Knowledge Dissemination and Best Practice Transfer on Biosafety, Biosecurity and Biorisk Management Through a Sustainable and Effective Education and Awareness System

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Abstract

Education is the first step to create a society that respects the others and the environment and that works to design and build a peaceful future. An effective and sustainable education system could rely on a tailored methodology that synergizes self-evaluation, gap-analysis, and train-the-trainers methods. This combination allows gathering information about real needs and expectations of training targets, elaborating a made-to-measure educational program and training future educators on topics of interest, making education and awareness system sustainable. Using these methodologies, we set up a knowledge development and transfer of best practice system on biosafety/biosecurity/biorisk management, in order to spread awareness and know-how on these topics. Twenty-two countries, in four different regions (South East Europe, South East Asia, North and West Africa) were involved in the project titled “Knowledge development and transfer of best practice on biosafety, biosecurity and biorisk management”. National Experts (NEs) from each country have been trained by intensive and e-learning courses to improve learning efficacy, to raise awareness and to foster networking as well as best practice sharing within each region. Consequently, the trained NEs disseminated the knowledge in their own countries, tailoring the courses on their local needs and expectations, amplifying the educational impact of the project. Here, we review the methodologies applied to develop a sustainable education and awareness system and the training contents related to biosafety/biosecurity/biorisk management.
1 Introduction

The impact of an incident involving a biological substance can be enormous. Hospitals, research institutes and industrial facilities must combine their efforts to strengthen the global preparedness and response against incidents happened accidentally or intentionally. Working with such biological agents requires bio-safety, bio-security and biorisk-management.

To this end, it is necessary to build a responsible conduct in the life science and to achieve this goal, education and awareness raising constitute the main pillars. A sustainable education system together with awareness raising activities are indeed the first steps to promote a safety culture and create a society that respects the others and the environment and that works to design and build a peaceful future (National Research Council [NRC], 2010).

The importance of these two pillars has also been highlighted in the Report of the BWC Meeting of States Parties in 2008 (United Nations [UN] 2008; Australia et al. 2011), where the States Parties recognized the value of education and awareness programs:

(i) Explaining the risks associated with the potential misuse of the biological sciences and biotechnology;
(ii) Covering the moral and ethical obligations incumbent on those using the biological sciences;
(iii) Providing guidance on the types of activities which could be contrary to the aims of the Convention and relevant national laws and regulations and international law;
(iv) Being supported by accessible teaching materials, train-the-trainer programmes, seminars, workshops, publications, and audio-visual materials;
(v) Addressing leading scientists and those with responsibility for oversight of research or for evaluation of projects or publications at a senior level, as well as future generations of scientists, with the aim of building a culture of responsibility;
(vi) Being integrated into existing efforts at the international, regional and national levels.

Without any doubt, the interest in biosecurity education has increased recently but, as showed by an investigation conducted by the Landau Network-Fondazione Volta and the University of Bradford, it appears that this interest has not manifest in significant concrete action at the level of the life science academic community. Indeed, it becomes apparent that very little exists in terms of biosecurity related

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1In this paper, biosafety is used to “to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release” (WHO, LBM, 2003).

2In this paper, biosecurity refers to “to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins” (WHO, LBM, 2003).
education. Some exceptional existing cases could be considered as examples or models, but we are far from achieving the necessary levels of biosecurity related education for life sciences students to be able to generate a culture of responsibility (Mancini and Revill, 2008). Furthermore, there is also, in general, a lack of awareness of the risk of malevolent misuse of the biological sciences as demonstrated also by Dando and Rapper who conducted 90 interactive seminars with more than 2500 life scientists in 13 different countries (Dando and Rappert, 2005).

