Medical Evidence re the Public Health Challenge

Dr David Powell
Vinoop Goel

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Where is the evidence now on:

- **Vaccination:**
  - Efficacy against fatal and severe disease is clear
  - Impact on asymptomatic disease and on transmission is emerging [Hall, Milman, Pritchard, Sadoff, Shah, Thompson]
  - Duration and strength of immunity (post-vaccine, post-recovery) not certain but promising
  - Some variants have important effects on some vaccine performance
  - [Rare side effects noted with Az but prob not elevated with other viral vector vax]

- **Impact of variants:**
  - Increased transmissibility but no change to required public health measures in general
  - Some evidence disease severity increased with some variants
  - Vaccine escape in some cases (as above)
  - Testing efficacy problems appear only to be with single target antigen tests

- **Therapeutics**
  - Not yet having sufficient impact on outcomes to change public health approach

Key question in CAPSCA:

How effective is vaccination in preventing SARS-CoV2 transmission?

Subsidiary question, different but related:

How effective is vaccination in preventing asymptomatic infection?

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Does vaccination reduce infection rates?

COVID-19 Aviation Scientific Assessment Group (CASAG)

Group Members

Mitch Fox (ICCAIA - Chair)

Diego Garcia (Embry-Riddle)

Ansa Jordaan (ICAO)

Clive Brown (US CDC)

Susan Northrup (FAA)

Chuck De John (FAA/AsMA)

Nels Olson (Boeing)

Ken Knight (Exxon Mobil)

Kris Belland (FAA/AsMA)

Paulo Alves (MedAire)

Michael Comber (IATA)

David Powell (IATA)

Search the literature

Including Google Scholar, PubMed, and Cochrane Library

Evaluate the literature

Modified version of "GRADE" methodology

Pre-prints accepted

Assess QUALITY and STRENGTH of evidence

Consensus on findings – with any caveats

24 peer-reviewed + 13 pre-print

Narrowed to 14 + 9 = 23 papers:

1 phase lll clinical trial,
2 case-control studies,
11 cohort studies,
4 correspondence,
2 narrative reviews, and
3 modelling studies.

Study	N	Relevant Outcome	Reference
Ad26.COV2.S Phase III Trial – Sadoff et al	19,630	Efficacy of at least 66% for preventing asymptomatic infection.	NEJM. April 21, 2021 DOI: 10.1056/NEJMoa2101544
BNT162b2. Israel cohort – Haas et al	111,518	Vaccine effectiveness 7 days after the second dose was 91·5% against asymptomatic infection.	Lancet. May 5, 2021 DOI: 10.1016/S0140-6736(21)00947-8
UK COVID Symptom Study App – Menni et al	627,383	Infection rates after a single vaccine dose decreased by 72% after 45–59 days following BNT162b2, and 60% at 21–44 days following ChAdOx1 nCoV-19.	Lancet. April 27,2021 DOI: 10.1016/S1473-3099(21)00224-3
Clalit Health Services cohort (Israel) – Dagan et al	596,618	Vaccine effectiveness for asymptomatic infection was 90%, 7 or more days after the second dose.	NEJM. April 15, 2021 DOI: 10.1056/NEJMoa2101765
UK's COVID-19 Infection Survey – Pritchard et al	373,402	Reduction in odds of new infection episodes with no self-reported symptoms was 49% post second dose	MedRxiv. April 23, 2021 DOI: 10.1101/2021.04.22.21255913
Long-term care facilities cohort (Spain) – Monge et al	299,209	Indirect protection in the non-vaccinated estimated for naïve individuals was 81.4%	MedRxiv. May 25, 2021 DOI: 10.1101/2021.04.08.21255135
Households of healthcare workers (Public Health England) – Shah et al	144,525	Household members of vaccinated healthcare workers had a lower risk of COVID-19 case compared to household members of unvaccinated healthcare worker (hazard ratio 0·70)	MedRxiv. Mar 21, 2021 DOI: https://doi.org/10.1101/2021.03.11.21253275
Patients screened prior to procedures (Mayo Clinic) – Tande et al	39,156	Compared to unvaccinated patients, the risk of asymptomatic SARS-CoV-2 infection was lower among those >10 days after 1st dose (RR=0.21) and >0 days after 2nd dose (RR=0.20)	Clinical Infectious Diseases, 10 Mar 2021, https://doi.org/10.1093/cid/ciab229

