SARS-CoV-2 rapid diagnostic testing: Canadian consensus guidance for pharmacists

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Introduction

The first official case of SARS-CoV-2 infection in Canada was reported on January 25, 2020, after which national case numbers began to increase rapidly, followed by successive waves as new and more infectious variants emerged. In many domains of care related to the pandemic, frequent updates and changes to public health guidelines were necessary due to rapidly evolving science.[1]

Quick and accurate diagnostic testing to track the incidence of SARS-CoV-2 cases is crucial to containing the virus and preventing further spread. Outside of testing for clinical decision making, accurate outpatient diagnostic results can help predict where resources should be allocated or where more stringent public health measures should be implemented to attenuate viral spread. Rapid diagnostic tests (RDTs) are a quick, cost-effective and relatively accurate method of testing large populations for the virus,[2] and these tests retain clinical accuracy across SARS-CoV-2 variants, including the Omicron variant.[3-5] However, the accuracy of RDTs can vary depending on the goal of testing (i.e., to detect all cases or only infectious cases) and who is performing the test.[6] Tests performed by self-trained lay people have a lower sensitivity (57.5%) than tests performed by a trained health care provider (HCP) (70%) or laboratory scientist (78.8%).[6]

Even before the SARS-CoV-2 pandemic, pharmacies played key roles in preventing disease and improving public health, through routine vaccinations, health promotion and education, patient and medication counselling, point-of-care testing, ensuring access to medications and more.[7] As the pandemic has progressed, the roles of pharmacists and their teams have expanded to include testing patients for SARS-CoV-2 using RDTs and, in some jurisdictions, reverse transcription polymerase chain reaction (RT-PCR) testing.[8-10] A standardized national guidance surrounding protocols for pharmacies performing these tests is lacking. This project describes a model of implementation and aims to provide safe and effective clinical guidance for pharmacy employees performing RDTs for SARS-CoV-2 in Canada. The practice algorithms developed from the consensus statements are intended to be adapted into any community pharmacy workflow setting, where the individual components can be flexibly plugged into existing workflows.

Methods

A team of 14 Canadian subject matter experts, including 2 infectious disease physicians and 12 pharmacists (Appendix 1, available in the online version of the article), was assembled to gain insight into the unmet procedural needs surrounding rapid diagnostic testing for SARS-CoV-2 performed in a community pharmacy setting. Subject matter experts were recruited for this project to represent community (independently owned, corporate and franchised), academic and institutional pharmacies in multiple geographical areas across Canada, as well as infectious disease physicians; each expert has clinical experience in performing rapid diagnostic tests for SARS-CoV-2. As this study did not use animal or human subjects, ethics approval was not required.

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SUMMARY

- There is a lack of a national consensus guidance on protocols relating to the standardized initiation, assessment and monitoring of activities associated with SARS-CoV-2 screening and testing in Canadian pharmacies.
- A multidisciplinary panel of subject matter experts found consensus on a number of unmet clinical needs, including processes and procedures concerning screening prior to testing, appointment logistics, maintaining patient and practitioner safety and communicating test results.
- These guidelines provide essential standardized guidance toward creating a safe and effective workflow model for SARS-CoV-2 rapid diagnostic testing that can be implemented in community pharmacies.
- The value and relevance of the pharmacy practice model outlined here are meant to extend beyond SARS-CoV-2 testing and serve as a blueprint for the implementation of other pharmacist-led screening and diagnostic services (e.g., strep throat, urinary tract infections, metabolic panels).

RÉSUMÉ

- Il n'existe pas de consensus national sur les protocoles relatifs au lancement, à l'évaluation et au suivi normalisés des activités associées aux tests et au dépistage du SRAS-CoV-2 dans les pharmacies canadiennes.
- Un groupe multidisciplinaire d'experts en la matière a trouvé un consensus sur un certain nombre de besoins cliniques non satisfaits, y compris les processus et procédures de dépistage préalable au test, la logistique des rendez-vous, le maintien de la sécurité des patients et des praticiens, et la communication des résultats des tests.
- Ces lignes directrices fournissent des conseils standardisés essentiels pour créer un modèle de flux de travail sûr et efficace pour le test de diagnostic rapide du SRAS-CoV-2, qui peut être mis en œuvre dans les pharmacies communautaires.
- La valeur et la pertinence du modèle de pratique pharmaceutique décrit ici sont destinées à s'étendre au-delà du dépistage du SRAS-CoV-2 et à servir de modèles pour la mise en œuvre d'autres services de dépistage et de diagnostic dirigés par les pharmaciens (p. ex. la pharyngite streptococcique, les infections des voies urinaires et les groupes métaboliques).

