An Approach to Screening for SARS-CoV-2 at YVR
UBC-YVR-WestJet COVID-19 Screening Study

PROTOCOL

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SIGNATURE PAGE

TITLE: An Approach to Screening for SARS-CoV-2 at YVR

I, the undersigned, have read this protocol and agree that it contains all necessary information required to conduct the study.

Principal Investigator Signature	Date
_____	_____
Co-Investigator Signature	Date
_____	_____

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INTRODUCTION AND BACKGROUND INFORMATION

Background

As of November 13, 2020, the COVID-19 pandemic has infected over 53 million individuals and killed more than 1,300,000 people worldwide.[1] The economic consequences of the pandemic have also been very severe. During the peak of the "lockdown" in April, 2020, the Canadian gross domestic product (GDP) dropped by 17%, the unemployment rate rose to beyond 15% and international exports decreased by 36%.[2] Aviation industry was one of the hardest hit sectors of the economy as air travel fell by more than 90% for international destinations including the US, and even domestic travel dropped by 70%. Although travel has recovered slightly over the past few months, domestic travel is still only at 50% of the pre-pandemic levels and international flights are at less than 20% of the pre-pandemic levels.[2] A recent survey indicates that even with safe distancing policies introduced by the many airlines, 72% of Canadians indicate that "they are not comfortable flying" and not surprisingly given these results 85% of Canadians have no plans to travel outside of the country this year.[3]

While the world waits for an effective and safe vaccine, according to experts in the field, the pandemic is likely to rage on for another 12 months or longer. For these sectors to survive (in the short-term), COVID-19 mitigation strategies are urgently needed. The current strategy that is used in many airports is to require airlines to conduct a health check of travellers before they board a flight and to check their body temperature at ticketing areas or boarding gates.

However, this strategy is not very effective because these measures are relatively insensitive (only a minority of COVID-19 patients have raised temperature at any given point in time during their disease course) and thus unlikely to identify individuals with SARS-CoV2, who are minimally symptomatic or completely asymptomatic at the time of travel. Indeed, public health experts have poignantly stated that transmission of the virus through asymptomatic individuals is the "Achilles' Heel of Current Strategies to Control COVID-19".[4] This is because, unlike SARS-CoV1, the cause of the original SARS epidemic in 2003, SARS-CoV2 sheds at high concentrations from the nasal cavity even in asymptomatic individuals, who may harbor the virus but have yet to demonstrate any symptoms during the prodromal phase of the disease.[5] Even with masking and social distancing, such individuals would be at a high risk of spreading the virus during air travel, especially during long flights.[6] One approach to reducing the risk of SARS-CoV2 transmission during flights is to "screen" for those travelers who are likely to harbor the virus (even though they may have no or minimal symptoms) at airports across the country. However, the current diagnostic approach, which uses real-time reverse transcriptase polymerase chain reaction (RT-PCR) to detect the presence of viral RNA from nasopharyngeal swabs, cannot be easily deployed for this purpose

As it is expensive (>$100/test), time-consuming (with turnaround times of 1-2 days) and requires trained health care personnel to administer the test. A potential solution to this conundrum is to use a "point-of-care" test, which can be deployed at airports and whose results will be available within 1 hour of testing.[7-9] However, for these assays or platforms to be viable, they will need to be used as "screening" rather than "diagnostic" tests (see below for more detailed discussion on this topic), and be relatively simple to use (so ideally they can be self-administered) and inexpensive.

What is the difference between diagnostic and screening tests?