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Main findings

a) Several studies show that SARS-CoV-2 vaccination substantially reduces **asymptomatic infections** as well as symptomatic cases of COVID-19.

b) Some human studies show that **viral load is reduced** in fully vaccinated people who subsequently test positive for SARS-CoV-2.

c) Some human studies looking at defined populations including families of healthcare workers, care home residents, or workplaces, have demonstrated **reduced transmission by those few who have been vaccinated and subsequently become infected**.

d) Of the few infections which occur in vaccinated persons, most are likely to be asymptomatic. If there is a need to reliably detect those infections, symptoms will not be a reliable way to do so.

Main caveats/limitations

a) Many of the reports are from **pre-print** rather than peer-reviewed papers.
b) Many of the studies are necessarily **observational** in nature. However, a few controlled trials are also included.
c) **Not all vaccines** currently in use have been represented in the body of evidence. The greatest number of studies looked at Pfizer-BioNTech, Moderna and Astra-Zeneca vaccines. Further data may be required for others.
d) Further study is required regarding **mixed vaccine approaches** ("heterologous prime-boost"), where the second dose is different from the first) or **non-standard intervals** between vaccine doses.
e) Not all studies have taken into account currently **emerging variants**. Variants of Concern (VoC) will continue to appear and need to be considered in applying these conclusions.
f) The **duration of immunity** is currently unknown. Vaccine induced protection from COVID is well established at 2 weeks after the final dose and appears to last for at least 6 months thereafter. Further data may mean this time could be extended, or that booster doses may be required.
g) Finally, there are studies showing that vaccine effectiveness is likely reduced amongst those with **suppressed immune responses**.

Summary of CASAG findings

The numerous pre-print and peer-reviewed studies included in the CASAG review consistently indicated that **vaccination against COVID-19 substantially reduces mild/asymptomatic infections**, (as well as preventing most severe/fatal infections).

The evidence supports that **vaccination substantially reduces transmission of SARS-CoV-2**. This indicates that on a travel setting, fully vaccinated travellers might not be drivers of onward transmission of SARS-CoV-2.

Some **limitations** that should be considered include vaccine types, variant emergence, non-standard intervals/combinations, certain medical conditions, and possible decline in immunity over time.

Where is the evidence now on:

Reducing risk of importation by travelers - including testing

Risk-based approach to quarantine and testing

- Destination countries must decide the risk they can accept
- Then consider existing risk at either end of journey
- Quarantine (14 days) highly efficacious if supervised/managed – less so if self-monitored
- Such quarantine drastically reduces ability/wish of people to travel [IATA surveys and travel patterns]
- PCR testing pre-travel reduces risk during travel and to some extent importation risk [Johansson, Kiang]
- RAT efficacy in asymptomatic populations may not suit it well for on-off use in travellers
- Testing + shorter quarantine can match efficacy of long quarantine for high-risk travel [Johansson, Kiang]

Implementation also depends on:

- Facilitating contact tracing
- Trusted digital systems for certifying test results and/or vaccination/immunization
- Have emphasized to WHO their need to play a lead role in establishing standards

Where is the evidence now on:

- **Risk of transmission DURING travel is not the main concern:**
  - We believe it SHOULD be low based on nature of airflow and protections in place (PHC)
  - We believe it IS low, especially compared with other indoor environments, based on
    - Computational fluid dynamics study especially US TRANSCOM [Kinahan]
    - Reported cases and their analysis (half of reported 2^0 cases are from 2 flights) [Khanh, Speake, Freedman]
    - Even lower with pre-flight testing
    - But probably higher proportionally with transmissible variants
    - Surface spread has probably been overestimated as a risk

What's happening?

