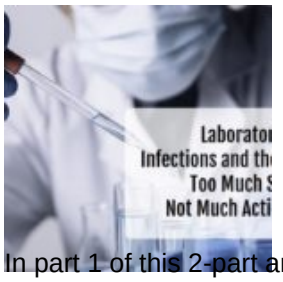
Laboratory-Acquired Infections and the Pandemic. Too Much Speculation, Not Much Action! (Part 2)

By: Dr. Stefan Wagener SM

Date : May 2, 2023



In part 1 of this 2-part article, we looked at the concerns raised by potential laboratory-acquired infections (LAIs). To reiterate, LAIs happen and will happen in the future unless we do something about it. And no, there is no conclusive evidence that a laboratory caused the COVID pandemic, nor is there conclusive evidence that it started at a particular meat market.

However, since the start of the COVID epidemic, there have been lab-related incidents and accidents associated with SARS-CoV-2 being worked with in the lab. We also know that the SARS virus has an animal origin. The main concern ought not be whom to blame, who was responsible, or which government might be doing a cover-up, but rather what can be done to prevent a laboratory working with highly infectious agents from becoming the reason for a pandemic.

In this part 2, I propose three immediate opportunities to address the new and old risks involved in infectious disease research, including expanding the working definition of “biorisk” as it pertains to laboratories, requiring laboratories to establish comprehensive Biorisk Management Systems (e.g., ISO 35001:2019), and establishing an international oversight entity for high containment laboratories.

Expanding the working definition of “biorisk” as it pertains to laboratories

The definition most often used for “biorisk” is limited to risks associated with the safety and security of biological materials. This means that the safety of biological materials is addressed within laboratory biosafety, primarily focusing on the practices, procedures, and infrastructure to limit exposure to these materials within the lab and their accidental release. Security aspects are addressed within biosecurity in the lab, focusing on people, their reliability, and accessibility, as well as preventing loss, theft, or misuse of biological materials.

If the definition of biorisk management is, as stated in the biorisk management standard ISO 35001:2019, “the *effect of uncertainty expressed by the combination of the consequences of an event and the associated likelihood of occurrence, where biological materials are the source of harm”* (ISO, 2019), then we cannot limit the risks to just safety and security (as ISO 35001, unfortunately, is doing) but need to incorporate a third component which is *bioethics*, addressing the moral and ethical risks associated with the use of biological materials in laboratories for research purposes. This way, biorisk management is all about managing the critical risks from a biosafety, biosecurity, and bioethics point of view.

Adding bioethics to the biorisk definition creates the ability, responsibility, and duty to implement formal bioethics risk assessments. In addition to the necessary biosafety and biosecurity assessment, a bioethical assessment is done before the research either secures funding or can proceed. The proposed work will now be assessed from a third important aspect by asking critical ethical and moral questions on the need, benefits, risks, etc. This allows us to evaluate these projects' moral and ethical aspects and ensure they align with our values, principles, and societal

norms. This is especially important with the increase in Gain of Function (GOF) and enhanced potential pandemic pathogen (ePPP) work (see part 1). Bioethics questions and discussions outside of biosafety and biosecurity can guide the development of much-needed public policies and regulations, ensuring that scientific disease research is done responsibly and does not harm individuals, communities, or the environment.

Re-Establish Public Trust In Infectious Disease Research, Medicine, And The Biotechnology Industry By Demonstrating Transparency, Accountability, And Ethical Responsibility

Assessing the research from a bioethics perspective will help us evaluate the benefits and risks, enabling us to make informed decisions about whether the potential benefits outweigh the potential harms and are not just a smokescreen for more money or scientific ego. This will help re-establish public trust in infectious disease research, medicine, and the biotechnology industry by demonstrating transparency, accountability, and ethical responsibility. However, we must understand that we as a society also have the responsibility to stop certain aspects of research from going forward. In the assessment, saying no to proceeding with the research must be one of the options!

Institutions and funding agencies need to change their approach to make this happen. In general, many but not all research institutions have an internal committee that looks at biosafety and biosecurity aspects of the newly proposed research. These committees, often called the Institutional Biosafety Committee (IBC), are historically established with researchers within the institution, sometimes a member of the public and *ex-officio* members comprising of the local safety entity (e.g., biosafety officer). Most institutions publish their terms of reference on their website (Smith, 2022 & Institutional, n.d.). While most of these committees will look at the use of human subjects and animal work, no formal bioethics review is required, which needs to change. For example, the university must bring competent and trained bioethics professionals to the table who are not necessarily part of the institution or IBC unless there is an ethics department or a medical school with formal ethical education opportunities.

In addition, regulatory bodies and funding agencies must mandate the institutional bioethics review. At the same time, funding agencies need to do their part to assess the bioethics aspect of a particular project when the funding request is received.

In addition to bioethics, the overall management of biorisk in laboratories needs to change radically. We must move beyond “biosafety and biosecurity programs,” focusing only on regulatory compliance. This will lead us to the second opportunity.

