



ICAO

Doc 10152

Manual on COVID-19 Cross-border Risk Management

Third Edition, 2021



Approved by and published under the authority of the Secretary General

INTERNATIONAL CIVIL AVIATION ORGANIZATION



| ICAO

Doc 10152

Manual on COVID-19 Cross-border Risk Management

Third Edition, 2021

Approved by and published under the authority of the Secretary General

INTERNATIONAL CIVIL AVIATION ORGANIZATION

Published in separate English, Arabic, Chinese, French, Russian
and Spanish editions by the
INTERNATIONAL CIVIL AVIATION ORGANIZATION
999 Robert-Bourassa Boulevard, Montréal, Quebec, Canada H3C 5H7

For ordering information and for a complete listing of sales agents
and booksellers, please go to the ICAO website at www.icao.int

Third edition, 2021

Doc 10152, *Manual on COVID-19 Cross-border Risk Management*

Order Number: 10152

ISBN 978-92-9265-582-2

© ICAO 2021

All rights reserved. No part of this publication may be reproduced, stored in a
retrieval system or transmitted in any form or by any means, without prior
permission in writing from the International Civil Aviation Organization.

FOREWORD

This manual has been prepared by aviation health experts led by the International Civil Aviation Organization (ICAO) with support from the United States Centers for Disease Control and Prevention (CDC), European Centre for Disease Prevention and Control (ECDC), Aerospace Medical Association (AsMA), and others, and it has been reviewed by the World Health Organization (WHO). Contributions from other United Nations organizations, governments and industry stakeholders ensured the practical applicability of this guidance in the aviation sector, no matter how big or small the State and no matter what scale of COVID-19 challenge they face. Together, these experts and stakeholders form the ICAO Collaborative Arrangement for the Prevention and Management of Public Health Events in Civil Aviation (CAPSCA) programme. CAPSCA brings together international, regional, national and local organizations to work together to improve preparedness planning and response to public health events that affect the aviation sector.

CAPSCA developed this guidance in close collaboration with the ICAO Council Aviation Recovery Task Force (CART), which requested updated guidance on the inclusion of COVID-19 testing, vaccination and its interdependencies with other risk mitigation tools for those States that choose to include testing and vaccination as elements of their overall COVID-19 risk management process.

The CART has published updated recommendations to States in the High-Level Cover Document (HLCD) including Recommendations 13, 17, 18 and 19 on testing and vaccination, respectively quoted below:

Recommendation 13: "Member States using testing in their COVID-19 risk management strategy should apply the approach outlined in the ICAO *Manual on COVID-19 Cross-border Risk Management* (Doc 10152), recognizing that robust testing strategies allow for early detection of potentially infectious travellers. However, testing may not be universally recommended by public health authorities as a routine health screening method due to priority and resource considerations."

Recommendation 17: "Member States should implement and recognize certificates of testing, recovery and vaccination based on the protocol, minimum data set and implementation approaches outlined in the ICAO *Manual on COVID-19 Cross-border Risk Management* (Doc 10152) to facilitate air travel. States are encouraged to ensure such certificates are secure, trustworthy, verifiable, convenient to use, compliant with data protection legislation and internationally/globally interoperable. Proof of vaccination could be based upon the World Health Organization (WHO) International Certificate of Vaccination or Prophylaxis (ICVP) and should be issued in an internationally/globally interoperable format aligned with the technical specifications and guidance outlined by the WHO. Existing solutions should be considered and could incorporate a visible digital seal – non-constrained (VDS-NC) or other interoperable formats from regional or global intergovernmental bodies, or internationally recognized organizations."

Recommendation 18: "Member States should facilitate access for air crew to vaccination as quickly as possible as recommended by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) Stage II for air crew who work on aircraft that carry goods and no passengers and Stage III for other aviation workers."

Recommendation 19: "Member States are encouraged to promote, to the greatest extent possible, a harmonized and inclusive approach to facilitate international travel and entry of fully vaccinated and recovered passengers. In this regard, Member States should consider alleviating or exempting testing and/or quarantine measures for individuals who have been fully vaccinated or those with a history of previous SARS-CoV-2 infection who are no longer infectious. The alleviations and exemptions should be made in accordance with a State's accepted risk threshold, national framework, the COVID-19 situation and the multilayer risk management framework described

in the Take-off: Guidance for Air Travel through the COVID-19 Public Health Crisis. In view of the global unequal access to vaccines and the unsuitability or intolerance of use of vaccines by some individuals, vaccination should not be a prerequisite for international travel.”

In addition, the CART revised Recommendation 14 in the HLCD concerning Public Health Corridors (PHCs) as follows:

“Member States considering the formation of a Public Health Corridor (PHC) should actively share information with each other to implement PHCs in a harmonized manner. To facilitate the implementation, the ICAO Implementation Package (iPack) on establishing a PHC is available to States, in addition to PHC-specific tools published on the ICAO website and the application (App) providing a template PHC arrangement between States.”

CART guidance aligns with updated WHO guidance:

- a) with regard to PHCs, the WHO supports exploring bilateral, multilateral and regional agreements across countries, particularly with neighbouring countries and others of socioeconomic importance, with the aim of facilitating the recovery of key activities for which international travel plays an important role, such as tourism or the movement of a cross-border workforce¹;
- b) testing and vaccination can be considered as part of national multilayered risk mitigation strategies. The WHO has stated that proof of vaccination should not be required as a condition of entry or exit to a country; and
- c) the WHO suggest that proof of vaccination could be based upon the ICVP or, if digital, should be issued in an interoperable format aligned with the technical specifications and guidance outlined in the Digital Documentation of COVID-19 Certificates: Vaccination Status technical specifications and implementation guidance document. The format recommended by ICAO (“visible digital seal for non-constrained environments” (VDS-NC)) is one possible option.

Furthermore, the WHO recommends, based on growing experiences from countries where national authorities continue to review and adjust their travel-related measures to facilitate non-essential international travel, in addition to prioritizing international travel for essential purposes as defined by national authorities, applying measures that take into account individual travellers’ transmission risk, depending on their infection status, vaccination status and/or recovery status².

As part of its CART endeavours, CART has updated the fourth edition of the *Take-off: Guidance for Air Travel through the COVID-19 Public Health Crisis (TOGD)*³, originally issued in June 2020 and revised in September 2021. The fourth edition of the TOGD reflects technological and medical advancements and provides the latest operational and public health guidance related to air travel reflecting technological and medical advancements. The recommended multilayer risk management strategy has been supplemented with considerations on testing protocols and proof-of-results certification interoperability, considerations for testing and vaccination, as well as including evidence of vaccination for crew and passengers. Guidance on the establishment of PHCs has been expanded and guidance on the transition to routine operations in the future has been added.

The third edition of this manual was revised in close collaboration with CAPSCA. It provides updated detailed guidance on risk management, PHCs, information on current scientific developments regarding Variants of Concern (VOC), COVID-19 testing, vaccination, proof of recovery, health certificates, the interdependencies of public health risk mitigation measures within a State’s multilayer risk management framework and considerations for transitioning to routine operations

¹ <https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy-Brief-Risk-based-international-travel-2021.1>

² <https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2021.1>

³ <https://www.icao.int/covid/cart/Pages/CART-Take-off.aspx>

in the future. This guidance supplements the measures already outlined in the CART HLCD and TOGD⁴ and provides a risk management process to facilitate States' assessments of the applicability of a combination of measures available today. Given the dynamic nature of the COVID-19 pandemic, this manual is intended to be a living document and will be updated as new information becomes available.

COVID-19 testing, managing recovery from previous infection and vaccination, if applied according to the guidance contained in this manual, could reduce reliance on measures that restrict air travel and the movement of persons arriving in a country, such as quarantine, which evidence suggests is a disincentive to several important categories of travel, of which the following list is non-exhaustive: pilot certification, pilot simulator training, essential business flights and tourism for some States that are dependent on inbound tourism for economic sustainability. In addition, proof of recovery or vaccination could reduce the need for additional COVID-19 testing, enabling quicker movement of air crew and passengers through check-in and customs procedures, and reduce costs for travellers and States. Restoring confidence in aviation is a key priority.

Note.— There are many available serologic assays (antibody tests) that measure the antibody response to SARS-CoV-2 infection, but at the time of publication of this manual, the correlates of protection were not well understood. The use of serologic assays is not recommended to prove recovery status given the limitations that are outlined in the scientific brief “COVID-19 natural immunity”⁵.

Quarantine may still apply for persons infected with SARS-CoV-2, as well as known close contacts of persons diagnosed with COVID-19, while self-isolation, self-quarantine or other measures could be applied for other individuals in accordance with a State's assessed risk tolerance.

In implementing testing and vaccination as components of States' overall COVID-19 multilayered risk management strategy, they are reminded that an effective application of a multilayered risk strategy, including testing and vaccination, is one in which:

- a) States perform a risk assessment⁶ using epidemiologic criteria including, but not limited to, disease incidence and prevalence, new variants, disease trajectory, national testing strategy⁷, screening capabilities, hospital capacity and robustness of contact tracing and status of national vaccination strategy;
- b) States share the results of the risk assessments, the local epidemiology (including genomic sequencing of VOC, if possible) and transmission scenarios in the departure and destination countries or areas, as well as the public health and health system capacity and performance to detect and care for returning travellers and their contacts with other States to facilitate the opening of air routes or PHCs;
- c) States consider their risk tolerance, and issues such as socio-economic and human rights, as a part of their risk assessment;
- d) States that choose to use testing for screening purposes in aviation after consideration of national testing capacity⁸ and the local epidemiology in departure and destination countries, apply a cut-off value, based on evidence generated from asymptomatic individuals, for sensitivity and specificity as high as possible (with a minimum of 95 per cent sensitivity and specificity for molecular tests; and a minimum of

4. <https://www.icao.int/covid/cart/Pages/Documents.aspx>

5. https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Natural_immunity-2021.1

6. WHO guidance on Considerations for implementing a risk-based approach to international travel in the context of COVID-19 <https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2020.1>

7. Scientific brief on COVID-19 diagnostic testing in the context of international travel <https://apps.who.int/iris/handle/10665/337832?locale-attribute=fr&>

8. <https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2021.1>

80 per cent sensitivity and 97 per cent specificity for rapid antigen tests) to reduce inaccurate test results, although these values might change as science matures⁹;

- e) States that use testing and vaccination as part of their multilayer risk management strategy take into account any recent test results, proof of recovery from COVID-19 and vaccination status, when considering the need for additional post-arrival testing or quarantine; including the duration of quarantine, when addressing higher risk scenarios; and
- f) States harmonize their procedures to the maximum extent possible.

This manual describes the risk management measures that can be applied; how epidemiology can be used to advise States in developing a risk management strategy; possible testing protocols that might be put in place where there is differential prevalence and therefore risk; vaccination as an effective mitigation factor including a series of examples to help States in their decision-making processes; and information and tools to assist States with sharing of information regarding the implementation of public health risk mitigation measures and the recognition thereof in order to open air routes and global travel.

Note.— The content of this manual is largely based on information and studies conducted prior to the emergence of the Delta variant. At the time of publication of this manual, the scientific information regarding the Delta and other variants was limited but was included in this version. Further updates will be needed as more information becomes available.

Scientific evidence that supports the guidance contained in this manual are available on the CAPSCA website¹⁰.

9. SARS-CoV-2 antigen-detecting rapid diagnostic tests: An implementation guide
<https://www.who.int/publications/i/item/9789240017740>.

10 <https://www.icao.int/safety/CAPSCA/Pages/default.aspx>.

TABLE OF CONTENTS

	<i>Page</i>
Glossary	(xi)
Chapter 1. Introduction	1-1
Chapter 2. General risk management principles applied to air transport	2-1
Chapter 3. Testing, vaccination and cross-border risk management measures	3-1
3.1 Overview	3-1
3.2 Assessment of epidemiological indicators	3-3
3.3 Testing as a screening strategy applied to aviation	3-5
3.4 Quarantine practices	3-16
3.5 Combined testing and quarantine strategies	3-18
3.6 Vaccination and vaccinated persons	3-19
Chapter 4. Implementation — Model for multilayer assessment and mitigation	4-1
4.1 Overview	4-1
4.2 Generic baseline model for multilayered risk assessment and determining mitigation measures (four-step process)	4-2
4.3 Sample scenarios	4-4
Chapter 5. Public health corridor	5-1
5.1 Principles	5-1
5.2 Elements of a PHC	5-2
5.3 Implementation of a PHC arrangement between States	5-5
5.4 Stakeholder and passenger communication	5-6
Chapter 6. Transitioning from crisis response to routine operations	6-1
Attachment A. Epidemiologic primer	Att A-1
Attachment B. Estimated effectiveness of individual risk mitigation measures	Att B-1
Attachment C. Decision aid	Att C-1

GLOSSARY

LIST OF ACRONYMS AND ABBREVIATIONS

Ab	Antibody
Ab-RDT	Antibody-detecting rapid diagnostic test
Ag	Antigen
Ag-RDT	Antigen-detecting rapid diagnostic test
API	Advance Passenger Information
ATM	Air traffic management
CAPSCA	Collaborative Arrangement for the Prevention and Management of Public Health Events in Civil Aviation
CART	Council Aviation Recovery Task Force
CASAG	COVID-19 Aviation Scientific Assessment Group
COVID-19	Coronavirus disease 19
CRRIC	COVID-19 Response and Recovery Implementation Centre
ECDC	European Centre for Disease Prevention and Control
EUL	Emergency use listing
FTL	Flight time limitation
HLCD	High-Level Cover Document
IHR	International Health Regulations
ICVP	International Certificate of Vaccination or Prophylaxis
NAAT	Nucleic acid amplification test
NPV	Negative predictive value
MRTD	Machine Readable Travel Documents
PCR	Polymerase chain reaction
PHC	Public health corridor
PNR	Passenger Name Record
PPE	Personal protective equipment
PPV	Positive predictive value
RDT	Rapid diagnostic tests
RT-PCR	Reverse-transcription polymerase chain reaction
SAGE	Strategic Advisory Group of Experts on Immunization
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SRA	Stringent regulatory authorities
TOGD	Take-off Guidance for Air Travel through the COVID-19 Public Health Crisis
VDS-NC	Visible digital seal – non-constrained
VOC	Variant of concern
VOI	Variant of interest
WHO	World Health Organization

DEFINITIONS

Asymptomatic. A person infected with COVID-19 who does not develop symptoms.

Breakthrough infection. A COVID case that occurs in someone who is fully vaccinated.

Contact. A person in any of the following situations from two days before and up to fourteen days after the onset of symptoms in the confirmed or probable case of COVID-19:

- face-to-face contact with a probable or confirmed case of COVID-19 within one metre and for more than fifteen minutes;
- direct physical contact with a probable or confirmed case of COVID-19;
- direct care for an individual with probable or confirmed COVID-19 without using proper personal protective equipment; or
- other situations, as indicated by local risk assessments.

Refer to WHO for full definition <https://www.who.int/publications/i/item/contact-tracing-in-the-context-of-covid-19>.

Contact tracing. An investigative procedure aimed at acquiring contact information to approach contacts that were potentially exposed to the virus, which is a key strategy for interrupting chains of transmission of SARS-CoV-2 and reducing COVID-19-associated mortality.

Diagnostic. Relating to or using the methods for diagnosis.

Emergency use listing procedure. The WHO emergency use listing procedure (EUL) is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency.

Epidemiology. The branch of medicine which deals with the incidence, distribution and possible control of diseases and other factors related to health.

False negative test. A result that indicates that the disease is not present when the person actually does have the disease.

False positive test. A result that indicates that the disease is present when the person actually does not have the disease.

Fully vaccinated. For the purposes of this manual and CART guidance, an individual is defined as fully vaccinated ≥ 14 days after receiving all recommended primary doses of a COVID-19 vaccine that is listed for emergency use by the World Health Organization or approved by other stringent regulatory authorities (SRAs).

Genomic sequencing. The process of determining the entirety, or nearly the entirety, of the DNA sequence of an organism's genome, supporting the monitoring of the disease's spread and evolution of the virus.

Immune escape. Immune escape occurs when the immune system of an individual is no longer able to respond adequately to a pathogen such as a virus; in other words, the virus may escape the body's immune response despite vaccination or prior infection.

Incidence. The number of new cases in a specified population during a specified period of time.

Isolation. Separation of ill or contaminated persons in such a manner as to prevent the spread of infection or contamination.

Molecular testing. A type of diagnostic tests, such as RT-PCR tests that detect the virus's genetic material.

Monte Carlo approach. A broad class of computational algorithms that rely on repeated random sampling to obtain numerical results.

Negative predictive value (NPV). How likely a negative test is a true negative.

Partial vaccination. Individuals who have partially completed the recommended primary dosage schedule of a COVID-19 vaccine that is listed for emergency use by the World Health Organization or approved by other stringent regulatory authorities (SRA).

Point-of-care tests. Tests that provide results within minutes of the test being administered, allowing for rapid decisions.

Positive predictive value (PPV). How likely a positive test is a true positive.

Prevalence. Disease burden expressed as a percentage or rate with the total population as the denominator; in this context, the number of existing cases in a defined population at a given point in time.

Proof of recovery. For the purposes of this manual and CART guidance, proof of recovery refers to individuals providing proof of previous SARS-CoV-2 infection as confirmed by real time RT-PCR (rRT-PCR), and not on the basis of serological immune assay (antibody) test results.

Quarantine. The restriction of activities and/or separation from others of suspect persons who are not ill in such a manner as to prevent the possible spread of infection or contamination.

Rapid diagnostic antigen tests. Tests that detect the presence of viral proteins (antigens) expressed by the COVID-19 virus in a sample from the respiratory tract of a person.

Risk management. Identification, evaluation, and prioritization of risks followed by coordinated application measures to minimize, monitor, and control the probability or impact of the risk.

