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Managing Biological Risks in Biomedical laboratories of Public Hospitals in Athens, Greece, based on the Biosafety requirements

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Abstract

Objectives: The aim of the present study was to review the laboratory workers' perception on the biological risks in biomedical laboratories of public hospitals in Athens, Greece. It was also to evaluate how they are managing the biological materials and to propose mitigation measures according to the existing risks, based on the local legislation and the international Biosafety guidelines. **Materials and Methods:** The study was

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designed as a cross-sectional study with a detailed health and safety (H&S) questionnaire focused on biosafety and biorisk management. A total of 36 biosafety level-2 biomedical laboratories in 20 public hospitals were assessed for their biosafety containment specifics and compliance with biosafety practices. Laboratory staff (medical laboratory doctors, medical laboratory technologists, laboratory assistants, biologists and biochemists, n = 415) completed the questionnaire. **Results and Discussion:** The results showed, that a significant percentage of laboratories lacked proper management of the biological agents and biological materials in general, as could be seen in the following reduced percentage data: restricted access (48.9%), controlled and independent ventilation (36.6%), use of BSCs (31.8%), biorisk management system in place (31.6%), risk assessments (28.4%), biosafety manuals (21.4%), SOPs (35.9%), assigned biosafety officers (10.8%), occupational medical doctor (34.9%), emergencies plan (34.2%), accidents reporting (25.5%), and biosafety training programs (28.2%). **Conclusion:** There are marked deficiencies in containment and administrative controls, as well as in the implementation of the Greek and EU biosafety legislation. This emphasize the urgency of addressing critical gaps in biosafety and in emergency preparedness in Greek biomedical laboratories. Therefore, a Biorisk Management System, risk assessments, SOPs, assignment of Biosafety Officers, staff trainings and emergency response plans should be developed, applied and enforced, in compliance with the local and European legislation and guidelines.

Keywords: Biosafety, Biorisk Management, Risk Assessment, Biosafety legislation, Biomedical laboratories

Introduction

Laboratory findings are very crucial for decision-making in the healthcare systems, since approximately 60-70% of medical decisions are based on the results of laboratory diagnostic tests (Kessel, 2014). Biomedical laboratories are considered as the facilities in a hospital or a health center in which diagnostic tests are performed on patient samples. They contribute significantly to the healthcare systems (Brown et al., 2015) towards diagnose, treat and disease prevention (Farr and Shatkin, 2004). Clinical microbiology, clinical chemistry and hematology laboratory departments were the focus of the present study.

Despite their undeniable value and significance, **biomedical laboratories can pose biological risks** for the workers and the environment, if containment measures and protocols are not followed and enforced properly. The above risks, are due to the uncertainty of any infectious biological agents in the diagnostic samples. Biological agents are microorganisms (bacteria,

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viruses, parasites, fungi), toxins, cell lines and genetically modified organisms (GMOs). Although many of these agents are found in nature and they are harmless for humans, some may cause diseases and laboratory acquired infections (LAIs). For this reason, WHO, CDC and the most national health organizations have divided the biological agents into 4 risk groups, according to their main biological characteristics, the consequences of the potential disease and the availability of an effective treatment (WHO, 2020; CDC, 2020; NIH, 2024). **LAIs** include infections acquired in the laboratory, or lab-related activities that could be either symptomatic or asymptomatic (Sewell, 1995). Several LAIs have occurred in various parts of the world and they may cause serious diseases to the personnel via aerosols, spills, needle sticks, splashes, failing recipients and technical failures of equipment (Pike, 1976; Wurtz et al., 2016; Blacksell et al., 2024). Contagious disease-related LAIs have also shown the ability to extend outside of the laboratory and into the larger community (Gaudioso and Zemlo, 2007; Weinstein and Singh, 2009), but can be prevented by biosafety mitigation measures.

Biosafety is the scientific field used to describe and control this accidental exposure or release of biological agents, thus defined as: "Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release" (WHO, 2020). A system that could help control and mitigate these risks to an acceptable level for the laboratory professionals, the community and the environment, is the "Biorisk Management System." **Biorisk management** is a system for the monitoring of safety and security threats in laboratories (WHO, 2014; Salerno and Gaudioso, 2015), improving laboratory operations and activities and managing risks more efficiently (ISO 35001:2019). Therefore there is an enhancement of overall safety, by creating a safe working environment for the laboratory staff (CDC, 2015).

Risk assessment is the core part of a Biorisk Management System, which should be proportionate to the conditions of each laboratory. Under specific steps, the information gathered is used: **i. to identify the risks** (Vourtsis et al., 2022), by calculating the likelihood that an event in connection with a particular hazard will take place and the consequences of that incidence (WHO, 2010; WHO, 2020; Gribble et al., 2015), and **ii. to determine the appropriate control measures**, in order to mitigate the risks to an acceptable or manageable level (Sandia National Laboratories, 2014), like the Hierarchy of controls system, which is a combination of engineering and administrative controls, good microbiological practices and appropriate personal protective equipment (PPE) (CDC, NIOSH, 2021). Upon this facility-specific risk assessment and according to the European and Greek legislation, as well as by the guidelines of international organizations, BMBL 6th ed. (CDC, 2020) and WHO 3rd ed. (WHO, 2004), **biomedical laboratories must be functioning**

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at least as Biosafety Level 2 (BSL-2). BSL-2 is appropriate for working with biological agents of the risk group 2, that represent a moderate risk of infection for workers and the environment (BMBL, 2020). Also with some certain biological agents of the risk group 3, because they are not normally infectious by the airborne route (Directive 2000/54/EC). Each biosafety level for laboratories determines the design, containment, equipment, the working practices and the personal protective equipment, ensuring that the health of the laboratory staff is protected from biological agents, as well as the community and the environment as a whole (WHO, 2004). **This classification according to the local risk assessment has been incorporated into European (Directive 2000/54/EC) and the Greek legislation (Presidential Degree 102/2020).** The risk mitigation measures are proportional to the level of the classified containment, on safeguarding employees against hazards associated with biological agent exposure at work.

