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Research Article

Pakistan's experience with risk assessment training and implementation of concepts from the 4th edition of the WHO laboratory biosafety manual

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ABSTRACT

Introduction: The cyclical process of hazard identification, risk assessment, risk mitigation, and review is a key step in developing a biorisk management (BRM) system. This paper describes how this process was initiated in two laboratories in Pakistan using a unique model of blended learning.
Methods: A training needs analysis showed that the staff had very little knowledge of BRM systems. A workshop using a unique blended model was conducted in which virtual and in-presence learning occurred simultaneously. This workshop aimed to train the participants by applying two key concepts from the World Health Organization Laboratory Biosafety Manual 4th edition: 1) the cyclical process of risk assessment and 2) mapping the core biorisk and establishing heightened control measures in the laboratories of the participants based on the risk assessment. All scenarios and examples used in the training were from the participants' laboratory work processes.
Results: Prior to this project, no risk assessment was conducted in these laboratories. After the workshop, a risk assessment was performed for six work processes. In addition, seven core requirements and three heightened control measures were mapped, a biorisk officer was appointed, and a biosafety committee was convened. Furthermore, a biorisk manual, a biological waste management plan, an occupational health center, and a system for audits and inspections are being developed.
Discussion and conclusion: BRM training is not a one-time effort; it has to be strengthened to ensure the development and implementation of a comprehensive and sustainable BRM system. Training must be applicable to local settings and incremental, in a way that participants are not overloaded with information.

1. Introduction

A biorisk management (BRM) system[1–5] is a systematic way of addressing and controlling risks encountered by laboratories that handle biological materials, such as infectious agents and toxins. BRM includes a range of documented processes and physical infrastructure, which are developed to ensure that both biosafety and biosecurity risks are adequately controlled. Biosafety is a discipline that protects workers, communities, and the environment from infectious agents that are used at work. Conversely, biosecurity ensures that infectious agents are not used for malicious purposes. This includes prevention of unauthorized entry and the theft of infectious agents. The combination of biosafety and biosecurity risks is termed biorisk.[4] Biorisk is identified and managed via a range of written procedures and practices.

Typically, BRM includes a complete spectrum of controls, including physical building-related features and administrative measures. Administrative measures include ensuring compliance with standard operating procedures (SOPs),[6–7] work instructions, workflow processes, bench aids,[8] and other written documents that instruct staff on how to perform their work safely and securely. One international standard that can be followed to develop an effective BRM system is ISO 35001:2019.[9] This standard has ten elements, and element 6.1.1 is devoted to hazard and threat identification and analyses. The 4th edition of the World Health Organization (WHO) Laboratory Biosafety Manual (LBM),[10] which has adopted a risk-based approach, emphasizes the importance of gathering information and identifying possible hazards as the first step in developing a BRM system. The WHO

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LBM describes a cyclical process of risk assessment, starting from gathering information, evaluating risks, developing a risk control strategy, selecting and implementing control measures, and reviewing risks and control measures, as explained in Fig. 2.1 of the manual. Additionally, Biosafety in Microbiological and Biomedical Laboratories 6th Edition (BMBL)[11] also describes hazard identification as the first step in the process of risk assessment. In this cyclical process, the first step of information gathering is often elusive, and laboratory workers tasked with developing a BRM system are unclear on how and where to gather the information. The term "risk evaluation" is the same as "risk assessment," and it is a process used to evaluate the level of risk posed by a hazard, as not all hazards present risks. This is a very important process that allows an organization to use its resources to develop accurate risk control measures most effectively.[12]

There are several regions worldwide where the concept of BRM has only recently gained attention, and laboratory workers are struggling to develop a locally implementable BRM system. There is no universal BRM system; one that is copied from another organization and is not locally implementable will fail.[13,14] Hazard identification is a difficult step and is often not addressed in detail during risk assessment training. Textbook examples are of little use to lab workers, whereas real-life examples are significantly more helpful. Emphasis should be laid on where and how the crucial step of hazard identification can begin in specific laboratories.

Most laboratories that are in the process of establishing a BRM system have written documents for the work they undertake. For example, there could be SOPs, simple written instructions for performing diagnostic tests, written instructions for the use of equipment such as an autoclave, protocols that come with diagnostic kits, or protocols downloaded from the Internet. These can form the starting point for identifying hazards. As lab workers go through the hazard identification process, they become familiar with the method and proficient in identifying hazards in their tasks. Lab workers also realize which of the work processes do not have written documents and can address this. Once the hazards are identified from any of these sources, risk assessment can be performed, and mitigation measures can be established. Thereafter, in a cyclical manner, lab workers need to modify the SOPs to incorporate the mitigation measures that they have developed and selected. Once this cyclical process is initiated, they can regularly review the SOPs and repeat the process of hazard identification, risk assessment, risk mitigation, and review of mitigation methods.[6,10] The written documents (such as SOPs and work instructions) must be aligned with the risk mitigation measures that need to be implemented.