Risk threshold or tolerance. The amount of risk that governments, organizations and stakeholders are willing to accept.

Screening. Medical examination of a person or group to detect disease or abnormality, especially as part of a broad survey rather than as a response to a request for treatment.

Sensitivity. The likelihood that a test will correctly identify a person with the disease; the "true positive" rate.

Serologic test. A blood test that measures the antibody response in an individual.

Specificity. The likelihood that a test will correctly identify a person without the disease; the "true negative" rate.

Stringent regulatory authority. A stringent regulatory authority (SRA) is a national drug regulation authority which is considered by the World Health Organization (WHO) to apply stringent standards for quality, safety, and efficacy in its process of regulatory review of drugs and vaccines for marketing authorization and listed on the WHO website (<https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs>).

Translocation. Travel-associated transfer (exportation, importation and onward transmission) of SARS-CoV-2 from one region to another.

Vaccination. The administration of a vaccine to help the body's immune system develop protection from a disease.

Variant of concern¹. A VOI (as defined below) is a variant of concern (VOC) if, through a comparative assessment, it has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance:

- increase in virulence or change in clinical disease presentation; or
- decrease in effectiveness of public health and social measures or available diagnostics, vaccines or therapeutics; or
- assessed to be a VOC by the WHO in consultation with the WHO SARS-CoV-2 Virus Evolution Working Group.

Variant of interest (VOI). A SARS-CoV-2 isolate is a variant of interest (VOI) if it is phenotypically changed compared to a reference isolate or has a genome with mutations that lead to amino acid changes associated with established or suspected phenotypic implications;

AND has been identified to cause community transmission/multiple COVID-19 cases/clusters, or has been detected in multiple countries;

OR is assessed to be a VOC by the WHO in consultation with the WHO SARS-CoV-2 Virus Evolution Working Group.

¹ <https://www.who.int/docs/default-source/coronaviruse/situation-reports/20210225-weekly-epi-update-voc-special-edition.pdf>

Chapter 1

INTRODUCTION

1.1 This guidance is intended for use by State regulators, service providers and other concerned entities, to address cross-border risk management in commercial air transport operations. The objective of the guidance is to inform States about public health risk management strategies, including those that could be applied to aviation personnel and passengers to reduce the probability of translocation (transfer) of the disease from one region to another. This document contains guidance for implementing a systematic process to identify risks related to the COVID-19 pandemic and mitigate those risks to an acceptable level as determined by each individual State. The final objective is to create a harmonized and cooperative effort to maintain global connectivity while ensuring public health security. Updates will be provided as new scientific evidence becomes available, with States being informed of updates through the publication of electronic bulletins. In the future, as more States begin to plan their route out of COVID restrictions, this updated manual offers clear guidance on how best to use public health mitigation measures, including testing and vaccination, to reduce travel restrictions and gradually return to restoring air connectivity in a safer way.

1.2 The guidance provides assessment tools that States can use to evaluate and implement measures as part of their decision-making process. For this purpose, an example of the process is presented and applied to a strategy that utilizes a range of risk mitigation measures. This guidance does not constitute a recommendation for application of any specific measure but rather a guideline on how to assess different mitigation measures and on how they can contribute to public health risk management. As an example of this approach, the document will provide the description of a strategy based on the assessment of epidemiological indicators, testing, vaccination and quarantine practices. Additional detailed guidance for States will be included as attachments by ICAO and references to the WHO publications.

1.3 This manual has been developed using the most recent information as of its publication date. The urgency, continued rapid developments, and observed consequences of the pandemic required an expedited approach based on expert consensus and current scientific evidence. Consequently, regular updates will be required as the evidence evolves and as technology advances. Data-driven adjustments to the guidance will be made as the situation evolves.

1.4 Each State will need to conduct its own assessment and is encouraged to use the processes outlined in this manual as the basis for its assessment. Risk tolerance varies between States and depends on many factors. This has an influence on the amount of residual risk a State can accept. The determination of such level cannot be universal as it depends on specific priorities and the sovereignty of each individual State.

Chapter 2

GENERAL RISK MANAGEMENT PRINCIPLES APPLIED TO AIR TRANSPORT

2.1 A multilayered risk management process is considered essential in the context of a public health risk management framework and aligned with the intent of the WHO “Considerations for implementing a risk-based approach to international travel in the context of COVID-19”¹. The objective of this process is to identify the residual risk, considering various risk mitigation measures in place for unknowingly transporting an infectious passenger or translocating the SARS-CoV-2 virus. This approach is scalable in complexity and considered the baseline for more sophisticated processes, e.g. end-to-end risk assessment models (see 2.6).

2.2 The proposed risk assessment process relies on a continuous process that considers risk holistically by defining a risk scenario instead of focusing on a single hazard or threat. The determination of an inherent risk results from evaluating the likelihood of the risk scenario, as well as defining the resulting impact. It is essential to consider risk mitigation measures, which are already in place when conducting the initial assessment of the inherent risk. This step does not consider future or potential management measures as it intends to provide the “as is” situational assessment. The result provides States with information relevant to determining if the risk scenario lies within its public health management capacity. As the inherent risk changes, States will need to modify their risk management measures. (Attachment C of this manual illustrates an example of a basic decision-making process to determine such risk). In addition, States should consult the Safety Management Manual (Doc 9859) and the ICAO Handbook for CAAs on the Management of Aviation Safety Risks related to COVID-19 (Doc 10144).

2.3 The modelling of a risk scenario is the starting point in the process, based upon the existing situational assessment but considering multi-agency collaboration within the context of the State. A generic baseline example for such a scenario could be “the risk to be assessed is of an infectious person being on board an international flight” or “the risk of translocation of the virus through air transport”. The risk scenario will need to address a State’s view on the most critical aspect of public health management. The process then progresses through different available mitigation measures that affect the overall risk. It is designed in a way that the efficacy of each mitigation measure can be assessed either qualitatively or quantitatively.

Box 1. Risk management terminology

Risk avoidance. It is often the most powerful tool of risk management and aims at reducing the likelihood of risk by avoiding it. It is, however, also the most limiting tool.

Risk mitigation. It aims at reducing the impact of the risk (by addressing the likelihood, magnitude, or both when risk cannot be avoided).

1. <https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2020.1>

Risk transfer. It aims to move the impact of the risk to a different environment. This is complex and should only be used if the risk can be fully measured, addressed and mitigated by the environment it is transferred to (an example could be to transfer risk to a State with better health-care capacity).

Risk tolerance/acceptance. It is the process of accepting the consequence (impact) of a risk. This technique is often advisable only when the risk is small but may need to be considered in complex risk scenarios.

2.4 Risk mitigation is the most appropriate strategy in the context of pandemic risk management in air transport. In the further conduct of the risk assessment process, it might be necessary to employ most of the available mitigation measures such as requiring masks, completion of passenger locator forms, testing, physical distancing, quarantine, etc., at airports and during flights. Vaccination is likely the strongest risk mitigation tool that is effective, with increasing use globally, but factors such as access to vaccines and vaccine hesitancy is a concern and it delays the overall response to contain the pandemic. In multilayered defence models, the various mitigation measures are depicted as layers (e.g. based on the James Reason Swiss Cheese Model — see Figure 2-1). Risk-free travel is not possible but the risk can be reduced through the combined application of these mitigation measures. Currently, there may be limited scientific peer-reviewed evidence-based efficacy for these mitigation measures, and the scope of their impact on transforming the inherent risk is based on expert consensus and available evidence. However, the availability of peer-reviewed scientific evidence is increasing. As a result, much of the risk assessment is qualitative and, as such, provides the flexibility to be adopted and integrated into national public health and aviation plans. The risk assessment process will consider the chosen mitigation measures, and regularly evaluate how they affect the likelihood and impact of the inherent risk. A State can then determine if the residual risk is within public health management capacity.

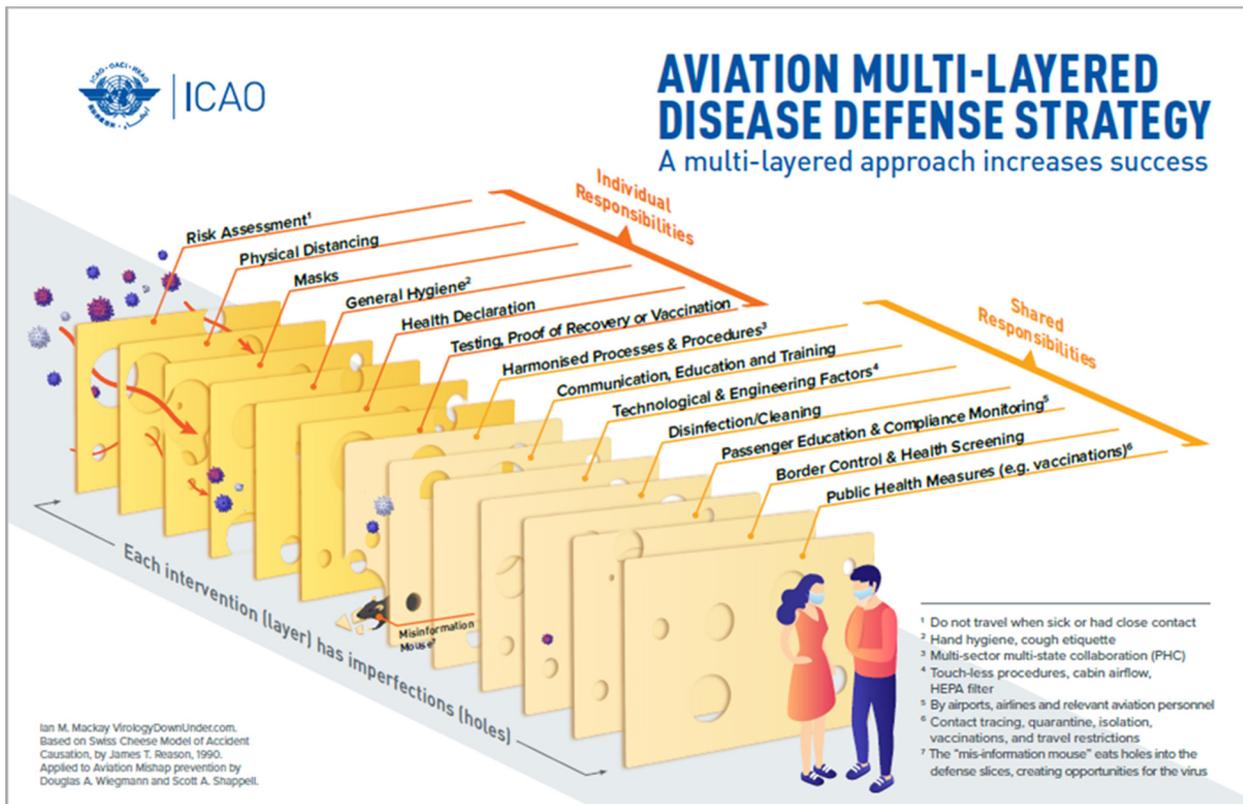


Figure 2-1. Aviation multilayered strategy based on the James Reason Swiss Cheese Model

2.5 Health risks (as related to air transport) can be approached in a similar way to aircraft safety and must be addressed together. To this end, aeroplane manufacturers, for example, have created end-to-end risk assessment models which calculate the risk of virus transmission and virus translocation by modelling steps and parameters in the door-to-door, air travel journey. One example leverages an open data platform, considering a variety of airport, aircraft, personal health and safety considerations, and different testing and quarantine scenarios. The model covers the complete air travel, from entering the departure airport to leaving the arrival airport and relying on internal expertise and safety experience. The model's objective is to support government agencies in making performance-based, data-substantiated decisions when applying and evaluating risk management principles and strategies to secure air travel for the flying public.²

2.6 Another such model compares different screening approaches through one or more COVID-19 tests in order to provide safe options that will allow the reopening of international travel. It uses a Monte Carlo approach to simulate a group of COVID-19 infected travellers, each with an individual infection timeline, and a model test performance as a function of that timeline, to compare the effectiveness of different screening strategies. The model provides an avenue to compare the relative performance of different screening and quarantine strategies and to determine which approaches may be appropriate for country-pair-specific travel journeys. It is built as a web-based tool that will provide users a flexible interface to compare multiple screening options for travel between any two selected countries with available COVID-19 prevalence data. The inclusion of prevalence data allows for computation of a "post-screening prevalence" for screened travellers (calculated using the negative predictive value) in order to compare the starting prevalence of the origin country, the post-screening prevalence for a variety of screening options, and the prevalence of the destination country. This allows for comparison of the prevalence among screened travellers to the existing prevalence in the destination country.³

2.7 One more model is a multi-disciplinary, adaptive, software-based risk management tool designed to support risk-based decision-making that restores safety, confidence and convenience in commercial aviation. The model employs a semi-quantitative, deterministic modular approach with group-structured mixing to demonstrate relative effectiveness of layered disease control measures that protect against airborne and surface borne disease transmission throughout the end-to-end travel journey in global transportation systems.⁴

2.8 The crucial result of an effective risk management process is that the residual risk is within the public health management capacity of the State concerned. This determination needs to be done under the sovereignty and responsibility of each State. Faced with a fast-evolving pandemic, the risk assessment process must be regularly reviewed so that States' mitigation measures are keeping the risks within the capacity of its public health system. WHO has developed a suite of health service capacity assessments in the context of the COVID-19 pandemic to support rapid and accurate assessment of current, surge and future capacities of health facilities throughout the different phases of the COVID-19 pandemic⁵.

2.9 In the future, some of these risk mitigation measures might be gradually relaxed or removed following a comprehensive risk assessment process, based on residual risk as informed by scientific evidence and aligned with WHO guidance⁶. However, additional measures may also be needed based on the evolving situation and emergence of new scientific evidence.

2. AIRBUS: "End-to-end risk assessment model".

3. Boeing CTI passenger screening model.

4. Boeing Travel Risk of Infection Prevention (TRIP).

5. <https://apps.who.int/iris/rest/bitstreams/1313691/retrieve>

6. Considerations for implementing and adjusting public health and social measures in the context of COVID-19: interim guidance, 14 June 2021 <https://apps.who.int/iris/handle/10665/341811>

Chapter 3

TESTING, VACCINATION AND CROSS-BORDER RISK MANAGEMENT MEASURES

3.1 OVERVIEW

3.1.1 Air connectivity will be essential to enable economic recovery. As States restart international travel, they will need effective strategies for mitigating the risk of active case importation and disease transmission within the air transport system. States will rely on community accountability and ownership, traveller education, and other internationally agreed cross-border measures in collaboration with other States

3.1.2 Given the high complexity of the crisis, **there is no single measure that can be deemed as a definitive solution**. Every mitigation measure affects the system in different ways. States should identify and compare levels of risk cognizant that public health risks cannot be eliminated. Therefore, the layered risk-mitigation defence discussed in Chapter 2 is strongly recommended. The following guidelines are meant to assist States in understanding how current mitigation measures can contribute to managing public health risks.

3.1.3 Emerging strategies should be considered and revised as new scientific evidence is published, innovative approaches are tested, and potential outcomes are modelled. As the pandemic evolves, new approaches such as probabilistic models, innovative testing technologies, air quality improvement, disinfection methods, vaccination and other processes are under rapid development and should be added to the strategies as their efficacy and cost-effectiveness is substantiated.

3.1.4 The layered defence measures against COVID-19 include steps being taken individually, at airports and on board. Appropriate measures should be applicable to all passengers, as well as aviation personnel, including duties such as training or certification activities, flight and cabin crew, maintenance engineers/technicians, air traffic management (ATM) workforce, staff that have contact with the travelling public and ground service agents. Mitigation measures can be categorized into personal and shared responsibilities and may include some or all the measures listed below:

- a) promoting participation of aviation personnel in national vaccination programmes, recognizing that vaccination offers protection from infection by reducing the likelihood of transmission and reducing the severity of COVID symptoms in most cases;
- b) administering and recognizing vaccination in alignment with the International Health Regulations, WHO recommendations (including the recognition of emergency use listing (EUL)-approved vaccines¹), and national policies;
- c) testing protocols consistent with the State's public health capacity and testing capacity, in particular, risk threshold, transmission patterns, scientific evidence and multi-sector consultation;

¹ [https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic)

- d) COVID-19 testing, isolation and quarantine, when applicable, with the exception of crew, in accordance with the CART TOGD;
- e) adhering to State, provincial, local policies and civil aviation procedures in both departure and arrival States;
- f) engineering factors, environmental control systems, such as the optimization of heating, ventilation and air-conditioning (HVAC) systems;
- g) enhanced cleaning and disinfection; contactless boarding/baggage processing; use of physical barriers and disinfection in airports;
- h) self-awareness orientation, including various channels of passenger communication to allow passengers to identify symptoms and complete/submit health declarations or health attestations and practice personal hygiene²;
- i) physical distancing at airports and during boarding; use of face masks; separation between passengers on board when feasible³;
- j) general hygiene, hand hygiene, avoid touching face, covering cough;
- k) communication, education and training;
- l) facilitation of contact tracing if a passenger or crew member develops infection⁴;
- m) adjustment of food and beverage service to reduce contact; control of access to aisles and bathrooms to minimize contact; and
- n) entry and exit screening (fever, loss of sense of smell or taste, chills, cough, shortness of breath, headaches, muscle pains, etc.) and/or health declaration.