A modified Delphi method was used to determine consensus recommendations (Figure 1). An agreement of 75% of the participants on an answer was set as the threshold to designate a consensus finding.[11] Project co-chairs determined key areas or domains of interest, from which the first questionnaire was developed. Each participant reviewed and revised the questionnaire and was subsequently required to answer all independent questions; some answers prompted additional follow-up questions. The first questionnaire consisted of 24 questions, separated into 4 areas of interest: screening (6 questions), logistics (4 questions), environment and safety (3 questions) and communication (11 questions). After the first questionnaire data were analyzed, a second questionnaire was sent to the participants for additional voting. The second questionnaire consisted of 20 questions, divided into 4 defined domains. There were 8 screening questions, 3 logistics questions, 3 environment and safety questions and 6 communication questions. Numerous round 1 questions were modified to provide clarity in the second round of questioning. Modifications were implemented by rephrasing questions or isolating ideas into multiple questions with revised and improved answers. Only 3 completely new questions were added to the survey, all of which were in the communication section. After the 2 rounds of voting, all participants reviewed the results and provided insights on the data.

Surveys were produced using Qualtrics XM software. Analysis of survey responses was performed using Microsoft Excel.

FIGURE 1 Ten-step consensus initiative: guidance for performing rapid diagnostic tests in Canadian pharmacies

