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Access and benefit-sharing by the European Virus Archive in response to COVID-19



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Biobanking infrastructures, which are crucial for responding early to new viral outbreaks, share pathogen genetic resources in an affordable, safe, and impartial manner and can provide expertise to address access and benefit-sharing issues. The European Virus Archive has had a crucial role in the global response to the COVID-19 pandemic by distributing EU-subsidised (free of charge) viral resources to users worldwide, providing non-monetary benefit sharing, implementing access and benefit-sharing compliance, and raising access and benefit-sharing awareness among members and users. All currently available SARS-CoV-2 material in the European Virus Archive catalogue, including variants of concern, are not access and benefit-sharing cases per se, but multilateral benefit-sharing has nevertheless occurred. We propose and discuss how a multilateral system enabling access and benefit-sharing from pathogen genetic resources, based on the European Virus Archive operational model, could help bridge the discrepancies between the current bilateral legal framework for pathogen genetic resources and actual pandemic response practices.

Introduction

The COVID-19 pandemic has highlighted persistent challenges in global preparedness and response. Despite the wealth of scientific and policy discussions, one issue has not received mainstream attention: who owns pathogens with pandemic potential and what are the corresponding international legal obligations?²¹⁻³

The rapid availability of pathogen genetic resources and genetic sequence data (known as digital sequence information [or DSI] under the Convention on Biological Diversity) are crucial to responding to animal, human, and plant infectious disease outbreaks. Beginning with the identification and characterisation of the causative agent, to the development of risk assessments and evidence-based interventions, through to the development of countermeasures (eg, diagnostics, vaccines, and therapeutics),¹⁴ every step requires access to pathogen genetic resources and to genetic sequence data. Despite this global reliance, countries are not obligated to share pathogen genetic resources or genetic sequence data.⁵ Instead, only the sharing of relevant information for managing public health emergencies of international concern is codified within the International Health Regulations. There are many barriers to sharing pathogen genetic resources;⁶ in particular, the issue of ownership (sovereign rights) and benefit-sharing is especially tricky, which is explored in this Personal View.

The legal status of pathogens

Pathogen genetic resources (excluding a single virus covered by the Pandemic Influenza Preparedness Framework) fall within the scope of the Convention on Biological Diversity and its Nagoya Protocol. The Nagoya Protocol is the legally binding framework that implements the third goal of the Convention on Biological Diversity, which calls for the fair and equitable sharing of benefits arising from the use of genetic resources, also known as access and benefit-sharing. Access and benefit-sharing measures under the Nagoya Protocol are agreed to on a

bilateral basis between users (usually scientists) and the provider country (usually the ministry of environment) of genetic material through the negotiation of prior informed consent and mutually agreed terms. However, pathogens are vastly different from typical biodiversity that is meant to be protected, conserved, and sustainably used under these treaties.

Although the Nagoya Protocol recognises the International Health Regulations, and Article 8b calls on parties to pay due regard for expeditious access to pathogen genetic resources during public health emergencies of international concern, only four states have actually adopted specialised measures on pathogens.¹ WHO, in cooperation with the Secretariat of the Convention on Biological Diversity, investigated the effect of the Nagoya Protocol on the sharing of pathogens and public health action and noted that the implementation of bilateral access and benefit-sharing requirements for sharing pathogens had a negative effect on outbreak response because of the associated legal uncertainty, bureaucracy, and delays,^{2,3} which hinder research collaborations and the development of non-pharmaceutical and pharmaceutical interventions.

Furthermore, most pathogens do not respect borders and, in a globalised world, travel and trade provide endless opportunities for spreading. Therefore, pathogens often eventually end up in countries without access and benefit-sharing measures, and researchers have no incentive or need to go through the Nagoya Protocol system. Ultimately, the idea of sovereignty and control over access and the ability to require bilateral benefit-sharing on pathogen genetic resources does not match their biological nature.

The European Virus Archive (EVA): a model for pandemic preparedness, response, and benefit-sharing

EVA has had a pivotal role in supporting the global response to the COVID-19 pandemic. Notably, EVA is a

Lancet Microbe 2022;
3: e316–23

Published Online
November 16, 2021
[https://doi.org/10.1016/S2666-5247\(21\)00211-1](https://doi.org/10.1016/S2666-5247(21)00211-1)

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model for what is needed from a biobanking infrastructure, how access and benefit-sharing of pathogen genetic resources can be addressed, and how these two elements combine to enable a pandemic response that is efficient, fair, and equitable.

