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Evaluating Biological Risks in Biomedical Laboratories of Primary Health Care

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Abstract

Biomedical laboratories in primary health care centers play a critical role in disease detection, diagnosis, and management. However, the handling of diagnostic samples presents significant biological risks, particularly when biosafety measures are insufficient. This study focuses on analyzing the biological risks in 35 BSL-2 biomedical laboratories within health facilities in Athens, Greece, by examining compliance with biosafety regulations, personnel safety awareness, and biorisk management practices. A cross-sectional survey was conducted combining a customized checklist and a structured health and safety questionnaire, both developed based on the existing literature, including the international biosafety guidelines (BMBL 6th ed., WHO Biosafety Program Management, 2020). On-site evaluations were performed by a certified biorisk management advisor, and 158 laboratory

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professionals anonymously completed questionnaires on biosafety practices. The collected data were analyzed qualitatively, and where possible, quantitatively, by using SPSS software and p-values from the McNemar test. The results revealed widespread deficiencies in biosafety culture and risk management. Key gaps were identified in all layers of engineering controls, administrative controls, personal protective equipment (PPE), and emergency preparedness. Many laboratories failed to meet international biosafety standards set by organizations such as the WHO, CDC, and ECDC, as well as Greek legislation, highlighting the need for urgent improvements. To address these issues and mitigate the observed gaps, the implementation of comprehensive Biorisk Management Systems, enhanced biosafety training, and stricter enforcement of national and European biosafety regulations is strongly recommended. These measures are essential to protect laboratory personnel, the surrounding community, and the environment from lab-acquired infections and other biological threats.

Keywords: Biorisk management, Biosafety, Biomedical laboratories, Risk evaluation, Primary Health Care

Introduction

Biomedical laboratories are crucial components of every healthcare system, significantly contributing to the diagnosis, management and treatment of diseases, as well as in emerging infections and in research (Brown et al., 2015). Nevertheless, if containment controls and safety procedures are not adhered to and imposed rigorously, laboratories can present biological hazards to both staff and the environment. The combination of infectious biological agents that could be found in all forms of testing samples, with the procedures for analysis, may lead to laboratory-acquired infections (LAIs) and containment breaches (Blacksell et al., 2023; Wurtz et al., 2016).

Ensuring the safe receipt, management, transfer, and storage of these samples and materials necessitates the implementation of appropriate mitigation strategies in line with optimal practices within suitably equipped and confined structures (NIH, 2024), as part of a laboratory biorisk management system and under a biosafety framework. Biosafety is a scientific discipline that encompasses the principles, methods, and procedures used to define and avert unintentional exposure to biological agents or their accidental release (WHO, 2020).

Risk assessment is an essential aspect of the laboratory biorisk management system and should be tailored to the specific circumstances of each laboratory or scenario. In accordance with the EU Directive 2000/54/EC and the Greek law (Presidential Degree 102/2020), which aim to safeguard workers from hazards associated with exposure to biological agents, Article 3/

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EU Directive 2000/54/EC stipulates that any activity that poses a potential biological risk, necessitates a risk assessment. When conducting a risk evaluation, the data collected are utilized:

a. **to discover the risks by assessing the likelihood of a hazard alongside its potential effects** (WHO, 2020; Gribble et al., 2015). In line with the European directive 2000/54/EC and Greek law PD 102/2020, as well as the international instructions, such as BMBL 6th ed. (CDC, 2020) and WHO 3rd ed. (WHO, 2004), biomedical laboratories are required to be designed and operated at the BSL-2 level, based on this specific risk assessment.

b. **to mitigate these risks to a tolerable level, and to avoid laboratory-acquired illnesses** (LAIs), by implementing appropriate control measures. By applying the following three steps of the hierarchy of controls system (CDC, NIOSH, 2021), it is possible to effectively block the pathways of biological agents, ensuring a safe working environment and reduce biological dangers to a tolerable status for the lab staff, the surrounding population, and the environment (Tun, 2017):

- **Engineering Controls,** which comprise elements of architecture and technology, to safeguard and contain both the internal and external environments of the laboratory. They include among others HVAC (Heating, Ventilation, and Air Conditioning) systems, biological safety cabinets and safety centrifuges.
- **Administrative controls** encompass a range of local legislation and international principles, regulations and recommendations, Good Laboratory Practices and Procedures (GMPP) and Standard Operating Procedures (SOPs). Also an **essential component is the education** of lab personnel, which should be adopted, endorsed, and advanced by the administration.
- **Personal Protective Equipment (PPE)** is gear worn by lab personnel to shield them from potential susceptibility to biological substances. While PPE serves as an effective barrier, its use must correlate with the local risk assessment (Bathula & Rakhimol, 2017).

Materials and Methods

Risk can be characterized through qualitative and quantitative approaches. This study was structured as a cross-sectional survey, merging the risk evaluation of an expert using a checklist (qualitative method) and a subjective risk perception of the lab staff, which was collected through questionnaires given to them (quantitative method). The objective was to examine the biological hazards within biomedical laboratories and evaluate the understanding and compliance to biosafety regulations and practices among the lab personnel.