Another key shift in the new WHO LBM is the move away from the prescriptive definition of biosafety levels to that of core requirements and heightened control measures. Fig. 2.2 of the WHO LBM manual explains this concept. In most facilities, the majority of laboratory activities are low-risk. The concept of separating core requirements to ensure that they apply to all laboratory activities is judicious. Such core requirements include good microbiological practices and procedures, basic training, and basic personal protective equipment (PPE). This will ensure that resources such as additional PPE, safety equipment, and specialized training are reserved for activities and areas where the risk is higher. This is especially critical for resource-challenged regions, ensuring that the money is spent where it is most needed.[15,16]

Two laboratories in Pakistan applied these concepts as a starting point to develop BRM systems. This project started with a training needs analysis (TNA), which led to two workshops in 2019 and 2020. The 2019 in-person workshop focused on the generic principles of BRM, and the 2020 workshop focused on practical locally relevant hazard identification and risk assessment training. This paper describes the outcomes of the two workshops. The 2020 workshop used a unique model of a blended learning technique that incorporated active learning strategies for adult learners. Blended learning is a concept in which learning is achieved using online and face-to-face methods in various combinations. Various different models have been used based on the needs of training programs. Blended learning for adult learners adopts suitable methods such as active learning.[17–20] In active learning, learners are not passive listeners but are themselves a source of knowledge for the learning process, while the trainer acts more as a facilitator. This paper describes how BRM concepts from the WHO LBM were applied to the two laboratories in Pakistan using the unique model of blended learning, as well as the subsequent outcomes.

2. Materials and methods

2.1. Subject laboratories

a) Lab 1, Islamabad, Pakistan:

This facility, located in Islamabad, uses biological materials of animal origin for diagnosis, research, and surveillance activities.

b) Lab 2, Islamabad, Pakistan:

This lab conducts disease surveillance, diagnosis, and research focusing on major emerging and re-emerging poultry diseases. In collaboration with public and private sector stakeholders, this laboratory plays a significant role in capacity building in Pakistan.

In addition to the above tasks, these laboratories coordinate the surveillance of antimicrobial resistance for the Fleming Fund project.[a] The project requires the development and implementation of a BRM system to ensure the safety and security of personnel, products, and the environment.

2.2. Training needs analysis

A training needs analysis (TNA)[21,22] was conducted in 2019 (Table 1A and 1B) in these two laboratories to identify inadequacies in BRM knowledge, capacity, and implementation. The critical inadequacy identified was a lack of awareness of BRM and its elements. This highlights the need for effective training for both the scientific and technical staff. In addition to the questions mentioned in Table 1A on BRM capacity and implementation, staff's knowledge about biosafety and biosecurity was assessed through another set of questions (Table 1B). These pertained to applicable regulations, roles, and responsibilities of staff in implementing BRM, risk group classification and biosafety containment levels, effectiveness of different risk mitigation measures, and the correct use of biosafety cabinets (BSC). The overall average score was 42.2% with very low scores (less than 25%) in the following areas: roles and responsibilities, applicable local regulations, waste management, levels of containment for different types of biological agents and procedures, correct use of BSC, and choice of PPE. Table 1B lists questions in which the participants scored less than 25%. Major knowledge gaps in the fundamental concepts of BRM were identified, substantiating the findings in Table 1A.

At the end of the TNA, the participants were asked about their confidence in their ability to manage biosafety and biosecurity risks in the lab; 88.9% said they were confident. However, based on their responses to the questions mentioned above, it was seen that their knowledge was inadequate for developing and implementing a BRM system. For example, 66.7% considered PPE as their first option for risk mitigation and were unable to apply the hierarchy of risk controls to mitigate risks. Additionally, 88.9% of respondents said that they could operate BSC equipment; however, 77.8%

[a] https://www.flemingfund.org/wp-content/uploads/e60c75488f63bb97ce6ca9bd0c35ca12.pdf

Table 1A
Key questions and responses on biorisk management capacity and implementation gathered during the 2019 training needs assessment.

S No.	Question	Yes	No
1	Are you aware of any standards for a biorisk management system?		100%
2	Do you have an institutional biosafety committee (IBC)?		100%
3	Have you ever performed or participated in risk assessment?	50%	50%
4	Does your laboratory have a SOP for spill management?		100%
5	Does your laboratory have a SOP for reporting laboratory-acquired infections?	100%	
6	Has there been any laboratory-acquired infection reported by the laboratory personnel?		100%
7	Does your laboratory have SOPs for waste management?	100%	
8	Is the dedicated waste management staff/cleaner trained in waste handling?	50%	50%
9	Do staff working in your lab follow proper donning and doffing of PPE and proper decontamination of counters/surfaces?	100%	
10	Is safety equipment functional in your lab? (eyewash/ safety shower)		100%

Table 1B
Key questions and responses gathered during the 2019 training needs assessment to assess staff knowledge of biorisk management.