Funded by the European Commission through three successive programmes, the consortium has grown to 38 international partners and become a well recognised entity by WHO, the World Organisation for Animal Health, the European Centre for Disease Prevention and Control, and the UN Food and Agriculture Organization. EVA has provided rapid early outbreak access to viral strains and derivatives, such as Chikungunya, influenza A (H1N1), MERS-CoV, Ebola, Zika, and the current SARS-CoV-2. Although services and products are offered through a centralised catalogue,⁷ swift response is enabled by the decentralised biobanking structure composed of an international network of 43 laboratories worldwide. This decentralisation enables the preservation of biologically diverse pathogen genetic resources, which is crucial for preparedness given that the causal agent of the next outbreak or pandemic is uncertain. For example, in the current COVID-19 crisis, viruses closely and distantly related to SARS-CoV-2 were needed for diagnostic specificity testing, and the availability of the necessary viruses (positive and negative controls) from EVA members was crucial in enabling a record-breaking early response.⁸

The distributed nature of EVA also requires upfront knowledge of access and benefit-sharing and national legislation. During the current project phase, the EVA catalogue has been updated to ensure that all available material will be compliant with, and transparent about, potential access and benefit-sharing obligations. Because legal compliance is done in advance by an expert team, EVA is prepared to deliver access and benefit-sharing compliance, if needed, during an outbreak. The proactive commitment of EVA partners to access and benefit-sharing improves the usability and legal certainty of pathogen genetic resources for users and builds trust with providing countries and public health actors. The compliance efforts are complemented by EVA's material transfer agreement that limits use of pathogen genetic resources to non-commercial research purposes. For commercial use of EVA materials, a separate licensing agreement has to be established with the collection or, in an access and benefit-sharing case, with the providing country.

The COVID-19 pandemic case study—access and benefit-sharing practices within EVA

To explore access and benefit-sharing practices by EVA during the COVID-19 pandemic, we examined SARS-CoV-2 resource distribution and how access and benefit-sharing worked in light of the current legal regime.

Notably, none of the SARS-CoV-2 pathogen genetic resources shared by EVA had access and benefit-sharing obligations at the time of access. All SARS-CoV-2

resources shared through the EVA platform were accessed and isolated from patients in 12 countries that do not have applicable access and benefit-sharing regulations (table; appendix p 1). This finding also includes material based on the original SARS-CoV-2 genetic sequence data uploaded publicly at the beginning of the pandemic in January, 2020.⁹ If SARS-CoV-2 materials could only have been obtained through bilateral negotiations (ie, came exclusively from countries with access and benefit-sharing restrictions), the politicisation of the epidemic response could have had wide-reaching consequences. For example, the number of scientists and institutes allowed to research on SARS-CoV-2 and develop knowledge to control the virus might have been restricted, biobanking infrastructures might have been limited in redistributing the material, authentication and quality control checks might have been impaired,¹⁰ and the development of pharmaceutical and non-pharmaceutical countermeasures might have ultimately suffered. These concerns are not unfounded. During the Zika outbreak in 2016, the specificity of early Zika diagnostics was compromised due to the difficulties in delivering and accessing viral materials from the most affected countries due to delays in logistical and procedural challenges, including access and benefit-sharing issues.^{11,12} In fact, these delays had important societal impacts because higher rates of Zika diagnostic false positives probably lead to unnecessary abortions due to concerns about fetal congenital abnormalities, such as microcephaly.¹³

EVA currently has the largest collection of SARSCoV-2 variants of concern (table). With the emergence of new SARS-CoV-2 variants, the material shared by EVA has, again, been sampled from patients in free access countries (eg, the Netherlands, Germany, and Sweden) even though the variants emerged in, for example, South Africa and Brazil, countries which do have access and benefit-sharing regimes in place (table). Interestingly, the Italian Ministry of Health relinquished non-exclusive commercial rights of strain SARS-CoV-2 (item 008V-04005 in table) to WHO in November, 2020, to facilitate the commercial use of the strain for vaccine development. Because SARS-CoV-2 material was and continues to be shared relatively fluidly by the countries listed in table, political attention paid to access and benefit-sharing implications for pandemic preparedness has been minimal. Most of the attention continues to focus on the scarcity of benefit-sharing (eg, global vaccine distribution) while overlooking the indispensable worldwide access enabled by just a few countries.