- **Travel restrictions have a public health cost**
  - Large scale job losses [WTTC Estimates]; economic downturn and its downstream effects [Hensher, Jin]

- **Patchwork of measures in place - at 16 April (WHO):**
  - 96 countries require testing of travelers
  - 34 countries require more than one test
  - 18 accept other than PCR
  - 79 require quarantine
  - 15 will shorten quarantine based on test results
  - 10 will exempt from quarantine based on proof of vaccination/immunity
  - 8 exempt from testing based on vaccination/immunity

- **Since then, various changes including:**
  - US CDC advises no quarantine post-travel (dom/int) for those vaccinated
  - EU signaled opening for those vaccinated

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What is this evidence suggesting?

- **Now:**
  - Risk-based approach to quarantine
  - Quarantine only for travel from high/unknown risk to lower risk, unvaccinated
  - In other cases, quarantine/testing may not be justified (in absence of immune escape VOC's)
  - Risk can be further reduced with suitable testing (saliva PCR, ?RT-LAMP, ?RAT)
  - Quarantine can be shortened/removed with validated testing programmes
  - Variants continue to be monitored for exceptions to above
  - Need digital solutions to verify ID, certify vaccine status, prevent fraud, etc.

- **Coming developments:**
  - More rapid full PCR testing (salivary samples preferred)
  - Improved RAT performance
  - Other testing eg breath spectroscopy
  - Rapid antibody testing in support of vaccination?

Where might the evidence be leading us?

Focus areas

- **Outlook for COVID-19:**
  - COVID-19 likely to become endemic - need to learn to live with the virus
  - Need for a **'coordinated, time-limited, risk-based, and evidence-based approach**'

- **Quarantine:** Virtually equivalent to a full border closure

- **Vaccination:** Strong and growing case for alleviation of more burdensome measures
  - Robust evidence on **efficacy, impact on transmission**
  - Evidence on **impact of variants on vaccine performance** is encouraging for most combinations

- **Testing:** Addressing **cost and lack of standardization**
  - Types of test and cost of testing
  - **Certification** – standardization and digitization (also for vaccination / prior infection)

- **Contact Tracing:**
  - An 'in-country' complement to border measures

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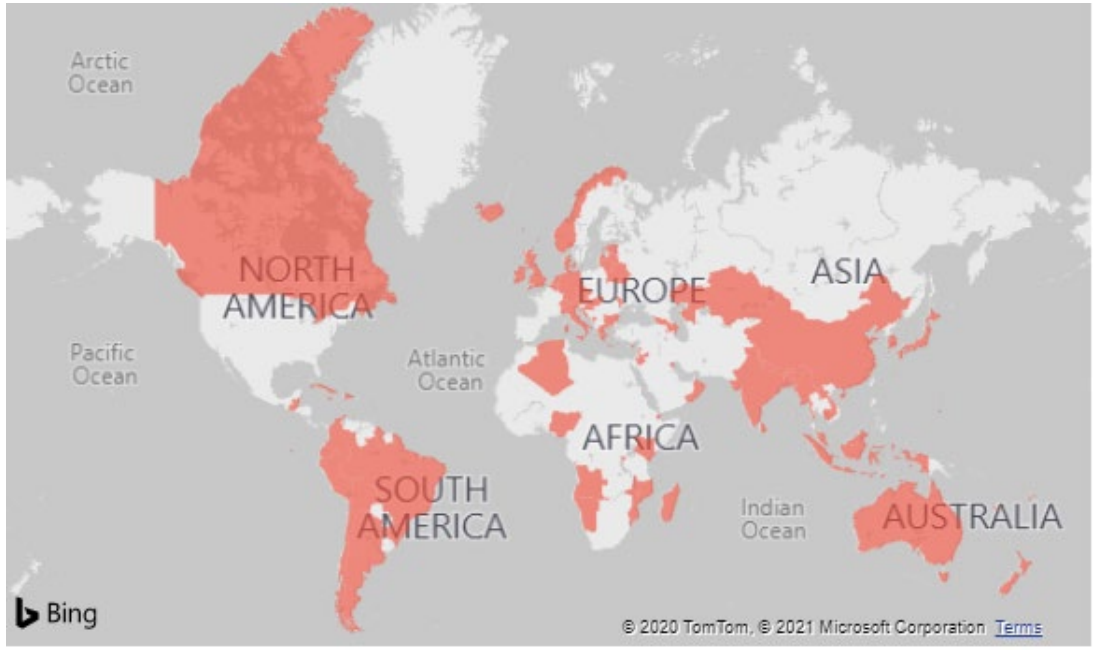
Open borders without quarantine is the objective

