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Combining biosafety expert's evaluation and workers' perception regarding the Biological Risks in Biomedical laboratories of Public Hospitals in Athens, Greece

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Abstract

Objectives: The aim of the present study was by combining an expert's evaluation and laboratory workers' perception, to review the biological risks in biomedical laboratories of public hospitals in Athens, Greece. It was also to evaluate how they are managing the biological materials, the level of safety awareness and training of the personnel, and to propose mitigation measures according to the existing risks, based on the local legislation and the international Biosafety guidelines. **Materials and Methods:** A total of 36 biosafety level-2 (BSL2) biomedical laboratories in

20 public hospitals were assessed for their biosafety containment specifics and compliance with biosafety practices. The study was designed as a cross-sectional study, with a checklist and a detailed health and safety (H&S) questionnaire, focused on biosafety and biorisk management. An expert biosafety officer observed and filled in a checklist for each biomedical laboratory (n=36) of the 20 hospitals. Laboratory staff (medical laboratory doctors, medical laboratory technologists, laboratory assistants, biologists and biochemists; n = 415) filled in a specific to biosafety H&S questionnaire in each of these laboratories. **Results:** Both the results from the checklists and the questionnaires showed that in a significant percentage of laboratories there are the following deficiencies: restricted access and signage at the entrance, autoclaves in the laboratory area, ability to use the washbasins hands-free, biorisk management system, written risk assessments, biosafety manuals, standard operating procedures (SOPs), assigned biosafety officers, protocols about the use of Personal Protective Equipment (PPE), insufficient biosafety training programs, accidents reporting, eyewash emergency shower system, first aid kits and emergency telephone numbers. On the positive site laboratory procedures are separated from management, sanitary and rest areas, laboratory surfaces and floors are easy to clean and disinfect, good laboratory Practices followed for all procedures, waste management is in compliance with the current Greek legislation and there are sufficient PPE available. **Conclusion:** In the laboratories studied there are significant shortcomings in containment and administrative controls, in the application of Greek and EU biosafety legislation, and in the proper management of biological agents and materials in general. This emphasizes the importance of closing key gaps in biosafety and emergency preparedness, in the biomedical laboratories. Using the results of this study, actions should be developed, applied and enforced, in compliance with the local and European legislation and guidelines. This could enhance the safety of these facilities, and the laboratory professionals, the community and the environment could be better protected from possible harmful biological agents and the possibility of Laboratory acquired infections (LAIs). This study also demonstrated the value of the laboratory workers participation in the risk evaluation, despite their propensity to over or under-estimate the risk level of the possible hazards. That fact should be considered in future studies when enhancing hospital staff.

Keywords: Biorisk Management, Biosafety, Biological Risk Assessment, Biomedical laboratories, Laboratory personnel awareness, Biosafety legislation

Introduction

Biomedical labs are unquestionably important and valuable in every healthcare system (Farr and Shatkin, 2004; Kessel, 2014; Brown et al., 2015) . But if containment measures and procedures are not followed and enforced, they could present biological risks to both personnel and the environment. These biological risks, which could be present in all kinds of diagnostic samples or materials that are processed, in combination with the handling and analysis procedures, result in an ongoing risk for Laboratory-acquired infections (LAIs) and breach of the containment. Numerous LAIs have happened around the world, and they have the potential to expose workers to dangerous infections through aerosols, spills, needle sticks, splashes, and equipment malfunctions (Pike, 1976; Sewell, 1995; Wurtz et al., 2016; Blacksell et al., 2023).

Therefore ensuring that samples and materials containing infectious biological agents can be safely received, handled, transported and stored, proper mitigation measures must be put in place, in accordance with best practices, in adequately equipped and contained facilities (NIH, 2024), thus a Biosafety regime. **Biosafety** is the scientific field used to describe and control the unintentional exposure or release of the biological agents, thus: "Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release" (WHO, 2020).

The "Biorisk Management System" is one approach that could assist in controlling and mitigating these risks to a manageable level for laboratory personnel, the community, and the environment. Biorisk management is a strategy for monitoring laboratory safety and security threats (WHO, 2014; Salerno and Gaudioso, 2015), enhancing laboratory operations and activities, and managing risks more effectively (ISO 35001:2019). As a result, the overall safety could be improved, providing a safe working environment for laboratory staff. An essential component of a Laboratory Biorisk management system is Risk assessment, because:

- According to the European Union Directive 2000/54/EC and the Greek legislation (Presidential Degree 102/2020, on the protection of workers from risks related to exposure to biological agents at work), in Article 3, for any activity where there may be a risk of exposure to biological agents, a risk assessment must be contacted.
- Every organization that handles biological agents has an obligation to its staff and the community to perform a risk assessment in relation to the tasks it does (WHO, 2020).

When contacting the risk assessment, the information gathered is used to identify the risks (Vourtsis et al., 2022), by integrating the likelihood

of a hazard with its consequences (WHO, 2010; WHO, 2020; Gribble et al., 2015). Then to minimize these risks to a bearable or controllable level and prevent LAIs (Sandia National Laboratories, 2014), proper control measures should be taken, like the **hierarchy of controls system**. By using the last 3 steps of the hierarchy of controls system, which is a combination of engineering and administrative controls, good microbiological practices and adequate personal protective equipment (CDC, NIOSH, 2021), there could be an efficient blocking of the transmission routes of the biological agents in the Biomedical laboratories, thereby giving the laboratory employees a safe place to work in:

i. **Engineering Controls** are the containment of the materials used in the lab, which is a combination of architectural and mechanical design of the laboratory itself. The purpose is to protect the environment inside and outside the laboratory area. Examples of containment are physical separation of the laboratory from traffic flow within the building reducing risk of exposure to passing individuals, self-closing of laboratory doors, biological safety cabinets (BSC), safety centrifuge, and HVAC (Heating, ventilation and air conditioning) systems.

ii. **The Administrative controls** are a collection of measures to control risks, such as local and international policies, standards and guidelines, Good microbiological practices and procedures (GMPP), standard operation procedures (SOPs), education and training of the laboratory staff. Good microbiological practices and procedures is general behavior and practices, which are relevant to all types of laboratory activities with biological agents and should always be followed (WHO, 2020). Without them the risk cannot be adequately controlled, even if there are all the other control measures. Another important aspect of laboratory safety is the safety culture and training of laboratory staff, which must be adopted, supported, and developed by top management in order to eliminate or minimize biological hazards to an acceptable level for the laboratory professionals, the community, and the environment (Tun, 2017).

iii. **Personal Protective Equipment (PPE)** is equipment worn by laboratory staff to protect them against exposure to biological materials and agents. In general, PPE include gloves, laboratory coats, face protection shields, face masks and respiratory protection, safety glasses, goggles, hoods, shoe covers, gowns, and other specific items. All of these materials and safety elements must be offered to the laboratory staff and must be within the legal reach of each laboratory's managerial aspects (Bathula and Rakhimol, 2017). PPE

can be an effective line of defense but must be proportionate to the local risk assessment.

