SNIS Final Report: "Understanding the norms and practices of pathogen-sharing to improve global health security"

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Abstract of the Executive Summary

The fair, reliable and rapid international sharing of pathogens and related benefits—which we refer to here as pathogen- and benefit- sharing (PBS)—is critical for protecting global public health, particularly in the event of outbreaks of infectious disease. This research project was motivated by the need to increase understanding of current practices in PBS and identify workable solutions for their improvement. We conducted 86 interviews with experts involved in PBS internationally (n=53), during Liberia's 2014–16 Ebola epidemic (n-20) and during Brazil's 2015–16 Zika epidemic (n=13). We triangulated our interview data with quantitative data on influenza virus shipments from the Influenza Virus Traceability Mechanism (IVTM) and 26 Material Transfer Agreements (MTAs). Respondents expressed significant concern around the incoherent global governance of PBS, particularly in light of the coming into force of the Nagoya Protocol on Access and Benefit-Sharing in 2014. Pathogen-sharing relied heavily on interpersonal relationships of trust and was not reliable during emergencies, although such sharing occurred regularly outside of outbreaks. Benefit-sharing practices varied widely, with a broad range of understandings regarding what "benefits" could or should mean concretely. Power disparities between stakeholders shaped which pathogens and benefits were shared, with whom and on what terms and conditions, with the security and economic value of both pathogens and benefits escalating rapidly during emergency outbreaks. Our research found no single solution supported by a critical mass of stakeholders, but enough consensus on key principles for a small representative group of stakeholders to start the process of clarifying international normative frameworks for PBS governance. Further case studies are needed on PBS in specific outbreaks, the kinds of benefit sharing arrangements that have been implemented, as well as studies on PBS practices in plant and animal health.

Executive Summary

Introduction

A perennially thorny issue hampering the global community's ability to manage infectious disease outbreaks is the fair, reliable, and rapid international sharing of pathogens and related benefits, which we refer to here as pathogen- and benefit- sharing (PBS). When outbreaks of infectious diseases occur, healthcare workers and researchers often take samples of biological materials (e.g. blood, saliva, tissue) from infected persons for both medical and research purposes. Access to pathogen samples and related data is critical for researchers seeking to identify and understand pathogens or to develop medical countermeasures (e.g. diagnostics, drugs, vaccines). At the same time, the ability for pathogen-sending countries to access the medical countermeasures developed from the use of pathogens is critical for outbreak control and prevention. This research project was motivated by the need to increase understanding of current practices in PBS and identify workable solutions for their improvement, especially in light of the scarcity of empirical data to inform the negotiation of such arrangements.

Presently, there is no publicly available and centralized data source tracking the international movement of pathogens or related benefits – with the important exception of one type of pathogen, influenza viruses of pandemic potential (IVPP) – and, as such, we do not have a clear picture of who shares which pathogens with whom, how quickly, under what terms and conditions, what benefits (if any) apply to those exchanges, or which are the most frequent hurdles preventing or delaying PBS. Furthermore, while the literature on PBS has focused on a relatively small number of cases in which pathogen sharing was controversial (e.g. 2007 H5N1 influenza, 2013 Middle-East Respiratory Syndrome (MERS)) [1]–[5], there remains little clarity on PBS practices for other pathogens of pandemic potential, or pathogens more broadly. In terms of the governance of pathogen sharing, the literature [6]–[9] has largely focused on the relevant international legal norms, namely the 2005 International Health Regulations (IHR) [10], the 2011 Pandemic Influenza Preparedness (PIP) Framework [11], and the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (hereafter, the Nagoya Protocol) to the Convention on Biological Diversity (CBD) [12]. Important gaps remain in understanding the role of other factors relevant to PBS, including the conditions under which PBS is likely to become problematic, informal norms governing PBS, such as those between scientists or networks of research institutions, and agreements between organizations, such as material transfer agreements (MTAs) or research contracts.