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The data collection concerning biological risks occurred in the biomedical laboratories of 35 primary health care facilities situated in Athens, Greece, between March 2021 and June 2022. The analysis of the data was performed using SPSS software version 29 (under an Academic license), employing descriptive statistics to present an overview of the results.

The biomedical laboratories within these health centers in Greece integrate clinical microbiology, clinical chemistry, and hematology as a single laboratory department. The biological samples analyzed included the collection of whole blood, plasma, serum, urine, and feces, utilizing the most common laboratory techniques such as working with automated analyzers, conducting manual tests and urine cultures. The research design was organized into two main components:

First research component: evaluation by a Biosafety Professional (Checklists)

A tailored checklist was created from the existing literature, including the BSL-2 labs checklists from the Federal Select Agent Program (FSAP), Division of Regulatory Science and Compliance (DRSC), based on the BMBL 6th ed. (CDC, 2020), and the Audits checklists from WHO Biorisk Programme Management monograph (WHO, 2020). A trained and accredited biosafety professional assessed a total of 35 biomedical laboratories located in the Primary health care centers. The professional filled out the checklists by conducting local observations and engaging in conversations with laboratory managers and staff, focusing on containment, procedural protocols, use of PPE, emergency preparedness and biosafety training. The 45 items of the checklist were categorized into four primary sections:

A. Laboratory facilities and Containment Measures (Engineering Controls), 18 items
B. Laboratory practices and procedures, and Training (Administrative Controls), 11 items
C. Personal Protective Equipment (PPE), 7 items
D. Emergency Preparedness, 9 items

Second research component: comparing the Findings of the Biosafety Professional (Checklists) with the H&S Anonymous Risk Survey (Questionnaires) of the Laboratory Personnel

A dedicated biosafety health and safety anonymous questionnaire was distributed to 158 laboratory personnel in the biomedical labs where the biosafety professionals' checklist was carried out. The staff completed the questionnaire within their work lab environment. That custom questionnaire was also created by combining checklists from the BMBL 6th ed. (CDC, 2020) and the WHO Biorisk Programme Management monograph (WHO, 2020). It

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included 15 primary questions, divided into 77 sub-questions and organized into two key sections:

The first six primary questions collected general data regarding the professions of the lab workers, the type of laboratory, and how the biological samples being managed. More specifically:

a. The professional qualification of the lab staff was laboratory technologists (44.9%), laboratory assistants (29.1%), laboratory medical doctors (20.9%), biologists and biochemists (3.2%), and others (1.9%).
b. Except one of the labs they did not had any ISO 9001 certification or ISO 15189 accreditation.
c. The biological materials analyzed was whole blood/plasma/serum (88.6%), urine/feces (84.8%) and tissues samples (0.6%)
d. The most common laboratory procedures were automated analyzers (72.1%), manual tests (48.1%), cultivations (28.5%) and a combination of them (29.1%).

The remaining nine questions were aimed at obtaining data about biosafety measures and laboratory procedures, focusing on the last three components of the hierarchy of controls, thus engineering controls (Table 5), administrative controls and biosafety training (Table 6), personal protective equipment (Table 7), as well as emergencies (Table 8). All questions required a Yes or No response to the indicated items.

Results

1. Evaluation of the Biosafety Expert (Summary of Checklist Findings)

Descriptive Statistics

Table 1. Laboratory Facilities and Containment Measures (Engineering Controls)

A. Engineering Controls			
		Count	**Count %**
A.1 Entry to the laboratory is restricted only to authorized personnel	YES	11	31.4%
	NO	24	68.6%
A.2 The entry door of the laboratory features signs and information regarding the Biosafety Level	YES	1	2.9%
	NO	34	97.1%
A.3 The entry door of the laboratory is equipped with a self-operating closing mechanism	YES	8	22.9%
	NO	27	77.1%
A.4 There are designated lockers and storage areas for the belongings of the lab staff	YES	18	51.4%
	NO	17	48.6%
A.5 The management and secretariat areas are distinctly separated from the laboratory analysis spaces	YES	16	45.7%
	NO	19	54.3%
A.6 Blood collection occurs in a designated and separate area, which is adequately sized	YES	29	82.9%
	NO	6	17,1%
A.7 The laboratory's doors and windows can be securely closed during analyses	YES	34	97.1%
	NO	1	2.9%

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A.8 Laboratory surfaces, benches and floors are intact, constructed from rugged materials, and easy to clean and disinfect	YES	33	94.3%
	NO	2	5.7%
A.9 Laboratory seats have stable base, are made from non-fabric materials, and can be easily disinfected	YES	26	74.3%
	NO	9	25.7%
A.10 Regular checks of the air conditioning system (HVAC) are conducted and documented	YES	32	91.4%
	NO	3	8.6%
A.11 There is at least one certified biological safety cabinet (BSC) present	YES	0	0%
	NO	35	100.0%
A.12 A safety centrifuge is available, equipped with separate covers for each rotor	YES	4	11.4%
	NO	31	88.6%
A.13 An autoclave for sterilization is located within the laboratory area	YES	3	8.6%
	NO	32	91.4%
A.14 Washbasins are conveniently situated at the exit of the laboratory	YES	31	88.6%
	NO	4	11.4%
A.15 The washbasins can be operated hands-free, utilizing automatic functionality	YES	2	5.7%
	NO	33	94.3%
A.16 Biological agents are stored securely and in appropriate locations	YES	33	94.3%
	NO	2	5.7%
A.17 Reagents are kept in appropriate locations and in a safe manner	YES	32	91.4%
	NO	3	8.6%
A.18 The laboratory provides sufficient light and space to conduct the analytical procedures, including maintenance and disinfection	YES	31	88.6%
	NO	4	11.4%