Additionally, quality and biosafety are interrelated and complement each other, as could be seen in the accreditation ISO 15189:2022 (Medical laboratories - Requirements for quality and competence). There the requirements for laboratory safety are in line with the principles of ISO 15190:2020 (Medical Laboratories – Requirements for Safety), as standard operating procedures (SOPs) and protocols contribute and improve the quality of diagnostic testing performed in these laboratories.

Methods

The collection of the research data was between March 2021 till June 2022, in 36 laboratories of 20 public hospitals, in Athens, Greece. Laboratory staff (medical laboratory doctors, medical laboratory technologists, laboratory assistants, biologists and biochemists, n = 415) filled in the specific biosafety H&S questionnaire, which was based on a review (WHO Biorisk Programme Management monograph 2020; BMBL 6th ed., 2020). The data were analyzed by SPSS version 29 (Academic license).

The study was conducted according to the ethical principles mentioned in the Declaration of Helsinki and it has been approved by the Ethical Committee of the University of West Attica (UniWA), on 16-11-2020 with protocol number 89760/06-11-2020. Necessary permissions were requested and granted by all hospitals' scientific committees, and the facilities confidentiality was strictly maintained and ensured throughout the study. The questionnaires were anonymous and informed consent was obtained from the participants, regarding the study purposes and their voluntary participation.

The first questionnaire page has a brief description and directions for filling in the answers. It contains two main sections with 15 main questions divided into 77 sub questions. The first six (6) questions are for gathering general information about the laboratory, the professionals, the biological

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materials handled and the procedures used. The following nine (9) questions are for gathering information on biosafety measures and procedures in place in the laboratory, and include the last 3 steps of the hierarchy of controls, ie. engineering controls, administrative controls, personal protective equipment, as well as the emergency procedures, the education and adherence to biosafety practices. All questions were answered by choosing the words Yes or No, in the item specified (The choice Yes meant obviously that the laboratory takes the proper biosafety measures).

Materials

The 415 respondents were medical laboratory technologists (36.1%), followed by specialized medical doctors in microbiology, biochemistry and hematology (27.2%), medical laboratory assistants (19.5%) and a smaller percentage of biologists or biochemists (14.5%). These professionals, work in distinct locations of hospital laboratories such as, microbiology (38.3%), biochemistry (30.1%) and hematology (27.0%), of the 36 laboratories in the 20 public hospitals.

The majority of respondents indicated that their laboratory has not received certification (57,8%), followed by ISO 15189 accreditation and ISO 9001 certification.

The biological materials analyzed was whole blood/plasma/serum, urine/feces and tissues samples, under the most common laboratory procedures (automated analyzers, manual tests, cultivations and a combination of the above).

Results and Discussion

Descriptive Statistics

Table 1. Answers of laboratory personnel regarding the technical biosafety measures

Group question 7: In your workplace which of the following technical measures exist for the reduction of the biological risks:			
		Count	**Count %**
7.1 Restricted access	YES	203	48.9%
	NO	212	51.1%
7.2 Signage (biological sign) at the entrance	YES	44	10.6%
	NO	371	89.4%
7.3 Automated door closing mechanism	YES	143	34.5%
	NO	272	65.5%
7.4 The doors and windows of the laboratory could be closed	YES	96	23.1%
	NO	319	76.9%
7.5 Laboratory administration office is separated from laboratory analysis procedures	YES	216	52.0%
	NO	199	48.0%
7.6 There are separate sanitary and rest areas for laboratory personnel	YES	211	50.8%
	NO	204	49.2%

7.7 Controlled and independent ventilation and air conditioning system	YES	152	36.6%
	NO	263	63.4%
7.7.1 Air conditioning operation checks are carried out regularly and recorded	YES	132	31.8%
	NO	283	68.2%
7.8 Special insulation and durable construction of floors, walls and ceiling of the laboratory	YES	58	14.0%
	NO	357	86.0%
7.9 Construction of the surface material of laboratory benches made of HPL, or other type of durable material	YES	123	29.6%
	NO	292	70.4%
7.10 Laboratory surfaces and floors are easy to clean and disinfect	YES	289	69.6%
	NO	126	30.4%
7.11 There is an autoclave in the laboratory area	YES	91	21.9%
	NO	324	78.1%
7.12 Biological safety cabinets (BSC), Class I or II (with HEPA filters)	YES	132	31.8%
	NO	283	68.2%
7.12.1 An annual inspection of the proper functioning of the BSC is carried out	YES	81	19.5%
	NO	334	80.5%
7.13 The washbasins are located near the exit of the laboratory	YES	118	28.4%
	NO	297	71.6%
7.14 Ability to use the washbasins hands-free, with automatic operation, or with the use of the legs	YES	17	4.1%
	NO	398	95.9%
7.15 Eyewash and emergency shower system	YES	25	6.0%
	NO	390	94.0%
7.16 None of the above	YES	25	6.0%
	NO	390	94.0%

Engineering Controls - Technical Measures (Table 1) focus on containment of the materials used in the laboratory, thus a combination of architectural and mechanical design and physical changes to workstations, equipment, and the laboratory itself

The strict separation of the administrative offices from the laboratory was 52.0% (question 7.5) and the sanitary and rest areas for laboratory staff was 50.8% (question 7.6), which are favorable aspects and minimize the risk of cross-contamination between laboratory and personnel spaces. Laboratory surfaces and floor easy to clean and disinfect were 69.6% (question 7.10), maintaining a clean working environment.