Methods and analysis

We reviewed the literature on PBS, including known cases of contested PBS and broader analyses of relevant international norms, rules, and political economy. We also searched for any publicly available data on the actual international movement of pathogens and related benefits, and found only one source – the Influenza Virus Traceability Mechanism (IVTM), established as part of the PIP Framework [11]. We identified an initial list of interviewees based on published experts on the topic, inputs from our advisors and project partners, and our knowledge of the field and relied on snowball sampling to expand the list until thematic saturation. In total, we conducted 86 interviews between November 2018 and October 2020. Between November 2018 and December 2019, we focused on interviewing 53 experts involved in international policymaking or scientific practice around PBS. We then focused on two in-depth case studies, one on Ebola PBS in Liberia during the 2014–2016 Ebola Virus Disease (EVD) epidemic, for which we conducted 20 interviews (mostly in-person in Liberia) in November 2019, and another on Zika PBS in Brazil during the 2015–2016 Zika epidemic, for which we conducted 13 online interviews from July 2020 to October 2020. We also searched for publicly available documents and solicited documents from interviewees, particularly MTAs, applicable legislation, and organizational policy documents, collecting 26 MTAs throughout the study period. Altogether, we triangulated among these data sources to generate the findings and conclusions presented in this research. Interviews were recorded with the consent of respondents, or otherwise detailed hand-written notes were taken, and transcripts were analyzed thematically. Ethical approval was granted by the Institutional Review Boards of the Graduate Institute of Geneva (IHEID), the University of Liberia (UL-PIRE) and the National Commission for Research Ethics (CONEP) in Brazil.

Limitations

This study has a number of limitations. There is little quantitative or qualitative data in the public domain on the sharing of pathogens or related benefits. Therefore, we sought to reconstruct from interviews a necessarily impressionistic picture of current practices and drivers. In addition to the near total absence of quantitative data, key documents such as executed MTAs or other contracts are usually confidential. Despite our efforts to cover a broad range of interlocutors, the number and breadth of interviewees does not capture all countries or stakeholder groups. The results should be interpreted with these limitations in mind. Moreover, while interviewees generously shared their time and knowledge, the political sensitivity of the topic is likely to have limited the kinds of information and documents shared with us. Finally, two important issues were outside the scope of our research: PBS for animal, environmental and plant pathogens where practices may differ from those for human pathogens, and the sharing of genomic sequence data (GSD), which we examined in relation to the sharing of physical samples but did not analyze in-depth. Both issues merit further in-depth research. Despite these limitations, we believe this study represents the largest collection of empirical data on PBS practices for emerging infectious diseases that is available in the public domain.

Results

Respondents expressed significant concern that PBS was becoming increasingly complex and uncertain. Particularly in light of the coming into force of the Nagoya Protocol on Access and Benefit-Sharing in 2014, respondents noted a need for coherence across international and national principles, guidelines, rules, and regulations. While respondents largely agreed that timely sharing of pathogens is important, there is a recognition that rapid pathogen sharing may only be realizable once uncertainty around benefits are reduced. Respondents have reported that the formal and informal norms that govern PBS – the principles, guidelines, laws, and regulations – are becoming increasingly complex.

Where formal norms for PBS are concerned, two main issues were raised by interviewees related to the implementation of the Nagoya Protocol. First, that its implementation may impact the everyday functioning of global pathogen sharing networks, such as the Global Influenza Surveillance and Response system (GISRS) and, secondly, that the emergence of a mosaic of national legislation around PBS may complicate timely and effective PBS more broadly. Variation among countries was noted, with some having a clear system for managing PBS, while others are characterized by competing norms and policies across different governmental sectors (such as health, environment, and trade). This research also confirmed that informal norms play an important role for PBS. Trust, personal relationships, long-term collaborations, and the desire to behave ethically or promote equity emerged as key factors that impact the way PBS takes place in scientific practice. Personal relationships were particularly emphasized and were reported to precede legal arrangements. This leads to a wide variety of case-by-case agreements, negotiations, and the absence of clear standards for PBS. Respondents anticipated tensions between informal and formal norms as PBS practices become formalized. As such, calls for increased coherence in governing PBS are not only about reconciling formal norms, but also about bridging formal and informal norms.

