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## Review Article

# Access and benefit-sharing of the pathogenic microorganisms such as SARS-CoV-2

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## ABSTRACT

With the outbreak of coronavirus disease 2019 (COVID-19), it is essential to share pathogens and their data information safely, transparently, and timely. At the same time, it is also worth exploring how to share the benefits of using the provided pathogenic microorganisms fairly and equitably. There are some mechanisms for the management and sharing of pathogenic microbial resources in the world, such as the World Health Organization (WHO), the United States, the Europe, and China. This paper studies these mechanisms and puts forward “PICC” principles, including public welfare principle, interests principle, classified principle, and category principle, to strengthen cooperation, improve efficiency, and maintain biosafety.

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## 1. Introduction

Pathogenic microbial resources are vital to maintaining national biosafety as an essential strategic biological resource. Furthermore, the outbreaks of the coronavirus disease 2019 (COVID-19) pandemic highlight the importance of rapid and broad sharing of pathogens and their data for effective monitoring, timely diagnosis, research and development, containment of infectious diseases, and improvement of human health [1,2]. Therefore, it is urgent to foster equitable access to scientific resources, facilitating the sharing of scientific knowledge, data, and information, enhancing scientific collaboration to respond to global emergencies [3]. Therefore, it is necessary to study the access and benefit-sharing mechanisms of pathogenic microbial resources at home and abroad to provide suggestions for improving the level of international pathogenic microbial resource sharing.

Biological resources include genetic resources, organisms or parts thereof, biotic populations, or other biotic components of ecosystems with actual or potential use or value for humanity [4]. Strengthening the protection of biological resources and their continuous renewal and reproduction is significant in supporting human production, life, research, sharing, and utilization [5]. In 1992 the United Nations adopted the Convention on Biological Diversity [4] (hereinafter referred to as the Convention). At the fifth meeting of the conference of the parties (COP5) to the Convention on Biological Diversity in 1998, the working group on access and benefit-sharing (A.B.S.) was established [6]. By October 2010, COP10 had adopted the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity* (hereinafter referred to as the Nagoya Protocol) in Nagoya, Japan. The Nagoya Protocol proposes monetary and non-monetary benefits [7,8].

## 2. International status of access and benefit-sharing of pathogenic microbial resources

Pathogenic microorganisms, as a kind of biological resources, refer to microorganisms that can invade the human body, cause human infection, and even infectious diseases [9]. Some sharing mechanisms

of pathogenic microorganisms such as the World Health Organization (WHO) Pandemic Influenza Preparedness Framework (PIPF), BioHub system, European Virus Archive – GLOBAL (EVAg), Biodefense and Emerging Infectious Diseases Research Resources Repository (BEI Resources), Federal Select Agent Program (FSAP) and China National Pathogen Resource Center (NPRC), are already in place.

### 2.1. Influenza virus sharing based on PIPF and SARS-CoV-2 sharing based on BioHub under the framework of the WHO

#### 2.1.1. Multilateral sharing mechanism of influenza virus based on PIPF

The WHO adopted PIPF in 2011 to improve the prevention and response of pandemic influenza, improve and strengthen the WHO Global Influenza Surveillance and Response System (GISRS), share H5N1 and other influenza viruses that may cause human pandemic on an equal basis, and obtain vaccines and share other benefits [10]. PIPF stipulates influenza virus sharing mechanism, benefit-sharing mechanism, and governance and review mechanism.

Among them, the virus sharing mechanism is implemented through two material transfer agreements: Standard Material Transfer Agreement 1 (SMTA1), which applies to the transfer of all PIPF biological materials among influenza laboratories within GISRS; Standard Material Transfer Agreement 2 (SMTA2), which is an agreement signed with institutions outside GISRS. SMTA1 stipulates that neither the Provider nor the Receiver shall seek any intellectual property rights related to the materials. As the contracting party of SMTA1 is a scientific research institution, the value orientation of the agreement focuses on the protection of public health rather than intellectual property rights. Therefore, this agreement does not include provisions for protecting intellectual property [11]. After signing the SMTA 2, WHO will have predictable access to products responding to pandemics, such as vaccines, antiviral drugs, and diagnostic kits, when in urgent need [12].