In contrast, the low percent of limited restricted access was 48.9% (question 7.1), biological warning sign at the entrance was 10.6% (question 7.2) and automated closing mechanism was 34.5% (question 7.3), probably leading to unauthorized access to laboratory areas. That posing a significant exposure and contamination risk to patients and staff, and compromising the integrity of medical equipment.

Other gaps or vulnerabilities in the laboratory physical barriers that can compromise security measures: windows not closed during working hours was 23.1% (question 7.4), ventilation and air conditioning system not controlled and independent was 36.6% (question 7.7), and air conditioning checks not

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carried out regularly or not recorded was 31.8% (question 7.7.1), no special insulation and durable construction of floors, walls and ceiling of the laboratories was 14.0% (question 7.8), construction of the laboratory surface materials and benches not made by a durable material was 29.6% (question 7.9). Also there were only a few autoclaves 21.9% (question 7.11) and BSCs 31.8% (question 7.12) available in the laboratory area, and annual checks of the proper functioning of the BSCs not always carried out was 19.5% (question 7.12.1). Washbasins not located near the exit of the laboratory was 28.4% (question 7.13), not possible to use them hands-free was 4.1% (question 7.14), and an eyewash system and emergency shower not present were 6.0% (question 7.15). Finally, 6.0% of respondents choose none of the above (question 7.16), which suggests that there is a number of laboratories that have not taken any specific technical measures to control biological hazards, at all.

These containment measures gaps raise serious concerns about the ability to respond adequately to infections and accidents or release of biological agents in the environment, particularly those involving hazardous materials. Laboratories should use these findings as opportunities to improve biosafety measures, including access control, signage, containment integrity and acquisition of critical safety equipment such as BSCs and autoclaves. This precautionary approach is obviously essential to maintain a safe environment for laboratory staff, patients and the environment.

Table 2. Answers of laboratory personnel regarding proper biosafety procedures during sampling and analysis

Group question 8: At your workplace which of the following procedures are followed during the sampling and analysis of the biological samples:			
		Count	**Count %**
8.1 There is a policy for visitors and non-laboratory staff	YES	176	42.4%
	NO	239	57.6%
8.2 There is a policy for employees with long hair and beard	YES	34	8.2%
	NO	381	91.8%
8.3 Samples are taken in a separate area of the laboratory administration	YES	306	73.7%
	NO	109	26.3%
8.4 Staff know what to do in case of sample leakage or loss of a sample	YES	301	72.5%
	NO	114	27.5%
8.5 Staff know what to do in case of accidental contact with blood or biological fluids	YES	338	81.4%
	NO	77	18.6%
8.6 Workplaces and benches are regular disinfected	YES	294	70.8%
	NO	121	29.2%
8.7 Good Laboratory Practices are always followed for all procedures	YES	257	61.9%
	NO	158	38.1%
8.7.1 Avoiding smoking, eating or drinking in the laboratory	YES	260	62.7%
	NO	155	37.3%
8.7.2 Pipetting by mouth is prohibited	YES	276	66.5%
	NO	139	33.5%

8.7.3 Washing hands after each contact with biological agents and before leaving the laboratory	YES	284	68.4%
	NO	131	31.6%
8.7.4 Not wearing jewellery or watches on hands during work	YES	253	61.0%
	NO	162	39.0%

Table 3. Answers of laboratory personnel regarding the administrative measures and laboratory biosafety procedures

Group question 9: At your workplace which of the following administrative measures and other laboratory procedures are followed:			
		Count	**Count %**
9.1 There is a biorisk management system	YES	131	31.6%
	NO	284	68.4%
9.2 Risk assessment is performed for all laboratory procedures	YES	118	28.4%
	NO	297	71.6%
9.3 There is a biosafety manual	YES	89	21.4%
	NO	326	78.6%
9.4 The laboratory has written working protocols (SOPs) for all procedures	YES	149	35.9%
	NO	266	64.1%
9.5 There is an assigned biorisk management advisor	YES	45	10.8%
	NO	370	89.2%
9.6 Manipulations of biological agents that can potentially cause aerosols or droplets are performed in a properly maintained and certified biological safety cabinet	YES	166	40.0%
	NO	249	60.0%
9.7 Any procedure carried out outside the Biological safety cabinet shall be performed in such a way as to minimize aerosol production and with appropriate personal protective equipment	YES	174	41.9%
	NO	241	58.1%
9.8 Centrifugation of samples is carried out in a safety centrifuge with a separate rotor covers	YES	138	33.3%
	NO	277	66.7%
9.9 Glass tubes are still used	YES	86	20.7%
	NO	329	79.3%
9.10 There is a pneumatic mail transfer system	YES	186	44.8%
	NO	229	55.2%
9.10.1 If yes, is there an emergency protocol in case of leakage during transport	YES	52	12.5%
	NO	363	87.5%
9.11 If needles are used, a sharps management program is in place and followed	YES	298	71.8%
	NO	117	28.2%
9.12 Waste Management is carried out in compliance with the current Greek legislation (Law 4042/2012 – Joint Ministerial Decision 146163/2012)	YES	289	69.6%
	NO	126	30.4%