3.1.5 The following mitigation measures are specifically applicable to crew required on board for the air operator to support the flight, including those that may be required to position before or after a duty, to facilitate the continued operation of aircraft. The measures outlined below are consistent with the layered approach and are based on a risk assessment for crew. States should, taking into consideration a State's national framework and situation:

- a) recognize crew members as essential personnel to contribute to the continuity of critical transport services during the COVID-19 pandemic;
- b) recognize crew members are required to cross international borders as a part of their duties and, as such, conduct a separate risk assessment and implement minimal requirements to ensure global connectivity;
- c) not subject crew to screening or restrictions applicable to other travellers, but apply minimal requirements aligned with the crew module in the TOGD;

2. [https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic)

3. WHO: Mask use in the context of COVID-19 ([https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak))

4. <https://www.who.int/publications/i/item/contact-tracing-in-the-context-of-covid-19>

- d) exempt crew from testing measures considering the frequency of travel and use of existing occupational health programmes;
- e) if crew cannot be exempted from testing, apply tests that are minimally invasive and reduce the need for multiple tests on a journey (for example, by only requiring testing at the home base immediately prior to and after duty);
- f) facilitate access for air crew to vaccination as quickly as possible within the WHO Strategic Advisory Group of Experts on Immunization (SAGE) Stage II and III recommendations⁵, the WHO Emergency Committee Statement⁶ and applicable national policies;
- g) follow vaccination guidelines for aviation workers described in 3.6.3;
- h) not impose quarantine measures on crew who need to layover, or rest, for the purposes of complying with flight time limitation (FTL) rest requirements; and in accordance with WHO guidelines on fully vaccinated crew (refer to 3.3.1.4 h));
- i) exempt fully vaccinated crew and crew with documented recovery from COVID-19, from testing;
- j) expedite security and immigration clearance (e.g. dedicated crew line);
- k) provide separate waiting areas from travellers;
- l) provide access to dedicated ground transportation; and
- m) implement layover protocols to prevent transmission of SARS-CoV-2 between crews, passengers and the general public.

3.2 ASSESSMENT OF EPIDEMIOLOGICAL INDICATORS

3.2.1 General

3.2.1.1 States could consider implementing testing as part of their COVID-19 risk management strategy, taking into consideration national testing capacity and resources and the principles of a “generic risk management process” contained in Chapter 2 and the detailed Epidemiology Primer (Attachment A).

3.2.1.2 A critical step in assessing risk for States is understanding the real time epidemiologic indicators of incidence and prevalence and the disease trajectory (escalated spread, diminishing cases or emergence of new variants) in addition to the availability of testing, health-care system saturation, and robustness of contact tracing. Studying these factors will allow countries to compare disease rates between points of origin and arrival by Member States or region, and in some cases by cities depending on the detail of the disease reported by public health authorities and the ability of a State or region to correctly identify and treat ill people. There are several sites reporting rolling averages of new cases per 100 000 people including the WHO (<https://covid19.who.int/>), the European Centre for Disease Prevention and Control (ECDC) (<https://gap.ecdc.europa.eu/public/extensions/COVID-19/COVID-19.html#global-overview-tab/>) and Brown

5. WHO: WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply <https://www.who.int/publications/i/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply>

6. [https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic)

Public Health (<https://globalepidemics.org/key-metrics-for-covid-suppression/>). The reliability of the case numbers is affected by the availability of tests, testing intensity, national testing strategy in each phase of the pandemic and the timeliness and accuracy of reporting of data.

3.2.1.3 Prevalence is the proportion of the population with a disease at a given time. In considering the goal of lowering the risk of disease transmission during travel and disease translocation risk to the destination country, the potential number of persons on board an aircraft who could be infectious during the journey is vital. That data must be inferred as there is no current ability to determine it directly through routine surveillance testing. It can be estimated by multiplying the cases per 100 000 by the infectivity period and then factoring in the asymptomatic rate. This number is then converted to a percent infectious per 100 persons. In this case, prevalence is a better indicator of potentially infectious individuals than incidence (new cases per day); however, an awareness of incidence will influence the shrinking or growth of the disease cases in a given area.

3.2.1.4 Disease trajectory refers to whether the number of new cases of disease remains stable, increases or decreases over time. An awareness of which way the infection rates are going may assist in monitoring risk. For instance, if a State level of disease is in a moderate range, but there is a doubling of case rates per week, a State may want to rethink requirements or risk mitigation strategy.

3.2.1.5 To gain a true picture of the prevalence and trajectory of disease, testing should be readily available and utilized routinely when individuals are either displaying symptoms or are identified as close contacts. States may wish to consider the proportion of testing compared to the population, the percentage of positive results, and the proportion of positive tests in symptomatic or close contacts compared to asymptomatic persons. Testing strategy is further detailed in WHO's interim guidance on Recommendations for national SARS-CoV-2 testing strategies and diagnostic capacities (<https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>).

3.2.1.6 States may use this information to classify or stratify cities, States, or regions by risk level (see Chapter 4). By developing these benchmarks, States and regions can begin to discuss mitigation strategies necessary between States, including potential bilateral, multilateral or regional arrangements to facilitate air transport (i.e. Public Health Corridors), or temporarily expanding or liberalizing cargo traffic rights.

3.2.2 Variants of concern (VOC)

3.2.2.1 The pandemic continues to evolve with additional variants of concern (VOC) emerging, which are more transmissible, may cause more severe disease and/or may lead to possible immune escape. It is further likely that possibly more dangerous VOC may emerge in the future that may be even more challenging to control, especially in areas and groups with high incidence and low vaccine coverage.

3.2.2.2 The scientific community continues to monitor emerging data regarding SARS-CoV-2 variants and immunity following recovery, including the ability of emerging virus variants (variants of interest and variants of concern) to evade immune responses.

3.2.2.3 Vaccine breakthrough cases are expected to occur regardless of virus strain because no vaccine is 100 per cent effective. Breakthrough cases should not necessarily be seen as a failure of the vaccine. However, vaccine breakthrough cases may signal reduced vaccine effectiveness against emergent viruses or virus variants. It is thus essential to assess how vaccines perform against new variants, to inform vaccination programmes⁷.

7. https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccine_effectiveness-variants-2021.1

3.2.2.4 In view of the continuing emergence of VOC and the risks they might represent, States are encouraged to include the emergence and circulation of VOC in their risk assessments and refer to the relevant WHO epidemiology⁸ updates.

3.2.2.5 States are further encouraged to conduct surveillance using genomic sequencing and share epidemiological information on a regular basis with WHO (in accordance with WHO requirements) and other States, specifically where PHC agreements exist with other States.

3.3 TESTING AS A SCREENING STRATEGY APPLIED TO AVIATION

3.3.1 Testing concepts

3.3.1.1 States using testing in their COVID-19 risk management strategy should apply the approach outlined in this manual, recognizing that robust testing strategies allow for early detection of potentially infectious travellers. However, testing may not be universally recommended by public health authorities as a routine health screening method due to priority and resource considerations.

3.3.1.2 In addition, in view of inaccessibility to vaccines or inability to use vaccines in some instances, as well as the emergence of VOI and VOC, testing is considered to be an important mitigation measure in the detection of possible SARS-Co-V-2 infection.

3.3.1.3 Antigen detection rapid diagnostic tests (Ag-RDTs) have a number of advantages for screening used within the aviation environment due to their ability to detect active infection, their ability to detect current circulating variants, the shorter waiting periods for results which enables testing closer to the time of departure, their high availability, and the lower cost of their use. However, PCR testing is still considered to be the most reliable diagnostic test.

3.3.1.4 For those States that employ testing as a part of an overall risk mitigation strategy, the following concepts could be considered:

- a) Reducing risk to zero is impossible, but testing can be **one measure** supporting a multilayered risk mitigation process.
- b) There are four main reasons to consider testing:
 - 1) reducing potential transmission during the actual travel;
 - 2) reducing potential introduction of disease in a destination region/country;
 - 3) potentially reducing or eliminating quarantine for the traveller at their destination; and
 - 4) helping to identify imported cases of new variants through genomic sequencing.
- c) States could also consider limiting the exportation of disease and developing methods to communicate to travellers the need to remain at their residence when ill, when in isolation, when in quarantine, if they have a pending test following the onset of symptoms compatible with COVID-19 and any other relevant measures as recommended by the relevant Public Health Authority.

8. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>

- d) The current approved COVID-19 tests that are recommended by public health authorities are for testing of symptomatic or exposed individuals for diagnostic purposes. Use in an asymptomatic population may yield different test performance than that of symptomatic cases. In Attachment A, Epidemiologic Primer, a margin of error is described and used to account for asymptomatic cases in the development of the positive and negative predictive values. The use of antigen testing in low-prevalence settings including asymptomatic individuals is described in detail in 3.3.2.
- e) In areas with low test availability, States should balance the diagnostic needs in symptomatic individuals and individuals in high-risk groups and high-risk settings (where the public health impact is greater) against screening of healthy or asymptomatic potential travellers.
- f) Testing requirements may reflect the difference in the epidemiological situation of the point of origin and destination and where the epidemiological situation is equal, there should, in principle, be no testing requirements, in accordance with States' national policies.
- g) For all tests, accurate results depend on good clinical sampling. Testing should thus be performed by individuals in accordance with the appropriate authorities' policies and procedures. At least one authority has authorized the use of home-testing kits for travel purposes under specific criteria. Standards and procedures for presenting test results for travelling purposes is described in 3.3.8 (Standardization and validation of testing certificates) and included as PHC Form 5 in the CART TOGD to facilitate recognition by different authorities. An initial positive test regardless of type should be considered positive, unless it has been cleared by additional confirmatory testing (when appropriate), or the individual has been assessed and cleared by a healthcare provider, or the individual has provided proof of a previous SARS-CoV-2 infection.
- h) Exempting travellers/air crew from measures, such as testing and/or quarantine requirements, to individual travellers who:
 - 1) were fully vaccinated, at least two weeks prior to travelling, with COVID-19 vaccines listed by the WHO for emergency use or approved by a stringent regulatory authority⁹ or;
 - 2) have had previous SARS-CoV-2 infection as confirmed by real time RT-PCR (rRT-PCR) within the six months prior to travelling and are no longer infectious as per WHO's criteria for releasing COVID-19 patients from isolation¹⁰.
 - For symptomatic patients: ten days after symptom onset, plus at least three additional days without symptoms (including without fever and without respiratory symptoms).
 - For asymptomatic cases: ten days after positive test for SARS-CoV-2.
- i) Offer alternatives to travel for individuals who are unvaccinated or do not have proof of past infection, such as through the use of negative RT-PCR tests, or antigen detection rapid diagnostic tests (Ag-RDTs) that are listed by the WHO for emergency use or approved by other stringent regulatory authorities should be considered¹¹.
- j) However, other basic mitigation strategies (wearing masks, physical distancing, etc.) should remain in place while studies are under way to determine duration of immunity and until conclusive evidence is available to support reduction of basic measures.

9. <https://www.who.int/initiatives/who-listed-authority-reg-authorities/SRAs>

10. <https://www.who.int/publications/i/item/criteria-for-releasing-covid-19-patients-from-isolation>

11. <https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy-Brief-Risk-based-international-travel-2021.1>

3.3.2 Testing methods and performance-based recommendation

Note.— Refer to Attachment A, Epidemiologic Primer for definitions, meaning of prevalence for testing and sample equations.

3.3.2.1 Robust testing strategies are an essential aspect of preparedness and response to the COVID-19 pandemic, allowing for early detection of potentially infectious individuals¹². At the time of publication, molecular testing (e.g. real time RT-PCR) is recommended by the WHO for routine diagnosis. However, the WHO allows for antigen detection rapid diagnostic tests (Ag-RDTs) that are listed by the WHO for emergency use or approved by other stringent regulatory authorities, to be used as alternatives¹³. Ag-RDTs with a minimum specificity of at least 97 per cent are recommended to avoid false negative results, thus reducing the introduction of infected passengers into the travel continuum.

3.3.2.2 The performance of Ag-RDTs has significantly improved, allowing faster and cheaper, yet still effective, ways to detect infections. Ag-RDTs have increasingly become an important part of the overall response to the pandemic where reliable and cost-effective testing within short timeframes are needed; or where access is needed by individuals who are unable to provide proof of vaccination. Rapid antigen tests will most often be positive when viral loads are highest and patients are most infectious, typically one to three days prior to the onset of symptoms and during the first five to seven days after the onset of symptoms – and will become negative as the patient clears the infection and recovers. Some States have implemented high-performing Ag-RDTs successfully as a screening option for work, recreation or socio-economic purposes. It has been used successfully in aviation for screening aviation employees prior to work; and for screening passengers prior to pre-departure and following arrival.

3.3.2.3 Confirmatory testing by a Nucleic Acid Amplification Test (NAAT) is recommended to exclude false positive Ag-RDTs results. Where NAAT tests are not readily available and in view of the advantages of Ag-RDTs, it is recommended that Ag-RDTs with a minimum sensitivity of at least 95 per cent could be used for confirmatory testing.

3.3.2.4 Serological tests should not be utilized as the sole factor for COVID-19 diagnosis or recovery from infection. They should be used in conjunction with clinical evaluation and judgment.

3.3.2.5 As more and different tests are approved for emergency use, including some that were previously considered to be less effective, specifying a particular test or set of tests as the “best” regimen to use in a specific scenario becomes challenging. Each of these tests has distinct advantages and disadvantages which need to be considered. The table below describes the advantages and disadvantages of different testing methods. It should be noted that RT-PCR remains the “gold standard” for diagnostic testing in health settings. More information can be found in the WHO guidance on SARS-CoV-2 antigen detecting rapid diagnostic tests and in Table 3-1 below¹⁴.

12. COVID-19 diagnostic testing in the context of international travel https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-international_travel_testing-2020.1

13. <https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy-Brief-Risk-based-international-travel-2021.1>

14. <https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays>

Table 3-1. Advantages and disadvantages of testing methods for SARS-Cov-2

<i>Test type</i>	<i>Advantages</i>	<i>Disadvantages</i>
Nucleic acid amplification testing (NAAT), e.g. RT-PCR tests	<ul style="list-style-type: none"> • Detects active SARS-CoV-2 infection • High sensitive and specificity 	<ul style="list-style-type: none"> • Turnaround time of hours to days • Labour intensive • Requires laboratory infrastructure and skilled personnel • More expensive than RDTs
Rapid diagnostic tests: Antigen-detecting tests	<ul style="list-style-type: none"> • Detects active SARS-CoV-2 infection • Can be used at the point of care (outside laboratories) • Easy to perform • Quick results (typically under 30 minutes) enabling rapid implementation of infection control measures, including contact tracing • Less expensive than NAAT 	<ul style="list-style-type: none"> • Variable sensitivity and specificity, generally lower than NAAT • Lower sensitivity means negative predictive value is lower than for NAAT, especially in settings with high prevalence of SARS-CoV-2 • Confirmatory NAAT testing of RDT positives is advised in all low-prevalence settings and for RDT negatives in high-prevalence settings • Negative Ag-RDT results cannot be used to remove a contact from quarantine
Rapid diagnostic tests: Antibody-detecting tests	<ul style="list-style-type: none"> • Ab-RDTs can be used to detect previous infection with SARS-CoV-2 • Can be used at the point of care (outside laboratories) or in higher throughput formats in laboratories • Easy to perform • Quick results (typically under 30 minutes for point-of-care testing) • Less expensive than NAAT 	<ul style="list-style-type: none"> • Clinical significance of a positive Ab-RDT results is still under investigation • Positive Ab-RDT results do not guarantee presence of neutralizing antibodies or protective immunity • Ab-RDTs should not be used for determining active infections in clinical care or for contact tracing purposes • Interpretation of Ab-RDT results depends on the timing of the disease, clinical morbidity, the epidemiology and prevalence within the setting, the type of best used, the validation method, and the reliability of the results

3.3.2.8 One of the aims of this guidance is to establish a performance-based recommendation for testing regardless of the methodology that the States could consider if they choose to use testing as a part of their risk mitigation measures. This is aligned with the ICAO risk-based approach, supporting State sovereignty to make decisions based on a State's risk assessment and risk tolerance, guided by their own priorities and consideration of epidemiological indicators, practical testing limitations and other relevant considerations.

3.3.2.9 States are advised to:

- a) continuously consider and re-evaluate the performance of the tests available in the market and the application for which it is being considered for use (e.g. study the population upon which performance data is based, whether the performance data supports screening, diagnosis or monitoring, etc.);
- b) implement a strategy to manage positive and false positive test results (e.g. confirmatory testing);
- c) record and review testing data on a frequent basis;
- d) monitor scientific developments and adjust their testing protocols accordingly; and
- e) distinguish between passengers, crew members and other aviation occupations who are covered by occupational health programmes, i.e. consider the role of existing occupational health programmes when assessing crew risk.

3.3.3 Pre-departure testing

3.3.3.1 The goal of pre-departure testing is to limit the potential transmission of COVID-19 during travel and may contribute to the reduction in the risk of translocation of the disease. A single pre-departure test alone is more effective in mitigating on board transmission than in reducing the translocation of disease. Adding testing as a component to a multilayered risk mitigation strategy reduces reliance on recognizing and reporting symptoms as a sole means to identify infected travellers. No testing regime can reduce the risk to zero (completely eliminate the risk). Hence, travellers must continue to employ routine recommended public health measures at all times. The current understanding of COVID-19 allows the assumptions below. The closer the testing is to the departure time, the more likely the person will remain unable to infect others during the journey. Therefore, the use of rapid antigen testing could be beneficial in pre-departure testing, providing cost-effective testing within a short time period just prior to travel. Testing too far in advance of departure results reduces the advantage of the risk reduction allowed by pre-departure screening. Testing within 72 hours of departure is still valid, considering the practical limitations with PCR testing. However, the optimum risk reduction results can be achieved by PCR or rapid antigen testing as close as possible to the departure. This conclusion is based upon the following:

- a) incubation time: 2 to 12 days (95 per cent of cases) with a median of 5 to 6 days;
- b) viral shedding can occur 48 hours prior to symptom onset;
- c) the most sensitive tests turn positive 1 to 3 days (24 to 72 hours) prior to symptoms; and
- d) leaving a 2- to 4-day period where a person could be infected but not contagious while travelling (i.e. a negative test if the median incubation period is used). However, this could miss very short incubation cases.