Based on this facility-specific risk assessment, and in accordance with European and Greek legislation, as well as the international organization guidelines, BMBL 6th ed. (CDC, 2020) and WHO 3rd ed. (WHO, 2004), biomedical laboratories must be built and operate at a BSL2 level.

Materials and Methods

Risk may be defined with qualitative, semi-quantitative and quantitative methods (Raafat and Sadhra, 1999). The present study was designed as a cross-sectional survey, by combining methods and sources, thus a qualitative method (an expert's evaluation with a checklist), with the subjective risk evaluation of the laboratory staff (questionnaire). The data collection of the biological risks, in 36 laboratories of 20 public hospitals, in Athens, Greece, has been contacted between March 2021 till June 2022. It was designed to evaluate the biological risks in these biomedical laboratories and assessing the level of biosafety regulations, knowledge and practices among laboratory workers. These professionals, worked in distinct locations of hospital laboratories such as, microbiology, biochemistry and hematology. The research design for this project had 2 parts:

1. A biosafety expert's evaluation.

A custom Checklist that has been developed based on the available literature: the CheckList for BSL2 labs from BMBL 6th ed., 2020 and the Self-Audits Checklists from the WHO (Biorisk Programme Management monograph, 2020). A total of 36 biomedical laboratories BSL2 in the 20 public hospitals were assessed, by a trained and accredited Biosafety officer who observed and filled in a checklist trough on-site observations and discussions with the laboratory directors and personnel, regarding the containment of the laboratories, the procedures, the PPE, the emergencies, and education for biosafety practices. The 45 checklist items were divided into 4 main sections:

A. Facilities and Technical Containment Measures, 18 items
B. Administrative measures, laboratory practices and procedures, 11 items
C. Personal Protective Equipment (PPE), 7 items
D. Emergencies, 9 items

2. Combining the results of the biosafety expert with a subjective risk survey of the laboratory staff

The specific biosafety H&S anonymous questionnaire was administered to 415 laboratory workers (medical laboratory doctors, medical laboratory technologists, laboratory assistants, biologists and biochemists) at the same biomedical laboratories where the biosafety expert's checklist has been contacted, and was filled in by the staff in their workplaces.

The questionnaire was developed based on a review of the literature (WHO Biorisk Programme Management monograph, 2020; BMBL 6th ed., 2020). The questionnaire consisted of 15 main questions, divided into 77 sub questions and 2 main sections: 6 main questions for gathering general information about the type of the laboratory, the profession of the laboratory staff, and the biological materials handled. The following nine (9) questions were for gathering information on biosafety measures and procedures in the laboratory, regarding the last 3 steps of the hierarchy of controls, ie. engineering controls, administrative controls, personal protective equipment, as well as the emergency procedures, and the education to biosafety practices. All questions were answered by choosing the words Yes or No, in the item specified.

The data were analyzed by SPSS software version 29 (Academic license) and descriptive statistics were used to summarize the data.

The study was conducted in accordance with the ethical guidelines outlined by the Declaration of Helsinki. The questionnaires were anonymous and informed consent was obtained from the participants about the study purposes and their voluntary participation, but also for the possibility of withdrawing the questionnaire in a later stage. On the first stage the Study has been approved, for the protocol as well the questionnaire, from the Ethical committee of the University of West Attica (UniWA), on 16-11-2020 with protocol number 89760/06-11-2020. Before the visits in the laboratories a written permission from the scientific committee of each hospital where the laboratories were placed has been obtained, and the facilities confidentiality was strictly maintained and ensured throughout the study.

Results and Discussion

Descriptive Statistics

A. Presentation of the Checklist results

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

A. Facilities and Technical Containment Measures			
		Count	**Count %**
A.1 There is an access control to the laboratory, only to authorized personnel	YES	17	47.2%
	NO	19	52.8%
A.2 At the entrance of the laboratory there is signage and	YES	3	8.3%

information of the Biosafety Level	NO	33	91.7%
A.3 The main entrance door of the laboratory has an automatic closing mechanism	YES	15	41.7%
	NO	21	58.3%
A.4 There are separate locker rooms and storage areas for the belongings of the laboratory staff	YES	29	80.6%
	NO	7	19.4%
A.5 The administration and the secretariat are separated from the laboratory analysis areas	YES	33	91.7%
	NO	3	8.3%
A.6 Blood collection is carried out in a specified, separate and sufficient size area	YES	35	97.2%
	NO	1	2.8%
A.7 Doors - Windows of the laboratory: They can be closed correctly during analysis	YES	34	94.4%
	NO	2	5.6%
A.8 Laboratory surfaces, floors and benches are intact, made of durable material and easy to clean and disinfect	YES	31	86.1%
	NO	5	13.9%
A.9 The laboratory seats have a stable base, their material is not fabric and is easy to disinfect	YES	27	75.0%
	NO	9	25.0%
A.10 Air conditioning checks are carried out regularly and are recorded	YES	34	94.4%
	NO	2	5.6%
A.11 There are one or more certified Biological Safety Cabinets (BSCs)	YES	20	55.6%
	NO	16	44.4%
A.12 There is a safety centrifuge (with separate cover for each rotor)	YES	18	50.0%
	NO	18	50.0%
A.13 There is an autoclave for sterilization inside the laboratory area	YES	18	50.0%
	NO	18	50.0%
A.14 The washbasins are located near the exit of the laboratory area	YES	28	77.8%
	NO	8	22.2%
A.15 There is the possibility of using them hands-free, with automatic operation	YES	6	16.7%
	NO	30	83.3%
A.16 The storage of biological agents is carried out in a safe manner and in a suitable place	YES	34	94.4%
	NO	2	5.6%
A.17 Reagents are stored safely and in a suitable place	YES	36	100.0%
A.18 The luminosity and spaces are sufficient for the safe conduct of laboratory analyses, maintenance and disinfection	YES	34	94.4%
	NO	2	5.6%

The initial part of the checklist, Facilities and Technical Containment Measures, focus on containment of the materials used in the lab, which is a combination of architectural and mechanical design of the laboratory.