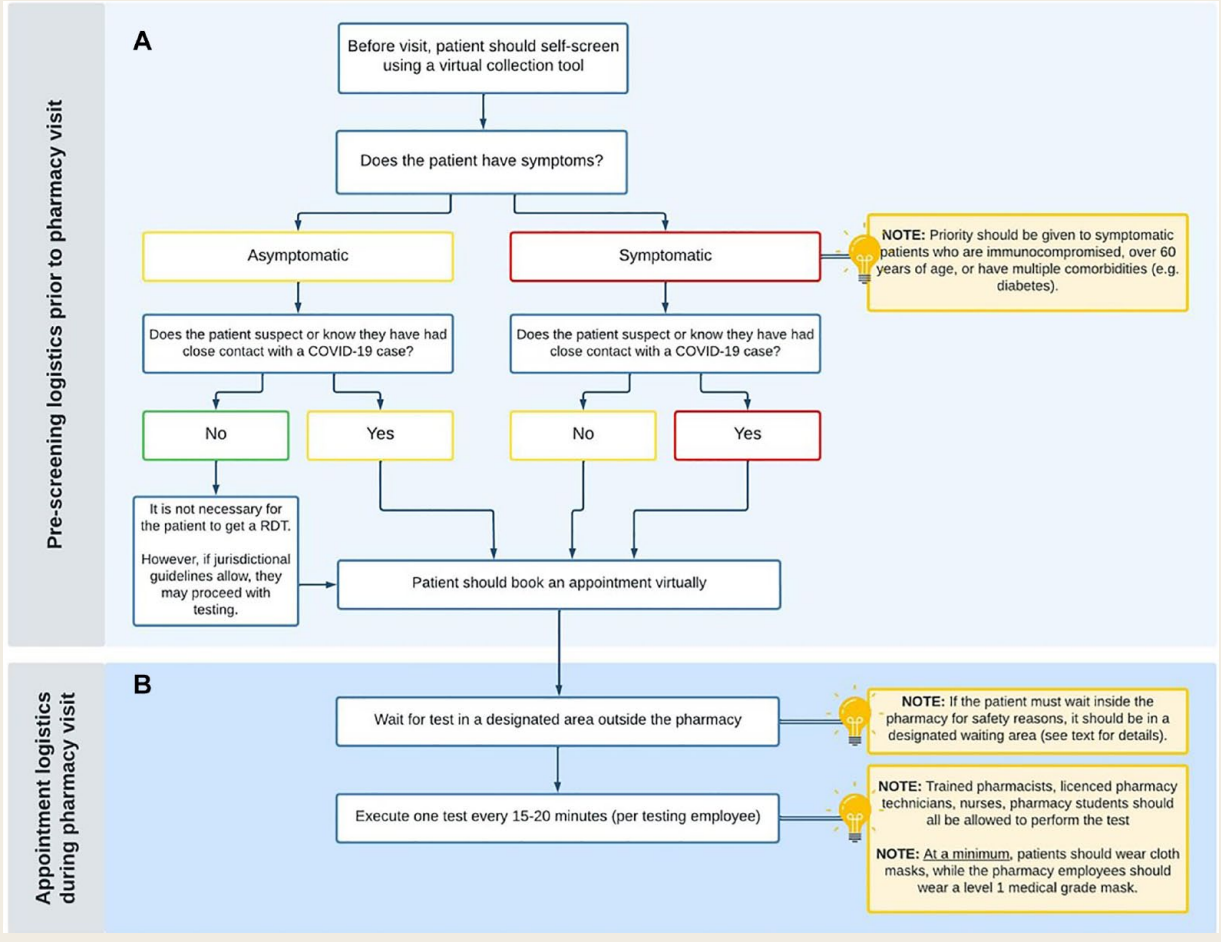
Results

The areas of interest identified for consensus voting were screening, logistics, environment and safety, and communication. In round 1, 25% (6/24) of questions reached consensus, which included 33% (2/6) of screening questions, 25% (1/4) of logistics questions and 36% (3/11) of communication questions. No questions from the environment and safety section reached consensus in round 1. In round 2, 55% (11/20) of all questions

TABLE 1 Summary of question development and consensus analysis in rounds 1 and 2

	Total	Screening	Logistics	Environment and safety	Communi-cation
No. of questions posed in round 1	24	6	4	3	11
Percentage of questions that reached consensus in round 1	25	33	25	0	36
No. of questions posed in round 2	20	8	3	3	6
No. of round 1 questions modified or clarified for round 2	10	4	1	2	3
No. of new questions added to round 2	3	0	0	0	3
Percentage of questions that reached consensus in round 2	55	63	100	33	33

FIGURE 2 (A) Patient prescreening in the context of pharmacy workflow and (B) appointment logistics during pharmacy visit for rapid diagnostic testing

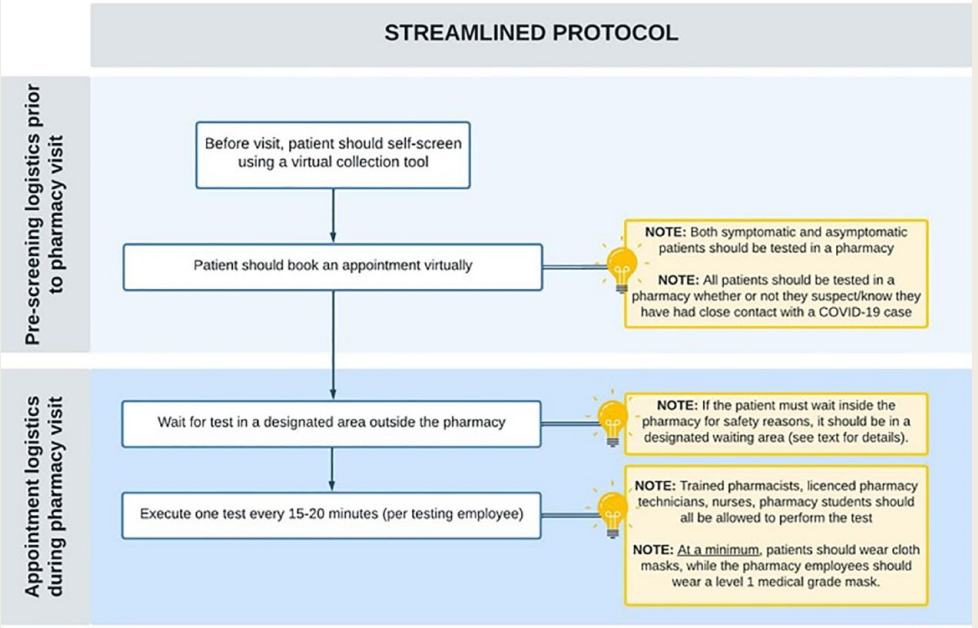


reached consensus, including 63% of screening questions (5/8) and 100% of logistics questions (3/3). Both the environment and safety section and the communication section found 33% consensus (1/3 and 2/6, respectively) (Table 1).