3.3.3.2 Figure 3-1¹⁵ provides an overview of the use of antibody and virus detection tests in relation to transmission of the SARS-CoV-2 with reference to guidance from the Ministry of Health of Spain¹⁶.

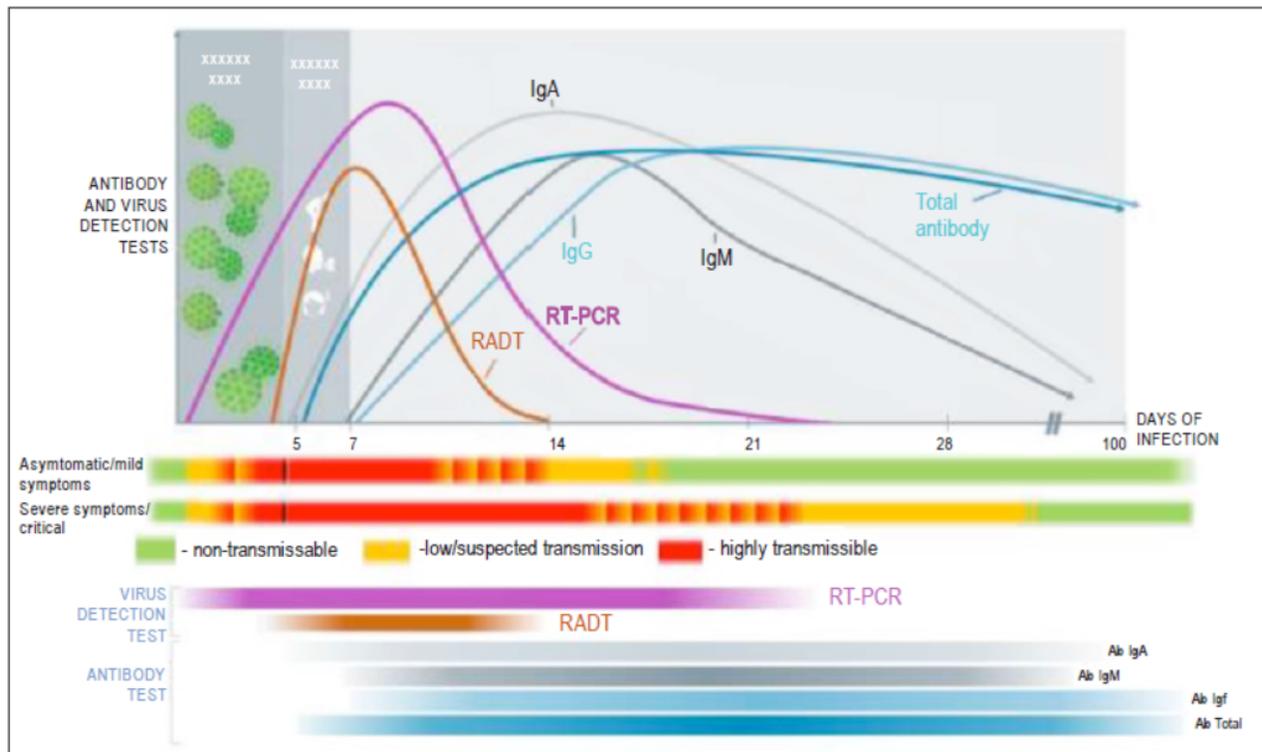


Figure 3-1

3.3.4 Combined pre-departure and post-arrival testing

3.3.4.1 Post-arrival testing, in conjunction with pre-departure testing, can result in risk reductions. Consequently, as part of a State's risk assessment and determination of risk tolerance, a State may consider reducing quarantine time frames.

3.3.4.2 Both PCR and rapid antigen testing could be used for post-arrival testing, but PCR testing could help identify imported cases of new variants through genomic sequencing which could be communicated to States that share PHCs.

3.3.4.3 Modelling suggests that pre-departure testing, preferably close to departure, in combination with post-arrival testing on day 4 to 5 and a shorter quarantine, may perform as well as a 14-day quarantine alone. These models are currently undergoing further refinement, and updated findings will be included in future revisions.

15. EASA Guidelines for Aero-Medical Centres and Aeromedical Examiners regarding the examination and assessment of applicants <https://www.easa.europa.eu/document-library/general-publications/guidelines-aero-medical-centres-and-aeromedical-examiners>

16. <https://www.synlab-sd.com/en/blog/covid-19-tests-everything-you-need-to-know/>

3.3.4.4 The study results of 16 361 arriving passengers at Toronto Pearson Airport found that a single arrival PCR test will pick up two-thirds of individuals who will become positive, with most of the remaining individuals detected on the second test at day 7. These results and other scientific papers¹⁷ support strategies from modelling that a reduced quarantine combined with testing can be as effective as a 14-day¹⁸ quarantine. Alternative strategies include daily antigen testing after arrival.

3.3.4.5 Models have also been developed taking into account vaccinated individuals, with some States using pre-departure testing in combination with testing two days after arrival for vaccinated travellers. Additional modelling and close follow-up of travellers will further refine when to conduct post-arrival testing in combination with pre-departure testing. Refer to Chapter 4, 4.2 for more detailed information.

3.3.6 Selecting test devices based on statistical analysis

Note. — See Attachment A, *Epidemiologic Primer for definitions and sample equations.*

3.3.6.1 With the goal of allowing the greatest number of people to travel without increasing the risk of SARS-CoV-2 importation and onwards transmission, or exportation, the test device in the prevalence level in the traveller's population should have a high negative predictive value, meaning a negative test is in all likelihood truly negative. While there will be a few false negatives who would enter the system, a significant number of false positives who are not infected and could travel otherwise might be denied travel. A plan to evaluate false positives should be developed.

3.3.6.2 Even tests with relatively low specificity (the ability to correctly identify those who do not have the disease as negative), result in high negative predictive values. Establishing a higher test sensitivity cut-off (i.e. the ability to correctly identify those with the disease) will limit those with the disease but who might enter the travel corridor or be released from quarantine.

3.3.6.3 For those States choosing to utilize testing, it is recommended that the cut-off values for sensitivity and specificity be as high as possible, but with a minimum of 95 per cent¹⁹ for molecular tests (sensitivity cut-offs are based on reported sensitivity for cases in the peak contagious period, not for very early or very late-stage infections) and a minimum of 80 per cent sensitivity and 97 per cent specificity for rapid antigen tests based on data generated from asymptomatic individuals. Given the reported test values were from the manufacturers as part of their Emergency Use applications, where possible independently validated sensitivities and specificities should be used. No specific diagnostic test(s) is recommended as the number of fielded test devices are growing too rapidly. Hence, a performance-based approach to the selection of a test device(s) using sensitivity and specificity is preferred. States should use tests that have been authorized for screening by relevant public health authorities or have been listed by WHO as part of their Emergency Use Listing (EUL) procedure.

17. <https://www.icao.int/safety/CAPSCA/Pages/Coronavirus.aspx>

18. <https://www.medrxiv.org/content/10.1101>

19. The recommendation for a minimum sensitivity and specificity level of 95 per cent for molecular tests is based on the following:

- The minimum values of 95 per cent for sensitivity and specificity will allow for a wider range of test devices to be used that are currently fielded as opposed to forcing States to procure newer models that are frequently hard to obtain.
- This range also allows for the use of rapid antigen tests as a screening device which are more accessible and practical for application in the aviation environment; and are faster and less expensive to use. In addition, it would reserve the more expensive real-time RT-PCR tests for confirmation of positives in conjunction with clinical correlation.
- Setting the specificity at 95 per cent reduces the false positives.
- Setting the sensitivity at 95 per cent will also reduce the risk of false negatives.
- In low prevalence settings (equating from 10 to 25 cases per 100 000 on a rolling average), the NPV equates to mislabelling an infected person as negative between 1 in 5 000 and 10 000 negative tests. In a higher prevalence setting (equating to over 50 cases per 100 000 on rolling average) the mislabelling rises close to 1 in 300.
- In the same low prevalence and higher prevalence range, the PPV improves from correctly labelling of positive from approximately 5 to 10 per cent, to slightly better than 1 out of 2 of positive tests.
- These are minimum recommended values. States should determine their own minimum levels for sensitivity and specificity that they may require to improve test performance.

3.3.6.4 Polymerase chain reaction (PCR) tests are in short supply in some States and typically expensive. Due to short supply, PCR tests are often reserved only for symptomatic individuals. This might cause significant delays in obtaining results. They are usually based on swab techniques which require suitable trained personnel, premises, and equipment for the sampling process. This means they are difficult to apply in an airport setting. Many countries have called for pre-travel PCR tests, but this creates problems of a window of possible infection after testing, as well as requirements for test approval, identity verification and fraud-proofing of the test results. These have led to interest in using more rapid point-of-care tests including antigen tests that could be used for screening purposes, with consideration of protocols to manage positive test results. Refer to section 3.3.2 for more information regarding the use of rapid tests for screening and confirmatory purposes.

3.3.7 Management of positive tests and proof of recovery

3.3.7.1 All positive tests should be referred for clinical diagnosis. Test results should be interpreted in the context of the prevalence of infection or disease, the testing device's performance characteristics and instructions for use, as well as the patient's clinical signs, symptoms and history.

3.3.7.2 States should ensure their testing regimes include clearly published processes for recovered cases to obtain medical clearance for travel, which should be regularly updated in accordance with current scientific evidence. A positive test in a traveller or crew member with a history of infection and clinical recovery could be considered safe for travel.

3.3.7.3 Positive antigen tests should be referred for clinical correlation and require confirmatory testing. For positive rapid antigen tests in particular, a confirmative molecular test or different rapid antigen test of high specificity can be considered when the pre-test probability is low, such as asymptomatic individuals with no known exposure. In symptomatic cases, depending on the symptoms, negative antigen tests should be referred for clinical evaluation and might require confirmatory testing.

3.3.7.4 PCR tests can remain positive for weeks to months following infection and depending on severity of disease in some patients. Some authorities do not recommend additional PCR tests within a 90-day period of confirmation of diagnosis.

3.3.7.5 Rapid diagnostic tests detecting viral proteins have the potential to expedite and simplify the detection of active infection. Antigen tests that are listed by the WHO for emergency use or approved by other stringent regulatory authorities may be considered to separate current infection from past/recovered infections.

3.3.7.6 Most patients, who have clinically recovered and who have mounted an antibody response to the virus, are not considered to remain infectious²⁰, although duration of this immunity is currently unknown. Current available evidence indicates a period of immunity of at least six months. Individuals who have had previous SARS-CoV-2 infection, as confirmed by real time RT-PCR (rRT-PCR) within the six months prior to travelling, should be assessed for infectiousness as per the WHO's criteria for releasing COVID-19 patients from isolation²¹:

- For symptomatic patients: ten days after symptom onset, plus at least three additional days without symptoms (including without fever and without respiratory symptoms).
- For asymptomatic cases: ten days after positive test for SARS-CoV-2.

20. WHO: Interim position paper: considerations regarding proof of COVID-19 vaccination for international traveller (Interim position paper: considerations regarding proof of COVID-19 vaccination for international travellers (who.int))

21. <https://www.who.int/news-room/commentaries/detail/criteria-for-releasing-covid-19-patients-from-isolation>

3.3.7.7 Available scientific data suggests that, in most people, immune responses remain protective against reinfection for at least six months after infection²². There are many available serologic assays (antibody tests) that measure the antibody response to SARS-CoV-2 infection, but at the present time, the correlates of protection are not well understood. The use of serologic assays is not recommended to prove recovery status given the limitations that are outlined in the scientific brief “COVID-19 natural immunity²³”.

3.3.7.8 The COVID-19 Aviation Scientific Assessment Group (CASAG) performed a literature search and systematic review of scientific articles and technical reports regarding the duration of naturally acquired (post-infection) immunity. Available evidence, at the time of publication, concluded that the duration of naturally acquired immunity following SARS-CoV-2 infection is at least six months, and is likely longer. The main limitation is that all studies were limited by the available duration of follow-up data, and that data from future studies could indicate an extension of the period. CASAG will continue to monitor developments and update findings accordingly on the ICAO CAPSCA website²⁴.

3.3.7.9 Other limitations are that not all studies have taken into account all of the circulating VOC and the possibility of altered immune responses to variants, which may need to be considered in applying the conclusions. More studies would be needed to determine the full spectrum of immune responses and special consideration should be provided for individuals with reduced immune response, in particular, those having received renal transplant, and those under treatment for blood-related cancers.

3.3.8 Standardization and validation of testing, recovery and vaccination certificates

3.3.8.1 Many States require pre-departure testing for COVID-19 as an entry requirement. Standardizing testing certificates will facilitate mutual acceptance by States. Information should be reported in English (mandatory). Where the certificate is issued in a language other than English, the certificate should include an English translation.

3.3.8.2 ICAO has established a minimum data set for testing certificates to facilitate States' recognition and harmonization of their use for air travel. The minimum information to be recorded on the certificate includes:

- a) personal information of test subject:
 - 1) full name (surname, given name);
 - 2) date of birth (YYYYMMDD);
 - 3) ID document type²⁵ (mandatory); and
 - 4) ID document number (mandatory);

22. https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Natural_immunity-2021.1

23. https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Natural_immunity-2021.1

24. <https://www.icao.int/safety/CAPSCA/Pages/default.aspx>

25. Refers to any type of documentation, it does not need be a travel-specific document.

- b) service provider:
 - 1) name of testing facility or service provider (mandatory);
 - 2) country of test (mandatory); and
 - 3) contact details (mandatory);
- c) date and time of test and report:
 - 1) date and time of specimen collection (mandatory); and
 - 2) date and time of report issuance (mandatory);
- d) test result:
 - 1) type of test conducted: molecular (PCR); molecular (other); antigen; antibody (type) (mandatory);
 - 2) result of test (normal/abnormal or positive/negative) (mandatory); and
 - 3) sampling method (nasopharyngeal, oropharyngeal, saliva, blood, other (optional));
- e) optional data field: issued at the discretion of the issuing authority.

3.3.8.3 ICAO has also established a minimum data set for proof of recovery certificates to facilitate States' recognition and harmonization of their use for air travel. The minimum information to be recorded on the certificate includes:

- a) personal information of test subject:
 - 1) full name (surname, given name);
 - 2) date of birth (YYYYMMDD);
 - 3) ID document type²⁶ (mandatory); and
 - 4) ID document number (mandatory);
- b) test result:
 - 1) Member State of test; and
 - 2) date of first positive test result (mandatory);
- c) health-care provider/certificate issuer.

3.3.8.4 Where States do not issue a digital certificate of recovery, the minimum information described in 3.3.8.3 would need to be included in a paper-based format on a formal letterhead of the health-care provider. The document should contain clear contact information and be manually signed by the health-care provider. The individual traveller could be required to have evidence of the positive test result, and any additional certificates issued by the health-care provider, to present to the relevant authority when requested to do so. Verification of paper-based certificates should be compliant with data protection legislation.

3.3.8.5 ICAO has published a core data set for proof of vaccination, recommended by the WHO in August 2021. The information to be recorded on the vaccination certificate includes:

- a) unique certificate identifier (required);
- b) certificate valid from (optional);
- c) certificate valid to (optional);

26. Refers to any type of documentation, it does not need be a travel-specific document.

- d) personal identification:
 - 1) name (required);
 - 2) unique identifier (recommended);
 - 3) additional identifier (optional);
 - 4) sex (recommended); and
 - 5) date of birth (conditional with unique identifier);
- e) vaccination event:
 - 1) vaccine or prophylaxis (required);
 - 2) vaccine brand (required);
 - 3) vaccine manufacturer (conditional with marketing authorization holder);
 - 4) marketing authorization holder (conditional);
 - 5) disease or agent targeted (recommended);
 - 6) date of vaccination (required);
 - 7) dose number (required);
 - 8) country of vaccination (required);
 - 9) administering centre (required);
 - 10) vaccine batch number (required); and
 - 11) due date of next dose (optional).

Notes:

- 1.— “REQUIRED” means that the definition is an absolute requirement of the specification.
- 2.— “RECOMMENDED” means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
- 3.— “OPTIONAL” means that an item is truly optional. One user may choose to include the item because a particular application requires it or because the user feels that it enhances the application, while another user may omit the same item.
- 4.— “CONDITIONAL” means the usage of an item is dependent on the usage of other items. It is therefore further qualified under which conditions the item is REQUIRED or RECOMMENDED.

Example with regard to conditional: the field of vaccine marketing authorization holder is conditional; however, if the marketing authorization holder is unknown, the vaccine manufacturer is REQUIRED.

3.3.8.6 The ICAO Machine Readable Travel Documents (MRTD) Technical Report on Visible Digital Seals for non-constrained environments (VDS-NC) contains the aforementioned minimum and core data sets for testing and vaccination certificates and can readily incorporate the newly developed minimum data set for recording a previous SARS-CoV-2 infection (proof of recovery certificate). More detailed information is available in the manual on *Machine Readable Travel Documents* (Doc 9303, Part 13) specifications.

Validation of testing, recovery and vaccination certificates

3.3.8.7 Member States should implement and recognize certificates of testing, recovery and vaccination based on the protocol, minimum data set and implementation approaches outlined in this manual to facilitate air travel. States are encouraged to ensure such certificates are secure, trustworthy, verifiable, convenient to use, compliant with data protection legislation and internationally/globally interoperable. Proof of vaccination could be based upon the WHO International Certificate of Vaccination or Prophylaxis (ICVP) and should be issued in an internationally/globally interoperable format aligned with the technical specifications and guidance outlined by WHO. Existing solutions should be considered and could incorporate a Visible Digital Seal (VDS-NC) or other interoperable formats from regional or global intergovernmental bodies, or internationally recognized organizations.

3.3.8.8 Certificates may be issued in paper or digital format, depending on capabilities and preferences.

3.3.8.9 There are a number of potential procedural challenges in verifying testing, proof of recovery or vaccination certificates that could cause delays or other potential problems for passengers.

