



GLOBAL HEALTH CENTRE WORKSHOP REPORT

GOVERNING PATHOGEN- AND BENEFIT-SHARING

FROM PANDEMIC INFLUENZA TO OTHER
PATHOGENS OF PANDEMIC POTENTIAL

GOVERNING PATHOGEN- AND BENEFIT-SHARING: FROM PANDEMIC INFLUENZA TO OTHER PATHOGENS OF PANDEMIC POTENTIAL

WORKSHOP REPORT

AUTHORS

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This workshop report is part of the project "Understanding the norms and practices of pathogen-sharing to improve global health security", supported by the Swiss Network for International Studies (SNIS).

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Access to pathogens and the sharing of benefits arising from their use is a key concern for global health. Across recent outbreaks, including Ebola, Zika, MERS-CoV, and the newly emergent SARS-CoV-2, questions around the sharing of samples and related genomic sequencing data (GSD) and their associated benefits have been central considerations. Given a growing recognition of the need to ensure timely and fair pathogen- and benefit-sharing (PBS)¹ for pathogens of pandemic potential among humans, a 4-hour online workshop, *Governing Pathogen- and Benefit-Sharing: From pandemic influenza to other pathogens of pandemic potential*, was held on July 2, 2020. In advance of the meeting, the organizers² prepared a draft research report on drivers and challenges for PBS and the breadth and scope of policy options proposed for PBS governance. The aims of the workshop were to:

- Provide feedback on the research findings regarding the current state of PBS practice,
- Provide feedback on the various policy options for PBS governance found in the research,
- Discuss next steps for PBS governance.

This workshop report summarizes the main points from the workshop presentations and discussions. The event took place under a modified Chatham House rule whereby views and comments are not attributed to specific individuals, but the list of participants is not confidential. About twenty stakeholders, including scientific researchers, policy practitioners, and civil society actors, participated in the workshop (Annex 1).

PRESENTATION OF RESEARCH REPORT

The draft research report, “*‘Everybody knows this needs to be done, but nobody really wants to do it’: Governing Pathogen- and Benefit-Sharing*,” summarized key findings on current PBS practices, governance arrangements currently in place, drivers for the sharing and non-sharing of pathogens, and what research participants identified as working and or not working.

The research team gathered data from interviews with 73 stakeholders, an analysis of data from WHO’s Influenza Virus Traceability Mechanism (IVTM), and 25 sample and enacted Material Transfer Agreements (MTAs). The research report noted a climate of uncertainty surrounding the informal and formal norms governing PBS. There was

¹ *Pathogen- and benefit-sharing* (PBS) is used here to designate *access- and benefit-sharing* (ABS) of pathogens. PBS encapsulates a broad range of issues related to the sharing of pathogens (from viral sovereignty issues to biosecurity and biosafety issues), and the sharing of any benefits that may result from use of the pathogens.

² The research team is composed of Suerie Moon (Principal Investigator), Gian Luca Burci (co-Principal Investigator), Anthony Rizk (doctoral researcher) and Anna Bezruki (researcher). The project benefited from the expertise of its advisers, namely Anne Huvo (WHO), Tolbert Nyenswah (Johns Hopkins Bloomberg School of Public Health), Jorge Bermudez (Fundacao Oswaldo Cruz), Mosoka Fallah (National Public Health Institute of Liberia), Rebecca Katz (Georgetown University), Stephanie Dagon (University of Geneva), and Sylvie Briand (WHO). The research is funded by the [Swiss Network for International Studies \(SNIS\)](#).

consensus among interviewees on the need for fair, equitable, and reasonable benefits, but significant uncertainty about what that concept means in practice. Drivers for the sharing of pathogens of pandemic potential include instrumental reasons (e.g., outbreak response or receipt of benefits), scientific norms, political considerations, national security or biosecurity concerns, commercial and financial interests, and legal obligations (e.g., participation in the PIP Framework or enforcement of the Nagoya Protocol).

Researchers interviewed reported generally being able to acquire pathogen samples, often through existing partnerships, with some exceptions. However, fair and equitable benefit-sharing does not always occur, whether during emergencies or in routine practice. Particularly in emergencies, ensuring adequate PBS is made more challenging when the stakes are higher and sharing becomes more time-sensitive, and it is by no means guaranteed. Interviewees noted that disparities in technology and laboratory and human capacity, biosecurity and biosafety concerns, and commercial interests all shape decisions to share pathogens and negotiations around associated benefits. For example, those with limited laboratory infrastructure may experience pressure to send samples to countries with greater resources, particularly when biosafety concerns are involved. Scientific researchers may be hesitant to share with commercial actors due to lack of confidence in receiving benefits, lack of clarity around the emerging national and international rules, negative previous experiences, or lack of institutional arrangements to work with commercial actors. In addition, interviewees noted disparate capacities among smaller and larger institutions and researchers to respond to the increasing complexity of rules surrounding PBS, for example due to implementation of Nagoya.