Given a lack of global tracking mechanisms, it is unclear how many countries are actively engaged in PBS; however, analysis of international sharing of Influenza Viruses of Pandemic Potential (IVPPs) found that, in the past two decades, a relatively small number of countries – about 15 – have been actively engaged in their international sharing. Drivers for pathogen sharing are multi-faceted and encompass instrumental, political, economic, and legal reasons. Trust, personal relationships, and long-term collaborations were identified as playing a defining role in the success or failure of effective PBS. The absence of trusted collaborations has often led to slow, inefficient, and potentially detrimental barriers to access pathogens or benefits, which may be difficult to overcome quickly in times of crisis. Overall, there appears to be growing recognition among interview respondents of the need for benefit sharing on equal footing with pathogen sharing. However, there is little consensus on what constitutes fair, equitable and reasonable benefits and we found large variations in practices and views among different groups and across global divides.

We organized respondents' different understandings of benefit-sharing around four non-mutually exclusive understandings of benefits: 1) benefit as the "global good" that pathogen sharing generates for global public health, 2) benefits as access to countermeasures, and increasing local preparedness and response capacities, 3) benefits as scientific and intellectual recognition in academic spheres, 4) benefits as the realization of economic benefits for pathogen-sending countries. Two key areas of contention around benefit-sharing emerged. The first was distinguishing 'academic' from 'financial/economic' benefits, where some respondents argued that academic benefit-sharing is becoming disproportionately represented at the expense of economic benefits. The second revolved around how to ascertain the value of pathogens and what constitutes fair and equitable benefit-sharing, where little international guidance is available. Furthermore, our analysis of Material Transfer Agreements (MTAs)—legal contracts that govern the transfer of research materials and associated data between parties—showed significant variations in benefit-sharing provisions in MTAs examined, where acknowledgement in publications was more widely represented than capacity building and training or access to research outcomes.

Interviewees pointed to areas in which current PBS arrangements are working, as well as ways in which they are falling short. In general, researchers reported being able to get desired pathogens under certain conditions and in normal (non-outbreak) situations and that collaborations that resulted in shared benefits were more likely to build trust and willingness for future sharing. Another area that appears to be a bright spot in PBS is the evolution of informal norms of scientific collaboration to include recognition of all partners in acknowledgements and co-authorship of scientific publications and that measures that "put ethics first" above and beyond international and national legal requirements in regard to sharing benefits are becoming enshrined in organizational policies, many of which are now codifying provisions on PBS. However, timely sharing during outbreaks was more problematic and numerous barriers to PBS were described, including disparities in technology and capacity, complications due to biosecurity and biosafety concerns and the involvement of commercial interests. Furthermore, many reported limited awareness of changing rules and the lack of clear or responsive arrangements or regulations as complicating factors for PBS going forward.

In Liberia's Ebola Virus Disease (EVD) epidemic (2014-2016), an absence of clear rules governing PBS resulted in a large unregulated exodus of EVD samples during and after the outbreak response. For EVD samples that were shared with the agreement of the Liberian government due to the biosecurity concerns involved in keeping samples in-country, Liberia negotiated retaining ownership of EVD samples sent to the United States. There was a clear preference among Liberian scientists for samples to be kept in-country; this, however, was contingent on building the needed capacity for their safe and secure storage. Liberian scientists stressed the need to leverage access to pathogens for laboratory capacity building and infrastructure development projects in Liberia in order to build sustainability and reduce dependency on external capacities going forward.

In Brazil's Zika Virus Disease (Zika) epidemic (2015-2016), the Zika outbreak coincided with a period of changes to Brazil's biodiversity laws that codified PBS. The law, however, created a regulatory vacuum between the time of its coming into force and the creation of the online registration system and legal instruments to enforce it, which coincided with the entire period of the acute phase of the Zika epidemic. This led to initial delays in sharing Zika samples for global health response. Brazilian scientists reported further drivers for hesitancy in sharing pathogen samples internationally, including previous experiences of inadequate benefit-sharing and a belief in the importance of using national capacities, fostering equitable international collaborations and securing official benefit sharing arrangements.