3.3.8.10 States are encouraged to implement the approaches provided in this manual and consider the following processes and/or procedures to facilitate travel through the airport:

- a) make available tools that allow travellers to submit travel-related health certificates;
- b) inform passengers and stakeholders of the requirements with regard to testing, vaccination and verification for international travel purposes;
- c) provide the necessary guidance, resources and support to assist stakeholders; and
- d) ensure these processes and/or procedures are in full compliance with applicable laws and regulations on data protection and privacy.

3.3.9 Guidance on using both testing and vaccination

3.3.9.1 Vaccination provides very effective protection against severe disease, hospitalization and mortality. While vaccination is a key mitigation measure to achieve widespread immunity, the scientific data is not yet mature enough to make a definitive recommendation regarding the efficacy of all currently available vaccines to confer protective immunity, the possible duration of such immunity and the efficacy of vaccination in reducing transmission of current or new emerging VOC. This guidance will be amended as new evidence becomes available and is validated.

3.3.9.2 States are encouraged to share and publish evidence related to their vaccination campaigns as soon as that becomes available, including interim reports to allow for early identification of trends.

3.3.9.3 The WHO recommends that Member States consider a risk-based approach to the facilitation of international travel by lifting measures, such as testing to individual travellers who were fully vaccinated, at least two weeks prior to travelling, with COVID-19 vaccines listed by the WHO for emergency use or approved by a stringent regulatory authority. In addition, there should be consideration for non-vaccinated travellers (refer to 3.3.1.4 i)).

3.3.9.4 Vaccinated individuals may be exempted from testing and/or quarantine measures, in accordance with a State's accepted risk threshold, national framework and COVID-19 situation. However, vaccination should not be a prerequisite for international travel. In view of the global inequity of access to vaccines and the limitations as described in 3.3.9.1, it is recommended that basic multilayer risk mitigation measures, including hygiene, masks and physical distancing where possible, as included and periodically updated in the CART TOGD²⁷ and this manual, are maintained during air travel.

3.4 QUARANTINE PRACTICES

3.4.1 Many States have instituted a period of quarantine for incoming passengers as a measure to prevent importation of new cases. States' implementation of quarantine measures varies and may range from voluntary self-quarantine, to mandatory quarantine in their residence and to enforced restrictions at specified locations. Contracting States implementing quarantine for arriving passengers should comply with the IHR Article 43, which stipulates that such additional health measures should be based upon scientific principles and supported by available scientific evidence of a

27. <https://www.icao.int/covid/cart/Pages/Documents.aspx>

risk to human health, while recognizing that the IHR do not preclude States implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern.

3.4.2 The quarantine period typically applied by States is 10 to 14 days. The WHO recommends the quarantine of contacts of persons with confirmed and probable SARS-CoV-2 infection, for a duration of 14 days from the last contact with the confirmed or probable case, to minimize risk of onward transmission²⁸. However, many States are exploring reducing the quarantine period based upon testing results and vaccination status. There can be considerable logistical difficulties and cost in implementing a quarantine regime, and States electing to utilize quarantine need to plan and prepare accordingly. Quarantine should only be implemented following a thorough risk assessment and with respect for travellers' dignity, human rights and fundamental freedoms, while minimizing any discomfort or distress associated with the health measures applied to them, as outlined in the IHR (2005)²⁹. Depending on the implementation model, States may need to ensure that all needs for transport, accommodation, food, exercise and communication are met and that there is no cross-contamination between those in the quarantine facility including the staff. In some cases, given the frequency of asymptomatic infection, the quarantine is now accompanied by COVID-19 testing.

3.4.3 The WHO identifies two scenarios in which quarantine could be implemented³⁰:

- 1) the restriction of movement of travellers upon arrival from areas with community transmission; and
- 2) for contacts of individuals with confirmed or probable SARS-CoV-2 infection. For all contacts of individuals with confirmed or probable SARS-CoV-2 infection, the WHO continues to recommend quarantine in a designated facility or in a separate room in the household, for a duration of 14 days from the last contact with the confirmed or probable case, to minimize risk of onward transmission.

3.4.4 International travellers should not be categorized as suspected COVID-19 cases and are not considered contacts of COVID-19 in principle unless a traveller meets the definition of a contact. For travellers, the WHO recommends self-monitoring for symptoms on arrival for 14 days, and reporting symptoms and travel history to local authorities, as per instructions received by authorities in the host country, prior to departure and/or on arrival. Any traveller identified as a contact of a COVID-19 case should be supported and quarantined – as part of national response strategies in accordance with WHO guidance for quarantine – and tested if symptoms develop at any point during the quarantine period.

3.4.5 Quarantine may be most applicable to countries with a low incidence of COVID-19 and/or relatively high volumes of unvaccinated arriving air travellers, as well as countries at the tipping point of exponential growth and/or with limited public health and health system capacities to detect and care for new cases. The positive benefits of quarantine in reducing SARS-CoV-2 transmission must be balanced against the related risks of infringement of human rights, psychosocial and economic harm, disruption to travel and trade, reductions in the movement of essential goods and workforce mobility³¹.

3.4.6 If States choose to implement quarantine measures for all passengers upon arrival, they should do so based upon a risk assessment and consideration of above-mentioned considerations, including those for exemption of individuals with vaccine-induced or natural immunity. While quarantine can be an effective means of ensuring any imported cases by asymptomatic passengers do not spread the disease in the community, it can be a disincentive³² to travel, particularly if required after both (outbound and return) legs of an international journey, as can government advisories recommending against travel.

28. <https://www.who.int/publications/i/item/WHO-2019-nCoV-IHR-Quarantine-2021.1>

29. Considerations for implementing a risk-based approach to international travel, Interim Guidance, WHO – 16 December 2020.

30. <https://www.who.int/publications/i/item/WHO-2019-nCoV-IHR-Quarantine-2021.1>

31. <https://apps.who.int/iris/handle/10665/342212>

32. <https://www.iata.org/en/iata-repository/publications/economic-reports/travel-impact-of-quarantine2>

3.4.7 Given the complexities and implications of quarantine, States choosing to implement a quarantine regime should do so after conducting a risk assessment, taking into account the local epidemiology in departure and destination countries; travel volumes between countries; the public health and health system capacity; public health and social measures implemented; and contextual factors, such as assessing all the implications, including non-health related implications, and considering them in accordance with their own national decision-making processes.

3.5 COMBINED TESTING AND QUARANTINE STRATEGIES

3.5.1 For States that choose to apply quarantine measures, such measures should be implemented in conjunction with other public health risk mitigation measures and in accordance with a risk-based analysis conducted by the destination State, considering the epidemiological situation of both origin and destination country or countries and other possible mitigation measures (see Section 3.2 above). A metric may be chosen to assist in this assessment, such as the test positivity rate.

3.5.2 In applying the risk assessment, States should consider their risk tolerance and the risks posed by the travel, and how different mitigation measures may reduce that risk. If travel is from an area of low prevalence to one of high prevalence, then the value of quarantine as a measure may be diminished. In situations where travel is between two countries with similar levels of transmission in the community, any travellers who had been tested negative for COVID-19, meeting the performance based criteria described in Section 3.3.2, upon departure, or had developed natural immunity due to infection and had fully recovered, or had been fully vaccinated would be of lower statistical risk than the non-tested members of the surrounding communities in either country. Travellers that have been tested negative for COVID-19 or have developed natural immunity or have been fully vaccinated could be subjected to no more restrictions than the others in the community at destination.

3.5.3 While quarantine can be effective in reducing SARS-CoV-2 importation when travelling from an area of high community transmission to an area of low community transmission, the introduction of vaccination and testing into the measures applied could potentially be used to reduce the risk of translocation and the duration of quarantine. There is evidence to show that tests reduce the risk of an undetected positive case by some degree, and that a second test (in combination with a period of quarantine) further reduces that risk³³.

3.5.4 Public health authorities should make the final decisions about how long quarantine should last, based on local conditions and needs. Options to consider reducing quarantine are as follows:

- After day 10 without testing or after day 7 after receiving a negative test result (test must occur on day 5 or later)
- After stopping quarantine, a person should:
 - monitor for symptoms until 14 days after travel;
 - if symptoms develop, immediately self-isolate and contact the local public health authority or healthcare provider;
 - wear a mask, stay at least 6 feet from others, wash hands, avoid crowds, and take other steps to prevent the spread of COVID-19; and

33. Animal and Plant Health Agency (APHA), UK. Rachel A. Taylor, et al.; Tropical Medicine, UK, Samuel Clifford, et al and "Investigation into the effectiveness of "double testing" travellers incoming to the UK for signs of COVID-19 infection", Public Health England Modelling Cell.

- while a quarantine for 14 days is the general recommended period, a quarantine period shorter than 14 days reduces the burden to travellers and the community. Public health authorities should continue to evaluate new information and update recommendations as needed.³⁴

3.5.5 On a careful analysis of the risks and evidence, as well as the government's risk tolerance, if the prevalence of infection at the point of origin of the passenger is less than or equal to, depending on risk tolerance, to the local prevalence at destination, and the passenger is not ill and/or has a negative test for COVID-19, or is vaccinated, or has recovered from COVID-19 infection, governments might consider relaxing or avoiding quarantine measures. Alternatively, governments may determine that quarantine measures can be combined with other measures including testing to reduce the duration of quarantine. A model has been developed taking into account serial antigen testing as a possible option to reduce quarantine duration. This model is undergoing refinement and further updates might be provided in the future.

3.5.6 Several studies conclude that the combination of quarantine with other public health and social measures improves its effectiveness; and that combining quarantine with SARS-CoV-2 testing, particularly repeated testing, may not only improve effectiveness but also reduce the duration of quarantine³⁵. Policies for testing and quarantine should be regularly reviewed to ensure they are lifted when they are no longer necessary.

3.6 VACCINATION AND VACCINATED PERSONS

3.6.1 Vaccination concepts

3.6.1.1 Vaccination is a critical public health tool to bring the COVID-19 pandemic under control globally. At the time of publication, some vaccines have been recommended by WHO, with additional vaccines being added progressively for assessment for emergency listing/ pre-qualification.³⁶ States have begun to roll out their vaccination programmes, with the aim of protecting their populations and stop the spread of the virus.

3.6.1.2 Control of SARS-CoV-2 will depend on:

- a) the prevalence of infection and of circulating variants;
- b) the rate of growth or decline in incidence;
- c) the types, use of and adherence to control measures in place;
- d) the speed with which vaccination occurs;
- e) the targeting and uptake of the vaccines among high-risk groups;
- f) vaccine effectiveness;
- g) natural immunity and vaccine coverage in the population; and
- h) emergence of new VOC.

34. <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html>

35. <https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2021.1>

36. https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_16Feb2021.pdf

3.6.1.3 There are increasing levels of protection of the general population through natural infection and vaccine-derived immunity. Vaccines have shown high levels of protective efficacy against COVID-19, however, some vaccinated persons may still become infected and develop disease, which in most instances is mild. Vaccinated individuals may also still transmit the virus, albeit at lower intensity. International travellers who are vaccinated are unlikely to develop severe COVID-19 disease and consequently they do not impose increased strain on health systems at the countries of destination.

3.6.1.4 WHO data also indicate that vaccination reduces transmission of SARS-CoV-2, although this data did not include information on VOC. Current preliminary data indicate that the Delta variant can be transmitted by vaccinated individuals, although further studies are needed to provide further information. Preliminary data on Delta variant breakthrough infections indicates that high-risk individuals, e.g. older persons and those with chronic illnesses or being treated with immune-system drugs are at a higher risk. Such individuals might benefit from booster doses of vaccines.

3.6.1.5 The CAPSCA COVID-19 Aviation Scientific Assessment Group (CASAG) performed a literature search and review of scientific articles and technical reports, including observational studies in vaccinated populations to demonstrate:

- a) an association between vaccination and protection of an individual from asymptomatic infection; and
- b) an association between vaccine coverage and protection from transmission within the population.

3.6.1.5 The main conclusions of the CAPSCA report: "Vaccination and its Effect on SARS-CoV-2 Onward Transmission: A Narrative Review"³⁷ based on available evidence, include that:

- a) vaccination against COVID-19 substantially reduces mild/asymptomatic infections, (as well as preventing most severe/fatal infections); and
- b) vaccination substantially reduces transmission of SARS-CoV-2, which indicates that on a travel setting, fully vaccinated travellers might not be drivers of onward transmission of SARS-CoV-2.

3.6.1.6 However, limitations identified by the review, including vaccine types, variant emergence, non-standard intervals of administering vaccine doses, combinations of different vaccines, certain medical conditions, and possible decline in immunity over time, need to be monitored and updated as new evidence becomes available.

3.6.1.7 Available data across different population groups and VOC, confirm that the protection against asymptomatic and symptomatic infection and severe disease conferred by full vaccination (specific vaccines were assessed) is significantly higher than with partial vaccination. Evidence is limited with regard to long-term effectiveness of partial vaccination³⁸. The ECDC recommends that, in the context of increasing circulation of the Delta VOC, full vaccination should be achieved as early as possible and the second vaccine dose be administered after the shortest possible interval, with priority given to population groups at highest risk of severe outcomes following SARS-CoV-2 infection.

3.6.1.8 Evidence from studies on heterologous ('mix and match') vaccination suggests **strong or enhanced antibody response** and that the combination of vaccines were generally well tolerated (specific combinations were assessed³⁹). While research is ongoing to provide more evidence on long-term safety, duration of immunity and effectiveness, the use of heterologous schedules may offer flexibility in terms of vaccination options, particularly to mitigate the impact on the vaccine roll-out should a vaccine product not be available, or if it is discontinued or paused. States are encouraged to share such vaccination information with other States and accept these measures for bilateral recognition in order to restore international travel.

37. <https://www.icao.int/safety/CAPSCA/Pages/default.aspx>

38. <https://www.ecdc.europa.eu/en/publications-data/partial-covid-19-vaccination-summary>

39. <https://www.medrxiv.org/content/10.1101/2021.07.26.21261130v1>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233006/>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8381713/>

3.6.1.9 Other areas where there is limited evidence available and where more research is needed regarding the effects of vaccination on protection from the effects of COVID-19 and onward transmission include:

- a) the need for booster vaccine shots;
- b) vaccination of children and adolescents; and
- c) the need for two doses of vaccine when considering the immunity conferred in relation to recovery from COVID-19 infection.

Note 1.— The rationale for implementing booster doses should be guided by evidence on waning vaccine effectiveness, in particular a decline in protection against severe disease in the general population or in high-risk populations, or due to a circulating VOC⁴⁰.

Note 2.— Preliminary laboratory evidence suggests that antibody responses following COVID-19 vaccination provide better neutralization of some circulating variants than does natural infection. Preliminary study findings suggest that full vaccination provides additional protection against reinfection⁴¹. Further studies are required to provide more information.

3.6.1.10 ICAO will continue to monitor available evidence and update guidance material accordingly. At the time of publication, vaccines against COVID-19 are not available across all States. There is also limited evidence regarding the efficacy of vaccines against current and potentially new VOC.

3.6.1.11 In summary, until the majority of the global population has been vaccinated, control of disease will continue to rely on the use of a multilayer risk management approach, e.g. wearing of masks and testing, modulated by different levels of vaccination⁴².

3.6.2 A multilayered risk management strategy: calibrating testing and quarantine strategies for vaccinated persons

3.6.2.1 In addition to its important role in bringing the pandemic under control, vaccination may also play an important role in aviation recovery as the vaccinated proportion of the global population increases over time.

3.6.2.2 Early evidence points in the direction that unvaccinated individuals are more susceptible⁴³ to symptomatic infection than vaccinated individuals. Furthermore, vaccination significantly reduces the severity of symptoms and morbidity should a vaccinated individual become infected. Due to the limited availability of vaccines, it should be used for priority populations considered at high risk of severe COVID-19 disease. In the context of limited supply, the WHO does not recommend COVID-19 vaccination of travellers, unless they belong to a high-risk group (including older persons or those with underlying medical conditions) or in epidemiological settings identified in the WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines.⁴⁴

40. <https://www.who.int/news/item/10-08-2021-interim-statement-on-covid-19-vaccine-booster-doses>

41. <https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm>

42. <https://www.who.int/publications/i/item/considerations-in-adjusting-public-health-and-social-measures-in-the-context-of-covid-19-interim-guidance>

43. <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>

44. WHO: WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the context of limited supply <https://www.who.int/publications/i/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply>.

3.6.2.3 States should also facilitate access for air crew for vaccination as quickly as possible within the WHO SAGE Stage recommendations as an important means to recovery of international civil aviation. The SAGE prioritization roadmap supports countries in planning and suggests public health strategies and targeting priority groups for different levels of vaccine availability and epidemiologic settings. At the time of publication, aviation workers, other than cargo aircraft crew, would be included in the category of transport workers, falling within Stage III, i.e. to be vaccinated when there is moderate vaccine availability and between 21 per cent and 50 per cent of the national population has been vaccinated. Air crew who work on aircraft that carry goods and no passengers fall within Stage II, when there is limited vaccine availability and between 11 per cent and 20 per cent of the national population has been vaccinated

3.6.2.4 The protective effect of vaccination of individuals is another layer of the multilayer risk strategy in the mitigation of the effects of COVID-19 and reduction in disease transmission. The situation is evolving rapidly considering the emergence of new variants and the efficacy of current vaccines on these variants. It is likely that not all vaccines will offer the same level of protection against the different variants and that different vaccines could be used in different parts of the world.

3.6.2.5 States should also take into consideration other relevant factors, such as local incidence rates of the travel origin of the vaccinated person or the potential community transmission of new viral strains against which the existing vaccines may offer a lower level of protection.

