EVALUATION OF A BSL-3 LABORATORY BIOSAFETY TRAINING PROGRAM IN KENYA

Shingo Inoue1, Martin Bundi1,4, Gabriel Miring’u1, Betty Muriithi1, Salame Ashur1, Ernest Wandera1, Cyrus Kathiiko1, Erick Odoyo1, Allan ole Kwallah5, Amina Galata1, Sora Huka1,2, Mohammad Shah1, Mohamed Karama1,3, Samuel Kariuki2, Yoshio Ichinose1*

1 Institute of Tropical Medicine, Nagasaki University- Kenya Research Station, Nairobi
2 Kenya Medical Research Institute - Center for Microbiology Research
3 Kenya Medical Research Institute - Center for Public Health Research
4 National Biosafety Authority
5 Kenya Medical Research Institute- Production Department

*Corresponding author e-mail: ichinose@nagasaki-u.ac.jp

ABSTRACT
Biosafety training is an effective approach of increasing biosafety and biosecurity capacity of laboratorians working in a containment laboratory. A biosafety training program is a critical tool in training BSL-3 laboratory users due to its capability to deliver skills and knowledge comprehensively and systematically. Nagasaki University Institute of Tropical Medicine- Kenya Medical Research Institute (NUITM-KEMRI) installed a BSL-3 laboratory and developed a biosafety training program to train prospective BSL-3 laboratory users. The program covers theoretical and practical aspects of biosafety and biosecurity. To evaluate the program’s effectiveness in increasing biosafety and biosecurity capacity and assess the importance of structured biosafety training, the training program was administered to eleven laboratory technologists. Effectiveness was established by comparing pre and post-training written test scores, alongside analysis of hands-on evaluation scores and trainee feedback. Importance of structured biosafety training was examined by comparing hands-on evaluation scores of the trainees by exposure status. After training, there was an average improvement of 14% in performance in the written test and above pass mark scores in hands-on evaluation, indicating a substantial increase in knowledge and competence. Moreover, trainee feedback rated the training program as satisfactory. Importance of structured biosafety training was demonstrated by preferential performance among the unexposed trainees relative to exposed trainees in hands-on evaluation. A biosafety training program facilitates training of new BSL-3 laboratorians as well as instruction on proper safety practices and procedures among previously trained users. Training should be complemented with mentoring and refresher training in order to nurture and sustain biosafety and biosecurity capacity.

Key words: Training, BSL-3 laboratory, Biosafety, Biosecurity, Kenya
INTRODUCTION

Safety of BSL-3 laboratory users and the environment at large is highly correlated with knowledge of biosafety and biosecurity concepts, as well as adherence to good laboratory practices (Homer et al., 2013). A BSL-3 laboratory employs physical and technical strategies to allow for safe manipulation of highly infectious biological materials while preventing their accidental release. Although such facilities enhance safety, they have to be used correctly for total realization of the benefits they confer to users and the environment (Richards et al., 2014). Simple errors such as inappropriate donning of personal protective clothing or inappropriate usage of safety equipment among others, can pose great danger to users and the public. Although it is not possible to completely eliminate such errors and other potential risks, proper training of BSL-3 laboratory users can minimize them significantly.

Dynamics of laboratory accidents are dominated by human error, poor laboratory techniques and technical faults (World Health Organization-WHO, 2006; Kaufman and Berkelman 2007; Tun et al., 2009). Particularly, human error accounts for majority of the laboratory incidents, many of which are due to incompetence as a result of inadequate or absence of training (Bakanidze et al., 2010; Delany et al., 2011). Further, lack of training has been identified among the main challenges in development of biosafety and biosecurity capacity (Heckert et al., 2011). Biosafety training of laboratory staff has hence been named as an effective measure of preventing laboratory incidents, with powerful influence on user and public safety (Lucero and Sineriz 2005; Richards et al., 2014). Subsequently, recent increase in the number of high containment facilities has not yielded any significant rise in laboratory accidents due to an equal increase in vigilance against laboratory risks through proper training (Homer et al., 2013). Comprehensive biosafety training is therefore highly beneficial to both new and seasoned BSL-3 laboratory users.