One of the standout areas of concern is the lack of controlled access to laboratories in the majority of the hospitals (47.2%) and only a few self-closing mechanisms on entrance doors (41.7%). These findings were particularly alarming because unauthorized access to lab areas could lead to potential contamination, compromise the integrity of medical equipment, and pose a significant risk to patients and staff. The lack of adequate labelling and information on biosafety levels (91.7%) is a notable shortcoming. Appropriate labelling and dissemination of information are essential to create staff awareness of biosafety protocols and containment measures. This is

especially critical in healthcare settings where biological materials and hazards exist. The lack of full availability of safety centrifuges with separate covers for each rotor (50.0%) raises concerns about emergency preparedness. Similarly the number of autoclaves (50.0%) for sterilization within the laboratory area underlines the need for safer disinfection methods, as autoclaves are essential for sterilizing equipment and materials, and their availability is vital to prevent cross contamination and ensure biosafety.

The presence of designated changing and storage areas for laboratory staff in the majority of the laboratories (80.6%), the separation of administration areas from laboratory areas in almost all of laboratories (91.7%) and that the blood collection carried out in a specified, separate and sufficient in size area (97.2%) were favorable aspects. These spaces help minimize the risk of cross-contamination between laboratory, personal and administrative spaces, which is essential for biosafety, enhances overall biosafety within the labs and ensures the safety of both patients and healthcare workers. Almost in all laboratories (94.4%) doors and windows can be closed safely, which is a fundamental condition for containment. Gaps or vulnerabilities in the laboratory's physical barriers can compromise security measures. The presence of durable, easily cleanable surfaces for laboratory countertops and equipment in (86.1%) of laboratories was also a positive sign. These surfaces are essential for effective disinfection and maintaining a clean working environment.

Other positive points were:

- The seats of the workshop have a stable base and they could be easy to disinfect (75%)
- Air conditioning operation checks are carried out regularly and recorded (94.4%)
- There are one or more certified Biological Safety Cabinets (BSC) (55.6%)
- The washbasins are located near the exit of the laboratory area (77.8%), but it is not possible to use them hands-free, with automatic operation (16.7%).
- The storage of biological agents (94.4%) and reagents (100%) is carried out in a safe manner and in a suitable place
- The luminosity and spaces are sufficient for the safe carried out of the tests in the laboratory analyses, their maintenance and disinfection (94.4%).

In conclusion, the findings of the checklist in the session A. Facilities and Technical Containment Measures highlight both positive construction and areas that need immediate attention and improvement. Laboratories

should use these findings as opportunities to improve biosafety containment measures, including access control, labelling and information of the Biosafety Level at the entrance and acquisition of critical equipment, such as BSCs and autoclaves. This precautionary approach is essential to maintain a safe environment for both laboratory staff and the patients.

Table 2. Administrative measures, laboratory practices and procedures

B. Administrative measures, laboratory practices and procedures			
		Count	**Count %**
B.1 Risk Assessment is carried out for all laboratory procedures (P.D. 102/2020)	YES	1	2.8%
	NO	35	97.2%
B.2 There is a Biosafety Manual	YES	2	5.6%
	NO	34	94.4%
B.3 There is an authorized Biosafety officer	YES	1	2.8%
	NO	35	97.2%
B.4 The laboratory is certified or accredited	YES	10	27.8%
	NO	26	72.2%
B.5 The laboratory has written working protocols (SOPs) for all performed practices and procedures to minimize or eliminate risks, especially those that may cause splashes, droplets, aerosols or leaks	YES	21	58.3%
	NO	15	41.7%
B.6 It is not allowed to eat, drink, smoke and apply cosmetics in the workplace	YES	35	97.2%
	NO	1	2.8%
B.7 Laboratory benches and work surfaces are disinfected after any possible leakage of potentially infectious materials and at the end of each day's work, following the appropriate protocols and procedures	YES	36	100.0%
B.8 Hands are washed after each contact with biological agents and before leaving the laboratory	YES	36	100.0%
B.9 Introductory and continuing training and information on potential hazards at work and Safe Laboratory Practices are provided to all staff	YES	10	27.8%
	NO	26	72.2%
B.10 Housekeeping and support staff receive appropriate training	YES	16	44.4%
	NO	20	55.6%
B.11 Waste Management is carried out in accordance with the applicable legislation (Law 4042/2012 and KYA 146163/2012)	YES	36	100.0%

The evaluation of Administrative Measures, Procedures, and Laboratory Practices in the laboratory checklist provides valuable information about the state of biosafety protocols, policies, standards and guidelines in laboratory environment, and education and training of the laboratory staff.

The absence of a risk assessment process for laboratory procedures (97.2%) is a critical gap in biosafety practices. Risk assessment is the cornerstone of any biosafety program, helping to identify, evaluate, and mitigate potential hazards. Without this foundational step, laboratories may operate without a clear understanding of the risks involved in their work, potentially jeopardizing the safety of both patients and healthcare workers. Moreover, the lack of a Biosafety Manual (94.4%) and of an authorized Biosafety Officer (97.2%) suggests a deficiency in comprehensive biosafety procedures and expertise within the laboratories. These components are pivotal for establishing and maintaining effective biosafety programs, and their absence is a matter of significant concern. The absence of a biosafety manual indicates a lack of documented safety guidelines, which makes it difficult for staff to consistently follow standard biosafety practices. The creation and deployment of a biosafety manual, adapted to the needs of each laboratory, is imperative to establish clear safety procedures. In addition, the absence of a licensed biosafety officer for all laboratories is a notable concern and a gap. The Biosafety Officer plays a key role in overseeing biosafety practices, providing guidance and ensuring compliance with safety standards. Without a licensed biosecurity officer, they may struggle to maintain a proactive approach to biosafety. The assignment of a qualified professional to this role is crucial for an effective safety management.

Only some laboratories (27.8%) are certified or accredited, suggesting a lack of a formal recognition of adherence to specific quality and safety standards, as safety and quality complement each other. Certification or accreditation can serve as an external validation of quality and safety measures and should be sought to enhance their biosafety credentials.

Only few laboratories (27.8%) provide their staff with introductory and continuing training and information on potential workplace hazards and Safe Laboratory Practices. This commitment to staff training is not aligned with biosafety best practices, ensuring staff are well informed and able to effectively mitigate risks. Adequate training is crucial for ensuring that healthcare workers are aware of and capable of following safety protocols when working with biological materials. That finding signifies a missed opportunity to enhance safety practices. Also the training of support staff (44.4%), is another negative aspect. 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.

On the positive side:

More than half of the laboratories (58.3%) have documented SOPs to minimize risks associated with laboratory procedures. SOPs are essential to

provide step-by-step guidance on safety protocols, particularly for procedures involving potential splashes, droplets, aerosols or leaks. The absence of SOPs in some cases highlights a gap in standard security practices and their development to specific laboratory procedures should be a priority.