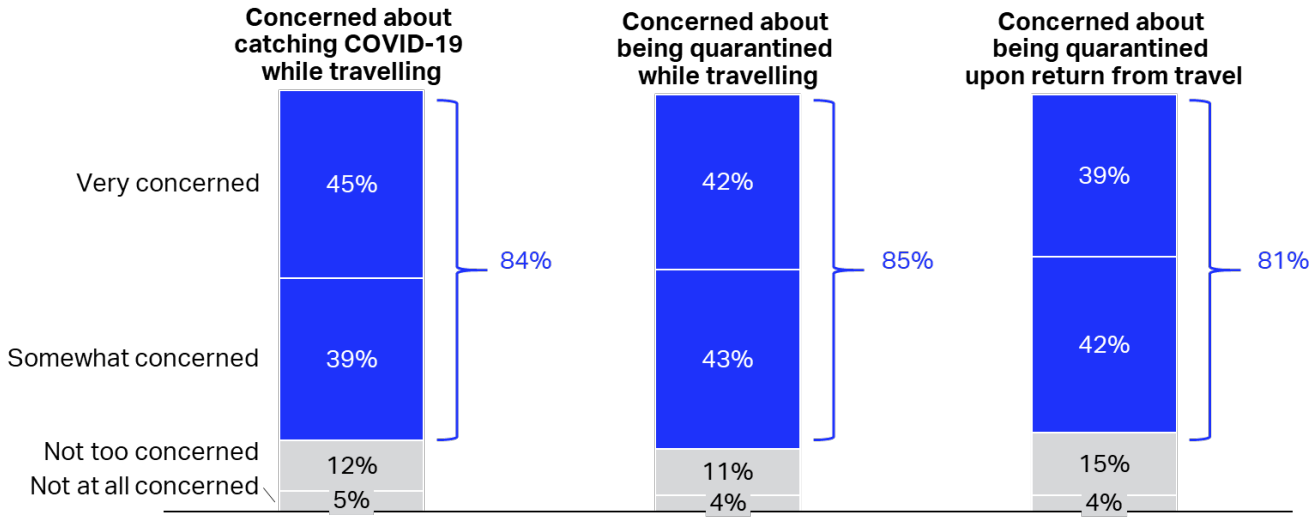
Quarantine virtually equivalent to a full border closure

~135 countries have quarantine requirements for travelers from some or all origin countries