Sr. No.	Questions	% of Correct Answers
1	When it comes to the roles and responsibilities of different stakeholders in the biowaste management process, it is the role of the _____ to provide information about the agents, processes, and equipment in use.	11.1%
2	Incineration is an ideal method for treating biomedical waste.	11.1%
3	Surgical masks and N-95 respirators both provide respiratory protection.	11.1%
4	It is recommended by the CDC/NIH that Biosafety Level 2 laboratories must have a hand-washing sink, screens on windows, and locks on doors.	22.2%
5	Risk Group 2 pathogens are manipulated in a _____ lab.	22.2%
6	PPE is the first option to consider when we think of specific risk mitigation.	22.2%
7	Local rules and regulations should be given priority over international standards and guidelines for biowaste management.	22.2%
8	UV lights are essential in maintaining sterility in a biological safety cabinet.	22.2%

said that ultraviolet (UV) light is essential, and they were not aware of the pitfalls of using UV light. This indicated that the participants could not translate their knowledge into actual safe work practices within their laboratories and chose the most appropriate mitigation measure from various possibilities.

Taking this into consideration, a hands-on training on BRM was conducted in 2019. This training provided the participants with generic knowledge and skills about biosafety and biosecurity. Pre- and post-workshop evaluation results showed that the knowledge gained via the 2019 workshop was substantial. However, through personal communication with some of the participants, it was clear that this knowledge was generic and they were not able to apply it to their everyday work in the laboratories. For example, knowledge gained from the spill management demonstration did not include a risk assessment to determine the risk of the spilled material (different chemicals and biologicals), the risk of the quantity spilled (small vs. large spills), or risk of the location of the spill (inside or outside the BSC). In addition, the spill management demonstration did not include the choice of the contents of the spill kit and suitable location in the laboratories where these kits should be stored for easy access. Thus, although the workshop provided generic knowledge, the participants could not fully apply this knowledge to their everyday work. A second training session on hazard identification and risk assessment was conducted in November 2020 to enable the participants to apply the contents of the first workshop to their everyday work processes. This workshop emphasized practical applications rather than theoretical knowledge about the process of hazard identification and risk assessment.

2.3. Description of two-day blended learning workshop conducted in November 2020

A two-day workshop was conducted with 14 participants from the two laboratories, of which a quarter had attended the 2019 BRM workshop. This workshop focused on the process of hazard identification, risk assessment, risk control, and modification of SOPs to incorporate the control measures, in a cyclical manner, as described in the WHO LBM. The laboratories used their own SOPs and work processes to perform the cyclical process.

Fourteen participants were selected from the bacteriology, virology, and molecular biology laboratories of the two facilities. Their work experience ranged from one month to 18 years, with an average of 6.6 years. Prior to this training, the participant with 18 years of work experience had received risk assessment training. Based on the participant's personal communication, the previous risk assessment training took place over two days and included both lectures and activities. However, in the opinion of the participant, it was not comprehensive, and the risk assessment method was complex and not suitable for addressing biorisks in the laboratory. Combined with the lack of follow-up, this made it difficult for the participants to incorporate risk assessment in both laboratories. Two other participants had received risk assessment training and, according to personal communication, that risk assessment was specifically for one laboratory diagnostic test.

2.4. Concept and methodology adopted in the workshop

Currently, virtual training has become common because of the travel restrictions imposed by the COVID-19 pandemic. Virtual learning can be conducted via online platforms, where participants and trainers are logged into an online platform and utilize virtual meeting/discussion rooms. Although this reduces travel and the use of resources, the participants and trainers are in a virtual space, which limits the transfer of knowledge. Therefore, we used a type of blended learning concept in which the participants were present at a training venue while the trainer conducted the workshop virtually. One facilitator was physically present in the room to help the discussion, keep communication open with the trainer, and organize the presentation of each group. This blended learning method is a unique combination of in-presence and virtual learning in the same session. This method uses active learning principles,[23–26] which are very effective strategies for adult learners, where active discussion and participation allows learning not only from the trainer to the learners but also among the learners. Active learning principles require participants to think critically, evaluate and reflect on the concepts that they learn during training, and share this knowledge with other participants.

The 14 participants were assigned to three groups based on the nature of their work (e.g., serology, virology, molecular biology, bacteriology), the length of laboratory experience, and whether they were technical or scientific staff. This allowed participants with diverse backgrounds to collaborate to facilitate discussion and problem-solving. The participants were asked to complete an

online pre- and post-workshop questionnaire to capture their understanding of the risk assessment process.

