Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Editorial

COVID-19 vaccines under the International Health Regulations – We must use the WHO International Certificate of Vaccination or Prophylaxis

The first vaccines against SARS-CoV-2 have now received emergency use authorization by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and national authorities in China, India, UK, and Russia; and are rapidly being distributed in more than 30 countries since the end of the 2020. So far vaccines are being used by the respective countries after national approval based on promising efficacy reports and safety data, however, data on some of these vaccines have not yet been published in international peer-reviewed journals. The World Health Organization (WHO) has a role in "pre-qualifying" COVID vaccines, but WHO pre-qualification may not be necessary to record the use of immunization or prophylaxis in WHO International Certificate of Vaccination or Prophylaxis (ICVP, aka Carte Jaune or Yellow Card) as this has not been the case with other vaccines which may not be WHO prequalified. Every dose of any COVID vaccine should be entered in the WHO Yellow Card.

The COVID-19 vaccines will change the national control efforts as they become available over the coming months either offered free of charge through government-sponsored, free immunization programs or delivered through private clinics. It will also change the travel trends whether for work or leisure.

At present, the spread of COVID-19 through international travel is an immense concern and different control efforts vary among different countries. Pre-and post- travel control measures have recently been reviewed and will not be discussed here (Chen & Steffen: In press; Bielecki et al., 2020). These include mandatory testing by RT-PCR pre-arrival, testing on arrival using predominantly RT-PCR or less accepted rapid, antigen-detection assays followed by quarantine until the results are obtained, mandatory health insurance covering hospitalisation for COVID-19 in the country of arrival, quarantine without testing if arriving from countries defined by national authorities as high risk countries.

Can the vaccines open international travel?

Cross border control of infectious diseases through international travel is regulated by the International Health Regulations (WHO, 2005), an international convention mandated under the World Health Organisation (WHO, 2005). The aim of the IHR is to "prevent, protect against, control and provide a public health response to the international spread of disease, while avoiding unnecessary interference with international traffic and trade" (WHO, 2005). Historically, smallpox vaccination immunization requirements were recorded under the IHR and this contributed to the successful eradication of smallpox (Fenner et al., 1988). The issue has recently been discussed in a comment by von Tigerstrom et al. (2020).

The best-known example of successful use of the IHR is vaccination against yellow fever (YF) which is mandatory for travellers to YF endemic countries and non-endemic countries with a potential for introducing YF virus (Reno et al., 2020). The IHR allows for the addition of other vaccines (article 36 and Annex 6).

Under the IHR, travellers are requested to provide documentation in the WHO Yellow Card, of proof of YF immunisation (IHR Annex 7), by a stamp and the signature of the person authorised by the national authorities to give the vaccine. The yellow fever vaccine is not 100% and the disease is a lot more deadly than COVID-19 yet we accept the IHR certification.

SARS-CoV-2 vaccines could easily be included in the WHO immunisation certificate

We propose that persons who have completed a full course of immunisation with an approved SARS-CoV-2 vaccine by an authorised provider should be allowed to travel freely for a specified period of time after completion of the last dose of immunisation.

For instance, the YF vaccination is considered protective 10 days after the injection and as of 2016 is valid for the life of the traveller (WHO, 2021). The time frame when protective immunity is present will be known for SARS-CoV-2 vaccines from follow-up of the Phase III trials and other studies. The duration of protection is not yet known, but starting with a six month period seems prudent and is expected to be longer as post-vaccination follow-up data become available.

In the UK the authorities issue an immunisation app documenting immunisation against COVID-19 (BMJ, 2021) and the Danish authorities provide immunised persons with a certificate in Danish and English on-line which can be printed (Reuters, 2021a, 2021b). We recommend that airlines and national authorities in other countries accept these documents, electronic or paper, as proof of vaccination. The International Civil Aviation Organisation (ICAO) has indicated they will accept proof of SARS-CoV-2 immunisation in the WHO yellow card. In this digital age an

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electronic “Yellow Card” is an obvious solution but so far no WHO-endorsed platform is available.

The decision to include approved SARS–CoV-2 vaccines for travellers under the IHR will need to be proposed and adopted at the World Health Assembly (WHA) with upcoming meeting in May 2021. There are however a number of questions that will need to be addressed before the IHR will expand to cover SARS-CoV-2 vaccines. These includes exploring the effect of vaccination on transmission, efficacy and safety in different populations and age groups and co-morbidities and duration of immunity. These questions did not prevent the smallpox or the yellow fever documentation regimens in the WHO Yellow Card.

In the statement issued at the sixth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic the 15th January 2021, advice on health measures in relation to international traffic was made that “

“. . . . . at the present time, do not introduce requirements of proof of vaccination or immunity for international travel as a condition of entry as there are still critical unknowns regarding the efficacy of vaccination in reducing transmission and limited availability of vaccines; that proof of vaccination should not exempt international travellers from complying with other travel risk reduction measures; and. . . to implement coordinated, time-limited, risk-based, and evidence-based approaches for health measures in relation to international traffic in line with WHO guidance and IHR provisions (WHO, 2021).

