HIGHLIGHTS

FROM **SCIENCE POLICY INTERFACE SESSIONS**

AT THE 8TH ESWI INFLUENZA CONFERENCE
#ESWI2021 VIRTUAL EDITION

THE EIGHTH ESWI INFLUENZA CONFERENCE

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VIRTUAL EDITION
4 - 7 DECEMBER 2021

SPI
SCIENCE POLICY INTERFACE

THE EIGHTH ESWI
INFLUENZA CONFERENCE

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The 8th ESWI Influenza Conference – Hot topics on Influenza, RSV and COVID-19 – took place online from 4 to 7 December 2021. This report summarises ESWI's interpretation of the key messages from the individual talks within the Science Policy Interface (SPI) track of the conference.

Organised by

ESWI

EUROPEAN SCIENTIFIC
WORKING GROUP
ON INFLUENZA AND OTHER
RESPIRATORY VIRUSES

↘ Contents

Why influenza is a priority for policymakers

SUNDAY 5 DECEMBER 10:00 - 11:45 CET

CHAIR:

Roman Prymula
Charles University Prague, Czech Republic

Keynote opening: The future European Union for Health to fight influenza

DOLORS MONTSERRAT, EUROPEAN PARLIAMENT, BELGIUM

Seasonal influenza presents a significant challenge to the health systems of the European Union (EU). Compared to other infectious diseases, seasonal influenza has one of the highest impacts in terms of yearly incidents in the EU. In addition, it is estimated that the disease is causing up to 70,000 deaths every year in the EU alone, largely amidst at-risk groups and older adults.

The existing objective of the WHO and the European Council is to reach 75% influenza vaccination coverage for the at-risk population, however, so far only a limited number of EU Member States have reached this target. Nevertheless, the COVID-19 pandemic has sparked a renewed political debate on influenza vaccination and it has become clear that a long-term vision on influenza preparedness is needed to mitigate the costs of future possible pandemics as this affects the EU's capacity to fight annual influenza waves.

From an EU policy-making perspective, there are two important aspects at the moment, starting with the need to secure the EU's industrial autonomy. We need to support a prepared seasonal influenza industrial capacity and delivery capability as this is a cornerstone in pandemic preparedness. Furthermore, we will address the current vulnerabilities and strategic dependencies related to development, production procurement, stockpiling and distribution of vaccines through the new European Health Emergency Preparedness and Response Authority (HERA) along with the recently reinforced European Medicines Agency (EMA) and European Centre for Disease Prevention and Control (ECDC).
This will contribute to building a stronger, more autonomous EU programme.

Secondly, in order to quickly respond to health emergencies, we need an updated and credible regulatory framework. This is needed to guarantee flexibility and security of vaccine supply to European countries and to facilitate timely access for all European citizens to the new generation of vaccines, as we did for COVID-19 vaccines. The new Pharmaceutical Strategy for Europe, recently approved in plenary, also highlighted this need.

"I am sure that the European Health Union which we are building will have a big role in strengthening the efforts to promote influenza vaccination and secure the health of all European citizens."

A key priority of our policymaking activities is to collectively engage for higher influenza vaccination coverage of EU citizens through the promotion of clear, targeted and positive communication with the support of our healthcare professionals. Moreover, as a strategic pillar of national pandemic preparedness plans, we need to encourage Member States to increase investments in vaccine prevention. It is of additional importance that we guide Member States to organise multi-stakeholder committees at national level to strengthen the implementation of national vaccination programmes, including industry, public authorities, scientific experts and patients.

Vaccination is the most effective measure for disease prevention. We know that the EU can achieve great things by working together in a unique and coordinated manner, a recent example of this being the very successful EU COVID-19 vaccination campaign. This campaign was only possible as it was built on cooperation, solidarity, dialogue and a common vision.

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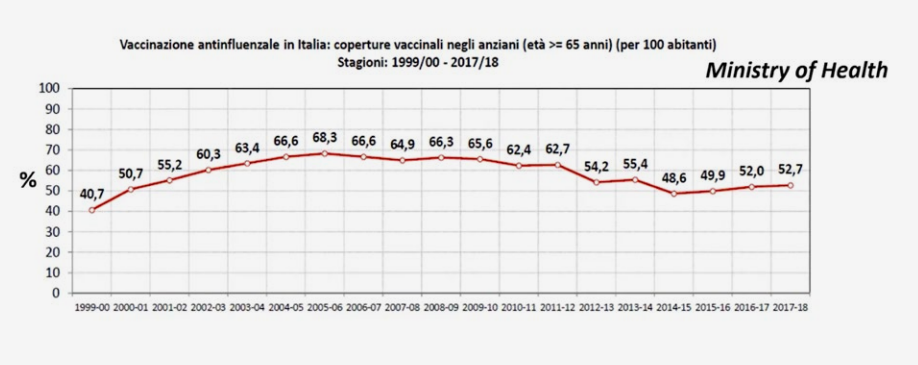
Effectiveness of adjuvanted trivalent vaccine (aTIV) for influenza over 18 epidemic seasons

FRANCESCO LAPI, HEALTH SEARCH CENTRE, SIMG, ITALY

Various studies support the higher effectiveness of MF59®-adjuvanted trivalent influenza vaccine (aTIV) compared to non-adjuvanted trivalent (TIV) or quadrivalent (QIV) influenza vaccine in preventing influenza-related hospitalisations in the older adults. However, such studies cover only a few influenza seasons, have a limited geographical spread in Italy, and do not cover available evidence in the primary care setting.

A study was therefore conducted to evaluate the relative effectiveness of aTIV compared to TIV or QIV in preventing all-cause hospitalisation in patients aged 65 years or older across 18 seasons.

The importance of this study is that it links the public health systems burden and hospitalisation with vaccine coverage in the older adults population in Italy which is currently insufficient. The figure of 60% (2018-2019) is far from optimal and needs to be improved, especially with the risk of the COVID-19 pandemic increasing the pressure on the Italian public health system. The combination of influenza and COVID-19 could significantly increase hospitalisations of the older adults.



A nested case-control analysis of older adults (> 65 years) was conducted from 2001/2002 to 2018/2019 influenza seasons in Italy, using the Health Search Database (HSD), an Italian data source of primary care. The study identified almost 60,000 patients across 18 influenza seasons, with a mean age of 76 years old. The majority were women.

The use of aTIV compared to TIV/QIV was associated with a 12% significantly lower risk of hospitalisation. When the outcome was limited to hospitalisations due to respiratory causes, the use of aTIV was associated with a 37% lower risk than TIV/QIV.

There are some limitations to this study. It underestimates the number of patients actually vaccinated. This is because in Italy, GPs need to input data twice: once for the public health platform and again in their own software. There was also an underestimate of the hospitalisation rate because it was a primary care database. A final factor is the accuracy of the event definition.

"Across 18 influenza seasons, the study confirmed the effectiveness of aTIV vs. TIV/QIV among patients aged at least 65 years for the prevention of hospitalisation in Italy. This confirms the relevance of the vaccine choice in a primary care setting, and supports efforts by public health providers in Italy to increase vaccination coverage in the older adults population."

Public health benefits of switching to a recombinant quadrivalent vaccine in the Murcia and Valencia regions of Spain for seasonal influenza vaccination of adults

GEORGINA DRAGO MANCHÓN, SANOFI PASTEUR, HEVA & PRICING, MARKET ACCESS, SPAIN

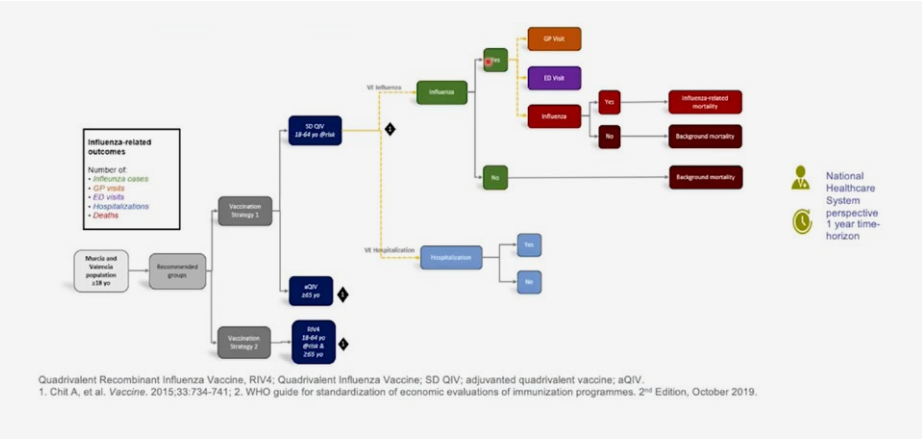
In Spain, public health was transferred to the regions in the 1980s. This means that regional public health departments are responsible for allocating vaccine budgets, purchasing and delivery of vaccines, and the implementation of the vaccination programme.

Seven new vaccines with different manufacturing technologies are being developed. The decision as to which vaccines should be used in the WHO recommended groups is also taken at a regional level.

The first approved influenza vaccine produced with recombinant DNA technology is RIV4 and is authorised for use in Europe since 2020. It is the only licensed influenza vaccine in the US and EU markets using recombinant technology, which ensures an exact match to the WHO recommended viral strains. RIV4 has demonstrated good immunogenicity, safety and greater protection compared to the standard dose quadrivalent influenza vaccine.

A study was performed in Spain to assess the clinical impact and healthcare consumption differences associated with the switch from an egg-based to this recombinant quadrivalent influenza vaccine (RIV4) in the recommended adult population (18+) in the regions of Murcia and Valencia.

A decision tree model was used to compare the burden of influenza disease in adults aged 18 years or older vaccinated with RIV4 vs. SD-QIV (18-64 years old at risk) and aQIV (≥65 years old), from the perspective of the Spanish National Healthcare System. The model is consistent with the WHO economic evaluation guidelines for influenza vaccines.