2.5. Details of the two-day workshop

On the first day, the participants were given an overview of the basic concepts of hazard identification and risk assessment via a virtual lecture. Understanding these basic concepts was important for the risk assessment exercises of the next day. The second day followed a focus group approach and emphasized group work that was designed to trigger discussion and debate on current biosafety and biosecurity practices in both laboratories. Each group was given one technical SOP from one of the laboratories and a soft copy of the 5 × 5 risk assessment matrix method template (Fig. 1) adopted from the WHO LBM 4th Edition and the accompanying risk assessment monograph.[10]

In the first activity of the second day, each group used the template shown in Fig. 1 to identify and record hazards from the SOP that was assigned to it. Then, the groups shared their work via the virtual platform and opened up a discussion for additional input from their peers. Due to time constraints, each group practiced only on one SOP. However, during the discussion, the participants were able to go beyond that written diagnostic test SOP and identify hazards in other tasks they performed.

The second activity aimed to evaluate risks posed by the hazards identified in the first activity and list all existing control measures in their laboratories on the same risk assessment template. The assessment of whether these control measures lowered the risks to an acceptable range is discussed in this section. During the entire process, the trainer facilitated the groups by visiting each breakout room as needed. The local facilitator moved among the groups and provided guidance, as well as feedback to the facilitator who was on the virtual platform. This exercise helped the participants recognize the need to implement additional controls to bring any outstanding, residual, or unacceptable risks within the acceptable range. The participants were asked to share their work with other groups at the conclusion of this activity for further feedback and suggestions.

In the third activity, this risk assessment practice was translated into discussing and identifying core and heightened requirements as per the LBM. The core requirements were the best biosafety practices incorporated throughout the laboratory activities and would be applicable in all areas of any laboratory. The heightened control measures were relevant to specific diagnostic tests or activities that were assessed to be of higher risk and needed more mitigation measures.

3. Results

3.1. Results of activities performed in the workshop

Participants worked on the SOP that was assigned to them using the cyclical process of gathering information and identifying hazards, performing risk evaluation, and identifying and implementing control measures. In the following example, the SOP for the detection of *Escherichia coli* in poultry clinical samples was used (Fig. 2). Some hazards identified in this study included the following:

Material-based: infectious agents present in the samples and chemicals used, such as ethanol or culture/growth media.
Equipment-based: malfunctioning of BSC, use of Bunsen burner on an open bench, gas leakage, burns due to heated spatula, injuries during the use of an autoclave, malfunctioning of autoclave and centrifuge, etc.
Procedure-based: improper labeling of samples leading to mixing, cross-contamination, or loss of samples, as well as sample package breakage, spills, use of sharps, inoculation of agar plates, etc.
Human factor-based: lack of awareness of biosafety and biosecurity, absence of competency assessment mechanisms, noncompliance with the established procedures, etc.

The participants described some of the existing risk control measures as follows:

PPE
BSC for work with infectious samples
Use of suitable disinfectants
Regular maintenance of BSC and other equipment
Sample segregation and labeling procedures
Sample inventory management
Waste management procedures
Availability of spill kits and trained staff to handle spills
Smoke detector
Fire extinguisher

Furthermore, participants graded the severity and likelihood of each hazard using the existing risk-control measures. The risk level for this particular SOP was moderate. This process of performing risk assessment on just one written diagnostic procedure prompted discussion about the need to understand biorisk holistically and to include risks and mitigation that fall outside a specific diagnostic procedure. These included overarching risk assessment and mitigation measures such as managing sample inventory, managing waste, reporting incidents, assessing training needs for different categories of staff, establishing a biosafety committee to provide oversight, and engaging a biorisk officer to guide on biosafety and biosecurity matters. The next step was identifying core and heightened requirements; with guidance from the trainer, the participants proposed a set of SOPs that were common to different laboratories of the two facilities and the different services they performed (Fig. 3). Examples of these SOPs are basic PPE requirements, needle stick injury response, safe use of BSC, safe use of sharps, hand washing using the laboratory sink without tissue papers (tissue paper is not available), basic procedure for spill management (disinfectant depends on the different infectious agents and belongs in heightened requirements), basic procedures for disinfection and decontamination of contaminated surfaces (disinfectants depend on the different infectious agents and belong in heightened requirements). Heightened requirements were identified as 1) additional PPE (goggles or face shield) when working with liquid cultures and disposable gowns when working with high-risk pathogens such as avian influenza and 2) additional hand washing requirement for work involving certain infectious agents or certain sample collection procedures. Handwashing was required each time specific tasks were performed, and the location of the sink was specified. Tissue paper was reserved for hand washing in this situation, as the supply was scarce; this is an example of allocating resources where they are needed most, and this can be done only via a systematic process of risk assessment. For example, work with Shigella and other infectious agents transmitted via the fecal-oral route is subject to this additional requirement. The final heightened requirement was the selection of disinfectants based on different infectious agents for spill kits and disinfection/decontamination.