Since implementing PIPF in 2011, the WHO has secured 420 million doses of pandemic influenza vaccine in pandemics, and received more than \$100 million donations from manufacturers [13,14]. PIPF has played an essential role in promoting the fair distribution of global vaccines and related benefits and is an excellent example of the exist-

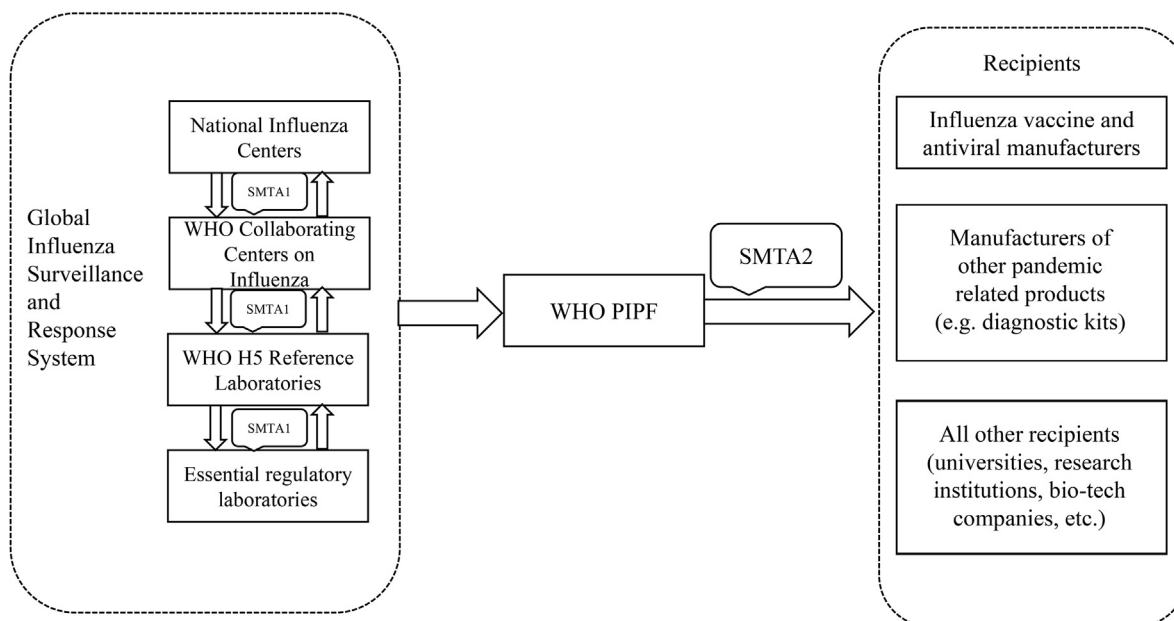


Fig. 1. SMTA flow chart of PIPF [12]. WHO: World Health Organization; SMTA: Standard Material Transfer Agreement; PIPF: Pandemic Influenza Preparedness Framework.

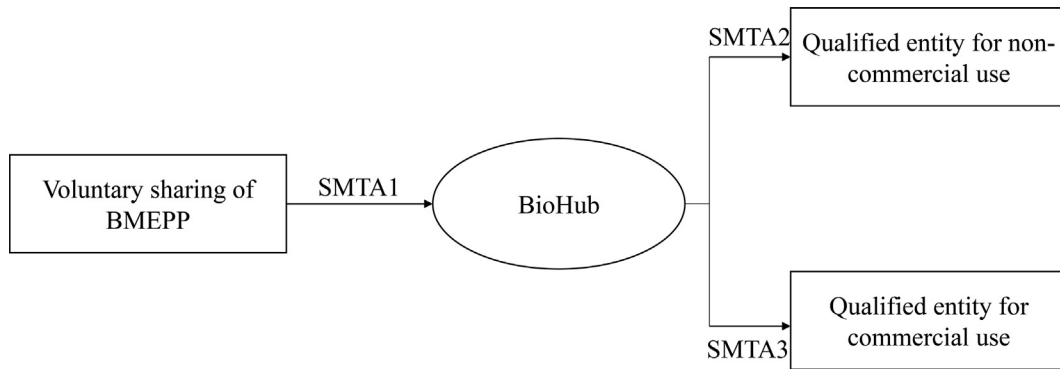


Fig. 2. SMTA flow chart of BioHub. BMEPP: Biological Materials with Epidemic or Pandemic Potential; SMTA: Standard Material Transfer Agreement.

ing multilateral system. However, the framework relies heavily on the existing pandemic influenza virus sharing infrastructure [15] and has high administrative costs (\$2.8 billion per year) [16]. However, after the outbreak of COVID-19, some studies suggested that the scope of the framework should be extended to COVID-19 [13,17]. The SMTA flow chart of PIPF is shown in Fig. 1.