3.6.2.6 Recognizing the dynamic evolution of such a diverse scenario, States' assessment of the risk of a vaccinated person carrying the SARS-CoV-2 virus could factor in both the vaccine efficacy against transmission of the virus and the incidence rate of the travel origin. This would help to determine the degree of relaxation of testing requirements or quarantine requirements for vaccinated persons (dependent on efficacy of vaccines against transmission and access to vaccination).

3.6.2.7 WHO has updated its previous position as of 5 February 2021 and now recommends that proof of vaccination could exempt international travellers from some specific travel risk reduction measures (refer to section 3.3.9.4). States are encouraged to accept all types of vaccines that have been recommended by WHO on the EUL for vaccines.

3.6.2.7 Updated guidance on these issues will be published periodically as evidence becomes available and as the WHO updates its guidance.

3.6.3 Safety considerations for vaccinated aviation workers

3.6.3.1 States are encouraged to recognize aircrew, front-line aviation workers and aviation workers in critical safety and security positions as essential workers to ensure the availability of air transportation during the COVID-19 pandemic. They should be encouraged to be vaccinated as an added layer of individual protection and follow the recommended vaccination considerations and protocols. States should facilitate the vaccination of these essential air transport workers in accordance with the WHO SAGE Stage II and Stage III recommendations.

3.6.3.2 Vaccination considerations and protocols for crew:

- a) Air crew vaccination should be administered using vaccines approved for use, including emergency use, by the Health Authority or the Civil Aviation Authority of the State in which the air crew member's licence is issued or rendered valid.
- b) Dosing intervals for the vaccine should take into account the impact on operations with vaccination being given at different times to different individuals to ensure continuity of service.
- c) After vaccination, flight crew may return to duty if they are fit to do so in accordance with national guidelines.

- d) ICAO does not recommend a universal mandatory administrative post-vaccination grounding period. However, States may wish to consider post-vaccination grounding periods or other mitigation measures based on their own risk assessments. Considerations include:
- 1) vaccine side-effect profile;
 - 2) type of vaccine authorization (e.g. licensed or authorized for emergency use);
 - 3) individual reactions after first dose, which could indicate a grounding period after the second dose (if applicable).

3.6.3.3 In States where crew have already been vaccinated or where States are considering vaccinating crew, it should be noted that vaccines authorized in one country/region may not be under consideration or may be explicitly unauthorized in others. To this end, States should use vaccines considered within the WHO EUL/PQ evaluation process⁴⁵.

3.6.4 Validation of vaccination certificates

3.6.4.1 In view of the current evidence regarding the extent and duration of immunity after infection or vaccination, and in line with WHO recommendations, issuance of an “immunity passport” or “risk-free certificate” is currently not recommended.⁴⁶ While the WHO does not include international travellers in a priority category for vaccination, vaccinated individuals should be given documentation in accordance with national policies.

3.6.4.2 The WHO encourages States to consider recording proof of COVID-19 vaccination in the International Certificate of Vaccination or Prophylaxis (ICVP), as stated in the WHO interim position paper: considerations regarding proof of COVID-19 vaccination for international travellers. The WHO’s Digital Documentation of COVID-19: Vaccination Status Technical specifications and implementation guidance⁴⁷ provides Member States with guidance on the necessary requirements for a digital solution, as well as implementation considerations to take into account.

3.6.4.3 States are encouraged to request that evidence of vaccination status is captured in hard copy or digital documentation or within an appropriate national registry, as determined by relevant national authorities. Member States should implement and recognize vaccination certificates based on the core data set outlined in Section 3.3.8.5.

3.6.4.4 States are encouraged to ensure that vaccination certificates are secure, trustworthy, verifiable, convenient to use, compliant with data protection legislation and internationally/globally interoperable. Proof of vaccination could be based upon the WHO ICVP and should be issued in an internationally/globally interoperable format aligned with the technical specifications and guidance outlined by the WHO. Existing solutions should be considered and could incorporate a VDS-NC or other interoperable formats from regional or global intergovernmental bodies, or internationally recognized organizations.

45. Status_COVID_VAX_16Feb2021.pdf (who.int)

46. <https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19>

47. <https://reliefweb.int/report/world/digital-documentation-covid-19-certificates-vaccination-status-technical-specifications>

Chapter 4

IMPLEMENTATION — MODEL FOR MULTILAYER ASSESSMENT AND MITIGATION

4.1 OVERVIEW

4.1.1 Many States have implemented risk mitigation strategies such as temperature measurements, traveller symptom questionnaires, COVID-19 testing, vaccinations, and a variety of travel restrictions such as border closures, entry bans from specific States, quarantines, etc. However, these measures are not harmonized across States. Furthermore, there is very limited mutual recognition of mitigation measures even for States with equal COVID-19 prevalence. States should assess their own level of COVID-19 disease burden, health system capacity, availability of testing and vaccines, and level of risk tolerance. Once established, States can share risk assessments with other States and begin to discuss developing bilateral or multilateral agreements to open public health corridors and stimulate the return of air travel. Harmonization of procedures is crucial for facilitating air transport, and new practices should be coordinated with other States and stakeholders. In developing bilateral arrangements, States will need to consider the implications of hub traffic flows, and how they will accommodate third country-originating passengers.

4.1.2 To establish an internal State risk level, States should identify experts from State authorities, including but not limited to aviation (national authorities and industry), public health, customs and immigration, diplomatic organizations and legal departments, who can work collaboratively to assess the State's current status with respect to disease patterns. This collaborative assessment effort should be undertaken in a forum appropriate to a State's system, but can be undertaken by each State's National Air Transport Facilitation Committee (or equivalent) as per CART report Recommendation 6, which urges Member States that have not done so, to immediately establish a National Air Transport Facilitation Committee, as required by Annex 9 — *Facilitation*, in order to increase national level cross-sectoral coordination. The assessment should address the current capabilities to identify, diagnose, and treat COVID cases as well as the status of the health-care system and the State's overall willingness and readiness to accommodate increased passenger flows. After reviewing this document and the CART Take-off Guidance available on the ICAO public site (<https://www.icao.int/covid/cart/Pages/CART-Take-off.aspx>), States should identify the risk tolerance they can accept on a bilateral basis and the mitigation measures that could be employed to meet that target using a safety management system (SMS) approach.

4.1.3 Although data-driven decision making is encouraged, the current scenario may require a qualitative approach, as validated data and information is incomplete. By implementing a combined strategy and assessing if an acceptable residual risk is achieved, States should also evaluate alternatives to reduce or eliminate the burden to the system posed by selected mitigation measures. Some consideration must be given to how those measures should vary according to different stages of the pandemic in accordance with the stages in the CART Take-Off Guidance document (<https://www.icao.int/covid/cart/Pages/CART-Take-off.aspx>).

4.1.4 Procedures related to each stage and measure should be aligned while considering availability, efficacy, costs and implementation challenges for each State.

4.1.5 Consistency with the State's national COVID-19 response policy and strategy is important, for example, medical masks may be recommended in aviation, but their availability should be prioritized for health workers and the public health response. In considering restrictions on aviation, the State should consider the role that aviation plays in the

economy of the State and the public health response itself (such as the distribution of personal protective equipment (PPE), test kits, medicines and vaccines). States should ensure alignment between the various public policies and measures applied across government.

4.2 GENERIC BASELINE MODEL FOR MULTILAYERED RISK ASSESSMENT AND DETERMINING MITIGATION MEASURES (FOUR-STEP PROCESS)

4.2.1 Introduction

This model has been developed to illustrate a baseline approach that States could use on a bilateral or multilateral basis to assess risk at the points of origin and destination, and to assist in the selection of available risk mitigation measures. States should align the process to integrate with other national decision-making processes and to meet available conditions.

4.2.2 Step one — Determine that the following conditions have been met

This model is based upon the following assumptions (refer to CART take-off guidance (<https://www.icao.int/covid/cart/Pages/CART-Take-off.aspx>) and on WHO travel advice (guidance “Technical considerations for implementing a risk-based approach to international travel in the context of COVID-19”).

- a) travellers follow appropriate universal precautions at every stage of the travel continuum and:
 - 1) do not travel when sick;
 - 2) adhere to hand and respiratory hygiene practices;
 - 3) use a face mask (with exceptions as appropriate);
 - 4) practice physical distancing to the extent possible to lower the risk of disease spread; and
 - 5) adhere to instructions provided by airport and airline personnel;
- b) persons who test positive or are diagnosed with COVID-19 pre-travel do not travel and public health authorities are notified;
- c) persons who test positive at arrival isolate, and public health authorities are notified;
- d) close contacts of persons who test positive or are diagnosed pre-travel should be identified, quarantined, and not travel;
- e) close contacts of persons who are positive post travel should be identified (including fellow passengers), and quarantined. Where necessary, international contact tracing operations should be launched;
- f) persons who have not been fully vaccinated or do not have proof of previous SARS-CoV-2 infection and are at increased risk of developing severe disease and dying, including people 60 years of age or older or those with comorbidities that present increased risk of severe COVID-19 (e.g. heart disease, cancer and diabetes) should be advised to postpone travel to areas with community transmission;

- g) all incoming travellers must follow recommendations and continue to adhere to personal protective measures, such as the use of masks and physical distancing both while on board aircraft and at airports; and
- h) mechanisms are established to obtain and share complete, accurate and timely contact information to allow public health authorities to execute necessary public health actions.

4.2.3 Step two — Identify the effectiveness of existing measures

There is a range of measures to reduce translocation of disease. The measures vary in their effectiveness; effectiveness in this context is defined as the extent to which the measures are estimated to reduce the risk of introducing infectious individuals into the community at the destination. Each measure represents a defence layered in a multilayered risk management process and will also need to be assessed for its efficacy and interdependency, when implemented in concert with other measures. Multiple models and tools allow States and other interested parties to estimate effectiveness of multilayered approaches. While a multilayered risk mitigation process should be followed, the relative merit of individual strategies is provided in Attachment B and will be updated in the future in accordance with scientific evidence.

4.2.4 Step three — Determine relative risks

The risk of translocating (transferring) COVID-19 from one State to another can be determined by looking at four conditions within States: percentage of immune persons (vaccinated and naturally acquired), prevalence, test positivity rate and testing rate. The cut-off values associated with each condition below is intended to provide guidance on a possible framework for determining the risk levels in accordance with a colour code:

Potential cut-off values:

1. Percentage who are non-immune persons (vaccinated or naturally acquired) – below 30 per cent.
2. Prevalence — 7-day cases per 100 000 rate (rolling rate averages) with a cut-off of 25 cases per 100 000.

Note.— Some States favour using a rolling rate determined over a 14-day period.

3. Test positivity rate — 5 per cent as the cut-off with the goal of being below 5 per cent where tests are widely available for screening.
4. Testing rate — This condition would only be met if a State meets a testing capability of 250 tests per 100 000 people per week.

Possible colour coding based on conditions and cut-off values:

- Green: The origin State/area is below the cut-off values of 1, 2 and 3 above.
- Orange: The origin State/area is below the cut-off values of 2 of the three values above, but not all three.
- Red: The origin State/area exceeds the cut-off values for all three.
- Grey: there is insufficient data, or the State/area does not meet item 4.

Note.— This risk assessment framework might be updated in future taking into account different or additional conditions, testing strategies, potential cut-off values or colours as the pandemic continues to evolve.

4.2.5 Step four — Determine measures based upon identified risk levels

4.2.5.1 The model below is given as an example of how relative risk levels could be used in determining the appropriate risk mitigation measures:

- From green to any colour: No restrictions or requirements.
- From orange to any colour: Could require passenger locator forms and/or tests, but no travel restrictions.
- From red or grey to any colour (particularly to green): Could restrict traveller's movements depending on symptoms and exposure and/or test.

4.2.5.2 States should consider the following exemptions subject to a risk assessment:

- crew members (including those positioning to and from duty);
- personnel critical for health-care delivery; or
- workers essential to maintaining the safety of the airspace.

Such personnel should not be made to quarantine unless they are ill or have been in close contact with symptomatic individuals. Should States decide to require testing for such personnel, rapid and non-invasive testing should be given preference.

4.2.5.3 As COVID-19 vaccination becomes more available and is progressively implemented across the world, it would be appropriate for States to consider the vaccination status of travellers and crew members when determining the measures to be applied, on the basis of reduced risk of translocating COVID-19 cross-border by the vaccinated persons compared to non-vaccinated persons. Conceptually, a lower risk classification may be applied for vaccinated persons.

4.2.5.4 States that have vaccinated a large proportion of their vulnerable population may also consider their risk levels given the reduced possibility of mortality within their State due to translocation.

Note.— Travellers originating outside of the departure State may need to be separately evaluated upon arrival in comparison to people who were in the departure State for over 14 days. Where a suitable legal and administrative framework is in place to allow for such use, Passenger Name Record (PNR) data, Advance Passenger Information (API), border control records and other passenger information tools could be used to assist in identification of some passengers who do not self-declare.

4.3 SAMPLE SCENARIOS

The case scenarios below are provided as practical illustrations of the risk assessment process outlined above. Additional case scenarios, incorporating the effects of vaccination and VOC, will be provided as supplementary attachments as more evidence becomes available in the future, and as the pandemic continues to evolve.

Scenario 1

State A has a 7-day rolling average of 7.0 cases per 100 000, a downward trajectory of cases, readily available testing, less than 5 per cent positive tests, and over 25 per cent of hospital beds empty. State B has a 7-day rolling average of 7.8 cases per 100 000, a stable trajectory of cases, readily available testing, less than 2 per cent positive tests, and over 20 per cent availability of hospital beds. States A and B could reasonably enter into a discussion to allow free travel between regions and implement minimal risk mitigation measures.

Options:

- As they are both in the “green” category, no intervention is a potential option.
- Providing passenger information on routine public health measures with public health authority contact details, and requiring reporting should someone become ill.
- Electronic-based monitoring for a period of time if a more active approach is desired.

Scenario 2

State C has a 7-day rolling average of 43.4 cases per 100 000, an increasing disease trajectory, testing only for symptomatic cases and close contacts, over 20 per cent positive tests, and less than 10 per cent available hospital beds. State D has a 7-day rolling average of 12.6 per 100 000, readily available tests, and 20 per cent availability of hospital beds. States C and D could negotiate a risk mitigation agreement where citizens of State D could freely travel to State C, but citizens of State C would be subject to enhanced mitigation strategies.

Options:

- Travellers from State D could move freely about State C with a combination of one or all of the following: traveller education on routine public health measures with public health authority contacts and reporting procedures, electronic based monitoring, and/or traveller questionnaires with contact details.
- Travellers from State C to D could be quarantined with testing for early release, utilize serial testing, or some other active monitoring (smartphone applications, routine call-ins from public health authorities, limited restrictions such as business activities only). Travellers with a valid vaccination certificate or certificate of recovery may be subjected to less stringent testing and quarantine requirements. Passenger education could be a part of the overarching measures as stated above. PHC questionnaires could be utilized for rapid contact tracing if necessary.

Scenario 3

Testing details and hospital data are unavailable. State E has a 7-day rolling average of 30.2 per 100 000 and readily available tests. State F has a 7-day rolling average of 23.6 per 100 000 and tests only available for symptomatic cases and close contacts. State F is dependent on tourism.

Options:

- These States could enter an agreement where persons from State F could travel to State E with minimal mitigation strategies similar to travellers from State D to C as above.
 - Those from State E to F could have slightly enhanced strategies depending on each State’s risk tolerance. Options could include some or all of the following: serial testing with reduced or no quarantine, short periods of isolation with a negative test for release, electronic contact tracing/monitoring with daily reporting of symptoms and a post-arrival test at 5-7 days, and/or the use of “do not board” lists for recalcitrant individuals. Travellers with a valid vaccination certificate or certificate of recovery may be subjected to less stringent testing and quarantine requirements. Passenger education of public health measures and reporting requirements would be critical.
-

Chapter 5

PUBLIC HEALTH CORRIDOR

5.1 PRINCIPLES

5.1.1 A public health corridor (PHC) is formed when two or more States or regions agree to recognize the public health mitigation measures each has implemented on one or more routes between their States. The PHC concept enables essential cargo services, humanitarian flights, repatriations and medical evacuations to continue with minimal interruptions or delays, while protecting the health of aircrew, and mitigating the spread of the disease. It also plays a significant role in aviation safety, enabling aircrew and maintenance personnel to renew their licences and obtain recurrent training. PHCs are built upon a risk-based approach to ensure as far as possible a “COVID-19 free” journey.

5.1.2. States are strongly encouraged to consider PHCs as an effective useful way to structure a collaborative approach to managing cross-border health risks. For example, exchange of information through PHCs will enable States to mutually recognize their respective public health risk management frameworks and to establish temporary and exceptional bilateral or multilateral arrangements within which air travel can be resumed.

5.1.3 To support States in the establishment of PHCs, ICAO has developed:

- a) targeted assistance in the ICAO Implementation Package (iPack);
- b) a PHC template on the COVID-19 Response and Recovery Implementation Centre (CRRIC)¹ that enables States to actively share information;
- c) a new application (PHC App) featuring the PHC arrangement template and online builder to facilitate discussions between two or more States and/or a region; and
- d) general tools published on the ICAO PHC website², providing detailed guidance, tools and checklists for implementing public health risk mitigation measures using a multilayered risk-based approach.

5.1.4 States are encouraged to actively share information with other States by means of the PHC template on the CRRIC. The PHC App takes into account data and information provided by States on the PHC template, as well as the local epidemiology in departure and destination States that have been reported to WHO, which is incorporated into the PHC App. The App uses the data to calculate the risk of transmission between States utilizing a traffic light system (refer to section 4.2.4) and includes a template to establish a PHC arrangement, identification of routes for the arrangement, data regarding disease translocation risk levels, and a list of public health measures to be considered in the arrangement.