The lack of clear consensus on how to strengthen the governance of PBS was a key finding of the research. Rules to govern PBS could range from non-binding informal to binding formal rules. The geographic scope (e.g., regional or club models), scope of pathogens included (e.g., priority pathogens), and scope of use (e.g., types of use permitted) could all vary. Options identified in the research or by participants include adoption of a PIP+/PIP-like approach; use of specialized international ABS instruments within Nagoya; expanded use of MTAs; creation of biobanks; and/or creation of a traceability mechanism. These options are not mutually exclusive, and several could be combined to form a functioning system.

PBS: WHAT IS WORKING AND NOT WORKING

In keeping with the report's findings, participants noted the absence of a reliable and predictable system to ensure access to pathogens or benefits. The current system's reliance on personal relationships was highlighted as both a strength and a weakness; in times of emergency and scarcity, personal relationships may be both necessary yet insufficient to maintain timely PBS. Participants agreed that formalized governance approaches are needed, even though this could complicate successful informal collaborations on a personal basis. Participants also noted that norms on the

importance of pathogen-sharing have been clarified and strengthened over time – particularly with respect to public health emergencies – but there has not been the same clarification regarding benefit sharing.

Benefit sharing was seen as being limited by a lack of knowledge and enforcement of existing frameworks (e.g., the Nagoya Protocol), and it was noted that those in low-resource settings may feel compelled to share without sufficiently fair and equitable benefits due to lack of laboratory capacity and the immediacy of an emergency. Although defining benefit sharing remains contested, there was a general recognition that benefit-sharing could not be one-size-fits-all, and varies based on the interests of the sample provider (e.g., low-resource settings may prioritize capacity building over academic recognition), the anticipated research outcome (e.g., sharing intellectual property or financial benefits may be more or less relevant depending on the objectives of the research) and the type of receiving institution (academic vs. commercial, for example). In addition, ascribing specific value to pathogens was identified as very challenging, particularly when samples are used for basic research.

CONSIDERATIONS FOR PBS GOVERNANCE

There was consensus that achieving timely and fair PBS would require clarifying and developing the rules governing it, which must be consistent with existing international frameworks. Participants offered a range of views on how to achieve this.

PURPOSE OF PBS GOVERNANCE

Participants identified several considerations regarding the purpose of PBS governance:

- Governance should foster a PBS system that facilitates sharing in a manner that promotes equity between sending and receiving countries and institutions.
- Rules should explicitly consider GSD. Important differences remain between GSD and physical pathogen samples, especially in terms of their utility and their priority for laboratories with different technological capacities. Participants underscored that, as GSD usage spreads, it is blurring understandings of obligations and expectations of PBS, and debate continues over whether, and under what conditions, GSD sharing should be tied to benefit-sharing, and the nature of such benefits. Nevertheless, participants emphasized that any policy solutions for PBS governance should consider applicability to both GSD and physical pathogen samples.
- The benefits that can reasonably be expected from pathogen-receiving institutions was discussed, especially the distinction between academic/government and commercial institutions. Some participants were concerned about placing identical expectations on non-commercial and commercial actors, arguing that a straight line cannot necessarily be drawn between basic research and the development of products with commercial

application. However, others were concerned about inappropriately exempting non-commercial researchers from material benefit sharing, arguing that the line between non-commercial and commercial actors was sometimes blurred due to out-licensing of IP, commercial spin-offs from academic labs, and follow-on sharing of samples with third-party commercial actors. Individual pathogen-sharing entities may also seek quite different benefits, depending on the pathogen, country, outbreak, or potential technology at stake.

POLICY OPTIONS

Participants considered various options, differing in formality and/or scope, for PBS governance. While there was a lack of clear consensus around any single policy approach, there were several areas of general agreement:

- Participants emphasized that any agreement should be consistent with the existing frameworks (i.e., the Convention on Biological Diversity (CBD), the Nagoya Protocol, and the International Health Regulations (IHR)). However, what constitutes consistency needs further clarification.
- Participants generally concurred that any agreement would need to account for the special considerations related to human pathogens, be public-health oriented, and navigable for scientists (particularly those with limited resources).
- Whether the PIP Framework (PIPF) could simply be expanded or replicated for other pathogens of pandemic potential was questioned, given that influenza is associated with an existing sample-sharing framework through the Global Influenza Surveillance and Response System (GISRS) as well as a consistent economic demand (i.e., for seasonal influenza vaccine) that is not necessarily applicable for other pathogens. Furthermore, some respondents expressed concerns around the length and difficulty of the PIPF negotiations and that the PIPF has not yet been tested in a pandemic situation. Others noted that the time invested in the negotiations helped establish both common understandings and mutual investment in the outcome, noting that complex multi-stakeholder agreements take time but can yield long-term benefits. Nevertheless, key principles underlying the PIPF could be more broadly applicable, such as putting pathogen and benefit-sharing on equal footing, implementing a traceability mechanism, at least some degree of standardization of MTAs, identifying a financing system, and clarifying and pooling access to the associated benefits so that countermeasures are provided to countries in need, rather than only those that have shared specific samples.

