



Extended Biosafety Advisory Group (BAG) meeting

Meeting Report

Geneva, Switzerland, 24-26 November 2014



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Abbreviations and acronyms

AFRO	WHO Regional Office for Africa
AMRO	WHO Regional Office for the Americas
BAG	Biosafety Advisory Group
BEP	United States Biosecurity Engagement Program
BMBL	Biosafety in Microbiological and Biomedical Laboratories (US Department of Health and Human Services)
BRM	Biological risk management
BRM-ATP	Advanced training programme in BRM
BRMS	Biological risk management systems
BSL	Biosafety level of laboratories – levels 1 (lowest) to 4 (highest)
BSL A	Biosafety level of laboratories with animal facilities
CARPHA	The Caribbean Public Health Agency
CBB	Centre for Biosecurity and Biopreparedness (Denmark)
CBRN	Chemical, biological, radiological, nuclear
CDC	US Centers for Disease Control and Prevention
CEN	European Committee for Standardization
CLSI	Clinical and Laboratory Standards Institute (US)
CPHL	Central public health laboratory
CWA	CEN workshop agreement
DEVCO	European Commission Development and Cooperation
EEAS	European Union External Action Service
eISST	Online refresher training in ISST
EML	European mobile laboratory
EMR	Eastern Mediterranean Region
EMRO	WHO Regional Office for the Eastern Mediterranean
EU	European Union
EVD	Ebola virus disease
FAO	Food and Agriculture Organization of the United Nations
GMO	Genetically modified organism
HEPA	High-efficiency particulate arrestance filters
IATA	International Air Transport Association

ICAO	International Civil Aviation Organization
IEGBBR	International Expert Group on Biosafety and Biosecurity Regulation
IFBA	International Federation of Biosafety Associations
IFBLS	International Federation of Biomedical Laboratory Science
IHR	International Health Regulations
InDRE	Institute of Diagnosis and Epidemiological Reference (Mexico)
IPT	Institut Pasteur Tunis
IPV	Inactivated polio virus vaccine
IS	International standard
ISO	International Organization for Standardization
ISST	Infectious substance shipping training
IVD	In vitro diagnostics
LAIS	Laboratory acquired infection survey
MERS-CoV	Middle East respiratory syndrome coronavirus
MSS	Management system standard
NE	National experts
NPHL	National Public Health Laboratory (Nepal)
NSB	National standards bodies
OIE	World Organisation for Animal Health
PAHO	Pan American Health Organization
PCR	Polymerase chain reaction
PHAC	Public Health Agency of Canada
PHLN	Public health laboratory network
PPE	Personal protective equipment
SARS	Severe acute respiratory syndrome
SBB	Biosafety and Biotechnology Unit, Scientific Institute of Public Health (Belgium)
SEAR	South-East Asia Region
SEARO	WHO Regional Office for South-East Asia
SOPs	Standard operating procedures
TC	Technical committee
TS	Technical specification
VDP	Vaccine-derived polio virus
WPV	Wild-type poliovirus

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Executive summary

The meeting was called to review progress under the WHO laboratory biorisk management strategic framework for 2012–2016, with its vision of “safe and secure environments in and around every laboratory in the world”, and to see how WHO could rationalize its input. Participants, including experts from international organizations, biosafety associations, technical partners, donor agencies, national agencies, and WHO offices, shared and discussed activities, improvements, challenges, research and future priorities in laboratory biological risk management.

Trainings in biosafety and biosecurity, such as workshops, online courses, training of trainers, mentoring and networking, were the predominant activities discussed. Other activities included laboratory design and maintenance, production of publications, assessment of laboratory capabilities, and, in the area of regulations, preparing decrees on toxins and pathogens, drafting a biosafety strategy, establishing a nationwide biosecurity system, and implementing a regulatory framework for pathogens.

Thus progress in developing sustainable global, regional and national plans relating to laboratory biological risk management is being made, as per the aim of the Strategy, but many challenges remain. Frequently mentioned challenges included shipping of infectious substances, dealing with infectious waste, and lack of awareness among policy-makers; others included insufficient resources, rapid staff turnover, maintenance of equipment, and lack of laws/regulations (e.g. requiring laboratories to implement a biosafety system).

Recent research indicates that, today, human factors play an important role in laboratory-acquired infections. Laboratory surveys for the years 2007–2012 in Belgium indicated the main group of incidents was caused by needle and cutting stick accidents, and *Shigella* was responsible for most instances. These are useful results and can be applied elsewhere. In Canada, reporting of laboratory-acquired infections is now mandatory under a new regulatory framework designed to strengthen biosafety in the country. The need for preparedness for infectious spills and needlestick injuries was mentioned often during discussions.

Another topic that arose often during discussions concerned the different levels of safety of laboratories. Level 3 facilities are very expensive to run, and it was felt important not to “overdesign” laboratories. Level 3 activities could be carried out in level 2 facilities with the right safety precautions/awareness etc. In the European Union biosafety level 3 laboratory used during the Ebola crisis in West Africa, the major biosafety concern is broken glass in samples.

An objective of the meeting was to discuss the possible conversion of CWA 15793 to an ISO deliverable. This Workshop Agreement is increasingly used as a key reference in international guidance documents and by international agencies, and data suggest there is support within the biological risk management community for its conversion; it can help improve overall biological risk performance, awareness, management, collaboration and evaluation. For conversion to an ISO deliverable, there would be a three-year development cycle.

WHO future priorities will include leadership and communication, identification of tools and methods to support implementation of biosafety and biosecurity best practices, competence development through facilitating access to training resources, and the setting of norms and standards including guidance on regulations for the transport of infectious substances and updating of the WHO Laboratory biosafety manual.

Introduction

An Extended Biosafety Advisory Group (BAG) meeting was held in Geneva from 24–26 November 2014 (for agenda, see Annex 1).

The objectives of the meeting included to:

- review the strategic framework for action 2012–2016, as formulated at the previous BAG meeting in 2010¹, redefining the roles and functions of WHO in the strategy given the Organization's current resources limitations;
- coordinate and exchange ideas with partners and stakeholders;
- share information concerning conversion of CEN CWA 15793 to an ISO deliverable; and
- consider how best to revise the WHO Laboratory biosafety manual², the current edition of which was published in 2004.

Participants (Annex 2) at the meeting included a mix of experts from international organizations, biosafety associations, technical partners, donor agencies, national agencies, and WHO and its regional offices. In welcoming the participants, Dr Florence Fuchs, Coordinator of Support to International Health Regulations (IHR) Capacity Assessment, Development, and Maintenance Unit spoke of the particular gap in laboratory capacity highlighted at a recent meeting on the IHR. She said that safe laboratories were essential for the IHR, but that many countries were far from achieving the laboratory capacity (among other capacities) required. It was hoped that, during this meeting, with its mix of technical agencies, international organizations and donor agencies, technical needs could be matched with resources.

¹ World Health Organization. Laboratory Biorisk Management: Strategic Framework for Action 2012–2016. World Health Organization; 2012 (WHO/HSE/2012.3; http://whqlibdoc.who.int/hq/2012/WHO_HSE_2012.3_eng.pdf?ua=1, accessed 26 January 2015).

² World Health Organization. Laboratory biosafety manual, Third edition. Geneva: World Health Organization; 2004. (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/, accessed 6 December 2014).

1. Review of the WHO Laboratory Biorisk Management Strategic Framework for Action 2012–2016 (five-year plan)

Dr Kazunobu Kojima of the WHO, Geneva, and the focal point of biosafety and biosecurity, led the review of the Strategic Framework for Action 2012–2016. The vision (“safe and secure environments in and around every laboratory in the world”) and the mission were still considered valid, although there was discussion over the term “biorisk management” and whether or not it was defined clearly enough. It was felt that in general there is confusion with the term, and that it might be more clearly defined as “laboratory biosafety and biosecurity management”. It is also not clear in the mission statement that “biorisk” consists of two aspects – safety and security.

With the aim of development of sustainable regional and national plans/strategies relating to laboratory biological risk management, WHO’s primary function as laid out in the five-year plan is to take a coordinating role (developing the framework; setting targets and indicators, and monitoring progress; identifying and coordinating needed resources; and identifying and engaging delivery partners). It was felt that WHO could still provide this leadership function, despite its limited resources.

The background section of the Strategy can be updated. At the present time, many countries remain without regulatory and oversight mechanisms, and levels of awareness are generally low among regulators and laboratory personnel. Laboratory design is often confusing, and may be questionable and lacking in evidence of its biosafety; all laboratory infections need to be looked into because they may not result from an engineering design fault but from a basic fault such as pipetting. Furthermore, many “solutions” require huge resources, and may not apply universally (e.g. basic maintenance provision and measures may not be available locally).

Considering the objectives of the Strategic Framework, all remain valid. However, in future, WHO would only be able to guide countries towards these (rather than maintaining this as a “primary” WHO responsibility). Research on biosafety is being carried out (in Canada and Belgium, described below) and the results/measures can be applied elsewhere.

Regarding the activities listed in the annexes of the strategic framework, many of these are still valid but may no longer be a priority.

Raised during the discussion was the point that perhaps it was time to stop training people on risk assessment and instead to provide mentorship. Thus laboratories would be given a bit more guidance in the beginning, and then gradually let go of through mentorship. Another point raised was that it was time to move beyond the guidelines of the last ten years and the training courses, and make biosafety and biosecurity mandatory and part of national legislation (as in Denmark).

The priority areas for 2015–2016 are found in section 13.

2. WHO regional office activities and strategies related to biosafety and laboratory biosecurity

The Region of the Americas

Dr Jean-Marc Gabastou, of the WHO Regional Office for the Americas, spoke of the continual threats being faced by this Region – including outbreaks of many tropical and other diseases (e.g. cholera, dengue, malaria, influenza, TB, HIV/AIDS, Chikungunya). At the same time, arrangements were being made for Ebola preparedness.

At the present time, the objectives for the Region are to implement and maintain good laboratory practices in laboratory services in order to strengthen patient care and surveillance. This is undertaken through e.g. training and technology transfer, and promotion and support of networking.

Achievements include the international substance shipping training (ISST) of more than 500 professionals (since the year 2000), production of anthrax standard operating procedures (SOPs) (in 2001), workshops on biosafety (2005–2006), and trainings on disinfection and maintenance of biosafety cabinets (2001–2002).

Advanced trainer programmes in biological risk management have been conducted since 2011, and replicated by and within countries, as in the Caribbean where there has been regional training on waste management, and replications of biological risk management (BRM) and ISST trainings.

A focus at the current biennium (2014–2015) is on laboratory design and maintenance, in conjunction with the US Centers for Disease Control and Prevention (CDC), and projects are ongoing in a number of countries.

Other activities include production of publications (e.g. Manual de mantenimiento para equipos de laboratorio); a fourth edition of the WHO Laboratory biosafety manual is needed.

Biosafety level 3 (BSL3) facilities are now available in the Caribbean (one BSL3), Argentina (a BSL3 and a BSL3A for animal facilities) and in Mexico (at InDRE).

A sampling kit for emergency situations and outbreak containment is available for water-borne and air-borne organisms, each module with personal protective equipment (PPE).

Work is also ongoing with CDC for Ebola virus disease (EVD), the EVD WHO Collaborating Centre in the Americas, and with the Public Health Agency of Canada (for zoonotic diseases and special pathogens).

Challenges in the Region include training, waste management, and networking. Particular needs are for: more integration with vertical programmes and the IHR, procedures to validate BSL3 processes, consolidation of the eISST in Spanish, and, most of all, for establishment of a global agreement for shipping of infectious substances. Although in principle the process for shipping of samples in category A works, a global agreement is needed because unless shippers are certified samples cannot be shipped outside a country.

The Eastern Mediterranean Region

Dr Humayun Asghar, of the WHO Regional Office for the Eastern Mediterranean, mentioned that this WHO region spans North Africa and South Asia and is very diverse. Threats faced in the Region are from biosafety, biosecurity, and bioterrorism, as well as from influenza, Middle East respiratory syndrome coronavirus (MERS-CoV), EVD, polio, etc. The vision of BRM in the Region is of a safe, secure laboratory environment, producing reliable and timely results for use in public health laboratories.

