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Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits

The sharing by countries of influenza virus samples is important for vaccine development, and for understanding how viruses are mutating. Developing countries have thus freely provided samples to the World Health Organisation (WHO). But when private pharmaceutical companies use the samples to develop and patent vaccines which the same developing countries cannot afford, this is unjust and exposes thousands of people in developing countries to preventable deaths. This policy brief outlines the opportunities that African countries have to negotiate for equitable benefit sharing in the use of viral resources, through international treaties. The United Nations Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources provide for fair and equitable sharing of benefits from the use of biological resources. The brief provides information on their enabling clauses and outlines the options that African countries may consider in their negotiations for an equitable system.

Influenza viruses: a shared threat?

The increased movement of people across nations and continents has been accompanied by an increased risk of spread of disease across borders. From 2003 to 2011 there were 539 cases notified to World Health Organisation (WHO) of Avian Influenza A/(H5N1) and 318 deaths worldwide (WHO 2011a), although only one case was been reported in Sub-Saharan Africa. The outbreak of Influenza A (H1N1) in 2009 raised again the challenge to contain and manage the cross border spread of disease. While cases of the H5N1 or H1N1 viruses were not reported from Africa in 2008-2011 except for cases in Egypt, Nigeria, South Africa (H1N1), and suspected cases in Benin and Zambia. Nevertheless, the threat of pandemic influenza is present and preparedness essential. Countries need to strengthen their health systems for early detection of new strains of the influenza virus infection in humans; to set up disease surveillance and laboratory facilities for early confirmation of cases; and to finance control measures. This calls for sharing of technology, information and resources for detection and to produce strain specific vaccines.

States have the primary responsibility for ensuring an effective response to new disease outbreaks, but have very different levels of resources to achieve this. The 2009 World Health Report noted the challenges that many countries, particularly in Africa, face in accurately identifying, diagnosing and reporting infectious diseases, including the remoteness of communities, lack of transport and communication infrastructure, and a shortage of skilled health-care workers and laboratory facilities to ensure accurate diagnosis (WHO 2009). Such shortfalls can in part be addressed by collaboration across countries, to ensure access to vaccines, anti-virals, technology and vaccine production capacities. While African countries committed in the Maputo Declaration to build laboratory capacity as part of their primary healthcare strategy and to set up integrated laboratory networks at the community, district, regional and national levels (WHO Afro 2008), there is a further factor undermining the response, not noted in the report, which is the inequity in influenza virus sharing.

Global mechanisms to respond to influenza

Since 1952, the WHO has convened the Global Influenza Surveillance Network (GISN) as a global alert mechanism for the emergence of influenza viruses with pandemic potential (WHO, 2011). The 135 National Influenza Centres (NICs) in 105 countries within the GISN sample patients with influenza like illnesses in and submit these samples to WHO Collaborating Centres for further analysis. The results inform recommendations for the production of vaccines that contain the major virus strains predicted for that year. The GISN ensures that countries throughout the world share

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influenza viruses for the development of vaccines as the African NICs shown in the table below are not adequate to cover the continent, benefit from the wider network is critical for these countries.

Country	Centre
Cameroon - Yaoundé	Laboratoire de Virologie, Centre Pasteur du Cameroun
Central African Republic- Bangui	Institute Pasteur de Bangui
Côte d'Ivoire Abidjan	Laboratoire de Virologie des Grippes, Unité des Virus Respiratoires, Dépt des Virus Epidémiques, Inst Pasteur de Côte d'Ivoire
Ghana – Accra	National Influenza Laboratory, Virology Department, Noguchi Memorial Inst for Medical Research, University of Ghana
Kenya – Nairobi	Center for Virus Research
Madagascar - Antananarivo	National Influenza Laboratory, Institut Pasteur de Madagascar
Nigeria – Ibadan	College of Medicine, University of Ibadan
Senegal – Dakar	Medical Virology Unit, Institut Pasteur de Dakar
South Africa - Sandringham	National Institute for Communicable Diseases / NHLS
South Africa - Cape Town	Institute of Infectious Disease and Molecular Medicine, Faculty of Health Sciences, University of Cape Town
Sudan - Khartoum	University of Khartoum, Dept of Microbiology and Parasitology
Uganda - Entebbe	Uganda Virus Research Institute (UVRI)

Source: adapted from WHO website: http://www.who.int/csr/disease/influenza/centres/en/index.html

Equity in benefits sharing

In late 2006, Indonesia announced that it had stopped sharing H5N1 virus samples with the GISN to oppose a situation where developing countries freely provide samples to the WHO, but are not then able to afford the vaccines that pharmaceutical companies develop and patent using the same samples. Indonesia cited an Australian company's application for a vaccine patent derived from an Indonesian H5N1 strain to make this point (Molenaar 2011). This triggered debate over its impact on the pandemic influenza surveillance and pandemic preparedness efforts, but also served as a wake-up call on the global inequities in access to vaccines. It highlighted the inequitable benefit sharing in access to vaccines, anti-virals and other technologies at prices affordable to developing countries (Shashikant 2010).