Last but not least, alongside these intentional misuse concerns, safety risks arising from the unintentional exposure to pathogens and toxins of humans, animals and plants are of great concern, especially with the increasing number of advanced research laboratories dealing with higher-level pathogens (Butler, 2009). Scientists often recognize the biohazards related to pathogens they are researching accidentally infecting people and animals or contaminating the environment outside the laboratories, rather than recognizing the risk of theft or intentional malicious use of bioagents for biocrime and terrorism (Gaudioso, 2006). Moreover, in her survey of Asian life scientists, Gaudioso described how the main means to manage biohazard management in laboratories are biosafety operations manual, institutional biosafety committee, biosafety training procedures, and laboratory management plan, while biosecurity issues do not figure as predominantly in most biohazard assessment, and simple biosecurity measures are utilized to protect laboratories containing pathogens or toxins (Gaudioso, 2006). Therefore, in this context, biosafety education for scientists working with highly pathogenic microorganism and toxins is based on WHO and CDC (Center for Disease Control and Prevention) manuals and, in some cases, on national or institutional regulations. Biosafety training and dissemination of good practices are mostly responsibility of the institutes where the pathogens are used and, as it happens for biosecurity principles, they are very seldom integrated in future scientists education as topics discussed during university courses.

Of course there is no “one-size-fits-all” approach dealing with bio-related issues, as different aspects should be taken into consideration that differs from case to case, namely local and regional needs and priorities, past and present national efforts implemented (such as training organized, regulations, certification/accreditation for laboratories, general level of knowledge and awareness on these issues, etc.), structure of academic curricula, and different linguistic and cultural backgrounds (Minehata et al. 2013). Therefore, a multidisciplinary and holistic approach should be applied in order to address and cover all the aspects related to biosafety and biosecurity.

This paper intends to describe the project titled “Knowledge development and transfer of best practice on biosafety, biosecurity and biorisk management”, and implemented by the Insubria Center on International Security in the framework of the EU CBRN Centres of Excellence (CoE) Initiative jointly implemented by the European Commission (EC) and the United Nations Interregional Crime and Justice Research Institute (UNICRI). In particular, the methodology used, the training contents, the project’s added value and the lessons learned are highlighted hereafter.
The strategic objective of the project was to promote sustainable knowledge development in four geographical regions (South East Europe, the Southern Caucasus, Moldova and Ukraine, South East Asia, North Africa and African Atlantic Façade) on bio-safety, bio-security and biorisk management, via subsequent train-the-trainer phases in order to deliver to the regions sustainable capacity (Fig. 1). In particular the project planned to:

- Develop holistic and multidisciplinary approach to bio-related issues;
- Strengthen regional and international cooperation on knowledge sharing and best practice exchange;
- Raise awareness on bio-related issues and support synergies among scientific communities and institutions.

Fig. 1  Schematic representation of the project objective, outcome and main results

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3In this region, the participating countries were Albania, Armenia, Croatia, Georgia, Moldova, Republic of Macedonia, Serbia and Ukraine.

4In this region, the participating countries were Cambodia, Brunei Darussalam, Laos, Myanmar, The Philippines, Singapore, Thailand and Vietnam.

5In this region, the participating countries were Algeria, Tunisia, Libya.

6In this region, the participating countries are Gabon, Mauritania, Morocco.
2 Methodology

The methodology used to implement the project was aimed at guaranteeing the highest level of ownership and sustainability of the actions carried out. An effective education system should rely on a tailored methodology that synergizes self-evaluation, gap-analysis, and train-the-trainers methods. This combination allows gathering information about real needs and expectations of training targets, elaborating a made-to-measure educational program and training of future educators on topics of interest, making education and awareness system sustainable (Fig. 2).

First activities implemented were the self-evaluation, by disseminating to the local stakeholders in the four regions a survey questionnaire in order to understand local situation and local needs, and consequently gap analysis. The results of these activities showed a big discrepancies among the countries (some more technological advanced than others) and showed that regions have differentiated needs from an educational point of view. Differences emerged not only among countries of the same region, but even within each country, between main cities and the periphery or rural areas.