The prohibition of activities such as eating, drinking, smoking, or using cosmetics within the laboratories (97.2%) is a positive observation. These activities can introduce infectious agents and pose a risk to personnel. Strict rules should always be followed against these activities to maintain a clean and safe working environment.

The proper disinfection of all laboratory benches and work surfaces (100%) demonstrates the commitment to maintaining a healthy laboratory environment and preventing cross-contamination, especially after potential spills. Also hand hygiene practices in laboratories is robust, with (100%) emphasizing hand washing after any contact with biological agents and before leaving the lab. Proper hand hygiene is a fundamental biosafety practice and is adequately enforced. Also all laboratories (100%) follow compliance with Greek legislation on the waste management regulations. Proper waste management is vital to prevent the spread of biohazards and maintain a safe environment. The high compliance rate in this aspect indicates a commitment to responsible waste management practices.

In conclusion, many laboratories have demonstrated advantages in some areas of administrative practices, such as Good laboratory practices and procedures, hand hygiene, disinfection of the laboratory surfaces and waste management. But there are significant gaps in risk assessments for the laboratory procedures, lack of a biosafety manual and authorized biosafety officers, continuing training and information of the laboratory and housekeeping personnel, underlining the need for enhanced guidance. Addressing these gaps should be a priority for laboratories in order to enhance biosafety and ensure the protection of both staff and the environment. It is essential to ensure that these procedures are consistently followed and that staff members are adequately trained to understand and implement them.

Table 3. Personal Protective Equipment (PPE)

C. Personal Protective Equipment			
		Count	**Count %**
C.1 Appropriate Personal Protection Equipment (PPE) are sufficient and worn	YES	35	97.2%
	NO	1	2.8%
C.2 The type of personal protective equipment is proportional to the risk assessment	YES	3	8.3%
	NO	33	91.7%
C.3 There are procedures for using, applying and disposing of PPE	YES	14	38.9%

in the laboratory	NO	22	61.1%
C.4 The laboratory coats are buttoned and can only be used inside the laboratory	YES	10	27.8%
	NO	26	72.2%
C.5 There is a procedure and equipment (e.g., hangers) for laboratory coats to be worn when entering the laboratory and removed before leaving for any reason	YES	7	19.4%
	NO	29	80.6%
C.6 There is a policy when to change laboratory coats with clean ones	YES	4	11.1%
	NO	32	88.9%
C.7 The disinfection and washing of the laboratory coats is done at home and not in specific areas of the Hospital or in a special external laundry	YES	24	66.7%
	NO	12	33.3%

PPE is equipment worn by laboratory staff to protect them against exposure to biological materials, it is an important line of defense and must be proportionate to the local risk assessment (Bathula and Rakhimol, 2017).

The alignment of the type of PPE with the findings of the risk assessment was only in a small fraction of laboratories (8.3%) and there is no policy when to change laboratory coats with clean ones (11.1%). This means that only a limited number of laboratories take into account 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, ensuring that personnel are adequately protected during all operations. There is room for improvement in this aspect to increase the effectiveness of the PPE selection. Regarding the procedures for the use, application and disposal of PPE in the laboratory, only some laboratories (38.9%) have established procedures. Well-defined procedures are essential to ensure that PPE is properly worn, used and disposed of. The absence of such procedures in the majority of laboratories indicates a possible gap in coherent and standardised PPE practices.

A noteworthy observation is that laboratory coats are buttoned and worn only within the laboratory area in a small percentage (27.8%) and there are no procedures and equipment (e.g., hangers) for the use of laboratory coats exclusively within the laboratory (19.4%). These practices are not aligned with biosafety principles, as they prevent possible contamination of personal clothing and ensure that laboratory coats are confined to the workplace. This demonstrates a lack of understanding of the importance of minimizing the spread of infectious agents and of limiting and preventing the spread of infection beyond the laboratory environment. Also, the decontamination and washing of laboratory clothes is done mostly at home, and not in special areas of the hospital or in a special external laundry

(66.7%). This practice increases the risk of cross-infection outside the laboratory and the hospital setting, which is vital for infection control.

On the positive site almost all laboratories (97.2%) have an adequate supply and of PPE. This demonstrates a strong commitment to staff and patient safety and it is a key component of biosafety, especially when it comes to potentially infectious materials.

In conclusion, while the majority of laboratories demonstrate a strong commitment to the availability of PPE, there are many areas for improvement. These include the need for standardized procedures for the use of PPE, the proportionate alignment of PPE to the risk assessments, and the development of formal policies for changing and disinfecting laboratory coats. These improvements will contribute to enhanced biosafety practices in the laboratory facilities.

Table 4. Emergencies

D. Emergencies			
		Count	**Count %**
D.1 There is a plan to deal with emergencies and accidents	YES	31	86.1%
	NO	5	13.9%
D.2 There is an alternative energy supply for lighting and laboratory equipment	YES	34	94.4%
	NO	2	5.6%
D.3 There is a fire safety system and special escape signs in case of an emergency	YES	34	94.4%
	NO	2	5.6%
D.4 There is an eyewash system in case of an accident	YES	2	5.6%
	NO	34	94.4%
D.5 There is a First Aid Kit	YES	7	19.4%
	NO	29	80.6%
D.6 There are obvious electrical hazards in the laboratory	YES	7	19.4%
	NO	29	80.6%
D.7 Emergency telephone numbers are indicated in the laboratory areas	YES	9	25.0%
	NO	27	75.0%
D.8 There is an Occupational Doctor, and Preventive health checks of employees are carried out	YES	27	75.0%
	NO	9	25.0%
D.9 Accident reports: There is a system for reporting and managing occupational accidents related to exposure to biological agents and materials	YES	21	58.3%
	NO	15	41.7%

The assessment of Emergency Preparedness regarding the presence of basic safety measures and emergency plans in the laboratories facilities.

The absence of eye wash systems (5.6%) and the limited presence of first aid kits (19.4%) raises concerns about the ability to respond adequately to accidents and injuries, particularly those involving hazardous materials. Eyewash stations are vital for immediate treatment in case of eye infection, and their absence in these laboratories represents a significant gap in

emergency preparedness. First aid kits are essential to provide immediate medical attention in case of minor injuries. The majority of laboratories do not have a first aid kit readily available, which is a gap in basic safety measures. Only a small percentage (25.0%) of laboratories had emergency contact numbers posted on site. Easily accessible emergency contact numbers are crucial for rapid response to critical situations.

Also only half laboratories (58.3%) had an incident and accidents reporting system specifically related to exposure to biological agents and materials. This system is vital for documenting and managing workplace accidents and incidents.