### 2.1.2. Multilateral sharing mechanism of SARS-CoV-2 based on BioHub

Since the PIPF has been in operation for ten years and the world is fighting against COVID-19, the WHO is aware of the shortcomings of the existing global health security framework. Therefore, to develop the globally agreed pathogen sharing mechanism, a new era of cooperation is needed in this background; WHO announced in November 2020 and launched the *BioHub* system in May 2021 [1].

The system is not intended to replace the existing structure but as a complement to the existing structure. The purpose is to encourage and support the rapid and broad sharing of Biological Materials with Epidemic or Pandemic Potential (BMEPP) after discovering abnormal events. The system is based on equitable distribution and sharing of benefits generated by BMEPP for public health purposes [18].

The WHO *BioHub* adopts a step-by-step and phased approach to establishing a new system. From now on, it will be in the Pilot Testing Phase by May 2022. During this phase, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) will be used as a “test BMEPP”, and continuous research and exploration will be carried out. After completing this stage, the application scope of pathogens will be expanded to improve the global governance framework. Two standard

material transfer agreements (SMTA1 and SMTA2) have been prepared to share BMEPP non-commercially [19]. The agreement for commercial use (SMTA3) is still under development. SMTA1 is used to share BMEPP with a WHO BioHub facility voluntarily. SMTA2 is used to share BMEPP with a qualified entity for non-commercial public health use. The SMTA flow chart of BioHub is shown in Fig. 2.

### 2.2. American pathogenic microorganism sharing mechanism based on registration management

#### 2.2.1. B.E.I. Hierarchical registration and sharing management

B.E.I. Resources was established in 2003 by the National Institute of Allergy and Infectious Disease (NIAID), under the management of the American Type Culture Collection (ATCC), providing reagents including SARS-CoV-2 for infectious disease research [20,21]. B.E.I. Resources is a U.S. Government-funded program that is separate and distinct from other collections at the ATCC.

B.E.I. Resources adopt management by levels and classifications. Level means that infectious materials are divided into three levels according to the biosafety level: Level 1 registration applies to non-pathogenic materials at Biosafety Level 1 (BSL-1). This registration does not include materials for Level 2 and level 3; Level 2 registration applies to non-regulatory BSL-2 materials. This registration does not include materials applying for Level 3 and requires more registration information; Level 3 registration is applicable to select agents, and materials from the BSL-3 laboratory are required. Level 3 registration can also obtain Level 1 and Level 2 materials. Classification refers to

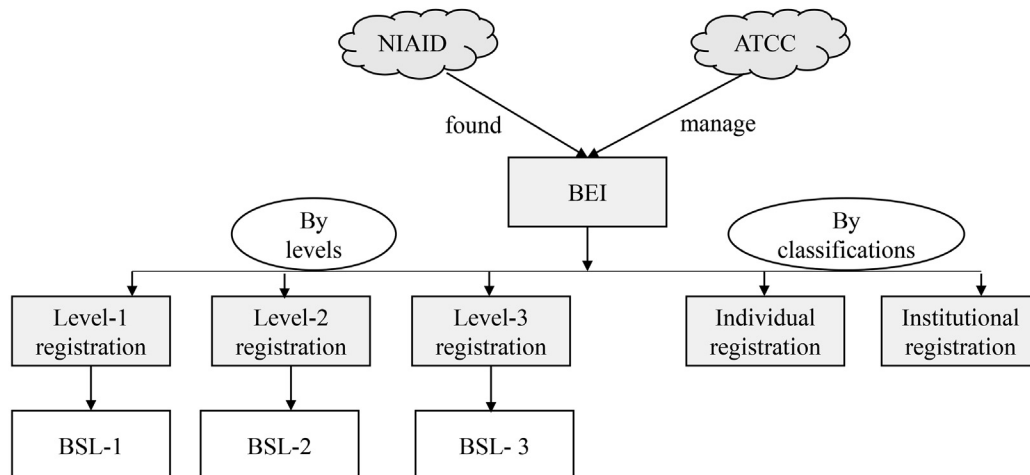


Fig. 3. Management hierarchy chart of Biodefense and Emerging Infectious (BEI). NIAID: National Institute of Allergy and Infectious Disease; ATCC: American Type Culture Collection; BSL: Biosafety Level.