Source: IATA Travel Centre

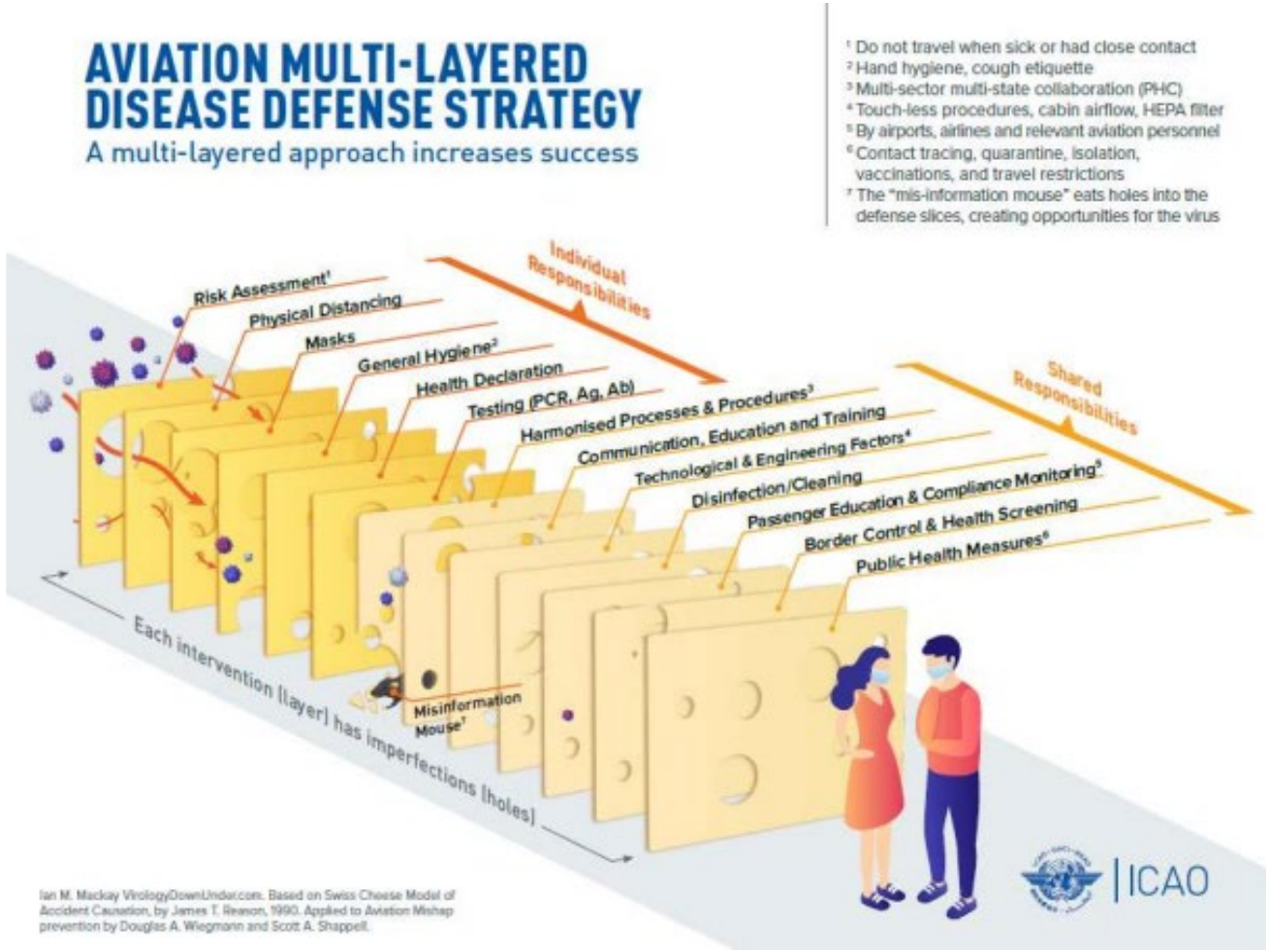
Travelers are as concerned about quarantine as they are about catching the virus



Source: Rockland Dutton for IATA

Multi-layered measures to address COVID risks

Aviation industry experienced at risk management



- COVID-19 likely to become endemic
- No zero-risk way to reopen borders

- Aviation implementing a multi-layered approach
- Risk modelling to understand impact of different measures

- **No visibility of models / assessment criteria that governments / PHAs are using**

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Vaccination a major pathway for reopening borders