EVA, as a publicly funded infrastructure, serves as an impartial, high-quality source of pathogen genetic resources worldwide. Between January, 2020, and June, 2021, EVA distributed more than 2300 SARS-CoV-2 products to 109 countries for the academic and industrial sectors (figure; appendix pp 2–3), including the authenticated and characterised strains of SARS-CoV-2 and all

Description	Country of collection	Date of Collection	Genebank reference	Nagoya Protocol status	Providing institute	
Virus-derived material from the EVA catalogue						
004N-02005*	SARS-CoV nucleic acid	Germany	March 15, 2003	..	No access regulation	CUB
004N-EVA254*	SARS-CoV nucleic acid	Germany	March 15, 2003	..	No access regulation	CUB
006N-03938	SARS-CoV-2 nucleic acid	Slovakia	March 6, 2020	..	No access regulation	BMC SAS
006N-03939	SARS-CoV-2 nucleic acid	Slovakia	March 6, 2020	..	No access regulation	BMC SAS
008N-03894	SARS-CoV-2 nucleic acid	Italy	Jan 29, 2020	..	No access regulation	INMI
011N-03868	SARS-CoV-2 nucleic acid	Netherlands	Jan 16, 2020	..	No access regulation	ERASMUS MC
026N-03889	SARS-CoV-2 nucleic acid	Germany	Jan 28, 2020	..	No access regulation	CUB
001S-04010	SARS-CoV-2 virus	France	March 16, 2020	..	Microorganisms exempt until 2022	AMU
001V-03967	SARS-CoV-2 virus	France	March 16, 2020	..	Microorganisms exempt until 2022	AMU
002V-03991	SARS-CoV-2 virus	Germany	March 19, 2020	..	No access regulation	BNI
006V-03933	SARS-CoV-2 virus	Slovakia	March 6, 2020	..	No access regulation	BMC SAS
006V-03937	SARS-CoV-2 virus	Slovakia	March 6, 2020	..	No access regulation	BMC SAS
006V-03971	SARS-CoV-2 virus	Slovakia	March 6, 2020	..	No access regulation	BMC SAS
008V-03893	SARS-CoV-2 virus	Italy	Jan 29, 2020	..	No access regulation	INMI
010V-03903	SARS-CoV-2 virus	Netherlands	Feb 28, 2020	..	No access regulation	ERASMUS MC
014V-03890	SARS-CoV-2 virus	France	Jan 27, 2020	..	Microorganisms exempt until 2022	IP
014V-04030	SARS-CoV-2 virus	Netherlands	March 3, 2020	..	No access regulation	RIVM
014V-04092	SARS-CoV-2 virus	Netherlands	Dec 22, 2020	..	No access regulation	RIVM
026V-03883	SARS-CoV-2 virus	Germany	Jan 28, 2020	..	No access regulation	CUB
Variant of concern strains						
017V-04211	SARS-CoV-2 (A.27)	Mayotte	Jan 13, 2021	..	Microorganisms exempt until 2022	IP
001V-04191	SARS-CoV-2 (A.27)	France	Jan 25, 2021	..	Microorganisms exempt until 2022	AMU