Quadrivalent Recombinant Influenza Vaccine, RIV4; Quadrivalent Influenza Vaccine; SD QIV; adjuvanted quadrivalent vaccine; aQIV.
1. Chit A, et al. *Vaccine*. 2015;33:734-741; 2. WHO guide for standardization of economic evaluations of immunization programmes. 2nd Edition, October 2019.

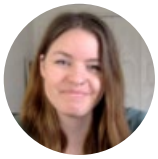
"A switch from current standard of care to RIV4 in Murcia and Valencia would contribute to reducing excess mortality due to influenza and reducing the consumption of healthcare resources."

The model predicts averted influenza cases, influenza-related general practitioner (GP) and emergency room (ER) visits, hospitalisations attributable to influenza, and influenza-related deaths, within a one-year time horizon for these health outcomes.

After analysis, it was found that switching from SD-QIV to RIV4 in at-risk adults aged 18 to 64, and from aQIV to RIV4 in those aged 65 or older, would (in the Murcia and Valencia regions of Spain), reduce hospitalisations by 13%, ER visits by 12%, deaths due to influenza by 12%, influenza cases by 11%, and GP visits by 11%. Such a switch is therefore highly recommended.

↘ Open Science Practices are favoured by most surveyed influenza researchers despite a lack of perceived peer support

KELLY SUTHERLAND, THE CENTER FOR OPEN SCIENCE, USA



A lack of pre-clinical data sharing and transparency of research agendas is not just a crisis that was brought to light in the social and behavioural sciences ten years ago – it is also an issue in microbiology. While practices such as data sharing and pre-registration have spread in some communities, they are not widespread in areas such as virology or pre-clinical influenza research. This has become especially evident as a result of the COVID-19 pandemic, which has served as a catalyst for the rapid adoption of practices such as pre-printing and open access to COVID-19 articles.

Open science means data transparency; unbiased results reporting including reporting of null results; and pre-registration of study designs and analyses to address unreported data flexibility. To encourage transparency in influenza research, it is first necessary to understand how open science practices are considered and perceived by researchers in the field.

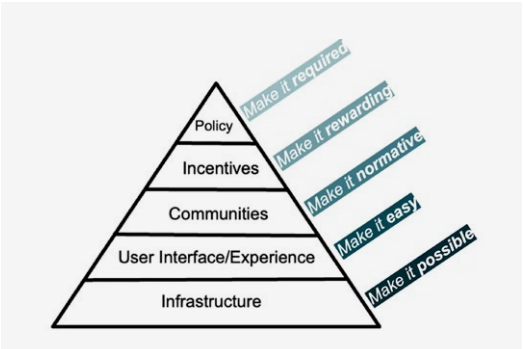
"Illuminating the overall favourability of influenza researchers toward open science practices may ultimately lead to a more transparent influenza research process. This is important for policymakers to focus on because transparency in influenza research can save lives."

To learn more about open science in the virology community, the Open Scholarship Survey asked influenza researchers about their beliefs, behaviours and perceptions regarding open science practices for replication and null results reporting. A questionnaire with 77 questions was distributed to 228 researchers within the fields of influenza and virology research.

Overall, the influenza community reported favourable attitudes toward the open science practices of replication and null results reporting. However, these same respondents perceived their peers to have much less favourable views towards these same activities.

A minimal number of respondents indicated that they included a replication (22%) or null result (15%) in their most recent publication. Interestingly, only 40% of respondents think that their peers think publishing results is a good idea, whereas almost 80% approve of the actual action. This seems indicative of an institutional barrier, which there is: institutional incentives to publish all types of results.

The presented data demonstrate a disconnect between what influenza researchers believe regarding open science and how influenza researchers think their peers see open science practices. This disconnect may partially explain why influenza researchers report favourable views toward open science practices, such as replication and null results reporting, but do not engage in these practices regularly.



The Center for Open Science wants to emphasise making open science projects possible with good open-source infrastructure that is easy to work with. It strives to make open source normative in communities, by, for example, providing incentives to make it rewarding. Finally the Center is working to make open science required by policies. This theory of change leads to specific recommendations which researchers and science policymakers can take.

Societal impact of influenza and COVID-19

SUNDAY 5 DECEMBER 12:00 - 13:45 CET

CHAIR:

Terho Heikkinen
University of Turku, Finland

The importance of vaccinating children against influenza

TERHO HEIKKINEN, UNIVERSITY OF TURKU, FINLAND

There is wide agreement throughout the world that people with certain underlying illnesses should be vaccinated annually against influenza, and this extends to children. When considering the vaccination of healthy children against influenza, there needs to be a substantial burden of illness, and an effective vaccine.

In regard to the burden of illness, more than one hundred million episodes of influenza are recorded every year in children younger than five years old, alongside close to one million hospitalisations, and approximately 35,000 deaths. The vast majority of deaths occur in low/middle-income countries, but high-income countries are not exempt. In the US, on average around 100 children die of influenza every year, almost half of whom did not have any high-risk conditions.

In all studies of all influenza outbreaks around the world, the attack rate of influenza is far higher in children than in adults. Moreover, the clinical presentation of influenza varies. Most children with influenza have a respiratory tract infection with a fever, and suffer from a range of complications. Acute otitis media is the most frequent complication, affecting about 40% of children under three.

Children are also frequently hospitalised with influenza. This is dependent on age, with the highest rates of hospitalisation being in children younger than six months of age. This is a major problem considering the unavailability of a licensed vaccine for this age group.

It is also important to understand that hospitalisations only account for a small proportion of the full burden of influenza in children. The vast majority of influenza cases are seen in outpatient clinics, where children are often treated without viral diagnosis.

"Influenza places a great burden of illness on the population, but especially on young children. Influenza vaccines are effective in preventing disease, complications and hospitalisations in young children. The children are the primary beneficiaries, but indirectly other members of society also benefit."

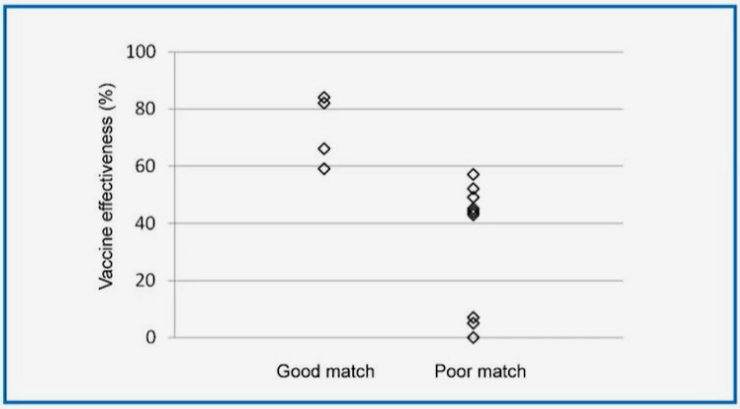
Furthermore, children are the main transmitters of influenza both in households and in society in general. This is because the attack rates are highest in children, they shed viruses longer than adults, and the titres of viruses are higher than in adults.

When discussing vaccination of children against influenza, two factors need to be considered. Vaccination prevents influenza in the vaccinated children, so there is clearly a benefit for the children themselves. But it also reduces transmission of influenza in the community, leading to benefits for other age groups. This is not a 50:50 divide; the greatest benefit is clearly for the children themselves.

The WHO has clear recommendations for seasonal influenza vaccination, with the highest priority being pregnant women, followed by children aged 6-59 months. The US has shown the way for years with a vaccination coverage in this age range of 70%. In Europe, only a few countries (e.g. Finland and the UK) recommend influenza vaccination of healthy children.

Doubts regarding the effectiveness of influenza vaccination in children have been put forward, but these are misplaced. The key issue is not the age of the recipient of the vaccine but the accuracy of the match between the selected vaccine strains and the circulating strains. When there is a good match, the effectiveness of the vaccine in children is around 70%, but when the match is poor, the effectiveness is lower. This is a problem with influenza vaccination for everyone, not just children.

Effectiveness and safety of influenza vaccination in children: European perspective



Heikkinen & Heinonen, Vaccine 2011

↘ The economic burden of influenza among adults aged 18-64: A systematic literature review

CAROLINE DE COURVILLE, SANOFI PASTEUR, FRANCE

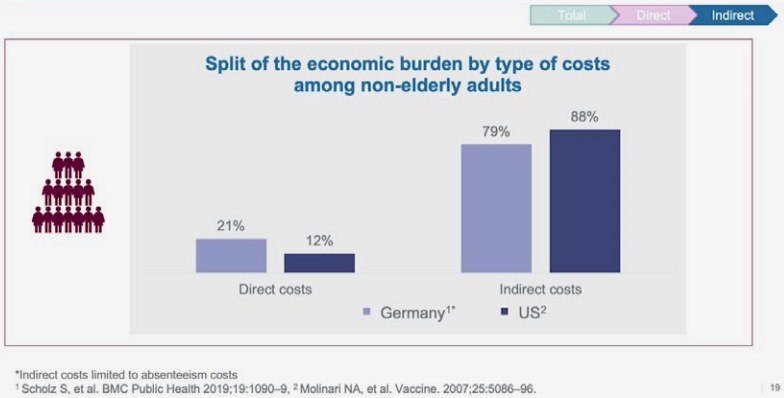
While the economic burden of influenza infection is well described among adults aged 65 and older, less is known for other adult age groups. A systematic literature review was therefore conducted to find research on the economic burden of seasonal influenza in adults aged 18-64. It aimed to identify the main determinants of direct and indirect costs and to highlight any gaps in the existing published evidence. The manuscript has been accepted and published: https://pubmed.ncbi.nlm.nih.gov/35122389/

Peer-reviewed publications were sought in medical databases from 2007, and conference proceedings from 2018, both up to the search date in February 2020. In addition, bibliographies of systematic literature reviews and meta-analyses captured by the search were reviewed to identify any relevant missing publications. Publications were then screened against the inclusion and exclusion criteria. Resulting trials, real-world observational studies, or cost-effectiveness studies were included only if primary influenza-related cost data (direct or indirect) or absenteeism data were reported.