A biosafety training program is a critical tool in training BSL-3 laboratory users. It provides a holistic approach of imparting practical biosafety and biosecurity knowledge and skills (Kauffman and Berkelman 2007). A program offers a greater opportunity for structuring of biosafety training, which enables delivery of biosafety and biosecurity concepts and skills in a formal and systematic manner. Further, it allows for comprehensive coverage of biosafety and biosecurity, to teach the range of skills and knowledge needed to recognize, respond and mitigate potential risks.

Inadequate training manifests through instances such as laboratory acquired infections and accidental release of pathogenic materials to the environment (Bakanidze et al., 2010). While protocols for managing biosafety and biosecurity may be in place in most containment laboratories, these can only be useful when accompanied by proper knowledge and understanding on how and where to use them. Moreover, laboratories have a tendency of passing down incorrect procedures since new staff are trained by the more experienced staff who may not necessarily be well versed with good safety practices or were trained using a similar approach, and without any formal guideline (Mitchell et al., 2005).

In order to guide training of new and potential BSL-3 laboratory users, NUITM-KEMRI developed a biosafety training program following the installation of its BSL-3 laboratory in 2007 (Bundi et al., 2014; Ichinoe et al., in press.) The program provides for theoretical and practical training on biosafety and biosecurity. It is administered through an annual workshop. Training procedures includes lectures, demonstrations, discussions, training review and training evaluation. This report evaluates the effectiveness of the biosafety training program in improving knowledge and competency of BSL-3 laboratory users, alongside the importance of training BSL-3 laboratory staff using a structured approach.

METHODOLOGY

a) Participants

Eleven trainees were enrolled for a two-day long biosafety training workshop. All the trainees were workers of research laboratories, and had significant experience in a range of laboratory procedures. Five of the trainees worked in enhanced BSL-2 laboratories but had accessed a BSL-3 facility previously hence they were familiar with BSL-3 procedures. Of the five, two trainees had received in-lab training from NUITM while the rest received initial instructions in different laboratories. However, the five hadn’t participated in the NUITM BSL-3 biosafety training workshop previously. This group is henceforth referred to as the “exposed” group in this report. The other six trainees did not have prior experience working in a BSL-3 facility and also had never received any BSL-3 biosafety training. The six worked in
basic BSL-2 laboratories. This group is henceforth referred to as the “unexposed” group in this report.

b) The BSL-3 training program
The NUITM-KEMRI biosafety training program as described by Bundi et al. (2014) was used to conduct the training. The program is divided into three sections; pre-training assessment, training phase and post-training assessment. Pre-training assessment was conducted using a written test. The test was a multiple choice examination whose questions were drawn from the content covered during the workshop. The training phase comprised of a theoretical session and a practicum. Topics on concept and knowledge on biosafety and biosecurity, NUITM BSL-3 system; features, maintenance and management, and operations inside the BSL-3 laboratory were covered during the theory session (Table 1). The practicum session was conducted inside the facility. The trainers first performed a demonstration on the correct procedure of entering the BSL-3 laboratory, working inside the facility and exiting the BSL-3 laboratory. A hands-on practice was then conducted by the trainees based on a task that covered an entire laboratory session. The task was divided into the three stages for systematic assessment of correctness of procedures, and scored using a checklist. Finally the post-training assessment was conducted using a written test that was identical with the pre-training assessment test. The pass mark for all evaluations was 70%.

c) Biosafety training program evaluation
Pre-training assessment was conducted in order to assess initial level of knowledge while post-training assessment examined extent of comprehension of the training content. Pre-training and post-training assessment scores were compared to determine whether there was an increase in knowledge while the hands-on evaluation examined gains in competency. Trainee feedback was obtained using questionnaires issued at the end of each lecture. Trainees used the questionnaires to rate the lecture content, training method, the trainer, and to provide a general opinion on the entire workshop. The importance of a structured training approach was assessed by comparing the hands-on evaluation scores between exposed and unexposed trainees.