Laboratories must establish a comprehensive Biorisk Management System

Laboratories, especially those involved with high-consequence infectious disease research, need to establish a comprehensive Biorisk Management System (BRMS). The emphasis is on the “system.” This is where the new international standard for biorisk management comes in. ISO 35001:2019 is a standard based in parts on the ISO 9001 quality management system and the ISO 45001 occupational health and safety management system standards. For the first time, biorisk management, from an ISO system perspective, introduces the concept of a comprehensive and integrated framework that encompasses all aspects of an organization's operations, including objectives, policies, processes, procedures, and resources, with the goal of continual improvement. This makes the biorisk management system approach so powerful! The institutions are now enabled to look beyond the reactive, compliance-based

approach establishing clear, tangible, and desirable outcomes (e.g., safe, secure, and ethical research) with a process involving constant checking and acting to improve the performance of their biorisk management continually. Biorisk Management “Programs” are not “Systems”.

It is also important to realize that a BRMS and ISO 35001:2019 are performance-based and not descriptive how-to-do-it biosafety or biosecurity manuals, which always fall short since they cannot address everything. In addition, ISO 35001 is an international standard written by experts from all over the globe, which makes it so much easier to be implemented around the world. By constantly assessing the biorisk performance and establishing a constructive biorisk management culture that rewards information on what is not working, reporting incidents and accidents and identifying the root causes, making people part of the success, and not blaming them for mishaps, we will be able to reduce LAIs, and at a minimum control any consequences early and effectively. Finally, we cannot forget that what happens in the lab in another country is as important as in the lab next door. Infectious disease outbreaks do not stop at a country's border. That’s why any approach needs to be international.

Establishing an international oversight entity for high-containment laboratories

We began this conversation in Part 1 by looking at laboratory-acquired infections and incidents worldwide and the need for better processes, procedures, and oversight. We accept that our local regulatory agencies need to have a robust oversight function, especially if we talk about containment and high-containment laboratories that deal with the most dangerous infectious agents. The question now arises: Are the regulatory bodies in all those countries that operate and plan new labs aligned? The answer is no.

There Are Currently No Uniform Regulatory Standards

There are currently no uniform regulatory standards. What is regulated in most developed countries is somewhat aligned. Our regulatory bodies are talking to each other in various forums, but more is needed, especially with countries that are not aligned or lack a robust regulatory system. The World Health Organization (WHO) is trying to help with its guidance documents. However, since the WHO biosafety office relies on its so-called Collaborating Centers, which do not support performance-based systems, something else is required. We need an independent international oversight entity within a UN framework based on the mutual agreement by all countries operating high containment laboratories.

This group or entity will be able to provide state government entities with clear guidance and performance-based standards (not just guidelines). It will have the right to do onsite inspections, verifications, and performance assessments. This will allow for much-needed transparency, continuous improvement and safeguards for safe, secure, and ethical research involving infectious agents.

Any Solution Needs To Be International

It is also important to consider that what happens in the lab in another country is as consequential as in the lab next door. Therefore, any solution needs to be international. Case in point, we already have a fitting example in the “International Atomic Energy Agency” (IAEA). This UN-based agency does exactly what we need, just within the nuclear field. For those interested in how they provide guidance and standards, the IEAA published their latest General Safety Guide, the GSG-13, in 2018 (Functions, 2018). So, it is possible to establish, for example, an “*International*

Infectious Agent Research Agency" (IIARA) and standards like the ISO 35001:2019, although not perfect, can be a starting point. What will it take? In essence, the will of countries not to have a laboratory-acquired infection, accident, or lab release be the start of the next pandemic.

It is time to start, and the old laboratory biosafety and biosecurity paradigm must change. Bioethics will help us better control what is being done in line with our societal ethical and moral values. With a biorisk management system, we can focus on biorisk performance and the culture in the lab and make infectious disease research safer, more secure, and ethical. With international oversight, we can create an environment for global standards and transparency.

Let's make infectious disease research worldwide "**B-safe, B-secure, and B-ethical**!"

Disclaimer:

Dr. Stefan Wagener was a former Scientific Director and CAO of the Canadian Science Centre for Human and Animal Health (CSCHAH) in Winnipeg, Manitoba, Canada's Level 4 high containment lab. He was also involved in the initial discussion and planning for the Wuhan (China) Level 4 high containment virology laboratory.

References:

Functions and Processes of the Regulatory Body for Safety | IAEA. (2018). From https://www-pub.iaea.org/MTCD/Publications/PDF/P1804_web.pdf

Institutional Biosafety Committee. Institutional Biosafety Committee | Research Support. (n.d.). Retrieved May 1, 2023, from https://www.bu.edu/researchsupport/compliance/ibc/

ISO 35001:2019. ISO. (2019, November 12). Retrieved May 1, 2023, from https://www.iso.org/standard/71293.html

Smith, J., & Shepherd, M. (2022, November 16). *2022 IBC Charter University of Washington*. Institutional Biosafety Committee. From https://www.ehs.washington.edu/system/files/resources/ibc-charter.pdf