Administrative controls in both (Table 2) and (Table 3), are local and international policies, standards and guidelines, good microbiological practices and procedures (GMPP), detailed written instructions of the procedures (SOPs), education and training of the laboratory staff (Tun, 2017)

Regular disinfection of workplaces and benches was 70.8% (question 8.6), and knowledge of the staff about the procedures in case of accidental

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contact to blood and biological materials was 81.4% (question 8.5). Also, proper Laboratory Practices always followed for all procedures was 61.9% (question 8.7), thus: avoid smoking, eating or drinking in the laboratory, pipetting by mouth is prohibited, hands are washed after each contact with biological agents and before leaving the laboratory and no usage of jewelry or watches on hands during work. Biological samples are collected in a separate area was 73.7% (question 8.3), ensuring the safety of both patients and healthcare workers. Laboratories still using glass tubes was only 20.7% (question 9.9), laboratories having a sharps management program was 71.8% (question 9.11), and waste management in accordance with the current local legislation was 69.6% (question 9.12).

It is encouraging that there is a relatively high level of compliance with all the above measures, because they are important to minimize the risk of exposure and contamination to biological agents, and to comply with regulatory requirements. Otherwise they can present a serious risk to human health and the environment, if strict rules are not always followed. Proper hand hygiene is a fundamental biosafety practice and is adequately enforced. The proper disinfection of all laboratory benches and work surfaces demonstrates the commitment to maintaining a healthy laboratory environment and preventing cross-contamination, especially after potential spills. Proper waste management is also vital to prevent the spread of biohazards and maintain a safe environment and the high compliance rate in this aspect indicates a commitment to responsible waste management practices.

On the negative site the policy for visitors and non-laboratory staff was 42.4% (question 8.1) and existing policies for workers with long hair and beard was 8.2% (question 8.2). A pneumatic mail transport system was 44.8% (question 9.10), but an emergency protocol in case of leakage during transport was only 12.5% (question 9.10.1). Also the availability of Biorisk Management System was 31.6% (question 9.1), risk assessments performed was 28.4% (question 9.2), biosafety manuals was 21.4% (question 9.3), written working protocols (SOPs) for all the procedures was 35.9% (question 9.4), and assigned biosafety officers was very low 10.8% (question 9.5). The manipulation of biological agents that can potentially cause aerosols or droplets performed in a properly maintained and certified BSC was 40.0% (question 9.6), procedures carried out outside the BSC in a way that the production of aerosols is minimized were 41.9% (question 9.7), and centrifugation of samples in a safety centrifuge was 33.3% (question 9.8).

It is discouraging that most laboratories have not implemented these basic safety measures for handling biological samples, and policies to ensure the safety of their employees and visitors. **Addressing these gaps should be an immediate priority for laboratories** in order to improve safety measures,

and also essential to ensure that these procedures are consistently followed and that laboratory staff is adequately trained to understand and implement them.

Table 4. Answers of laboratory personnel regarding the use of personal protective equipment (PPE)

Group question 10: In your workplace what applies to Personal Protective Equipment (PPE):			
		Count	**Count %**
10.1 There are sufficient PPE	YES	265	63.9%
	NO	150	36.1%
10.2 The selection of PPE is made by the management or the supervisor of the employees	YES	169	40.7%
	NO	246	59.3%
10.3 The choice of PPE is made by the employee	YES	155	37.3%
	NO	260	62.7%
10.4 It is mandatory to use PPE in the laboratory	YES	207	49.9%
	NO	208	50.1%
10.5 Laboratory coats are worn, buttoned and are with long sleeves	YES	325	78.3%
	NO	90	21.7%
10.6 There is a policy when to change laboratory coats	YES	68	16.4%
	NO	347	83.6%
10.7 The use of the laboratory coat is done only in the laboratory	YES	182	43.9%
	NO	233	56.1%
10.8 There are written protocols for the application and removal of PPE	YES	102	24.6%
	NO	313	75.4%
10.9 Vaccinations are carried out to laboratory staff	YES	252	60.7%
	NO	163	39.3%
10.10 There is an occupational doctor assigned and medical examinations are carried out for preventive control	YES	145	34.9%
	NO	270	65.1%
10.11 There are measures in place to protect pregnant women, immunocompromised and vulnerable groups of workers	YES	108	26.0%
	NO	307	74.0%

Personal Protective Equipment (Table 4) is equipment worn by laboratory staff to protect them against exposure to biological materials and must be under the legal scope of the managerial aspects of each laboratory (Bathula and Rakhimol, 2017). PPE can be an important line of defense and must be proportionate to the local risk assessment

Sufficient PPE were available 63.9% (question 10.1) and the mandatory use of PPE in the laboratory was 49.9% (question 10.4). Buttoned and with long sleeves laboratory gowns was 78.3% (question 10.5), but written protocols for the use or removal of PPE were 24.6% (question 10.8). The selection of PPE by the employee himself was 37.3% (question 10.3) and not by the laboratory management or after a risk assessment was 40.7% (question 10.2). The policy when to change laboratory coats was 16.4% (question 10.6), while their use inside the laboratory was 43.9% (question 10.7). In addition, having an occupational doctor responsible for the health of employees and

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carrying out medical examinations for preventive check-ups was 34.9% (question 10.10). Protection measures in place for pregnancy, as well as for immunocompromised and vulnerable groups of workers was only 26.0% (question 10.11), but in contrast there is a high percentage of vaccinations 60.7% (question 10.9), that are carried out in the laboratory staff.