Despite stark differences between Liberia's EVD and Brazil's Zika outbreaks – including different national capacities for outbreak response and governance frameworks – our case studies found a number of characteristics common to both cases of PBS: First, outbreak pathogens became highly sought-after and valuable resources at the onset of the epidemics. Second, previous experiences with benefit sharing perceived as unfair informed the decisions of governments and scientists in these specific outbreaks. Third, the absence of previously negotiated benefit sharing arrangements resulted in intense negotiations around PBS, some of which impacted either rapid pathogen sharing or fair and equitable benefit sharing. Fourth, access to pathogens has been leveraged for certain benefits in both outbreaks. Last, both countries experienced post-outbreak formalization of PBS processes through the institutionalization of standardized MTAs and legislative or regulatory change.

Evidence from these case studies support the conclusion that national governance of PBS is an emerging reality that global health actors will have to contend with. It is not certain that PBS will be timely or equitable in either country in the next epidemic, leaving many of the original problems unresolved.

Overall, we found broad consensus that clarifying and improving the coherence of national and international normative frameworks around PBS was a priority, with strengthening the governance of benefit sharing needing particular attention. Respondents identified many options to address PBS governance, including less formal principles or codes of conduct, binding or non-binding formal rules, and expanded use of standardized MTAs. Each of these normative instruments could vary in terms of the scope of included countries, pathogens, uses and benefits. While each of these options have their proponents, there was no clear policy direction that was strongly supported or advocated by a critical mass of respondents.

Conclusions

Though policy options are many, the way forward is unclear. Additional research into PBS is needed. For example, further case studies are needed on PBS in specific outbreaks, the kinds of benefit sharing arrangements that have been implemented, as well as studies on PBS practices in plant and animal health. A complementary but separate stream of research should be dedicated to the sharing of genetic sequence data, which is becoming increasingly important and has replaced sample sharing on some occasions. Nevertheless, a few conclusions about possible next steps can be advanced based on this research.

1. Traceability. Improving the tracking of PBS will be necessary both to increase understanding of current practices, and to assess how well any future policies perform. More traceability and transparency of information on the movement of pathogen-samples and related benefits is feasible, as demonstrated by the PIP Framework. A traceability mechanism may be a component of a comprehensive negotiated framework, or a first step that could contribute to building one.

2. Leadership from a small group of countries. Given preliminary findings on the relatively small number of countries actively involved in global pathogen sharing, a relatively small group of stakeholders could start the process for developing normative frameworks for PBS governance. However, given that PBS is highly politicized, and that "club model" approaches could be seen as excluding opposing views, it will be critical to include a diversity of views and interests in early negotiations in order to avoid further entrenching existing tensions.

3. There is agreement to build on. There is cautious optimism that, a decade after the PIP Framework, there is wide-spread acceptance of the importance of benefit-sharing being on equal footing with pathogen-sharing. However, substantial efforts need to be devoted to clarifying benefit sharing as it relates to human pathogens.

4. Coherence within the complexity of existing rules. Though existing rules and their interactions are complex and need to be carefully studied in the development of new rules and frameworks, this need not block the development of specific rules for PBS so long as consistency with the objectives of the IHR, CBD and Nagoya Protocol is maintained. It will be critical to consider how to govern the sharing of genomic sequencing data (GSD) alongside physical pathogen-samples, rather than leaving this issue on the sidelines. It remains an open question whether GSD would be better governed through a separate framework or integrated into rules pertaining to physical pathogen samples, but it is clear that the issue cannot be left unaddressed.

5. Time to move forward. It is time to push for new international rules tailor-made for PBS. The Nagoya Protocol and Covid-19 pandemic may be the push that global health actors need to begin resolving the key issues associated with global PBS. As the case studies of Ebola and Zika underscored, PBS arrangements need to be in place ahead of outbreaks—at both national and international levels—to ensure fair and reliable sharing of both pathogens and benefits in the future. Real-world experiences and perspectives from Liberia and Brazil can and should inform debates and negotiations that aim to develop global frameworks for PBS that are fair, acceptable, and functional. While there was considerable political hesitance among respondents to address

the governance of PBS head-on, COVID-19 reminds us that nature does not wait. It is time to push for new international rules tailor-made for PBS.