Two countries are highly endemic for polio, and three countries have been re-infected since 2013, and one country had circulating vaccine-derived polio virus (VDPs) during 2013. This situation is due to war and conflicts in the Region, thus the term “biosafety” can apply in situations other than laboratories (e.g. geographical).

Some of the countries cannot afford even basic biosafety, and samples cannot be shipped from the countries. Of the 23 countries in the Region, six are not covered by any carrier company, and for Ebola there is no shipping capacity.

Facilities and capacities in diagnostics are not evenly distributed across the Region. Central public health laboratories (CPHL) are the typical laboratories with ability to support diagnostic activities, despite constraints due to ownership, coordination, manpower, and finances. At the present time, there are two BSL3 laboratories in the Region. Shipment of samples is always a problem.

Challenges to BRM include ownership (inadequate support from higher authorities) and implementation gaps (in manpower, financial support, equipment, shipping, information and data management). Competent manpower goes abroad, so that, although the Region has the manpower, it does not have the competency.

Achievements in BRM include the large number of people trained in the biorisk management advanced trainer programme (BRM-ATP) and in ISST. Trainings in ISST have been taking place in the Region since 2007, and trainings in awareness, BSL3 practice, BRM-ATP, biosafety etc. since 2009. In 2014, BRM-ATP trainings were undertaken in five countries, and ISST national training workshops were held in six countries. However, the training is not sustainable due to high staff turnover. Only 40% of trainees have trained other staff nationally, and the ISST licenses are expiring.

So far, what is missing is a culture of BRM, and awareness of policy and decision-makers, sharing of the concept with the community and civil society, and communication of the scientific community. In future, European Commission Development and Cooperation (DEVCO) funding will be used to facilitate awareness meetings for policy and decision-makers, physicians, etc., and for national assessments, ISST, BRM guidelines development. The way forward includes serious investment in BRM, an advocacy plan to create awareness, mapping of donors to avoid duplication, national rather than regional activities, addition of BRM to laboratory technology teaching curricula, and networking and twinning.

The European Region

Dr Eugene Gavrilin, of the WHO Regional Office for Europe, mentioned that the Region has 53 Member States of diverse sizes, populations and economies, and is the WHO region with the highest number of WHO collaborating centres.

The main areas of work are on: the emergence of new or newly recognized pathogens (e.g. Ebola, Marburg, severe acute respiratory syndrome (SARS) and other novel coronaviruses); the resurgence of well characterized outbreak-prone diseases (e.g. cholera, dengue, measles, poliovirus, yellow fever); and the potential release (accidental or deliberate) of a biological agent (e.g. smallpox, SARS, anthrax, poliovirus).

Regional office activities cover the networking of laboratory personnel, including through an annual laboratory network meeting. A time-consuming activity is the accreditation each year of 150 laboratories (mostly public health laboratories) through on-site assessments. Other activities comprise hands-on biosafety trainings, mostly at BSL2 level, sometimes at BSL3 (not BSL4), and other trainings such as BRM and ISST. A biosafety video course of six modules (disinfection, autoclaving and waste management; laboratory infrastructure; personal protective equipment; emergency procedures; training; laboratory equipment and maintenance) has been created.

Future activities will include continued collaboration with the State Research Center of Virology and Biotechnology (VECTOR) in Russia, and containment of wild poliovirus (WPV). There are inactivated polio virus vaccine (IPV) production sites in operation in Belgium, the Netherlands, France, Denmark and Sweden. Between 2010 and 2013, around 22 countries of the Region had WPV, while the number of laboratories dealing with WPV decreased from 146 to 65.

A better laboratory incident reporting mechanism is needed. Laboratory incidents reported for 2011–2013 by the US Army Medical Research Institutes for Infectious Diseases (USAMRIID)³ indicated that, in BSL3 laboratories, incidents were often due to spills, leaks, abrasions and lacerations, and only sometimes due to equipment malfunction. In BSL4 laboratories, incidents were mainly due to mishaps with positive pressure encapsulating suits and gloves. The risk is always there, but is small compared to the benefit.

Needed also are studies on synthetic biology security, microbial forensics, and open-source intelligence (OSINT) on chemical, biological, radiological, nuclear (CBRN) operational capability and motivation.

Terrorism has changed. Today weapons of mass destruction (WMD), horizontal as opposed to conventional hierarchical networks, and indiscriminate targeting are being faced. Thus multidisciplinary collaboration of state and non-state actors is needed.

³ <http://www.usamriid.army.mil/biosafety/>

The South-East Asia Region

Dr Aparna Shah, of the WHO Regional Office for South-East Asia, said that this WHO region has 11 Member States, including 6% of the global land mass, 25% of the global population, and 30% of the global disease burden. Laboratories get low priority within the health services, and safety concepts are minimal in public health laboratories. Communicable diseases pose enormous challenges; emerging infectious disease (EID) outbreaks and risks in recent years have included avian flu, SARS, Nipah, multidrug-resistant tuberculosis (MDR-TB), pandemic flu H7N9, MERS-CoV.

The trigger for safety awareness was the three laboratory acquired SARS infections in 2003/4, an incident which drew international attention to the issue of laboratory biosafety. The IHR came into force in 2007 to develop core capacities to prevent international spread of disease, and an Asia Pacific Strategy for Emerging Diseases (APSED) was developed.

The major issues in health laboratories in the Region include the often limited public health laboratory capacity, the lack of laboratory policies and plans, of national frameworks of health laboratories, of new technologies, of resources, of systematic assessment of laboratory quality and biosafety, of continuous supply of reagents, and of resources, as well as limited access and inadequate biosafety–biosecurity awareness and practices.

Thus the picture in South-East Asia Region (SEAR) countries is one where safety awareness and good laboratory practices worsen from central to peripheral laboratories. There is lack or limited availability of training on biosafety, officers in biosafety, guidelines on biosafety, regular safety inspections, waste management, appropriate immunization of laboratory personnel and health and medical personnel, certification of biological safety cabinets, documentation on safety errors and laboratory acquired infections, PPE, coordination between stakeholders in the planning and construction of BSL3 and BSL4 facilities, regional and national associations, and of dedicated national funds.

However, as reported under the IHR, the biosafety/biosecurity situation in the Region does not appear too bad (according to 2011 monitoring data), but these data are self-reported and can be subjective.

Priorities in terms of biosafety, laboratory biosecurity and biological risk management vary substantially from country to country. In five Member States there are BSL3 laboratories, and India has a BSL4 laboratory. Most of the countries have BSL2 laboratories.

WHO support includes training in biosafety and biosecurity, on-site assessments, help to develop SOPs and guidelines, International Air Transport Association (IATA) and cold chain management packaging and shipping training, and distribution of supplies and PPE.

Achievements by some countries include the increasing awareness and involvement of national policy-makers, national laboratory policy which includes a biosafety component, a biosafety assessment committee, development of BSL2 and BSL3 facilities, laboratory safety inspections, biosafety and biosecurity associations to foster biosafety and biosecurity practices, biosafety trainings and use of PPE, biological waste management, good laboratory practices, and infection prevention and control (IPC) guidelines/trainings.

The way forward includes further advocacy and awareness creation for development of national policy and allocation of resources; technical support for policy development and implementation, trainings, guidelines; independent reviews/appraisals; and networking and collaborations.

3. Activities and initiatives of other institutions and organizations

US Centers for Disease Control and Prevention (CDC)

Ms Cristina Bressler, of the CDC Office for Environment, Safety and Health Compliance, mentioned that this office had recently been restructured; there are two occupational health and safety specialists.

The CDC international programmes currently operate five laboratories worldwide with an approximate workforce of 130 laboratory staff (who work for CDC). Activities internal to CDC include training of its laboratory staff, laboratory advisors and partners on the essentials of biosafety, infectious substances shipping, biological risk assessment, etc., with hands-on scenarios. Further training for staff is on the use, maintenance and basic design of biological safety cabinets, and on BSL3 scenarios (design, PPE, spills, emergencies, waste management/autoclave safety). For global health security, CDC provides biological risk consultation and training in 18 countries where the CDC Center for Global Health is actively working⁴. Provision of consultation in partnership with the US Defense Threat Reduction Agency will begin in 2015.

External biosafety activities of CDC include the co-sponsoring of a biennial CDC International Biosafety Symposium, which provides biosafety/biological risk professionals with the latest information, and the co-editing of Biosafety in Microbiological and Biomedical Laboratories (BMBL), the US national biosafety guidance document. As well, CDC participates in US government working groups, including in the Inter-Agency Biorisk Management Work Group (Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response), the Federal Experts Security Advisory Panel (FESAP), the Beyond the Border Bi-National Working Group with Canada, and the Agriculture Research Service's (USDA/ARS) Biosafety and Biocontainment Symposium Steering Committee.

International projects are being undertaken in Asia. In Cambodia, ongoing work includes mentorship in BRM to a group of biosafety professionals, and technical assistance to address biosafety gaps identified by CDC Quality Management subject matter experts in 2013–2014. This work is coordinated with CDC-Thailand. In Oman, consultation is ongoing on development of a new central public health facility for regional training in biosafety and biosecurity, in collaboration with the Sultanate of Oman Ministry of Health. The workshop training is in three stages and started in October 2014 with tier 1 (design and construction, waste management, bloodborne pathogens, risk assessment); tier 2 (biosafety cabinets, ISST, preparation of a biological risk manual) is scheduled for 2015. In India, similar consultation as in Oman is ongoing, with similar biosafety and biosecurity training, to begin in 2015, provided through the three-tiered workshop agenda in collaboration with the Sultanate of Oman Ministry of Health and coordination of activities with CDC-India (Global Disease Detection).

Recent biosafety and biosecurity activities in conjunction with WHO (mostly with PAHO) include: participation in BRM and ISST trainings in the Americas (e.g. in Chile, Panama, Peru), and translation (into Spanish) and reviewing of BRM texts (e.g. translation of the Responsible Life Sciences Research (RLSR) global health security document).

⁴ Vietnam, Kenya, India, Uganda, Côte d'Ivoire, Ethiopia, Tanzania, Cameroon, Democratic Republic of the Congo, Nigeria, Senegal, Indonesia, Bangladesh, Philippines, Pakistan, Myanmar, Mali, Burkina Faso

Food and Agriculture Organization of the United Nations (FAO)

Dr Gwenaëlle Dauphin, of FAO, said that this Organization does not have specific standards or frameworks on biological risk management, and for overall guidance uses the World Organisation for Animal Health (OIE) standards and the WHO Laboratory biosafety manual.

The Organization has its network of high containment laboratories for foot and mouth disease, rabies, H5N1 (veterinary biosafety), rinderpest. For zoonotic influenza, funding is now reduced but many laboratories are being maintained, often without capacities. Along with OIE, WHO and the US Agency for International Development (USAID), FAO is involved in a strengthening laboratory capacities and networking project.

Some of the FAO reference centres are now being designated Centres in Biorisk Management. The aim is to assist in developing strategies etc., especially in developing countries, and to advise on key technologies. A laboratory-mapping tool is used to assess overall laboratory strengths and gaps, and to generate a profile; this tool may be expanded into a practical biological risk module.

FAO has endorsed the Global Health Security Agenda, in which WHO and public health laboratories are partners, and has links with US agencies.

Activities in the Congo Basin have included assessment of 12 laboratories (scores 0%–83%), and trainings, including on equipment maintenance. Many laboratories are trained for H5N1, complemented with biosafety training. FAO also gives on-site assistance e.g. with BSL cabinets, and will look at laboratory network platforms.

FAO in South and South-East Asia:

Dr Stuart Blacksell mentioned that he is the only person with FAO dedicated for biosafety in South and South-East Asia. The FAO S/SE Asia Regional Biosafety Program is part of a larger regional network, for which the objective is to enhance the quality of biosafety management and practices in laboratories, and to ensure maintenance of equipment and access to essential biosafety supplies.

In 2012–2014, activities included on-site assessments of laboratory capabilities using the FAO laboratory-mapping tool, which gives an estimate of capability, in which biosafety and biosecurity is just one category. For assessing specific needs in biosafety management, the BMBL checklist is used.

FAO has 21 regional network laboratories in 11 countries in Asia (including 10 laboratories in Indonesia), varying from BSL3, required e.g. for foot and mouth disease, to small provincial laboratories with basic capabilities. Since 2012, a median increase in laboratory mapping scores over two visits has occurred, of about 9% in the overall scores (110 questions in 18 categories), including, in the area of biosafety, an increase of about 30%.