005V-04144	SARS-CoV-2 (A.27)	Slovenia	March 2, 2021	..	No access regulation	UL
005V-04110	SARS-CoV-2 (A.27)	Slovenia	March 2, 2021	..	No access regulation	UL
017V-04219	SARS-CoV-2 (B.1.616)	France	Feb 26, 2021	..	Microorganisms exempt until 2022	IP
001V-04044	SARS-CoV-2 (B.1.1.7)	France	Jan 12, 2021	..	Microorganisms exempt until 2022	AMU
012V-04194	SARS-CoV-2 (B.1.1.7)	Sweden	Dec 22, 2020	..	No access regulation	FoHM
012V-04193	SARS-CoV-2 (B.1.1.7)	Sweden	Dec 20, 2020	..	No access regulation	FoHM
008V-04185	SARS-CoV-2 (B.1.1.7)	Italy	Dec 26, 2020	..	No access regulation	INMI
001V-04080	SARS-CoV-2 (B.1.1.7)	United Kingdom	Dec 24, 2020	..	No access regulation	AMU
006V-04083	SARS-CoV-2 (B.1.1.7)	Slovakia	Jan 26, 2021	..	No access regulation	BMC SAS
004V-04032	SARS-CoV-2 (B.1.1.7)	United Kingdom	Dec 24, 2020	..	No access regulation	DH
012V-04052	SARS-CoV-2 (B.1.1.7)	Sweden	Dec 23, 2020	..	No access regulation	FoHM
008V-04049	SARS-CoV-2 (B.1.1.7)	Italy	Dec 20, 2020	..	No access regulation	INMI
008V-04005	SARS-CoV-2 (B.1.1.7)	Italy	Feb 24, 2020	..	No access regulation	INMI
008V-03992	SARS-CoV-2 (B.1.1.7)	Italy	Feb 28, 2020	..	No access regulation	INMI
008V-04048	SARS-CoV-2 (B.1.1.7)	Italy	Aug 18, 2020	..	No access regulation	INMI
008V-04047	SARS-CoV-2 (B.1.1.7)	Italy	Aug 20, 2020	..	No access regulation	INMI
008V-04050	SARS-CoV-2 (B.1.1.7)	Italy	Dec 22, 2020	..	No access regulation	INMI
017V-04055	SARS-CoV-2 (B.1.1.7)	United Kingdom	Jan 22, 2021	..	No access regulation	IP
017V-03960	SARS-CoV-2 (B.1.1.7)	France	March 4, 2020	..	Microorganisms exempt until 2022	IP
014V-03968	SARS-CoV-2 (B.1.1.7)	Netherlands	March 28, 2020	..	No access regulation	RIVM
014V-03981	SARS-CoV-2 (B.1.1.7)	Netherlands	March 28, 2020	..	No access regulation	RIVM
014V-04031	SARS-CoV-2 (B.1.1.7)	Netherlands	Dec 13, 2020	..	No access regulation	RIVM
005V-04053	SARS-CoV-2 (B.1.1.7)	Slovenia	Jan 25, 2021	..	No access regulation	UL
005V-03961	SARS-CoV-2 (B.1.1.7)	Slovenia	April 27, 2020	..	No access regulation	UL
012V-04195	SARS-CoV-2 (B.1.351)	Sweden	Feb 3, 2021	..	No access regulation	FoHM
006V-04183	SARS-CoV-2 (B.1.351)	Slovakia	Feb 8, 2021	..	No access regulation	BMC SAS
005V-04107	SARS-CoV-2 (B.1.351)	Slovenia	March 1, 2021	..	No access regulation	UL
001V-04067	SARS-CoV-2 (B.1.351)	France	Jan 25, 2021	..	Microorganisms exempt until 2022	AMU
004V-04071	SARS-CoV-2 (B.1.351)	United Kingdom	Feb 1, 2021	..	No access regulation	DH