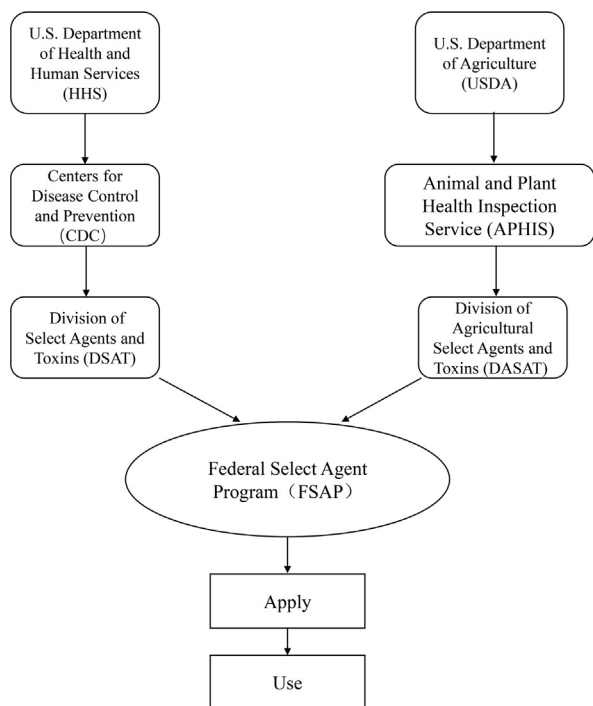


Fig. 4. Management hierarchy chart of Federal Select Agent Program.

the classification by the subject of the application, including individual registration and institution registration.

Generally, once B.E.I. staff receives all application information, Level 1 registration will be passed in 1–2 weeks, and higher-level registration may take additional time. Finally, materials will be packaged and delivered by applicable laws and regulations. The recipient's responsibility is to ensure that all licenses required for the order are obtained and provided to ATCC. The management hierarchy chart of B.E.I. is shown in Fig. 3.

### 2.2.2. Regulations on application and use of the select agent in the United States

The materials included in B.E.I. 3 registration are select agents and materials requiring Biosafety Level 3 laboratories. The select agents are solely subject to and managed by the Federal Select Agent Program (FSAP) [22]. The project's objective is to regulate the safe and reliable possession, use, and transfer of pathogens and toxins that may pose a severe threat to the public, animal or plant health, or animal and plant products. Currently, there are 67 pathogens on the control list, which is reviewed every two years to determine whether there is a need for additions or deletions.

The following two departments jointly manage the project: 1) the Division of Select Agents and Toxins (DSAT) in the Centers for Disease Control and Prevention (CDC) under the U.S. Department of Health and Human Services; 2) the Division of Agricultural Select Agents and Toxins (DASAT) in the Animal and Plant Health Inspection Service (APHIS) under the U.S. Department of Agriculture.

The conditions and procedures for obtaining the project are: Firstly, the applicant needs to have a Secure Access Management Services (SAMS) account to ensure that sensitive and non-public information is not disclosed. Secondly, access the eFSAP system (the security information system of FSAP) through the SAMS account; entities submit “APHIS/CDC Form 1” through eFSAP for registration to possess, use and transfer select agents and toxins.

The project will review the entities using pathogens by CDC and/or APHIS annually and form an annual report. The annual report from 2015 to 2020 has been issued [23]. Reporting is an essential tool for

providing critical feedback to entities that possess, use or transfer select agents and toxins. These reports contain FSAP inspection results and usually require entities to take corrective actions. In addition, timely inspection reports enable entities to quickly address practical problems to improve the safety of select agents and toxins.

The project regulates the select agents and toxins in the United States from biosafety, risk assessment, due diligence, pathogen inactivation, legislation and rules and regulations, personnel suitability assessment, application for registration, identification report, theft, and loss, and forming a complete management system. The management hierarchy chart of FSAP is shown in Fig. 4.