Looking at different levels of biocontainment, the reality is that most laboratories have barely level 2 facilities, and thus BSL2 minimal standards with level 3 work practices are recommended, where appropriate. BSL3 laboratories are discouraged as they are difficult to maintain. Most laboratories have a dire need for biosafety administration (including e.g. manuals, SOPs, risk assessments). Biosafety administration and management still lacks prominence and importance among managers of laboratories. The Regional Laboratory Network for Training of Trainers held a workshop in biosafety management, and in December 2013 a hands-on biosafety course for managers was held in Thailand, with IATA dangerous goods training and certification for successful trainees.

Where FAO works, the needs for biosafety awareness and training are fairly universal. Therefore FAO provides training with training-of-trainers components, so the participants go back home and train. So far there have been five two-day biosafety trainings.

Infectious waste is the biggest issue – how to deal with carcasses and sharps etc. FAO purchased autoclaves, and a system to make sure these are working correctly. Robust SOPs are in place, and the Organisation provides advice on equipment e.g. incinerators and biosafety cabinets. The testing programme for biosafety cabinets is three years old. At first (2011), nearly one third of cabinets failed, but by 2014 (192 cabinets tested by the manufacturer ESCO), only 12.5% failed. One of the major issues is dust, which blocks the supply filters. Some cabinets are not fit for the purpose (horizontal air flow type), or are of poor design (e.g. do not offer suitable protection to the user). In case of loss of electricity, uninterruptable power supplies (UPSs) for biosafety cabinets are recommended; these allow six minutes for the cabinet to shut down safely and have been purchased for a number of laboratories.

Regarding the many types of PPE, FAO has tried to standardize their sourcing, and training in their use.

Needed is preparedness for infectious spills and needlestick injuries, and for equipment failure. SOPs have been developed, and training provided, and spill kits recommended for all laboratories. In future, activities will continue to address biosafety gaps in assessment of laboratories, training, translation of biosafety resources into local languages, certification, purchasing of biosafety consumables (e.g. PPE), and developing a generic regional medical surveillance programme.

Impacts of the S/SE Asia Regional Biosafety Program are seen in the risk assessment of laboratory procedures with a biosafety focus, and in the provision of a safer working environment for laboratory staff and surrounding people/environment. There is improved personal awareness of the importance of biosafety including personal protection strategies, and knowledge has been created on mechanisms for biosafety administration. Infectious waste disposal processes have been validated, emergency procedures have been developed, and independent assessment of laboratory capabilities using the laboratory-mapping tool has been conducted.

The World Organisation for Animal Health (OIE)

Dr Keith Hamilton said that this intergovernmental organization (which is not part of the UN system) was formed for veterinary services in 1924, to improve animal health. The headquarters is in Paris; there are 180 member countries in 2014, and 12 regional and subregional offices.

The Organisation develops standards for surveillance and disease reporting, biosafety and biosecurity, to detect, control and prevent spread of disease. These cover the most important diseases for animal health and zoonotic diseases.

A biological threat reduction strategy⁵ was developed, and published in 2012, to respond to potential deliberate releases of animal health diseases and zoonoses. The strategy focuses on strengthening and enhancing cross-linking between existing health systems. An OIE Global Conference on Building Capacity to Reduce Biological Threats through Stronger and Integrated Health Systems will be held in 2015 in France.

⁵ OIE Biological threat reduction strategy – strengthening global biological security. World Organisation for Animal Health; 2012 (http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/A_Biological_Threat_Reduction_Strategy_jan2012.pdf, accessed 26 January 2015).

For biosafety and biosecurity, resources include the OIE manual of diagnostic tests and vaccines for terrestrial animals, which contains standards for diagnostic tests, for manufacture of safe, potent and effective vaccines, also for sample collection, shipment and biosafety and biosecurity. The biosafety and biosecurity guidance in this manual has recently been updated. Two chapters on sample collection and transport were updated and adopted in 2013, and, at the OIE general session in May 2014, a new chapter on standards for managing biological risk was adopted, bringing OIE standards into line with a risk management approach also reflected in the CEN workshop agreement (CWA).

The risk analysis process proposed in the new chapter broadens the focus of the biosafety and biosecurity approach, which traditionally has been on characteristics of the biological agent. The broadened focus also takes into consideration the health and economic consequences of an exposure or release, and laboratory infrastructure, resources, proposed activities, and appropriate control measures. Currently there are two chapters (one on biosafety and biosecurity and based on use of the traditional checklist for inspections, and one on assessing and managing biological risk); the plan is to merge the two chapters and put the new chapter up for adoption in 2015. Many threats are not a threat to human health (e.g. foot and mouth, for which measures in non-endemic countries are more stringent).

Capacity building activities mainly serve to help countries comply with standards, so veterinary services are being improved to respond to anything (not just to one disease). There is a twinning programme for laboratories working on specific diseases or topics; quality assurance, biosafety and biosecurity are integral to all projects.

The network of OIE reference laboratories also gives advice on biosafety and biosecurity related to their specific diagnostic capability, and the OIE collaborating centres provide technical support.

International Federation of Biosafety Associations (IFBA)

Ms Michelle McKinney (of IFBA) explained that this international non-profit organization partners with biosafety associations to strengthen global biosafety. Established in 2001, today it has over 60 members worldwide, and observers. The latter include governments and academia (e.g. biosafety professionals, scientists, laboratory technicians, doctors, veterinarians, academics, architects, engineers, managers); they are critical to the organization.

The main goal is to improve biosafety capacity in terms of fighting against emerging infectious diseases because the capacity to safely conduct routine diagnostics and surveillance is limited in many countries.

While considerable effort has gone into improving health services in many regions of world, much of the focus has been on specific disease control programmes (e.g. HIV/AIDS), with attention only being paid to biosafety in times of crisis. Biosafety is not generally recognized as critically important within the greater framework of strengthening global public health. In 2011, a stakeholders' conference created a declaration of the IFBA main focus and strategic plan, with the mission statement of "safe, secure and responsible work with biological materials", and the vision of becoming the global resource for biological risk management.

IFBA's role is to advocate at international level, promoting best practices etc., while national and regional associations work at national level to adapt biosafety guidelines and solutions to the local context.

Laboratory technicians and biomedical scientists have a crucial role in biosafety for their institutions. Thus the IFBA has a memorandum of understanding with the International Federation of Biomedical Laboratory Science (IFBLS), and e.g. links local members from the Cameroon Biological Safety Association (CamBSA) with IFBLS.

Through national biosafety associations, the IFBA works with local Stop TB partners in the area of TB biosafety. A key priority is “risk-based and sustainable engineering solutions for TB laboratories”.

The IFBA has also supported WHO efforts in Africa with regard to improving the quality of public health laboratories to achieve ISO 15189 standards. The Organization engages with local members and partners in implementation of the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) safety components, and reaches into the security community, working with Interpol in cross-training and creating linkages between security and public health laboratory communities to ensure collaboration in dealing with biological materials.

In helping to bring together law enforcement, biosafety and public health communities, to enable quick and effective response to bioterrorism events, clandestine laboratories and other emergencies, a series of workshops was held, in the Middle East, Africa, Central Asia, Southeast Asia, South America, to identify gaps in capacities and opportunities to fill the gaps.

Among the challenges in resource limited countries are the costs of building and maintaining facilities. Laboratory space (especially BSL3) is very expensive to build, operate and maintain, and working in this level of laboratory is less efficient (e.g. requires protective clothing, entry/exit procedures, medical surveillance), so it is important not to “overdesign” laboratory facilities. The IFBA Biocontainment Engineering Working Group (BEWG), which consists of a variety of professionals (scientists, biosafety professionals, architects, engineers, facility maintenance staff, equipment manufacturers) from around the world, is looking for risk-based practical solutions to laboratory infrastructure that can be cost-effectively sustained in the long term.

IFBA works with the International Standards Organization (ISO) in building biological risk management capacity. IFBA applied for Liaison Status with ISO to provide technical input from its worldwide members, and can work together with IFBLS to implement CWA 15793 at local level.

Because of the mix of skills and competencies generally found in biosafety and biological risk management, IFBA has been working, since 2010, on a new certification programme for laboratory workers and professionals engaged in biosafety and biosecurity activities. Stakeholder consultations identified two priority technical disciplines for 2014: basic biological risk management and biological waste management. Further priority certifications to be developed in 2015 are on: biocontainment laboratory design and maintenance, programme management, laboratory biosecurity, animal biosafety, and biological safety cabinets. The Biological risk Management Professional Certification was launched in November 2014; 31 individuals⁶ completed the exam. It is anticipated to launch a web-based programme in December 2014. Among the benefits of certification can be mentioned recognition of competence, maintenance of biosafety and biosecurity in the laboratory, and the increased credibility and influence individuals gain as experts in this field.

Thus the IFBA community complements all other efforts by governments and other stakeholders. in strengthening global biosafety, helping to bring a variety of technical experience to the table together with practical, local solutions that can be sustained in the long term.

⁶ from Indonesia, Malaysia, Singapore, Korea, Pakistan, Georgia, Morocco, Australia, New Zealand, USA, Mexico

National Institute for Public Health and the Environment (RIVM), The Netherlands

Dr Marja Agterberg of the Netherlands Biosecurity Office⁷ explained that this Office is an information centre, founded by the Government of the Netherlands in 2010. The Office supports the Government in developing biosecurity policy and knowledge concerning the handling of human, animal and plant pathogens. Coordination is among six ministries: of Infrastructure and Environment; Economic Affairs, including Agriculture; Education, Culture and Science; Security and Justice; Health, Welfare and Sport; Social Affairs and Employment.

A biosecurity policy in the Netherlands is currently being sought in order to raise CBRN resilience in vital infrastructure in the Netherlands, and in hospitals.

There is no Dutch regulation for biosecurity. It is voluntary, and the Government wants to extend existing regulation, and to integrate biosafety and biosecurity.

Activities of the biosecurity office include education and creation of awareness, and development of tools. Workshops are held in schools and universities, and a biosecurity toolkit⁸ has been developed, with eight biosecurity pillars (e.g. awareness, management, information) and up to ten questions in each pillar.

4. Country perspectives, priorities and realities

Region of the Americas: Mexico

Dr Carindha Franco Delgadillo, of the Institute of Diagnosis and Epidemiological Reference (InDRE), explained that implementation of biological risk management systems (BRMS) in Mexico's national network of public health laboratories is promoted and evaluated through two initiatives, one public and one private.

InDRE leads the public initiative. This organization generates information on epidemiological surveillance for public health policy, and coordinates the 31 laboratories in the public health laboratory network (PHLN). It provides diagnostic services, human resources training, evaluation and research expertise and undertakes technological development.

The Mexican Association of Biosafety A.C (AMEXBIO) leads the private initiative. This initiative promotes sharing of experience and education in biosafety among scientists, coordinating with both domestic and foreign organizations, and participates in the design of studies on biosafety. It also finances investigations into finding solutions to the problems of biosafety in Mexico.

The main strategies used by InDRE to promote biological risk management include training and advice, evaluation of technical competence in diagnostics, and financing of public health actions. The main difficulties encountered in implementing include staff turnover in laboratories, recent political changes, lack of a specific law that requires laboratories to implement a biosafety system, and the minimal or nonexistent budget.

Altogether since 2008, InDRE has trained about 900 personnel in workshops on biosafety and biosecurity, biological risk assessment, basic biosafety laboratory practices, and transport of infectious substances. Evaluation of these efforts to share biosafety issues to the national PHLN was undertaken in 2013. While more than 60% had an updated inventory of biological materials, and datasheets on biological safety, and a person responsible for managing

⁷ www.bureaubiosecurity.nl/en, accessed 26 January 2015.

⁸ <http://www.bureaubiosecurity.nl/en/Toolkit>, accessed 26 January 2015.

biohazards, and 70% had documentation of biosafety and biosecurity processes, less than 20% had risk assessment methodology.

As well as training, InDRE's priorities include aligning laws and regulations to the concepts of biosafety and biosecurity, and establishing national regulatory positions e.g. biosafety officer and biological risk manager to promote and take responsibility for implementing the BRMS. Other priorities are to promote the use of the BRMS in biological risk assessment, establishing mitigation control measures, and to set up a biological risk management committee to develop/rethink plans for implementation of biological risk management systems in the laboratories.