(Table continues on next page)

Description	Country of collection	Date of Collection	Genebank reference	Nagoya Protocol status	Providing institute	
(Continued from previous page)						
008V-04101	SARS-CoV-2 (B.1.351)	Italy	Feb 5, 2021	..	No access regulation	INMI
017V-04087	SARS-CoV-2 (B.1.351)	France	Jan 18, 2021	..	Microorganisms exempt until 2022	IP
014V-04058	SARS-CoV-2 (B.1.351)	Netherlands	Jan 8, 2021	..	No access regulation	RIVM
014V-04091	SARS-CoV-2 (B.1.429)	Aruba	Feb 21, 2021	..	No access regulation	RIVM
008V-04186	SARS-CoV-2 (B.1.525)	Italy	Feb 19, 2021	..	No access regulation	INMI
005V-04109	SARS-CoV-2 (B.1.525)	Slovenia	March 6, 2021	..	No access regulation	UL
009V-04187	SARS-CoV-2 (B.1.617)	Germany	April 28, 2021	..	No access regulation	RKI
017V-04212	SARS-CoV-2 (P.1)	French Guiana	Feb 12, 2021	..	Microorganisms exempt until 2022	IP
001V-04190	SARS-CoV-2 (P.1)	Japan	Jan 2, 2021	..	No access regulation	AMU
001V-04189	SARS-CoV-2 (P.1)	Japan	Jan 2, 2021	..	No access regulation	AMU
014V-04089	SARS-CoV-2 (P.1)	Netherlands	Jan 18, 2021	..	No access regulation	RIVM
014V-04090	SARS-CoV-2 (P.1)	Netherlands	Jan 11, 2021	..	No access regulation	RIVM
001N-04051	SARS-CoV-2 nucleic acid (B.1.1.7)	France	Jan 12, 2021	..	No access regulation	AMU
005N-04054	SARS-CoV-2 nucleic acid (B.1.1.7)	Slovenia	Jan 30, 2021	..	No access regulation	UL
014N-04147	SARS-CoV-2 nucleic acid (B.1.351)	Netherlands	Jan 8, 2021	..	No access regulation	RIVM
001N-04192	SARS-CoV-2 nucleic acid (B.1.351)	France	Feb 12, 2021	..	Microorganisms exempt until 2022	AMU
005N-04108	SARS-CoV-2 nucleic acid (B.1.351)	Slovenia	March 10, 2021	..	No access regulation	UL
014N-04146	SARS-CoV-2 nucleic acid (B.1.429)	Aruba	Feb 21, 2021	..	No access regulation	RIVM
005N-04125	SARS-CoV-2 nucleic acid (B.1.525)	Slovenia	March 20, 2021	..	No access regulation	UL
009N-04244	SARS-CoV-2 nucleic acid (B.1.617)	Germany	April 28, 2021	..	No access regulation	RKI
014N-04148	SARS-CoV-2 nucleic acid (C.2)	Netherlands	Dec 22, 2020	..	No access regulation	RIVM
014N-04150	SARS-CoV-2 nucleic acid (P.1)	Netherlands	Jan 18, 2021	..	No access regulation	RIVM
014N-04149	SARS-CoV-2 nucleic acid (P.2)	Netherlands	Jan 11, 2021	..	No access regulation	RIVM
Genetic sequence data-based products						
001V-04006	SARS-CoV-2 virus	China	..	NC045512	Unclear	AMU
022P-04134	SARS-CoV-2 protein	China	..	MN908947.3	Unclear	FLI
022P-04124	SARS-CoV-2 protein	China	..	MN908947.3	Unclear	FLI
100P-03957	SARS-CoV-2 protein	France	..	MT777677	No access regulation	AMU _b
100P-03956	SARS-CoV-2 protein	France	..	MT777677	No access regulation	AMU _b
003N-03901	SARS-CoV-2 nucleic acid	China	..	MN908947	Unclear	CUB
026N-03866	SARS-CoV-2 nucleic acid	China	..	MN908947	Unclear	CUB
022P-03958	SARS-CoV-2 protein	China	..	MN908947.2, MN908947.3	Unclear	FLI
022P-03940	SARS-CoV-2 protein	China	..	MT380724.1	Unclear	FLI
For each item, information on country of collection, date of collection, Nagoya Protocol or access benefit-sharing obligations, and providing institute is listed. For variant of concern strains, the respective lineage annotations are used. Material listed in this table is current as of June, 2021, with new items continuously added as they become available. AMU=Aix Marseille University. BMC SAS=Biomedical Research Center of the Slovak Academy of Sciences. BNI=Bernhard Nocht Institute for Tropical Medicine. CUB=Charité-Universitätsmedizin Berlin. DH=The Department of Health, UK. ERASMUS MC=ERASMUS Medical Center. EVA=European Virus Archive. FLI=Friedrich Loeffler Institute. FoHM=The Public Health Agency of Sweden. INMI=Istituto Nazionale Malattie Infettive Lazzaro Spallanzani. IP=Institute Pasteur. RIVM=Dutch National Institute for Public Health and the Environment. RKI=Robert Koch Institute. UL=University of Ljubljana. *Derived from SARS-CoV, related to the 2003 severe acute respiratory syndrome pandemic, and were essential to the COVID-19 response as reference materials.						
Table: SARS-CoV-2 virus and virus-derived material available in the EVA catalogue for distribution by EVA catalogue product ID						

related products (eg, antigens, plasmids, in-vitro transcripts, detection assays, and recombinant proteins). The access to pathogen genetic resources provided by 12 countries (table) enabled benefits received in 97 countries, although no formal bilateral benefit-sharing obligations were in place.

