Issues list for airlines considering passenger and crew testing for COVID-19

The following is a summary of issues airlines should consider when adopting diagnostic testing for passengers. This list does not focus on temperature scans, sniffer dogs or other forms of less invasive screening, or other mitigations such as masks and physical barriers between seats. This list does consider diagnostic testing for flight crews, but does not explore similar questions for other customer facing personnel, such as gate agents.

Choice of Test

The first issue is the choice of test. There are two types of diagnostic tests, each with their own advantages and disadvantages.

- **Molecular tests**. These tests detect genetic material from the SARS-CoV-2 virus from clinical samples (e.g., nasal or throat swabs) to diagnose a patient's current COVID-19 status. Currently, most of these tests may be performed in the United States only by sophisticated laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to conduct moderate or high-complexity testing. A small number of these tests are authorized to be performed at the point of care by an entity that has a lower level CLIA certificate, called a CLIA "Certificate of Waiver." Thus, to use this form of testing, an airline would need to determine if an airport has the necessary CLIA certification and/or partner with a CLIA-certified laboratory.
- **Serological tests**. A serology test is conducted on a sample derived from the blood (e.g., whole blood or plasma) to identify antibodies to SARS-CoV-2. Serological tests are relatively easy to administer, and the results arrive quickly. However, these tests are currently designed only to identify whether an individual previously had COVID-19. They do not identify current COVID-19 infection status and are not intended as the sole tool to diagnose COVID-19. There have also been questions raised regarding the quality of some test kits available in the United States market. Finally, at this time in the United States, serological tests are not a viable option because they must be administered by a laboratory certified under CLIA to conduct non-waived tests. No serological tests are authorized by the FDA for use as point of care tests. However, at least one jurisdiction outside of the United States has permitted serological testing.

Implementation of Testing

Once the form of testing has been determined, the following issues should be considered in connection with implementation of the testing:

<u>Compliance</u>

- **Privacy.** The tests will generate health data, which constitutes a sensitive or "special category" data under most privacy laws, such as the E.U.'s General Data Protection Regulation (GDPR). Enhanced levels of protection therefore apply to the collection, storage and processing of such medical data, and some data protection regulators have challenged whether private companies would have a legal basis to process medical data in connection with at least some COVID-19 response activities in the absence of cooperation with public health authorities. Even across the European Union, where

member states are governed by the GDPR, there is a significant degree of variance between countries that have published guidance on COVID-19 privacy considerations. Further, there may be certain additional privacy frameworks that apply to health care providers that could apply in some jurisdictions depending on who is administering the tests.

- **Medical device and health regulations.** The procurement and administration of diagnostic testing will engage a range of other relevant regulatory considerations, including the use of an FDA authorized test (or equivalent rules ex-U.S. such as EU CE-marking requirements), reporting of notifiable diseases to local health authorities (a duty generally imposed on any third party medical professional retained by employers to conduct tests), and national or local laboratory licensure and certification requirements (i.e., the U.S. federal requirement that all laboratories performing COVID-19 testing obtain CLIA certification).
- **Contact-tracking and reporting.** Once airlines possess relevant health data, they will need to develop procedures for passenger and crew contact-tracking. If a passenger or crew member tests positive for COVID-19, this will raise additional privacy considerations. Tracking initiatives should be implemented in coordination with any internal privacy officers, human resources (HR), compliance teams and unions. Airlines should consider adopting a separate COVID-19-influenced health and safety policy. The airline will also need a process for responding to government authority requests for reports on and access to testing results. Given the sensitivity level of the data, the airline will want to ensure that requests by government authorities are lawfully authorized, and that necessary and appropriate disclosures are made about its process for responding to government requests.

<u>Informed Consents and Sales and Operational Implementation</u>

- **Content of the informed consent.** For the informed consent to be meaningful, it will need to be independently reviewed for intelligibility for the average consumer and take into account local health guidelines for informed consents. The informed consent would need to be available in the native language of the passenger and crew member. To the extent that flight crew members are collectively represented (e.g., by a union), their representatives should be consulted on the form and presentation of the informed consent. This may also be required by applicable collective bargaining agreements. In some jurisdictions, it may be required to obtain a specific form of patient authorization or consent to the processing of health data.
- **Mandatory testing.** Presumably testing will need to be mandatory, and this will need to be explained as part of the booking process.
- **Pre-existing bookings.** For those passengers that have pre-existing bookings at the time when the testing is commenced, a refund may need to be offered in the case of a passenger who does not wish to take the test (otherwise the validity of the informed consents would be compromised).
- **Booking process and terms.** The booking process with direct and indirect channels will need to be updated to forewarn passengers before purchasing that they will be tested before traveling. Conditions of carriage will need to be updated to contemplate the requirement of testing and the use of the test results.
- **Training.** Front line team members will need to be trained on what to communicate to the passengers about testing, the results and how the passenger's data will be used.

- **Reconfiguring the workplace**. Airlines may need to incur expenses related to implementation of testing capabilities and processes, such as reconfiguration of check-in and boarding areas for passengers.

Immunity certificates/passports/apps

- Airlines will need to consider local requirements and practices in the country of departure with respect to so called immunity certificates or passports, or the various contact-tracking apps in use in that country. Although separate from diagnostic testing, the information provided by these certificates, passports and apps could be used in combination with the results from testing. Airlines should monitor local requirements and practices as they evolve.

Managing liability risks

- **Liability waivers.** Prospective waivers of personal injury claims against airlines may be subject to legal challenges. Nonetheless, conditions of carriage should be evaluated for updates to include such waivers and to generally mitigate the risks of continuing to operate during the crisis.
- **Clear policies and disclosure.** Sales channels and booking confirmations should clearly explain the requirement of testing, the limitations of testing and that passengers are responsible for deciding if the planned trip is worth the associated risks. Policies and their communication to passengers and crew need to be simple and clear, with appropriate training for crew members.
- **Coordination with unions.** Careful coordination with all the relevant team member representatives will be important.
- **Supply chain issues.** Airlines should ensure to the extent possible that they have a secure and reliable supply of tests, including one or more alternative sources, before launching testing. It would be damaging to the airline brand to launch testing and then have to suspend or limit the testing due to lack of supply.
- **Monitoring updates.** Airlines will need to monitor local health authority guidance with respect to use and results reporting of diagnostic testing for COVID-19.
- **Conflicting requirements.** Airlines may experience challenges in balancing home/flag country regulations with the requirements of regulations in all their destination countries. For example, a form of testing on citizens of one country may not be permissible for citizens of other countries.
- **Other operational steps**. The diagnostic testing should be combined with other mitigating steps, including cabin cleaning and touchless boarding and baggage check-in.

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