Based on the data analyzed, it is evident that the majority of laboratories do not comply with the PPE control measures and indicate the need for increased awareness and enforcement of standardized procedures in the workplace. Only a limited number of laboratories consider the specific risks associated with their laboratory procedures, when selecting and using PPE. For optimal safety, it is vital to match the choice of PPE with the identified risks by a risk assessment, ensuring that personnel are adequately protected during all operations. In addition, the results show that only a small percentage of laboratories have written protocols for the use and removal of personal protective equipment, as well as protective measures for vulnerable workers. This is a cause for concern, as it suggests that there is a significant risk of exposure to biological hazards in these laboratories and demonstrates a lack of understanding of the importance of minimizing the spread of infectious agents, limiting and preventing the spread of infection beyond the laboratory environment. It is important for these cases to take immediate action and implement appropriate safety measures to ensure the well-being and protection of their employees and patients.

Table 5. Answers of laboratory personnel regarding the use of emergency measures

Group question 11: What applies about the emergencies in your workplace:			
		Count	**Count%**
11.1 There is an inform to employees about the hazards in the laboratory	YES	234	56.4%
	NO	181	43.6%
11.2 There is a plan in place to manage emergencies and accidents	YES	142	34.2%
	NO	273	65.8%
11.3 There is an organized or an anonymous occupational accident reporting system	YES	106	25.5%
	NO	309	74.5%
11.4 There is a biological spill kit	YES	39	9.4%
	NO	376	90.6%
11.5 There is a first aid kit	YES	98	23.6%
	NO	317	76.4%
11.6 Emergency telephone numbers are indicated in the laboratory premises	YES	128	30.8%
	NO	287	69.2%
11.7 It is clear to all employees who is responsible for biosafety in the laboratory	YES	70	16.9%
	NO	345	83.1%
11.8 None of the above	YES	105	25.3%
	NO	310	74.7%

Emergencies (Table 5), regarding the presence of basic safety measures and emergency plans in the laboratories' facilities

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The responses, concerning workplace emergencies, are also not very encouraging. Although of the respondents reported that information provided to employees about the risks present in the laboratory was 56.4% (question 11.1), a plan in place to manage emergencies and accidents was only 34.2% (question 11.2). In addition, accident reporting was only 25.5% (question 11.3), which is a cause for concern as it could lead to underreporting of accidents and incidents. In addition, available biological spill kits, first aid kits and emergency phone numbers, were only 9.4% (question 11.4), 23.6% (question 11.5) and 30.8% (question 11.6) respectively. These are simple but important measures that can make a big difference in emergency situations. Another worrying fact that could lead to confusion in emergency situations and make it difficult to coordinate an effective response, on how clear to all employees it is who is responsible for biosafety, was only 16.9% (question 11.7). Also, a significant percentage of 25.3% (question 11.8) reported that none of the above applies.

Overall, the above results suggest that there is a significant area for improvement in workplace emergency preparedness. It is important that employers and laboratory managers prioritize the safety of their workers and take preventive measures to minimize risks and ensure that appropriate safety equipment and procedures are in place. In a healthcare setting, preparedness for various emergency scenarios is paramount. Without a clear plan in place, laboratories could not respond effectively to critical situations, potentially putting staff, patients, and the environment at risk. More specifically "Incident Reporting System" is vital for documenting and managing workplace accidents and incidents, first aid kits are essential to provide immediate medical attention in case of minor injuries, and easily accessible emergency contact numbers are crucial for rapid response to critical situations.

Table 6. Answers of laboratory personnel regarding the importance of certain protective measures

Group question 12: In your opinion which of the following are important for an effective protection of laboratory workers:			
		Count	**Count %**
12.1 Disinfection of benches and laboratory equipment	YES	393	94.7%
	NO	22	5.3%
12.2 Safety needles and blood collection systems for phlebotomy	YES	301	72.5%
	NO	114	27.5%
12.3 Waste management	YES	361	87.0%
	NO	54	13.0%
12.4 Biosafety Manual	YES	289	69.6%
	NO	126	30.4%
12.5 Staff training (introductory and continuing)	YES	359	86.5%
	NO	56	13.5%
12.6 Availability of biological safety cabinets	YES	254	61.2%

	NO	161	38.8%
12.7 Sufficient Personal Protective Equipment	YES	348	83.9%
	NO	67	16.1%
12.8 Labelling for potential biological hazards	YES	275	66.3%
	NO	140	33.7%
12.9 Contingency and accident response plan	YES	318	76.6%
	NO	97	23.4%
12.10 Written Standard Operating Procedures for every procedure in the laboratory (SOPs)	YES	265	63.9%
	NO	150	36.1%

Opinion for the most effective measures for the protection of laboratory workers (Table 6)

The results show that the majority of respondents consider all the listed measures important for the effective protection of laboratory workers. The measures with the highest scores were: disinfection of laboratory benches and equipment 94.7% (question 12.1), waste management 87.0% (question 12.3) and safe needle and blood collection systems 72.5% (question 12.2). These results suggest that respondents prioritize measures related to preventing the spread of infections and diseases in laboratories.