Direct costs relate to the disease itself. These can refer to drugs, lab tests and imaging, primary care visits, emergency department visits, and hospitalisations. Indirect costs are associated with premature deaths and workplace absenteeism, which may include productivity loss and replacement. Cost was also classified as to whether it was at an individual or population level.

Overall, the extracted data highlighted that within the 18-64 age group, most of the economic burden of influenza was attributable to indirect costs (up to 88%), whereas up to 75% of overall direct costs were attributable to hospitalisations. Furthermore, within this group, influenza-related costs increased with age and underlying medical conditions. The reported cost of influenza-related hospitalisations was found to be up to 2.5 times higher among at-risk compared to not-at-risk populations.

Economic burden of influenza is driven by indirect costs among adults aged ≤60 or ≤65 yo



"Indirect costs are generally not recognised by decision-makers, especially in economic evaluations, leading to an underestimation of the economic impact of influenza."

This literature review documents the considerable economic impact of influenza among adults aged 18-64. In this age group, most of the influenza costs are indirect and generally not recognised in economic evaluations, leading to an underestimation of the economic impact of influenza. Furthermore, this review highlighted significant gaps in the literature, limiting generalisability and interpretation.

In order to address current gaps, more studies are needed with a focus on the economic burden of influenza outside the US, on those at-risk of severe outcomes, and on lab-confirmed influenza patients.

Evaluation of psychometric properties of a patient-reported outcome measure for the assessment of COVID-19 signs and symptoms: A cross-sectional observational study

ERIC K. H. CHAN, JANSSEN GLOBAL SERVICES LLC, USA

A Patient-Reported Outcome (PRO) is any report that comes directly from a patient without the interpretation of anyone else. Validated PRO instruments provide standardised assessment of the patient experience. They are increasingly recognised by various stakeholders, including clinicians, regulators, Health Technology Assessment (HTA) bodies, National Immunisation Technical Advisory Groups (NITAGs), and patients, as an important means for collecting patient-centred data, also during clinical trials. At the time of this study, no fit-for-purpose COVID-19-specific PRO measures were available, however a few have been developed since.

To address this unmet need, a cross-sectional, observational study was conducted in the United States to evaluate preliminary psychometric properties of a PRO measure: the Symptoms of Infection with Coronavirus-19 (SIC).

The team developed the SIC instrument following a targeted literature review, with feedback from patients with COVID-19, experts in infectious diseases, and clinicians who treat patients with COVID-19. The SIC is based on a checklist approach, with 30 items to assess the presence or absence of signs/symptoms of COVID-19 in the prior 24 hours. Participants were also asked to assess the severity of the symptom.

The SIC: Checklist approach

30 items assess presence or absence of signs/symptoms of COVID-19 in the prior 24 hours

- Participants are asked to respond "yes" or "no" if they have each symptom
  - For **25 symptoms**, if the participant indicates "yes," then they are asked to assess the severity
  - **1 question** regarding fever: if yes, the participant is asked to record the highest temperature
  - **4 additional symptoms** in which the patient is asked to indicate "yes" or "no" with no severity rating, as severity of these symptoms was not considered relevant (eg, decreased sense of taste)

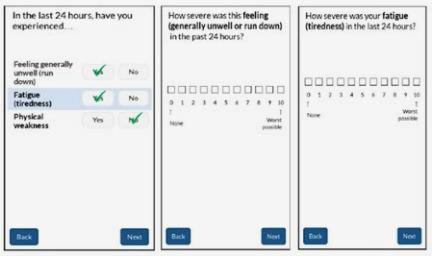


Figure 3

"Accurate COVID-19-specific PRO measures may facilitate diagnosis, contact tracing, clinical management decisions, and long-term follow-up of COVID-19 patients."

Participants aged 18 years or over with a self-reported positive COVID-19 test within the previous two weeks and at least two COVID-19 symptoms completed the web-based SIC. The SIC then assessed the presence of 30 signs/symptoms of COVID-19, and the severity of 25, if present.

152 diverse populations of participants completed the PRO measures, with a mean age of 51. About two-thirds were women, and about half had one or more co-morbidities, placing them at high risk of developing severe COVID-19.

Most participants reported moderate symptoms (47%) versus mild (26%) or severe (26%) for a mean duration of 14.9 days. 28% of participants were hospitalised with a mean stay of 3.2 days. The most frequently endorsed SIC symptoms were fatigue (78%), feeling unwell (66%), cough (61%), physical weakness (60%), and headache (60%). Fatigue had the highest severity rating.

The results support the reliability and validity of the SIC items and composite scores as appropriate and useful measures of COVID-19 symptom severity for use in clinical trials of COVID-19 vaccines and treatments in adults. For more information see also intervention by Carla DuMuro Romano).

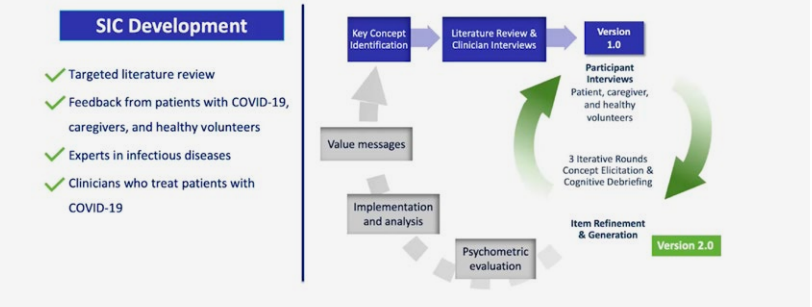
Qualitative interviews from a cross-sectional study to support the content validity of a patient-reported outcome measure of COVID-19 signs and symptoms in adults

CARLA DEMURO ROMANO, RTI HEALTH SOLUTIONS, USA

A disease-specific Patient Reported Outcome (PRO) measure was developed to assess the presence and severity of key signs and symptoms of COVID-19: the Symptoms of Infection with Coronavirus-19 (SIC). A cross- sectional study was conducted to perform a preliminary psychometric evaluation of the SIC (see also intervention by Eric Chan).

As part of this, an exit survey was administered and qualitative interviews conducted after the study to collect additional evident to support the content validity of the SIC. Best practices were followed to develop the SIC.

Best practices were followed to develop the symptoms of infection with Coronavirus-19 (SIC)[1-5]



"Overall, participants felt the SIC was an accurate measure to report and track COVID-19 symptom onset, emergence of new signs/ symptoms, and changes in symptoms over time."

The study was conducted in adults 18 years of age or older in the United States who self-reported at least two COVID-19 symptoms and a positive COVID-19 test within two weeks of screening. Participants completed a set of web-based PRO measures. Also included were two additional questions asking participants to identify symptoms that had to be resolved in order to return to usual activities, and four questions about access/barriers to COVID-19 testing and care. From study participants who agreed to a follow-up qualitative telephone interview, a subset was selected to represent a diverse population, targeting at least 50% minority representation.

A total of 152 participants completed the survey and 20 completed follow-up interviews. Participants who completed the follow-up interview were racially diverse (45% African-American, 25% white, 5% American-Indian, 10% mixed race, and 15% other). 65% were women, and the mean age was 51.5. Almost half (45%) had a pre-existing risk factor increasing the likelihood of severe COVID-19 outcomes, and 45% were hospitalised due to COVID-19.

Participants described a wide variety of signs and symptoms, the most common being fatigue, cough, shortness of breath, and decreased sense of smell and taste. Shortness of breath, headache, and fatigue were identified as the greatest barriers to return to normal activities.

Participants reported hesitancy to self-identify their COVID-19 experience as severe disease if not hospitalised or requiring supplemental oxygen, despite half of them reporting symptoms consistent with severe disease.

Most participants (85%) reported that their lives were impacted by needing to self-isolate and they experienced anxiety regarding what would happen to them and/or family members. Interview participants endorsed the content and format of the SIC and described the measure as straightforward, comprehensive, and easy to self-complete, even when ill.

Benefits of vaccinating healthcare workers and other risk groups

MONDAY 6 DECEMBER 10:00 - 11:45 CET

CHAIR:

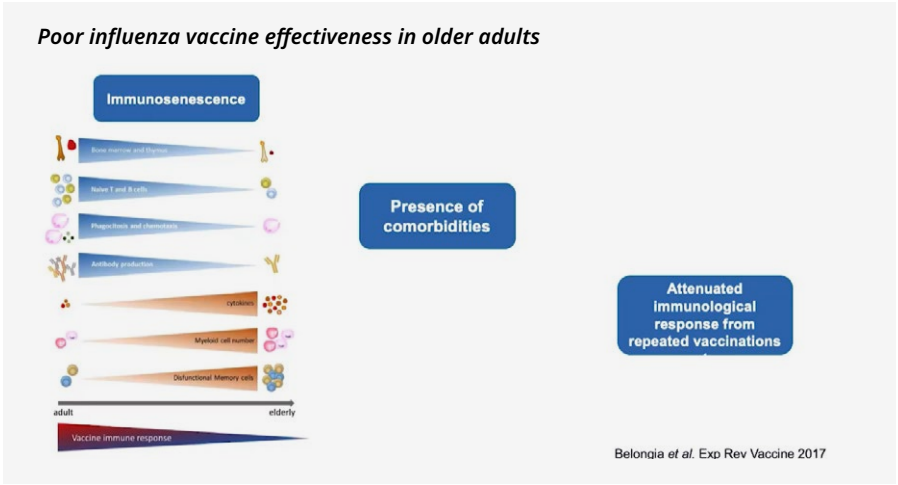
ANTONIA HO
MRC-UNIVERSITY OF GLASGOW CENTRE
FOR VIRUS RESEARCH, UNITED KINGDOM

↘ Introductory lecture on the benefits of vaccinating healthcare workers and other risk groups

ANTONIA HO, MRC-UNIVERSITY OF GLASGOW CENTRE FOR VIRUS RESEARCH, UK

Influenza vaccine effectiveness worsens with age of recipient. This is due to a combination of immuno-senescence, in which ageing affects both innate and adaptive immunity; increased number of comorbidities; and attenuated immunological response due to repeated vaccinations.