It is encouraging that there is an Emergency Response Plan in the most laboratories (86.1%). In a healthcare setting, preparedness for various emergency scenarios is paramount. Without a clear plan in place, laboratories could respond effectively to critical situations, potentially putting staff, patients, and the public at risk. Almost all laboratories (94.4%) have alternative energy sources for lighting and laboratory equipment. This readiness is critical during power outages or electrical failures. Ensuring uninterrupted power supply is essential to maintain critical operations in healthcare facilities, especially during emergencies. Also almost all (94.4%) of the laboratories had a fire safety and evacuation system, which is a positive sign of preparedness for fire-related emergencies. Fire safety measures are vital in healthcare settings, where the safety of patients and staff is paramount. Many laboratories (75.0%) had a contract with an occupational doctor and carrying out preventive health checks for employees. This suggests enhancement of the health and well-being of the laboratory workforce.

Also the majority of laboratories (80.6%) had no visible electrical hazards, which indicates adherence to electrical safety standards.

In summary, regarding the results of the checklist in emergencies, while some laboratories demonstrate preparedness in some aspects, like in emergency plans, alternative energy supply, fire safety systems, and occupational doctor there are notable gaps in others. These gaps include the lack of eyewash systems, first aid kits, visible emergency contact numbers, and incidents and accidents reporting system. Addressing these gaps is essential to enhance emergency preparedness.

B. Comparative analysis of expert's evaluation (Checklists) and staff's perception (Questionnaire).
Summarizing key findings from both sources and identifying any notable differences or similarities.

In comparing the questionnaire and checklist results for laboratories, it's important to note that the questionnaire provides a more detailed qualitative information, but while the checklist focuses on binary yes/no responses, provides a more structured assessment. Tables 5-8 contains the positive (Yes) answers of questionnaires and checklists of all the questions which have been investigated. The column "EU and Greek Legislation" contain the articles of EU and Greek laws which are relevant to the certain question. The differences of the positive answers between questionnaire and checklist investigated statistically with McNemar test. McNemar test is similar to Chi-square test but more convenient to our data. It is applied to 2x2 contingency tables like our data where we compare the answers Yes/No of each common question of questionnaire and checklist. If P value of McNemar test is below 0.05 the positive ("yes") answers of questionnaire and checklist of Tables 5-8 differs significant statistically for the certain question.

Table 5. Comparing the Facilities and Technical Containment Measures (Engineering Controls)

P value has been calculated by McNemar test and shows the statistical significant of the differences of Yes/No answers of questionnaire and checklist of each question of the table.

A. Technological Measures for the Reduction of Biological Risks					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
7.1 Restricted access	48.9%	47.2%	0.013	A1	ANNEX V, A8
7.2 Signage at the entrance	10.6%	8.3%	1.000	A2	ARTICLE 6.2
7.3 Automated door closing mechanism	34.5%	41.7%	0.001	A3	
7.4 The doors and windows of the laboratory could be closed	23.1%	94.4%	0.000	A7	
7.5 Laboratory management is separated from laboratory analysis procedures	52.0%	91.7%	0.000	A5	
7.6 There are separate sanitary and rest areas for laboratory personnel	50.8%	80.6%	0.096	A4	ARTICLE 8.1
7.7.1 Air conditioning operation checks are carried out regularly and recorded	31.8%	94.4%	0.000	A10	
7.8 Special insulation and durable construction of Floors, Walls and Ceiling of the laboratory	14.0%	86.1%	0.000	A8	ANNEX V, A7
7.9 Construction of the surface material of laboratory benches made of HPL, or other type of durable material	29.6%	86.1%	0.000	A8	ANNEX V, A7
7.10 Laboratory surfaces and floors are easy to clean and disinfect	69.6%	86.1%	0.001	A8	ANNEX V, A6 / A10
7.11 There is an Autoclave in the laboratory area	21.9%	50.0%	0.031	A13	
7.12 Biological safety cabinets (BSC), Class I or II	31.8%	55.6%	0.001	A11	ANNEX V, A3
7.12.1 An annual inspection of the proper functioning of the BSCs is carried out	19.5%	55.6%	0.000	A11	
7.13 The washbasins are located near the exit of the laboratory	28.4%	77.8%	0.000	A14	
7.14 Ability to use the washbasins hands-free, with automatic operation or with the use of the legs	4.1%	16.7%	*	A15	
7.15 Eyewash and emergency shower system	6.0%	5.6%	1.000	D4	ARTICLE 8.1

*McNemar test could not be calculated

Regarding the Facilities and Technical Containment Measures both the results from the questionnaires and the checklists showed that a significant percentage of laboratories have deficiencies in:

i. the access control: (restricted access (48.9% and 47.2%), signage at the entrance (10.6% and 8.3%), and automated door closing mechanism (34.5% and 41.7%)
ii. Availability on autoclaves (21.9% and 50.0%), and BSCs (31.8% and 55.6%)
iii. washbasins with automatic operation (4.1% and 16.7%) and Eyewash and emergency shower systems (6.0% and 5.6%)

On the positive site laboratory surfaces and floors are easy to clean and disinfect (69.6% and 86.1%), and laboratory procedures are separated from management (52.0% and 91.7%) and sanitary and rest areas of the laboratory personnel (50.8% and 80.6%).

Table 6. Comparing the Administrative measures, laboratory practices and procedures. P value has been calculated by McNemar test and shows the statistical significant of the differences of Yes/No answers of questionnaire and checklist of each question of the table.

B. Administrative measures and Laboratory procedures					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
8.3 Samples are taken in a separate area of the laboratory administration	73.7%	97,2%	0.006	A6	
8.6 Regular disinfection of workplaces and benches	70.8%	100%	*	B7	ANNEX V, A10
8.7.1 Avoiding smoking, eating or drinking in the laboratory	62.7%	97%	0.002	B6	ARTICLE 8.1
8.7.3 Washing hands after each contact with biological agents and before leaving the laboratory	68.4%	100%	*	B8	
9.2 Risk Assessment is performed for all laboratory procedures	28.4%	2.8%	0.625	B1	ARTICLE 3.1
9.3 There is a Biosafety Manual	21.4%	5.6%	1.000	B2	
9.4 The laboratory has written working protocols (SOPs) for all procedures	35.9%	58.3%	0.115	B5	ARTICLE 8.1
9.5 There is an authorized Biosafety officer	10.8%	2.8%	1.000	B3	
9.8 Centrifugation of samples shall be carried out in a safety centrifuge with a separate rotor cover	33.3%	50.0%	0.302	A12	
9.12 Waste Management is carried out in accordance with the current Greek legislation (Law 4042/2012 – Joint Ministerial Decision 146163/2012)	69.6%	100.0%	*	B11	ARTICLE 6.2
13. Theoretical or practical Biosafety training programs are provided to all staff	28.2%	27.8%	0.146	B9	ARTICLE 9

*McNemar test could not be calculated

There is a lack of compliance with the recommended biosafety measures:

In relation to the Biological Hazard Management System, both the questionnaires and checklist indicate a significant percentage of laboratories having the following issues: Written Risk assessments are rarely performed (28.4% and 2.8%), there are no Biosafety Manuals (21.4% and 5.6%), few written working protocols (SOPs) for the procedures (35.9% and 58.3%), not assigned Biosafety officers in the laboratories (10.8% and 2.8%) and

Biosafety training programs are limited (28.2% and 27.8%). Also the centrifugation of samples is only rare carried out in a safety centrifuge with separate rotor covers (33.3% and 50.0%).