POLITICAL PROCESS

Participants discussed the conditions that need to be met for advancing the governance of PBS:

- Participants favored pursuing a more multilateral (rather than solely bilateral) approach, despite what one participant identified as the current crisis of multilateralism more broadly.
- Participants emphasized the importance of having a process in which a diverse and representative group of stakeholders (e.g., pathogen providers and recipients; representatives from the Global South and the Global North;

commercial and non-commercial actors) are involved, but the details of precisely the role they should play in final decision making (e.g., whether the agreement should be solely among state actors or should include non-state actors), were not addressed in detail.

- Participants highlighted the importance of addressing the interests of all stakeholders in any PBS governance framework, and noted that reaching agreement on what exactly is fair and equitable benefit-sharing will be a key challenge.
- Participants recommended a focus on function before form – that is, on clarifying and establishing basic agreement on what any PBS governance framework would need to do before deciding upon the normative instrument that might be most appropriate.

NEXT STEPS FOR RESEARCH AND ACTION

RESEARCH

Participants recommended that additional research is needed on:

- The specific positions of states on PBS and their respective expectations, their perceptions on fair and equitable benefits, and their interest in a bilateral or multilateral approach.
- Empirical understanding and documentation of PBS experiences and approaches in the Global South
- The question of benefit-sharing in GSD, including the positions of states on benefit sharing for GSD, and the extent to which different databases do or do not lead to fair and equitable benefit-sharing.

LEADERSHIP

There was general agreement that the Covid-19 pandemic has reminded the world of the importance of strengthening the global governance of outbreaks, and therefore opened a window of opportunity for action; if this is delayed, the political will to craft new international agreements on PBS may dissipate. Champions – a state or group of states willing to take on a political leadership role in advancing PBS governance – are needed to carry this forward. Participants noted that next steps would likely involve a smaller group of stakeholders (at least initially) and recommended that the group be based on shared interest, rather than regional proximity, given the significant inter-regional variability in PBS political positions and laws. Furthermore, there was also consensus that, to be effective, any high-level political coalition should contain a balanced representation of interests and fora where all voices can be heard, with leaders from the Global South and the Global North, from pathogen providing and receiving countries, and the involvement of non-commercial and commercial non-state actors.

ANNEX 1. WORKSHOP PARTICIPANT LIST

NAME	ORGANIZATION
Anna Bezruki	Global Health Centre, Graduate Institute of Geneva, Switzerland
Anne Huvos	Pandemic Influenza Preparedness (PIP) Framework Secretariat, WHO
Anthony Rizk	Global Health Centre, Graduate Institute of Geneva, Switzerland
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Edward Hammond	Third World Network
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Stephen Gunther	Department of Virology, Bernhardt Nocht Institute, Germany
Stephanie Dagon	Faculty of Law & Faculty of Medicine, University of Geneva, Switzerland
Steven Solomon	Principal Legal Officer, WHO
Suerie Moon	Global Health Centre, Graduate Institute of Geneva, Switzerland
Summer Galloway	Influenza Division, Centers for Disease Control and Prevention, USA
Tolbert Nyenswah	Johns Hopkins Bloomberg School of Public Health
Wenqing Zhang	Global Influenza Programme, WHO

ANNEX 2. WORKSHOP PRESENTATION OF PRELIMINARY RESEARCH FINDINGS

Governing Pathogen- and Benefit-Sharing

From pandemic influenza to other pathogens of
pandemic potential

WORKSHOP

July 2nd 2020 – 13:00 – 17:00 CEST

Research team:

Suerie Moon (PI), Gian Luca Burci (co-PI), Anthony Rizk (Researcher), Anna Bezruki (Researcher)



Funded by the Swiss Network for International Studies (SNIS)

The Global Health Centre, Graduate Institute of Geneva
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Project advisers:

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Anne Huvo, WHO

Rebecca Katz, Georgetown University

Tolbert Nyenswah, Johns Hopkins Bloomberg School of Public Health

Overview

- Workshop Report Summary
 - Research Methodology
 - Preliminary Research Findings
 - What do we (not) know?
 - What does benefit sharing mean in practice?
 - Why do we share pathogens?
 - What is working and what is not working in PBS?
 - Options for Governing PBS
 - Project Next Steps
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Workshop Report

*"Everybody knows this needs to be done,
but nobody really wants to do it":*

Governing
Pathogen- and Benefit-Sharing

Objectives

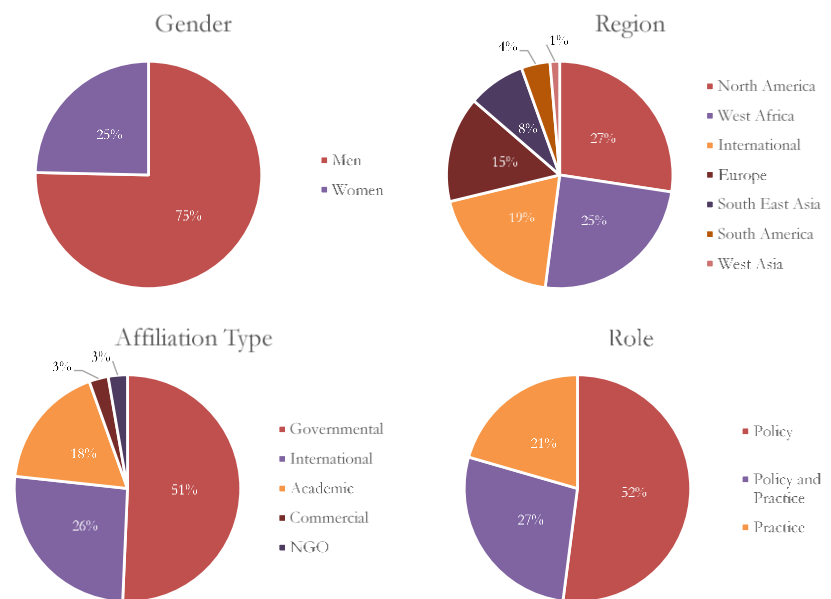
- Clarify current practices of pathogen- and benefit-sharing
- Identify potential solutions for its improvement