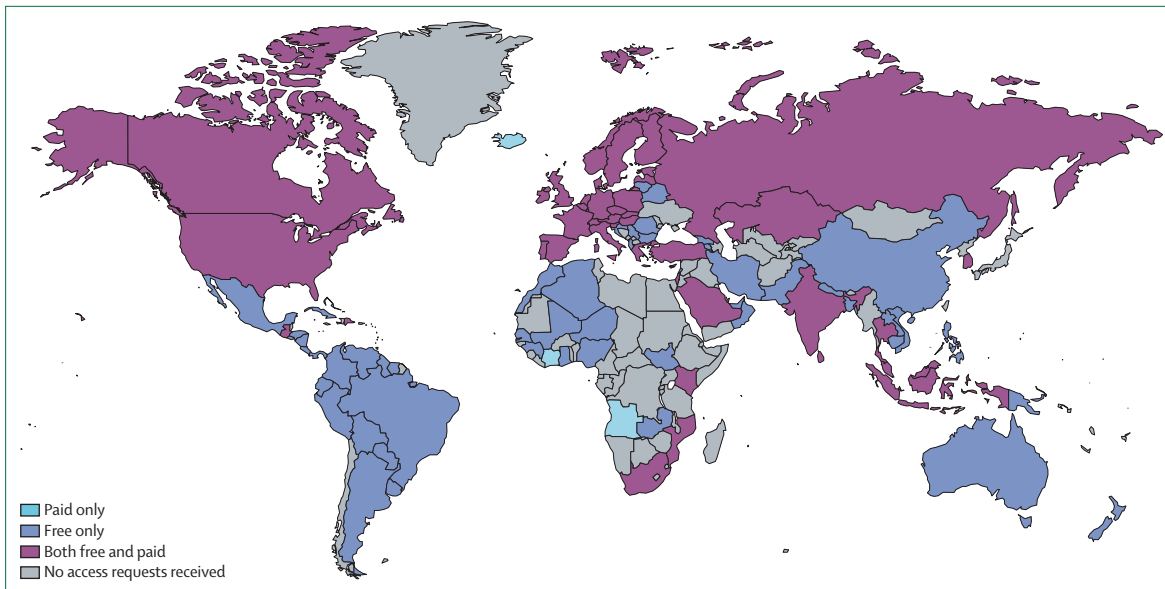


Figure: Distribution of SARS-CoV-2 strains and derived material from the European Virus Archive catalogue from January, 2020, to June, 2021, to academic and private sectors worldwide

Pink represents receivers of material both free of charge and paid for, purple represents receivers of material exclusively free of charge, and blue represents receivers of materials exclusively paid for. All public sector entities were able to order material for free if they chose to.

Most SARS-CoV-2 products (78%) were delivered to the public sector, with 72% of these distributions provided free of charge; all materials delivered to the private sector (22%) were paid for. Users can request EVA products free of charge through a transnational access application, which subsidises the catalogue price if they fulfil certain requirements.¹⁴ As a non-profit infrastructure, the goal of EVA is not to compete with commercial developers, but rather to fill production gaps in the non-commercial public health and research sectors. Thus, although the products in the catalogue have a price tag, these are calculated to cover production costs and provide a zero-profit margin. Free-of-charge pathogen genetic resources cost the non-profit EVA infrastructure approximately €900 000, with emergency funding provided by the European Commission for the COVID-19 pandemic response (total of €1.2 million). While some users actively decided against this free-of-charge option, we believe that this decision was to avoid double funding or the mistaken assumption that free material might implicate limitations or restrictions on the use, as compared with paid material. During emergency situations, measures to facilitate expedited exchange, such as a 24-h review decision on all transnational access applications, are in place. Under normal circumstances, a maximum of 20% of accesses via the transnational access application can be allocated to non-EU countries. However, in agreement with the European Commission, this rule was waived to unlimited distribution for non-EU countries during the 2016 Zika epidemic and current COVID-19 pandemic. Between January, 2020, and June, 2021, 73% of material distributed through a transnational access application was to non-EU

countries (appendix pp 2–3), of which 53% were distributed to low-income and middle-income countries (LMICs) (appendix pp 2–3).

Beyond the distribution of SARS-CoV-2 materials, we also assessed non-monetary benefits the EVA network provided in response to the COVID-19 pandemic (panel; appendix p 6). However, for scientists and their organisations to provide these (non-monetary) benefits, monetary investments had to be made. Incurred costs included laboratory work, personnel, shipping of materials, quality control experiments, publishing charges, provision of materials and data, organising events, education, quality assessment, and regulatory approval (appendix p 6). In short, benefit-sharing of pathogen genetic resources, like the pathogens themselves, is cosmopolitan. Unfortunately, the legal framework has not yet caught up.

A global multilateral access and benefit-sharing framework for pathogen genetic resources based on EVA

As shown by EVA's SARS-CoV-2 benefit-sharing analysis, pathogen genetic resources do not fit a bilateral access and benefit-sharing model. Parties must come together to establish a simple and clear multilateral mechanism that can be applied to all pathogens and associated genetic sequence data, institutions, and countries, to protect global health. Existing biobanking networks structures are global public goods and should be brought to the forefront of attention during pathogen access and benefit-sharing discussions as the main actors for rapid, efficient, impartial, and safe access to pathogen genetic resources, and fair and equitable benefit-sharing.^{15–17}

For more on the COVID-19 platform see <https://www.covid19dataportal.org>

Panel: Examples of SARS-CoV-2 non-monetary benefits shared by the European Virus Archive (EVA) network*

Sharing of sequence data (modalities of shared genetic sequence data via databases, such as the Global Initiative on Sharing Avian Influenza Data and the International Nucleotide Sequence Database Collaboration, integrated into the COVID-19 platform):

- Bilaterally with another country or organisation (reported by three survey respondents).
- In a private hub (reported by two survey respondents).
- In public databases (reported by 10 survey respondents).

Sharing of material (modalities of shared SARS-CoV-2 biological material, such as viruses, proteins, and nucleic acids):

- Bilaterally with another country or organisation (reported by six survey respondents).
- In closed collaboration (reported by seven survey respondents).
- In biobanks (reported by two survey respondents).