Table 1: Structure and content of the training phase of the biosafety training program

<table>
<thead>
<tr>
<th>Session</th>
<th>Description</th>
<th>Training method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Theoretical session</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Concept and knowledge</td>
<td>- Background of laboratory-acquired infections</td>
<td>• Lectures</td>
</tr>
<tr>
<td></td>
<td>- Microorganisms risk groups classification</td>
<td>• Discussion</td>
</tr>
<tr>
<td></td>
<td>- Biosafety containment levels</td>
<td>• Demonstration by trainers</td>
</tr>
<tr>
<td></td>
<td>- Biosafety containment strategies; facilities and techniques</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Sample packaging and transportation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Basic mycology, virology and bacteriology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Waste management</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NUITM BSL-3 system: features, maintenance and management</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Laboratory design</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Components of NUITM-KEMRI BSL-3 laboratory; physical and operational features</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Biosafety equipment</td>
<td></td>
</tr>
</tbody>
</table>
• Operations inside the BSL-3 laboratory
  − Routine care and maintenance
  − Laboratory entry check-points
  − Documentation
  − Personal protective equipment
  − Working in the BSL-3 laboratory; protocols and procedures
  − Exit procedures and troubleshooting

Practicum session
• Demonstration and hands-on practice
  − Site visit to the check-points
  − Demonstration of the correct procedure of entering, working inside the facility and exiting the BSL-3 laboratory
  − Hands-on evaluation session

• Demonstration by trainers
• Hands-on practice by trainees

Data analysis
Data was analyzed using STATA 11 (Statacorp). Pre-training, post-training and hands-on evaluation scores were summarized into averages. Students T-test (95% confident interval, p<0.05) was used to evaluate the extent to which pre-training scores differed from post-training scores.

RESULTS
a) Evaluation of the biosafety training program
Post-training written test scores and hands-on evaluation scores of all trainees were above the pass mark. The pre-training and post-training tests average scores were 76% and 90% respectively as shown in Figure 1. There was a significant improvement (p<0.001) in the written test following training.

![Figure 1: Mean pre-training and post-training scores (n=11)](image)

For a more detailed examination of pre-training and post-training performance, scores of each learning objective as covered in the theoretical session (Table 1) were averaged to establish the mean score per learning objective. Of the three, NUITM...
BSL-3 system presented the highest score after the training workshop, while concept and knowledge was the most improved as shown in Figure 2.

![Figure 2: Pre-training and post-training scores by category](image)

In the hands-on evaluation, the average score was 77%, satisfactorily above the pass mark. ‘Entering the BSL-3 laboratory’ was the best performed procedure as shown in Figure 3 below while ‘working in the BSL-3 lab’ category presented the lowest scores.

![Figure 3: Hands-on evaluation scores by section](image)
Finally, the overall rating of the training program was satisfactory. Most of the trainees either agreed or strongly agreed that the contents, training materials, structure and the trainers were suitable, facilitated learning and met their expectations.

b) Assessment of the importance of conducting a structured BSL-3 biosafety training

Hands-on evaluation scores categorized by exposure status were used to examine the importance of structured biosafety training. A comparison of the two categories yielded no significant difference (p>0.05). However, unexposed trainees had a fairly higher average score (77.5%) than the exposed trainees (73.3%) as shown in Table 2. Amongst the exposed trainees, those trained within the NUITM laboratory system had a higher average score than those trained externally (Table 2).