Methods

- Interviews (n=73)
- Influenza Virus Traceability Mechanism (IVTM) analysis
- MTA analysis (n=25)

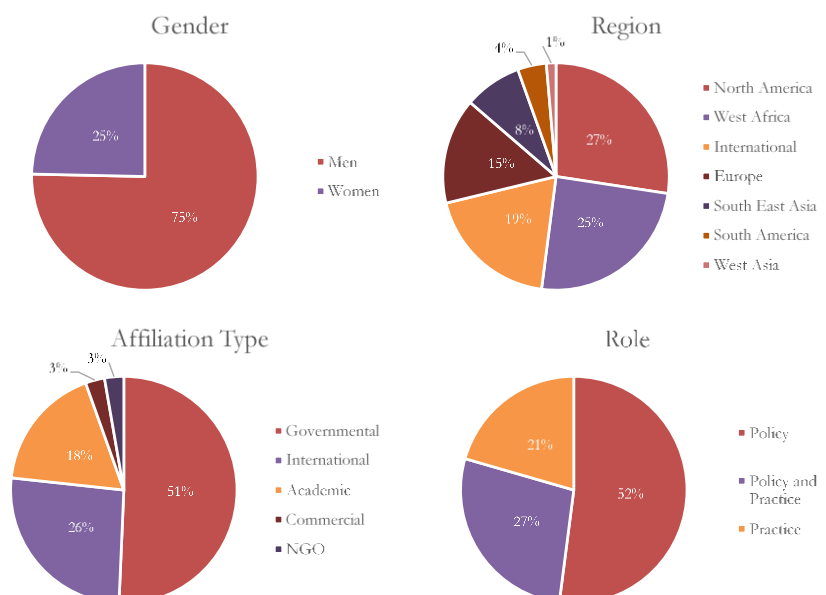
Figure 1: Interviewee Characteristics



Limitations

- Reconstruction from interviews is necessarily limited by our sample
- Sample limitations: difficulties interviewing commercial actors and key countries in the global South
- Signed MTAs are usually confidential
- Political sensitivity of the topic
- Focus on human pathogens

Figure 1: Interviewee Characteristics



What do we (not) know? A climate of uncertainty

- Uncertainty on PBS going forward
 - “You know, if I share my influenza virus, what's happening? Do I lose ownership or not? And this is the uncertainty, I think, which makes things more difficult.” (1.39)
- PBS norms are in flux
 - Tensions anticipated between formal norms (IHR, PIP, CBD, the Nagoya Protocol and national laws)
 - Tensions anticipated with informal norms and established practice
- Large support for benefit-sharing on equal footing with pathogen-sharing, but uncertainty around rules and practices
- Many are calling to move towards increased coherence and clarity in PBS governance

IVTM Analysis Global flow of influenza viruses of pandemic potential

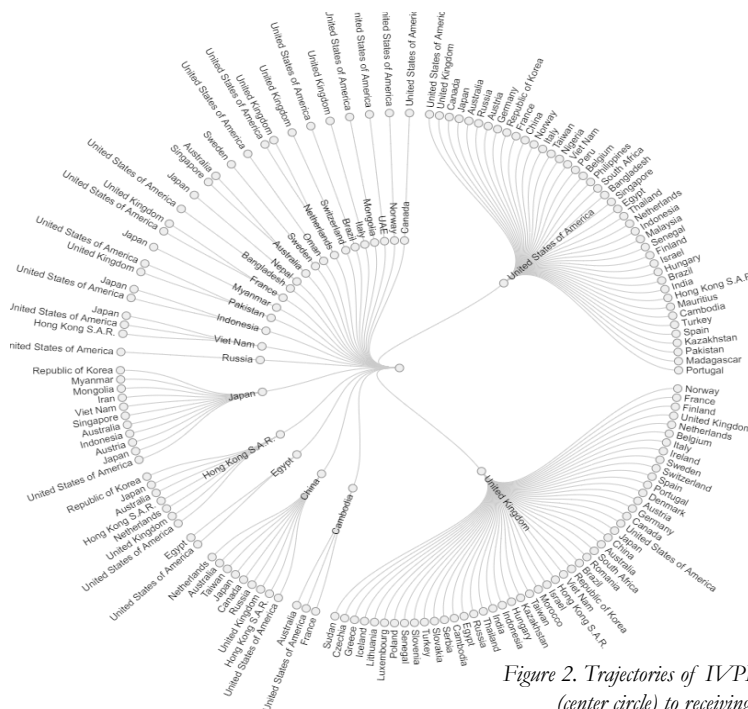


Figure 2. Trajectories of IVPP sharing from sending (center circle) to receiving (outer circle) countries