One of the prominent issues identified was the insufficient controlled access in the laboratories across most health centers (31.4%), the absence of proper labeling and information regarding the biosafety level (2.9%), and the limited presence of self-closing mechanisms on the entrance doors (22.9%). These results represent a significant deficiency, as unauthorized entry into lab spaces could result in infections and jeopardize the functionality of lab equipment, presenting considerable risks to both visitors and staff. Also the lack of safety centrifuges with individual caps for each rotor (11.4%), the absence of Biological Safety Cabinets (0%), the limited number of autoclaves inside the laboratory (8.6%) and the segregation of administrative areas from analysis areas in only a portion of the laboratories (45.7%) had raised alarms regarding emergency preparedness and the prevention of cross-contamination, which is especially important in healthcare environments where biological materials and potential hazards are present.

On a positive side, some laboratories (51.4%) had dedicated areas for changing and storing the belongings of the lab staff, and blood collection was performed in a separate and appropriately sized areas (82.9%). These designated spaces assist in reducing the risk of cross-contamination between lab personnel and management areas, thereby improving biosafety in the laboratories and ensuring the protection of outpatients and lab staff. In nearly

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all laboratories (97.1%), doors and windows were kept securely closed during procedures, which is a critical requirement for tight containment. The fact that 94.3% of laboratories featured durable and easy-to-clean surfaces for countertops and equipment was a promising indication of effective disinfection, ensuring a clean work environment.

Additional encouraging observations included:

- Lab seats had a stable base and could be easily disinfected (74.3%).
- Routine checks of air conditioning systems were performed consistently and were documented (91.4%).
- Washbasins were positioned near the laboratory exits (88.6%), although only a very small amount were equipped with a hands-free operation.
- Biological agents (94.3%) and reagents (91.4%) were stored safely and in appropriate locations.
- The level of light in lux per square meter and available spaces were adequate for conducting safe analytical tasks in the laboratory, as well as for maintenance and disinfection (88.6%).

Table 2. Laboratory practices and procedures (Administrative Controls)

B. Administrative Controls			
		Count	**Count %**
B.1 Risk assessments are conducted for all laboratory activities	YES	0	0%
	NO	35	100%
B.2 A biosafety manual is in place	YES	0	0%
	NO	35	100%
B.3 A designated biosafety officer is appointed	YES	0	0%
	NO	35	100%
B.4 The laboratory holds certification or accreditation	YES	2	5.7%
	NO	33	94.3%
B.5 The laboratory has documented standard operating procedures (SOPs) for all activities, aimed at minimizing or eliminating risks, particularly those associated with splashes, droplets, aerosols, or spills	YES	3	8.6%
	NO	32	91.4%
B.6 Consumption of food, smoking, and cosmetic application are prohibited in the work area	YES	30	85.7%
	NO	5	14.3%
B.7 Laboratory work surfaces and benches are disinfected following any potential spill of biological samples and at the end of every workday, in line with proper protocols and procedures	YES	32	91.4%
	NO	3	8.6%
B.8 Hands are sanitized after any interaction with biological samples and prior to exiting the laboratory	YES	33	94.3%
	NO	2	5.7%
B.9 All personnel receive initial and ongoing training and is informed about the potential workplace hazards and the safe laboratory practices	YES	1	2.9%
	NO	34	97.1%
B.10 Housekeeping and ancillary staff undergo suitable training	YES	7	20.0%
	NO	28	80.0%
B.11 Waste management is conducted in compliance with the Greek laws (4042/2012 and KYA 146163/2012)	YES	34	97.1%
	NO	1	2.9%