Measures can be relaxed or modified for vaccinated travelers

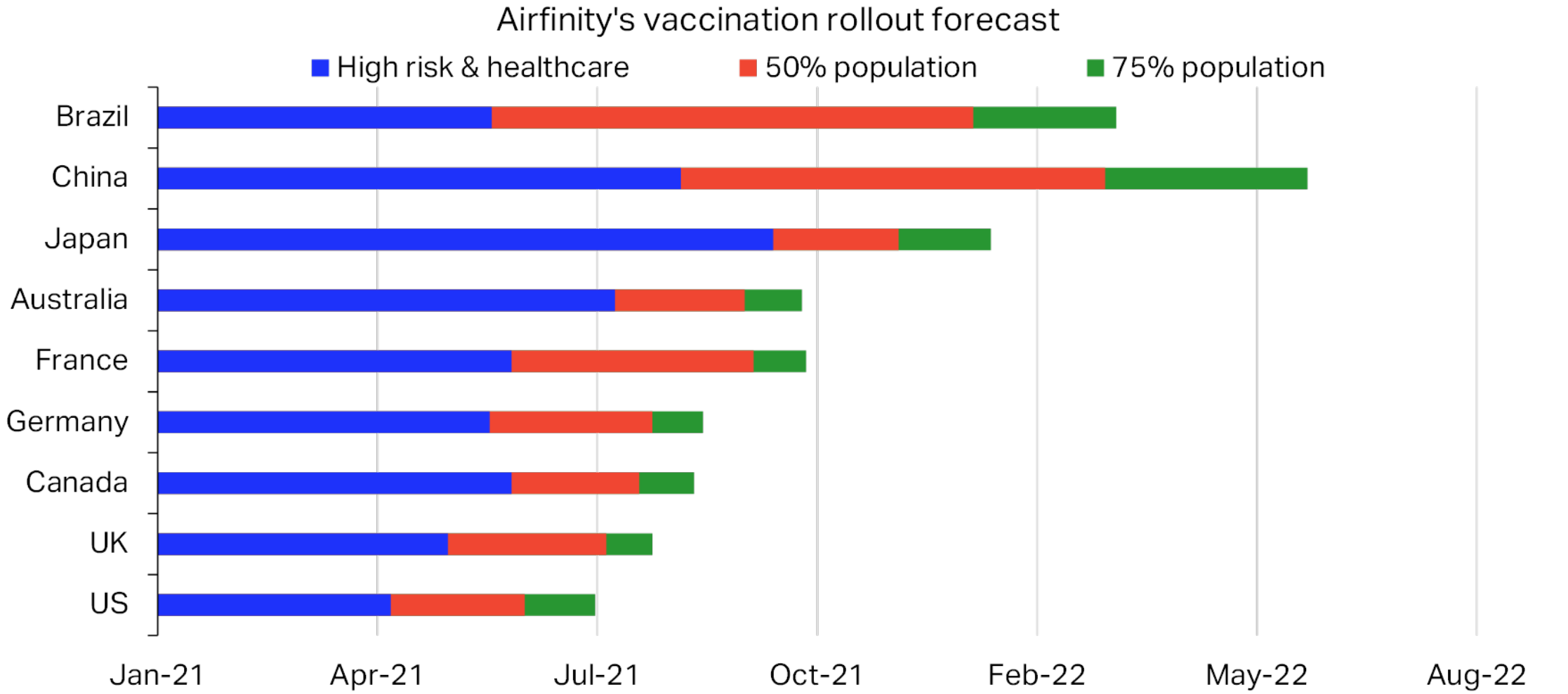
- **Waiting for vaccination before reopening borders not an option**
  - Global vaccine roll-out is likely to take at least 12-24 months.
  - Implementing testing is the bridge solution – critical for industry survival

  - Travelers who have been vaccinated should not need to quarantine.
  - Testing protocols should also be modified for vaccinated travelers
  - Accompanying minors should follow the rules that apply to parents / guardians

- **Governments should modify border restrictions once vulnerable groups vaccinated:**
  - Risks to population and healthcare system greatly reduced
  - Vaccination should not be a mandatory government requirement for international travel

- **Governments should prioritize aviation for access to vaccines**
  - Recognition of the role of aviation in vaccine distribution
  - Aircrew and other aviation workers – once health workers and vulnerable groups vaccinated

Geographic coverage of access to vaccines uneven



Source: IATA Economics using forecasts from Airfinity Science Tracker https://science.airfinity.com/covid-19-science-macro as of 11 May 2021

Asia Pacific vaccine rollout lagging North America and Europe

Testing can enable non-vaccinated to travel

Alternative pathways key to addressing equity concerns

- **Governments should introduce testing protocols that enable quarantine requirements to be removed or reduced for travelers who have not been vaccinated**

- **Testing strategies should avoid creating an additional barrier to travel due to the cost or complexity of the requirements**

  - Testing costs exceed average air fares for many markets, especially where multiple tests must be performed
  - WHO Regulations state that States should pay where testing is a government requirement

  - Testing protocols should be simple to understand and comply with and governments should ensure that the requirements are communicated to travelers in a clear and timely fashion

