted and used in furthering science. Therefore, their adoption is deemed necessary in different areas of application, including laboratory medicine, the pharmaceutical industry and biotechnology. In these fields, accurate and precise laboratory information is crucial in the decision-making process and in protecting public health. GLPPs assist in avoiding mistakes, cross-contamination, and incorrect analysis, which can have severe implications [17-19].

One of the most prominent frameworks for GLPPs is the Organisation for Economic Co-operation and Development (OECD) GLP Principles, which are widely used in countries such as the US, UK, and EU. These principles focus on Test Facility Organisation and Personnel, Quality Assurance Programme, Facilities, Apparatus, Material, Reagents, Test Systems, Standard Operating Procedures (SOPs), and Storage and Retention of Records and Materials [24]. Another essential guide is the WHO GLP Training Manual, which identifies five basic points: Resources (organisation, personnel, facilities, and equipment), Characterisation (test items and test systems), Rules (written procedures and study plans), Results (archives, final reports, and raw data), and Quality Assurance [25].

IMPLEMENTATION OF GLPPs

The clinical laboratory implementation of GLPPs consists of several processes. These include (i) Education and competency of staff to make sure all employees are trained and competent to work in the clinical laboratory (ii) SOPs for all laboratory processes, such as the operation of equipment, handling of samples, and recording of data (iii) Laboratory layout and design to minimise contamination and to achieve sufficient storage and ventilation (iv) Ensuring accurate and precise measurement through regular calibration and maintenance of all equipment (v) Appropriate labelling, storage, handling and disposal of reagents and chemicals (vi) Adherence to appropriate protocols regarding the receipt, processing, and storage of each submitted sample (vii) Data administration for precise and secure data recording, storage and retrieval (viii) Quality control and assurance through regular audits (ix) Following biosafety recommendations, such as proper PPE use, decontamination procedures and incident reporting (x) Compliance with SOPs and (xi) Periodic audits and inspections for conformity to the principles of GLPPs [17-19, 26].

One notable example of the benefits of implementing GLPPs is the case of the Global Polio Eradication Initiative. The initiative aims to reduce the risk of *poliovirus* reintroduction by ensuring that all *poliovirus*-handling facilities adhere to stringent biosafety protocols. Laboratories covered under this programme have implemented GLPPs to minimise the number of facilities working on *polioviruses* to the minimum necessary for essential processes, such as vaccine production and research, in an effort to reduce the risk of accidental leakage [27]. Another classic example is utilising BSLs, which are included in GLPPs. BSLs range from 1 to 4, each corresponding to specific safety procedures depending on the risk category of the organisms being

worked with. For example, BSL-2 labs, which work with moderate-risk pathogens, employ special practices such as restricted access and immunisation of personnel [28].

In practical contexts, the adoption of GLPPs has been key in averting laboratory-acquired infections. For instance, during the coronavirus disease (COVID-19) pandemic, laboratories that adhered to GLPPs were better prepared to work safely with *severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)*, thereby curbing transmission between workers and the environment. Moreover, GLPPs have helped generate national preparedness plans and biosafety training initiatives, furthering laboratory safety [29]. The focus on GLPPs has also led to an enhancement of laboratory biosecurity, ensuring that biological materials are not only handled safely but also stored safely and protected from theft and misuse [29]. Generally, the incorporation of GLPPs in laboratory practices has greatly enhanced biosafety levels, safeguarding both lab workers and the general community from biological threats.

FUTURE DIRECTIONS IN BIOSAFETY

The biosafety landscape is changing rapidly with emerging technologies that will transform the way we safeguard laboratory workers and contain biological hazards. These innovations present key opportunities to establish stronger foundations for biosafety practices and address the complex challenges facing laboratories today.

