



BioPREVAIL

Biological Preparedness and Resilience through Evolution and Innovation of Laboratories

A Health Security Innovation Initiative for Sustainable Laboratories

Diagnostic laboratories play a critical role in global efforts to prevent, detect and respond to infectious disease outbreaks, but are often unsustainable due to high costs and technology barriers. **BioPrevail aims to generate innovative solutions for labs to be operated in low-resource environments, with the objective of meaningfully and sustainably strengthening global health security.**

Global biological threats are on the rise and diversifying in their nature and complexity, presenting urgent challenges for every nation and region. The vulnerability of the international community to disease outbreaks was underscored by the COVID-19 pandemic, which brought the world to a virtual standstill, undermined global security and caused untold human suffering and loss of life. The pandemic also had staggering economic impacts, with the World Bank attributing a 4.3% contraction of the global economy in 2020 to COVID-19 and the International Monetary Fund forecasting that the pandemic will cost more than \$12.5 trillion through 2024. **The international community's increasing vulnerability to biological threats is compounded by the growing availability of dual use technologies (such as synthetic biology), the potential for misuse of materials and technologies, the escalating frequency of emerging disease events, the endemicity of pathogens in countries with limited capacity and the persistent interest of certain states and non-state actors in bioweapon capabilities.**

In the global campaign to prevent, detect, and respond to natural, accidental, and deliberate disease threats, infectious disease diagnostic laboratories that safeguard biological agents, equipment, and methodologies play a key role. These labs have the potential to support surveillance and early detection of disease events, enable rapid disease containment,

facilitate life-saving research, and allow rapid scale-up to manage surges in sample testing when disease outbreaks occur.

While the critical importance of well-functioning, reliable and efficient diagnostic laboratories is broadly recognized, the inefficiency of such facilities in many parts of the world poses a significant risk to global health security. **Laboratory design is a leading contributor to this glaring disparity.** High containment diagnostic laboratories were pioneered in and designed for high income countries and are therefore often too complex, too expensive to build, operate and maintain, and not sufficiently adaptable to be sustained, particularly in low- and middle-income countries (LMICs). As the absence of regionally appropriate and sufficiently robust diagnostic laboratory capacity undermines hard-won global health security gains, **a new multi-sectoral collaboration – BioPrevail – has been launched.**

The objective of BioPrevail is to move away from the 'one size fits all' approach to biocontainment laboratory infrastructure and to identify and implement new and innovative solutions for safe and effective laboratories that can be operated sustainably in all settings, including lower- resource environments.



Old Problems Demand New Solutions

Laboratory sustainability faces many complex challenges, particularly in LMICs, including significant organisational, technical, and financial barriers. Factors include:

- **Organisational and operational:** including inappropriate facility design and construction, inadequate equipment maintenance, limited availability of reagents and other consumables, and developing and maintaining the skills and competencies of staff.
- **Technological:** including unreliable access to power and other utilities, lack of proper access controls, inability to dispose safely of dangerous waste, dysfunctional systems and equipment due to lack of spare parts or skilled engineers and technicians for certification and maintenance.
- **Financial:** including insufficient budgets for operation and maintenance, lack of political support, insufficient long-term planning, particularly from well-meaning external partners (who often support lab establishment and initial operation) and the governments that inherit the long-term responsibility for operation and maintenance.
- **Environmental:** including extreme local climatic conditions (extreme heat or cold, drought, storms) and geographic inaccessibility (mountains, poor transport networks) affecting supply chains (power, sample shipment, delivery of consumables).

As a direct result of these factors, many laboratory facilities in LMICs are simply unable to meet their core objectives, posing a threat to national, regional, and global health security.

The lab sustainability dilemma is not new. For decades, collaborating entities (e.g. governments, international and regional organisations, civil society, and philanthropic partners) have been working with LMICs to improve lab capacity. A well-intended approach often taken is to provide conventional infrastructure and equipment not adapted to the operational, technological, environmental and budgetary challenges in low resource settings.

The underlying challenges and conditions that have undermined global lab capacity development and impacted negatively on lab sustainability are unlikely to change in the near term, particularly in LMICs. At the same time, the longstanding binary approach to

laboratories (i.e., low tech, low capability vs. highly complex and expensive laboratories) has proven that it is simply not fit for purpose.