Diagnostic testing for SARS-CoV-2 is intended to identify occurrence at the individual level and is performed when there is a reason to suspect that an individual may be infected, such as having symptoms or suspected recent exposure, or to determine resolution of infection. Examples of diagnostic testing include testing symptomatic individuals who present to their healthcare provider, testing individuals through contact tracing efforts, testing individuals who indicate that they were exposed to someone with a confirmed or suspected case of coronavirus disease 2019 (COVID-19), and testing individuals present at an event where an attendee was later confirmed to have COVID-19. The U.S. Food and Drug Administration's (FDA) FAQs on Testing for SARS-CoV-2 also address diagnostic testing for SARSCoV-2. Screening tests for SARS-CoV-2, on the other hand, are intended to identify occurrence at the individual level even if there is no reason to suspect infection—e.g., there is no known exposure. This includes, but is not limited to, screening of non-symptomatic individuals without known exposure with the intent of making decisions based on the test results. Screening tests are intended to identify infected individuals without, or prior to development of, symptoms who may be contagious so that measures can be taken to prevent further transmission. Examples of screening include testing plans developed by a workplace to test its employees, and testing plans developed by a school to test its students, faculty, and staff. In both examples, the intent is to use the screening testing results to determine who may return and the protective measures that will be taken. FDA's FAQs on Testing for SARSCoV- 2 also address screening testing for SARS-CoV-2. In sum, a screening COVID-19 test is one that is specific for SARS-CoV2 but has a lower sensitivity (i.e. ability to pick up the virus) than that of a diagnostic test. Thus, even those who have a negative screening test should be considered potentially infectious and must adhere to social distancing and masking rules as per all the other passengers on the plane. Those who are tested positive on the screening test must be assumed to have COVID-19 until proven otherwise by a confirmatory RT-PCR test (which is the gold standard). This approach of using "point-of-care" screening tests was recently advocated by The New England Journal of Medicine.[10]

Primary Objective

The primary objective of this pilot study is to determine the feasibility and effectiveness of a COVID-19 screening program for passengers departing from YVR. This research study is conducted by The University of British Columbia (UBC) and Providence Health Care, sponsored by WestJet and Vancouver Airport Authority. The experimental study investigates point-of-care rapid test device for detecting SARS-CoV-2, the virus responsible for COVID-19. The study is investigating a method of rapid-testing for COVID-19 and will help inform the safest and most efficient way of testing departing passengers prior to security screening at Vancouver International Airport (YVR). This study is also evaluating a new passenger management system.

Summary of the Research Proposal

Purpose:

The purpose of this pilot study is to determine the feasibility and effectiveness of a COVID-19 screening program at YVR for WestJet and KLM passengers.

Hypothesis:

SARS-CoV-2 infection can be effectively screened using point-of-care rapid antigen assays.

Justification:

Passengers are required to wear masks and physically distance while traveling by air. However, the majority of general public is still worried about the potential risk of contracting COVID-19 on airplanes, especially during long flights. We need to develop methods and strategies to quickly screen for SARS-CoV-2 infection, prior to boarding flights.

Objectives:

1. To develop and deploy a management algorithm for COVID-19 screening at YVR that will involve the use of point-of-care rapid test device.

2. To evaluate the acceptability of such screening algorithm and determine the costs of deploying the program.

Research Design:

Study Population: Working in collaboration with WestJet and KLM we will invite all passengers meeting Inclusion/Exclusion on outbound flights from YVR Airport to participate in this study.

Phase 1: We will work with YVR and WestJet to enroll 200 subjects into the study. For this initial phase we are looking to determine the rate of positivity in the cohort. This initial phase is needed to evaluate the feasibility of this pilot program and to refine the initial management algorithm. Health Canada-approved Panbio Covid-19 Ag Rapid Test Device by Abbott Rapid Diagnostics (approved for Lab-based test and Point of care test on 2020-10-05) will be uses in Phase 1.

Phase 2: Strategies for achieving higher-throughput will be determined after completion of Phase 1. In phase 2, we will continue to work with YVR and WestJet, with the addition of KLM, to enroll 700 subjects into the study. Phase 2 will further assess the efficiency of our COVID-19 screening and passenger management algorithm.

The study is purposefully designed to be as minimally invasive to the passengers' travel plan as possible. The Study Plans for Phase 1 and Phase 2 are detailed below.

Statistical Analysis:

- When we aggregate the data for analysis, we will use basic statistics to determine mean, variance, standard deviation, and positivity rate...etc.