Screening questions

There was robust discussion on the safest and most effective method of screening patients before testing in a pharmacy setting (Figure 2A). Consensus voting found that patients should

FIGURE 3 Streamlined protocol for when sufficient resources are available and testing is available for all patients



fill out their own screening data virtually before their pharmacy visit, using a downloadable form or an app or over the phone. If jurisdictional guidelines allow, both asymptomatic and symptomatic individuals should be tested in a pharmacy setting. If patients do not suspect they had close contact with a SARS-CoV-2-positive case, it is not necessary for asymptomatic individuals to get tested; however, if jurisdictional guidelines allow,[12] individuals may proceed with testing. In the event of limited resources, priority testing should be provided to symptomatic patients who are immunocompromised, who are older than 60 years or who have multiple comorbidities. As RDTs and personal protective equipment (PPE) are currently abundant, there are no restrictions on which patients can be tested in a pharmacy, streamlining the screening logistics (Figure 3). Consensus was not reached on whether patient consent is required to collect or store screening data.

Logistics

Guidance for strategic planning of testing appointments was determined (Figure 2B). All experts agreed that testing appointments should be booked virtually (online or via phone call) before testing; walk-in appointments should not be accepted. Testing appointments should be scheduled approximately 15 to 20 minutes apart (per testing employee). Patients should wait outside of the pharmacy until their testing time slot is available, ideally within a designated area outdoors, but on the pharmacy premises. Our team of experts noted that many pharmacies are too small to have a designated indoor waiting area for patients and it would be safer for patients to wait outside. If patients cannot wait outdoors (due to safety concerns, inclement weather, etc.), they should be allowed to wait indoors if there is enough room.