On the positive site very important is that Waste Management is carried out in accordance with the current Greek legislation (69.6% and 100.0%), and hand washing is performed after each contact with biological agents and before leaving the laboratory (68.4% and 100%). Also workplaces and benches are regular disinfected (70.8% and 100%) and smoking, eating or drinking in the laboratory is avoided (62.7% and 97%).

Table 7. Comparing the Personal Protective Equipment (PPE).
P value has been calculated by McNemar test and shows the statistical significant of the differences of Yes/No answers of questionnaire and checklist of each question of 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 are sufficient Personal Protective Equipment (PPE)	63.9%	97.2%	0.000	C1	ARTICLE 8.1
10.2 The selection of PPE is made by the management or the supervisor of the employees	40.7%	8,3%	0.289	C2	
10.3 The choice of PPE is made by the employee himself	62.7%	8.3%	0.001	C2	
10.5 Laboratory coats are worn, buttoned and with long sleeves	78.3%	27.8%	0.000	C4	
10.6 There is a policy when to change lab coats	16.4%	11.1%	0.687	C6	
10.8 There are written protocols for the application and removal of PPE	24.6%	38.9%	0.013	C3	
10.10 There is an Occupational Doctor and Medical Examinations are carried out for preventive control	34.9%	75.0%	0.001	D8	ARTICLE 14

There are deficiencies regarding the selection and use of the PPE: The selection of PPE is not made by the management or the supervisor of the employees, or after a risk assessment (40.7% and 8,3%), there is not a policy when to change lab coats (16.4% and 11.1%) and there are not written protocols for the application and removal of PPE (24.6% and 38.9%).

On the positive site there are sufficient PPE available (63.9% and 97.2%).

Table 8. Comparing the Emergencies
P value has been calculated by McNemar test and shows the statistical significant of the differences of Yes/No answers of questionnaire and checklist of each question of the table.

D. Emergencies					
Questionnaire Questions	**Questionnaire Count %**	**Checklist Count %**	**P value of McNemar test**	**Checklist Question**	**EU/Greek Legislation**
11.2 There is a plan in place to deal with emergencies and accidents	34.2%	86.1%	0.000	D1	ARTICLE 6.2
11.3 Accidents Reporting - There is an Occupational Accident Reporting System	25.5%	58.3%	0,115	D9	ARTICLE 10
11.5 There is a First Aid Kit	23.6%	19.4%	0.754	D5	
11.6 Emergency telephone numbers are indicated in the laboratory premises	30.8%	25.0%	1.000	D7	

In relation to emergency Preparedness, both sources found deficiencies in emergency procedures and preparedness, thus in Accidents Reporting (25.5% and 58.3%), and the availability of a First Aid Kit (23.6% and 19.4%) and emergency telephone numbers in the laboratory premises (30.8% and 25.0%).

Discussion for comparing the checklist and questionnaire results

In summary, both sources highlight common challenges and areas for improvement in biosafety practices, regarding the containment, the administrative controls, the PPE and the emergences, and offered assistance in confronting perceived and actual workplace hazards.

The observations and responses from the laboratory staff highlighted the difficulty in evaluating the risks, therefore **there is not always an alignment between the questionnaire and checklist results for laboratories.** Staff limited awareness of biosafety issues led to both an overestimation and an underestimation of the risk. Experts may also have overestimated or underestimated the current risk level in their capacity as external evaluators in a cross-sectional study.

The observed disparities in the perceived risk estimation of the hazards between subjective staff questionnaires and the expert's evaluation highlight the importance and need of the biosafety training. This training should be tailored to clear out the employees' perceptions of risk and also to provide suggestions for improving their safety. Incorporating workers' perceptions of risk with adequate education, which can provide a more comprehensive overview of the workplace condition.

Conclusions

While there are some positive findings, much work still needs to be done to ensure effective biosafety in the workplace. The results show that few laboratories have an effective biorisk management system in place, and there is also a low biosafety culture within the organizations. The administration does not seem aware of their responsibilities in performing risk assessments and provide introductory and continuous training to the laboratory staff.

These are also **issues in the implementation of the national Greek legislation**. There is no enforcement of the national Greek legislation, not only by the competent authorities, but also not by the administration of the organizations in the hospitals. More specifically the following items referred in the Presidential Decree 102/2020 are rarely performed, according both the checklist and the questionnaire results: Restricted access (ANNEX V, A8 – Table 5, 7.1), Signage at the entrance (ARTICLE 6.2 - Table 5, 7.2), Eyewash and emergency shower system (ARTICLE 8.1 - Table 5, 7.15), Risk Assessments performed for all laboratory procedures (ARTICLE 3.1 - Table 6, 9.2), SOPs for all procedures (ARTICLE 8.1 - Table 6, 9.4), Biosafety training programs provided to all staff (ARTICLE 9 - Table 6, 13), and minimal Accidents Reporting System (ARTICLE 10, Table 8, 11.3).

It may be clear from the above presented results that many of the Biomedical laboratories assessed do not comply with the international accepted BSL-2 standards, such as WHO, ECDC and CDC. Therefore there is a significant need for more comprehensive and proactive measures to reduce the risk of exposure to hazardous biological materials and agents, as well as adequate training and education for all workers. The findings suggest that interventions aimed at improving knowledge and adherence to these practices are needed to ensure the safety of laboratory workers and the general public. The following strategic recommendations for the biomedical laboratories could already be implemented to improve Biosafety, and equate at the international BSL-2 level:

1. Development and effective implementation of a structured and sustainable Biorisk Management System (ISO 35001:2019), based on the management strategic commitment and resources, and a continuous improvement mindset, through a cycle of planning, implementing, reviewing (European Committee for Standardization, 2011; WHO, 2011). This could improve the operations and activities of the laboratories, and assist their quality standards (ISO 15189:2022; 15190:2020) and legal requirements (WHO, 2016).
2. Contact risk assessments with the 5-step methodology that is described in the risk assessment monograph of the WHO Laboratory Biosafety Manual 4th ed. (WHO 2020), or with a

custom procedure for biomedical laboratories, like the one proposed in Annex I.