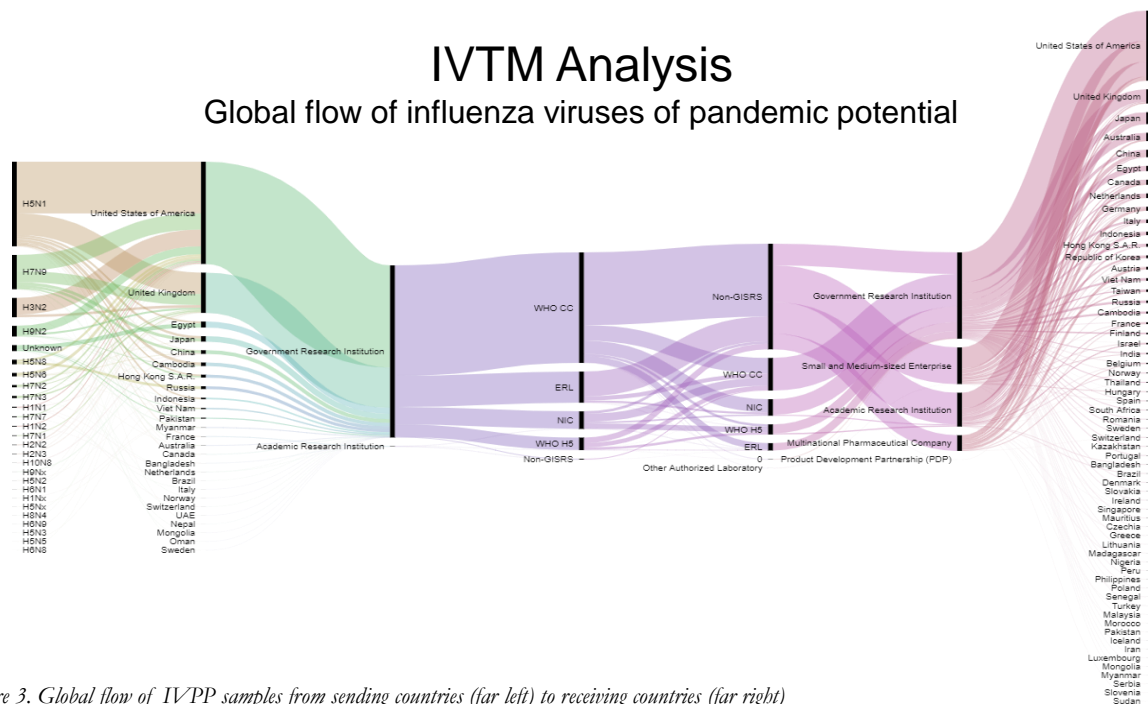


Figure 3. Global flow of IVPP samples from sending countries (far left) to receiving countries (far right)

Why do we share? Drivers for sharing pathogens

- **Instrumental:** to functionally respond to outbreaks & to receive benefits from participation in pathogen-sharing networks
- **Scientific Obligation:** convention of open sharing among scientists
- **Political:** political standing
- **Security:** national security and biosecurity
- **Economic:** financial and commercial interests
- **Legal:** participation in PIP Framework or enforcement of Nagoya Protocol

Benefit sharing

What does it mean in practice?

- Consensus on need for fair, equitable, and reasonable benefits
 - But – disagreement on what this means
 - *“Getting agreement of what it [benefit sharing] is or what it should be unleashes a whole can of worms because it's also about the inequity in the current system. I think you can't always right all the wrongs. It's not a reason not to attempt to right something, some of the wrongs, but realistically that's not always possible so where you draw the line is really, really, complex.” (1.26)*
 - Challenges in valuing pathogens and their associated benefits
-

Benefit sharing

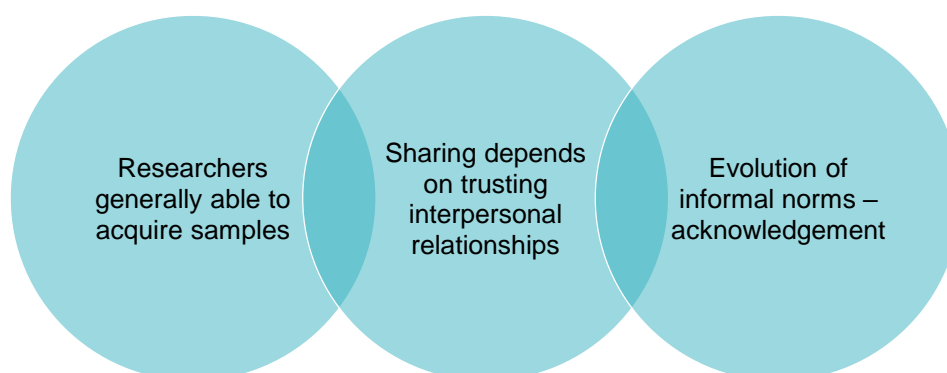
What does it mean in practice?