InDRE works closely with the national authorities. The Mexican Official Standard (NOM-107-SSA2-2012) establishes the criteria, specifications and guidelines for operation of the national epidemiological surveillance system. Under section 11, on the national reference laboratory and the national network of public health laboratories, paragraph 11.8 states that laboratories of the PHLN must establish a biological management system in order to ensure biosecurity of staff, custody of valuable biological materials and environmental care. This is a slightly different concept to what is needed in BRM.

A working paper on guidelines for a biological risk management system in PHLN, and other guidelines applicable to the PHLN, are available⁹.

Region of the Americas: the Caribbean

The Caribbean Public Health Agency (CARPHA) is an institution of the Caribbean Community (CARICOM) established by inter-governmental agreement in 2011 and operational since 2013. Ms Sacha Wallace-Sankarsingh (of CARPHA) said that the Agency's many core functions include health emergency preparedness and response, laboratory reference and referral services, resources mobilization, and human resources development and training, as well as surveillance, information and communication, research, policy development and evaluation. Its many priorities include infectious diseases and IHR, as well as noncommunicable diseases, injuries and violence, environmental health, tourism and health, and regulation of medicines.

CARPHA biosafety and biosecurity activities include workshops on ISST and biological risk management for the laboratory. In 2010–2012, two regional and seven national workshops were held in conjunction with the Caribbean Epidemiology Centre (CAREC)/PAHO; since 2013, two sub-regional and three national workshops have been held.

CARPHA is the implementation arm for region-specific activities under the WHO/PAHO project on capacity building for biosecurity and disease surveillance in the Caribbean and Central America. To respond to States needs, CARPHA is strengthening its capacity by implementing a modular BSL3 laboratory (donation agreement with the Global Partnership Programme, Foreign Affairs, Trade and Development (DFATD), Canada).

Priorities include compliance with IHR core capacity requirements, sustaining of existing capabilities in laboratories and enhancing of capacity to provide quality laboratory services, access to laboratory services for the identification of potential high risk pathogens, and movement of samples to reference and referral laboratories.

Challenges include the constant need for training and retraining, maintenance of laboratory equipment, waste management, and access to courier services for transport of category A infectious substances.

⁹ http://www.indre.salud.gob.mx/interior/publicaciones_tecnicas.html, accessed 27 January 2015.

Eastern Mediterranean Region: Jordan

Dr Ghaya Abdellatif Alwahdane, of Jordan's Central Public Health Laboratory (CPHL), said that this Laboratory is under the authority of the Hospital Directorate, with its own structures. It provides public health information and data to policy-makers, and proposes technical regulations and laboratory protocols to peripheral public health laboratories. CPHL acts as a reference laboratory for special, confirmatory tests and new diagnostic laboratory techniques and researches.

The CPHL plan for surveillance and response has the objectives of providing accurate and reliable information and timely communication of laboratory results, and ensuring full compliance with biosafety instructions and guidelines throughout laboratory operations.

The laboratory directorate considers laboratory biological risk management as important as the accuracy and timeliness of laboratory results. Activities in biological risk management (BM) began immediately after the biological risk management workshop in Amman organized by WHO for seven EMRO countries in 2010. A workshop in BM to select trainers was conducted, and three selected as BM officers. A training-of-trainers workshop was conducted for the Eastern Mediterranean Region (EMR) in 2013.

A biological risk management unit has been introduced into CPHL but is still to be approved by the Ministry of Health. Many people have now been trained under the biological risk management training programme; in 2011–2012, four workshops for laboratory technologists were conducted, and the trained technologists officially nominated as part-time BRM focal points in their laboratories. A job description for BRM focal points (officer) was developed, as well as guidelines, implementation checklists, SOPs, a biosafety manual (yet to be revised and authorized). A biological risk management team from the laboratory directorate conducts regular field visits to monitor and assess implementation of the biological risk management guidelines. So there are officers and a kind of BRM skeleton now.

Similar challenges to BRM implementation are being encountered as found in other countries, e.g. resources, training, maintenance.

There are legislations regulating biosafety issues, e.g. in public health (by laws of licensing of private laboratories and private hospitals, conducting pharmaceutical research, managing medical waste), and in environment protection (by laws of protecting the environment and water and air from contamination, and of managing solid wastes).

The BRM plan includes establishing a national training team (staff turnover is a challenge), holding BM workshops for decision-makers, training and assigning BM focal points in each private hospital laboratory, creating awareness through production of a newsletter, including BRM in the university teaching curriculum, and for Jordan to become a leading BRM training centre in EMR.

Eastern Mediterranean Region: Tunisia

Dr Sana Masmoudi of the Pasteur Institute, Tunis, described the five main projects ongoing under the Biosafety Strategy and Project in Tunisia.

Through the Cartagena project, 2007–2014, a national biosafety framework for Tunisia is being implemented. The first stage of the project concerned genetically modified organisms (GMO), the second stage, toxins and pathogens. There are many objectives, including implementation of a harmonious and effective biosafety system, integration of biosafety into a national development strategy, promotion of public awareness and participation, and preparation of training guides and manuals.

Outputs have included preparation of the biosafety strategy, and training and guidelines on regulatory regime, as well as a decree (recently approved) to create a national authority on biosafety for GMO, and a draft decree for toxins and pathogens. Methodologies for risk management based on the draft regulatory regime have been prepared, as well as biosafety office user manuals.

Outputs in monitoring and enforcement include preparation of methodologies/procedures and training guides, creation of a national laboratories network for GMO detection and quantification, and training sessions on detection and control of GMOs.

To create public awareness, biosafety meetings have been organized and a commission of communication and public awareness created. Training guides and related materials have been published, and there has been training and capacity building of the different stakeholders involved.

The European Union (EU) CBRN CoE Project 3, 2012–2014, taking place within the framework of the EU CBRN initiative¹⁰, involves 24 countries belonging to four regions worldwide. The goal is to promote sustainable knowledge development on biosafety, biosecurity and biological risk management, and transfer best practices through training of trainers. The project also works to harmonize international biosafety and biosecurity standards among participating countries and to strengthen regional and international collaboration.

In the first stage of the project, selected national experts (NEs) were trained in biosecurity, biosafety and biological risk management. Selected and qualified NEs are now training further national experts. An e-learning platform is to be provided to deliver distance learning materials and to support the training of NEs and national participants. The original seven NEs in Tunisia aim to train about 40 others in the country by March 2015, who will then become local trainers.

The German Partnership Program for Excellence in Biological and Health Security will realize partnerships in more than 18 countries within the next three years, and Tunisia is identified as a priority country. Commitment for cooperation with the German Biosecurity Program was confirmed in June 2014. The biosafety and biosecurity, and detection and diagnostics teams, identified the Institut Pasteur Tunis (IPT) as a priority partner¹¹. The experts intend to work with different IPT units on improving BSL3 laboratory capacities, biosafety, and diagnosis of highly pathogenic viruses, as well as on procurement and training. This project will start in 2015.

¹⁰ initiative by the European Commission's Joint Research Centre (JRC) and the United Nations Interregional Crime and Justice Research Institute (UNICRI), under the aegis of the European Commission's Directorate General for Development and Cooperation – EUROPEAID (DG DEVCO) and the European External Action Service (EEAS).

¹¹ along with Direction des Soins de Santé de Base (DSSB), the Observatoire Nationale des Maladies Nouvelles et Émergentes (ONMNE), the WHO Regional Office, and the Unité des Laboratoires Biologie Medicale (ULBM).

Another project is undertaken with WHO cooperation, which has supported a number of training sessions, e.g. a team of 15 national biological risk management trainers was trained in June 2014. These trainers are now training healthcare staff.

The BioProtech project, supported and funded by the European Commission, aims, among other things, to improve research capacities in bio-processes for biotech applications in line with the European research area. The support will be organized in six work packages covering the technological aspects of bioprocesses (fermentation, microarray and biosafety). To achieve the objectives, five European partners have been selected who are highly qualified and specialized in each of the topics. The results will support local economic development through creating new or supporting existing high-tech companies and more scientific collaborations with the EU.

European Region: Denmark

Dr John-Erik Stig Hansen of the Centre for Biosecurity and Biopreparedness, Copenhagen, described how, within four years and using relatively few resources, a nationwide biosecurity system was established in Denmark, a country where no such system or legislation had previously existed. This was achieved as follows.

An audit conducted in 2006, to investigate the extent of biosecurity measures implemented in the absence of formalized security standards and legislation, revealed that although some measures had been taken, especially in the private sector, it would have been fairly easy to remove sensitive biological agents unnoticed, especially from public facilities such as universities. Therefore a law – the Biosecurity Act – was passed in 2008, forming the basis for an executive order (981) in 2009, in compliance with UN Resolution 1540 (that mandates any nation to have in place effective measures for domestic control of any biological materials that might be used for biological weapons). Today a license from the centre is needed before any work on certain biological agents and toxins can be undertaken.

The biosecurity legislation also covers information from research that has the potential for misuse, which is also something that UN Security Council resolution 1540 has explicitly included as an obligation for all states.

In addition to laws, a knowledge base has been established through examining what is known about previous development and use of biological weapons, and through experiments and field trials. The aim is to neither overregulate nor leave any security gaps open; this will probably always be a balancing act requiring a combination of disciplines (in science, weapons construction, intelligence assessment methods, etc.).

As the basis for what to control, the Australia Group common control list is used, which is identical to a EU Council Regulation on export control. This control list is revised and adjusted in accordance with new technological developments.

To obtain a license, there must be a legitimate purpose, a vulnerability assessment and a security plan, with security procedures, which are then approved by the Centre for Biosecurity and Biopreparedness (CBB). Companies and institutions must also appoint biosecurity officers responsible for biosecurity, who are to receive mandatory training from CBB. The security requirements are mandatory.

Seminars, and awareness raising activities all around the country are being used to try to establish a biosecurity culture at universities, private companies and other places where research is performed and new technology developed, because it is not possible to check all research activities. Thus responsibility for screening new research projects with dual use potential is put on the individual scientist in charge. It may not be possible to know of all relevant research projects, but the key criterion for regulation is the potential for weaponization, so biosecurity is being placed into a greater context of responsible scientific and social

behaviour . Finally, it is important to remember that there is a penalty, which may include fines or imprisonment, if one does not follow the rules.

Thus based on the biosecurity regulation and subsequent inspections around the country, unauthorized acquisition of biological dual use material is today significantly harder than it was previously. The risk of any Danish institution unwittingly becoming a supplier of components for a biological attack has been considerably reduced.

At the same time, a way to increase security has been found in Denmark, and the health system has benefited by streamlining of the way hospital laboratories work in fighting infectious diseases.

South-East Asia Region: Nepal

Dr Raj Kumar Mahato, of the National Public Health Laboratory (NPHL) in Nepal, explained that it is the reference laboratory for basic public health functions and clinical sample testing in the country. It is linked directly with 290 government laboratories and hospitals. and with 1237 private sector laboratories. It also functions as the regulatory authority for laboratories, and as the focal point for blood transfusion services.

NPHL's regulatory role includes registration/licensing of diagnostic laboratories and of blood transfusion service centres; monitoring and supervision of diagnostic laboratories and blood transfusion centres; and networking of hospitals, primary health centres and health-post based laboratories.

Nepal has two BSL2 laboratories: the National Influenza Centre (NIC), and the HIV reference laboratory. The NIC was designated as such in 2012, and is a member of the Global Influenza Surveillance Network. The HIV reference laboratory performs diagnosis, immunological profiling, antiretroviral therapy (ART) monitoring, research on viral load.

A BSL3 laboratory has been developed and is in process of certification. The physical infrastructure was developed with World Bank support through the Zoonoses Control Project (follow-up project to the Avian Influenza Control Project (AICP)).

There is need to enhance country capacity in laboratory biosafety and biosecurity. Priority areas include, among other things, developing national standards/protocols for BRM, training human resources in BRM, promoting good laboratory practices including waste management and transport of biological materials, and raising awareness at policy level.

Nepal has many challenges to overcome. The country is geographically diverse, ranging in altitude from 30m to 8848m; it has resource limitations, transport difficulties, communication disparities, and limited expertise and awareness. And all laboratories handling pathogens need to strengthen their biosafety (especially peripheral level laboratories).