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The complete lack of a risk assessment for the laboratory procedures (0%) represented a fundamental flaw in biosafety regime. Risk assessment is the core bone of any biorisk management system, as it aids in identifying, evaluating, and mitigating possible hazards. In the absence of this critical step, laboratories may not be able to understand the existing risks, potentially endangering both outpatients and healthcare staff. Furthermore, the total absence of a biosafety manual (0%) and designated biosafety officers (0%) highlighted a gap in the biosafety protocols within the laboratories. The lack of a biosafety manual reveals a shortfall in the documentation of the safety protocols, which complicates the ability of the staff to reliably adhere to established biosafety practices. It is vital to develop and implement a biosafety manual tailored to the specific requirements of each laboratory to ensure evidence-based safety protocols. Additionally, the lack of assigned biosafety officers in the laboratories represents one more significant gap, as they are crucial for overseeing biosafety measures, offering guidance, and ensuring adherence to safety regulations. Only 5.7% of the laboratories held a certification or accreditation, indicating a deficiency in formal recognition in compliance with particular standards, as quality and safety are interdependent. Certification or accreditation status could provide an endorsement of quality and safety practices and should be utilized to strengthen biosafety validation. A very limited number of laboratories (8.6%) had documented standard operating procedures (SOPs) to mitigate risks related to laboratory operations. SOPs are crucial for offering detailed instructions on safety protocols, especially for tasks that could involve splashes, droplets, aerosols, or spills. The lack of SOPs points to a shortfall in established safety practices, and creating these procedures for specific laboratory tasks should take precedence. **Also, a limited percentage of laboratories (2.9%) offered their employees initial and ongoing training regarding possible risks and safe lab practices**. This deficiency in staff education does not align with best practices, which stress the importance of having informed staff who can effectively manage risks. Appropriate training is vital for ensuring that lab workers understand and adhere to safety protocols when handling biological materials, highlighting a missed opportunity to improve safety measures. Additionally, the lack of training for support staff (20.0%) was another concerning factor. It is critical that all personnel, including support staff, receive training in biosafety protocols to ensure broad safety and demonstrate a comprehensive strategy to biosafety, which encompasses more than just the lab staff.

On a positive note, findings included:

The ban of activities like eat, drink, smoke, or applying cosmetics in the laboratories (85.7%) which was a favorable observation, because these actions can introduce pathogens and present risks to the staff. The effective disinfection of most lab benches and work surfaces (91.4%) illustrated a

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dedication to sustaining a healthy lab space and avoiding cross-contamination. Furthermore, hand hygiene habits were effectively implemented and enforced in the laboratories (94.3%), highlighting the importance of washing hands after any interaction with biological materials and prior to exit the laboratory. In addition, all laboratories (97.1%) adhered to Greek regulations regarding waste management. Adequate management of the wastes is critical to avoid the dissemination of biological hazards and ensure a high level of conformity and responsible commitment to safe practices.

Table 3. Personal Protective Equipment (PPE)

C. Personal Protective Equipment			
		Count	**Count %**
C.1 PPE are sufficient and are used	YES	33	94.3%
	NO	2	5.7%
C.2 The type of PPE used corresponds to the risk assessment	YES	2	5.7%
	NO	33	94.3%
C.3 Established procedures exist for the use, donn and doff of PPE inside the laboratory	YES	4	11.4%
	NO	31	88.6%
C.4 Laboratory coats are buttoned and designated for use solely in the laboratory	YES	6	17.1%
	NO	29	82.9%
C.5 There are policies and accessories (e.g., hangers) to put-on the lab coats upon entering and for removing them before exiting for any reason	YES	5	14.3%
	NO	30	85.7%
C.6 A policy is in place regarding when to replace laboratory coats with clean ones	YES	3	8.6%
	NO	32	91.4%
C.7 Lab coats are disinfected and washed at home, and not in designated areas of the health center, or through nd external washing service	YES	30	85.7%
	NO	5	14.3%

Only a small percentage of laboratories (5.7%) demonstrated an alignment between the category of PPE and the outcomes of the risk assessment, and there were minimal policies in place regarding the replacement of lab coats with clean ones (8.6%). This suggests that very few laboratories considered the correlated risks between their procedures and choosing the appropriate PPE. To ensure maximum safety, it's crucial to align the selection of PPE with the estimated risks, thereby guaranteeing that lab personnel are fully covered during all their tasks. Concerning the protocols for the use, donn and doff of PPE in the laboratory, only a small fraction of laboratories (11.4%) had established procedures. Clearly defined protocols are vital for ensuring that PPE worn, utilized, and disposed of correctly, and the lack of such procedures in almost all laboratories indicated a potential shortfall in consistent and standardized PPE practices. Furthermore, only a small fraction of laboratories (17.1%) ensured that lab coats were buttoned and exclusively worn in the laboratory area, and there was a noticeable absence of procedures and accessories (e.g., suitably placed hangers) to guarantee that the

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lab coats remained within the laboratory (14.3%). Also the decontamination and laundering of lab clothing predominantly occurred at home instead of dedicated areas of the health centers or through an external laundry service (85.7%). Such practices are inconsistent with biosafety standards and indicate a lack of awareness, heightened the likelihood of cross-contamination beyond the laboratory and the health center environment, which are critical for effective infection control.

The sole positive finding reflecting a strong dedication to safety was that nearly all laboratories (94.3%) possessed an adequate supply of personal protective equipment (PPE).