Poor influenza vaccine effectiveness in older adults



"Strategies for the indirect protection of vulnerable groups through vaccinating children and healthcare workers may help to overcome the lower vaccine efficacy and effectiveness seen amongst older adults."

Strategies have been put in place to improve vaccine effectiveness in older adults. These include the use of enhanced vaccines, higher dosages, or adjuvants. Another strategy is to avoid the adaptation of viruses that happens when they are grown in eggs, by growing cell-cultured vaccines in mammalian cells, or expressing recombinant vaccines in insect cells. Limited data is available on whether these enhanced vaccines have greater efficacy and effectiveness, but many countries are now preferentially recommending them over standard trivalent or quadrivalent vaccines.

Another strategy to protect vulnerable groups is indirect protection by vaccinating other groups, for example those that have contact with these vulnerable groups or are key transmitters of influenza. These are children and healthcare workers.

Children are a good group to target because they are major transmitters of influenza. Children have a large number of extra-household contacts, tend to be more susceptible to influenza infection due to their immature immune system, and often have a higher viral load and a more prolonged duration of viral shedding. Modelling studies have demonstrated substantial benefits of vaccinating school-age children, including reductions in GP visits, febrile illness, work absenteeism, ICU admissions, and infection of household members.

Healthcare workers are also an important group to target. Vaccination protects them and their families, reduces risk of nosocomial transmission, and reduces absenteeism. Vaccinating healthcare workers has now been recommended by most European countries, the US, Australia and the WHO. However, vaccine coverage is variable, between 11-84%. Vaccine mandates and non-mandatory strategies are subject to ongoing research and controversies.

The efficacy of vaccinating healthcare workers has been studied, also in long-term care facilities. The studies show similar benefits to those found when vaccinating children.

↘ Influenza vaccination coverage rates during the COVID-19 pandemic: Data from 11 countries

MARCO DEL RICCIO, NETHERLANDS INSTITUTE FOR HEALTH SERVICES RESEARCH (NIVEL), NETHERLANDS

Older adults (aged 65+) are at a higher risk of developing serious influenza complications. For example, in the US in 2019/2020 it is estimated that more than half of seasonal influenza-related deaths occurred in this group. For this reason, the WHO recommends the annual vaccination of older adults to prevent influenza infections, reduce the severity of disease, and reduce complications and deaths. Specifically, WHO recommends that at least 75% of older adults are vaccinated against influenza. In addition, WHO Strategic Advisory Group of Experts on influenza immunisation (SAGE) defined this group as one of the highest priority groups to receive the influenza vaccine during the COVID-19 pandemic.

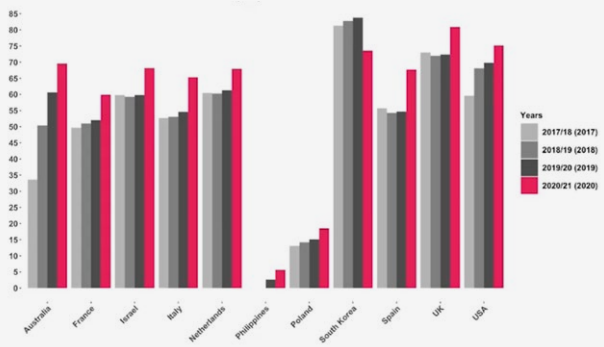
The FluCov project aims to better understand the impact of SARS-CoV-2 on influenza activity in 21 countries worldwide by assessing the available data on influenza vaccination coverage rates (VCRs) in older adults. Interesting data was collected from 11 of these 21 countries.

Reports and websites of public health institutes and international organisations were reviewed from 2019 to 2021 to collect influenza VCRs in older adults in the pandemic and pre-pandemic periods. VCR data were extracted and the differences between 2019/20 and 2020/21 calculated (pre-COVID-19-pandemic and post-pandemic seasons).

During the winter of 2020/21, influenza VCRs in older adults increased in France (+7.9 pp), Israel (+8.4 pp), Italy (+10.7 pp), Spain (+13.0 pp), The Netherlands (+6.6 pp), Philippines (+5.7 pp), Poland (+3.1 pp), UK (+8.5 pp), and USA (+5.4 pp). The UK and US both exceeded the WHO target of 75%. Australia is the only country with data from two post-pandemic seasons, and showed VCR increases of +9.0 pp and +4.3 pp. South Korea was the only country where a decrease was observed (-5.4 pp) Australia is the only country with data from two post-pandemic seasons, and showed VCR increases of +9.0% and +4.3%.

South Korea was the only country where a decrease was observed (-5.4%), although this is the only country that previously had attained the 75% VCR among older adults. The decrease is possibly due to reports of vaccine-related deaths that attracted significant media attention. Despite this decrease, influenza VCR in South Korea is still high, at only just below the 75% target.

Influenza VCRs (%) in eleven countries

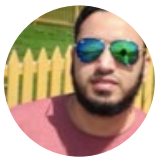


"It is important to maintain high vaccine coverage rates – especially in risk groups such as older adults – to avoid a potential resurgence of influenza cases during the coming winter."

Possible reasons for the overall increase in VCR include both individual and collective factors. The COVID-19 pandemic may have increased the risk perception among older adults of influenza infection. And national governments have strongly advocated influenza vaccination. However, the low levels of influenza activity since the start of the COVID-19 pandemic and the small number of cases observed during the 2020/21 winter may lead to an increase of the susceptible population in 2021/22.

Attitude and beliefs about the seasonal influenza vaccination among healthcare workers during the COVID-19 pandemic in Kashmir, India

HYDER MIR, SHERI KASHMIR INSTITUTE OF MEDICAL SCIENCES, INDIA

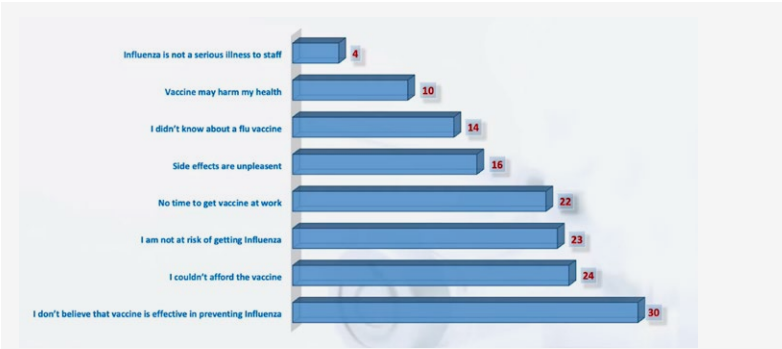


A project was established to assess the uptake of the influenza vaccine during the COVID-19 pandemic in north India. It also intended to look at the reasons why healthcare workers would refuse the influenza vaccination, and to identify potential modifiers of the decision-making process regarding the uptake of the 2020/21 influenza vaccine. This study followed previous studies on the same subject by the Kashmir Institute that first started in 2010.

The study was questionnaire-based and was designed to test the knowledge, attitude and practices of healthcare workers about seasonal influenza vaccination. Questions addressed demographic information, profession, location of work, type of patients cared for, and importance of the influenza vaccine. An analysis took place between March 2020 and June 2020, a period which witnessed the COVID-19 country-wide lockdown in India.

Of the 493 participants in the study, 56% were male and 44% female. Over half belonged to the 26-39 age range, and 56% were physicians or trainee physicians, with nurses, trainee nurses, allied health professionals and support staff the other main professions studied. 87% (430) considered influenza as a potentially severe disease and 96% (473) were aware about the existence of a vaccine against influenza.

382 participants said they intend to take the influenza vaccine this year; 112 said they didn't intend to. Ineffectiveness of the influenza vaccine (14%) was the main reason cited by the participants for not getting vaccinated, among a variety of other reasons.



"In the light of the COVID-19 pandemic, identifying the hurdles to influenza vaccination uptake among healthcare workers may also assist in developing successful awareness strategies to promote COVID-19 vaccination."

Even though 84% (416) of the healthcare workers agreed that vaccines are generally beneficial, slightly more than one-third of them believed that adverse effects of the vaccines are under reported. When asked how the organisation could make vaccination easier for them, the majority suggested that specific appointments in the clinic would help, instead of queuing for a vaccine.

Suggestions put forward by healthcare workers to increase the vaccine uptake included a one-time vaccine for lifelong immunity, raising awareness, free of cost availability, and improving the effectiveness of the vaccine.

When compared with a previous study conducted in 2012, it is clear that the uptake of the vaccine has increased significantly over the past decade, with the highest increase recorded when the vaccines were provided free of charge.

However, vaccination among healthcare workers in north India is still low. Creating awareness regarding influenza vaccination among healthcare workers is of utmost importance in order to eliminate the fear of vaccine-related severe adverse effects and misconceptions regarding its effectiveness.

Cost-effectiveness of High-Dose Quadrivalent Influenza Vaccine (HD-QIV) versus adjuvanted Quadrivalent Influenza Vaccine (aQIV) in the Italian older adults population

FILIPPO RUMI, ALTEMS, ITALY

Influenza is a serious public health problem, both for society and national health systems. In Italy, a study estimated that hospitalisations resulting from diagnosed influenza complications amount to over 300,000 per year.