5.1.5 A PHC arrangement is built on the principles of a stand-alone arrangement in bilateral (or multilateral) State relations due to its exceptional and temporary nature. It would not be considered an amendment to existing air services agreements or a reason for future re-negotiations of air services agreements, and States should use the instrument appropriate to their legal systems, whether treaty- or less-than-treaty-status instruments, such as a Memorandum of Understanding. As with any other Memoranda of Understanding, the inclusion of a provision on registration with ICAO (in reference to Article 83 of the *Convention on International Civil Aviation*) is up to the Parties' discretion.

1. <https://www.icao.int/covid/Pages/crric.aspx>

2. [https://www.icao.int/safety/CAPSCA/Pages/Public-Health-Corridor-\(PHC\)-Implementation-.aspx](https://www.icao.int/safety/CAPSCA/Pages/Public-Health-Corridor-(PHC)-Implementation-.aspx)

5.1.6 In forming a PHC, it is anticipated that participating States would apply a mutually supportive multilayered risk-based approach to their implementation of public health mitigating risk measures, which includes a wide-ranging set of considerations spanning across different sectors. A combination of risk mitigation measures will provide better protection than the implementation of only one or two selected risk mitigation measures. By collaborating on the measures implemented, States can establish a risk mitigation strategy that most effectively aligns to their risk tolerance and to their health and safety management systems. Dependent upon the agreements between States, crew or passengers might be exempted from COVID-19 testing, quarantine or other requirements. Alternatively, they could benefit from reduced requirements.

5.1.7 A PHC arrangement should include criteria for regular review (including scheduled review and whenever circumstances change), suspension (e.g. in case the number of infections raise dramatically in one State in comparison to another State) and termination (e.g. when the pandemic has been brought under control).

5.1.8 ICAO developed the “Establishing a PHC” Implementation Package (iPack), which expands on existing guidance, provides access to certificated training courses, as well as a practical hands-on workshop updated regularly with the latest scientific evidence and lessons learned. It also includes dedicated subject matter experts to work remotely with States and industry partners.

5.2 ELEMENTS OF A PHC

5.2.1 Crew journey through a PHC

- a) Pre-departure testing is conducted based on a risk assessment and requirements of the departure and destination States.
 - 1) Test standards are established taking into consideration recognition of the test by the destination State, avoiding the need for an additional test on arrival.
 - 2) Considerations are made for vaccinated crew in accordance with scientific understanding, as discussed in Chapter 3, 3.1.5 and 3.6.
 - 3) Considerations should be made for crew who have recovered from a COVID-19 infection and may return a positive test while not being in an infectious phase of the disease, as discussed in Chapter 3, 3.1.5 and 3.3.7.
- b) Crews are separated from the general public in the airport, including through the use of dedicated security and immigration facilities as recommended in the CART Take-Off Guidance Airport module (<https://www.icao.int/covid/cart/Pages/CART-Take-off.aspx>). Airports are encouraged to become accredited through the Airport Health Accreditation programme run by Airports Council International (ACI) and supported by ICAO. Airport Health Accreditation provides assurance to States and passengers that the health and hygiene guidelines in the TOGD are being implemented. Airlines are encouraged to make use of the International Air Transport Association (IATA) Health Safety Checklist for Airline Operators also directed to ensuring alignment with ICAO guidance and industry best practices.
- c) The aircraft is disinfected in accordance with the manufacturer’s instructions, as recommended in the CART Take-Off Guidance Aircraft module.
- d) In the aircraft, the crew take appropriate precautions against the transmission of COVID-19, as described in the CART Take-Off Guidance Crew module. Operators should provide the necessary procedures, training and equipment.

- e) At the destinations where crews disembark from the aircraft:
 - 1) crew are separated from the general public for any necessary immigration, security or health checks;
 - 2) crew are provided with disinfected transport where COVID-safety protocols are able to be applied;
 - 3) where crews are making use of a rest period, a clean hotel room is provided;
 - 4) quarantine of crew members, if required, takes into account the prevalence of the disease and segregation factors;
 - 5) for crew members subjected to quarantine requirements:
 - i) adequate food is available at times that correspond to the needs of the crew member; and
 - ii) access to exercise or outdoor space is provided with COVID safety protocols implemented to promote mental well-being.
- e) On the return to base, crew members who have operated within the PHC with limited exposure to the general population at the destination airport, should be considered to have a similar risk profile as any other resident and should therefore not be subjected to additional testing or quarantine.

Note.— Guidance for crew management according to the measures identified in the airline's own risk assessment should be consulted in accordance with the CART TOGD Crew Module (page A-40 'Layover') (<https://www.icao.int/covid/cart/Pages/CART-Take-off.aspx>).

5.2.2 Passenger journey through a PHC

An example of information to be communicated to passengers prior to booking a flight, taking into account data protection considerations, is described below.

5.2.2.1 Pre-departure

- a) Confirm and follow the States' requirements (departure, transfer, and arrival) at time of booking and close to departure.
- b) Consult airport/airline website and get acquainted with COVID-19 specific airport/airline recommendations and instructions.
- c) Obtain a COVID-19 health insurance (if necessary or recommended).
- d) Ensure that vaccination is completed at least two weeks prior to travel, if choosing to be vaccinated.
- e) Book an appointment in an approved testing facility in time to comply with States' requirements.
- f) Present an identification document during the test and collect testing results.
- g) Obtain authorized test result, proof of recovery certificate or proof of vaccination (if applicable); and upload it to a Smartphone App and/or provide relevant information via a government portal (if applicable).

- h) Ensure all travelling and entry requirements are fulfilled prior to departure to the airport.
- i) Make sure to have a copy of the printed test result, proof of recovery or proof of vaccination (if applicable) or the digital certificates available to present at the airport.
- j) Prepare your own travel kit (sufficient number of face masks for travel, hydro alcoholic gel less than 100 ml, etc.).
- k) Do not travel if you are feeling unwell, have symptoms suggestive of COVID-19 or if you have been in contact with someone with COVID-19, and inform the air carrier in advance.
- l) Check for possible changes in requirements prior to travel and ensure that there have been no recent changes.

5.2.2.2 *At the airport*

- a) Arrive within the time frame as communicated by the airline.
- b) Check in online or check in early to ensure compliance with travel requirements.
- c) Comply with airport/airline instructions, including completion of any additional forms as requested.
- d) Respect COVID-19-specific recommendations measures in place, including face masks, physical distancing, etc.
- e) Comply with designated airport pedestrian traffic movement and management indicators in place for COVID-19, including one-way corridors, separation of staff and traveller areas, physical distancing indicators, and hygienic recommendations for the use of touch screens, pens, etc.

5.2.2.3 *On board*

- a) Listen and follow crew instructions:
 - when to wear or remove face masks;
 - how to dispose of face masks; and
 - how to use lavatories, etc.
- b) Avoid touching other passengers' belongings.
- c) Occupy only assigned seat.
- d) Minimize movement in the cabin.
- e) Complete passenger locator form, health questionnaire or other required documentation as completely as possible.

5.2.2.4 On arrival

- a) Comply with airport COVID-19 specific recommendations and instructions.
- b) If required, ensure health certificates (digital or printed) are readily available to show health or border control authorities.
- c) Respect measures in place, including face masks, physical distancing, etc.
- d) Complete passenger locator form, health questionnaire, customs declaration and other documents as requested.

5.3 IMPLEMENTATION OF A PHC ARRANGEMENT BETWEEN STATES

Bilateral and/or multilateral agreements should be based on the following principles:

- a) national and international policies (health, welfare, transport, immigration, legislation, etc.);
- b) available public health capacity;
- c) State priorities and operational needs;
- d) availability of resources (including equipment, system requirements, financial resources, human resources);
- e) implementation of public health measures based on the epidemiological situation;
- f) agreement on criteria for implementation of testing and vaccination policies (including advantages and disadvantages, resources, availability, costs, practicalities of administration, duration of immunity, ensuring integrity of certificates, etc.);
- g) implementation of quarantine policies;
- h) management of multiple scenarios within a specified corridor and possible impact on other corridors managed within each State;
- i) establishment of a robust information exchange system agreed among all participants (including contact points, chain of command, type of data to be shared, data quality, processes and procedures to share results, analysis of the results, etc.);
- j) channels for information-sharing, within and outside of the PHC arrangement;
- k) obligation to inform participating States immediately and comprehensively if epidemiological situation, risk assessment or public health requirements change; and
- l) decision-making framework based on the mutual recognition of acceptable risk thresholds of participating States.

5.4 STAKEHOLDER AND PASSENGER COMMUNICATION

5.4.1 Establishing PHCs between States requires the sharing of information within national departments of a State, and internationally between States, necessitating cooperative decision-making. Existing cooperation mechanisms may not be sufficient to implement bilateral or multilateral arrangements between States during public health emergencies, especially when there are several States and multiple sectors involved.

5.4.2 In order to mitigate the challenges of implementing a PHC, it is important to work in close coordination with all relevant national stakeholders, including aircraft and airport operators in each stage of the PHC planning, thus establishing a shared understanding of the outcomes each State wishes to achieve and ensuring clear communication channels with all relevant stakeholders and the travelling public.

5.4.3 States are encouraged to share any relevant information about their PHC arrangements on the ICAO CRRIC, with other States not party to a specific PHC arrangement and all relevant stakeholders, in order to promote, as far as possible, a harmonized approach through recognition of mitigation measures globally.

5.4.4 States and relevant stakeholders are further encouraged to share relevant information with the public in order to avoid confusion and disruptions that could negatively affect passenger confidence and return to travel.

Chapter 6

TRANSITIONING FROM CRISIS RESPONSE TO ROUTINE OPERATIONS

6.1. In the future, once the immediate crisis has been managed, performance indicators would need to be developed to determine the transition from a crisis management mode to a “new normal” or routine operational mode, which could be similar or different from pre-pandemic operations.

6.2 Performance indicators could serve as signposts as to when States could consider transitioning to a normalized operational mode. This transition is typically based on the assessment of required vs. available resources to manage the residual risk, taking into consideration criteria discussed in this manual. Additional criteria might also be considered by a State based on other non-COVID-19 related considerations.

6.3 Such performance indicators could include, for instance, the percentage of the population that has been vaccinated, findings relating to the use of vaccination passports, the capacity or capability of the health-care system to manage new or severe COVID-19 infections, etc.

6.4 Transition can start from crisis response to routine operations, once States and organizations have developed relevant key performance indicators and meet these adequately, and when the COVID-19 pandemic no longer exceeds their risk and public health management capacity.

6.5 The post-emergency phase, normally considered to have started when the core emergency priorities have been addressed with some level of stability, is an opportunity to address broader health- and aviation-related activities, thus preparing better for the future.

6.6 Some measures, such as contactless processes and the digitalization of paper-based applications, have already been implemented as part of the new routine operations. These should result in improved passenger flow and enhanced customer experience in the future.

6.7 Lessons learned from the application of the multilayer risk mitigation measures; either how to implement existing measures better or how to implement these measures differently, could provide further guidance for transitioning to new operations.

6.8 Furthermore, the aftermath of a crisis provides an opportunity for innovation and for building resilience for potentially similar situations in the future

Attachment A

EPIDEMIOLOGIC PRIMER

GOAL: Provide the best testing advice to minimize the risk that a person infectious with SARS-CoV-2 could transmit the virus during travel and propose a testing regimen to minimize quarantine.

TERMINOLOGY:

		Disease status		
		Present	Absent	
Screening test result	+	A	B	Total positive tests
	-	C	D	Total negative tests
		Total infected (Ti)	Total not infected (Tni)	Total population (Tp)

- A: True Positives
- B: False Positives
- C: False Negatives
- D: True Negatives

Prevalence. Disease burden, expressed as a percentage or rate with the total population as the denominator. Prevalence in this context refers to the number of existing cases of disease in a specified population at a given point in time.

Incidence. Number of new cases of disease in a specified population during a specified period of time.

Sensitivity. The likelihood that a test will correctly identify a person with the disease. $A/(A+C)$ is the mathematical formula.

Specificity. The likelihood that a test will correctly identify a person without the disease. $D/(B+D)$ is the mathematical formula.

Positive predictive value (PPV). How likely a positive test is a true positive. $A/(A+B)$ is the mathematical formula.

Negative predictive value (NPV). How likely a negative test is true negative. $D/(C+D)$ is the mathematical formula.

STEP ONE

Determine test performance requirements to maximize the number of people who could travel with reasonable certainty.

Prevalence assumptions/issues

1. It is important to know who might be infectious during travel as opposed to prevalence since the beginning of the outbreak. This is calculated by multiplying the incidence with the time period of infectiousness.
2. The Brown School of Public Health website, among others, tracks the incidence or current new cases per 100 000 people: <https://globalepidemics.org/key-metrics-for-covid-suppression/>. However, it should be noted that some statistics might not be accurate due to limitations of testing and reporting systems.
3. Among those who are sick, the vast majority of people are infectious from two days prior to symptom onset to nine days following symptom onset; hence, 12 days are used to determine the time period where people could most likely infect others.
4. The asymptomatic rate is assumed to be 40 per cent in accordance with a CDC reference published in September 2020: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html>. This implies that 60 per cent of people are symptomatic. Further assuming that mainly symptomatic people get tested, the number of positive tests represents only 60 per cent of the total number of people who are potentially infectious.

Calculating prevalence

To calculate the prevalence of potentially infectious people with positive tests, use the Brown daily average of new cases per 100 000 people (a 7-day moving average; based on Assumption 2 above) and multiply it by 12 (the number of days a person might be infectious; based on Assumption 3 above).

$$\begin{aligned} \text{Prevalence} &= \text{incidence} \times \text{duration} \\ &= \text{number of people per 100 000 with positive tests} \times 12 \\ &= \text{potentially infectious people with positive tests per 100 000 people} \end{aligned}$$

Taking into account that the number of positive tests represents only 60 per cent of the total number of people who are potentially infectious, the total number of potentially infectious people needs to be calculated. Setting the total number of people who might be potentially infectious as "X", the number of people with positive tests must equal 0.6 times "X" (based on Assumption 3 above).

$$\text{Potentially infectious people with positive tests} = 0.6 \times \text{total number of potentially infectious people ("X")};$$

$$\text{Total number of potentially infectious people ("X")} = \text{potentially infectious people with positive tests} / 0.6$$

To calculate the prevalence percentage, divide "X" by 100 000 to get the ratio, then multiply it by 100 to get the percentage.

$$\begin{aligned} \text{Prevalence percentage} &= \text{ratio} \times 100 \\ &= \text{"X"} / 100\,000 \times 100 \\ &= \text{x per cent} \end{aligned}$$

Example:

For State A, using the data from 21 September 2020 with a daily average of 12.6 per 100 000 people, the equations are as follows:

$$\begin{aligned} \text{Prevalence} &= \text{incidence} \times \text{duration} \\ &= \text{number of people per 100 000 with positive tests} \times 12 \\ &= 12.6 \text{ per 100 000} \times 12 \\ &= 151.2 \text{ potentially infectious people with positive tests per 100 000 people} \end{aligned}$$

$$\text{Potentially infectious people with positive tests} = 0.6 \times \text{total number of potentially infectious people}$$

$$\begin{aligned} \text{Total number of potentially infectious people (X)} &= \text{potentially infectious people with positive tests} / 0.6 \\ &= 151.2 \text{ per 100 000} / 0.6 \\ &= 252 \text{ per 100 000 people} \end{aligned}$$

$$\begin{aligned} \text{Ratio} &= X / 100\,000 \\ &= 252 / 100\,000 \\ &= 0.00252 \end{aligned}$$

$$\begin{aligned} \text{Prevalence percentage} &= 0.00252 \times 100 \\ &= 0.252 \text{ per cent} \end{aligned}$$

Quick calculation of prevalence:

Because the only variable in this calculation that changes is the daily average, while all others are fixed, the whole calculation can be done by simply dividing the daily average per 100 000 people by 50. For example, State A with a daily average of new cases per 100 000 people of 12.6 has a prevalence of $12.6 / 50 = 0.252$ per cent. It should be noted that this is only valid if the number of new cases is expressed per 100 000 people.

Performing the same functions for State B (7-day rolling average of 14.6/100 000) and State C (24.6/100 000 and the highest average on the Brown site) yields 0.292 and 0.492 per cent.

Performing 2 x 2 tables

- The tables were developed initially with the sensitivity and specificity of a test with sensitivity of 97.1 per cent and specificity of 98.5 per cent.
- Then, the same prevalence values were run with the worst listed sensitivity (80 per cent) and specificity (92 per cent) on the John Hopkins' compendium of all COVID-19 tests currently approved.
- For additional comparison, the values for the poorest performing test were run using the highest prevalence in the United States County X.
- Finally, the tables were populated using the proposed sensitivity and specificity of 95 per cent.
- PCR testing typically has higher sensitivities and specificities and would have even higher performance.

Calculations used for the 2 x 2 tables

A quick reminder of the 2 x 2 table terminology:

Tp = the total number of people in the population

P = the prevalence as calculated above (daily average of new cases per 100 000 people divided by 50)

T_i = the total number of infected people in the population
 T_{ni} = the total number of people in the population who are not infected
 A = the total number of people who are true positive
 B = the total number of people who are false positive
 C = the total number of people who are false negative
 D = the total number of people who are true negative

The calculations are as follows:

P = daily average of new cases per 100 000 people / 50

$T_i = A + C = T_p \times P$

$T_{ni} = B + D = T_p - T_i$

Sensitivity = $A / (A + C)$

Specificity = $D / (B + D)$

PPV = $A / (A + B)$

NPV = $D / (C + D)$

(Prevalence of 10 per cent, sensitivity of 95 per cent, specificity of 95 per cent)

Step 1 — Using a population of 1 000, calculate the disease burden.

		Disease status		
		Present	Absent	
Screening test result	+			
	-			
		100	900	1 000

$1\,000 \times 0.10 = 100$ with the disease
 $1\,000 - 100 = 900$ without the disease

Step 2 — Using sensitivity, calculate A (true +) and C (false -).