- Benefits understood variously as:
 - **Global good:** “advancement of public health everywhere” (1.39)
 - **(National) preparedness & response (information, countermeasures):** “We should be certain that if I share the pathogen, whatever they're developing, would be marketed here and at an affordable price” (1.47)
 - **Academic recognition:** “The direct benefits are intellectual and scientific recognition ... we use that expertise to apply for grants and funding” (1.15)
 - **Economic returns:** “If you share pathogens then you are entitled to financial benefit” (1.14)


MTA Analysis Results

Benefits	Types of Provisions
Acknowledgement in Publications (n=17, 68%)	<ul style="list-style-type: none"> Recipient acknowledges source of samples in all written or oral presentations on resultant research, unless otherwise requested (n=13, 52%) Recipient acknowledges or provides co-authorship depending on level of involvement of provider (n=4, 16%)
Access to Research Outcomes (n=15, 52%)	<u>Provisions for providers</u> <ul style="list-style-type: none"> Provider to have access to research product for internal research purposes (n=3, 12%) Provider maintains right to share any research results (n=3, 12%) <u>Provisions for recipients</u> <ul style="list-style-type: none"> Recipient delivers report on research outcomes to provider (n=11, 44%) Recipient to donate for free or at reduced costs resultant products to developing countries (n=3, 12%) Recipient publishes research results in open access format (n=2, 8%)
Cost Recovery (n=11, 44%)	<ul style="list-style-type: none"> Recipient covers cost of shipping and handling (n=4, 16%) Optional cost reimbursement for provider (n=3, 12%) Provider does not charge recipient for shipping and handling costs (n=2, 8%)
Capacity Building/Training (N=2, 8%)	<ul style="list-style-type: none"> Sample provider receives capacity building and training from recipient (n=2, 8%)

Pathogen and Benefit Sharing: What is working?



Pathogen and Benefit Sharing: What is working?



Researchers
generally
able to
acquire
samples

- “People tend to get what they want” (1.12)
 - When it is *not* an emergency
 - Through existing partnerships & avoidance of challenging locales
 - Reliance on networks of known collaborators, developed over many years
 - “It’s often a very personal relationship and negotiation between two scientists” (1.16)
 - Sharing practices are “fundamentally about trust” (1.19)
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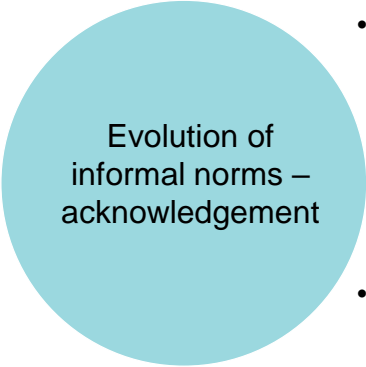
Pathogen and Benefit Sharing: What is working?

- These collaborations can be determinative above other considerations
 - “We do bilateral agreements with individual institutions in different countries ... we come to a common understanding and we don’t really get into whether or not, you know, our country has some treaty with them about a specific law that they have” (1.43)
- The system depends on these relationships
 - “It depends on the pathogen and depends on the community of people working on that pathogen. Most of these communities working on individual pathogens, like measles or malaria, are fairly close now, the people know each other. And it depends on how well they work among themselves” (1.30)



Sharing
depends on
trusting
interpersonal
relationships

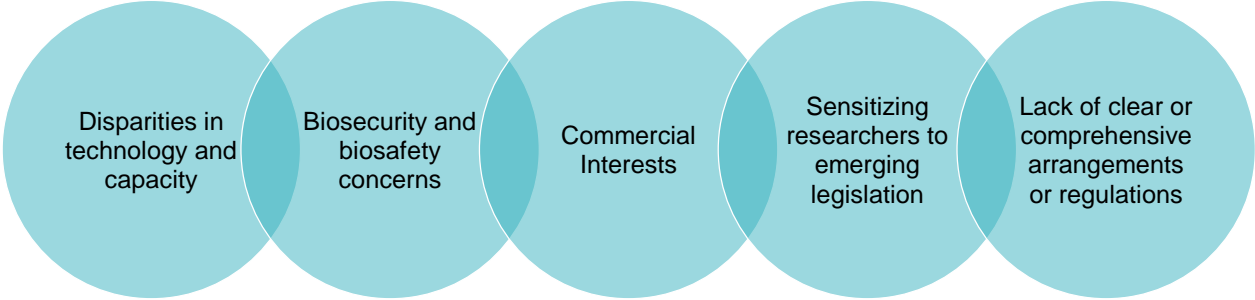
Pathogen and Benefit Sharing: What is working?



Evolution of informal norms – acknowledgement

- Evolution of informal scientific norms for recognition of all collaborations
 - Acknowledgment seen as the right thing to do: “we see that there is growing demand for that kind of exchange” (1.1)
 - “There is much, much more sharing, not only of microbes themselves, but a realization that you really have to share credit, you have to share intellectual academic credit” (1.10)
 - Reflected in some institutional practices and organizational policies, including sample MTAs
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Pathogen and Benefit Sharing: What is not working?