It is therefore necessary to change the approach to the health-security capacity building model and to pioneer an enhanced type of laboratory biocontainment facility, operational where required. Such a facility will be designed in full partnership with LMIC stakeholders and be capable of meeting all the requirements of the end-users in these countries, without compromising safety or security.

The gulf between labs in many LMICs and high tech equivalents cannot be bridged with existing approaches

BioPrevail

The Biological Preparedness and Resilience through Evolution and Innovation of Laboratories initiative is the culmination of more than a decade of research, analysis, consultation, and engagement. Initially conceived and supported by the World Organization for Animal Health (WOAH) and the Governments of Canada and the United Kingdom, BioPrevail seeks to build a multisectoral coalition of committed partners and stakeholders to work together to incentivize and identify innovative solutions to reinvent the diagnostic lab, making it fit-for-purpose in resource-limited contexts. The goal of this ambitious initiative is to reimagine laboratory infrastructure to reduce ongoing operational costs and ensure safe and secure handling of high-consequence pathogenic materials, whilst maintaining core functions of a diagnostic laboratory.

BioPrevail has the potential to revolutionize global health security. An enhanced type of diagnostic laboratory – purpose designed for operation and maintenance in low-resource environments – would accelerate implementation of the International Health Regulations (IHRs) and WOAH's International Standards, support the objectives of the Global Health Security Agenda (GHSA), make major contributions to an eventual international pandemic instrument and reinforce the biological threat reduction priorities of the G7-led Global Partnership Against the Spread of Weapons and Materials of Mass Destruction. It likewise presents leadership and collaboration opportunities for the G7, the G20, and others in the active discovery and implementation of transformative health-security solutions.

Call to Action

For too long, too little has been done to address the structural deficiencies, inequalities and global health security threats that are inherent in or a product of unsustainable diagnostic laboratories in LMICs. Different outcomes demand new approaches. Join us in this ambitious but attainable effort to enhance Biological Preparedness and Resilience through Evolution and Innovation of Laboratories.

How to Achieve Lab Sustainability in LMICs?

A diagnostic laboratory is a collection of functions which allow disease detection, characterization and pathogen storage in a safe a secure manner. Lab sustainability is a state when minimum functions and services can be maintained. Minimum functions and services include:

- safe and secure cold storage (at -4°C, -20°C and -80°C) of biological material (diagnostic samples, pathogens, reagents, cell lines);
- receipt, handling and processing of samples in a timely manner (whole carcasses of varying sizes (livestock to poultry)), serum, blood, tissues, exudates, faeces/urine, body fluids, environmental samples) for examination and diagnostic testing;
- conducting a minimum range of diagnostic and characterization procedures for common endemic and epizootic pathogens (and differentiate new and emerging infectious diseases) then interpreting and reporting results;
- safe and secure storage and shipment of samples and biological material (compliant with international standards) to Reference Laboratories for further confirmation/characterization;
- safe inactivation and disposal of contaminated materials (waste and samples);

These functions must be maintained in a 'low-resource' setting, which could be described as follows:

- a low- to middle- income country with only a limited operating budget for the facility and system;
- a weak national disease surveillance system with periodic fluctuations in sample submissions (e.g., a low level of submission with periodic surges);
- an endemic disease burden with a high risk of epidemics and epizootics.
- an insecure social environment, with potential for theft or illicit acquisition of equipment and biologic material;
- limited local expertise for engineering, maintenance, and certification.
- difficulties recruiting and retaining staff with the required competencies and no systematic process for continuing education.
- interruptions in the supply chain for consumables, equipment spare parts, laboratory reagents;
- frequent interruptions to power and water supply (which may last up to 6 days), energy and fuel prices fluctuate and may be prohibitive.
- a challenging climate (seasonal rainfalls and a high temperature range);
- unreliable ground transport networks.

BioPrevail will address the problem of lab sustainability from several angles:

- Continue to build the evidence base to identify the factors that challenge laboratory sustainability;
- Advocacy aimed at key decision makers, end-users, investment partners and implementers to raise awareness and invite them to join the call for action;
- Programmatic activities to laboratory improve sustainability, e.g. training in equipment maintenance; and innovation to actively seek transformative solutions to key engineering problems.