In addition, these results show that staff training is also considered important, with 86.5% (question 12.5) of respondents stating that both introductory and continuing training is necessary. This suggests that respondents recognize the importance of being informed, trained and prepared to take the necessary precautions to protect themselves and others in the laboratory areas.

The availability of appropriate PPE was also considered important, with 83.9% (question 12.7) of respondents stating that it is necessary to have sufficient and appropriate PPE in the laboratory. This result suggests that respondents recognize the importance of providing workers with the necessary equipment to protect themselves when working with hazardous materials. Other measures considered important were: an emergency and accident response plan 76.6% (question 12.9), a Biosafety Manual 69.6% (question 12.4), appropriate signage for potential biological hazards 66.3% (question 12.8), the existence of Standard Operating Procedures 63.9% (question 12.10), and the availability of BSCs 61.2% (question 12.6).

Theoretical and practical biosafety training programs provided (question 13)

Only 28.2% of respondents expressed that their laboratory provides theoretical or practical training seminars or training programs on biosafety for all staff. This finding shows that a significant majority of staff not received any such training, 71.8%. The insufficient biosafety training programs is discouraging. This commitment to staff training is not aligned with biosafety best practices, ensuring staff are well informed and able to effectively mitigate

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risks. Adequate training is vital to ensure that laboratory workers are aware of and able to follow safety protocols when working with biological materials. Therefore, appropriate education and training are crucial to ensure that staff are equipped with the necessary knowledge and skills to handle potentially hazardous materials and situations in a safe and effective manner. A lack of biosafety training of staff can be a major concern for the laboratory, as it increases the risk of accidents and incidents that can lead to staff failure or environmental contamination.

Ensuring that all staff members, including support staff, are trained in biosafety measures is essential to the overall safety and reflects a holistic approach to biosafety that extends beyond laboratory staff. Laboratories are recommended to prioritize continuing biosafety training and education programs for all staff to improve the overall biosafety culture and reduce the risk of incidents.

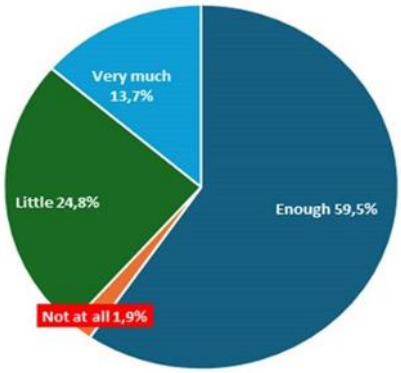

Diagram 1. Views of laboratory personnel concerning the extent of their knowledge about biosafety (question 14)

Knowledge of the laboratory staff about what biosafety is (Diagram 1)

The majority of laboratory personnel answered that they know enough about biosafety 59.5%. But the fact that 24.8% admit they know little, and 1.9% don't even know what biosafety is, highlights the need for further information and training on biosafety measures in the workplace.

Overall, the results suggest that respondents are aware of the importance of implementing an integrated approach to laboratory safety and prioritize measures related to preventing the spread of infections and diseases, training of the workers, and availability of appropriate PPE. This also stresses the importance and the need of raising awareness and promoting a biosafety culture in the laboratory environment.

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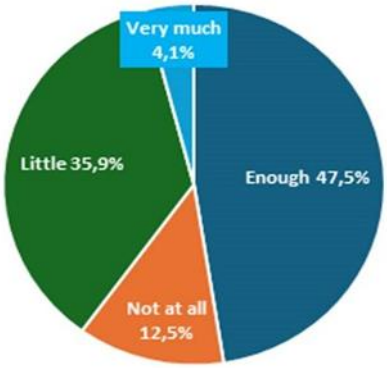

Diagram 2. Views of laboratory personnel concerning the extent of their satisfaction about the biosafety measures (question 15)

Satisfaction of the staff regarding the mitigation measures exist in their workplace (Diagram 2)

The results show that 47.5% of responses state that they are satisfied enough with the situation regarding biosafety. However, 35.9% are somewhat satisfied, while a smaller percentage 12.5% are not satisfied at all. Only 4.1% are very satisfied.

The medium satisfaction rate may reflect inadequate practices and measures adopted in the workplace to protect workers and address risks. There may be gaps in biosafety procedures and policies, as well as a lack of education and awareness of the corresponding measures to be followed. This information should be seriously considered by the laboratory management. It draws attention to the need for further training and information for workers and the adoption of more effective prevention and safety measures in order to improve the protection of staff and the environment in the workplace.

Deductive Statistics

Since all questions provide only two answers (Yes and No), we transform them to the numbers 1 and 2. The answer Yes (1) means the laboratory applies biosafety measures. Thus, as the sum of answers increases the laboratory takes more and more biosafety measures. We consider the total sum of "Yes" as the "biosafety degree" of the respondents of our study.