3.2. Long-term outcomes

There were approximately six diagnostic sections in each laboratory, with approximately eight technical/diagnostic SOPs in each

RISK ASSESSMENT FORM

TITLE:			REFERENCE NUMBER:	
Process/ Activity Location:		RA Members: 1. A 2. B 3. C 4. D 5. E 6. F	Approved by:	
Original Assessment Date:			Name:	
Approval Date:			Designation:	
Next Review Date:			Date	

I. Hazard Identification				II. Risk Evaluation				III. Risk Control					
No	Work Activity	Hazard	Possible Accident / Ill Health & Persons-at-Risk	Existing Risk Control	S	L	RL	Additional Risk Control	S	L	RL	Action Officer, Designation (Follow-up date)	Remarks
1.													
2.													
3.													
3.1.													
4.													
5.													
6.													
7.													

Likelihood / Severity	Rare (1)	Remote (2)	Occasional (3)	Frequent (4)	Almost Certain (5)
Catastrophic (5)	5	10	15	20	25
Major (4)	4	8	12	16	20
Moderate (3)	3	6	9	12	15
Minor (2)	2	4	6	8	10
Negligible (1)	1	2	3	4	5

Risk Level (RL)
High Risk (H)
Medium Risk (M)
Low Risk (L)

Fig. 1. Template of risk assessment using the 5 × 5 matrix method.

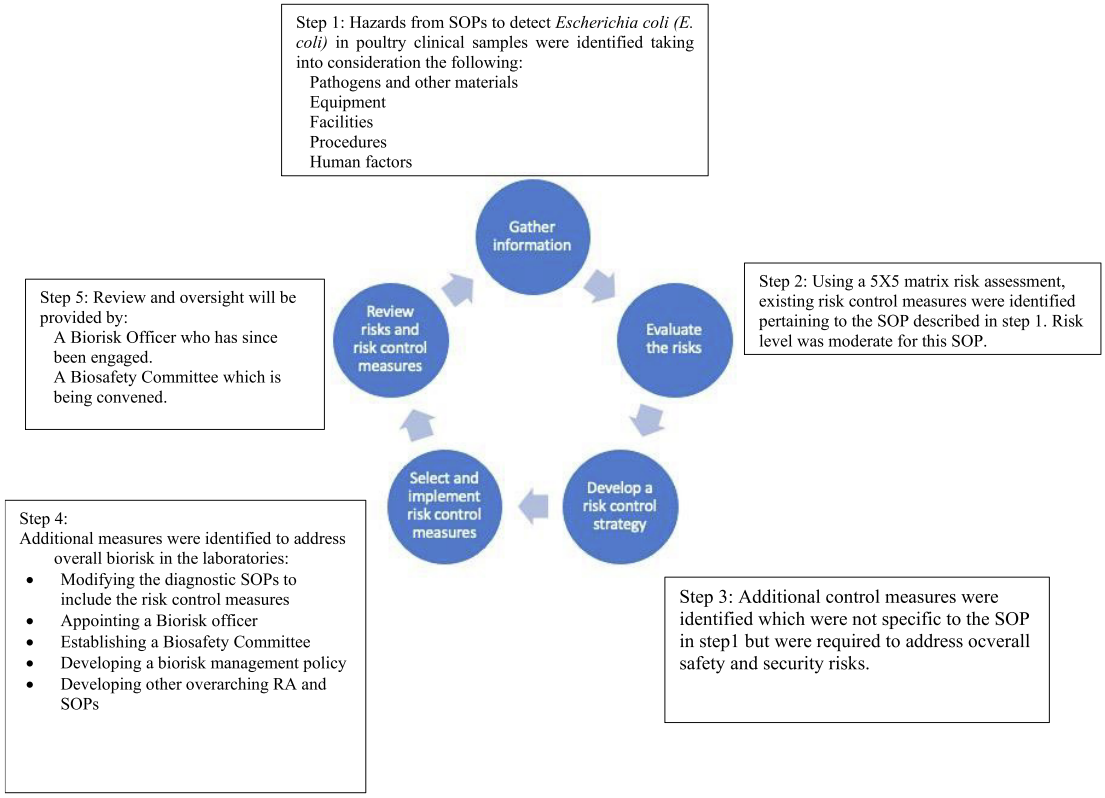

Fig. 2. Example of how the cyclical methodology of hazard identification – risk evaluation – risk mitigation – review of risk mitigation was adopted from the LBM.