The High-Dose Quadrivalent Influenza Vaccine (HD-QIV) contains four times the amount of antigens of the Standard-Dose Quadrivalent Influenza Vaccine (SD-QIV). It is the only influenza vaccine to have demonstrated higher clinical efficacy in randomised clinical trials than the SD-QIV to protect against lab-confirmed influenza and reduce hospitalisations for cardiorespiratory events in the older adults population. A study was carried out to estimate the cost-effectiveness of HD-QIV compared to that of the standard of care for the Italian older adults population: adjuvanted Quadrivalent Influenza Vaccine (aQIV).

The analysis is based on a decision tree model comparing the two vaccines over one year. The model estimates the health outcomes for both vaccines: GP visits, emergency department visits, hospitalisations, deaths, life years (LYs) and quality-adjusted life-years (QALYs). In particular, two different hospitalisation approaches are considered: hospitalisations conditional on developing influenza, and hospitalisations possibly related to influenza.

A key parameter is the Incremental Cost-Effectiveness Ratio (ICER) which can be used to make decisions on resource allocation. Only if the ICER is below a certain threshold can an intervention be judged cost-effective.

Considering hospitalisations directly attributable to influenza, it was found that HD-QIV is cost-effective in all the scenarios described. It has an incremental cost-effectiveness ratio (ICER) of €7,301, €9,805 and €14,733 per QALY, respectively.

"Vaccination with HD-QIV instead of aQIV among the Italian elderly could annually reduce the public health burden of influenza and its related complications."

When considering hospitalisations possibly related to influenza, HD-QIV is again seen as less expensive and more effective than aQIV. It is estimated to avoid nearly 70,000 cases of influenza, reduce hospitalisations by over 43,000, and avoid 602 emergency department visits and 1,876 deaths. This would save the Italian health service over €53 million, even after the cost of vaccination is taken into account.

Moreover, a probabilistic sensitivity analysis showed that, for a willingness-to-pay threshold of €30,000/QALY, HD-QIV has a 97% probability of being cost-saving compared to a QIV.

The conclusion is that the vaccination strategy with HD-QIV would be cost-effective if only hospitalisations conditional on developing influenza are included, and cost-saving when the full burden of influenza is considered.

Risk assessment and risk communication in acute respiratory virus infections

MONDAY 6 DECEMBER 12:00 - 13:45 CET

CHAIR:

BARBARA RATH
VIENNA VACCINE SAFETY INITIATIVE, GERMANY

↘ Understanding the variability of risk preferences for influenza vaccination among older adults (50+) during COVID-19 times: An 8-country survey

FREDERIC BOUDER, UNIVERSITY OF STAVANGER, NORWAY

A study was conducted to provide a post-COVID-19 update on people's perceptions of influenza vaccination. It focused on a representative sample of older adults (50+) in eight European countries.

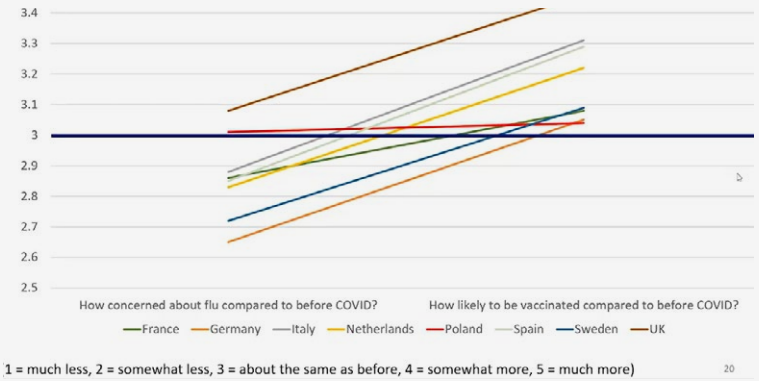
A substantial decline in the relative importance of influenza compared to COVID-19 was seen in some countries between 2019 and 2021. However, there was no significant change in time across the countries as to the perceived seriousness of the risk of influenza, with the exception being Spain, where influenza is considered to be a greater risk now than in pre-COVID-19 times. As to how serious influenza is compared to COVID-19 for people's health, in all countries COVID-19 is now seen as a greater risk to health than influenza.

A clear decline across all countries was noted as to the preventive measures people are willing to implement against influenza. Preventive measures also vary widely in different countries.

Perceptions on both influenza and COVID-19 vaccination were high. There was a decrease in the perception of unwanted side-effects of the influenza vaccination over time. In parallel, there was an increase in positive beliefs about influenza vaccines in all countries.

People were more concerned about influenza after COVID-19 than they were before, and are more likely to be vaccinated.

Concern about flu and flu vaccine behavioural intentions



"Personal experience and medical advice were seen to be the key drivers of decision making, confirming the important role of medical health professionals."

Regarding side-effects, people are slightly more concerned about the potential side-effects of the COVID-19 vaccine than of the influenza vaccine. The perception of effectiveness of the two vaccines was fairly similar. An increased perception in the positive beliefs of influenza vaccination was recorded, and a decrease in the negative beliefs. An outlier was Poland where there seems to be greater concerns about side-effects of influenza vaccination.

↘ COVID-19 response in Ireland: Vaccine risk communication

DONAL O'CONNOR, HEALTH PRODUCTS REGULATORY AUTHORITY, IRELAND

When discussing vaccine risk communication, it is essential to consider the differing needs of public health authorities, vaccine advisory committees, the health service and healthcare professionals, the general public, and the media. Key aspects of vaccine risk communication include monitoring the safety of vaccines post-approval; monitoring and reporting on safety; regulatory transparency with the public; national stakeholder communication and support; urgent safety issues; and putting the risk in context.

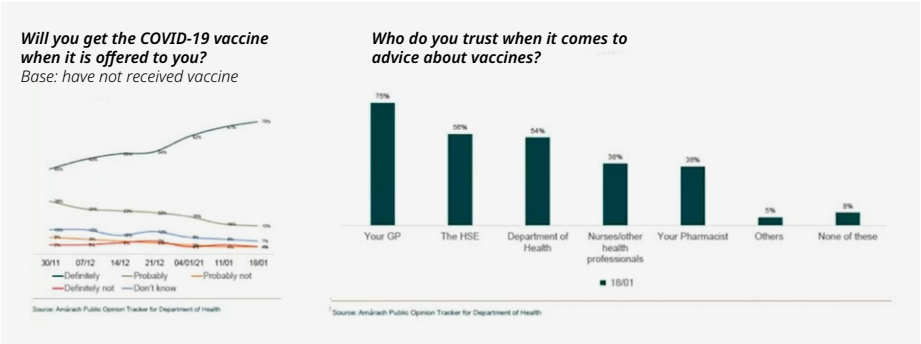
Right from the start of the vaccination programme in Ireland, it was considered important to reassure people that the vaccines had been thoroughly assessed through clinical trials, and the typical side-effects that could be expected. Also that a firm governance and monitoring system was set up. The language used had to be very clear and transparent when communicating with people outside the regulatory system.

Clear communication was also essential on the need for safety monitoring post-approval. This enabled any new or changing risk to be identified as quickly as possible, and appropriate action taken. In addition, a Risk Management Plan was specifically approved for each vaccine by the European Medicines Agency and was continually updated as moreinformation became available

Also very important was setting out the context for suspected side-effects. This included the active encouragement of reporting, including the reporting of events with only a suspicion of association, or that are mild/common, in order to carefully evaluate them all. At the same time it was necessary to communicate that reporting a suspected side-effect does not mean it was caused by the vaccine.

To support the vaccine campaign, the regulator (Health Products Regulatory Authority, HPRA) provided regular briefings to the national public health emergency team and often joined them for their public broadcasts. Efforts were made to be fully transparent through the public publishing of regular updates on the safety monitoring experience in Ireland and also the wider European experience. This also took place via the HPRA and EMA websites.

The Irish government carried out regular public surveys among around 2000 adults to show, for example, people's acceptability of receiving a vaccine, and who people trust the most for advice about vaccines.



"Frequent and consistent communication is key, through regulatory and safety updates that contextualise risk. With the support of vaccine campaign stakeholders, collaboration with regulators and public health bodies, and a responsible media, Ireland's national reporting experience supports the favourable assessment that the benefits of COVID-19 vaccines outweigh any risks."

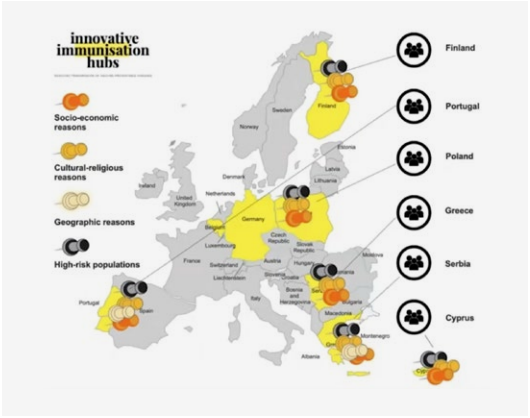
To date, 13 HPRA safety updates have been published. They have been able to reassure people that the majority of reported side-effects are consistent with those expected, and are mild to moderate in nature. The rapid and efficient handling of the very rare occurrences of thrombosis with low platelets helped to keep the vaccination campaign on track despite a temporary pause.

↘ ImmuHubs: Improving access to vaccination in disadvantaged and difficult to reach populations

BARBARA RATH, VIENNA VACCINE SAFETY INITIATIVE, GERMANY

The ImmuHubs Project aims to reduce transmission of vaccine-preventable diseases through an increased vaccination rate among disadvantaged, isolated, and difficult to reach population groups. It aims to do this by establishing proactive partnerships with a variety of stakeholders; creating innovative immunisation actions; and developing sustainable solutions for vaccine protection of EU citizens.