### 2.3. National Pathogen Resource Center, China

China has permanently attached great importance to the preservation of pathogenic microbial resources. Significantly since 2004, China has further strengthened the laboratory biosafety management mechanism, including the preservation of pathogenic microbial resources, and issued the *Management Measures for Preservation Organization of Human Pathogenic Microorganism* and the *Technical Requirement for Preservation Organization of Human Pathogenic Microorganism* (WS 315–2010), and the *Development Plan for Preservation Organization of Human Pathogenic Microbial Resources (2013–2018)*. Therefore, the management of China's preservation institutions has followed the track of legalization and standardization.

By the end of 2020, China had completed the network layout of preservation organizations. In June 2019, with the approval of the National Health Commission, the Ministry of Science and Technology, and the Ministry of Finance, the National Pathogen Resource Center (NPRC) was established affiliated with the Chinese Center for Disease Control and Prevention to undertake the task of national preservation of pathogenic microorganism resources, and 92.9% of the preservation centers have prepared the pathogenic microorganisms sharing agreement [24].

In order to provide solid support for COVID-19 prevention and control, in January 2020, the National Health Commission of the People's Republic of China issued the *SARS-CoV-2 Laboratory Biosafety Guideline*. Furthermore, in order to give full play to the sharing service of the NPRC resources, on January 24, 2020, the *Novel Coronavirus National Science and Technology Resource Service System*, jointly developed by the NPRC and the National Microbiology Data Center (NMDC), released the strain of SARS-CoV-2's electron microscopic photos, which was successfully isolated from National Institute for Viral Disease Control and Prevention of China CDC, SARS-CoV-2 nucleic acid detection primers and probe sequences, and other authoritative information [25]. In addition, relative shared services were also provided. At the same time, to do an excellent job in SARS-CoV-2 sample preservation management, the NPRC compiled standards such as the *Requirements for SARS-CoV-2 Sample Preservation* (T/CPMA019-2020) [26,27].

The flow chart of pathogenic microorganism application of NPRC is shown in Fig. 5:

### 2.4. European Virus Archive-global

European Virus Archive-global (EVAg) is a non-profit organization dedicated to the conservation, production, distribution, and characterization of biological materials in the field of virology, which is an international group of 46 laboratories, including 27 European Union (EU) and 19 non-EU research centers that represent an extensive range of virological disciplines [28]. The EVA. 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 [15].