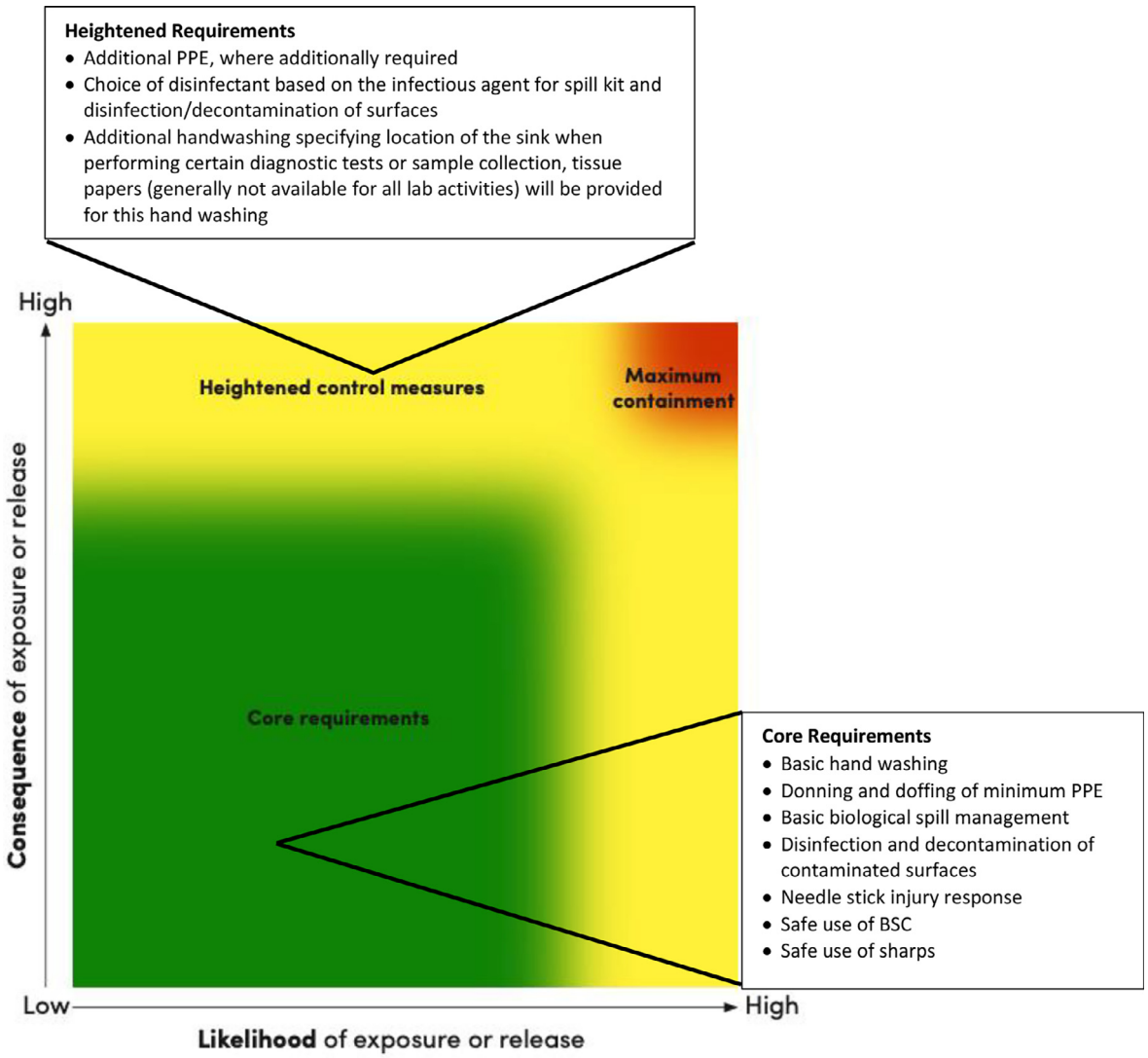

Fig. 3. Mapping the core and heightened requirements identified by the two laboratories adapted from Fig. 2.2 of the WHO LBM (4th edition).

diagnostic section. Prior to the workshop, no risk assessment was performed. Following this workshop, risk assessment was performed for work described in six SOPs, based on the work procedures and infectious agents involved in these laboratories. As risk assessment and mitigation are performed for more activities, the core and heightened requirements are also being updated. This is an ongoing process.

After the workshop, a BRM policy was developed, and a biorisk officer was appointed for each laboratory. The biorisk officer receives the necessary training and serves as a resource person for developing and implementing a complete BRM system. An institutional biosafety committee was convened to provide an overview of the BRM. The laboratories also established an in-house training plan for basic biosafety and biosecurity practices. Risk assessment and SOP development are key components of the training. In a cyclical manner, risk assessment and mitigation measures are included in all technical SOPs and work processes. This approach connects the risk assessment with SOPs, making it necessary for the SOPs to be constantly reviewed and updated when risk assessment is carried out. This ensures the rapid adaptation of the changes in the implementation of risk mitigation measures.