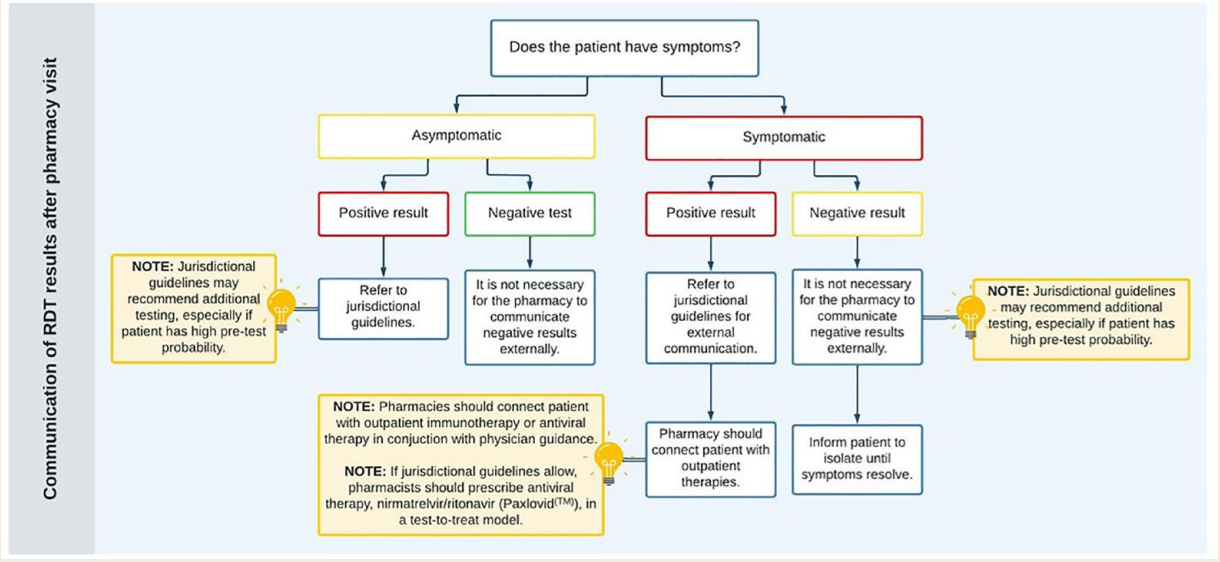
Environment, safety and testing

Environmental safety concerns were voted on and consensus was observed that pharmacists, licensed pharmacy technicians, nurses and pharmacy students should all be allowed to perform rapid diagnostic testing, once appropriately trained. It was determined that appropriately trained pharmacy assistants or other pharmacy employees should not perform testing, which is outside of their responsibilities, as there are other personnel who should be performing the testing. While there was no consensus regarding the minimum level of eye and face protection that the pharmacy employee performing the rapid diagnostic test should wear, it was agreed that pharmacy team members should not wear cloth masks. At a minimum, employees should wear medical/surgical masks (level I/II); ideally, employees should wear well-fitted medical/surgical masks (level III) or N95 respirators. Patients should also be required to wear masks, although cloth or medical/surgical (level I/II) are deemed most appropriate. No recommendations were agreed upon concerning filtration, CO_2 monitoring or ventilation for pharmacies that perform rapid diagnostic testing indoors.

Communication

Guidance surrounding the communication of post-test results was discussed (Figure 4). It was agreed that when communicating the results of the RDT, SARS-CoV-2 RDT test data should be stored by the pharmacy, either in the pharmacy

FIGURE 4 Indication and post-test communication of rapid diagnostic test results for SARS-CoV-2



patient database or in a separate SARS-CoV-2 database within the pharmacy database. There was no agreement on whether positive RDT results should be reported to a provincial database since, at the time of writing of this article, none existed; thus, pharmacy employees should follow the most up-to-date jurisdictional guidelines or recommendations for reporting positive results. Unless public health authorities state otherwise, it is not recommended to report negative results externally. If guidelines do recommend or require that RDT data be reported to a provincial or regional authority, reporting should be done virtually (email or platform, if secure and compatible with HIPAA regulations), rather than verbally (phone call). Additionally, HIPAA-compliant Software as a Service (SaaS) tools currently exist, which automatically capture patient results with consent options that allow for data sharing in real time between the pharmacy and patient.

Relevant survey questions were developed to help provide guidance on the communication of next steps for patients who underwent RDT testing. It was determined that symptomatic patients who test negative should be instructed to isolate until symptoms resolve. Further, any patients who test positive, whether they have symptoms or not, should follow the most up-to-date public health guidance when determining whether subsequent molecular testing is necessary; thus, no additional guidance is recommended. Critically, patients who test positive for SARS-CoV-2 who are at a high risk of progression to severe disease should be provided access to outpatient therapeutics, such as outpatient immunotherapy or antivirals as appropriate, in conjunction with clinician guidance and/or delegated medical guidelines.

The circumstance of patients being provided at-home testing kits was investigated in the questionnaires. No consensus was found on whether a pharmacy should add instructional information in addition to the at-home testing kit package insert. If a pharmacy does decide to include additional information, it is recommended that this be a document/flyer with advice on what to do if test results are positive/negative and a QR code with a link to an instructional video. When a patient was not available to pick up at-home testing kits, there was also no agreement on whether the kit could be given to a surrogate, such as the patient's caregiver.

Discussion

In this article, we summarize a process by which experts reached a consensus on the management of SARS-CoV-2 testing in the outpatient pharmacy setting. To our knowledge, this is the first such guideline in this context to be compiled. This summary provides a key framework and a model of implementation to pharmacists and other pharmacy employees who play a vital role in the management of the SARS-CoV-2 pandemic and fills a critical knowledge gap for these health professionals.