3. Develop written SOPs for all laboratory procedures.
4. Designate in every hospital an Appointed Biosafety Officer, responsible for Biosafety in the laboratories, with a directive from the administration. In order to oversee their biosafety and biosecurity programs, laboratories and other organizations need competent biosafety professionals. These professionals are a fundamental component of global health security, as well as for the preparedness and response to infectious disease outbreaks. This could be seen in:

- WHO LBM 4ed. (2020) monograph on Biosafety Programme Management: "A biosafety officer should be appointed to provide advice and guidance to personnel and management on biological safety issues. The role and knowledge of the biosafety officer is key to developing, implementing, maintaining and continually improving a biosafety and biosecurity programme".
- ISO 35001 (2019) Biorisk Management Standard: "a competent individual(s) shall be designated to provide advice, guidance, and assurance on biorisk management issues".
- WHO External Evaluation Tool (2005) (Action Package Prevent 3 – Biosafety & Biosecurity) "Biosafety officers certified and stationed at all laboratories that handle dangerous pathogens".

5. Elaboration of introductory and continuous training programs and raise awareness and responsibilities, to create a safety culture on the biological risks. Education and training are essential elements, for the proper implementation of the biosafety procedures and emergency response. This training should be organized by the management or should be in the mandate of the Biosafety Officer. Also to enhance the regional and national biosafety there is a need to form a local team of experts and educate and train biosafety professionals.
6. Ongoing collaboration and partnerships with biosafety associations and individuals with expertise. It is obvious that no individual governmental authority can make as big a difference alone. Therefore the role of the biosafety associations at local and in the international level is very important in:

- Networking and collaboration and the ability to share information about what has gone wrong and what solutions have been implemented
- Creating a safety culture and raise awareness of the risks
- Promotion of biological risk management practices and procedures

- Education and certification of the skills of Biosafety officers

By following these suggestions and with the enforcement of the existing laws and directives, a performance-based, holistic, risk-management system could be developed. This could result in the creation of safer laboratory facilities, the reduction of biological risks to acceptable levels, and the improvement of diagnostic tests quality. The positive outcome will be that the laboratory professionals, the community and the environment could be protected from possible harmful samples and biological agents.

In the face of a constantly evolving landscape of biological risks and threats, this highlights the importance of raising biosafety practices to higher standards. Laboratories are at the forefront of patient care, diagnostic research and biomedical advances. Using the results of this study, actions can be formulated to improve Biosafety safeguard by creating a Biorisk Management system in the Biomedical Greek laboratories, and also to enhance the Biosafety culture for the laboratory professionals. It is hoped that the findings of this survey will encourage employers to adopt a more proactive approach and invest the necessary resources to enhance biosafety.

Finally, this study also verified in accordance with other studies (Tziaferi, et al., 2011) the value of incorporating staff perception and expert evaluation to improve the efficiency of risk management in the laboratory environment and the enforcement of applicable regulations. As a result, these factors should be considered in future research studies, when enhancing the hospital staff in the risk evaluation procedure. Also the proposed methodology could be a useful tool for any hospital area and the results may contribute significantly to the hospital staff awareness of biosafety and to the enforcement of the Greek legislation.

Implications: The findings of this study have several implications for laboratory workers and the employers. First, there is a need for increased education and training on biosafety practices. Second, there is a need for improved laboratory containment and administrative measures, and resources to support and oversee them.

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References:

1. Bathula, S. R., & Rakhimol, A. (2017). Global Trends in biorisk Management. BioRisk, 12, 1–23. https://doi.org/10.3897/biorisk.12.12156
2. Brown, C.S., Zwetyenga, J., Berdieva, M., Volkova T., Cojocaru R., Costic N., Ciobanu, S., Hasanova, S., van Beers, S., Oskam, L. (2015). New policy-formulation methodology paves the way for sustainable laboratory systems in Europe. Public Health Panor. 2015; 1(1):41-7.
3. Blacksell, S. D., Dhawan, S., Kusumoto, M., Lě, K., Summermatter, K., O'Keefe, J., Kozlovac, J. P., Almuhairi, S. S., Sendow, I., Scheel, C. M., Ahumibe, A., Masuku, Z. M., Bennett, A., Kojima, K., Harper, D. R., & Hamilton, K. (2023). Laboratory-acquired infections and pathogen escapes worldwide between 2000 and 2021: a scoping review. The Lancet Microbe. https://doi.org/10.1016/s2666-5247(23)00319-1
4. Centers for Disease Control and Prevention (CDC), (2020). U.S. Department of Health and Human Services. Public Health Service. National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. 6th ed. Available at: https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf (Accessed: 03 July 2024)
5. Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), (2021). Hierarchy of Controls. Available at: https://www.cdc.gov/niosh/learning/safetyculturehc/module-3/2.html (Accessed: 03 July 2024)
6. Directive 2000/54/EC, (2000). Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000L0054&from=EN (Accessed: 03 July 2024)
7. European Committee for Standardization, (2011). CEN Workshop A greement.
   CWA 15793:2011, Laboratory Biorisk Management Standard. Availa ble at: https://internationalbiosafety.org/wp-content/uploads/2019/08/CWA-15793-English.pdf (Accessed: 03 July 2024)

8. Farr, J.M., Shatkin, L. (2004). Best jobs for the 21st century. JIST Works. p. 460. ISBN 978-1-56370-961-6.
9. Gribble, L.A., Tria, E.S., and Wallis, L. (2015). 'The AMP Model,' in Salerno, R.M. and Gaudioso, J. (ed.) Laboratory Biorisk Management: Biosafety and Biosecurity, Boca Raton: CRC Press, Taylor & Francis Group, pp. 31-42.
10. International Organization for Standardization (ISO), (2019). ISO 35001:2019. Biorisk management for laboratories and other related organizations. Availab le at: https://www.iso.org/standard/71293.html (Accessed: 03 July 2024)
11. International Organization for Standardization (ISO), (2020). ISO 15190:2020. Medical laboratories – Requirements for safety. Available at: https://www.iso.org/standard/72191.html (Accessed: 03 July 2024)
12. International Organization for Standardization (ISO), (2022). ISO 15 189:2022. Medical laboratories – Requirements for quality and competence. Available at: https://www .iso.org/standard/76677.html (Accessed: 03 July 2024)
13. Kessel, M. (2014). Neglected diseases, delinquent diagnostics. Science Translational Medicine, 6(226). https://doi.org/10.1126/scitranslmed.3008194
14. National Institutes of Health (NIH), (2024). NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines). DEPARTMENT OF HEALTH AND HUMAN SERVICES, National Institutes of Health. Available at: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf (Accessed: 03 July 2024)
15. Pike, R.M. (1976). Laboratory-associated infections. Summary and analysis of 3921 cases. Health and Laboratory Science vol 13, page 105-114.
16. Presidential Decree 102/2020 (Government Gazette 244/A'/07.12.20 20), (2020). Available at: https://www.et.gr/api/DownloadFeksApi/?f ek_pdf=20200100244 and https://www.gov.gr/sdg/work-and-retirement/health-and-safety-at-work/independent-authority-labour-inspectorate/obligations-of-companies (Accessed: 03 July 2024)
17. Raafat H, Sadhra SS. Risk characterization. (1999). In: Sadhra SS, Rampal KG, editors. Occupational health: risk assessment and management. 4th ed. Oxford (UK): Blackwell Science Ltd; 1999. pp. 177–193.
18. Salerno, M.R. and Gaudioso, J. (2015). 'Introduction: The Case for Biorisk Management,' in Salerno, M.R. and Gaudioso, J. (ed.)