Its central focus is on access to vaccines rather than vaccine hesitancy. The project is therefore looking at increasing vaccination rates among individuals who are excluded from mainstream medicine for social reasons; people who do not normally access vaccine information from licensed paediatricians; and people who visit clinics for homeless and other vulnerable people. Two other European projects are focusing on prison populations and recent migrants, so ImmuHubs is not prioritising these groups.



ImmuHubs works through six complementary work packages which allow for lean management and a clear focus on innovative immunisation actions. It is taking advantage of some very good tools that already exist to help find solutions to these unsupported groups, such as the Scarcity Induced Innovation Framework. The project is also very closely connected to the key European missions and action points identified during the 2019 Global Vaccination Summit organised jointly by the WHO and the European Commission.

The project has set itself some challenging targets:

- 10% increase in the uptake of childhood and life-course vaccines
- >75% accuracy in awareness of the immunisation status
- 80% accurate understanding of vaccination needs specific to the population group
- 20% increase in planned consultations with health mediators or professionals
- 20% increase in inter-generational vaccine communication in the household/family unit.

The technical platform is using four scientifically developed, validated and published mobile app approaches and combines them in different ways. These are the VAccApp, VIVI HealthSurvey, VIVI ScoreApp, and OmaOlo.

ImmuHubs is funded by the European Union's Health Programme (2014-2020). It has a simple organisational structure including a large stakeholder forum and advisory board.

"ImmuHubs is focusing on increasing vaccination rates among people who are disadvantaged or socially excluded due to economic, social, educational, ethnic or health reasons."

Global health perspectives on acute respiratory virus disease and how to ensure equitable access

MONDAY 6 DECEMBER 18:00 - 19:45 CET

CHAIR:

ANN MOEN
CENTERS FOR DISEASE CONTROL, UNITED STATES

Opening keynote lecture

KWABENA FRIMPONG-BOATENG,
GHANA'S PRESIDENTIAL COMMITTEE ON VACCINE DEVELOPMENT AND PRODUCTION

Ghana does not produce its own vaccines so is vulnerable to vaccine supply issues. However, various factors are changing the vaccine landscape in Ghana. These include a strong political commitment fuelled by lessons from the COVID-19 pandemic; a favourable Intellectual Property regime; new initiatives for vaccine manufacturing in Africa; a well-functioning WHO-recognised regulatory approach; a growing pharmaceutical industry; and a vibrant domestic research and scientific community. These have combined to motivate Ghana to develop its domestic capacity to produce vaccines.

A framework for action with key milestones has been agreed, in order to achieve a sustainable vaccine manufacturing industry on the continent. The goal set by the African CDC is that by 2040, African countries should be producing at least 60% of the vaccines used in Africa. Currently it is 1%.

A regional vaccine taskforce was established in October 2020 to explore opportunities for access to COVID-19 vaccines and their local production in the ECOWAS region. Consequently, Ghana is establishing a permanent National Vaccine Institute to coordinate vaccine research, development and manufacture to achieve vaccine self-sufficiency. The Ghana government has allocated USD 25 million to provide seed funding for this institute in its 2021-2022 national budget.

The roadmap put forward by Ghana is ambitious. In the short-term (within two years), the goal is to establish at least one domestic vaccine production plant for COVID-19 and other vaccines that meet WHO GMP. In addition, Ghana hopes to develop its R&D and HR capacity, conclude at least two financial partnerships and implement at least one tech transfer partnership. In five years' time this number needs to have grown to at least three such plants. In the long term (ten years), the goal is to produce vaccines domestically within the country. By then it is anticipated that Ghana's FDA will be in a position to regulate vaccine production from R&D to the final products.

> *"Ghana needs to be capable of producing vaccine candidates for new outbreaks of pandemics and epidemics, to attain a self-sustaining ecosystem for vaccine manufacture."*

FACULTY LECTURES on Equitable Access to COVID-19 vaccines

Asia-Pacific Alliance for the Control of Influenza (APACI)

MARY-LOUISE MCLAWS, PROFESSOR OF EPIDEMIOLOGY, HEALTHCARE INFECTION AND INFECTIOUS DISEASES CONTROL, UNIVERSITY OF NEW SOUTH WALES, SYDNEY, AUSTRALIA

In terms of the COVID-19 vaccine rollout, while Europe has currently achieved 87% full vaccination, in South-East Asia vaccine coverage is much less, at 60%, while in the Western Pacific region it is as low as 20%. Such vaccine inequity undermines local, regional and global safety, particularly with the rapid dominance of the Delta variant which is 60% more infectious than Alpha. Moreover, the newly identified Omicron variant has the potential to rapidly spread and become the more dominant variant. Those countries with a low vaccination rate may be more at risk for a potentially more infectious disease.

Vaccination is important because it reduces the likelihood of mutations, which means that vaccine equity is needed, rapidly. Vaccines plus mitigation strategies should be continued, in order to minimise viral transmission until maximum vaccine coverage is reached in the South-East Asia and Western Pacific regions. The WHO aims to achieve 40% vaccine coverage of these regions by end 2021, and 70% by mid-2022. For some countries this is unlikely unless the high-income countries start to provide more vaccine doses.

> *"The key question is how do we get the vaccine to the low- and middle-income countries of these regions to protect our global citizens and limit the potential of mutations."*

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)

BEVERLY TAYLOR

IFPMA, among others, is calling on manufacturers, governments, and NGOs to take immediate action to urgently advance COVID-19 vaccine equity and has come up with five necessary steps to do this. These are: accelerate dose sharing; continue to optimise production; call for the elimination of trade barriers; support country readiness; and drive further innovation with urgency.

In addition, IFPMA has outlined two ambitious projects to strengthen and improve pandemic preparedness. The first is to aim to develop safe pandemic products within 100 days of the declaration of a pandemic. The second is to collaborate with governments and multilateral organisations, other companies and sectors, to ensure equitable access to pandemic products worldwide. The key elements to achieve this goal are to improve global surveillance capabilities; strengthen health systems planning & delivery; sustain manufacturing capacity; and ensure effective pandemic procurement.

The establishment of COVAX was a big step forward towards effective pandemic procurement and equitable access for low-income countries.

> *"The high-income countries had earlier access to vaccines, not because of their ability to produce them, but because they had the financial capacity to procure them in high volumes, and they had the infrastructure to implement vaccine programmes."*

African Union Commission on COVID-19

LWAZI MANZI

The AU Commission has a twofold mandate, to identify gaps and opportunities in the current AU COVID-19 response strategy and to strengthen a future strategy and Africa's economic recovery post-COVID.

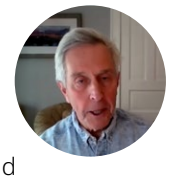
The AU Commission has been very much involved in the WHO process trying to get a consensus – which has now been agreed – to establish an inter-governmental negotiating body towards a convention or agreement on pandemic prevention and preparedness. The AU Commission has been instrumentally involved in developing the language around inclusivity, equity, accountability and transparency. As delegates enter these negotiations it is essential to have frank and open discussions, and to recognise that recent events with Omicron have illustrated that there is a price to pay for displaying these well-intentioned and important characteristics.

The Commission has co-hosted or been heavily involved in some recent important meetings on the topic of preparedness. These include the Stakeholder Consultation on the Healthcare Workforce; the Partnership on Africa Vaccine Manufacturing; a conference on Gender Equality and Health; and the upcoming conference for Public Health in Africa.

When it comes to equitable access, Africa has had to learn some hard lessons. The continent has a vaccination coverage of only around 7% to date. It is therefore vital that a plan is prepared to equitably distribute vaccines rather than have distribution be dictated purely by market dynamics.

> *"The next pandemic should not find us scrambling around because we have been bitten by the socio-economic fallout or by new variants or because we are unable to access medical countermeasures."*

The Rockefeller Foundation



BRUCE GELLIN

The bridge between science and policy is critical to this discussion. One of the current challenges facing vaccine equity is that as the supply of vaccines has been distributed around the world, relatively little has gone through COVAX. One reason is that the initial procurements and the bilateral deals that were made have meant that achieving vaccine equity has been difficult.

Transparency is key. A lot of promises have been made, but it is essential to look at these commitments and see how far they have come and how they can be moved forward.

Looking at the aspirational goal of 70% global vaccination, the longer it takes to get there, the more these viruses will mutate. Moreover, it's important to strengthen the global early warning system.

In the context of national equity, data systems that allow the sharing of information are important. Trust is also key, so that the information that is shared is then used for the purpose intended.

> *"We have to recognise that while there may have been equity in the planning, there was no equity in the execution. Unless equity is front and centre in execution, we are never going to reach our targets."*

Gavi (formerly the Global Alliance for Vaccines and Immunisation)

MARTA TUFET

COVAX is a robust partnership between CEPI, Gavi, UNICEF and the WHO. It is the primary source of COVID-19 vaccines for low-income countries, and an important source for low/middle-income countries. It has signed agreements with 11 vaccine candidates.

However, COVAX has faced substantial supply barriers, such as a lack of financial capacity from LMICs to procure, and export bans from vaccine producing countries that have prioritised domestic vaccination. Despite the challenges, COVAX has still ensured that 94% of its participants received first shipments, resulting in around 37% vaccine coverage with at least one vaccine dose. But this is still short of the target to deliver 915 million doses by end-2021.

The key challenges to achieving vaccine equity include equity of supply access, equity of delivery capability, and intra-country equity. The latter includes the difficulty of vaccinating people in conflict settings or those who can not be reached by government vaccination campaigns. The global COVAX Humanitarian Buffer was designed for this purpose as a last resort equity mechanism to ensure access for the most vulnerable.