Collaboration in a research and development project (modalities of research and development collaborations):

- Shared research outcomes or results bilaterally (reported by six survey respondents).
- Coauthorship in publications (reported by seven survey respondents).
- Shared research outcomes or results publicly (reported by six survey respondents).

Sharing or transfer of research and development results (modalities of shared of research and development products and services):

- Equipment or tools, or both (reported by three survey respondents).
- Education or training programmes, or both (reported by three survey respondents).
- Vaccines (reported by one survey respondent), therapeutics (reported by one survey respondent), or diagnostic assays (reported by six survey respondents).

* The results are based on a survey sent to all EVA partners on the use and sharing of SARS-CoV-2 resources they did during 2020 (appendix pp 3–6).

The main goals of a multilateral system for pathogen access and benefit-sharing should be to allow for rapid access to pathogen genetic resources and genetic sequence data, while formalising best practices on international collaboration during outbreak response, and to secure legally binding commitments from product developers on the fair redistribution of medical countermeasures, including vaccines, to support global response.^{2,3} these goals would align with the principles and practices in the International Health Regulations, the Convention on Biological Diversity, and the Nagoya Protocol. Such a multilateral system would need to be endorsed by an intergovernmental agency to guarantee independency and

trust, and, in this case, the engagement of WHO as the primary normative, technical, and legal body for global health would be essential. Additionally, this multilateral system would probably need to be subsequently recognised as a specialised instrument under Article 4 of the Nagoya Protocol. To advance thinking on this idea, biobanking infrastructures like EVA can share the lessons learned with regard to access that are directly relevant for a fair and efficient multilateral benefit-sharing system.

First, benefit-sharing of pathogen genetic resources needs to be defined in a legal sense and coupled with access to pathogen genetic resources. Vaccine nationalism and deeply entrenched inequalities will be the decisive political issue in any discussions on multilateral pathogen genetic resources. Concerns from stakeholders in the low-income and middle-income countries that results of SARS-CoV-2 research and development products (eg, vaccines) are not being shared fairly are justifiable.^{4,18} However, although this advocacy rightfully calls for multilateral sharing of benefits, including vaccines, this can only be realised through a multilateral system that also covers open access to pathogen genetic resources and its associated genetic sequence data, both of which are essential to develop countermeasures in the first place. In the current COVID-19 pandemic, the pathogen genetic resources and genetic sequence data used for vaccine development was accessed from countries without access and benefit-sharing regulations (table). Viral resources from LMICs, shared perhaps under Article 8b of the Nagoya Protocol, are conspicuously absent. Thus, the calls for multilateral sharing of vaccines are based on ethical imperatives rather than the letter of the law of the Convention on Biological Diversity and its Nagoya Protocol, given that pathogen genetic resource access (and thus required benefit-sharing) cannot be demonstrated. To have a legally enforceable framework for pathogen genetic resources that governs sharing of vaccines, access and benefit-sharing of pathogen genetic resources and genetic sequence data must go hand-in-hand and be treated equally. All countries should provide rapid access to pathogen genetic resources and genetic sequence data and all should receive and share the outcomes of that access.

Second, a multilateral system for access and benefit-sharing of pathogen genetic resources should broadly encompass all (ie, human, animal, and plant) pathogens with outbreak potential. Although pathogen-specific governance (eg, only SARS-CoV-2 or only coronaviruses) might be more politically expeditious and could differentiate the handling of high-priority pathogens (with pandemic potential) from historical pathogens that can be shared with less urgency, experience within biobanks shows at least four reasons such a distinction would be short-sighted. First, it would be very difficult to classify pathogens in such categories, as, for instance, historical pathogens can mutate and become a present threat. Second, if the goal is to not only be responsive

to outbreaks but improve our capacity to predict and mitigate epidemics before they start, then rapid and open access to diverse pathogen genetic resources is crucial to harness the skills of scientists globally to identify and investigate such threats.¹⁹ Third, access to pathogen genetic resources is needed not only at the outset of epidemics but throughout them. Surveillance of circulating strains, for instance, is essential to spot new variants, as the past few months have made quite clear, and to ensure that public health measures and medical countermeasures remain effective. Finally, continuous access to pathogen genetic resources after crises is crucial to build preparedness to future outbreaks, as exemplified by the rapid development of the first SARS-CoV-2 diagnostic test that was only possible due to the availability of the historical severe acute respiratory syndrome materials in biobanking infrastructures and associated sequences in open-access databases.^{8,15–17}

