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Evaluating Biological Risks in Biomedical Laboratories of Primary Health Care

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Abstract

Biomedical laboratories within primary health care centers are vital for the detection, diagnosis, and management of diseases. However, handling diagnostic samples poses significant biological risks, particularly when biosafety measures are insufficient. This study focuses on analyzing the biological risks in 35 BSL-2 biomedical laboratories situated in health facilities across Athens, Greece, by examining compliance with biosafety regulations, awareness of personnel safety, and practices related to biorisk management. A cross-sectional survey was conducted by combining a customized checklist and a structured health and safety questionnaire, both have been created from the existing literature including the international biosafety guidelines (BMBL 6th ed., WHO Biosafety Program Management, 2020). An expert biorisk management advisor performed on-site evaluations,

while 158 laboratory staff members filled out anonymous questionnaires concerning biosafety practices. Findings indicate widespread deficiencies in biosafety culture and risk management. Key gaps were identified in engineering controls (such as restricted access and safety equipment), administrative controls (including risk assessments, standard operating procedures, biosafety manuals, biosafety officers, and ongoing training), personal protective equipment (PPE policies), and emergency preparedness (such as incident reporting, response plans, and occupational health services). Many laboratories failed to meet international biosafety standards set by the WHO, CDC, and ECDC, highlighting the need for urgent improvements. To mitigate these risks, the study recommends the adoption of comprehensive Biorisk Management Systems, enhanced biosafety training, and stricter enforcement of national and European biosafety regulations. Strengthening these measures is essential to protect the laboratory staff, the surrounding community, and the environment from potential biological threats and lab-acquired infections.

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; Kessel, 2014; Farr & Shatkin, 2004). 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; Sewell, 1995; Pike, 1976).

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 (European Committee for Standardization, 2011; 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/ 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; WHO, 2010;). 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) (Sandia National Laboratories, 2014), 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 (Raafat & Sadhra, 1999). This study was structured as a cross-sectional survey, merging the risk evaluation of an expert using a checklist (qualitative method) and 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.

The data collection concerning biological risks occurred in the biomedical laboratories of 35 primary healthcare 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, and contacting 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 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 are being managed. More specifically:
  a. The professional qualification of the lab staff were laboratory technologists (44.9%), laboratory assistants (29.1%), laboratory medical doctors (20.9%), biologists and biochemists (3.2%), and others (1.9%).
  b. Except for one of the labs they did not have any ISO 9001 certification or ISO 15189 accreditation.
  c. The biological materials analyzed were 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

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%
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 insufficiently 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 the 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 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 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 just 5.7% 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 luminosity 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%

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 stresses 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, the findings included:

The ban on activities like eating, drinking, smoking, or applying cosmetics in the laboratories (85.7%) 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 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 exiting the laboratory. In addition, all laboratories (97.1%) adhered to Greek regulations regarding waste management. Adequate management of the waste is critical to avoid the dissemination of biological hazards and ensures 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 wis orn, 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 lab coats remained within the laboratory (14.3%). Also, the decontamination and laundering of lab clothing predominantly occurred at home instead ofin 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%) 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 of 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. 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.

Table 5. Comparing the Laboratory Facilities and Containment Measures (Engineering Controls). The P-value has been measured using the McNemar test and shows the statistical significance of the differences in **Yes/No** answers between questionnaires and checklists for each question in the table.

