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FACT SHEET

Biosafety and Biosecurity

Background

Biosafety

Biosafety refers to "the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release".[1]

In the context of influenza research and the development and production of influenza products, biosafety risks relate to accidents during which laboratory workers or people in communities around laboratories could be infected by influenza viruses. This can happen, for example, if a laboratory worker is infected due to inadequate facilities or equipment, or if the virus is released due to inadequate air handling or waste decontamination systems.[2]

Biosecurity

The term "biosecurity" refers to the "institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins".[3] This includes measures that address access to facilities, storage of materials and data and publication policies.[4] For influenza, the main biosecurity risks have involved losing or confusing samples. As technologies advance, concerns have also been raised about resurrecting extinct viruses and constructing viruses that are typically guarded, or viruses for which there is no vaccine or which are drug-resistant.[5]

Biosafety and biosecurity in the PIP Framework

The PIP Framework makes several references to biosafety and biosecurity. It states that Global Influenza Surveillance and Response System (GISRS) or non-GISRS laboratories that access or share PIP biological materials "assume full responsibility for complying with their respective national biosecurity and biosafety regulations and rules as to import, export or release of biological materials".[6] In addition, WHO Collaborating Centres are required in accordance with their terms of reference to "have full and unrestricted access to biosafety level 3 laboratory facilities that meet recognized international and national standards".[7]

GSD databases and biosafety/biosecurity

"Biosafety/biosecurity concerns related to the use of GSD [genetic sequence data] are directly linked to ease of access to the sequences. To properly assess biosecurity/biosafety risks, the various aspects related to the free and easy circulation of GSD must be taken into account".[8] There may be different risks associated with the different types of GSD databases.

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[1] WHO, *Laboratory Biosafety Manual* (3rd ed.) (2004), available at http://www.who.int/ihr/publications/WHO_CDS_CSR_LYO_2004_11/en/index.html, p.47.

[2] See Centers for Disease Control and Prevention, Interim Risk Assessment and Biosafety Level Recommendations for Working with Influenza A(H7N9) Viruses, available at https://www.cdc.gov/flu/avianflu/h7n9/risk-assessment.htm

[3] WHO, Laboratory Biosafety Manual (3 ed.) (2004), available at http://www.who.int/ihr/publications/WHO_CDS_CSR_LYO_2004_11/en/index.html, p.47; Fidler DF and Gostin LO (2008), *Biosecurity in the Global Age: Biological Weapons, Public Health, and the Rule of Law* (Palo Alto, California: Stanford University Press).

[4] Uhlenhaut C, Burger R, Schaade L, "Protecting Society. Biological Security and Dual-use Dilemma in the Life Sciences –Status Quo and Options for the Future" (2013), *EMBO* reports, 14: 25.

[5] PIP Framework Advisory Group Technical Expert Working Group (TEWG) on GSD. Final Report to the PIP Advisory Group. Geneva: World Health Organization, 2014, pp 12-15.

[6] PIP Framework, Annex 1, Standard Material Transfer Agreement 1 (SMTA 1), article 8.

[7] PIP Framework, Annex 5, WHO Collaborating Centres for Influenza— Terms of Reference Related to Work with Pandemic Influenza Preparedness Biological Materials, core term of reference A6.

[8] PIP Framework Advisory Group Technical Expert Working Group (TEWG) on GSD. Final Report to the PIP Advisory Group. Geneva: World Health Organization, 2014, pp 12-15.