In order to take into consideration these results, the train-the-trainers model, applied to this project to develop knowledge and build a sustainable capacity in bio-related issues, was common among the above mentioned regions, yet flexible enough to be tailored to local needs. The model was inspired to EU levels of risk management, and designed in cooperation with international institutions and European partners. The development of a sustainable knowledge was achieved by
training, first, groups of local experts, i.e. National Experts (NEs), coming from the 22 participating countries, in the concepts of biosecurity, biosafety and biorisk management system and, then, by supporting the NEs, who successfully completed the training sessions and were qualified to become trainers in their own countries, in implementing the training locally addressed to second groups of local experts (hereafter referred to as “National Participants”), so that NEs become trainers locally.

The NEs and NPs were selected according to precise profiles, to make sure they had the necessary scientific, technical, educational and language (only for NEs) qualifications: a list of criteria were indeed proposed in each country, taking into account professional expertise, academic curriculum, age, geographical representation and female participation. The challenge in this phase of selection was to make sure to select experts really interested in further disseminating and delivering of acquired capacities at national level. The successful completion of training by NEs was evaluated against predetermined SMART (Specific Measurable Attainable Results-Focused Time-Focused) learning objectives using a range of assessment methods, including assignments, case studies and situational analysis. In total, the project trained 60 National Experts, and 410 National Participants, for a total of 470 trainers trained. These 470 trainers were doctors and technicians from hospitals, research institutes and industrial facilities so as officials from different ministries such as Health, Agriculture, Environment, Defense, Science and Technology, Internal affairs, Trade and, among the authorities, from Customs and Civil Protection in a multidisciplinary perspective. During the training sessions, the different background of the experts indeed helped and fostered the exchange of ideas and lessons learned, based on their own professional experience.

The training methodology was diversified and consisted of e-learning phases and intensive courses. The e-learning phases were delivered through a dedicated Learning Support Platform, housing different educational materials and e-libraries and based on open-source software (Moodle). In particular, the training modules were set up with presentations, assessment tests and interactive tools, such as forum and chat, to foster the discussion among the experts and the trainers. Open source papers, guidelines, and manuals were uploaded in the libraries, used as a repository of the documents and useful to deepen the topics discussed in the courses. This e-learning phase was conceived as a preparatory step for the intensive courses. At the end of the project, the Learning Support Platform remained as a tool available to National Experts and National Participants (Fig. 3).

Intensive courses (both theoretical and practical) were from one week up to two weeks duration and were structured through active learning methodologies. The intensive courses were a mix of frontal lessons, delivered through power point, and video presentations, brainstorming, analysis of case studies, open debates and group exercises. To animate the sessions, laboratory visits and demonstrations were organized as well. The interactive approach guaranteed the exchange of ideas, best practice and share of expertise, especially where the gap between the background and the level of knowledge on bio-related issues was significant. The heterogeneity
fostered a wide sharing of past experiences by the most skillful participants, coming from countries that are at a higher level in terms of awareness on biosafety and biosecurity issues, to the less experienced attendants.

The trainings of National Participants organized by the qualified NEs included only theoretical-practical intensive courses aimed at the common learning objectives, previously mentioned. In general, these training sessions addressed the management from the technical but also policy, legal, and “teaching methods” points of view related to biosafety, biosecurity and biorisk management.

3 Training Content

The content of the training modules addressed to NEs was conceived to have a common basis but at the same time to incorporate specific local requests, at regional level: it was based on identified transferable best practices, as well as on the further development of the lessons learned by past similar training efforts, and the common learning objectives, which were tailored and specified on the needs of each region.

Approaching the topics of biosafety, biosecurity and biorisk management a multidisciplinary, omni-comprehensive and holistic approach is pivotal to understand and apply good practices to safeguard security and to guarantee safety in all the aspects involving biological threats. In order to cover all the topics the training addressed to NEs was divided in 5 modules: Module 0 “Core training specifications for biosafety professionals (content from CWA 16335)”, Module 1 “Teaching and Assessment methods for bio-risk management training”, Module 2 “Legal, ethical, environmental aspects”, Module 3 “Laboratory Biorisk Management”, Module 4 “Accreditation, implementation and the CWA Standards”.