The major activities have been undertaken through a EU-funded project. A national meeting was organized to sensitize stakeholders to the issue of biological risk management. Guidelines/SOPs have been developed/adapted in biosafety practices for different levels of laboratory staff, as well as training and education materials for implementation of these SOPs/guidelines. Laboratory needs have been assessed, and equipment (PPEs, autoclaves, biosafety cabinets, deep-freezers) procured and distributed to laboratories. Follow-up activities (supervision/monitoring/refresher training) are being undertaken for effective implementation.

5. Focused areas of global financing instruments

The session was moderated by Dr Chua Teck Mean of the Asia Pacific Biosafety Association.

European Union External Action Service (EEAS)

Mr Bruno Dupre of EEAS mentioned that this service is the EU's diplomatic service, . EU launched the European Union Chemical Biological Radiological and Nuclear Risk Mitigation Centres of Excellence Initiative (or EU CBRN CoE) to strengthen the institutional capacity of countries outside the European Union to mitigate CBRN risks. The number of EEAS CBRN centres of excellence is increasing; in 2010, there were centres in 46 countries, increasing to nearly 70 in 2014. This is one of the biggest EU development projects.

Inside the CBRN centres of excellence, bio-related issues are priority – of 45 projects in three years, 25 are bio-related. At first there were two pilot projects in South-East Asia, then in the Arabic region, and then in central Asia and Africa.

A particularly positive thing about the centres of excellence is their local ownership – the national teams with national focal points and UN coordination. While there is little money, the focus is on local problems.

The EU is funding four mobile laboratories in Africa, and helped initially with triage for Liberia, Guinea and Sierra Leone. But there is lack of communication between prevention and response; e.g. in Ebola, none of the eight centres of excellence was able to play a key role because the response is changing and the personnel in the centres of excellence were not contacted.

Thus, after three years of identifying centres of excellence, attention has now begun to focus more on basic biosafety and biosecurity. UN Security Council Resolution 1540 (of 2004), which affirms that the proliferation of nuclear, chemical and biological weapons and their means of delivery constitutes a threat to international peace and security, is of low priority in many regions, where there are more pressing problems. Bio issues are of low political priority, lower than chemical issues; top priority are nuclear issues. So bio issues are really only just coming onto the radar screen and civil approaches are yet to be addressed.

Thus the EU has geographic priorities. The EU decision-making process takes two years, but there will soon be new money and new objectives. Recent decisions in the framework of EU strategy have been in support of WHO and biosecurity.

United States Biosecurity Engagement Program (BEP)

BEP was formed in 2006 to deal with the increasing number of biological threats. Mr Brett E. Goode, of the US Department of State BEP, said the mission is to reduce risk through building sustainable capacity for biosecurity, biosafety, disease surveillance and cooperative scientific research.

BEP promotes safe use of biological materials etc. In health, its focus is on problems that transcend national borders, and in security, the focus is on elimination or dismantlement of biological weapons infrastructure. BEP global partners are active in 44 countries (in Africa, South and Central America, Asia).

BEP works with international organizations, governments, and scientific and technical associations (e.g. CDC, WHO) to develop national biorisk programmes and create awareness. Its central activity in building sustainable capacity is laboratory BRM training, enabling facility risk assessments and pathogen surveys. In disease detection and control, there is emphasis on secure collection and diagnostics, and on building safe and secure laboratories and human

capacity. To foster research collaboration, there are cooperative R&D agreements, and training grants.

During the discussion, the issue of how to deal with sustainability, and counter brain drain, prevailed. Today mainly only older people are found working in laboratories because younger people move on once they are trained. In order to be sustainable there has to be the right equilibrium between local and other expertise. This is a challenge in many countries.

Other challenges are faced in the duplication of effort due to the number of partners working with countries. Thus coordination is a problem faced by all, which coordination by WHO could help to ease. In general there is not enough awareness of each other's role; there is a lot of good will but it needs catalysis.

Also discussed was the need to raise awareness on biosafety and biosecurity issues at political level. It was suggested that diplomats should attend technical meetings, so that experts and diplomats are mixed, not separated.

6. Conversion of CWA 15793 to an ISO deliverable

The session moderated by Dr Isabel Hunger-Glaser of the European Biosafety Association.

CWA 15793: overview

Ms Patricia Olinger, of Emory University, Atlanta, USA, explained that the CEN (European Committee for Standardization) Workshop Agreement (CWA) 15793 on Laboratory Biorisk Management is time limited, and could be converted to an ISO deliverable.

CWA 15793 is about management systems, and continual improvement: identifying activities and establishing goals, implementing, monitoring and evaluating, applying actions, and reviewing steps and modifying processes. This approach to biosafety and biosecurity in the laboratory was developed by 76 participants from 24 countries, facilitated by funding from the European Commission. The CWA was adopted in 2008, and renewed in 2011.

In 2012, a guidance document – CWA 16393 – was developed and adopted following the same international process. It is consistent with other standards such as ISO 14001 and OHSAS 18001.

CWA 15793 can be used for improving overall biological risk management performance, increasing awareness of biosafety and biosecurity, providing a framework for effective management, improving international laboratory collaboration, and performance-based evaluations. Its contents include: definitions; biorisk management policy; hazard identification, risk assessment and risk control; roles, responsibilities and authorities; training, awareness and competence; operational control; emergency response and contingency plans; inventory monitoring and control; accident and incident investigation; inspection and audit; biorisk management review.

CWA 15793 is not a technical document; it is a performance-based document (e.g. does the institute have controls in place to control the hazard). It is not intended to replace national or sub-national regulatory requirements that may apply.

A biological risk management programme was established at Emory University, Atlanta, Georgia. The Research Biosafety group (of four people) based there is located in the Environmental Health and Safety Office; the group interacts with about 500 investigators. Lessons learned in establishing the biological risk management programme, and in implementing the CWA, include the need for commitment from top management, which was essential in applying the CWA 15793 methodology. The gap analysis allowed an accurate

assessment of where the gaps were and thus better understanding of what direction to go in. Other lessons learned include the need to make it simple, involve employees at all levels, build on what activities are already in place, and communicate well (to inform employees of objectives, goals, plans, activities and progress). It is best to tackle a few key priorities first, and establish a road map.

An ongoing project to demonstrate how biological risk reduction can be achieved in low-resource environments through administrative controls and alternatives to expensive primary and secondary containment is the ERGRF BEAMSTM project, sponsored by BEP and CRDF (an independent non-profit organization that promotes technical and scientific collaboration), on Biorisk Reduction in Low Resource Environments. This project is being undertaken in Kenya¹².

Challenges and obstacles encountered with CWA 15793 include the fact that there is no tool box (no easy instructions for people to follow the CWA), and therefore mentoring is helpful. Perfectionism is also a problem – the CWA is about improvement, not perfection. Also, Phase I methodology for hazard identification and risk assessment is difficult to understand.

On the question of whether CWA 15793 is worth saving, existing data suggest there is support within the biological risk management community. The CWA is increasingly used as a key reference in international guidance documents.

In the discussion, questions were raised about whether the ISO deliverable will establish requirements or provide guidance/best practices and how it will fit with existing ISO laboratory standards use for accreditation of medical laboratories.

Conversion process, prospects and timeline

Dr Donald Powers, ISO Technical Committee 212 chairperson, mentioned that ISO is based in Geneva, Switzerland. This Organization has a membership of over 160 national standards bodies (NSBs), and more than 230 technical committees (TCs), which develop standards based on international consensus. ISO has almost 20 000 standards in its portfolio.

ISO was approached two years ago with the project for conversion of CWA 15793. In 2013, ISO Technical Committee 212 approved a resolution accepting the project for adapting the CWA 15793 laboratory biorisk management document into an ISO deliverable. Agreement has also been reached with CEN to transfer responsibility for CWA 15793 to ISO.

Joint working groups are being formed, but more experts are needed from developing countries. Originally it was thought that TC 212 (whose members include in vitro diagnostics (IVD) companies, pharmaceutical companies, major medical centres, public health agencies) would provide risk management expertise for human pathogens; that TC 34 (food products) would provide risk management expertise for animal, plant, fish, and insect pathogens; and that TC 276 (biotechnology), with a scope overlapping both committees, would appoint additional experts to fill any gaps. However, the current plan is for a joint working group (JWG) project between two or more committees.

There are two levels of consensus in the ISO process – the consensus of technical experts in the drafting stages, and of countries in the formal voting stages.

ISO policy is that committees must address the concerns of developing countries, that NSBs must inform and seek input from a broad range of national stakeholders, and that NSBs must

¹² <http://www.crdglobal.org/where-we-work/regions/sub-saharan-africa/success-stories/2014/09/12/reducing-biorisk-in-low-resource-environments-in-kenya>, accessed 27 January 2015.

provide relevant stakeholders with access to the national consultation process. So the consensus process takes into account the views of all concerned parties and reconciles conflicting arguments (consensus need not imply unanimity).

The steps in the proposed ISO process include:

- Developing consensus: on what the document is for, whether it is to establish requirements or to establish guidance, and whether it is needed for laboratory certification or demonstration of competence (i.e. accreditation), and if scope exclusions/restrictions are necessary.
- Creating a design specification: to identify stakeholders and clarify market needs, define the users, identify the issues to be addressed, and specify the requirements the deliverable must meet to satisfy user/stakeholder needs.
- Setting of a goal for the deliverable – is it an international standard (IS – developed according to ISO/IEC consensus procedures and approved by full ISO membership) or a technical specification (TS). If there is not consensus, the document is a TS; this is reviewed after three years (and either revised, confirmed or withdrawn) and again after six years, when it must be converted to an IS or withdrawn. In practice, an IS has considerably more credibility than a TS.
- Converting of terms and definitions as per ISO terminology rules.
- Restructuring of CWA 15793 using the ISO management system standard (MSS) template. An MSS is a standard that provides guidelines for organizations to develop and systematically manage their policies, processes and procedures in order to achieve specific objectives; it typically contains sections addressing: policy, leadership and management involvement; planning; support; implementation and operation; performance evaluation and assessment, and management review; improvement.

For certification, an IS with requirements is needed. If there is no need for certification, perhaps a guidance document will suffice (but a guidance document cannot be used for certification). ISO does not do certification activities and its standards follow the “neutrality principle” that “A standard shall not state a preference for one type of conformity assessment over another” and “must be written so that they can be applied by a manufacturer or supplier (first party), the user or purchaser (second party), and an independent body (third party)”¹³.

Scope restrictions will be applied. At this stage, ISO 35001 is not intended for medical laboratories that only perform routine diagnostic testing of human specimens (because ISO 15190, Medical laboratories – Requirements for safety, is intended for these laboratories), or for management of long-term risks from the use of genetically modified crops in agriculture (because the GMO debate is beyond the scope of this project).

There will be a three-year development cycle, from October 2014. Thus, the ISO would be published by 2017 (earliest 2016).

¹³ ISO/IEC Directives, Part 2, paragraph 6.7.1 (http://www.iec.ch/members_experts/refdocs/iec/isoiec-dir2%7Bed6.0%7Den.pdf, accessed 3 February 2015).

Certification and needs assessment: pros and cons

The discussion as to whether there is a need for a conformity assessment and certification approach in the field of biosafety was led by Ms Luann Ochs of the Clinical and Laboratory Standards Institute (CLSI, which publishes one relevant document¹⁴) in Wayne, USA. The pros and cons were put forward. If there is need for certification, this would impact the tone and contents of the ISO Standard.

The pros included the certain prestige that is attached to certification, and the clear need for conformity assessment. Certification/accreditation is a recognition mechanism, and assessments are very important, with plaques on walls. Certification can be considered a marketing tool. In raising budgets, biosafety is one of most important things, but for most laboratory directors it is not, so a marketing tool is important.

However, it was questioned if there is a market for certification, because ultimately people must work safely in their laboratories and certification can put a burden on them. With such a large number of laboratories as there are today, would certification be for all of them, or just a few? In many countries there are no laws in the laboratories, and no basic level at national level, so it would be difficult to talk of conformity assessment.