		Disease status		
		Present	Absent	
Screening test result	+	95		
	-	5		
		100	900	1 000

$100 \times 0.95 = 95$ true positives
 $100 - 95 = 5$ false negatives

Step 3 — Using specificity, calculate B (false +) and D (true -). Then, add up test positives and negatives.

		Disease status			
		Present	Absent		
Screening test result	+	95	45	140	$900 \times 0.95 = 855$ true negatives
	-	5	855	860	$900 - 855 = 45$ false positives
		100	900	1 000	

Step 4 — Calculate the positive predictive value (PPV) and the negative predictive value (NPV).

$$\text{PPV} = \text{true positives/test positives} = (95/140) \times 100 = 67.8 \text{ per cent}$$

$$\text{NPV} = \text{true negatives/all negatives} = (855/860) \times 100 = 99.4 \text{ per cent}$$

Examples of calculations

(Varying prevalence, sensitivity and specificity)

Example 1

State A: Prevalence of 0.25 per cent using a test with a sensitivity of 97.1 per cent and a specificity of 98.5 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	2 428	14 962	17 390
	-	72	982 538	982 610
		2 500	997 500	1 000 000

$$\text{PPV} = (2\,428/17\,390) \times 100 = 14.0 \text{ per cent}$$

$$\text{NPV} = (982\,538/982\,610) \times 100 = 99.99 \text{ per cent}$$

Example 2

State B: Prevalence of 0.292 per cent using a test with a sensitivity of 97.1 per cent and a specificity of 98.5 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	2 835	14 956	17 791
	-	85	982 124	982 209
		2 920	997 080	1 000 000

$$\text{PPV} = (2\,835/17\,791) \times 100 = 15.9 \text{ per cent}$$

$$\text{NPV} = (982\,124/982\,209) \times 100 = 99.99 \text{ per cent}$$

Example 3

State C: Prevalence of 0.492 per cent using a test with a sensitivity of 97.1 per cent and a specificity of 98.5 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	4 777	14 926	19 703
	-	143	980 154	980 297
		4 920	995 080	1 000 000

$$PPV = (4\,777/19\,703) \times 100 = 24.2 \text{ per cent}$$

$$NPV = (980\,154/980\,297) \times 100 = 99.98 \text{ per cent}$$

Example 4

State A: Prevalence of 0.25 per cent, worst case test with a sensitivity of 80 per cent and a specificity of 92 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	2 000	79 800	81 800
	-	500	917 700	918 200
		2 500	997 500	1 000 000

$$PPV = (2\,000/81\,800) \times 100 = 2.5 \text{ per cent}$$

$$NPV = (917\,700/918\,200) \times 100 = 99.94 \text{ per cent}$$

Example 5

State B: Prevalence of 0.292 per cent, worst case test with a sensitivity of 80 per cent and a specificity of 92 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	2 336	79 766	82 102
	-	584	917 314	917 898
		2 920	997 080	1 000 000

$$PPV = (2\,336/82\,102) \times 100 = 2.8 \text{ per cent}$$

$$NPV = (917\,314/917\,898) \times 100 = 99.93 \text{ per cent}$$

Example 6

State C: Prevalence of 0.492 per cent, worst case test with a sensitivity of 80 per cent and a specificity of 92 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	3 936	79 606	83 542
	-	984	915 474	916 458
		4 920	995 080	1 000 000

$$PPV = (3\,936/83\,542) \times 100 = 4.7 \text{ per cent}$$

$$NPV = (915\,474/916\,458) \times 100 = 99.89 \text{ per cent}$$

Example 7

County X: Prevalence of 5.994 per cent, worst case test with a sensitivity of 80 per cent and a specificity of 92 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	47 952	75 205	123 157
	-	11 988	864 855	876 843
		59 940	940 060	1 000 000

$$PPV = (47\,952/123\,157) \times 100 = 38.9 \text{ per cent}$$

$$NPV = (864\,855/876\,843) \times 100 = 98.6 \text{ per cent}$$

Example 8

State A: Prevalence of 0.25 per cent, worst case test with a sensitivity of 95 per cent and a specificity of 95 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	2 375	49 875	52 250
	-	125	947 625	947 750
		2 500	997 500	1 000 000

$$PPV = (2\,375/52\,250) \times 100 = 4.75 \text{ per cent, or only 1 out of approximately 20 will be a true positive.}$$

$$NPV = (947\,625/947\,750) \times 100 = 99.99 \text{ per cent, or 1 in approximately 10 000 testing negative might be positive.}$$

Example 9

State B: Prevalence of 0.292 per cent, worst case test with a sensitivity of 95 per cent and a specificity of 95 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	2 774	49 854	52 628
	-	146	947 226	947 372
		2 920	997 080	1 000 000

PPV = $(2\,774/52\,628) \times 100 = 5.27$ per cent, or only 1 out of approximately 20 will be a true positive.

NPV = $(947\,226/947\,372) \times 100 = 99.98$ per cent, or 1 in approximately 10 000 testing negative might be positive.

Example 10

State C: Prevalence of 0.492 per cent, worst case test with a sensitivity of 95 per cent and a specificity of 95 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	4 674	49 754	54 428
	-	246	945 326	945 572
		4 920	995 080	1 000 000

PPV = $(4\,674/54\,428) \times 100 = 8.59$ per cent, or nearly 1 out of 10 will be a true positive.

NPV = $(945\,326/945\,572) \times 100 = 99.97$ per cent, or 1 in approximately 5 000 testing negative might be positive.

Example 11

County X: Prevalence of 5.994 per cent, worst case test with a sensitivity of 95 per cent and a specificity of 95 per cent.

		Disease status		
		Present	Absent	
Screening test result	+	56 943	47 003	103 946
	-	2 997	893 057	896 054
		59 940	940 060	1 000 000

PPV = $(56\,943/103\,946) \times 100 = 54.78$ per cent, or slightly over 1 out of 2 will be a true positive.

NPV = $(893\,057/896\,054) \times 100 = 99.67$ per cent, or 1 in approximately 300 with a negative test might be positive.

Notes:

- 1.— *The prevalence does not affect the performance of the test with respect to the sensitivity and specificity. It affects the number of infected and uninfected persons in a cohort of people.*
- 2.— *As prevalence goes up when performing a screening test, so does the positive predictive value.*
- 3.— *In a low prevalence situation, the negative predictive value is very little affected by even relatively poor performing tests.*
- 4.— *Poor performing tests will significantly increase the number of false positives who would be denied boarding, at least initially until confirmatory test can be completed.*

Justifications for setting the minimum sensitivity and specificity levels at 95 per cent for molecular tests

1. It will allow a wider range of test devices to be used that are currently fielded as opposed to forcing States to procure newer models that are frequently hard to obtain.
2. The wider range also allows for the use of rapid antigen tests as a screening device which are more accessible and practical for application in the aviation environment; which are much faster and less expensive to use. In addition, it would reserve the more expensive real-time RT-PCR tests for confirmation of positives in conjunction with clinical correlation.
3. Setting the specificity at 95 per cent maintains a high NPV and reduces the false positives.
4. Setting the sensitivity at 95 per cent will reduce the risk of false negatives and improve the PPV.
5. In low prevalence settings (equating to 10-25 cases per 100 000 on a rolling average), the NPV equates to mislabelling an infected person as negative between 1 in 5 000 and 10 000 negative tests. In higher prevalence settings (equating to over 50 cases per 100 000 on a rolling average), the mislabelling rises close to 1 in 300.
6. In the same low prevalence and higher prevalence range, the PPV improves from correctly labelling a positive from approximately 1 in 10 to 20, to slightly better than 1 out of 2 of positive tests.
7. Few States set their sensitivity and specificity higher leading to further improvements in test performance.

STEP TWO: Pre-departure testing interval**Assumptions**

- Incubation time: 2-12 days (95 per cent) with a medial of 5-6 days.
- Shedding can occur 48 hours prior.
- The most sensitive tests turn positive 1-3 days prior to symptoms.
- Leaving a 2- to 4-day period where a person could be infected but not infectious with a negative test.
- The goal is to limit infectivity in flight.

Considerations

1. If the testing is placed at 72 hours before their departure, at least 60 per cent of those infected with a negative test will manifest their illness and hopefully remove themselves from travel even if they were infected walking into the testing facility.
2. If the person with a negative test is a true negative and becomes infected walking out of the testing facility, they should not begin shedding the virus in most cases until after arrival at the destination.
3. Moving testing to 48 hours prior to departure would potentially let a few more of the negative but infected slip through who could begin shedding the virus in flight before developing symptoms, but would increase the likelihood that a person subsequently infected would not become infectious in flight.

STEP THREE: Can quarantine be reduced with serial testing?**Considerations**

Consideration was given to two studies from the United Kingdom examining the relative effectiveness of various health measures on arrival to reduce the potential for onward transmission. It is summarized below:

- Quarantine of 14 days (Gold Standard): 78-99 per cent effective
- Single RT-PCR upon arrival: 39.6 per cent effective (2 in 5 cases detected)
- Single RT-PCR at 4 days after arrival: 64.3 per cent effective
- Single RT-PCR at 5 days after arrival: 88 per cent effective
- Upon arrival and 4 days after arrival (two tests): 68.9 per cent effective
- Single RT-PCR at 7 days after arrival: 94 per cent effective

Discussion

Assuming the effective percentages are the ability to find the people who could transmit the disease after release from quarantine, it seems reasonable to say that a 5 or 7-day window prevents most of the subsequent transmigration of disease.

1. The question is whether testing 72 hours prior to arrival, with a second test on day 4 or 5, would approach the 94 per cent effectiveness described for a single RT-PCR test 7 days after arrival.
2. Logically, it would appear a 7-day window of proven negativity would provide the same level of effectiveness.

Notes for consideration

- 1.— *In the screening environment, the exact test is not as important as the technique in conjunction with the sensitivity and specificity. The sensitivity and specificity should be of at least 95 per cent and performed by people adequately trained using the techniques specified by the manufacturer. Laboratory certification is preferred.*
 - 2.— *Evaluation of the positive cases must be considered.*
 - 3.— *With the level of prevalence in various States, the PPV with the best tests available are going to be in the 10 to 25 per cent range, meaning 1 in 4 to 10 will be true positives.*
 - 4.— *The other 75 to 90 per cent will be false positives and denied boarding.*
 - 5.— *If less sensitive and specific tests are used for screening, the numbers go up significantly to as many 24 out of 25 positive tests being false positives.*
 - 6.— *Furthermore, some of the true positives may be shedding viral remnants and no longer be infectious and could therefore travel.*
 - 7.— *Clinical correlation and more definitive testing will be required in case of positive screening test results.*
 - 8.— *States should consider what form would be acceptable to declare someone with a positive test as not infectious and ready to travel.*
-

Attachment B

ESTIMATED EFFECTIVENESS OF INDIVIDUAL RISK MITIGATION MEASURES

<i>Mitigation strategy</i>	<i>Estimated effectiveness*</i>	<i>Implementation cost**</i>
Universal travel bans	Very high (100%)	Low
Selected travel bans	Varies depending on the State selection and the timing of the measure	Varies
Travel restrictions, do not board lists, for persons ill with COVID-19 or high-risk contacts who defy public health recommendations	High	Varies
<i>Pre-departure strategies:</i>		
Isolation of potential COVID-19 infected cases and quarantine of contacts	High	Varies
Vaccination	Very high	Varies
Single pre-departure testing	Low for preventing translocation*	Medium to low
Health declaration forms (symptom and contact checks)	Very Low	Low
Temperature screening	Very Low	Low
High ventilation	Medium	Low to medium
<i>In-travel strategies:</i>		
Traveller health education	Medium	Low
Using appropriate general/basic public health countermeasures	Medium	Low
Managing and positioning of sick passengers	Medium	Low
Reduce plane capacity	Low	Medium to high
Airflow and HEPA filters	Medium	Low

By comparison, pre-departure tests have a higher effectiveness mitigating transmission during the journey. With regard to preventing translocation, effectiveness increases the closer to the time of departure the test of carried out.

<i>Post-arrival strategies</i>		
Quarantine for 14 days upon arrival	High to very high (78-99% for State supervised quarantine)	Varies (State supervised quarantine can be high)
Data collection/sharing for proper contact tracing	Medium	Low
Single PCR testing	Medium (40%)	Medium
Health declaration forms (symptom and contact checks)	Low	Low
Temperature screening	Low	Low

<i>Combined testing/quarantine strategies</i>		
7-day quarantine followed by testing	Very high (94%)	High
5-day quarantine followed by testing	High (88%)	Medium
Post-arrival testing and 4-day quarantine followed by the second testing	Medium (69%)	Medium
4-day quarantine followed by testing	Medium (64%)	Medium
Pre-departure testing with post-arrival quarantine and testing	Currently being explored. Early models show similar rates to quarantine	Medium

* The effectiveness estimates are based on:

- a) *strategies to reduce the risk of SARS-CoV-2 re-introduction from international travellers, Samuel Clifford et al., Centre for Mathematical Modelling of Infectious Diseases, Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, UK;*
- b) *the risk of introducing SARS-CoV-2 to the UK via international travel in August 2020”, Rachel A. Taylor et al., Department of Epidemiological Sciences, Animal and Plant Health Agency (APHA), UK; and*
- c) *public health authorities and expert consensus.*

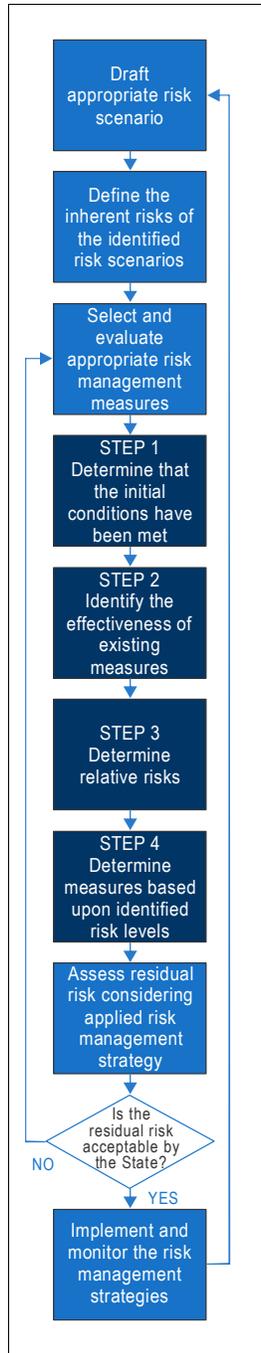
** Cost reflects the relative administrative expense of implementing a measure and is not meant to reflect societal or industry cost. States should consider the value of implementing a strategy with respect to potential gains of increased traffic. Note that these costs do not consider the impact of the measures on States' economies.

ATTACHMENT C

DECISION AID

Example of a basic decision process

Disclaimer: The chart below represents a basic decision process for a tabletop exercise. It is not complete, operational, or universally applicable, but can support the development of operationally viable inter-agency risk management processes.



- Draft scenarios to be assessed, considering if the risk is related to passengers, crew members, staff at airports and any other person inside the Public Health Corridor (PHC)

Example: An infectious person, whose condition is unknown or revealed, is boarding an international flight.

- Assess the likelihood of the risk scenario, considering existing management strategies
- Assess the impacts of the risk scenario and its context (health-care system, operational, social, political, organizational), considering existing management strategies
- Collect data and information to support qualitative and quantitative assessments
- Define the inherent risk as the combination of the likelihood and impacts of the risk scenario before any actions by the State

Example: The likelihood of an infectious passenger, whose condition is unknown or revealed, to board an international flight, is high. The application of the mitigation measures may result in a reduction of this likelihood.
A probabilistic estimation for the inflight transmission can be defined (x).

States should consider one or more risk management strategies to modify the inherent risk: **Avoidance, Transfer, Mitigation, and Acceptance.**
More information about risk management can be found in Chapter 2 of this manual.
 A State may determine that the inherent risk is acceptable depending on its public health capabilities. As needed, the State may select additional mitigation, considering the individual effectiveness and result of combined strategies for risk management.
The mitigation measures for public health risks are described in Chapter 3 of this manual.
 In order to select other mitigation measures, useful questions may be posed by the State to help the evaluation of the risk management strategy:

- What is the individual efficacy and effectiveness of each risk mitigation?
- If a risk management strategy is applied, would it reduce the likelihood of an infectious person to contaminate others or reduce the impacts from this contamination in the public health system?
- What are the measures commonly practiced internationally?
- What are the methods available to apply each risk mitigation?
- What would be the recommended procedures to assure or enhance the effectiveness of each risk mitigation?
- To what extent would procedures applied in aviation be applicable to domestic phases of the travel and connection with other modes of transportation?

Are the risk management strategies coordinated with other national, regional and international stakeholders and the aviation community?
More information about the selection of a combined strategy for risk mitigation is presented in Chapter 4 of this manual.
Example: The States coordinate procedures to be conducted before people engage in air travel, during the flight, in the airport environment and after arrival.
A probabilistic estimation for the transmission at the arrival can be defined (y).

- After the application of the risk management strategy, assess if States are expected to effectively modify the inherent risk
- The residual risk should be evaluated in order to be commensurate with the State’s public health capabilities and resilience

Example: After the assessment of combined strategies, the State considers that the residual risk is acceptable.
A probabilistic estimation for the local transmission in the State can be defined (z).

- The State should coordinate actions with other States in order to facilitate air travel
- After the strategies are implemented, their actual effectiveness, efficacy and the stabilization of the residual risk should be continuously monitored
- As States are subjected to changing conditions, it is important to recognize the need to review the risk scenarios and applied mitigation strategies to ensure continuity of traffic connections between States

Example: States should establish indicators and monitor the changing environment of their public health systems and measures implemented by other States, in order to identify the need to reassess their initial risk scenario.

ISBN 978-92-9265-582-2



9 789292 655822