Fig. 3 E-platform course page
In detail:

- **Module 0 “Core training specifications for biosafety professionals (content from CWA 16335)”**: was based on the CEN Workshop Agreement (CWA) 16335:2011 Bio-safety Professional Competences. It was conceived as a comprehensive introductory module and as a preparatory phase of training useful to provide the participants with a common and crosscutting background of knowledge required to attend successfully the following modules and to overcome the gaps existing among countries in the same region, emerged during the **gap-analysis and self-evaluation** phases of the project. In particular: the risks associated with biological agents and other hazards; concepts of containment and its limitations, the most important types of containment and their installation, validation, certification and maintenance; main elements of infection control, disinfection, decontamination and sterilization; biological waste management plans and requirements on transport, import and export, labelling and means of transport for different biological agents.

- **Module 1 “Teaching and Assessment methods for bio-risk management training”**:  
  - **Teaching and Training methodologies** consisted of four different subtopics, namely “Adult as Learners”, “Facilitation versus Teaching”, “Active Learning” and “Course Design”. This course was designed to help participants develop an in-depth understanding of facilitation techniques focused on adult training, concepts of active learning and active learning strategies for teaching bio-risk management. The training was designed to provide the attendants with the ability to distinguish among various approaches for adult training, to compare different methods for training in bio-risk management, to apply active learning methodologies in training and to distinguish among various types of assessment (Fig. 4).
  - **E-learning platform**: this theoretical and practical course was aimed to make experts more familiar with the e-learning platform. It illustrated how to use

Fig. 4 Moments of active learning
the platform as a student (i.e. updating personal profile, downloading course presentations, filling and uploading assessment tests and communicating through chats and forums) and as a teacher (showing how to create new courses and profiles, upload files and grade assessment tests).

- **Background elements of Quantitative Microbial Risk and Assessment and presentation of toolkit** focused on the biosafety and the biosecurity program in laboratories. To point out the synergy and potential conflicts between biosafety and biosecurity both programs were discussed in detail. The experts were provided with international guidelines (WHO, BMBL, CWA Laboratory Biorisk management) and tools like the biosecurity toolkit in order to think over biosecurity management in their own organization and to identify gaps in their biosecurity management system. The aim of this lecture was to show the importance of doing a risk assessment and how to create awareness. As an example of risk assessment, the basic steps of Quantitative Microbial Risk Assessment (QMRA) for food and water were explained: hazard identification, exposure assessment and risk characterization, including also variability and uncertainty.

- **Module 2 “Legal, ethical, environmental aspects”**

  - **Legal framework for Biosafety and Biosecurity** was aimed to review the basic legal concepts and ideas relating to biosafety and biosecurity and legislative provisions. During the training, participants were asked not only to compare and contrast the legislative frameworks in their respective countries but also to exchange ideas on best practices and areas where further regulation may be required.

  - **Environmental Biosafety and Biosecurity** focused on general environmental concepts (biodiversity, resilience, and sustainability), environmental impact assessment, and environmental management (Environmental Protection). In particular, biosafety, biosecurity and biorisk analysis, Environmental Impact Assessment (EIA), Environment Risk Assessment (ERA), Environment Management Systems (EMS) were presented and discussed. Moreover, the Invasive Alien Species (IAS) topic was developed elucidating the principle of invasion ecology, explanation of the invasion process, and determinants of invasiveness and invisibility. It was deeply analyzed the theme of biodiversity and the importance of its protection for earth and earth inhabitants health.