A. Engineering Controls					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
7.1 Access is restricted	36.7%	31.4%	0.109	A1	ANNEX V, A8
7.2 Biosafety sign is displayed at the entrance	1.3%	2.9%	*	A2	ARTICLE 6.2
7.3 A self-operating closing mechanism at the entry door is in place	19.6%	22.9%	1.000	A3	
7.4 The laboratory doors and windows can be securely closed	8.2%	97.1%	0.000**	A7	
7.5 Laboratory management is distinct from the analytical procedures	24.7%	45.7%	0.021**	A5	
7.6 There are designated rest areas for the lab staff	36.7%	51.4%	0.664	A4	ARTICLE 8.1
7.7.1 Routine checks and documentation of air conditioning operations are conducted	40.5%	91.4%	0.000**	A10	
7.8 Special insulation and robust materials for the floors, walls, and ceiling	10.8%	94.3%	0.000**	A8	ANNEX V, A7
7.9 Lab benches are made from HPL or other form of rugged materials	29.1%	94.3%	0.000**	A8	ANNEX V, A7
7.10 Surfaces and floors in the laboratory could be easily cleaned and disinfect	75.9%	94.3%	1.000	A8	ANNEX V, A6 / A10
7.11 An autoclave is available inside the laboratory	5.7%	8.6%	1.000	A13	
7.12 There are biological safety cabinets (BSC)	1.3%	0%	*	A11	ANNEX V, A3
7.13 Washbasins are situated near the laboratory exit	17.1%	88.6%	0.000**	A14	
7.14 Washbasins have hands-free operation	1.3%	5.7%	1.000	A15	
7.15 Emergency eyewash station and shower systems are provided	1.9%	0%	*	D4	ARTICLE 8.1

* McNemar test could not be computed

** 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 a considerable number of laboratories exhibited the following weaknesses:

- Access control: Restricted access (36.7% and 31.4%), entry biosafety sign (1.3% and 2.9%), and automatic door-closing systems (19.6% and 22.9%) according to questionnaires and checklists, respectively.
- Availability of autoclaves (5.7% and 8.6%) and biological safety cabinets (1.3% and 0%) according to questionnaires and checklists, respectively.
- Washbasins with automatic functionality (1.3% and 5.7%) and eyewash as well as emergency shower facilities (1.9% and 0%) according to questionnaires and checklists, respectively.
- Management area distinct from lab procedures (24.7% and 45.7%) and different sanitary and rest areas designated for lab staff (36.7% and 51.4%) according to questionnaires and checklists, respectively.

On a positive note, surfaces and flooring in the laboratory were straightforward to clean and disinfect (75.9% and 94.3%) for questionnaires and checklists, respectively.

Table 6. Comparing the Administrative controls, laboratory practices and procedures. The P-value has been measured using the McNemar test and shows the statistical significance of the differences in **Yes/No** answers between questionnaires and checklists for each question in the table.

B. Administrative Controls					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
8.3 Biological samples are collected in a designated area, separate from the laboratory administration	62.0%	82.9%	0.727	A6	
8.6 Workspaces and benches are regularly disinfected	76.6%	91.4%	0.727	B7	ANNEX V, A10
8.7.1 It is prohibited to smoke, eat, or drink in the laboratory	62.7%	85.7%	0.000**	B6	ARTICLE 8.1
8.7.3 Hands are sanitized after any interaction with biological samples and prior to exit the laboratory	62.7%	94.3%	0.000**	B8	
9.2 Risk assessments are conducted for all laboratory activities	25.9%	0%	*	B1	ARTICLE 3.1
9.3 There is a biosafety manual	11.4%	0%	*	B2	
9.4 The laboratory has documented standard operating procedures (SOPs) for all activities.	10.1%	8.6%	0.289	B5	ARTICLE 8.1
9.5 There is a designated biosafety officer	1.9%	0%	*	B3	
9.8 Samples are centrifuged using a	25.3%	11.4%	0.021**	A12	

safety centrifuge (equipped with separate rotor cover)					
9.12 Waste management is conducted in compliance with Greek laws (4042/2012 and KYA 146163/2012)	72.2%	97.1%	0.039**	B11	ARTICLE 6.2
13 Ongoing biosafety training programs, both theoretical and practical, offered to all personnel	15.8%	2.9%	0.000**	B9	ARTICLE 9

* McNemar test could not be computed

** 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 revealed a notable portion of laboratories facing the following challenges: infrequent completion of written risk assessments (25.9% and 0%), absence of biosafety manuals (11.4% and 0%), limited written standard operating procedures (SOPs) for various processes (10.1% and 8.6%), uncommon use of safety centrifuges equipped with separate rotor covers (25.3% and 11.4%), very few designated biosafety officers (1.9% and 0%), and a scarcity of biosafety training initiatives (15.8% and 2.9%).