INVESTIGATIONAL PLAN

Phase 1 Recruitment

Inclusion Criteria:

1. The subject must be between 19 and 80 years of age.
2. The subject must be a resident of B.C.
3. The subject must have a ticket to board a WestJet flight departing from Vancouver International Airport (YVR).
4. Have a minimum of 75 minutes of free time prior to the scheduled flight's departure.

Exclusion Criteria:

1. We will exclude subjects who have previously tested positive for COVID-19 within the past 90 days
2. We will exclude subjects who cannot provide written informed consent

Phase 2 Recruitment

Inclusion Criteria:

1. Subject has access to accommodation in Canada for safe-isolation as per public health guidelines
2. Between the ages of 13 – 90
3. Travelling on any WestJet or KLM flight
4. Have a minimum of 70 minutes (if travelling within Canada) or 90 minutes (if travelling International) of free time prior to the schedule flight's departure

Exclusion Criteria:

1. We will exclude subjects who have previously tested positive for COVID-19 within the past 90 days
2. We will exclude subjects who cannot provide written informed consent or assent

Onsite Recruitment

For Phase 1, we will approach eligible passengers arriving at YVR terminal between 8 AM and 12 PM noon. For Phase 2, we will approach eligible passengers arriving at YVR terminal between 6:30 AM and 10:30 AM to capture WestJet's largest carrier departing at 9 AM, and between 11:30 AM and 3:30 PM on Thursday and Sunday for KLM flights. We will also mention a discount coupon will be given to WestJet passengers who successfully complete the study.

a) Passengers will purchase tickets directly from WestJet or KLM. On the day of departure, passengers will make their way to the check-in kiosk where they will go through the normal protocol of checking their bags. The airline staff will ensure that the passenger has minimum free time prior to their flight. If that is the case the staff member will inform them of Optional study conducted by UBC, WestJet, KLM and YVR - looking into the feasibility of a COVID-19 point-of-care rapid test device and algorithm for passenger management.

b) If the Passenger is interested, they will be directed to the Welcome Booth where they will meet a Study Coordinator and/or YVR staff. The Study Coordinator will provide each passenger with a welcome package consisting of 1) Simple study info sheet covering the purpose, the study plan, inclusion exclusion and potentiality of missing their flight if they participate; 2) A brochure with high-level details and frequently asked questions (see "General Brochure" in accompanying collateral document) 3) A water bottle; and 4) A pen which they will use for filling out the informed consent form and study questionnaire.

c) All passengers meeting the inclusion/exclusion criteria will be approached after checking bags. We will ensure that passengers have minimum required time prior to flight departure. If the subject is interested, they will be escorted to Informed Consent Area or the Citizen Care Pod for the full run through of the Informed Consent Form. After informed consent, we will start the process of sample collection.

Advance Recruitment

For WestJet passengers only, we will also recruit by sending an email at 72 hours pre-departure to WestJet guests who are flying out of Vancouver (see "WestJet Email to Guests"). The email will point to a WestJet microsite with further information on the study (see "WestJet Microsite") and interested participants will be able to register in advance for the study at testingyvr.ca (see "Sign-up Microsite"). Those who choose to sign up in advance will receive a series of confirmation emails (see "Confirmation Emails"). Those signing up in advance must meet all the eligibility criteria and will follow the steps outlined above.

Details of Study Procedures

The study is purposefully designed to be as minimally invasive to the passengers' travel plan as possible. The General Study Plan is detailed below.

Welcome Booth

- Study Coordinator stationed here with YVR staff (all wearing masks and are able to maintain appropriate distance)
- Study banners stationed here, with high-level details including steps and eligibility criteria (see "Banners").
- Appropriate distancing markers on the floor to remind study participants to maintain distance while waiting in line
- Welcome Package: bottled water, pens, brochure (see "General Brochure"), and basic study plan (no informed consent form)
- Have alcohol-based hand rub (ABHR) station available to facilitate hand hygiene
- Provide a mask if passenger is not wearing mask
- Check basic inclusion/exclusion criteria
- Answer basic questions about the study
- Inform the risk of denied boarding, if screened positive
- If interested, direct to Informed Consent Area or Citizen Care Pod (5 stations) or wait inside terminal (5 seats allowing physical distancing with dividers)