3.3. Evaluation of the 2020 workshop by the participants

The pre- and post-workshop questionnaire used a Likert-type rating scale from 1 (strongly disagree) to 5 (strongly agree) for the 2020 workshop. The participants were asked to rate their understanding and skills to conduct a risk assessment at their workplace before and after the workshop. The post-workshop questionnaire reflected an increase in score, except for question 7 (Table 2). This was because the workshop made the participant aware of the critical role of the risk assessment process and how negligence in conducting risk assessment correctly can affect their safety, thereby undermining the person's confidence (personal communication). Some comments from the participants are given below. All participants agreed that the blended model was very effective.

> *"The blended approach gives us the opportunity to learn from international experts."*
> *"Virtual trainings are flexible, affordable and accessible and can be more effective than traditional training because you don't have to fly out a trainer or coach. . .More participants can attend which usually means a lower price-per-person."*

Table 2
Pre-and post-workshop questionnaire for the 2020 risk assessment workshop and respective average scores.

S No.	Questions	Average pre-workshop score	Average post-workshop score	Change in score
1	Do you know what biorisk assessment is?	3.70	4.63	+0.93
2	Do you understand why biorisk assessment needs to be done?	3.70	4.38	+0.68
3	Have you taken part in biorisk assessment at work?	2.73	3.38	+0.65
4	Do you know who should be involved in biorisk assessment?	3.37	4.56	+1.89
5	Have you been involved in SOP writing?	3.40	3.94	+0.54
6	Have you been involved in addressing biosafety issues at work?	3.67	3.88	+0.21
7	Do you feel comfortable leading a biorisk assessment at work?	3.53	4.00	+0.47
8	Do you feel confident that you can take part effectively in biorisk assessment at work?	4.37	4.25	−0.12

"The blended approach is useful under the travel restrictions, but a face-to-face training will be of more benefit in topics such as risk assessment."

"It was good and well managed course even if it was virtual. More related sessions should be arranged."

"...the risk assessment matrix method was very helpful and practical...the demonstrations and exercises provide clear concepts and overall approach."

"Workshop was very interesting; a lot of self-learning was to be done on our own to understand and put together into practice under the supervision of the national and international experts."

4. Discussion

This project aimed to equip the participants from two laboratories in Pakistan with knowledge and skills to develop and implement a BRM. A crucial step in the process is hazard identification followed by risk evaluation and mitigation.[1–5,27] Many laboratory workers struggle with this because, although they have generic and textbook knowledge on how to develop a BRM, they cannot apply this knowledge to their work. This was confirmed by the TNA that was performed in 2019.

Following the TNA, two workshops were conducted in 2019 and 2020. The 2019 workshop provided a generic understanding of the best biosafety and biosecurity practices. The 2020 workshop used a unique model of blended learning to provide practical skills using their own work practices and SOPs. Blended learning[18–20] using virtual platforms, which became prevalent during the COVID-19 pandemic, will be firmly established. Although virtual training cannot completely substitute in-presence training, it reduces the need for travel and incurred expenses and will continue to be practiced even after the pandemic ends[28,29]. The unique model adopted in the 2020 workshop allowed the trainer to virtually impart knowledge, while the participants were physically present in one location. The participants and a local facilitator were able to share their knowledge and expertise in presence during group exercises. Thus, in this model, virtual and in-presence training occurred simultaneously. The discussion groups were constructed to include staff with varied work experiences, which promoted healthy discussions. The authors noted that the staff who performed sample collection in the field viewed risk and mitigation measures differently from those working in the laboratories. These differences were discussed and allowed for lateral thinking[30] among the participants.

The development of a learning model termed conscious competence ladder, where learners go through four stages of learning to achieve skills and competence, has been credited to Noel Burch in the 1970s.[31] The model entails the following four stages of competence[32,33]:

Stage 1: Unconscious incompetence – individuals are not aware of the fact that there is a necessary skill they do not have, and therefore do not recognize the gap.
Stage 2: Conscious incompetence – individuals are aware that they do not have a necessary skill and understand the value of obtaining the skill.
Stage 3: Conscious competence – individuals understand how to do something, but require concentration to perform the task.
Stage 4: Unconscious competence – individuals are very familiar with the skill, the skill becomes easy to perform, and they can impart this knowledge to others.

Shumail *et al*[27] surveyed clinical and research laboratories in Pakistan and reported that the majority of the laboratory personnel were not aware of the biosafety risks that can be posed by the pathogens they handled and the work they performed. The authors also looked at biosecurity measures, which were found to be severely lacking in the examined laboratories. Based on the results, a lack of awareness seems to be the main issue; the staff would belong in stage 1: unconscious incompetence of the conscious competence ladder, which is the riskiest stage for a system.