On a positive note, it is noteworthy that both the questionnaires and checklists revealed that waste management practices adhered to the current Greek regulations (72.2% and 97.1%). Samples were collected in a designated section of the laboratory (62.0% and 82.9%), lab surfaces and benches were routinely disinfected (76.6% and 91.4%), handwashing was conducted after each interaction with biological materials and prior to exiting the laboratory (62.7% and 94.3%), and activities such as smoking, eating, or drinking within the laboratory were strictly prohibited (62.7% and 85.7%).

Table 7. Comparing Personal Protective Equipment (PPE)
The P-value has been measured using the McNemar test and shows the statistical significance of the differences in **Yes/No** answers between questionnaires and checklists for each question in the table.

C. Personal Protective Equipment (PPE)					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
10.1 There is an adequate supply of personal protective equipment (PPE)	62.7%	94.3%	0.180	C1	ARTICLE 8.1
10.2 The employee supervisor is responsible for the PPE selection	30.4%	5.7%	0.003**	C2	
10.5 Lab coats must be buttoned, have long sleeves, and only within the laboratory	77.2%	17.1%	0.000**	C4	
10.6 A policy exists regarding when lab coats should be replaced	12.0%	8.6%	1.000	C6	
10.8 Written procedures are in place for application and removal of PPE	11.4%	11.4%	1.000	C3	
10.10 An occupational doctor is available, and routine health checks are conducted	3.2%	2.9%	1.000	D8	ARTICLE 14

* McNemar test could not be computed
** 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 (30.4% and 5.7%), there was a lack of a specific policy regarding when to change lab coats (12.0% and 8.6%), written procedures for the application and removal of PPE were absent (11.4% and 11.4%) and there was no occupational doctor designated (3.2% and 2.9%) for the questionnaires and checklists, respectively.

On a positive note, there was an adequate supply of PPE available (62.7% and 94.3%) for questionnaires and checklists, respectively.

Table 8. Comparing Emergencies. The P-value has been measured using the McNemar test and shows the statistical significance of the differences in **Yes/No** answers between questionnaires and checklists for each question in the table.

D. Emergencies					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
11.2 A strategy has been established to manage incidents and emergencies	19.0%	51.4%	0.012**	D1	ARTICLE 6.2
11.3 There is a system in place for reporting occupational accidents in the laboratory	9.5%	8.6%	0.625	D9	ARTICLE 10
11.5 A first aid kit is available	25.9%	8.6%	0.039**	D5	
11.6 Emergency contact numbers are displayed within the laboratory area	15.8%	2.9%	0.625	D7	

* McNemar test could not be computed

** 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 sources noted shortcomings in emergency protocols and readiness, particularly highlighting the absence of a plan for handling emergencies (19.0% and 51.4%), limited accident reporting (9.5% and 8.6%), insufficient availability of first aid kits (25.9% and 8.6%), and the lack of emergency contact numbers displayed in lab areas (15.8% and 2.9%) as indicated in questionnaires and checklists, respectively.

Discussion

The information from the checklists and the comparison with the questionnaires in all four sessions revealed both strengths and weaknesses, which require urgent improvements in **Engineering controls, Administrative controls, Personal protective equipment (PPE) and Emergency readiness.** It is vital for all laboratories to address these gaps, to enhance biosafety practices and boost biosafety, in order to safeguard both personnel and the environment.

More specifically:

Checklist Results

- **In Session A (Laboratory Facilities and Technical Containment Measures):** 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, like biosafety cabinets, autoclaves and safety centrifuges.