<table>
<thead>
<tr>
<th>Table 2: Comparison of scores between exposed and unexposed trainees</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exposed trainees (number)</strong></td>
</tr>
<tr>
<td><strong>Hands-on evaluation score</strong></td>
</tr>
<tr>
<td>• Trained within NUITM laboratory system - 83.2% (2)</td>
</tr>
<tr>
<td>• Trained in a different laboratory - 66.7% (3)</td>
</tr>
<tr>
<td><strong>Written test score (Post-training evaluation)</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

DISCUSSION

Educational interventions such as biosafety training have extensively been acknowledged as powerful tools for instilling biosafety and biosecurity knowledge, and influencing adherence to safety practices (Ahmed et al., 2013). A biosafety training program enhances learning by providing a more targeted means of delivering knowledge and skills.

This assessment revealed a substantial increase in biosafety and biosecurity knowledge and competence following training, reflecting the overall effectiveness of the NUITM-KEMRI biosafety training program. A significant improvement (p<0.05) in the written test was observed after training, with 14% average improvement, as well as above pass mark scores in all the three learning objectives. Generally, these outcomes present a proof of learning. The high scores in the NUITM BSL-3 system category depict a high level of knowledge on BSL-3 laboratories most probably acquired through the training, especially since some of the trainees did not have any previous experience in a level three laboratory. Further, there was remarkable improvement in the concept and knowledge category despite being the broadest category.

The hands-on evaluation showed considerable proficiency and ability of the trainees to apply learned knowledge. Scores in all the three evaluation sections were well above the pass mark. Of the three categories, working in BSL-3 laboratory section was the least performed. Most trainees were able to perform the entry procedures and a few exit procedures correctly. Much difficulty was however experienced in setting, running and completing the experiments using correct biosafety and biosecurity procedures, although the trainees were able to draw corrective measures during the discussion session. Resulting competence and increase in awareness of good laboratory practices signifies that the training program is capable of delivering practical knowledge and skills as well as influencing safety habits. The lower scores observed in the working in the BSL-3 section could have been due to the limited time allocated for practical training. Such competency gaps are however addressed during BSL-3 laboratory user mentorship (Bundi et al., 2014).

Trainee feedback further confirmed effectiveness of the training program. The overall rating was satisfactory. Trainees reported that they had learned new biosafety and biosecurity concepts, which would make their work places safer. They also agreed that the training workshop was very useful and relevant to their work.

Generally, a biosafety training program enhances learning and application of biosafety and biosecurity skills and knowledge by providing for comprehensiveness of the
training content, logical delivery and continuous improvement of training content. The NUIITM-KEMRI biosafety training program packages a broad range of biosafety and biosecurity concepts necessary for developing biosafety awareness and technical expertise among level three laboratory workers. It adheres to the universal training guidelines on laboratory biosafety and biosecurity (WHO, 2004); with modifications to meet the institution’s research focus and settings. The program is organized in a sequential manner, which enables trainees to first learn a range of basic biosafety and biosecurity concepts, including general concepts and those specific to their job. This is followed by training on technical and practical aspects of BSL-3 laboratories. It is delivered using demonstrations, practicum and discussions, training methods that have been shown to make a training program more effective (Tun et al., 2009). Further, these techniques maximize participation of the trainees and significantly contribute to comprehension of concepts. Subsequently, BSL-3 laboratory users become more aware of potential threats that the BSL-3 biological agents pose to personnel and the public and the importance of adhering to proper biosafety practices. However, it is important to note that effectiveness of a biosafety training program is also influenced by institutional infrastructure and mentoring (Homer et al., 2013). Such support structures complement learned skills and knowledge.