Table 4. Emergency Preparedness

D. Emergencies			
		Count	**Count %**
D.1 There is a plan to address accidents and emergency situations	YES	18	51.4%
	NO	17	48.6%
D.2 An emergency power system is available for lighting and laboratory equipment	YES	20	57.1%
	NO	15	42.9%
D.3 There is a fire protection system in place along with emergency escape signs	YES	24	68.6%
	NO	11	31.4%
D.4 An eyewash station is provided for use in case of an accident	YES	0	0%
	NO	35	100%
D.5 First aid kit is available	YES	3	8.6%
	NO	32	91.4%
D.6 Noticeable electrical hazards present in the laboratory	YES	6	17.1%
	NO	29	82.9%
D.7 Emergency contact numbers are displayed in the lab areas	YES	1	2.9%
	NO	34	97.1%
D.8 An occupational doctor is available, and routine health checks for employees are conducted	YES	1	2.9%
	NO	34	97.1%
D.9 Accident and incident reporting: There is a system in place for documenting and managing workplace accidents related to vulnerability to biological materials	YES	3	8.6%
	NO	32	91.4%

The complete lack of eyewash stations (0%) and the minimal availability of first aid kits (8.6%) raised alarms about the capability to effectively handle accidents and injuries. Emergency eye wash stations are crucial for providing care in instances of eye exposure to biological agents, and their absence indicates a major deficiency in emergency readiness. First aid kits play a critical role in delivering prompt medical assistance for minor injuries. Only a small fraction of laboratories (2.9%) had emergency contact numbers displayed on-site, which is essential for quick action during urgent situations. There was no specific incident and accident reporting system (8.6%) in place for incidents involving exposure to biological materials, although a system like that is important for recording accidents and incidents in the laboratories. Additionally, only about half of the laboratories (51.4%)

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had an emergency response plan in place. In a healthcare environment, being ready for different emergency situations is essential and without an established plan, laboratories might not be able to handle critical incidents efficiently, which could endanger staff, outpatients, and the general public. Only 2.9% of laboratories had agreements with occupational physicians and conducted preventive health assessments for their employees, indicating a need for improvement in the health and safety of the lab staff.

On a positive note, nearly 57.1% of laboratories utilized emergency power systems for illumination and their equipment. This level of preparedness is crucial during instances of power cuts, or other electrical issues, as maintaining a consistent power supply is vital for the ongoing operations of healthcare facilities, particularly in emergency situations. Furthermore, a significant number of laboratories (68.6%) had implemented a fire safety and evacuation system, reflecting their readiness for fire-related risks. Additionally, most laboratories (82.9%) had no evident electrical hazards, suggesting compliance with electrical safety regulations.

B. Comparative analysis of biosafety professionals' assessment (Checklists) and lab staff's viewpoints (Questionnaires). Highlighting important conclusions from both sources and pointing out noteworthy variations or similarities.

When comparing the results from the checklists and questionnaires for laboratories, it is essential to recognize that in general, questionnaires generate more comprehensive qualitative data, whereas checklists, which emphasize binary yes or no answers, deliver a more organized evaluation. The tables 5-8 present the affirmative (Yes) responses from both the questionnaires and checklists for all the questions analyzed. The column labeled "EU and Greek Legislation" contains the numbering of the articles from European and Greek legislation that pertain to each question. Statistical analysis of the differences in affirmative answers between questionnaires and checklists was conducted using the McNemar test. The McNemar test is comparable to the Chi-square test, but is more appropriate for this type of data. It is utilized for 2x2 contingency tables, like the data where Yes/No responses were compared based on each shared question from questionnaires and checklists. A P-value from the McNemar test that falls below 0.05 indicates that the affirmative ("Yes") responses from questionnaires and checklists in Tables 5-8 statistically differ significantly for that specific question.

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Table 5. Comparing the Laboratory Facilities and Containment Measures (Engineering Controls). The p-value has been determined using the McNemar test and shows if there is a statistically significant difference in **Yes/No** answers between questionnaires and checklists

A. Engineering Controls					
Questionnaire Questions	**Questionnaire Count % YES**	**Checklist Count % YES**	**P-value of McNemar test**	**Checklist Question**	**Reference to EU/Greek Legislation**
7.1 Access is restricted	36.7%	31.4%	$p>0.05$	A1	ANNEX V, A8
7.2 Biosafety sign is displayed at the entrance	1.3%	2.9%	ND	A2	ARTICLE 6.2
7.3 A self-operating closing mechanism at the entry door is in place	19.6%	22.9%	$p>0.05$	A3	
7.4 The laboratory doors and windows can be securely closed	8.2%	97.1%	$p<0.05$	A7	
7.5 Laboratory management is distinct from the analytical procedures	24.7%	45.7%	$p<0.05$	A5	
7.6 There are designated rest areas for the lab staff	36.7%	51.4%	p>0.05	A4	ARTICLE 8.1
7.7.1 Routine checks and documentation of air conditioning operations are conducted	40.5%	91.4%	$p<0.05$	A10	
7.8 Special insulation and robust materials for the floors, walls, and ceiling	10.8%	94.3%	$p<0.05$	A8	ANNEX V, A7
7.9 Lab benches are made from HPL or other form of rugged materials	29.1%	94.3%	$p<0.05$	A8	ANNEX V, A7
7.10 Surfaces and floors in the laboratory could be easily cleaned and disinfect	75.9%	94.3%	$p>0.05$	A8	ANNEX V, A6 / A10
7.11 An autoclave is available inside the laboratory	5.7%	8.6%	$p>0.05$	A13	
7.12 There are biological safety cabinets (BSC)	1.3%	0%	ND	A11	ANNEX V, A3
7.13 Washbasins are situated near the laboratory exit	17.1%	88.6%	$p<0.05$	A14	
7.14 Washbasins have hands-free operation	1.3%	5.7%	$p>0.05$	A15	
7.15 Emergency eyewash station and shower systems are provided	1.9%	0%	ND	D4	ARTICLE 8.1

ND: not determined

Where the p-value is <0.05, the variances in risk perception between lab staff and the biosafety professional, may arise from the level of education, work experience, attitude toward risks and expertise, as discussed in the "Comparison of the Checklist and Questionnaire Results".