  - **Ethical/dual use aspects** discussed the ethical questions related to the dual use dilemmas in science and, in particular, it focused on the possibility to use the new emerging technologies, like nanotechnology, technologies based on atomic fission, chemistry and synthetic biology, for good as well as for bad purposes. The question of the moral responsibility of scientists and on their accountability in dual use dilemmas was deepened and some case studies were discussed.
Module 3 “Laboratory Biorisk Management”

- *Laboratory Biorisk Management* was divided in different subtopics. The first one focused on natural occurring bio emergency. In particular, the social, economical and demographical impacts of SARS outbreak (2003) were analyzed in detail. Moreover, the recent Ebola outbreak (2014) effects in society, economy and demography in the three most affected countries (Liberia, Guinea and Sierra Leone) and in the rest of the world have been discussed. The second course reviewed the classification of infective microorganism by risk group, the characteristics of microorganisms belonging to different groups, the bio containment levels that have to be applied for each group and the diagnostic tools used to identify viruses and bacteria. Moreover, this course aimed to refresh and improve knowledge about safety in clinical diagnostic Biosafety Level Laboratories 2, 3 and 4 (BSL2, BSL3 and BSL4) of L. Sacco University Hospital based in Milan (Italy), to encourage laboratory workers to think over safety issues while they are working and to stimulate the birth of a safety culture in biological laboratory. Guidelines to work safely in a contained laboratory were discussed and their implementations presented in details, analysing laboratory building, personal protective equipments and good laboratory practices, as well as how to face an accident or an emergency. Experts had also the possibility to visit both the cellular and molecular laboratories of a BSL2, BSL3 and BSL4 facilities. The laboratory visit and practical exercise consisted in donning the BSL3 and BSL4 suit and all the required PPE appropriately, in getting in the BSL3 and BSL4, where laboratory workers showed equipment and tools and explained in detail how to work safely in containment laboratories, using biosafety cabinets and appropriate protocols especially for decontamination of outgoing material (Fig. 5).

- *Biological Risk Assessment Methodologies* /Measurements and analysis of biorisk management system performance were mainly the Laboratory Biorisk Management through the AMP model (Assessment, Mitigation,
Performance). In particular, BioRAM, software for risk assessment developed by Sandia, and “What if” analysis, FMEA, FTA, HAZOP study were presented in detail as tools that can be used to assess biological risk correlated to a microbiological laboratory. The measures to mitigate the risk were highlighted as well, together with the methods to evaluate the performance.

- Module 4 “Accreditation, implementation and the CWA Standards”

- **Accreditation, implementation and the CWA/ISO Standards and A wide introduction to GMOs and GMO regulations** was a discussion and experience sharing among the experts from different countries. In particular, discussions focused on regulations already present in each countries, ISO, Standards and guidelines implemented and required for laboratory equipment and PPE. Moreover, Certification, Guidelines and Manuals used in Biosafety and Biorisk Management have been deeply analyzed, paying a particular attention to CWA15793 and ISO15190. The second part of this module was added to fulfil a request by the participants, emerged during module 1 and 2 attendance, and focused on Genetically Modified Organisms (GMOs) regulations and guidelines already present in each single country for the use of GMOs.

Concerning the National Participants’ training, National Experts, according to needs and specificities of their own countries, chose among the modules described above the ones that were more appropriate and interesting for their audience, tailoring the courses on local situations.

### 4 Project’s Added Value

Notwithstanding a number of trainings programmes already organised in the past and conducted in the four regions considered, the present project provided a significant added value in the bio-sector, based on the following four factors (Fig. 6):

(a) Regional and inter-regional coordinated approach;
(b) Demand-side and participatory approach;
(c) Holistic and multidisciplinary approach;
(d) Establishment of a sustainable training method.

(a) **Regional and inter-regional coordinated approach**

In line with the Centres of Excellence initiative, the project supported the development of capacities in a regional coordinated manner. The project developed and spread a common-ground of knowledge and expertise about bio-safety, bio-security and bio-risk management in the targeted regions. The training content, along with the involvement of stakeholders from different institutions and countries, contributed to stimulate networking, cooperation and strengthen synergies among...
the scientific communities and institutions, thus facilitating knowledge sharing and transfer of lessons learned at regional level. In order to maximise the networking and exchange of knowledge, the project relied on already established regional networks of local partners, well grounded in the targeted areas: this allowed to build on what has been already achieved and implemented and to further strengthen the regional networking, cooperation and mutual trust. The project promoted cross-fertilisation of ideas also across different regions. ICIS supported and foster exchange of knowledge, lessons learned and best practices beyond the regional boundaries, particularly through the e-learning platform.