Assessment of the importance of structured training aimed to determine whether initial non-structured instruction on biosafety interferes with training outcomes of a formal structured training. Hands-on practice scores were used since the session expects a trainee to use learned skills and knowledge, although there is always a possibility of using past experience to accomplish the tasks. In this assessment, unexposed trainees scored relatively higher scores as compared to exposed trainees, although the difference was not statistically significant. Specifically, unexposed trainees achieved better scores in technical evaluation points such as usage of biosafety equipment, spill management and waste management. Classifying trainees by institution of initial instruction (Table 2), a striking difference was observed between the three trainees who received initial instruction in a different laboratory and those instructed in-house. The later worked under the supervision of a trained NUIITM BSL-3 laboratory user. However, exposed trainees performed better than unexposed trainees in the written test.

These results show that the training had a greater impact on the unexposed trainees as compared to exposed trainees, despite having encountered BSL-3 laboratory settings previously. Lower scores among the exposed trainees could have been due to reluctance of trainees to adopt new practices since these conflicted with what they were taught at initial instruction. Initial instruction could have focused on getting them to adopt procedures as practiced in the laboratory they were working in rather than training them on best practices (Trevan et al., 2010). Scores were even lower among trainees who received initial instructions in other institutions. Higher scores among the unexposed trainees on the other hand demonstrate the extent of learning and ability to transfer concepts to an actual work environment achieved through the training workshop. Unexposed trainees however performed better in the written test as compared to exposed trainees probably due to previous exposure to basic biosafety and biosecurity concepts.

This outcome suggests that previous unstructured biosafety training of new BSL-3 laboratory users can limit learning during structured training, especially if initial training propagated incorrect or unclear procedures. Unstructured training is usually given in the form of on-the-job training mostly conducted by more experienced staff. In most cases, such training lacks a standard instruction manual. Although universal biosafety and biosecurity guidelines exist that could be in use in such laboratories, the guidelines are usually from different sources, and at times lacking clear direction on some core practices (Emmert 2013). Training BSL-3 laboratory users using this approach is therefore more likely to propagate poor laboratory practices that are difficult to undo, more so with increasing duration of experience. Moreover, BSL-3 facilities are uniquely different hence biosafety and biosecurity strategies of one facility may not apply to any other. Conducting biosafety training based on a biosafety training program on the other hand allows for compilation of core and facility-specific practices and delivery of these using varied methods, while taking into account training needs of the laboratorians, their learning differences and the changing biosafety and biosafety trends (WHO, 2004). This results in greater learning accompanied by a change in behavior, both of which are necessary in instituting a culture of safety (CDC, 2012). Subsequently, a BSL-3 worker is able to conduct risk assessment and implement safety practices necessary for minimization of potential risks when placed in a different laboratory.
A combination of comprehensive training content and varied training methodologies into an easy-to-follow training program facilitated learning among new BSL-3 laboratory users. Capability of the NUITM-KEMRI biosafety training program to increase skills, knowledge and overall capacity of BSL-3 laboratory users was therefore demonstrated, despite a small sample size. Importance of training new BSL-3 laboratory users using a structured approach was also shown. This assessment however did not examine the effect of the training on each trainee’s institution. A trained BSL-3 laboratory user must be able to influence positive change within the workplace, although this also requires proper institutional infrastructure and leadership that is supportive of biosafety and biosecurity management. This study also highlighted the need of conducting mentorship of new trainees and periodic refresher trainings to already trained BSL-3 laboratory users in order to maximize and sustain biosafety and biosecurity.

ACKNOWLEDGEMENT

We thank Dr. Solomon Mpoke (Director, Kenya Medical Research Institute) for providing technical support for our project activities. We also thank all the biosafety trainers and BSL-3 laboratory staff who facilitate our annual biosafety training seminars. Special thanks to Dr. Anne-Sophie Brocard (Director, Laboratory Biosafety Training Program, UTMB) and JeT’Aime Newton (Safety Consultant, Environmental Health & Safety, UTMB) for their valuable insights on how to improve our training program. This work was supported by Japan Society for Promotion of Sciences (JSPS) grant in aid for scientific research; grant number 15H05286.

REFERENCES


Source of Support: Nil Conflict of Interest: None Declared