- **In Session B (Administrative Measures, Laboratory Practices and Procedures):** laboratories showed strengths in certain aspects of administrative controls, such as maintaining good microbiological practices (consumption of food, smoking, and cosmetic application are prohibited in the work area), hand sanitation, disinfection of lab surfaces, and waste management. Nevertheless, substantial shortcomings were identified in conducting risk assessments and having written working protocols (SOPs) for all performed lab procedures, the lack of a biosafety manual and designated biosafety officers, and providing ongoing training programs to lab staff and cleaners.
- **In Session C (Personal Protective Equipment):** While most laboratories showed a strong commitment in providing sufficient PPE, several opportunities for improvement still exist. 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, donn and doff and disinfecting the lab coats.
- **In Session D (Emergency Preparedness):** Laboratories exhibited preparedness in a few areas, such as backup energy sources, fire protection systems and minimal obvious electrical hazards in the laboratory. Nonetheless, significant gaps were found in other areas, such as in the absence of emergency plans, eyewash stations, first aid kits, clearly observable emergency contact numbers, occupational health services and a system for recording incidents and accidents.

Comparison of the Checklist and Questionnaire Results

Problems were detected in the application of the Greek law, not only by relevant authorities but also by the administration of the health centers.

In particular, the following items mentioned in Presidential Decree 102/2020 were seldom put into practice, according to the findings from both checklists and questionnaires. These items 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).

Also this research, consistent with findings from other studies (Tziaferi et al., 2011), confirmed the significance of integrating staff feedback and expert assessment to enhance the effectiveness of risk management within the lab settings. These elements ought to be considered in researches that involve lab personnel in the risk assessment operations. Nevertheless, the insights and reactions from lab personnel indicated challenges in evaluating risks, as an alignment between questionnaire results and checklist outcomes for laboratories there was not always present. **The variances in risk perception between lab staff and experts, particularly the biosafety professional, are a recognized issue when employing questionnaires as an auditing tool. Such differences may arise from factors such as the level of education, work experience, attitude toward risks, and the expertise of lab workers compared to the biosafety professional.** Lab staff, who operate in the audited environment daily, may find it more difficult to identify deviations or the lack of standard operating procedures and layout. Conversely, the biosafety professional, who inspects the facility only once a year, is more likely to detect any deviations from established protocols or procedures. **Consequently, it would be advantageous to conduct not only internal audits by lab workers but also external audits by an biosafety professional 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 with the aim to enhance employees' understanding of risk and provide recommendations to improve safety.**

Recommendations

According to the results of this study, strategies can be developed to strengthen biosafety measures to foster a robust biosafety culture among lab workers in Greece and motivate employers to take a more cautious stance in the allocation of the required assets to improve biosafety. With the crucial requirement of sufficient training for all employees, the following recommendations could diminish the risks of exposure to unsafe biological samples and improve the biomedical laboratories in the health centers of primary health care, at the internationally accepted BSL-2 Level:

1. Establish and effectively enforce a standardized and viable **laboratory biorisk management system (ISO 35001:2019).** This system should rely on management's strategic commitment, resources, and a mindset focused on continuous improvement (European Committee for Standardization, 2011; WHO, 2011)
2. Initiate a strategy for the **certification or accreditation of the biomedical laboratories (ISO 15189:2022; ISO 15190:2020)**
3. **Perform risk assessments for all laboratory procedures**, using the 5-step approach outlined in the WHO Laboratory Biosafety Manual, 4th ed. (WHO 2020), or a validated custom methodology
4. **Create documented standard operating procedures (SOPs)** for all lab processes
5. **Appoint 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
6. **Develop introductory and ongoing training programs** to ensure proper execution of biosafety procedures and emergency response. Management should organize the training in collaboration with the Biorisk management advisor
7. Maintain continuous **collaboration and partnerships with international organizations (WHO, CDC, and ECDC), biosafety associations, and qualified individuals.**

Conclusion

Although there were some encouraging results, considerable efforts are still necessary to achieve effective biosafety standards in these laboratories. The findings show that a limited number of laboratories had a functional biorisk management system, and there was a noticeable deficiency in the biosafety culture within these organizations. It seemed that the administration was not entirely aware of its obligations regarding risk assessments and providing both initial and ongoing training for lab staff.

Consequently, it is clear 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.

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.

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