The third and final lesson is that mechanisms for clarifying and standardising access and benefit-sharing practices and procedures for pathogens are urgently needed. The Pandemic Influenza Preparedness Framework is a good example of an existing multilateral system for sharing pandemic influenza resources, but this framework heavily relies on existing pandemic influenza virus-sharing infrastructure (unlikely to expand to other pathogens) and has high administrative costs (US\$28 million annually).²⁰ The standard material transfer agreement provided by the Pandemic Influenza Preparedness Framework enables rapid access to materials in exchange for commercial users providing direct access to developed countermeasures and funds for building global pandemic influenza preparedness and response capacity.²⁰ This Framework is not a legally binding treaty, but rather a public–private partnership in which legal enforcement is enabled through the standard material transfer agreement. Whether such a model could be repeated for many types of pathogen genetic resources is a question that needs more attention. The EVA experience shows that access and benefit-sharing compliance can be handled more broadly (for multiple pathogen genetic resources) and embedded in operational practices, as suggested by the EVA material transfer agreement. A differentiated standard material transfer agreement regarding pathogen genetic resources, for example, for non-commercial and commercial use, might be a key opportunity for convergence.

EVA—a biobanking infrastructure committed to pathogen access and benefit-sharing

The EVA model exemplifies how rapid access to pathogen genetic resources, capacity building, and services can be provided to the global community during outbreaks, and, in parallel, serve as a multilateral system for benefit-sharing from pathogen genetic resources. Based on the

data we have presented in this Personal View, we recommend two future actions to WHO and Convention on Biological Diversity policy makers.

First, WHO's BioHub initiative should not waste time in trying to create new models, but rather make use of successful models as a foundation. In May, 2021, WHO and the Swiss Confederation launched the BioHub initiative, which has an objective to set up a global system for the sharing of pathogen and clinical material to facilitate the rapid development of medical countermeasures as global public goods.²¹ Given the contribution by the EVA network to the current global response to the COVID-19 pandemic and many other epidemics,¹⁶ it is unclear why policy makers are considering the development of a completely new system when there are existing and functioning infrastructures that can be used. Instead of building a new infrastructure out of nothing, the EVA model could be expanded and made permanent. Indeed, EVA is already tightly integrated into existing networks for pathogen genetic resources: eight out of the 26 recognised WHO reference COVID-19 laboratories are EVA core members²² and discussions are ongoing to add EVA to the Emerging Viral Diseases-Expert Laboratory Network, supporting the European Centre for Disease Prevention and Control in early detection and surveillance of emerging or re-emerging viral diseases in the European Economic Area.

Despite EVA's outsized role in the pandemic, its running costs are relatively low at around €4 million per year, which covers the costs of production and associated research and development on biobanking, and subsidises end-users to receive material free of charge under certain conditions.¹⁴ EVA partners are located on every continent, with new associated members in LMICs that could facilitate in-country capacity building and build trust. Furthermore, EVA can already navigate complex legal and ethical issues, including access and benefit-sharing. This capacity would enable preparedness during outbreaks, and could promote even wider and more rapid sharing of pathogen genetic resources from all countries, creating a virtuous cycle.

Finally, EVA should be included in international discussions regarding access and benefit-sharing of pathogen genetic resources. Because of EVA's hands-on experience with access and benefit-sharing and in-depth understanding of the needs of the broader community of users of pathogen genetic resources, EVA is a key stakeholder that should be included in discussions around the development of multilateral mechanisms for pathogen genetic resources. EVA can bring empirical data based on global distribution of pathogen genetic resources and access and benefit-sharing experience to these discussions as well as provide a scientific perspective and input while the global health community looks to find a benefit-sharing mechanism that properly addresses the cosmopolitan nature of pathogens.

Contributors

SS and CdSR wrote the original draft of the manuscript and, with the addition of CP, were responsible for the data curation. AHS, CP, and GH were responsible for funding acquisition. All authors were involved in the manuscript conceptualisation, formal analysis, investigation, methodology, writing, and editing of the manuscript. The European Virus Archive principal investigators endorsed this publication as signatory authors.

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Declaration of interests

We declare no competing interests.

Acknowledgments

The manuscript was written by the European Virus Archive access and benefit-sharing compliance team but would not have been possible without the front-line scientists that built up the European Virus Archive infrastructure and have worked tirelessly over the past year to support the global pandemic response. We welcome the European Virus Archive signatory authors who endorse this publication and its call for a multilateral pathogen genetic resources mechanism tied to a distributed biobanking infrastructure. This publication was supported by the European Virus Archive-GLOBAL project that has received funding from the EU Horizon 2020 research and innovation programme (grant agreement number 871029).

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