Immunity after natural infection?

Documenting immunity after a natural infection is an issue. There are FDA and EMA approved serological assays detecting SARS-CoV-2 specific IgG-antibodies. The sensitivity and specificity of these tests vary and their reliability for confirming immunity from reinfection is unknown especially with the appearance of new lineages of SARS COV-2. The absence of a positive serological test conversely may not exclude some protection. So called ‘immunity passports’ based on positive serology need further study. Approaches using T-cells are much harder to standardize. Whether these tests can be used to support ‘safe travel’ and documentation in the yellow card under IHR remains a question that urgently needs to be studied.

In conclusion, standardized documentation of vaccination of travellers against SARS-COV -2 should be considered under the IHR. A number of questions will need to be answered in order to enable adoption by IHR. It is recommended when people are immunized against SARS-COV-2, they bring their WHO Yellow Card with them and ask the provider to enter the vaccine name and batch, date, sign and stamp. If a person does not have a WHO Yellow Card, she/he should obtain a proof of vaccination card with this important information. Immunisation certificates issued by national authorities using approved vaccines should be accepted as proof of immunity by airlines and national authorities.

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Eskild Petersen[a,b,c,*]
[a]European Society for Clinical Microbiology and Infectious Diseases, ESCMID, Basel, Switzerland

[b]Institute for Clinical Medicine, Faculty of Health Science, University of Aarhus, Denmark

[c]International Society for Infectious Diseases, ISID, Boston, USA

Daniel Lucey[a,b]
[a]Department of Medicine and Infectious Disease, Georgetown University Medstar Hospital, Washington DC, USA

[b]Infectious Disease Society of America, IDSA, Arlington, USA

Lucille Blumberg
National Institute for Communicable Diseases of the National Health Laboratory Service and University of Pretoria, South Africa

Laura D. Kramer[a,b,c]
[a]New York State Department of Health, The Arbovirus Laboratory, Wadsworth Center, Slingerlands, New York, USA

[b]Department of Biomedical Sciences, State University of New York at Albany School of Public Health, Albany, New York, USA

[c]International Society for Infectious Diseases, ISID, Boston, USA

Seif Al-Abri
Directorate General for Disease Surveillance and Control, Ministry of Health, Oman

Shui Shan Lee[a,b]
[a]JC School of Public Health and Primary Care, The Chinese University of Hong Kong, Hong Kong Special Administrative Region, China

[b]Stanley Ho Centre for Emerging Infectious Diseases, The Chinese University of Hong Kong, Hong Kong Special Administrative Region, China

Tatiana de Castro Abreu Pinto
Instituto de Microbiologia Paulo de Goes, Universidade Federal do Rio de Janeiro Rio de Janeiro, Brazil

Christina W. Obiero[a,b]
[a]Clinical Research Department, KEMRI-Wellcome Trust Research Programme, Kilifi, Kenya

[b]Department of Global Health, University of Amsterdam Faculty of Medicine, Amsterdam, Noord-Holland, The Netherlands

Alfonso J. Rodriguez-Morales[a,b]
[a]Public Health and Infection Research Group, Faculty of Health Sciences, Universidad Tecnologica de Pereira, Pereira, Colombia

[b]Grupo de Investigación Biomedicina, Faculty of Medicine, Fundación Universitaria Autónoma de las Americas, Pereira, Colombia

Richard Yapi
Centre d'Entomologie Médicale et Vétérinaire, CEMV – Université Alassane Ouattara, Bouaké, Côte d'Ivoire

Aisha Abubakar
Department of Community Medicine, Ahmadu Bello University Zaria, Nigeria

Paul Anantharajah Tambyah[a,b]
[a]International Society for Infectious Diseases, ISID, Boston, USA

[b]Department of Medicine and Infectious Diseases, Translational Research Program, National University of Singapore, Singapore

Allison Holmes[a,b,c]
[a]International Society for Infectious Diseases, ISID, Boston, USA

[b]National Institute for Health Research, Health Protection Research Unit in Healthcare Associated Infections and Antimicrobial Resistance, Imperial College London, London W12 0NN, UK

[c]Department of Infectious Diseases, Imperial College London, London SW7 2AZ, UK

Lin H. Chen[a,b,c]
[a]International Society of Travel Medicine, ISTM, Atlanta, USA

[b]Harvard Medical School, Boston, USA

[c]Travel Medicine Center, Division of Infectious Diseases and Travel Medicine, Mount Auburn Hospital, Cambridge, USA

* Corresponding author at: Institute for Clinical Medicine, University of Aarhus, Palle Juul-Jensens Boulevard 82, DK-8200 Aarhus N.
E-mail address: eskild.petersen@gmail.com (E. Petersen).