Responding to this situation, the 60th World Health Assembly (WHA) 2007 adopted resolution WHA60.28 on 'Pandemic Influenza Preparedness: sharing of influenza viruses and access to vaccines and other benefits' requesting the WHO Director-General (DG) to convene an intergovernmental meeting to consider frameworks and mechanisms to strengthen timely sharing of influenza viruses with pandemic potential and the equitable access to the benefits from this (WHO, 2010). This is now a matter of ongoing negotiation between WHO member states. Several meetings were held in 2010 and April 2011 and a Framework was agreed on that has been tabled at the WHA in May 2011. The Framework known as "Standard Material Transfer Agreement" (SMTA) contains terms and conditions governing the sharing of influenza viruses and the resulting benefits, and obliges the pharmaceutical industry and other entities that benefit from the WHO virus sharing scheme to share benefits from it. It is thus a positive development in stating the equity principle. Most countries speaking at the WHA supported the PIP Framework and re-emphasized the importance of a more equitable and predictable global system (Molenaar 2011). There is, however, some critique of the Framework in that it uses non binding language on key issues and does not make mandatory the commitments to share knowledge, technology and know-how with developing countries on the production of vaccines, and other products (Shashikant 2011). It makes reference,

for example, to the granting of licences to manufacturers in developing countries for the production of vaccines, but is silent on patent issues and availability of affordable vaccines where there is no such manufacturing capacity.

Application of other treaties and conventions

The World Trade Organisation (WTO) agreement on **Trade Related Aspects of Intellectual Property Rights (TRIPs)** makes clear that intellectual property (IP) should not compromise countries' obligation to protect public health. IP cannot thus be used to deny countries affordable and timely access to vaccines, and the flexibilities that exist in TRIPS for governments to ensure access (compulsory licensing, parallel importation, bolar provision for early generic production) apply equally to vaccines.

In the April 2011 meeting, delegates made reference in the SMTA to the **Convention on Biological Diversity (CBD) and the associated Nagoya protocol on benefit sharing.** However, at the WHA, Australia observed that there was no consensus on reference to the Nagoya Protocol and proposed deleting this, with support from other member states.

Notwithstanding this, most member states of the UN have acceded to the CBD and it has relevance to issues of benefit sharing from biological diversity. Both the CBD and Nagoya protocol affirm that "States have sovereign rights over their own biological resources'. The CBD provides for three objectives, that is the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilisation of genetic resources (Article 1). Article 15 paragraph 7 of the CBD states that: *"Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."* The Nagoya protocol provides more specific information on monetary and non monetary benefits also not yet addressed in the SMTA.

Benchmarks on benefit sharing in the Nagoya protocol (not verbatim)

1. Monetary benefits may include, but not be limited to:
   - Access fees/fee per sample collected or otherwise acquired;
   - Up-front, milestone, royalty payments; Licence fees in case of commercialization;
   - Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   - Salaries and preferential terms where mutually agreed; Research funding;
   - Joint ventures and joint ownership of relevant intellectual property rights.
2. Non-monetary benefits may include, but not be limited to:
   - Sharing research and development results and contribution to local economy; food and livelihoods;
   - Collaboration, cooperation and contribution in scientific research and development, particularly biotechnological research, and research on priority needs such as in health and food security;
   - Participation in product development; admittance to facilities and databases of genetic resources;
   - Collaboration, cooperation and contribution in education and training; in where possible, and with full participation of countries providing genetic resources
   - Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, in particular, knowledge and technology that make use of genetic resources, or that are relevant to the conservation and sustainable use of biological diversity;
   - Capacity building, resources for technology transfer and enforcement of access regulations;
   - Access to relevant scientific information, including biological inventories and taxonomic studies;
   - Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities; Social recognition;
   - Joint ownership of relevant intellectual property rights.

Source: Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation to the Convention on Biological Diversity

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There is some debate over the application of the CBD, however. It refers to the benefits arising from the commercial and other use of genetic resources, defined as "any material of plant, animal, microbial or other origin containing functional units of heredity" that has " actual or potential value" (Article 2). It is argued that viruses do not contain functional units of heredity are are thus not covered by the CBD. It is also argued that the SMTA and its components are a specialised international instrument on benefit sharing and not linked to the CBD. There are counterarguments that as viruses contain RNA, they do contain functional units of heredity, are a part of the biological diversity recognised by the CBD in their own right and because of their association with their influenza potential in human beings. While the Nagoya Protocol together with the CBD thus have voluntary application, their provisions appear to imply that the SMTA should meet the same principles and provide no less protection of benefit sharing. Provisions such as the joint ownership of intellectual property in the Nagoya protocol offer innovative approaches to expedite technology transfer between high and low income countries to operationalise benefits sharing. Finally, provisions in the WHO's Global Pandemic Influenza Action Plan to Increase Vaccine Supply (GAP), and for Laboratory and surveillance capacity building required under the International Health Regulations (2005) also provide guidance in measures that should be included to operationalise benefits sharing.

Next steps

The May 2011 WHA adopted the SMTA. In implementing the Framework member states will need to ensure that it adequately remedies the inequity posed by Indonesia in access to vaccines in low income countries. The current inequity in benefits sharing calls for resources for capacity building for national surveillance and for an expanded number of NICs in Africa; as well as for exchange of information, transparency and timely delivery of both viral samples and vaccines. It is thus important that member states ensure, as proposed at WHA, full and unconditional implementation of the SMTA. This needs to be monitored, together with any benefits to countries.

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