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Extended Biosafety Advisory Group (BAG) meeting

Meeting Report

Geneva, Switzerland, 24-26 November 2014

World Health Organization

Global Capacities
Alert and Response

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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

Content

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 2010[1], 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 manual[2], 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).