Certification or accreditation is voluntary. If mandatory, questions such as which types of laboratories would be certified, and at what level (regional, subregional), and who would pay, must be considered. Would individuals or trainers become certified – should they be able to obtain a certificate for their biological risk procedures? Individuals could become certified in BRM, as BR managers.

Confusion in the terms “certification” and “accreditation” was explained. Certification can be obtained through study, but competency assessment and accreditation go beyond this, and certifies that the laboratory demonstrates its competence to carry out specific tasks.

Concerning the role of WHO, this organization is not an accreditation body, and the WHO country offices are very weak in the area of biosafety. Thus, while WHO is looked to for leadership, it has a limited capacity in the field in this area, and it would be difficult to guide the laboratories individually.

While there was some support for establishing requirements for certification or accreditation, most meeting participants felt that countries are not yet ready for accreditation/certification, and it would not serve public health at this time. Thus the majority felt it should be a guidance document and not to establish requirements.

Recommendations concerning conversion of the CWA

Meeting participants emphasized that:

- Biological risk management is not a replacement for existing regulatory frameworks and established technical standards for pathogen safety and security but a potential complement to help manage and reduce laboratory risks where no such complement exists.
- Neither certification nor accreditation is favourable at this time.
- There is need to better define exactly what stakeholders want from the ISO deliverable.

¹⁴ Clinical and Laboratory Standards Institute. CLSI M29–A4. Protection of laboratory workers from occupationally acquired infections; approved guideline; 4th edition, 2014 (available from <http://shop.clsi.org/M29.html>).

7. Evidence-based biosafety: knowledge gaps and research agenda

Dr Stuart Blacksell of Mahidol Oxford Tropical Medicine Research Unit (MORU) moderated the session.

Some thoughts on evidence-based biosafety

Mr Allan Bennett of Public Health England (Microbiology Service) said that while a lot of money is spent protecting staff and the public from the infectious diseases we work with, there is little evidence that this protection is working. We can look at whether our precautions work and are appropriate, or at the reduction in number of laboratory-acquired infections.

There is evidence that our equipment works. Autoclaves, filters, safety cabinets, effluent treatment, negative pressure, contained equipment e.g. centrifuges – these can all be certified and protection can be measured – but they can be very expensive. And are they all necessary? We are protecting against aerosol transmission, contact transmission, ingestion, needlestick injuries, conjunctival transmission.

A lot of money has been spent protecting against aerosols and a recent review¹⁵ indicates that aerosol exposure is no longer a major problem, but that ingesting (pipetting) and needlestick injuries are. Since the 1980s (after the smallpox infection), laboratories have been designed to prevent aerosol release to the environment, with heating, ventilation and air conditioning (HVAC) systems, filters, negative pressure, so now most infection work is done in cabinets and little is done on the bench.

In the 1960s, laboratory-acquired infections were seen to involve human factors, such as poor supervision and safety culture, less critical evaluation of working conditions with more emphasis on the value of safety equipment over attitude, and working too fast; people were conscious of taking risks¹⁶. Factors found to be significant amongst the people involved in accidents were smoking (88% cf. 42%), drinking (82% cf. 70%), divorce (12% cf. 0%), having fewer children (2.38 cf. 3.36), having previously had a laboratory infection (36% cf. 9%), and having had a previous injury (15% cf. 0%).

In the microbiology laboratory of 2014 with adequate resources, all infectious work is carried out in cabinets and any contamination is localized. Contained equipment is used in isolators, and little infectious work is carried out on the bench, compared to the 1960s, when e.g. there were no automatic pipettes and mouth pipetting was common.

¹⁵ Davies. Causes of laboratory acquired infections 1995–2010 (review); to be published.

¹⁶ Briggs Phillips G. Causal factors in microbiological laboratory accidents and infections (dissertation). New Work: New York University; 1965.

So while the laboratory is much safer today, human factors still come into play. Gloves prevent direct contact infection¹⁷; lack of glove use has been linked to laboratory infection¹⁸, and face touching linked to vaccinia and meningitidis laboratory infections. Outbreaks of *Salmonella* Typhimurium infection in 2011 and 2014 were associated with exposure to clinical and teaching microbiology laboratories. Compliance with glove use has been shown to be poor, e.g. only 46% of staff removed gloves on leaving a BSL2 laboratory¹⁹.

Thus there is a long way to go. Because if we look at the evidence base, laboratory infections are generally the result of people ignoring risk assessments, and the lack of laboratory codes of practice.

Biosafety should not hinder public health neither should it allow laboratories to become public health problems. We must investigate human factors and biosafety as there is no point in spending lots of money on facilities when people do not comply with basic infection control precautions.

Laboratory-acquired infection survey

Dr Nicolas Willemarck of the Scientific Institute of Public Health (Biosafety and Biotechnology Unit (SBB)), Brussels, spoke about two laboratory acquired infection surveys (LAIS) that had been carried out in Belgium by SBB to convince people that evidence-based biosafety is good and encourage those in the field to comply. SBB has two units: Contained Use (CU) and Deliberate Release (DR, e.g. GMOs). The Surveys were for the years 2007–2012.

Dr Willemarck explained that challenges in biosafety include the increasing number of techniques, particularly in synthetic biology, and the different incentives of players and stakeholders. Inspections are needed to determine the probability of risk and quantity.

Participation was high in the two surveys²⁰. The first survey collected absolute numbers, and the supplementary survey collected information on relative risk and incidents. The surveys were undertaken to get insights into the possible underlying causes of LAIs in Belgian microbiology laboratories so as to provide the biosafety community with knowledge and tools to enhance biological safety.

Results of the first survey indicated that 72% LAIs acquired from 2007 to 2012 were due to bacteria, 13% to virus infections, 9% to parasites, and 6% to fungi.

Of the bacterial infections, 31% were enterobacteria and 30% were airborne pathogens; bloodborne pathogens were 25% (and “others” 14%).

It was mainly (70%) technicians who were infected, followed by researchers (15%); the incidents occurred mostly in BSL2 laboratories. The main group of incidents was needle and cutting stick accidents; next was lack of compliance with biosafety measures. There has only been one case (*Brucella*) in Belgium in the last five years where an LAI was transmitted to another person. On average, each LAI costs seven days of disability to work.

¹⁷ Ng LS, Teh WT, Ng SK, Eng LC, Tan TY. Bacterial contamination of hands and the environment in a microbiology laboratory. *J Hosp Infect* .2011;78(3):231–233.

¹⁸ Srinivasan A et al. Glanders in a military research microbiologist. *N Engl J Med*. 2001;345(4):256–8.

¹⁹ Johnston J. Hand hygiene in the biosafety level-2 lab: is it a matter of training? ABSA 53rd Annual Biological Safety Conference. 2010 (<http://www.absaconference.org/pdf53/Session8-Johnston.pdf>, accessed 29 January 2015).

²⁰ www.biosafety.be – http://www.biosafety.be/cu/lai/intro_lai.html, accessed 29 January 2015.

The second survey – of LAIs during a fixed period (in 2007–2012) – was a quantitative evidence-based risk assessment in which the number of LAIs for certain organisms during a fixed period of manipulation was determined. The LAI incidence in R&D laboratories/1000 hours of manipulation and the LAI incidence in diagnostics laboratories/1000 positive samples were assessed. In R&D laboratories, *Shigella* was responsible for most LAIs; in diagnostics laboratories, mycobacteria (TB) occurred at four times higher incidence.

So close monitoring of compliance with required biosafety procedures was recommended, and close monitoring of LAIs and follow-up. Awareness should be increased so the impact of occupational and human factors is not underestimated.

Incident reporting: Canada's laboratory exposure reporting surveillance system

Ms Stacey Mantha of the Public Health Agency of Canada described the regulatory framework that was designed to strengthen biosafety in Canada, which includes mandatory reporting of LAIs. Reporting obligations are expected to come into force in December 2015. Licence holders will need to report inadvertent releases, possessions and productions, and missing and stolen pathogens.

Laboratory exposures can involve pathogens that are foreign to Canada or have been eliminated or eradicated from the population. Or they may involve greater concentrations of pathogens (e.g. direct exposure to a live pathogen culture) or uncommon routes of exposure, or pathogens with increased virulence (e.g. multidrug resistant organisms isolated and amplified from immunocompromised patient samples, or genetically/synthetically modified pathogens). These are the risks that are being avoided.

The public health objectives include managing pathogen exposure, informing decision-making, and recognizing trends in incidents. The primary objective of mandatory exposure reporting is to empower licence holders and biosafety professionals with information on what is happening in their laboratories and facilities by requiring all those working on activities under a licence to inform the licence holder of incidents, including exposures, as and when they occur. The collection of standardized, non-identifying information is expected to provide insights for continued improvement of biosafety practices.

Routes of exposure include inhalation, ingestion, inoculation, and absorption. In the reporting of exposures, it is necessary first to establish that exposure did indeed occur in a laboratory setting. If so, the Agency is to be notified immediately and a local investigation form completed and submitted, and followed up within a prescribed timeline (30 days for most pathogens or 15 days for high biosecurity agents). The notification report is timely but contains few details, and the follow-up report describes what happened and how, and how the situation was resolved. In this way it is hoped to increase awareness at local level.

The Agency will monitor exposure reports on an ongoing basis to detect potential risks early and issue alerts, notifications or advisories as appropriate. Data collected will enable analysis of trends over time and permit evidence-based improvement of biosafety policies and practices to reduce and prevent exposures and further safeguard public health.

Next steps include finalizing the design of the exposure reporting surveillance system, discussing and sharing definitions and standards with partners to align with activities in other countries, and integrating exposure reporting across countries.

Recommendations regarding evidence-based biosafety

Meeting participants recommended:

- Countries consider exposure reporting as a best practice.
- Using the evidence-based approach to optimize use of the limited resources.
- Strict compliance to basic good microbiology practices and other rules.
- Promotion of integration with existing vertical programmes (e.g. TB, HIV, vaccination) in order to ensure common messaging strategies in standards or guidelines.

8. Revision of the WHO Laboratory biosafety manual

Dr Kazunobu Kojima of WHO, Geneva, explained that the WHO Laboratory biosafety manual²¹, the “red book”, has for more than 30 years provided practical guidance on biosafety techniques for use in laboratories at all levels. The third edition was published in 2004, so 10 years have passed in this fast-evolving field, hence the need for a revision.

The manual is widely used across the world in a variety of settings, from resource-limited to advanced high containment laboratories. The third edition has been translated into many languages, and by all accounts has been serving the global laboratory community well. However, the manual contains some recommendations that are hard to attain in resource-limited settings (e.g. about safety cabinets).

The manual was reviewed with a view to how best to revise it and make it more useful. It was felt that the key concepts could be better defined; only some are defined, and others need to be made clearer, e.g. BSL3 and 4. The necessity for high containment is not well elucidated (i.e. why work in a BSL3 is not clear), the simple equation of the pathogen risk group and BSL is debatable and the concept of the management systems approach, the linkage of elements, is unclear or not well aligned.

Some sections need to be expanded or enriched, including the sections on equipment safety, PPE, the roles and functions of regulatory oversight mechanisms, GMO, and common causes of accidents.

The manual can also be improved in terms of language, which needs to be plain and clear. Potential new areas for consideration include the upsurge of high containment facilities, which may be underused, without proper planning and consideration. So a costing tool (construction, operation and maintenance costs) and checklist for planning could be useful.

During the discussion there was general agreement that revision of the WHO Laboratory biosafety manual is a necessity and a priority. Participants discussed whether the document should be revised as a manual or a guideline, and whether it should be prescriptive or performance-based; the level of prescriptiveness varies between chapters in the current manual.

²¹ World Health Organization. Laboratory biosafety manual, Third edition. Geneva: World Health Organization; 2004 (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/, accessed 6 December 2014).

It was felt it could be revised as either a manual or a guideline, but that it is a reference document and not a step-by-step guide, and should not be too detailed. Several meeting participants pointed to the need for the document to be slim and easy to read. There was general agreement that a user needs survey would be beneficial to determine how best to suit the user's needs.

There was discussion around levels of laboratory and the fact that cheaper options are available. All options should be considered because people need to know these options, e.g. a glove box system has been used in Guinea for Ebola instead of a BSL3 laboratory. There is also the need to consider energy conservation (e.g. a BSL3 laboratory run 24/7 for a year but only used for about eight weeks might be situated next to squatters who have no access to electricity). There are four levels of laboratory, but there should be compliance with all requirements of level 1 before going for a higher level. Thus there should be a guideline for the assessment and validation of containment processes and procedures, including BSL3 facilities, either within the revision or as a standalone document.