Directions for future research

This study has sought to fill gaps in the literature on PBS by investigating current practices of PBS and their drivers, at both international level and through two outbreak-specific case studies. Several areas of further inquiry would be useful. First, additional case studies of PBS practices would shed further light on these questions. For example, resource constraints prevented us from conducting a case study on PBS relating to MERS, but such a study could offer insights on practices in different regions of the world. Similarly, case studies on the drivers and practices relating to other pathogenic threats, such as antimicrobial resistance, would also be valuable. Second, understanding of the options for governance of GSD could be further improved through an exploration of the kinds of benefit sharing arrangements that have or have not been implemented. Finally, PBS practices relating to plant and animal health could uncover insights that would help to improve governance for human pathogens.

Research outcomes

The project has resulted in two events and two reports (Bezruki et al 2020; Rizk et al 2020) and the research also contributed to the discussion of PBS in a third publication (Moon et al 2020). On July 2nd 2020, the project team held a workshop to discuss preliminary research findings, a meeting that resulted in a workshop report (Bezruki et al., 2020). The project's research report has been published as Working Paper #23 (Rizk et al., 2020), for which we held a public event on December 8th 2020. The event recording can be found on the event webpage (https://www.graduateinstitute.ch/GHC-PBS). The project team is currently working towards peer-reviewed academic articles based on the research findings and the report.

Publications

Moon, S., Bezruki, A., Burci, G. L., Sunyoto, T., Vieira, M. (2020). The global governance of access to countermeasures. Graduate Institute of International and Development Studies, Global Health Centre. Accessed at https://apps.who.int/gpmb/assets/thematic_papers_2020/tp_2020_2.pdf

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Rizk, A., Bezruki, A., Burci, G. L., Moon, S., Fallah, M., Sieka, J., Nyenswah, T., Matta, G., & Paiva, E. (2020). "Everybody knows this needs to be done, but nobody really wants to do it": Governing Pathogen- and Benefit- Sharing. *Graduate Institute of International and Development Studies, Global Health Centre*. Accessed at https://www.graduateinstitute.ch/sites/internet/files/2020-12/GHC_WorkingPaper_No_23_Web.pdf

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Internal Report

Research plan and schedule

The project set out to gain an empirical understanding of the formal and informal norms governing PBS in order to advance the policy debate on how to manage outbreaks. As such, this research project asked: How can PBS practices be measured, described and meaningfully assessed? How do formal and informal norms of collaboration and sharing in scientific practice facilitate or impede rapid PBS? What drives decisions to share (or not) pathogens and related benefits? What global governance tools and instruments can improve PBS practices to ensure health security for all?

The project schedule was divided into three phases:

1- Phase 1 includes a) systematic literature and document review, b) semi-structured interviews with experts working on PBS and c) development of metrics to measure degree of sample sharing and degree of benefits sharing through using publicly available data on influenza PBS.
2- Phase 2 includes two case studies, the first a) on Ebola pathogen and benefit sharing in Liberia and b) on Zika pathogen and benefit sharing in Brazil and c) a revision of the metrics developed in Phase 1
3- Phase 3 will focus on a) drafting and publishing policy proposals and research publications and b) their dissemination as well as c) sharing data collected on a public platform.

In our mid-term report to SNIS, we reported successful completion of Phase 1 of research. Since then, and with SNIS' approval of a 3-month extension to the project given delays introduced by the COVID-19 pandemic, we have completed both Phases 2 and 3 of the project plan.

Phase 2: A research trip was undertaken to Monrovia, Liberia, from November 10-15, 2019, by two members of the project team (Dr. Suerie Moon and Mr. Anthony Rizk) and, alongside our collaborators in Liberia (Dr. Mosoka Fallah, Dr. Joseph Sieka and Ms. Lucia Bawo), we completed 20 interviews with Liberian scientists and policymakers. Due to the COVID-19 pandemic, two members of our project team (Dr. Gian Luca Burci and Mr. Anthony Rizk) could not complete a scheduled field visit to Rio de Janeiro, Brazil, in March 2020. Nevertheless, the project team conducted 13 online interviews alongside collaborators in Brazil (Dr. Gustavo Matta, Dr. Juliana Correa and Dr. Ester Paiva). Although this phase was completed successfully, the transition to virtual interviews for the Brazil case study introduced difficulties in securing interviews in Brazil and limited our access to people and data. In-person fieldwork, in our experience, remains extremely valuable in studying a topic that is considered sensitive by research participants.