Citizen Care Pod

- Passenger (potential study subject) will sanitize hands upon entry
- Potential study subject will sit at 1/5 station, facing curb-side side (these 5 stations will have partitions between participants as a physical barrier)
- Clinical Coordinator (all wearing PPE – gown, mask, shield, and gloves, more details below) will come up behind the subject to go through the informed consent
- Once signed consent form, proceed to collect NP swab and oral rinse
- Make sure the subject has no signs of bleeding after NP swab, and rest
- The subject will be given a questionnaire and directed outside of the Care Pod
- Another hand sanitization station will be available for subjects as they exit

Rapid COVID-19 Testing On Site

- For Phase 1, only the NP swab sample will be tested on site using the rapid test device. If the sample is positive, "Positive Screen Test Results" Protocol will be followed (see below). The remaining NP swab sample and oral rinse sample will be transferred back to research laboratory for confirmatory RT-PCR testing.
- For Phase 2, both the NP swab sample and the oral rinse sample will be tested on site using two separate rapid test devices. If either sample is positive, "Positive Screen Test Results" Protocol will be followed (see below). The remaining samples will be transferred back to research laboratory for confirmatory RT-PCR testing.

Results Office

- Results Office – a private room inside the YVR terminal
- Second waiting area will be available outside of Results Office (these 5 stations will have partitions between participants as a physical barrier)
- Subjects will be asked to fill out the questionnaire on paper, using the pens (to be taken home by study participants) received from Welcome Booth
- After 15-20 min, screening results will be available from Study Coordinator
- Questionnaire will be handed back to Study Coordinator (to obtain results)
- Copy of signed consent form given back to subjects
- For WestJet passengers, WestJet will provide subjects with a discount offer for future flights in appreciation of their participation (see "WestJet Promotional Card"). This will be advertised in advance for Phase 2.

Study Team Members – Daily Self-Assessment

- Prior to working on site every day, each Study Team Member will assess for COVID-19 symptoms using the BC COVID-19 Self-Assessment Tool (https://bc.thrive.health/covid19/en)
- The Clinical Team Manager will also review WorkSafe BC policies regularly (https://www.worksafebc.com/en/about-us/covid-19-updates/covid-19-returning-safe-operation) for updates

Angry Passengers

- The Study Team will be following specific YVR/airline protocol when passengers become upset or irate.
- We will have a daily YVR/airline point of contact person on site to assist the Study Team at all times.
- When a passenger/subject should become upset or irate, our Study Team will inform our YVR/airline point of contact.
- At this point, the YVR/airline staff will work with security and necessary authorities to resolve the situation.

Unclaimed Results

- If a Study Coordinator advises airline staff results have not been collected by the passenger, airline staff can change the status of the passenger's boarding pass/booking so they will be unable to board the flight.
- Terminal pages can be made for the passenger asking them to return to the check-in area.

"Positive Screen Test Results" Protocol

- All subjects who screen positive will be provided with a face mask if they are not wearing one (they do not need a new mask if they already are wearing one)
- Study Coordinator informs subject that they have a "positive" result and contact airline to advise as well.
- Study Coordinator will inform subject on next steps including Study Team + airline contacts
- A new NP swab sample for confirmatory RT-PCR test will be taken by the trained research staff.
- Passenger will be asked to self-isolate and monitor symptoms as per Public Health Guidelines
- Passenger will be provided a brochure with information and resources while waiting for confirmatory test results. The brochure includes public health information, details on rebooking, and frequently asked questions (see "Awaiting Confirmatory Test Results Brochure").
- Study Coordinator hands over passenger to airline
- Airline agent returns any checked baggage to the passenger and informs on rebooking options
- YVR/airline will coordinate the transportation of the passenger to get home (either private car pickup – curbside level 3 or taxi – YVR will provide voucher)
- Upon receiving the result of the confirmatory test, the passenger will be contacted by clinical team manager
- Airline will be contacted by clinical team manager to be notified of the test result. The passenger travel profile will be updated accordingly

Provision of Test Report for Negative Test Result

- In the event of a negative test result, the Study Coordinator will, upon the subject's request, provide the subject with a printed test report in the format agreed between the parties which will include the following information:
  - Given name and surname of subject;
  - Type of test used;
  - Test result;
  - Date and time of test; and
    - Name and contact information for institute/laboratory that conducted the test.