(b) Demand-side and participatory approach

The regional and inter-regional coordinated approach did not prevent to keep into duly account also local specificities. In practical terms, training modules were tailored on the specific needs of each region and, as far as possible, country. As previously described, the assessment of local specific training needs was carried out according to a participatory demand-side approach. Such a method better addressed local specific needs, keeping into account their past experiences, the existing level of knowledge, the difference among institutes operating in bio-related issues (either private or public), thus ensuring both the ownership and sustainability of the project. This entailed, for example, the possibility to translate key training materials in local languages, especially in those countries where English is not widespread. The
participatory approach was also reflected in the ‘train-the-trainer’ method, which transforms the trained people from passive users to active actors in the process of knowledge exchange, putting the grounds to deliver training beyond the time span of the project.

(c) Holistic and multidisciplinary approach

This project addressed a wide variety of bio-related issues spanning from bio-related international and national legal aspects, bio-related environmental and ecotoxicological aspects, to bio-ethical aspects, accreditation, implementation and the CWA standards and laboratory bio-risk management. Through such a multidisciplinary approach, the project aimed at filling the knowledge gaps in the region and at maximising existing capacities and knowledge in different fields.

(d) Establishment of a sustainable training method

The sustainability of the project’s training method was ensured firstly by the train-the-trainers model, not new in most of the countries involved, which was complemented by a modern methodological tool for training, i.e. a web based e-learning platform. The platform constituted an interactive tool favoring the active participation of both trainers and trainees (e.g. through a Question/Answer section, virtual classrooms, live sessions, etc.) within the same region, but also across different regions. Through the platform, experts from different regions had the possibility to interact and confront each other on common experiences, so as to increase inter-regional cooperation and networking and the exchange of knowledge. Moreover, by making training materials available on-line before the start of intensive training courses in presence, the e-learning platform guaranteed a preliminary common ground of knowledge among all participants to the training courses in preparation for the subsequent intensive course, so as to maximize the effectiveness of training. The most important feature of the e-learning platform is that it remains available as a tool to experts, to continue using and updating it. In this way, the e-platform represents a concrete legacy of the project, which will continue to favor information sharing and will put the basis for the potential organization of further intensive courses (both theoretical and practical) ensuring, in this way, the long-term sustainability of the project, by generating further positive effects in the regions and also increasing the number of beneficiaries beyond the project’s direct users.

5 Lessons Learned

Basing on this experience, some lessons learned can be highlighted so that these could be useful for future similar projects, aiming at knowledge development, also not necessarily in the bio-field. It is of outmost importance to:

• Apply and foster real participatory approaches: this methodology requires time, patience and understanding of mutual needs and institutional structures. To
guarantee ownership and commitment, it is necessary to devote efforts and energy especially at the beginning of the project;
- Transfer the importance of a multidisciplinary approach and the importance of bringing together experts with different backgrounds;
- Stimulate the use of simple and, where possible, open source tools that don’t imply financial costs to be supported also after the end of the project, tailored on the users’ real capacities and needs; it is important to evaluate the opportunity to use IT tools and adapt them to the local situation, taking into consideration the difficulties some countries may face with the internet connection;
- Create tailored didactic tools and training sessions, considering local needs and priorities, the cultural background, the importance of the human factor and interaction among experts with different skills and experiences;
- Produce/translate didactic materials in local languages, which is also a very important element in terms of sustainability and impact, since these can be shared and distributed also to non-English-speaking experts;
- Enhance awareness raising on bio-related issues and support synergies among the scientific community and institutions within each country;
- Create an international network of experts, fostering knowledge sharing and best practice exchange within and among regions;
- Last but not least, remain constantly engaged in the biosecurity and biosafety issues and on the biorisk evaluation and metrics aspects, due to the continuous development of the life sciences.

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