Phase 3: The project team successfully produced an open-access Working Paper[1] from the research and held a dissemination event on December 8th, 2020. The dissemination event had a

[1] Rizk, A., Bezruki, A., Burci, G. L., Moon, S., Fallah, M., Sieka, J., Nyenswah, T., Matta, G., & Paiva, E. (2020). "Everybody knows this needs to be done, but nobody really wants to do it": Governing Pathogen- and Benefit-

wide reach, with a total of 140 participants from 26 countries. Our research findings, by coincidence, followed shortly after the WHO announced the Swiss government was willing to provide secured lab facilities as a pathogen-sample repository for global use; our research findings were quoted and covered in an in-depth news report by SwissInfo on this lab initiative.[2] We have also shared our research findings directly with the Swiss authorities involved in this initiative. Earlier in the year, the research team held a high-level invitation-only workshop with 20 participants to discuss preliminary findings, which also resulted in the publication of a policy-oriented workshop report[3]. At the outset of this project, we committed to making our research data as openly available and accessible as possible for public use, within reasonable restrictions that would protect the confidentiality and anonymity of research participants. As such, we are currently preparing to share our project data, including anonymised interview transcripts (provided that research participants have the opportunity to review them and grant explicit approval for sharing) on the Zenodo platform hosted by CERN (https://zenodo.org/).

The COVID-19 pandemic introduced delays to the research schedule, necessitating a 3-month extension to meet the project plan. One of our original objectives – to develop metrics for the degree of sharing of pathogens and benefits – ultimately proved infeasible due to absence of appropriate data. We confirmed that the only available systematically collected quantitative data on pathogen- and benefit-sharing is the WHO's Influenza Virus Tracking Mechanism (IVTM) data; which limited the feasibility of developing metrics for pathogens other than influenza. We have been able to draw out conclusions on patterns of PBS with IVTM samples from this dataset that informed our research outcomes, though the systematic absence of certain variables in the dataset (most importantly, the 'date of delivery' of samples) limited our ability to develop a 'speed' metric as originally planned. The importance of establishing platforms for collecting such data in the future to improve traceability became the first recommendation in our research report. This aside, the research plan and schedule was followed and completed.

Activities undertaken during the research period

The project has resulted in two events and two reports, and the research also contributed to the discussion of PBS in a third publication (Moon et al 2020). On July 2nd 2020, the project team held a workshop to discuss preliminary research findings, a meeting that resulted in a policy-oriented workshop report (Bezruki et al., 2020). The project's research report has been published as Working Paper #23 (Rizk et al., 2020), for which we held a public event on December 8th 2020. The dissemination event had a wide reach, with a total of 140 participants from 26 countries. The event recording can be found on the event webpage.[4] The research also informed a commissioned paper for the WHO-World Bank Global Preparedness Monitoring Board, covering more broadly the issue of access to vaccines, drugs and diagnostics in the event of a

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[4] https://www.graduateinstitute.ch/GHC-PBS

pandemic (Moon et al. 2020). The project team is currently working towards peer-reviewed academic articles based on the research findings and the report.

Although we had initially planned on holding two workshops, financial difficulties in securing funding and the progression of the COVID-19 pandemic were the primary causes of difficulties in implementing workshops. Our application to the Brocher Foundation for workshop funding in January 2019 was refused. We were subsequently successful in being granted a SNF Scientific Exchange Grant. Due to the COVID-19 pandemic, we ultimately refunded purchases (mainly flight tickets) from the SNF Scientific Exchange Grant and successfully held the workshop online.