> *"The basic principles of equity needs to be an integral part of any vaccination strategy if we are to achieve that global of leaving no one behind when it comes to immunisation. COVAX calls upon the world and its partners to help deliver on its goals."*

Discussion

ANN MOEN: What one thing would you do, change, or implement to improve vaccine equity?

BEVERLY TAYLOR: Focus on vaccine procurement and delivery, and tackle vaccine hesitancy.

LWAZI MANZI: Develop an aggressive policy to prevent delivery schedules being stopped. And put mechanisms in place in countries that enable them to deliver the vaccines to people's arms.

BRUCE GELLIN: Continue to focus on equity issues, as the supply will never be able to meet the demand in a pandemic, and so this issue will recur. And acknowledge that the political element of vaccine nationalism is not going to stop either.

MARTA TUFET: Get behind COVAX, not just in principle but in practice. And move away from vaccine nationalism that has led to supply & delivery issues.

↘ FACULTY LECTURES: INFLUENZA IMMUNISATION ACCESS BARRIERS

Ready2Respond

MARIE MAZUR

Ready2Respond was launched in 2020 with the mission to ensure global readiness for the next pandemic through transformative change in vaccine access and immunisation policy in low-income countries. Its initial work plan focuses on burden of disease, risk communication, community engagement, and vaccine access. The organisation believes that innovation and vaccine access are two sides of the same coin, and has identified a systemic lack of data on the burden of disease as the biggest barrier on the critical path. There is also a lack of communication and a lack of a systemic approach to policy-shaping.

> *"Pandemic preparedness continues to be under-resourced and under-planned."*

ANN MOEN: How does Ready2Respond aim to break down the barriers?

MARIE MAZUR: We are bringing together partners from the public, non-profit and private sectors to design solutions to address the gaps and challenges we have identified. For example, we are developing a long-range vaccine forecasting tool that will allow public health managers and country vaccine health managers to predict and project the demand for vaccines five years ahead.

Partnership for Influenza Vaccine Introduction (PIVI)

JOE BRESEE

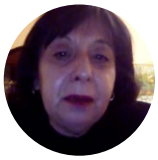
Every year, hundreds of thousands of deaths occur, and millions of cases occur, due to influenza. Most of these are among people who live in low-income countries. PIVI was established to create a mechanism to support the expansion of influenza vaccination programmes into these countries. Vaccination works both as a disease reduction tool (and therefore a cost reduction tool) and a pandemic preparedness tool. PIVI works in 18 countries, three of which have transitioned to full, self-sustaining programmes, and others will be doing so in the next few years. This shows that the way that PIVI works, as a partnership between ministries, technical partners and funders, can and does work notably by creating an enabling, policy framework for vaccine programmes.

> *"Only 6% of all vaccines made globally are sent to low/middle-income countries. There is a real mismatch between the value of the influenza vaccine and access to the vaccine."*

ANN MOEN: How is PIVI lowering the barriers in practice?

JOE BRESEE: PIVI works at the national level but also functions as a source of information and best practices to support regional collaboration. We define the economic and feasibility barriers towards global vaccination, and then strive to solve these barriers by collecting and disseminating best practices in vaccine planning, implementation and evaluation.

MOH-CDC Albania



SILVIA BINO

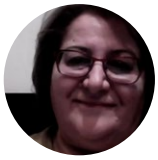
Increasing the influenza vaccination rate in Albania has gone alongside growing the evidence base, surveillance, and diagnostic capacity in the country. It started with a 1000-dose influenza vaccination programme for healthcare workers seven years ago. It then expanded to other groups such as the over-65s, those with chronic diseases, pregnant women, and children. More planning and resources were essential, in partnership with different professional and patient organisations. The impact of the programme was also documented through monitoring and evaluation.

> *"Even with the expansion of the influenza vaccination programme we still can't meet demand."*

ANN MOEN: How has COVID-19 vaccination impacted Armenia's influenza programme?

SILVIA BINO: COVID-19 vaccination did not negatively impact our influenza vaccination programme. On the contrary, we have seen an increase in demand for influenza vaccination and an increase in execution. It has also increased our knowledge of respiratory diseases.

MOH Armenia



GAYANE SAHAKYAN

Armenia joined PIVI in 2014 and the country then received 60,000 doses of influenza vaccine. Since then, PIVI has helped Armenia in the planning process, and has supported the development of evidence-based policy. PIVI has helped Armenia with training, and in the development of an influenza research package which includes a systemic literature review based on disease burden and epidemiology. The data collected were then used for the country's communication plans, educational campaigns, and capacity building.

> *"PIVI has played a pivotal role in Armenia, strengthening influenza vaccine access and providing technical support."*

ANN MOEN: How has PIVI helped Armenia prepare for a future pandemic?

GAYANE SAHAKYAN: Through the early development of in-country interventions and testing. And through simulation exercises with specific roles and responsibilities for polio, measles, and other pandemic situations.

ANN MOEN: How can Ready2Respond and PIVI improve equitable access to COVID-19 vaccines?

MARIE MAZUR: The inter-pandemic period is really the time to focus on preparing and planning for the next pandemic. Key components are the availability of epidemiological data at a country level, and the ability to demonstrate the value of vaccination.

JOE BRESEE: There is a tendency to think that the equity problem is going to be solved by the next great technology. In part it will. But the other part is vaccination implementation, the demand, and the tools that countries have available to deliver vaccination. These take as long to develop as vaccines. The two initiatives go in parallel.

ANN MOEN: Will the COVID-19 pandemic help Albania develop a regional procurement pool?

SILVIA BINO: Yes, because the political support is much higher and there is more interest in building partnerships. Albania is small, but together with other countries in the Balkan area we are stronger.

ANN MOEN: What's next for Ready2Respond?

MARIE MAZUR: Equity is about supply and demand. The countries have the responsibility to tell us about the demand they have. The stories we have heard from Albania and Armenia demonstrate through real-world evidence that influenza vaccination programmes really help COVID-19 vaccination deployment. At the same time we are learning a lot from COVID-19 that will help us improve our influenza vaccination programme. It's a virtuous circle we are creating in the midst of a crisis, with benefits for global health.

Closing remarks

ANN MOEN

Globally we are striving for equity but we are not there yet, especially when it comes to implementation, country readiness, and execution. Programmes like Ready2Respond and PIVI working from the bottom-up can meet those groups working at the regional and global level global that are trying to bring more equitable access. We have a long way to go, but there is considerable global will to build-in more equity and strive to achieve this across all countries and income levels.

Pandemic Preparedness Planning in Peacetime

TUESDAY 7 DECEMBER 12:00 - 13:45 CET

CHAIR:

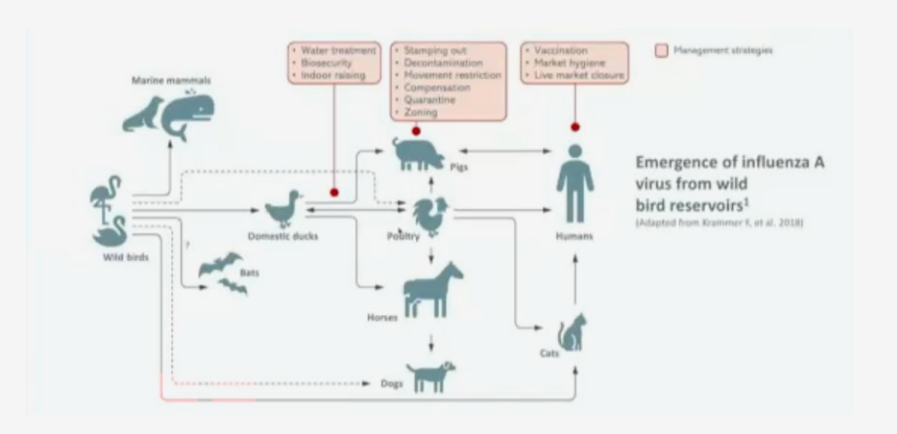
AB OSTERHAUS
TIHO, HANNOVER, GERMANY

↘ Advancing pandemic and seasonal outbreak preparedness

AB OSTERHAUS, TIHO, HANNOVER, GERMANY

An enormous reservoir of viruses exists in the animal world, especially in bats, rodents and birds. The last four influenza pandemics as well as recent SARS and MERS outbreaks and of course the COVID-19 pandemic are a reminder that unknown pathogens can emerge from wildlife anytime and anywhere. There is thus a clear need for better alert and response systems. Global cooperation and participation to intervene are crucial, although the lack of hospital capacity in case of a severe pandemic is not covered in a pandemic preparedness plan.

All these viruses come from the animal world, starting from migratory birds and spreading to bats, domestic birds, poultry, farm animals, domestic animals and eventually humans.



"Once a virus crosses the barrier from birds to humans, we are only a limited number of mutations away from yet another pandemic. Prediction and preparedness is key."

Moreover, once a virus crosses the barrier from birds to humans, only a small number of mutations are necessary for the virus to become transmissible. As animals are at the basis of viral threats, a OneHealth approach is vital, looking at agricultural production and trade systems of poultry and pigs; migratory patterns of wild birds; socio-economic factors; human behaviour; optimised virus detection and characterisation; and genetic data accessibility in the public domain.

For pandemic preparedness, it is vital that a number of crucial elements are put in place in "peacetime". These include early warning systems; pathogen discovery and characterisation platforms; diagnostic platforms; mathematical models; and animal models in BSL3 facilities. Furthermore, clinical trial platforms have to be established, alongside non-pharmaceutical intervention and treatment strategies. Pharmaceutical intervention strategies include antiviral platforms, vaccine platforms, and biological response modifiers. It is also necessary to broaden these two groups of viruses and to make these investments during "peacetime". Finally, clear communication at all points is essential, between scientists, policymakers and the general public.