The combination of Internet of Things (IoT) and artificial intelligence (AI) technologies is at the leading edge of biosafety innovation, providing capabilities hitherto unavailable for risk reduction and real-time monitoring. Sophisticated IoT systems are facilitating round-the-clock monitoring of laboratory environments, with sensors tracking air quality, equipment functionality, and other key parameters, adopting a preemptive rather than reactive approach to safety. These systems can identify anomalies before they become hazards, readjusting parameters or notifying staff of possible breaches in containment. The use of AI extends these capabilities further by analysing patterns and forecasting potential safety issues before they occur, significantly reducing the risk of laboratory-acquired infections and other biosafety incidents [30].

Risk assessment methods are being revolutionised by digital biosecurity control and analysis systems that offer objective information on personnel interactions, disinfection practices, and other key safety factors [31]. These systems go beyond traditional checklist methods, providing detailed scoring in multiple biosafety areas and identifying specific areas of weakness in visitor

access, specimen handling, or facility layout. Future biosafety strategies will increasingly be based on these data-driven methods, allowing more precise and effective enhancements to primary containment methods [31]. The move toward safety-by-design concepts represents another major leap, in which biosafety is integrated into plans from the earliest stages of laboratory design, rather than being added as an afterthought.

Even laboratory practices are being refined to a greater extent, as past outbreaks serve to inform more stringent protocols. Better specimen collection, processing, and storage methods are being developed that harmonise biosafety with specimen integrity [32]. Sophisticated disinfection practices are being implemented with novel next-generation formulations and delivery methods that effectively inactivate biological threats without contaminating laboratory equipment or the environment. The traditional hierarchy of biosafety controls is being bolstered by emerging technologies in PPE that provide higher levels of protection while enhancing comfort and ease of use, thereby addressing one of the long-standing challenges in sustaining compliance with safety standards [32, 33].

Augmented and virtual reality technologies are revolutionary tools for biosafety training and competency testing, enabling laboratory staff to conduct high-risk procedures in simulated environments before performing them with real biohazardous agents [34]. These simulated training environments can replicate emergencies that would be unsafe or impractical to rehearse in a conventional setting, ensuring that personnel are prepared for swift and proper action in response to spills, equipment malfunctions, or other accidents. Blockchain technology is also transforming the record-keeping aspects of biosafety, providing tamper-proof records of training, equipment calibration, and safety incidents that facilitate accountability and support regulatory compliance [34].

The ethical implications of biosafety are being readdressed as new technologies such as synthetic biology, gene editing, and nanotechnology introduce new risks that were not anticipated in traditional biosafety frameworks. Next-generation biosafety strategies will need to incorporate ethical oversight that aligns scientific progress with public security, involving interdisciplinary collaboration among scientists, ethicists, policy analysts, and community members [32]. The moral framework will increasingly assume significance as the digital-biological distinction narrows, posing sophisticated “cyberbiosecurity” challenges that entail risks far more severe than conventional cyber threats [35].

CONCLUSION

Collaborative solutions are the most promising route for future progress in biosafety. The knowledge and practice gaps revealed by previous and current outbreaks underscore the need for comprehensive, multi-stakeholder solutions that involve the clinical laboratory community, safety experts, regulators, and technology developers. Such collaborations will be vital to creating robust, consistent recommendations that address the distinctive features of various laboratory environments while defining overarching principles of biosafety excellence. Through the facilitation of such collective knowledge, the future of biosafety can move beyond single-discipline methodologies to a comprehensive system that protects laboratory workers, patients, the public, and the environment from biological hazards, while also promoting essential scientific advances.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

Declared none.

AUTHORS' CONTRIBUTION

MAK - Conceptualisation and Writing – review & editing.

MM & BA – Writing – original draft.

GENERATIVE AI AND AI-ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

During the preparation of this work, the authors used Perplexity AI to assist with language suggestions, minor proofreading and drafting certain aspects of the article. All AI-assisted content was thoroughly reviewed, edited, and refined by the authors, who take full responsibility for the final content of the published article.

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