

COMMENTS BY THE WORLD HEALTH ORGANIZATION ON THE DRAFT FACT-FINDING AND SCOPING STUDY “THE EMERGENCE AND GROWTH OF DIGITAL SEQUENCE INFORMATION IN RESEARCH AND DEVELOPMENT : IMPLICATIONS FOR THE CONSERVATION AND SUSTAINABLE USE OF BIODIVERSITY, AND FAIR AND EQUITABLE BENEFIT SHARING”, DATED 9 November 2017

DSI from pathogens is a global public health good that should benefit all.

Introduction

This document has been developed in response to notification No.2017-115 from the Executive Secretary of the Convention on Biological Diversity, seeking comments on the Fact-finding and Scoping Study on Digital Sequence Information on Genetic Resources¹. It provides information on the importance of rapid, timely and broad sharing of digital sequence information (DSI) for public health and elaborates principles that the World Health Organization (WHO) believes should govern the sharing of DSI from pathogens.

Rapid, timely and broad sharing of DSI for public health

Rapid, timely and broad sharing of digital sequence information (DSI) is essential to global health; it enables surveillance, response, preparedness, routine control and optimal clinical management of infectious diseases.

Public health emergencies and the International Health Regulations (2005)

The preamble to the Nagoya Protocol declares that Parties are: “Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes.” The International Health Regulations (IHR) are legally binding on 196 countries, with the goal to prevent, protect against, control and provide a public health response to the international spread of disease. To support this, articles 6-11 of the IHR require States Parties to share information with WHO about events which may constitute a Public Health Emergency of International Concern (PHEIC). Information shared under the IHR is used to conduct analyses that allow the fullest possible understanding of a public health emergency, and to ensure that recommendations and decisions made are based on the best available evidence.

WHO believes that rapid and timely sharing of DSI is as important for public health as the sharing of other event-related information under the IHR.²

Public health applications of DSI

DSI is used extensively for public health. Its applications vary broadly across different areas and are likely to become more widespread as technologies continue to develop rapidly and replace conventional techniques. For example, during outbreak responses, DSI is used for identification and detailed characterization of

¹ <https://www.cbd.int/doc/notifications/2017/ntf-2017-115-abs-en.pdf>

² Policy Statement on Data Sharing by the World Health Organization in the Context of Public Health Emergencies, 13 April 2016, available at http://www.who.int/ihr/procedures/SPG_data_sharing.pdf.

pathogens, including origin, epidemiology, transmission, evolution and reservoir, allowing rapid and targeted risk assessment and monitoring.

In the context of antimicrobial resistance, sequencing allows testing for resistant pathogen strains and DSI is used for drug resistance surveillance. This is expected to transform our ability to tailor treatment approaches in a number of disease areas, including HIV, tuberculosis and malaria.

For food safety monitoring, DSI has the potential to revolutionize our understanding of complex outbreaks, enabling a more rapid public health response and preventing economic damage, such as losses in trade. Because DSI constitutes a standardized format that is easily comparable, countries will be able to match novel genomes against all previously existing microbial genomes found in global DSI databases. This will enable rapid and accurate tracing of the origin and spread of a foodborne pathogen, from animals to humans, or across countries.

In the context of public health, DSI contributes to, inter alia:

- Enabling rapid and targeted risk assessment and monitoring of emerging pathogens at the national and international levels;
- Development of diagnostic tools to identify suspect cases, ensuring that patients are given appropriate medical care and allowing an assessment of the scope and spread of an outbreak;
- Disease surveillance and preparedness to enable more targeted interventions, speed up future responses to outbreaks and limit morbidity and mortality;
- Evidence-based national and global public health strategies and measures to better control endemic diseases and to prevent further spread of outbreaks;
- Development of more effective vaccines and therapeutics, and more accurate diagnostic tools;
- Scientific efforts, including research, leading to a better understanding of diseases.

Equitable sharing of benefits derived from the utilization of DSI

WHO believes that DSI from pathogens is a global public health good that should be widely available to all; in addition, benefits derived from use of DSI should be shared equitably with all, without impeding the rapid, timely and broad sharing of sequences for disease control, prevention and preparedness.

Principles for DSI sharing

The current practice for sharing DSI from pathogens focuses on the open sharing of data and the broad dissemination of significant scientific and public health information and knowledge. It is critical for public health that this current practice is advanced and supported, while fully respecting the public health imperatives of equitable benefit sharing.

WHO believes that principles for DSI sharing should:

- Support the rapid and broad sharing of DSI, and ensure that countries in need have fair and equitable access to diagnostics, therapeutics and vaccines, as well as other technologies and information derived from their use.
- Promote benefit-sharing without delaying the sharing of DSI;
- Create clarity and transparency at the country-level, including fair and non-arbitrary rules as well as clear and expeditious processes for access and benefit-sharing. Implementing these processes should work to assist public health institutions and laboratories in carrying out their important work;
- Reduce the administrative and financial burden on laboratories sharing and accessing DSI and on the databases that host the data.

Conclusion

Pandemics, epidemics, and outbreaks involving multiple countries and sectors, as well as antimicrobial resistance, constitute some of the greatest threats the world faces. The global response to those threats depends on the rapid, timely and broad sharing of DSI, as well as the fair and equitable access to the benefits derived from its use. These include scientific benefits, public health information, better treatment outcomes thanks to early identification of highly resistant organisms, new technologies and contribution to development of diagnostics, therapeutics and vaccines.

Global sharing of DSI is already underway on a large scale, and current practices generate considerable benefits, including scientific and public health information, that are likely to increase as technology continues its rapid progress.

It is critical to consider the public health implications of different approaches to handling DSI under the Nagoya Protocol. This in turn means placing a high priority on allowing current, timely, highly valuable broad sharing of DSI to continue while exploring innovative approaches to equitable benefit sharing.

WHO thanks the Secretariat of the Convention on Biological Diversity for sharing the draft Fact-Finding and Scoping Study and would recommend that the focus of the study be broadened to include “the emergence and growth of digital sequence information in research and development, and *public health*”.