In the Laboratory Facilities and Containment Measures, the findings from both questionnaires and checklists indicated that the majority of laboratories exhibited the following weaknesses in several areas of the hierarchy of control:

- Access control: Restricted access to the laboratory, a biosafety sign on the entrance door, and automatic closing of the entrance door
- Availability of autoclaves in the facility and biological safety cabinets in the lab
- Hand wash facilities that can be operated without using, and eyewash as well as emergency shower facilities

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- The management area is distinct from lab procedures and different sanitary and rest areas are designated for lab staff

On the positive side, surfaces and flooring in most of the laboratories were easy to clean and disinfect.

From the table it may be clear that for some questions there is a large difference between the opinion of the expert compared to the lab staff. In many of these cases the expert is more positive then the lab staff.

Table 6. Comparing the Administrative controls, laboratory practices and procedures
The p-value has been determined using the McNemar test and shows if there is a statistically significant difference in **Yes/No** answers between questionnaires and checklists

B. Administrative Controls					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P-value of McNemar test**	**Checklist Question**	**Reference to EU/Greek Legislation**
8.3 Biological samples are collected in a designated area, separate from the laboratory administration	62.0%	82.9%	$p>0.05$	A6	
8.6 Workspaces and benches are regularly disinfected	76.6%	91.4%	$p>0.05$	B7	ANNEX V, A10
8.7.1 It is prohibited to smoke, eat, or drink in the laboratory	62.7%	85.7%	$p<0.05$	B6	ARTICLE 8.1
8.7.3 Hands are sanitized after handling biological samples and prior to exit the laboratory	62.7%	94.3%	$p<0.05$	B8	
9.2 Risk assessments are conducted for all laboratory activities	25.9%	0%	ND	B1	ARTICLE 3.1
9.3 There is a biosafety manual	11.4%	0%	ND	B2	
9.4 The laboratory has documented standard operating procedures (SOPs) for all activities.	10.1%	8.6%	$p>0.05$	B5	ARTICLE 8.1
9.5 There is a designated biosafety officer	1.9%	0%	ND	B3	
9.8 Samples are centrifuged using a safety centrifuge (equipped with separate rotor cover)	25.3%	11.4%	$p<0.05$	A12	
9.12 Waste management is conducted in compliance with Greek laws (4042/2012 and KYA 146163/2012)	72.2%	97.1%	$p<0.05$	B11	ARTICLE 6.2
13 Ongoing biosafety training programs, both theoretical and practical, offered to all personnel	15.8%	2.9%	$p<0.05$	B9	ARTICLE 9

ND: not determined

Where the *P-value* is <0.05, the variances in risk perception between lab staff and the biosafety professional, may arise from the level of education, work experience, attitude toward risks and expertise, as discussed in the "Comparison of the Checklist and Questionnaire Results".

There was insufficient adherence to the suggested biosafety protocols associated with a laboratory biorisk management system. Both questionnaires and checklists showed a notable portion of laboratories facing the following

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challenges: infrequent completion of written risk assessments, absence of biosafety manuals, limited written standard operating procedures (SOPs) for various processes, uncommon use of safety centrifuges equipped with separate rotor covers, very few designated biosafety officers, and a scarcity of biosafety training initiatives.

On a positive side, it is noteworthy to say that both the questionnaires and checklists revealed that waste management procedures adhered to the current Greek regulations. Samples were collected in a designated section of the laboratory, lab surfaces and benches were routinely disinfected, handwashing was conducted after handling biological materials and prior to exiting the laboratory, and smoking, eating, or drinking within the laboratory were strictly prohibited.

Table 7. Comparing Personal Protective Equipment (PPE)
The p-value has been determined using the McNemar test and shows if there is a statistically significant difference in **Yes/No** answers between questionnaires and checklists

C. Personal Protective Equipment (PPE)					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P-value of McNemar test**	**Checklist Question**	**Reference to EU/Greek Legislation**
10.1 There is an adequate supply of personal protective equipment (PPE)	62.7%	94.3%	$p>0.05$	C1	ARTICLE 8.1
10.2 The employee supervisor is responsible for the PPE selection	30.4%	5.7%	$p<0.05$	C2	
10.5 Lab coats must be buttoned, have long sleeves, and only within the laboratory	77.2%	17.1%	$p<0.05$	C4	
10.6 A policy exists regarding when lab coats should be replaced	12.0%	8.6%	$p>0.05$	C6	
10.8 Written procedures are in place for application and removal of PPE	11.4%	11.4%	$p>0.05$	C3	
10.10 An occupational doctor is available, and routine health checks are conducted	3.2%	2.9%	$p>0.05$	D8	ARTICLE 14

Where the *p-value* is <0.05, the variances in risk perception between lab staff and the biosafety professional, may arise from the level of education, work experience, attitude toward risks and expertise, as discussed in the "Comparison of the Checklist and Questionnaire Results".