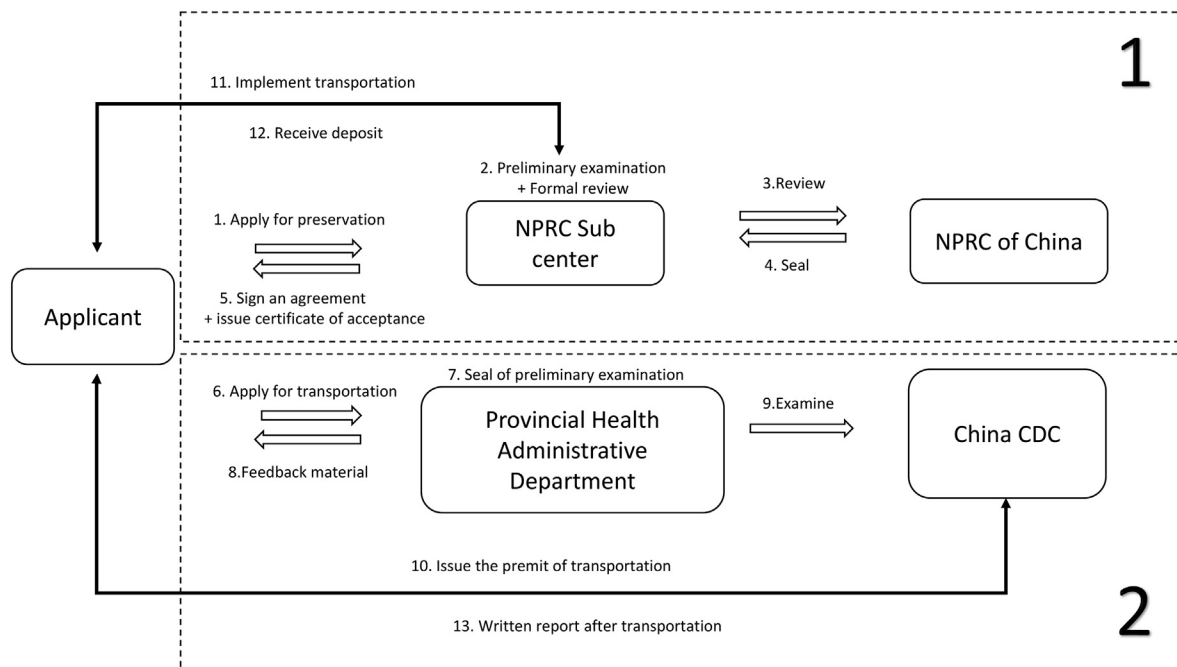


Fig. 5. Flow chart of pathogenic microorganism application in China. NPRC: the National Pathogen Resource Center. China CDC: Chinese Center for Disease Control and Prevention.

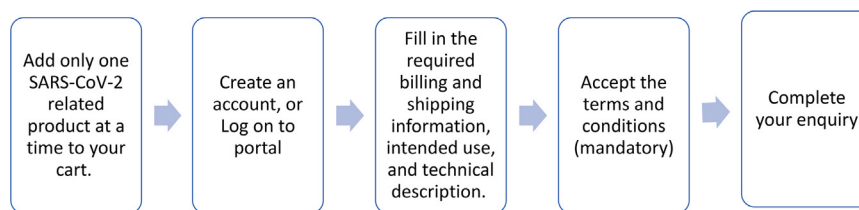


Fig. 6. Process of receiving free of charge severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) diagnostics controls and viral strains.

The usual time between ordering and receiving products from EVA is 2–3 weeks, but during COVID-19, an emergency procedure to check and approve or deny access to SARS-CoV-2-related products in less than 24 h [29], which has significantly improved the sharing efficiency.

The process of access to SARS-CoV-2-related products in EVA is shown in Fig. 6.

The applicant needs to have an EVA account to order products. First, use the web portal to place an online inquiry on the EVA website and receive a quote, and then sign the material transfer agreement between the applicant and the partner installation. Additionally, it is essential to note that all inquiries are evaluated in terms of biosafety.

### 3. Discussion

According to the above research, the BioHub has not been tested in action, while all other systems have. For lack of direct comparability between these infrastructures, however, it is not easy to make a direct head-to-head comparison as not all aspects are known. The comparison of performance of the pathogenic agents sharing instruments now in place is hindered by the lacking of data accessible on their real use by the scientific community. There is the possibility in the future that these infrastructures might compete for access to the same limited pool of biological samples during the early phases of an infectious diseases outbreak. At present, the international community is actively

exploring the issues related to the sharing of pathogenic microbes [14,15,17] and carrying out the preservation and sharing of SARS-CoV-2 during COVID-19, which has provided critical support for promoting resource utilization and vaccine research and development. United Nations Educational, Scientific and Cultural Organization has published “UNESCO Recommendation on Open Science” in 2021, which recognized the rights of knowledge holders to receive a fair and equitable share of benefits that may arise from the utilization of their knowledge [3]. However, there are still some problems in the sharing process. Through the above research, it is suggested that the international management and sharing of pathogenic microorganisms can be considered from the following aspects:

#### 3.1. Public welfare principle

This principle is followed under most country's decision. Both FSAP and B.E.I. of the United States do not charge any fees for the materials provided. In addition, article 22 of China's *Measures for the Management of Human Infectious Pathogenic Microbial (Virus) Species Preservation Institutions* stipulates that the preservation institutions shall not charge fees for storing and providing bacterial (virus) species and samples. Other agencies, such as the European Virus Archive, have played a vital role in the global response to the COVID-19 pandemic, distributing free and cost-price virus resources to users worldwide and providing non-monetary interest sharing [15].

Pathogenic microorganisms sharing aims to prevent public health emergencies, prevent infectious diseases, and deal with infectious diseases. Under this background, the products such as vaccines and drugs developed are also products with public attributes and have extensive social benefits. Particularly after the epidemic outbreak, pathogen sharing should be carried out quickly and timely based on public welfare.

Therefore, all the work on pathogenic microorganisms should first recognize the public welfare orientation of species preservation and sharing from biosafety and people's health interests.