Personal Protective Equipment

Study coordinators will have the following Personal Protective Equipment or PPE at their disposal for the purposes of the study:

- Surgical Gloves
- ASTM Level 3 Masks
- Face Shield
- Protective Gowns

Coordinators will dispose of PPE as per hospital protocol and re-apply new PPE once they have fully disinfected their work area and their person.

- new PPE does not need to be changed between study participants
- staff can change gowns when contaminated but gloves need to be changed between each study participant.

1. Read protocol: http://www.bccdc.ca/Health-Professionals-Site/Documents/COVID19_MOH_BCCDC_Donning.pdf
2. Hand hygiene: Clean all surfaces of hands and wrists
3. Don gown (cover torso and wrap around back, fasten in back of neck and waist), mask (secure ties at middle of head and neck, fit nose band to your nose and pull bottom down to completely cover chin), eye protection (place goggles or face shield over face and eyes and adjust to fit), and gloves (extend to cover wrist of gown)
4. Collect nasopharyngeal swab and oral rinse samples
5. Doff gloves, hand hygiene
6. Replace gown and/or gloves if visibly soiled or contaminated
7. Repeat hand hygiene

Protocol for Cleaning Subject Testing Area

The consenting and testing area will be taking place inside the Citizen Care Pods which will be placed just outside of the departure terminal doors. Hand sanitizers will be available upon entry and exiting. All frequent touch surfaces (e.g., countertops, chairs, and door knobs) will be disinfected before the subject enters and after the subject exits.

Storage and Disposal of Biohazardous Materials and Samples

All Samples will be kept in a refrigerator located securely in the Citizen Care Pod. Disposable bins with biohazardous bags will also be inside the Citizen Care Pod. This fridge and disposable bins will be carefully monitored at all times. A curtain will be providing additional separation between passengers entering the Care Pod. Please see Care Pod schematic attached. At the end of each day our Study Team will securely transfer the samples in batches (securely tightened samples be packaged in batches into biohazard bags) to the research and clinical labs for validation and confirmatory testing, respectively. No samples will be left on site at the end of the day. Bins with disposables (inside the Care Pod) will be

cleared by YVR maintenance staff on a daily basis, with daily cleaning and disinfecting. Once the validation and clinical testing has been completed in research or clinical labs, the remaining samples will be disposed of or stored as per study protocol.

Data Collection

Subjects who enroll in the study are entered into the secure database.
The following data will be collected using the Questionnaire:

- Age
- Sex
- Ethnicity
- PHN (optional)
- Date of enrolment
- Basic overall Medical history
- Lung Disease history
- Symptoms (e.g. fever, cough, shortness of breath, fatigue, pain, etc.)

Withdrawal from Study

Individuals will be withdrawn from the Study in case of any of the following reasons:

- Withdrawal of consent (no reason required)

Independent Ethics Committee or Research Ethics Board

Recruitment for this study will begin only after full approval of the protocol has been obtained from the Research Ethics Board.

Any protocol amendments will undergo the same review and approval process as the original protocol. A protocol amendment may only be implemented after it has been approved by the Research Ethics Board, unless immediate implementation of the change is necessary for subject safety. In this case, the situation must be documented and reported to the Research Ethics Board as soon as possible. Reports on, and reviews of, the Biobank and its progress will be submitted to the Research Ethics Board by the Investigator at intervals stipulated in their guidelines.

Ethics and Good Clinical Practice Compliance

Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve human subjects.

Compliance with this standard provides public assurance that the rights, safety, and well-being of research participants are protected; consistent with the principles that have their origin in the Declaration of Helsinki, and that the research data are credible.

Recruiting Sites

- Onsite at YVR Airport
- Offsite through WestJet digital channels (as outlined above)

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