There were shortcomings in the selection and use of personal protective equipment, including: the choice of PPE was not conducted by management or the employees' supervisor, nor was it informed by a risk assessment, there was a lack of a specific policy regarding when to change lab coats, written procedures for the application and removal of PPE were absent and there was no occupational doctor designated for the questionnaires and checklists, respectively.

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On the positive side, there was an adequate supply of PPE available for questionnaires and checklists, respectively.

Table 8. Comparing Emergencies

The p-value has been determined using the McNemar test and shows if there is a statistically significant difference in **Yes/No** answers between questionnaires and checklists

D. Emergencies					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P value of McNemar test**	**Checklist Question**	**Reference to EU/Greek Legislation**
11.2 A strategy has been established to manage incidents and emergencies	19.0%	51.4%	$p<0.05$	D1	ARTICLE 6.2
11.3 There is a system in place for reporting occupational accidents in the laboratory	9.5%	8.6%	$p>0.05$	D9	ARTICLE 10
11.5 A first aid kit is available	25.9%	8.6%	$p<0.05$	D5	
11.6 Emergency contact numbers are displayed within the laboratory area	15.8%	2.9%	$p>0.05$	D7	

Where the p-value is <0.05, the variances in risk perception between lab staff and the biosafety professional may arise from the level of education, work experience, attitude toward risks and expertise, as discussed in the "Comparison of the Checklist and Questionnaire Results".

In terms of emergency preparedness, both the questionnaire and checklist noted shortcomings in emergency protocols and readiness, particularly highlighting the absence of a plan for handling emergencies, limited accident reporting, insufficient availability of first aid kits, and the lack of emergency contact numbers displayed in lab areas.

Discussion

The information from the checklists and the comparison with the questionnaires revealed both strengths and weaknesses, which require urgent improvements. It is vital for all laboratories to address these gaps and enhance biosafety practices and boost biosafety, in order to protect both personnel and the environment. More specifically:

Engineering Controls: The laboratory surfaces, floors and benches were durable and easy to clean and disinfect. The configuration, separation, and lighting of laboratory spaces were adequate and the storage of biological agents and reagents was safe. However, deficiencies were noted in access restrictions, proper labeling and display of the biosafety level at the entry door, and the procurement of essential safety equipment, such as biosafety cabinets, autoclaves and safety centrifuges.

Administrative Controls: The laboratories showed strengths in certain aspects of administrative controls, such as maintaining good

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microbiological practices (no consumption of food, smoking, and cosmetic application), hand hygiene, disinfection of lab surfaces, and waste management. Nevertheless, substantial shortcomings were identified in having written working protocols (SOPs) for all performed lab procedures and a proper risk assessment of these procedures, the lack of a biosafety manual and designated biosafety officers, and providing ongoing training programs to lab staff and cleaners.

Personal Protective Equipment: While most laboratories showed a strong commitment to provide sufficient PPE, there are still several opportunities for improvement. These include the necessity for standardized procedures regarding PPE usage inside and outside the laboratory, in alignment with the risk assessments, and establishing policies for the use, donning, doffing, and disinfecting of lab coats. No SOPs were in place for this in most laboratories.

Emergencies: Laboratories exhibited preparedness in a few areas, such as backup energy sources, fire protection systems ,and minimal obvious electrical hazards were observed. Nonetheless, significant gaps were also found in other areas, such as in the absence of emergency plans, eyewash stations, first aid kits, clearly observable emergency numbers, occupational health services and a system for recording incidents and accidents.

Comparison of the Checklist and Questionnaire Results

In both the questionnaires completed by laboratory staff as well as in the checklist completed by a biosafety expert non-compliance was detected in the application of the Greek law. The following subjects of the Presidential Decree 102/2020 were seldom put into practice: encompass restricted access (ANNEX V, A8 – Table 5, 7.1), biosafety sign at the lab entrances (ARTICLE 6.2 - Table 5, 7.2), separate sanitary and rest areas for lab personnel (ARTICLE 8.1 - Table 5, 7.6), biological safety cabinets (ANNEX V, A3 – Table 5, 7.12), emergency eyewash stations and shower systems (ARTICLE 8.1 - Table 5, 7.15), risk assessments for all laboratory activities (ARTICLE 3.1 - Table 6, 9.2), standard operating procedures (SOPs) for all tasks (ARTICLE 8.1 - Table 6, 9.4), training programs for all employees regarding biosafety (ARTICLE 9 - Table 6, 13), occupational health services (ARTICLE 14, Table 7, 10.10), plans to address emergency situations (ARTICLE 6.2, Table 8, 11.2) and a system for reporting accidents (ARTICLE 10, Table 8, 11.3).