- **Proof of recovery / prior infection is an additional pathway to travel for travelers who have previously been infected with SARS-COV2**

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Need greater consistency in implementing measures

Complex web of testing regimes is a case in point

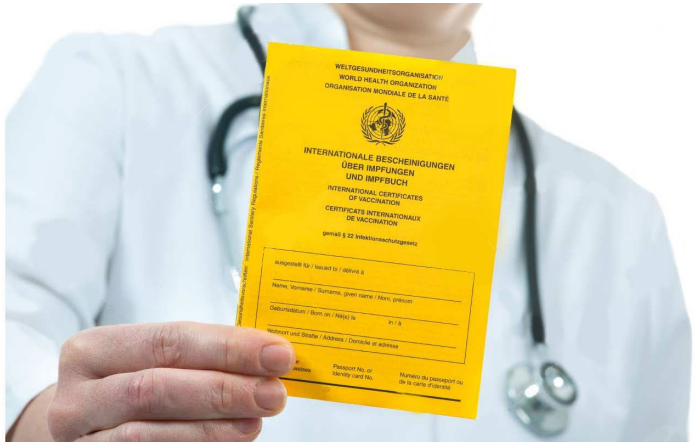
180 countries require a COVID test for arriving travelers

Source: IATA Travel Centre

Many countries waive quarantine requirements if travelers have a negative COVID test

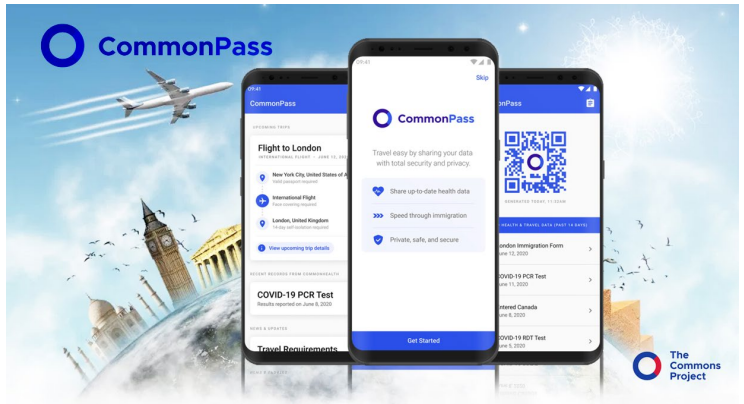
- But no harmonization / standardization of either testing regimes or certificates
- Limited mutual recognition leading to duplication of measures
- Different rules for crew, children and other categories
- Understanding and complying with rules a huge challenge for travelers and airlines

From this:



Today: Over 2.5 Billion doses given, majority of them not recorded in this way, many are not verifiable.
Use the yellow book!?!

To this:



Discussion

- **How to influence government decisions driven by PHAs?**
  - Enhancing the credibility / impact of industry advocacy
  - Scope to develop a network of aligned medical experts?
  - Risk-based modelling –
- **Risk-based approach: What role for quantitative modelling?**
  - Lots of work so far on testing. Much less on vaccines / variants
  - Little visibility on the models that governments / PHAs are using
- **Vaccination: Delivering an evidence-based position**
  - How to leverage alleviation of measures by first-mover States
  - Ethics / discrimination concerns real – vaccine non-mandatory; testing as an alternative
- **Testing: Focus on cost / standardization / certification**
  - Testing technology not the major barrier
  - Need to address traveler confusion with improved communication

Main points

The CAPSCA CASAG group and process appears to be useful as a means of evaluating data.

Evidence indicates (with some caveats) that **vaccination substantially reduces transmission of SARS-CoV-2**. Fully vaccinated travellers might not be drivers of onward transmission of SARS-CoV-2.

IATA advocates for cost-effective approaches to testing and vaccination, and for the rapid development of standards and systems for digital vaccination records.

IATA's stated position:

States should take a **data driven and cost-effective approach** to testing and vaccinations policies for travel while **adhering to WHO and ICAO guidance** on standards and digitalization.

https://www.iata.org/globalassets/iata/programs/covid/restart/covid-public-health-meausures-evidence-doc.pdf

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