Laboratory Biorisk Management: Biosafety and Biosecurity, Boca Raton: CRC Press, Taylor & Francis Group, pp. 1-23.
19. Sandia National Laboratories, (2014). Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document. Available at: https://internationalbiosafety.org/wp-content/uploads/2019/08/Laboratory-Biosafety-and-Biosecurity-Risk-Assessment.pdf (Accessed: 03 July 2024)
20. Sewell, D. L. (1995). Laboratory-associated infections and biosafety. Clinical Microbiology Reviews, 8(3), 389–405. https://doi.org/10.1128/cmr.8.3.389
21. Tun, T. A. (2017). Biomedical Laboratory: its safety and risk management. Journal of Experimental & Biomedical Sciences/Biomedical Science Letters, 23(3), 155–160. https://doi.org/10.15616/bsl.2017.23.3.155
22. Tziaferi, S., Sourtzi, P., Kalokairinou, A., Sgourou, E., Koumoulas, E., & Velonakis, E. (2011b). Risk assessment of physical hazards in Greek hospitals combining staff's perception, experts' evaluation and objective measurements. Safety and Health at Work, 2(3), 260–272. https://doi.org/10.5491/shaw.2011.2.3.260
23. Vourtsis, D., Papageorgiou, E., Kriebardis, A., Karikas, G. A., Van Willigen, G., & Karkalousos, P. (2022). A swift risk analysis for COVID-19 testing facilities using rapid tests. One Health & Risk Management, 3(4), 48–66. https://doi.org/10.38045/ohrm.2022.4.05
24. 2004 RA., Singh K. (2009). Laboratory-acquired infections. Clinical Infectious Diseases, Volume 49, Issue 1, 1 July 2009, Pages 142–147,. https://doi.org/10.1086/599104
25. World Health Organization (WHO), (2004). Laboratory Biosafety Manual. 3rd ed. Available at: https://www.who.int/publications/i/item/9241546506 (Accessed: 03 July 2024)
26. World Health Organization (WHO), (2005). International Health Regulations, Joint external evaluation tool – third edition. Available at: https://www.who.int/publications/i/item/9789240051980 (Accessed: 03 July 2024)
27. World Health Organization (WHO), (2010). Responsible life sciences research for global health security, A guidance document. Available at: https://www.who.int/publications/i/item/WHO-HSE-GAR-BDP-2010.2 (Accessed: 03 July 2024)
28. World Health Organization (WHO), (2011). Laboratory Quality Management System:

handbook, Available at: https://www.who.int/publications/i/item/9789241548274 (Accessed: 03 July 2024)
29. World Health Organization (WHO), (2014). Training Report, Hands-on Training Workshop on Cell Culture Techniques for the Laboratory Diagnosis of Polio/Enteroviruses and Measles/ Rubella in the Western Pacific Region. Available at: https://apps.who.int/iris/bitstream/handle/10665/208735/RS_2014_GE_11_HOK_eng.pdf?sequence=1 (Accessed: 03 July 2024)
30. World Health Organization (WHO), (2016). Development of national laboratory policies, Best practices document and facilitators' guide. Available at: https://www.who.int/europe/publications/i/item/WHO-EURO-2017-5659-45424-65013 (Accessed: 03 July 2024)
31. World Health Organization (WHO), (2020). Laboratory Biosafety Manual. 4th ed. Available at: https://www.who.int/publications/i/item/9789240011311 (Accessed: 03 July 2024)
32. World Health Organization (WHO), (2020). Laboratory biosafety manual, 4th edition: Biosafety programme management. Available at: https://www.who.int/publications/i/item/9789240011434 (Accessed: 03 July 2024)
33. Wurtz, N., Papa, A., Hukić, M., Di, A., Leparc-Goffart, I., Leroy, E. M., Landini, M., Sekeyová, Z., Dumler, J. S., Bădescu, D., Busquets, N., Calistri, A., Parolin, C., Palù, G., Christova, I., Maurin, M., La Scola, B., & Raoult, D. (2016). Survey of laboratory-acquired infections around the world in biosafety level 3 and 4 laboratories. European Journal of Clinical Microbiology & Infectious Diseases, 35(8), 1247–1258. https://doi.org/10.1007/s10096-016-2657-1

Appendix

Recommended Risk assessment for biomedical laboratories

1. **Comprehensive hazard identification:** The initial step is the thorough and comprehensive identification of biological hazards within the laboratory. This process should involve biosafety experts and the laboratory staff. All possible sources of hazards must be considered, including patient samples, infectious agents and laboratory equipment.
2. **Holistic risk profile:** Once risks have been identified, a holistic risk profile must be carried out. This includes assessing the full range of hazards, including biological, chemical, radiological and physical hazards. Risks should be categorized based on their potential impact on patients, healthcare workers, visitors, and the environment
3. **Advanced risk modeling:** Applying advanced risk modeling techniques to quantitatively assess the likelihood and severity of potential incidents. Leverage historical data, incident reporting systems, and predictive analytics to enhance the accuracy of the risk assessment. This data-driven approach allows for a more effective prioritisation of risks. Adoption of global standards: Aligning risk control measures with international biosafety and biosecurity standards and guidelines, like the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) to ensure best practices are followed.
4. **Multi-layered risk mitigation:** Development and implementation of multi-layered controls to mitigate risks. This includes a combination of technical controls (ventilation, containment facilities), administrative controls (policies, procedures and training) and personal protective equipment (PPE) for healthcare workers.
5. **Continuous monitoring:** Implement a real-time monitoring system to continuously assess and update risk profiles. This includes monitoring the emergence of new infectious diseases, and advances in medical technologies. Regular risk assessments must be part of the institutional culture.