### 3.2. Interests principle

The three parties in sharing, which are the provider, the preservation entity, and the recipient, shall respect the rights and interests of each other. The property right of biogenetic resources is the basis for determining the benefit-sharing subject and form of biogenetic resources [30]. One of the basic principles of the Convention is the principle of national sovereignty; that is, countries have sovereign rights over their genetic resources, which requires the administrative intervention of relevant national competent departments [31]. For the subjects in the country, the ownership should also belong to the provider.

As a written agreement for sharing and with legal effect, the content shall clarify the ownership of licenses, responsibilities, biosafety, confidentiality [32] and materials before and after the transfer, the ownership of intellectual property rights involved in the use of raw materials or derivatives of raw materials, and the distribution of benefits. If there are other problems in subsequent use, a supplementary agreement shall be signed in time to respect the rights and interests of the three parties, especially the provider.

The preservation and sharing of pathogenic microorganisms is the key to developing biological resources and improving the level of biotechnology transformation. It is of great significance to prevent and control the epidemic situation of infectious diseases, improve people's health level and strengthen international cooperation and exchange. Despite the progress made in understanding the need for having data-sharing frameworks, sharing well-characterized specimens remains a significant challenge in accelerating test development and evaluation [33]. Only by strengthening national legislation, improving the scientific level of sharing agreement, formulating agreements that clarify the ownership of materials, the rights and obligations of both parties and the preservation entity, interest distribution, intellectual property rights, other issues, and reasonably distributing interests, can we improve the willingness to share, standardize sharing, and improve the sharing efficiency. It plays an essential supporting role in preventing and controlling major infectious diseases and ensuring national biosafety.

### 3.3. Classified principle

Different pathogenic microorganisms have different biological hazard levels. Therefore in the process of sharing and managing pathogenic microorganisms, classified registration should be carried out in strict accordance with the hazard level of microorganisms.

Biosafety has been divided into Biosafety Level I, Level II, Level III, and Level IV. Similarly, it is divided into Level 1 to 4 in the sixth edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL) released by the U.S. CDC. *The list of human pathogenic microorganisms* formulated by the National Health Commission of the People's Republic of China divides bacteria, viruses, and fungi into Class I, Class II, Class III, and Class IV, respectively.

China has set up an online sharing service platform for the the NPRC database (<https://www.nprc.org.cn>). According to the law, the platform is a national preservation unit designated by the National Health Commission to preserve human infection pathogenic microor-

ganism resources. It is a professional institution with the widest variety and quantity of highly pathogenic microorganisms in China. For the management and sharing of pathogenic microorganisms, China suggested that the NPRC should involve the following contents: unified management, establishing a classified registration management system, building a classified registration information system, and forming data management models on pathogenic microorganisms for different levels and types of pathogens. In addition, other issues as dynamically mastering the use of national resources and regularly supervising and inspecting the shared entities to form a system from registration, application review, delivery to use, benefit-sharing, supervision and inspection, annual summary, and a series of complete processes should also be included.

### 3.4. Category principle

As an essential subject in the sharing process, users have different properties. In the SMTA2 of PIPF, users are divided into three categories according to the nature of users: category A is the manufacturer of influenza vaccine and antiviral drugs, and category B is the manufacturer of products that do not produce vaccines or antiviral drugs but are related to the prevention and response of pandemic influenza, and category C is all other recipients (universities, research institutions, biotechnology companies, etc.). According to the nature of the three types of entities, the benefits generated are also different. For example, category A needs to choose two of the six benefits listed in the agreement, category B needs to choose one of the six benefits, and category C should be appropriately considered.

Therefore, it is suggested that the sharing process should be classified according to different users, such as profit-making institutions and non-profit institutions. For profit-making institutions, both parties can share benefits with the provider according to the income of products based on friendly negotiation. Most non-profit institutions aiming at public welfare purposes such as scientific research or epidemic prevention and control express their gratitude to the provider in their publications and indicate the number of bacterial and virus species. At the same time, different types of sharing agreements are formulated for different sharing methods, such as public welfare sharing, cooperative research sharing, and resource exchange sharing.

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### Conflict of interest statement

The authors declare that there are no conflicts of interest.

### Author contributions

**Yalin Zhai:** Conceptualization, Investigation, Writing – original draft. **Geng Hong:** Writing – original draft. **Mengnan Jiang:** Writing – review & editing. **Qiang Wei:** Conceptualization, Funding acquisition, Supervision, Writing – review & editing.

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