Disparities in technology and capacity

Biosecurity and biosafety concerns

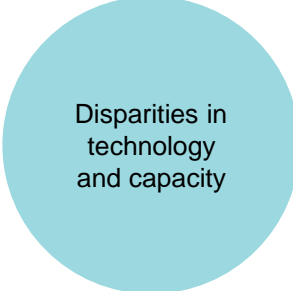
Commercial Interests

Sensitizing researchers to emerging legislation

Lack of clear or comprehensive arrangements or regulations

Pathogen and Benefit Sharing: What is not working?

- Wide range of disparities in laboratory capacity
- Capacity level shapes benefits sought in PBS
 - Low-income settings: Prioritization of capacity building and access to final products
 - High-income settings: Prioritization of academic recognition or see knowledge generation as a benefit
- General agreement – capacity building and technology transfer should be part of PBS



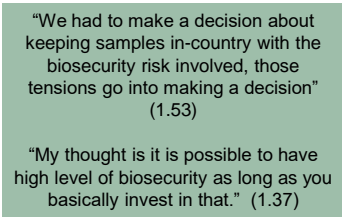
Disparities in
technology
and capacity

Pathogen and Benefit Sharing: What is not working?



Biosecurity
and
biosafety
concerns

- Few labs worldwide are BSL4-equivalent
- Biosecurity and biosafety concerns may lead to
 - Restrictions on sharing
 - Destruction of samples
 - Desire – or pressure – to give samples to countries with high-containment capabilities
 - Dangerous pathogen samples as bargaining chips for capacity building
- Politically charged process



"We had to make a decision about keeping samples in-country with the biosecurity risk involved, those tensions go into making a decision" (1.53)

"My thought is it is possible to have high level of biosecurity as long as you basically invest in that." (1.37)

Pathogen and Benefit Sharing: What is not working?

Commercial Interests

- Assigning value to pathogens
 - “How much are you going to ask as a payment when you don’t actually know the value of something?” (1.24)
- Distrust
 - “So we trust a lot, given that the organization with whom we share most commonly are not necessarily commercial organization.” (1.43)
- Material vs non-material benefits
 - “If you share pathogens then you are entitled to financial benefit” (1.14)
 - “By all means a population that is used to find a solution for a public health situation should benefit at no cost to them...[they] should not be paying for these Ebola vaccines” (2.20)
 - “I think that perception that information itself is a benefit is missing in a lot cases. A lot of people only see benefits as something tangible, as something in the bank account” (1.30)

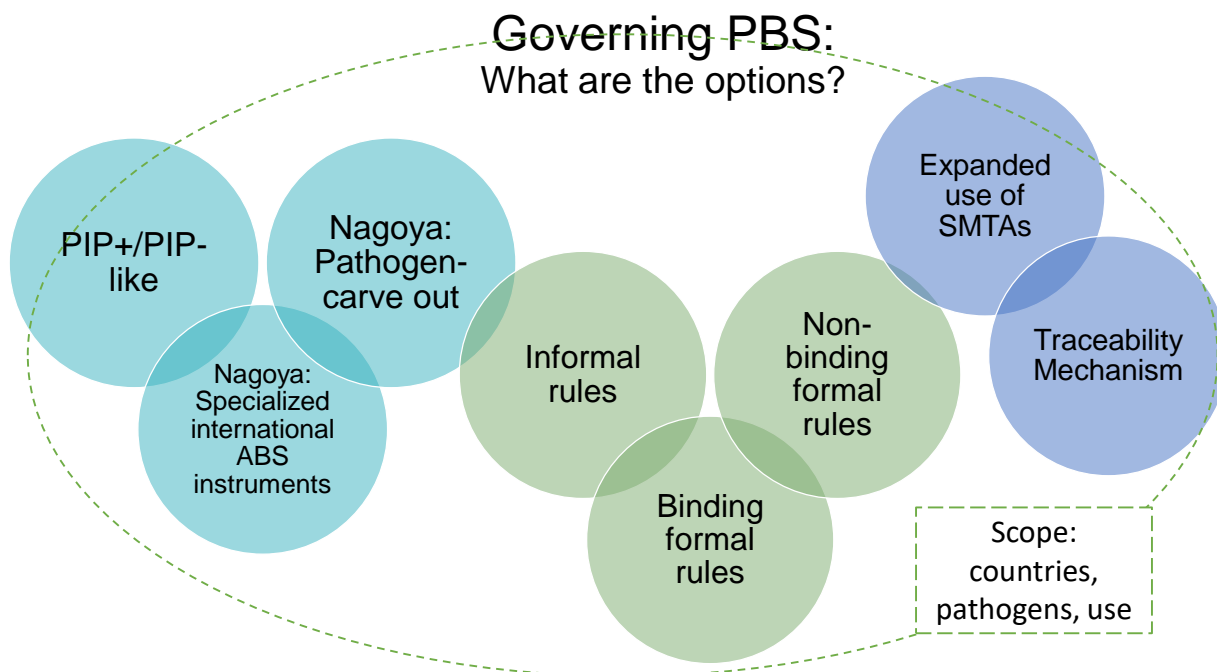
Pathogen and Benefit Sharing: What is not working?