Interestingly, looking at COVID-19, the virus came originally from bats and was transmitted to humans. But in between are a lot of different animal species. For example, about 4% of domestic cats in Europe are infected with the virus. It also infected mink farms, where new mutations were identified.

The National Academy of Medicine (NAM) Influenza Initiative: Key findings

VICTOR DZAU, PRESIDENT OF THE INSTITUTE OF MEDICINE, USA

Seasonal and pandemic influenza remain an imminent global health threat. An estimated one billion people worldwide are infected by seasonal influenza every year, resulting in as many as 650,000 deaths.

Influenza pandemics have occurred repeatedly throughout recorded history, devastating economies and healthcare systems. A moderate to severe influenza pandemic today would likely cost the global economy trillions of dollars.

However, influenza vaccine preparedness is consistently met with complacency and is deprioritized on health agendas and annual budgets. COVID-19 has illustrated the importance of global preparedness and response, and the world must start implementing lessons learned immediately.

"We are not adequately prepared for a novel pandemic influenza strain, and we must be. COVID-19 has emphasised that preparedness has to be an ongoing commitment."

Importantly, COVID-19 has enabled the emergence of new capabilities, technologies, collaborations and policies that could also be deployed before and during the next influenza pandemic.

In July 2020, an important partnership began to advance future influenza pandemic preparedness efforts. Given the global nature of this issue, the work is international and complementary to the WHO's influenza efforts.

The National Academy of Medicine (NAM) is establishing an International Committee (IT) to discuss emerging evidence related to vaccine R&D; distribution & supply chain; public health interventions & countermeasures; and coordination, partnerships & sustainable financing for influenza preparedness and response. The IT has already published four key Consensus Reports:

- Countering the pandemic threat through global coordination on vaccines: The influenza imperative
- Vaccine R&D to advance pandemic and seasonal influenza preparedness and response: Lessons from COVID-19
- Public health lessons for non-vaccine influenza interventions: Looking past COVID-19
- Globally resilient supply chains for seasonal and pandemic influenza vaccines.

Key findings and recommendations in each of these areas have been released, along with potential next steps. These include an implementation-focused roundtable series with key national and multilateral actors and global health stakeholders; a public symposium to summarise the initiative and next steps; expert-authored opinion pieces; a series of communication impact pieces; and a possible follow-up consensus study on improving response to influenza variants during a pandemic.

↘ Public Health Lessons for Non-Vaccine Influenza Interventions: Looking past COVID-19

PATRICIA J. GARCIA, SCHOOL OF PUBLIC HEALTH, CAYETANO HEREDIA UNIVERSITY, LIMA-PERU

The NAM IT Committee on Public health lessons for non-vaccine influenza interventions had key findings in five areas that the committee was tasked with, namely: analyse the effectiveness of key non-vaccine measures for pandemic and seasonal influenza; explore the social and political context; review promising COVID-19 therapeutic approaches applicable to influenza; highlight innovations around the world; and analyse prominent research and identify knowledge gaps.

The committee also considered the reality of the multi-scale, multi-step emergence of pandemic emergencies from the pre-emergence spillover of viruses into humans; the localised emergence of outbreaks; and eventually to the global emergence of the pandemic.

The findings in each area were described in detail. Following are the key findings and conclusions.

Regarding **event preparedness**, this should include investments to expand holistic strategies, such as the OneHealth approach. It should build surveillance capacity, improve the accuracy of data collection through defining critical data elements, and develop and maintain data integration platforms to ensure the timely detection of zoonotic pathogen strains with pandemic potential and large antigenic drifts and shifts.

> *"We hope that at a country and global level that these recommendations will be taken to heart so that we can really better prepare for the next pandemic to come."*

Preparedness efforts should consider the capacities to research, produce and stockpile therapeutic drugs for respiratory viruses, including any supplies needed for their delivery.

Methods for data collection, monitoring and adjustments for response plans should be included in preparedness efforts.

Preparedness efforts should include research into non-therapeutic mitigation strategies and supplies.

Regarding **response**, when sociocultural, economic, and other contextual factors are taken into account, non-vaccine control measures offer an effective means of responding to future season and pandemic influenza events. To minimise the harm to lives and livelihoods, these measures should be deployed simultaneously in a layered fashion. They should be accompanied by rigorous data collection, monitoring, and adjustments to the combination of measures in light of the evidence accumulated.

For non-vaccine control measures to be effective, people must be able and willing to use them. This means that necessary resources and support need to be distributed equitably. In addition, the value that they provide to individuals and the public needs to be clearly communicated.

A critical part of responding to a pandemic is conducting adaptive platform trials and rigorous research of therapeutics.

↘ Supply chain implications for influenza pandemic preparedness and lessons learned from COVID-19

ETLEVA KADILLI, UNICEF, DENMARK

With COVID-19, the world is seeing a two-track pandemic where low-income countries are left behind with lack of access to proper medical countermeasures including vaccines, leaving behind high-risk unvaccinated populations in the most vulnerable places across the world. Hence, we all need to work together across the globe, including national and international actors, to put the groundwork in place today. We need to leverage the investments made for COVID-19 and ensure that they are sustainable and leave us better prepared for what may come tomorrow. This is not an issue of "if", but "when".

UNICEF along with global actors need to work together to ensure there are:

- Well-funded and validated global preparedness plans that include improved global vaccine infrastructure covering manufacturing, distribution, and uptake.
- Financing architecture that can support not just the science and R&D but also manufacturing scale-up.
- Simultaneously, improve basic infection prevention and control measures such as handwashing and mask wearing that are tried and tested and which are complementary to other interventions.

The NAM Supply Chain and Distribution Committee has produced key findings and recommendations highlighting how to foster a well-coordinated approach to ensure the availability of a vaccine that is ready and globally accessible to respond to a global influenza pandemic. The committee has also identified the key global actors that can take this approach forward and support the recommendations to have a globally coordinated structure for access to pandemic influenza vaccines and ancillary products.

Some of the key findings are briefly discussed below.

One of the key findings from the study is the optimization for vaccine design for distribution and delivery. The diversity of the health supply system needs to be considered when designing and developing vaccines to ensure physical distribution and delivery in various global contexts. For example, mRNA vaccines require a complex cold chain and specific syringes. These factors merely increase complexity for distribution and scaling, as well as cost, particularly for low-income countries. Any new vaccine must be globally fit-for-purpose. Innovation is key so we should be looking at novel vaccine delivery mechanisms such as patches and nasal sprays which may be more fit-for-purpose and more scalable.

Traceability is another key element to avoid counterfeiting of products. This has to be integrated into the packaging and labelling from the outset. It will also help to build trust with the public. We also need to better understand the uptake challenges and optimise supply chain logistics, both upstream and downstream leading to a stronger and more resilient healthcare system and supply chain. Human capital needs to be seen as the backbone of everything, so investment in training is paramount to any emergency or pandemic response. This should be a continual global focus.

"An infrastructure for preparedness at scale is particularly vital for low/middle income countries which have less purchasing power and weaker supply chains. This is critical for the equitable distribution and access of vaccines."

The challenges regarding access to raw materials and equipment need to be addressed, as do export bans. This is a major barrier to scale. We all agree that from a supply chain and logistics side, it is much healthier to have a geographically diversified global vaccine portfolio and expand production around the world.

Vaccines are the most cost-effective public health interventions. However, they are not a silver bullet that alone will resolve the COVID-19 pandemic or a future pandemic. We must equally consider preparedness for all other tools including diagnostics, therapeutics, protective equipment, sanitation and hand hygiene, as well as access to clean water. And we need to tackle misinformation so that we build public confidence. The overall system-strengthening approach is a must to help us build better for the future.

↘ Panel discussion

AB OSTERHAUS: How can we do better in the future for non-pharmaceutical interventions, such as streamlining the use of face masks?

PATRICIA GARCIA: At the start of the pandemic we didn't have the evidence to support the use of face masks, but now we do. The evidence is very strong, from a variety of sources – even randomised trials – that face masks are effective. In countries with mask mandates, clear reductions in infections and deaths have been observed. It's now important to translate these findings into clear communication that people can understand and put into practice. At the same time we have to understand people's concerns and address them.

ETLEVA KADILLI: Initially there was a lack of access to masks so that prioritisation had to be given to healthcare workers. Better future preparedness is essential to avoid that scenario from happening again.

AB OSTERHAUS: What's your view on COVAX? Why hasn't it been as successful as first hoped?

ETLEVA KADILLI: COVAX has already distributed around 600 million doses around the world, which is not a small amount. But it has faced disappointments, mainly related to the challenges around lack of access, the lack of a fair equity agenda, and prioritisation of domestic needs by certain countries. Until we have a globally harmonised approach in which vaccines are equitably distributed then COVAX will continue to face challenges.

PATRICIA GARCIA: COVAX was created on the idea of global solidarity. What has been clearly shown is that during a pandemic, solidarity is largely forgotten. Equitable access needs to be discussed and agreed during peacetime, with treaties and agreements. At the same time we need to create capacities in low/middle-income countries to produce and manufacture not only vaccines but also diagnostics, PPE, supplies etc. At the minimum, regional hubs are necessary.

AB OSTERHAUS: What can be done to improve the reporting of novel virus outbreaks? Currently there is a degree of confusion over who should report and to whom.

PATRICIA GARCIA: One recommendation is to create a much better system that jumps over the related political issues and the potential economic damages that could arise once a virus outbreak is reported – resulting from the closure of borders, for example. Disincentives to reporting have to be removed, and replaced with incentives such as an insurance system. This would mean that a country or region reporting a virus outbreak is assured of receiving financial support. This should be from the global community because the world benefits from fast reporting.

AB OSTERHAUS: The NAM report is very valuable, but we now have to give it hands and feet to make sure the recommendations are implemented. Significant financial investments are now needed to put the recommendations into practice.

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