If time and resources had permitted, several additional online events could have been organized to increase the visibility of the project and its findings. First, in-country workshops to present the results would have allowed for further reflection and debate. Second, a more theoretically- and academically-oriented workshop to discuss the findings would have been useful for advancing our analysis, as well as the visibility of our results in the academic community. Publishing theoretically-oriented articles will help to achieve this goal as well, and this remains our plan for the coming year.

Publications

Moon, S., Bezruki, A., Burci, G. L., Sunyoto, T., Vieira, M. (2020). The global governance of access to countermeasures. Graduate Institute of International and Development Studies, Global Health Centre. Accessed at https://apps.who.int/gpmb/assets/thematic_papers_2020/tp_2020_2.pdf

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Participation of partners

The project benefited from the collaboration with project advisors and academic partners at the World Health Organization and in academic and policy spheres.

World Health Organization partners: We have worked closely with the WHO throughout the research project, specifically with Ms. Anne Huvos, the head of the Pandemic Influenza Preparedness programme, Mr. Steven Solomon, Principal Legal Officer, and Dr. Vasee Moorthy,

the coordinator of the Department of Information, Evidence and Knowledge. In particular, we attended several closed-door and open meetings with various departments of the WHO discussing the topic of pathogen- and benefit-sharing, as well as the World Health Assembly from 20-28 May 2019. Dr. Suerie Moon presented an introduction to pathogen and benefit-sharing at the WHO Member States Briefing on the Nagoya Protocol on April 4, 2019. WHO colleagues have particularly assisted the project with data collection by suggesting and connecting us with interviewees, especially scientists and participants from the Global South, as well as giving us feedback on analysis through participation in the high-level workshop. One of our original project advisors. Dr. Sylvie Briand, provided valuable advice early in the project but was directly and deeply-engaged in the WHO's Covid-19 response and therefore less involved in the latter stages.

Academic Partners: Prof. Stephanie Dagron and Prof. Rebecca Katz are academic partners based at the University of Geneva, Switzerland, and Georgetown University, USA, respectively. We have been in communication with them to exchange knowledge on the topic and to connect us to potential interviewees. We also interviewed Prof. Katz, who also pointed us to a source of MTAs. Prof. Katz became directly involved in the US Covid-19 response, and her availability was also directly-affected by the crisis. We expect and plan to engage further with Prof. Dagron as we develop the more theoretically-oriented academic papers.

Case Study Partners: The project benefited from the close collaboration of its case study partners in Liberia and Brazil. For the Liberia case study, we worked closely with Dr. Mosoka Fallah, previously at the National Public Health Institute of Liberia, and decided to include Dr. Tolbert Nyenswah within the case study team due to his expertise on the topic of PBS in Liberia. Dr. Joseph Sieka was indispensable to the fieldwork undertaken in November 2019 and Ms. Lucia Bawo provided necessary organizational support. For the Brazil Case Study, Dr. Jorge Bermudez introduced us to Dr. Gustavo Matta at the Zika Social Science Network, Fiocruz, who became our project partner. We worked closely with Dr. Gustavo Matta, who was critical in our efforts to transition our case study from an in-person to virtual interviewing. Dr. Juliana Correa and Dr. Ester Paiva assisted the case study across several phases till completion.

All project partners were consulted throughout the process, many of whom contributed to analysis, interpretation and write-up and co-authored this projects' Working Paper. Dr. Mosoka Fallah and Dr. Gustavo Matta presented the case study findings at the dissemination event and contributed to the discussions.

Storage of research results and project data

Both the workshop report and the research report are publicly available at the Graduate Institute of Geneva's public repository.

Project data has been shared publicly on the Zenodo platform, hosted by CERN:

> Moon, Suerie, Burci, Gian Luca, Rizk, Anthony, & Bezruki, Anna. (2021). Pathogen and Benefit Sharing (PBS) Project Data Repository [Data set]. "Everybody knows this needs to be done, but nobody really wants to do it": Governing Pathogen and Benefit Sharing

(PBS). Geneva, Switzerland: Global Health Centre, Graduate Institute of International and Development Studies, Geneva. http://doi.org/10.5281/zenodo.4647874

What has the SNIS support allowed you to do, to conclude or to recommend that would not have been possible without its support?