The presented results are consistent with findings from other studies, confirmed the significance of integrating staff feedback and expert assessment to enhance the effectiveness of risk management within the lab settings (Tziaferi et al., 2011). These elements ought to be considered in researches that involve lab personnel in the risk assessment operations. Nevertheless, the

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insights and feedback from lab personnel indicated challenges in evaluating risks, as an alignment between questionnaire results and checklist outcomes for laboratories is not always present.

The variance in risk perception between lab staff and experts, particularly the biosafety professional, is a recognized issue when employing questionnaires as an auditing tool. Differences may arise from factors such as education and training, work experience, attitude toward risks, and the expertise of lab workers compared to the biosafety professional. Lab staff find it more difficult to identify deviations or the lack of standard operating procedures and layout. The reason for this is that they work in an audited environment on a daily basis and become blind to the deviations. Conversely, the biosafety professional, who inspects the facility only once a year, is more likely to detect any deviations from established protocols or procedures. Based on this**, it is advantageous to conduct not only internal audits by lab workers themselves but also external audits by a biosafety professional on a regular basis, every 1 to 2 years. The observed discrepancies in risk estimation between the subjective responses from staff questionnaires and biosafety professional assessments highlight the essential need for biosafety training to enhance employees' understanding of risk and provide recommendations to improve safety.**

Recommendations

According to the results of the present study, strategies can be developed to strengthen biosafety measures to foster a robust biosafety culture among lab workers and the management in Greece. It will motivate employers to allocate sufficient assets to improve biosafety. Sufficient training of all employees is a crucial item in this. The following recommendations could diminish the risks of exposure to unsafe biological samples and improve the biomedical laboratories in the health centers of the primary health care, at the internationally accepted BSL-2 Level:

First effectively enforce a standardized and viable **laboratory biorisk management system (ISO 35001:2019)** should be established and enforced in Greek medical laboratories**.** This system should rely on management's strategic commitment, resources, and a mindset focused on continuous improvement. This will lead to the initiation of the performance of risk assessments of all procedures in the lab, which must be an integral part of SOPs of the lab processes. To comply with an international standard document, the risk assessments should be performed using the 5-step approach outlined in the WHO Laboratory Biosafety Manual, 4th ed. (WHO 2020). Only in situations that can't be evaluated using the WHO method, a validated custom methodology can be used. When these steps are completed, a strategy

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for the **certification or accreditation of the biomedical laboratories (ISO 15189:2022; ISO 15190:2020)** of these labs, ensuring that biosafety becomes an integral part of the medical labs accreditation.

To maintain the above-described measures, **a biorisk management advisor in each health region**, authorized by the administration to manage the biosafety and biosecurity initiatives of the laboratories in the health centers. This Biorisk management advisor can audit the labs on a regular basis and maintain and improve the Biorisk management system of the medical laboratories and assess the status of the points of improvement from the lab visits of the competent bodies for lab accreditation.

Having a Biorisk management system and the commitment of the management for enforcing this, a continuous training and education program to ensure proper execution and improvement. Also here a Biorisk management advisor will be a key factor in the organization of these trainings together with management.

A very important factor in improving a biosafety management system is starting and/or maintaining **collaboration and partnerships with other biomedical labs in and outside Greece, national and international organizations working in the area of biosafety, biosafety associations, and Biorisk management advisors.**

Conclusion

Although the results were sometimes encouraging, considerable efforts must still be made to achieve effective biosafety standards in the medical laboratories in Greece. The findings show that only a very limited number of laboratories had a functional biorisk management system, although there was a noticeable deficiency in the biosafety culture within these organizations. The administration and management were not entirely aware of their obligations regarding risk assessments and providing both initial and ongoing training for lab staff. Consequently of this is **that in many biomedical laboratories evaluated, there were challenges with adhering to national Greek regulations and laws, and therefore they did not fully align with the internationally recognized BSL-2 standards set by organizations such as the WHO, CDC, and ECDC.**

If the proposed strategies are put into action to enhance biosafety at the BSL-2 standards and to ensure full compliance with current laws and guidelines, a valuable asset for healthcare facilities will be established. The anticipated outcomes may considerably influence the biosafety awareness of laboratory personnel and Greek regulations, with the most advantageous outcome being the increased protection for lab workers, the local community, and the environment against potentially threatening biological agents and infections that could be acquired in the laboratory.

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Implications

The results of this research suggest important actions for both lab personnel and employers:

1. A requirement for enhanced engineering and administrative controls in the laboratories, coupled with the financial and human resources needed to implement and monitor them effectively.
2. Essential is a greater emphasis on education and training regarding biosafety protocols.

Declaration for Human Participants

The research was carried out in line with the ethical principles set forth in the Declaration of Helsinki. Participants completed anonymous questionnaires, and their informed consent was secured concerning the aims of the study, their voluntary involvement, and the option to withdraw from the questionnaire later on. In the initial phase, the study protocol and questionnaire received approval from the Ethical Committee of the University of West Attica (UniWA) on 16th November 2020, with acceptance number 89760/06-11-2020. Before accessing the laboratories, written approval was granted by the scientific committee of the health region, and strict confidentiality of the facilities was maintained and guaranteed throughout the duration of the study and thereafter.

Conflict of Interest: The authors reported no conflict of interest.

Data Availability: All data are included in the content of the paper.

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