In the two biomedical laboratories involved in this project, training mainly consisted of the performance of diagnostic tests, which was the primary reason for their employment. The competence of the participants in performing the diagnostic tests is likely categorized under stages 3 and 4 of the conscious competence ladder based on their experience levels (this was not assessed in the TNA). The competence in performing the diagnostic tests does not mean that they are competent in addressing biorisks in their work or developing a BRM system. The TNA was conducted in 2019 to identify gaps in BRM skills and knowledge. Based on the pre-workshop evaluation results, most of the participants were in stage 1: unconscious incompetence. Following the 2019 workshop, they moved to stage 2: conscious incompetence. The 2020 workshop was then designed to address the practical knowledge gap that was described in personal communications after the 2019 training. This workshop helped them improve, with a few participants reaching stage 4.

The BRM system needs to be developed and implemented in phases, local resources must be used, and all mitigation measures should be locally relevant. Most biorisk trainings equip participants with theoretical knowledge; however, the participants cannot correctly apply this knowledge to their everyday work. Chaudhri *et al*[34] described a large training initiative in a diverse array of laboratories in Pakistan to increase awareness and knowledge about BRM. Such initiatives will help participants climb the conscious competence ladder, but they must be followed up by focused training to progress to higher levels. The method adopted in the 2020 workshop uses the SOPs and work processes of each laboratory to identify hazards and assess and mitigate risks, thus allowing the participants to apply their knowledge in practice. This is the first step in the development of a complete BRM system. This

workshop helped the participants perform a risk assessment for work described in six SOPs. In addition, they identified seven core requirements that are common to all laboratory areas and three heightened requirements for specific laboratories where higher-risk work was performed. Furthermore, the laboratories directed limited resources to where they are needed most, as in the case of disposable gowns and tissue paper for hand washing. The participating laboratories also helped each other improve the cyclical process described in Fig. 2. A similar project in another resource-poor developing region was conducted by one of the authors, Viji Vijayan. This project started with two laboratories to initiate the development of a BRM system via the cyclical process described in this paper. The staff in the two laboratories have now helped initiate the same process in two large hospital laboratories. It is also important to realize that what works in one region may not work in another even within one country and that risk mitigation must be relevant to that laboratory, institution, or region.

Active learning[23–26] is a technique used in adult learning. Via this technique, learners are allowed to engage in high-level problem solving, synthesize and evaluate information, and critique each other's solutions. The simultaneous use of in-presence and virtual modes of learning ensures that participants are engaged and that there is active discussion among the groups. Participants were discussing plans to conduct informal inspections and audits of each other's laboratories to improve the processes learned in the workshop.

Following this project, a training plan, based on the same approach as actual examples from the laboratory's own work processes, was developed for nine sentinel laboratories across Pakistan. The participants that were trained during the workshop were actively involved in the implementation of the training. Based on the comments from the participants and the downward trend of score in the last question in Table 2 concerning their confidence in performing biorisk assessment, the next steps are being planned to include more in-depth training. This will consist of real-time practice with actual and current work processes (this is a test of competence in applying the knowledge) and on-site biorisk assessment workshops. Such programs will help participants ascend the conscious competence ladder, but they must be followed up by focused training for the participants to progress to higher levels of the ladder. One path that can be considered in this progression is on-the-job training for biorisk officers in the form of internships, which will enhance learning in classrooms and workshops and provide a means of testing the competency of the officer.[35] The laboratories are in the process of developing a biorisk manual, a biological waste management plan, an occupational health center, and a system for audits and inspections. Pursuing this, the laboratories established institutional biosafety committees and appointed biorisk officers.

5. Limitations

This project addressed only the risk assessment and mitigation components of BRM to initiate the development of a full BRM. The entire BRM consists of several components that were not addressed in this project. The long-term outcomes of this project need to be assessed over the coming months to fully ascertain the benefits of this approach.

6. Conclusion

BRM training is not a one-time effort; it must be sustained and should eventually lead to the development and implementation of a comprehensive and sustainable BRM system. It is important to understand the needs of local laboratories and institutions and their competence levels so that training can be devised to suit the situation. Moreover, training must be practical and applicable in local settings with locally available resources. If the training is targeted and progresses in a step-by-step manner such that participants are not overloaded with information and feel daunted, the development and implementation of a sensible and sustainable BRM is feasible.

Ethical Statement

Not Applicable.

Statement of Human and Animal Rights

Not Applicable.

Statement of Informed Consent

Written informed consent was obtained from the participants of the study.

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CRediT authorship contribution statement

Samreen Sarwar: Formal analysis, Writing – review & editing, Project administration,**Viji Vijayan:**Conceptualization, Methodology, Writing – original draft, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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