SNIS support has allowed us to carry out a research project on a timely, politically-sensitive yet crucial topic that has not received adequate attention, neither by scholars nor the diplomatic or the policy communities. It allowed us to approach the topic as independent researchers without conflicts of interest, an important asset on such a politically-polarized topic as this one.

How did the interdisciplinary nature of the project affect the results?

We benefited greatly from the interdisciplinary expertise within the core project team (global governance, international law, anthropology, medicine, epidemiology) as the nature of the problem itself spans many fields. By taking a problem-driven approach to the research (rather than by starting within a particular discipline), the integration of our team's disciplinary backgrounds came naturally. The final policy-oriented results and conclusions are a direct outcome of the initial problem-driven framing of the question, as opposed to starting from a theoretical question grounded in a single discipline.

Potential for application of research results

We certainly did not predict a major pandemic in 2020, but we were aware at the inception of the project that the issue of pathogen- and benefit-sharing was one of the key unaddressed reforms needed to strengthen the global system for outbreak preparedness and response. The finalization of our research report and public dissemination at the end of 2020 was very timely. While pathogen-sharing has not been a major barrier in the Covid-19 pandemic, the global devastation caused by the virus has highlighted the urgency of addressing PBS for future outbreaks. Furthermore, the rapid sharing of GSD to track mutations of the SARS-COV-2 virus has been essential for informing and enabling public health responses across all countries; that such sharing is not ensured in future outbreaks remains an issue of great concern. Because the topic of PBS is both complex and quite specialized – as well as politically-sensitive – we believe our research report will help to establish a shared understanding among a wide range of parties of the issues that must be addressed. We also expect that our findings will inform any future negotiations of a normative framework to better govern PBS.

What follow-up will you give to the project? Do you find it useful to maintain the network that was created? If so, how will you go about doing this?

We are currently engaged in various ongoing research projects regarding the global system of outbreak preparedness and response, building on what we learned in the SNIS-supported PBS project. For example, we developed a background paper for the WHO-World Bank Global Preparedness Monitoring Board on the global governance of access to countermeasures

(September 2020), which included a section on PBS.[5] As the issue of PBS is unresolved and will continue to arise in future policy debates, we believe the need for rigorous, independent academic research will continue. We are currently exploring funding options to allow us to further develop and continue this work. We will surely continue to tap into the very valuable networks of research collaborators, project advisers, workshop participants and interviewees that we developed through this project to support this future work. Some of this network maintenance may take place through formalized future research collaborations, but we expect most of it will be informal through future interviews, convening and discussions.

In hindsight, what would you do differently (organisation, method)?

In hindsight, we would add a second research assistant to the team. As we gathered more data and better appreciated the complexity of what we were discovering, it became clear that further human resources would be needed to conduct the analyses. We were able to draw from student volunteers (Rishbha Godara) and a highly-capable research officer working on a related project (Anna Bezruki) to assist with completing the project on time and at a high-level of quality. But in future, we would plan and budget for a larger research team from the start.

The budgetary report

The budgetary report is composed of the following three documents:
− The final financial report of the University that manages SNIS funds (signed by the accounting department and the project coordinator),
− A balance Excel sheet documenting and detailing the expenses incurred, use of co-financing, and in-kind contributions of all partners. Please make sure to use the same categories as in the accepted budget.
− A declaration, signed by the project coordinator, in which it is specified that the financial support other than that provided by the SNIS is in accordance with the co-financing plan and that expenses were made in accordance with the "Regulations Concerning the Rights and Duties of Recipients of SNIS Subsidies, 7 April 2017". If this was not the case, the SNIS requests an explanation regarding the reasons for, and information concerning, the current situation.

[5] Moon, S., Bezruki, A., Burci, G. L., Sunyoto, T., Vieira, M. (2020). The global governance of access to countermeasures. Graduate Institute of International and Development Studies, Global Health Centre. Accessed at https://apps.who.int/gpmb/assets/thematic_papers_2020/tp_2020_2.pdf