Table 7. The total degree of biosafety measures according to the type of laboratory

Laboratory	Laboratory Code	N	Minimum	Maximum	Mean	Median	Standard deviation
Microbiology	M	159	3,0	64,0	39,4	42,0	14,5
Hematology	H	112	8,0	56,0	28,3	26,0	10,5
Biochemistry	B	125	4,0	57,0	31,5	30,0	11,8
United	MHB	10	29,0	54,0	44,1	47,5	8,7
Other	Non-MHB	9	15,0	43,0	30,2	28,0	8,7

Differences of the views regarding biosafety measures between the different laboratories (Table 7)

We compared the sums of the answers of five different laboratories (Table 7). Because of the distribution of the sums of their personnel's answers about biosafety measures was no normal the compared their medians with the no parametric test Kruskal Wallis. The differences of the medians were statistically significant <0,001. Table 7 reveals that the personnel of Microbiology and United laboratories knew more about biosafety than the personnel of the other laboratories. The differences of Microbiology and United laboratories with Hematology and Biochemistry laboratories were statistically significant (Mann Whitney test p <0,01).

Table 8. Views of laboratory personnel according to their professional specification about the biosafety measures of their laboratory

Profession	N	Minimum	Maximum	Mean	Median	Std. Deviation
Medical laboratory doctors ("biopahologists")	113	9	64	37,07	37,0	13,89
Medical laboratory technologists	150	3	63	33,89	33,5	13,15
Biologist/Biochemist	60	14	56	34,62	33,0	12,34
Laboratory assistants/technicians	81	9	61	28,91	25,0	12,49
Other	11	18	60	35,82	30,0	15,32

Differences of the views regarding biosafety measures between the different laboratory professions (Table 8)

We checked if the views of the laboratory personnel differ accordingly their degree (medical laboratory doctors, medical laboratory technologists, laboratory assistants, biologists and biochemists). Like the check of the kind of laboratories we transform the answer "Yes" to one (1) and "No" to zero (0). After that, we added the answers of the 74 questions of the questionnaire. We compared the median values of five professions with Kruskal Wallis (p<0.001). The views of medical doctors seem that they understand the biosafety measures better than the others. The differences of views between medical doctors and the other professionals, except laboratory technician, are not statistically significant (Mann Whitney test).

Table 9. The views of laboratory personnel about biosafety measures accordingly the quality certification of their laboratory

Certification/Accreditation	N	Minimum	Maximum	Mean	Median	Std. Deviation
No	272	3	64	32,82	31,00	13,79
ISO 9001	44	9	57	36,13	39,50	12,08
ISO 15189	96	4	61	36,02	37,50	12,70
ISO 9001 & ISO 15189	3	27	48	36,00	33,00	10,81

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Differences of the views regarding biosafety measures from laboratory personnel with accreditation/certification and no any quality certification (Table 9)

We checked if the views of the laboratory personnel differ accordingly quality certification of their laboratory. Some of them responded that their laboratory has certification ISO 9001 or/and accreditation ISO 15189. The personnel of certified laboratories knew more about biosafety measures than the laboratorians without any certification. The differences were statistical significant (Kruskal Wallis, p=-.032<0.05).

Conclusions

Findings from the present surveys conducted shed light on common challenges and opportunities, and provided valuable information on the current state of biosafety in the workplace of the biomedical laboratories' environment in the public hospitals. This study also verified in accordance with other studies (Tziaferi, et al., 2011) the value of staff involvement in the risk assessment process, and this factor should be considered in upcoming research projects, in combination with an experts' evaluation.

There are marked deficiencies in containment (restricted access, HVAC, BSCs, construction material of benches, floors, walls and ceiling), administrative controls (biorisk management system, risk assessments, biosafety manuals, SOPs, assigned biosafety officers), emergency preparedness (occupational medical doctor, accidents reporting, emergencies plan), and in the provision of biosafety training programs. It is clear that a significant percentage of laboratories lack Biorisk Management systems, and are partially complied with the widely accepted BSL-2 standards, such as from WHO and CDC. There is also limited biosafety culture within the organizations and the management seems not fully aware of their responsibilities, in given regular training, performing risk assessments, working according to protocols and the use of PPE.

Additionally, there are issues in the implementation of the Greek and EU biosafety legislation. From a regulatory standpoint, there is no enforcement of the national legislation and there is lack of compliance with the recommended measures, by the competent authorities, as well as the management of the hospital organizations. More specifically the following items referred in the **Presidential Decree 102/2020** are rarely performed, according to the questionnaire results:

1. Perform of risk assessments was 28.4% (question 9.2), although in PD 102/2020, Article 3 - Determination and assessment of risks is referred that: "For any activity that may involve a risk of exposure to biological agents, the employer must have at his disposal a written risk assessment of the risks at work."

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2. Biological safety cabinets (BSC) was 31.8% (question 7.12), in contrast with PD 102/2020, Article 6, paragraph b: "Design of work processes and engineering control measures, to avoid or minimize the release of biological agents into the place of work", and ANNEX V, item 3: "Infected material including any animal is to be handled in a safety cabinet or isolation or other suitable containment"
3. Surfaces resistant to acids, alkalis, solvents, disinfectants was 29.6% (question 7.9), in contrast with PD 102/2020,ANNEX V, item 7.
4. Access control in the Biomedical laboratories was 48.9% (question 7.1), in contrast with PD 102/2020, ANNEX V, item 8 and use of the biohazard sign and other relevant warning signs was 10.6% (question 7.2), in contrast with PD 102/2020, Article 6, item e.
5. Drawing up plans to deal with accidents involving biological agents was 34.2% (question 11.2) in contrast with PD 102/2020, Article 6, paragraph f.
6. Introductory and Continuous training of laboratory staff by the employer was 28,2%, although in PD 102/2020, Article 9, is referred that: "Appropriate measures shall be taken by the employer to ensure that staff receive sufficient and appropriate training, in particular in the form of information and instructions".
7. Use the services of an occupational physician was 34.9% (question 10.10), in contrast with PD 102/2020, Article 14.