Sensitizing researchers to emerging legislation

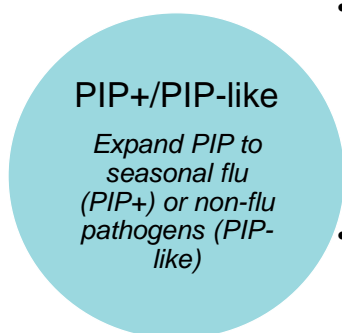
- Varied ability for institutions and researchers to respond to increasing legislation and bureaucracy surrounding PBS
 - Larger/better resourced institutions – with legal offices and ability to sensitize researchers to new legislation – are faring better

Lack of clear or comprehensive arrangements or regulations

- Concerns about excessive red tape and complications to share pathogens (particularly in outbreaks)
 - Concerns and hopes about Nagoya coexist
- **Consensus on need for new/revised normative frameworks around PBS**
 - to give countries adequate clarity and confidence to share
 - “we have a framework in sample sharing but don’t have a framework that’s working well for benefit sharing” except on a “case by case” basis (1.5)
 - “there’s a great deal of importance in having an international norm and having something in writing” (1.7)



Governing PBS: What are the options?



- Conditions for success for PIP may not apply to other pathogens
 - “A PIP framework type of instrument is possibility, but I think we are not there yet ... In the PIP, I think it was in a way more ready-made in the sense that there was a network of laboratories that are meeting regularly ... the PIP framework was really to put in place some terms and conditions because this system of sharing was really important to develop the vaccine” (1.14)
- Lack of political readiness or appetite
 - Need for clarity on scope, PBS conditions, role of WHO, and Nagoya implications
 - “No one wants to spend political capital on either expanding PIP, I’ve heard people say non-starter, not going to happen, forget about that ... There isn’t a center of gravity there that someone’s going to pick up on and run with” (1.11)

Governing PBS: What are the options?

Nagoya
related:
Pathogen
carve out

- Pathogens exempted from Nagoya Protocol ABS requirements in multilateral agreement
- Some respondents support, others concerned about weakening CBD protections
 - "I think the whole thing gets over-regulated and Nagoya gets used for things where it shouldn't be used for" (1.45)
 - "It's not about carve out or exemption, it's about an alternative implementation that is consistent with and not contrary to, [the Nagoya Protocol]." (1.35)

Nagoya
related:
Specialized
international
ABS
instruments

- SII to facilitate PBS for public health purposes
 - "And there could be a future wherein you have one or more specialized instruments that relate to other potentially pandemic pathogens and I think that would be a good thing, but...the agreements themselves need to exist and they need to be clearly consistent with and not contrary to the Nagoya Protocol in order to proceed in that direction" (1.32)

Governing PBS: What are the options?

Informal
rules

- Codified, non-binding rules, a set of principles agreed upon by stakeholders (e.g. Declaration of Helsinki or CIOMS Ethical Guidelines)
 - "...if you have a long cumbersome process that could just have people run away from it, I think you can get some sort of norm, an agreement." (1.10)

Non-binding
formal rules

- Codified non-binding norms, negotiated and agreed upon by governments through a formal process and backed by an intergovernmental entity (e.g., PIP Framework)
 - "If we can define timely sharing and what's a reasonable framework for negotiations around benefits [that would be good]" (1.23)

Binding
formal
rules

- Codified binding norms backed by an intergovernmental entity (e.g., IHR, CBD, and Nagoya Protocol)
 - "We have treaties in other areas than public health to try and have some norms in place that keep us from going off the rails." (1.23)
 - "Worldwide, I think, you may have expected reluctance from some countries in particular developed countries to enter into a binding agreement." (1.24)

Governing PBS: Scope of Rules

Geographic scope

- 'Club models' or regional models
- State and non-state actors can reach mutually acceptable norms, principles and arrangements
- A process can be kick-started by 10-15 sending and receiving countries

Scope of pathogens

- From narrow list of priority pathogens to broader scope
- Priority for international rules are where national security and commercial concerns are at stake
- Complexity of including novel pathogens

Scope of use

- Types of use permitted and benefits shared
- Standardized terms for non-commercial use may be easier to reach
- Economic benefits negotiated case-by-case with guiding principles?

Governing PBS: What are the options?

Other options

Expanded use of Standardized Material Transfer Agreements

- **Expanded use of SMTAs:** providing a standardized, but customizable approach
 - "That's all about hav[ing] the right agreements and enforcing them, so you need good negotiating capacity, if you fail in drafting, then there is no way of doing it." (1.24)

Traceability Mechanism

- **Traceability mechanism:** transparency on how and with whom sharing is occurring
 - "Let's see what's being shared with who and on what basis so that we can look at the adequacy and the timeliness of the sharing and evaluate that." (1.11)

Acknowledgements

We are grateful to:

- Workshop participants
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