Recommendations regarding revision of the WHO Laboratory biosafety manual

Meeting participants emphasized that:

- Revision to the Manual is a necessity and a priority.
- A needs survey would be beneficial in determining how best the Manual can suit the user's requirements.
- A guideline or standard for the assessment and validation of containment processes and procedures, including BSL3 facilities, would be useful either within the revision or as a standalone document.

9. Strategy for competence development: training and learning

Dr Kathrin Summermatter of the Institute of Virology and Immunology, Switzerland, moderated the session. Recommendations were required on how to harmonize and coordinate training in order to reduce overlap and ensure efficient use of resources.

Dr Magdi Samaan of WHO, Geneva, presented WHO's biological risk management training activities. There are two BRM training programmes in WHO. The BRM advanced training programme (BRM-ATP) is a nine-day course, and after six months there is a follow-up survey. Since 2010, 18 sessions (13 regional and 5 national) have been held in the six regions of WHO; the response rate to the follow-up survey was about 54%.

The return on investment (ROI) has been variable, depending on the country, but on average each participant trained 65 people in their countries. Some of them trained at institutional level, some at national level, and some at regional level. Some became BRM managers in their countries.

National trainings were undertaken in 2012–2014, during which time 198 trainers from 88 countries were trained.

The ISST training is a two-day course in classroom format (a face-to-face course). It was developed in agreement with IATA and the International Civil Aviation Organization (ICAO), and there is a certification exam. Training is offered only to the public and resource-limited laboratories. From 2007 to 2014, about 900 shippers were trained and certified. Challenges include the need for continual updating of the certificates, which are valid only for two years. Many people have been trained but many certificates are already invalid.

There is an online course for retraining and recertification. The online refresher training (eISST) is available for those who have attended the face-to-face ISST course. It is for recertification of shippers. The certificate carries the WHO, IATA and ICAO logos. The online course takes two hours.

Challenges include the language barrier; the on-line course is currently only available in English, so only AFRO, AMRO and EMRO have enrolled, and there is need to translate the course into other languages. Other challenges include the need for continual updating to reflect the changes in regulations, the limited IT support and need for distance learning courses, the high human resources turnover rate, and selecting the right participants. More trainers, and more partners and donors are needed.

The BRM + ISST course is for training of users. It includes the first three days of the BRM–ATP course combined with the ISST in a five-day back-to-back format. Thus a larger number of participants can be accommodated, and there is flexibility in terms of participant selection. Up to 30 people can be trained at a time; training materials are online.

Following these reflections on WHO's role in BRM training activities, there was appreciation for WHO's significant efforts in BRM and ISST training, with trained trainers increasing the reach. ISST was felt to be a model collaboration with IATA and ICAO, and is sustainable through the eISST model.

WHO had trained 900 people in three years, but is not a training academy. It has been a significant investment by WHO, but this Organization needs to be less involved as there are many others who can do the training.

During the discussion, the question of how to minimize overlap was raised, and how to ensure that training is reaching the right people. The challenges faced with limited availability of training in languages other than English were highlighted. On the issue of trainers, WHO would be able to provide, to donors and others who are interested, the names of people who have passed the course and who give their consent, allowing them to be advertised somehow. WHO would follow up with the training-of-trainer participants to compile a list of those who want to be involved. Participants spoke about a roster of expert trainers; CDC also has three very good trainers in Africa. And mentorship was also suggested. WHO talked about working only to train trainers, to make it more sustainable, but others were doubtful about this approach and had found that, after building a pool of trainers, perhaps only two or three of the trainees went on to retrain. Thus there are many initiatives, but there is no coordination amongst the trainers.

Having the use of the WHO training programmes content and the certificates of WHO was felt to be very useful but participants spoke about the need for a toolkit, and some offered in-kind support.

Summing up, Dr Summermatter, said:

- training is important
- WHO's efforts are appreciated
- WHO to take a coordinating role
- others to provide training using WHO training materials
- responsibility and quantity of content to match guidance
- message to be spread within countries to build on regional and national level expertise.

Recommendation

Meeting participants recommended that:

- WHO should continue to play a coordination role supported by training partners.

10. Matching needs with resources

Dr Donald Powers, ISO TC212 chairperson, moderated the session. Gaps between the needs of resource-limited countries and the “donor agenda”, the roles of WHO and its partners, and how technical agencies can contribute efficiently and effectively to WHO-led biosafety activities were the topics of discussion.

In considering how to bridge the gaps (in financial and technical resources) between the needs of resource-limited countries and the donor agenda, it was felt that international agencies had the best capabilities to use money in the soundest non-biased way, and that WHO was the right environment. Discussion turned to the way unilateral organizations allocated their budgets, and to the need for political will. While there may be financial resources, due to the technological nature of a programme, these cannot always be allocated in the most effective ways (e.g. while funds might not be allocated to “flu”, they might be allocated to “dangerous respiratory pathogens”). Security programmes are concerned with the highly pathogenic, with biomaterials that can be weaponized; however, this is not priority in a country where e.g. children are dying from malaria.

On the theme of health versus security, it was acknowledged that crisis situations provide opportunities for bridging gaps, and demonstrating linkages, between health and security. During crises, it is easy to work together. However, there is need to recognize that donors have specific interests that may differ, and work strategically to find convergent issues. It would be best to connect at regional level and work with donors to find where the overlapping is, before money is dispensed. It was felt the collaborating centres could play a role here. And donors need to align with the needs of the country; the Paris Declaration on Aid Effectiveness (2005) was mentioned.

There was discussion also around the issue of transparency concerning donor funds. Several participants mentioned negative reactions from countries on learning of sources of funding. Thus there is a need for transparency of donor funds.

In discussing the roles of WHO and its partners, it was felt that the WHO regional offices provide an opportunity for improving coordination among collaborating centres and other technical agencies. It would be very valuable if WHO would act as coordinating body for donors, and also help in breaking the red tape with respect to export of samples.

Thus, WHO could play a role in coordinating donor and NGO involvement. While WHO country offices do play a coordinating role, they do not have laboratory staff and this is a weakness, although some country offices are better equipped than others.

Thus, WHO regional and country offices can play a big role in connecting partners; this is part of the existing mandate. However, partners need to be encouraged to touch this base prior to engagement.

Recommendation

Meeting participants emphasized that:

- WHO collaborating centres could play a coordination role to assist WHO, promoting efficiencies in matching resources with needs.

11. Regulatory framework and other areas of interest

Dr Christine Uhlenhaut of the Robert Koch Institute, Germany, moderated the session.

The International Expert Group on Biosafety and Biosecurity Regulation (IEGBBR)

Dr Thomas Binz, Federal Office of Public Health, Switzerland, talked about the IEGBBR. This Expert Group serves as a community of practice for human pathogen biosafety and biosecurity regulators on a global scale. The incentive to fund it arose from the Public Health Agency of Canada in 2007, when regulators thought the world needed to exchange information about managing pathogens, and needed a legislative system based on specific country needs.

IEGBBR in-person meetings are held every two years; the next will be held in 2015 in Berlin, when the agenda will include new technologies (iGEM, synthetic biology), promotion of international biosafety, laboratory acquired infections, and regulatory updates.

The core members of IEGBBR are regulators and those in charge of national oversight mechanisms for human pathogens. This is a closed core group so discussions are more frank. The Group is open also to UN organizations and other experts, and invitations are extended to non-regulators for their expertise and input. The Group is governed by a steering committee (Canada, Singapore, Switzerland, Implementation Support Unit, Chair of the biannual meeting), the composition of which changes every few years. There are different subgroups, in Europe, Asia–Pacific, and North America.

Thus today IEGBBR is a maturing group, and looking for more members. Its objectives include:

- Acting as focal point for an international network of regulators in human pathogen biosafety and biosecurity (only human pathogens), and setting the stage for an international regulatory voice (e.g. could advise WHO how to deal with H5N1 within countries).
- Benefitting members through discussion of novel (e.g. synthetic biology) and emerging issues in human pathogen biosafety and biosecurity, and sharing best practices and lessons learned.
- Benefitting members through sharing of approaches and expertise, progress and capacity building opportunities.

- Encouraging coordination among national regulators in order to ensure greater compatibility and interoperability of biosecurity and biosafety systems and processes.
- Promoting the development of effective biosafety and biosecurity regulation internationally, including the building of capacity.

Through its network of biosafety regulatory experts, IEGBBR offers potential for “standardization” of risk assessment approaches and methodologies, allowing e.g. common approaches to containment assessment and requirements, and to new and emerging risks.

The Group can provide assistance to countries with no regulatory framework, and has potential to speak as a common voice from the “international regulatory community”. It can assist countries to meet their international obligations (IHR; WHA resolution 58.29, on enhancement of laboratory biosafety; Biological and Toxin Weapons Convention (BTWC)).

The difficulty of making statements about working only with human pathogens was raised, because with e.g. H5N1 it would be necessary to reach to the veterinary sector. This issue was currently being considered by IEGBBR; it was felt that reaching to the veterinary community would considerably increase the size of the Group.

Recommendation

Meeting participants recommended that:

- If IEGBBR is to provide technical advice in support of emerging issues, aligned with the One Health approach, the veterinary sector should be consulted, possibly via an international body.

Public Health Agency of Canada (PHAC)

The Public Health Agency of Canada (PHAC) Center for Biosecurity has implemented a new regulatory framework for pathogens in the country. Ms Kirsten Almquist of PHAC described the policy development approach taken by Canada, emphasizing the benefits of early and frequent stakeholder consultation, as a series of steps:

- Define the risks and problems (natural, deliberate, synthetic biology)
- Identify and assess what is contributing to the risk (e.g. inadequate training, inadequate SOPs)
- Identify the stakeholder groups who can contribute. Canada designed a framework of academic settings, public health laboratories and hospitals (public and private), industry (biotech, synthetic biology etc.), and distributors.
- Examine the critical intervention points and where the gaps are (e.g. activities, import/export controls, transportation, recruitment of biosafety and biosecurity researchers, distribution chain).
- Identify and assess policy instruments (tools to reduce risk), and see if new standards, or new licencing, or new security parameters are needed.
- Decide what tools are needed (e.g. create new regulations, update standards, establish training unit).
- Develop strategic plan. Engage stakeholders early in the consultation process (which may take several years); they are part of the dialogue and solutions.

- Set guiding principles (e.g. build a framework to promote safe use without compromising research or business), public health policy objectives, and expected outcomes.
- Decide on list of performance indicators to know if problems are being addressed satisfactorily, and validate it (e.g. number of laboratory acquired infections, and of laboratories licensed).
- Develop framework (e.g. build a new Act, regulations, update standards, adopt/adapt existing standards/training resources).
- Plan for implementation, allowing time for transition and for ramping up.
- Implementation.

Canada took five years to reach implementation. In December 2015, new regulations come into force, after which persons working on human pathogens will need to obtain clearance.

Discussion centred around what the key concerns of stakeholders were and how they were addressed. Among many things, the stakeholders had been concerned about the security clearance programme; they didn't really understand the risks of working with pathogens. Flexibility was built into the regulations, because security clearance can take some time (e.g. while waiting for clearance, a person may be supervised by someone who does have clearance).

The stakeholders were involved in every step, and appreciated this, thus increasing ownership and leading to higher rates of compliance. Staff of the Center continue to work with people to see if they are compliant or not (through on-site visits, training resources, and guidance documents); they have a good relationship with the stakeholders. A monthly newsletter is produced for updates.

12. Ebola outbreak updates

Dr Asa Bjorndal of the Public Health Agency, Sweden, moderated the session.

Ebola situation updates

Dr Pierre Fomenty, of WHO, Geneva, reported on the latest situation regarding the 2014 Ebola outbreak in West Africa. There were now 100 staff at the UN Mission for Ebola Emergency Response (UNMEER) hub in Accra and in the four (including Mali) affected countries, and 500 WHO staff and partners. The UN mission to contain the outbreak was formed because the outbreaks had created social/political crises in two of the three countries mainly affected, posing a threat to the governments. WHO was lead agency for planning and coordination and monitoring, and response.