The revealed areas of vulnerability in the management of biological agents emphasizing an urgent and critical need for more comprehensive, proactive and preventive measures to reduce the risk of release or exposure to hazardous materials and biological agents. Strategic recommendations for fortifying healthcare institutions and comprehensive biosafety mitigation measures, including a Biorisk Management System, risk assessments, written SOPs, assignment of an Appointed Biosafety Officer, staff trainings and emergency response plans should be developed, applied and enforced, in compliance with the local and European legislation and guidelines.

Therefore the biomedical laboratories in the hospitals should already start improving biosafety and the following strategic recommendations are the first steps that can already started on every institutional level, for an acceptable biosafety level:

1. **Development and effective implementation of a structured and sustainable Biorisk Management System, based on the ISO 35001:2019** as a safeguard against the biological threats. The Biorisk Management system could enable the biomedical laboratories to productively detect, assess, control, monitor and evaluate the biosafety and biosecurity risks associated with hazardous biological materials,

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as well as assist in meeting their legal and quality standards and requirements (WHO, 2016). By adopting a Biorisk Management system with the following characteristics, laboratories can become pillars of biosafety: A. conduct multidisciplinary **risk assessments**, B. develop written **SOPs** for all laboratory procedures and C. create **levels of access controls** in all biomedical laboratories. Key operational aspects are national and management strategic commitment and resources, and the "Focus on continual improvement," by making the continuous improvement a goal for every individual and prosses in the laboratory (European Committee for Standardization, 2011; WHO, 2011).

2. **Assignment in every hospital of an Appointed Biosafety Officer**, responsible for biosafety in the laboratories, with main role to advise, inform, guide and ensure the implementation of Good Laboratory Practices, the development of Biorisk Management systems, standard operating procedures, training programs, and contacting risk assessments. The professional designated with that function should have critical thinking and effective problem-solving skills that best meet the local need. The education and experience required should have the following core competencies, which shall be actively trained: Biorisk assessment and management, containment principles, international and national regulatory framework, standards and guidelines, infection control, biological waste management, auditing and inspections, human factors and Bioethics (WHO LBM 4th ed. monograph on Biosafety Programme Management (2020); ISO 35001 (2019); WHO Joint external evaluation tool 3rd ed. (2005); Kaufman et al., (2007)).
3. **Elaboration of introductory and continuous training programs**, in order to communicate the risks to the laboratory personnel, maintain the level of safety in the laboratory, the responsible work with the biological materials and their effective protection. Training is very important because "It can be argued, therefore, that the best designed and most well engineered laboratory is only as good as its least competent staff" (WHO, 2020). With the introduction of SOPs, laboratory staff must be trained properly on how to use every SOP, because if training is not supplied, SOPs have no additional benefit.
4. **Raising awareness on biological risks and responsibilities** during the work in the laboratories, among the management and the laboratory professionals. This could lead to the creation of a safety culture, providing a foundation upon which a successful biosafety programme can be developed.

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By adopting these strategic recommendations, laboratories can become pillars of biorisk management, and beacons of safety for patients, healthcare workers, and the wider community. This will also enhance the safety of every facility and promote the biosafety culture, with a result the laboratory professionals, the community and the environment will be better protected from incidents and accidents from possible harmful biological samples and agents. The goal is that safer laboratory facilities to be created, the biological risks to be eliminated or minimized to acceptable levels, and the current biosafety and biosecurity system to be re-evaluated towards a performance-based, holistic, risk-management system approach.

The results of this study could be used to set-up an educational and awareness program in Greece, and increase Biorisk Management to a higher level, so it will be at an international level in a few years, depending on the organization. Also the findings of this survey should encourage managers and the authorities to adopt a more proactive approach to biosafety and invest the necessary financial and human resources, to protect the safety of their staff. By doing so, they can significantly enhance the safety of the facilities, ultimately safeguarding the well-being of all individuals involved in these sensitive healthcare services, and the environment.

In this context healthcare institutions can improve biosafety practices and contribute to a safer and healthier world. Biosafety must become a global priority, with investments and efforts commensurate with the potential consequences of biohazards. This requires a proactive, multidisciplinary and data-driven approach. It also requires continuous improvement, international collaboration and commitment to innovation to address the evolving landscape of infectious diseases and biosafety challenges.

Implications

The findings of this study have several implications for laboratory workers and the employers. There is urgent need to:

1. increase education and training on biosafety practices
2. improve infrastructure and resources to enhance the core biosafety mitigation measures:
    - restricted access, primary and secondary containment measures
    - biorisk management system, risk assessments, SOPs, Biosafety officers
    - emergencies and accidents reporting plans

Declaration for Human Participants: The study was conducted according to the ethical principles mentioned in the Declaration of Helsinki and it has been approved by the Ethical Committee of the University of West Attica (UniWA), on 16-11-2020 with protocol number 89760/06-11-2020.

Necessary permissions were requested and granted by all hospitals' scientific committees, and the facilities confidentiality was strictly maintained and ensured throughout the study.

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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