The latest numbers of deaths and the latest epidemiological situations in the affected countries were reported. Currently there were about 400 new cases per week (not the 10 000 anticipated). There were now a lot of Ebola treatment units and 80% of burials were safe, although teams were still being trained, and the number of beds was small compared to what was planned.

Healthcare workers were however still becoming infected. Most of them (95%–97%) became infected when they were treating a patient for another complaint (e.g. malaria), when Ebola was not suspected.

The network of high security laboratories – the Emerging and Dangerous Pathogens Laboratory Network (EDPLN) – which was developed in 2008, consists of both human and veterinary diagnostic laboratories. At the present time there were 23 members globally, most of them WHO collaborating centres. There were also 13 mobile laboratories in the three countries with intense transmission, and eight more were pending from various partners.

Next steps would include distributing RNA specimens to 18 African countries to assess technical capacity to detect Ebola. An emergency mechanism to assess IVDs for Ebola infection had been implemented.

At the current time the number of samples per week was reducing; surveillance would now be increased as well as the number of people being tested (in non-Ebola health care facilities). So there would soon be a different strategy.

The first WHO-authorized in vitro diagnostic test for Ebola for procurement by United Nations and other partners was ready. This would save time, and also give a benchmark against which to compare other diagnostic tests.

UK laboratory deployment and the European mobile laboratory

Mr Allan Bennett of Public Health England (Microbiology Service) described two laboratory deployments to Western Africa in 2014. The European mobile laboratory (EML) was deployed in Guinea and Liberia, and there were UK deployments to Sierra Leone.

The EML laboratory was formed in 2011, funded by the European Union. It has rapid deployment capability and doesn't look like a laboratory – is small and cramped, collapsible, biosafety level 3, with CBRN filters, and a PCR SmartCycler (for quick results). The mobile laboratories have allowed very rapid response.

The laboratory design is such that there is clear separation of high and low risk activities, a unidirectional flow of work, and separate entrances for staff and samples. The major biosafety concern is broken glass in samples.

The UK had pledged 700 beds for Ebola treatment centres in Sierra Leone. Each centre needs about 16 staff, and these are recruited per month from Public Health England (PHE), the UK National Health Service (NHS), academia and pharmaceutical companies; at present there were volunteers from other countries. Three testing laboratories were being built, and easier isolator systems for equipment were being sought.

UK diagnosticians and healthcare workers (with PCR ability and experience in Africa) had been deployed. Prior to deployment, staff were trained in proper use of PPE, laboratory SOPs, scenario training. So far, the UK had trained 50 laboratory personnel and more than 150 Ministry of Defence and NHS staff.

The laboratory training is run over 4.5 days. The strategy is to teach principles rather than prescriptive methods, to use scenarios to reinforce the principles, and to carefully balance team composition to allow in-country development and mentoring. PPE removal is a high-risk step, and trainees are thoroughly drilled to ensure precise steps are used.

Among the topics of discussion were the costs of the European mobile unit, the cabinets and high-efficiency particulate arrestance (HEPA) filters. There was need for clear guidance on glove boxes and isolators etc. from WHO. So far there had been no accidental infections from the mobile laboratories.

Considering the sterilization of equipment, formaldehyde can be used for isolators at the end of use. Hypochlorite is also used, but this means the equipment might not be useable for long. There are different ways of decontaminating different types of equipment. Laboratories run on negative pressure, with a built in glove box, are stainless steel and easy to decontaminate. However, to decontaminate HEPA filters, contact time is needed; they do not need frequent changing, but dust needs to be removed from the exit filters.

Concern about the inactivation of samples was raised, and clear guidelines on this were requested; WHO guidelines are in production.

There was discussion also about PPE. While their delivery had been facilitated for 18 countries in Africa, there was a current shortage due to several countries (non-affected) purchasing large amounts of PPE, affecting distribution for priority countries.

Preparedness in non-affected countries

Dr Sebastien Cognat of WHO, Lyon, France, explained that an assessment of 41 non-affected countries in the WHO African Region indicated that 13 (32%) did not have access to specialized laboratories. While 33 countries did have EVD preparedness and response plans, there were major areas of vulnerability, e.g. weak surveillance and health systems, extensive movements of people, cultural practices/traditional beliefs, lack of case management experience and of infection prevention and control measures, and limited health capacities to respond rapidly.

So there is an urgent need to strengthen the capacity of unaffected countries to prevent and be ready to respond effectively to the disease. Fifteen African countries were prioritized as of concern in this respect, and partners were convened by WHO.

The strategic approach taken by WHO is that all countries should be as prepared as possible for potential EVD outbreaks, through engaging major international partners, building on previous assessment and existing work, and using multiple approaches (e.g. guidance, tools, country visits, identifying and closing gaps) to rapidly scale up.

All WHO regional offices are highly engaged and active. There is a consolidated checklist for Ebola disease preparedness, and components in place are assessed after 30, 60 and 90 days.

The priority African countries are receiving visits from teams of 5 to 10 experts, who assist the country in getting operationally ready, setting deliverables and indicators, and strengthening capacity. There are guidance documents on laboratory preparedness, quality control, etc., a shipping fund, training in transport of infectious substances, training in diagnostics and biosafety.

The challenges include the limited number of certified shippers. Shipping of category A specimens is a challenge for many countries, and many countries want capacity locally so are requesting training. Access to trainers and mentors is now a huge challenge.

13. WHO priority areas for 2015–2016

Ms Stacey Mantha of PHAC moderated the session. WHO priority areas for the forthcoming period are:

- **Leadership and communication:** WHO will play a coordinating role between technical and funding partners and recipients through participation in meetings and workshops at global and regional levels, and dissemination of knowledge and information through a variety of means (website, meetings, letters, etc.).
- **Governance, norms and standards:** top priority is revision of the WHO Laboratory biosafety manual and WHO guidance on regulations for the transport of infectious substances, and to contribute to discussions to inform the setting of standards relating to biosafety and biosecurity (OIE, ISO, etc.).
- **Tools and methodologies:** through its offices, WHO will continue to identify tools to support implementation of biosafety and biosecurity best practices.
- **Competence development:** WHO will facilitate access to training resources (materials, trainers, delivery partners, funding support).

Meeting participants emphasized that:

- The important role of country and regional offices in supporting national biosafety and biosecurity enhancement programmes needs to be recognized.

ANNEX 1: Agenda

Day 1: Monday 24 November

Session 0: Opening

09:00-09:30 Welcome and opening remarks
Overview and goals of meeting
Administrative announcements
Florence Fuchs
Kazunobu Kojima

Session 1: **Review of “WHO Laboratory Biorisk Management Strategic Framework for Action 2012–2016” (5-year plan)**

09:30-10:30

- 5-year plan
- WHO activities
- Achievements, challenges and lessons
- Discussions

Kazunobu Kojima

10:30-11:00 Coffee break

Session 2: **WHO regional office activities and strategies related to biosafety/laboratory biosecurity**

11:00-12:30

- WHO American Regional Office (AMRO/PAHO)
- WHO Eastern Mediterranean RO (EMRO)
- WHO European RO (EURO)
- WHO South-East Asia RO (SEARO)
- Discussions

Jean-Marc Gabastou
Humayun Asghar
Eugene Gavrilin
Aparna Shah

12:30-13:30 Lunch

Session 3: **Activities and initiatives of other institutions/organizations**

13:30-15:00

- CDC
- FAO (HQ + South-East Asia)

- OIE
- IFBA
- RIVM (Biosecurity Office)
- Discussions

Cristina Bressler
Gwenaelle Dauphin
Stuart Blacksell
Keith Hamilton
Michelle McKinney
Marja Agterberg

15:00-15:30 Coffee break

Session 4: **Country perspectives, priorities and realities**

15:30-17:00	<ul style="list-style-type: none"> • AMRO MSs: Mexico, the Caribbean • EMRO MSs: Jordan, Tunisia • EURO MS: Denmark • SEARO MS: Nepal • Discussions 	<p>C Franco Delgadillo S Wallace-Sankarsingh G Abdellatif Alwahdane Sana Masmoudi John-Erik Stig Hansen Raj Kumar Mahto</p>
17:00	Adjourn	
18:00-	Reception: WHO Main Cafeteria	

Day 2: Tuesday 25 November

Session 5: Focused areas of global financing instruments

9:00-09:45	<ul style="list-style-type: none">• EU EEAS• US Department of States (BEP)• Discussions	Bruno Dupre Brett E. Goode
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Session 6: Conversion of CWA 15793 to an ISO deliverable; certification

09:45-10:30	<ul style="list-style-type: none">• CWA 15793 – overview• Conversion to an ISO deliverable<ul style="list-style-type: none">○ Process, prospects and timeline• Certification: needs assessment<ul style="list-style-type: none">○ Pros and cons• Discussions	Patty Olinger Don Powers Luann Ochs
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10:30-11:00 Coffee break

Session 7: Evidence-based biosafety: Knowledge gaps and research agenda

11:00-12:00	<ul style="list-style-type: none">• Conversion to an ISO deliverable• Laboratory-acquired infection survey• Incident reporting• Discussions	Allan Burnette Nicolas Willemarck Stacey Mantha
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Session 8: Revision of the WHO Laboratory Biosafety Manual

12:00-12:45	<ul style="list-style-type: none">• Outline• Discussions	Kazunobu Kojima
12:45-13:45	Lunch	

Session 9: Strategy for competence development: training and learning

- 13:45-15:30
- Training examples
 - WHO HQ
 - WHO ROs
 - CDC, PHE, A-PBA, PHAS, BEP, OIE, FAO etc.
 - Needs? Evaluation of effectiveness?
 - What are expected for WHO?
 - Discussions
- Magdi Samaan

15:30-16:00 Coffee break

Session 10: Matching the needs with resources

- 16:00-17:00
- Panel discussions
 - Financial resources
 - Technical resources
 - WHO Collaborating Centre
 - Other institutes of excellence
 - Discussions with the floor

17:00 Adjourn

Day 3: Wednesday 26 November

Session 11: Regulatory framework and other areas of interest

- 09:00-09:30
- Regulatory framework
 - PHAC
 - IEGBBR
 - Discussions
- Kirsten Almquist
Thomas Binz

Session 12: Ebola outbreak updates

- 09:30-10:30
- Ebola situation update
 - UK lab deployment and the European Mobile Lab
 - Preparedness in non-affected countries
 - Discussions
- Pierre Formenty
Allan Bennett
Sébastien Cognat

10:30-11:00 Coffee Break

Recommendations and conclusions

Session 13:

- 11:00-12:30
- Summary
 - Recommendations and conclusions
 - Questions
- Rapporteur
Stacey Mantha
- 12:30 Adjourn

ANNEX 2: List of participants

Dr Marja Agterberg

The Netherlands Biosecurity Office
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Department for Environmental Health, Aftercare and Security
The Netherlands

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Biorisk management Coordinator
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Laboratory Directorate/Ministry of Health
Jordan

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Public Health Agency of Canada
Canada

Mr Allan Bennett

Public Health England
Microbiology Service
United Kingdom

Dr Thomas Binz

Federal Department of Home Affairs DHA
Federal Office of Public Health FOPH
Switzerland

Dr Asa Björndal

Public Health Agency of Sweden
Sweden

Dr Stuart Blacksell

Mahidol-Oxford Tropical Medicine Research Unit
Thailand

Ms Cristina Bressler

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Dr Gwenaëlle Dauphin

Food and Agriculture Organization of the United Nations
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Dr Carindha Franco Delgadillo

Instituto de Diagnostico y Referencia Epidemiologicos
Mexico

Mr Bruno Dupre

European Union External Action Service
Belgium

Mr Brett E. Goode
US Department of State
Biosafety Engagement Program
United States of America

Dr Keith Hamilton
World Organisation for Animal Health
France

Dr Isabel Hunger-Glaser
European Biosafety Association (EBSA)
Swiss Expert Committee for Biosafety
Switzerland

Dr Cezary Lusinski
Minister Counsellor for Disarmament and Non-Proliferation
EU Delegation to the UN and other international organisations in Geneva
Switzerland

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Canada

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Tunisia

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Sweden

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WHO Regional Office for Europe (EURO)

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Division of Communicable Diseases

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WHO Regional Office for South-East Asia (SEARO)

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