RDTs are already becoming less available to the public[13] and their availability will likely be further reduced as funding decreases. For patients to get tested outside of busy acute care centres, community pharmacies provide a good balance between home and acute facilities. Although RDTs can be performed at home, results are more accurate when performed by HCPs.[6] As such, having pharmacies prepared to become a resource hub in this situation is important. PCR tests are considered the gold standard for SARS-CoV-2 testing, although they are expensive and time-consuming and require laboratory facilities with specific expertise.[2,14,15] Other community pharmacy models have emerged in some provinces, whereby the pharmacy partner acts as a collection site with diagnostic laboratory providers to administer RT-PCR testing services for patients. In these scenarios, the practitioners implementing the services are pharmacists or other pharmacy team members, but the collected specimen

takes more time to obtain a result and must be sequenced by the accredited laboratory provider.[16] Antigen testing relies on a higher viral load compared with PCR testing, resulting in fewer positive tests, but is more accurate to detect infectiousness.[17,18] Repeat antigen testing may be necessary in select patients to improve sensitivity,[19] and multiplex testing, which combines SARS-CoV-2 and influenza tests, may be beneficial in patients exhibiting symptoms who continue to test negative for SARS-CoV-2 after repeat testing.[20] RDTs have quick turn-around times, are easy to interpret, are affordable and are very reliable in detecting infectiousness[2,15] and, as such, they will likely continue to play an important role in the future.

Recommendations

- Testing appointments should be booked virtually (online or over the phone) and pharmacies should not accept walk-in appointments.
- Screening patients should fill out their own screening data remotely before the pharmacy visit.
- Appointments should be booked 15-20 minutes apart (per testing employee).
- Patients should wait in a designated area outside the pharmacy until their appointment time slot; if patients must wait inside the pharmacy, there should be an area designated for this purpose.
- In the event of limited resources, certain (symptomatic) populations should be given priority for testing in a pharmacy, namely immunocompromised patients, patients over the age of 60 and those with multiple comorbidities (e.g., type 2 diabetes, congestive heart failure).

To cut down on wait times and backlog, it was agreed that appointments should be booked about 15 to 20 minutes apart (per testing employee). A standard RDT is performed by collecting a patient sample (nasal swab or nasopharyngeal swab), incubating the sample with extraction buffer for 2 minutes, adding the extracted solution to the test device and reading results after 15 minutes.[21-23] As such, having appointments 15 to 20 minutes apart is an appropriate amount of time to test and obtain results with minimal overlap between patients. Considering the tight timelines of each testing appointment and the recommendation for patients to wait outside the pharmacy until their timeslot, patients should be strongly encouraged to arrive on time to their appointments. These logistical guidelines aim to increase employee and patient safety in the pharmacy.

Recommendations

- Pharmacy employees should wear well-fitted surgical masks or N95 respirators.
- Patients should be required to wear a mask when being tested for SARS-CoV-2; if the patient does not have a mask, the pharmacy will provide one.
- Testing can be performed by properly trained pharmacists, licenced pharmacy technicians, nurses or pharmacy students.

A key practice that increases safety in the RDT testing setting is mask-wearing for both pharmacy employees and patients, even if it is not required by law or local public health directives.[24] At a minimum, pharmacy employees should wear well-fitted surgical masks or N95 respirators. Patients may be permitted to wear cloth masks but should ideally wear, at minimum, surgical masks. It is important for both the patient and pharmacy employee to be masked during testing so that maximal protection is achieved for both parties against inhaling infectious particles.[24] Masking has been demonstrated to be beneficial in community settings, such as in settings where mask mandates are associated with significantly lower rates of SARS-CoV-2 case growth,[25,26] lower rates of hospitalization[27] and fewer SARS-CoV-2-related deaths.[26] Additionally, mask efficacy can vary significantly, with cloth masks able to filter anywhere from 28% to 91% of small aerosol particles (<300 nm) and commercial masks capable of filtering 53% to 75% of small particles.[28] Notably, the literature has shown that mask fit was more important than the material the masks are composed of, where tight-fitting masks are more effective, especially cone-shaped masks.[28] Thus, the pharmacy should have surgical masks on hand to provide to patients who do not bring a mask to the appointment.

Recommendations

- Jurisdictional guidelines surrounding storage and reporting of RDT results should be followed.
- Pharmacies should facilitate access to outpatient therapeutics in conjunction with clinician guidance and/or delegated medical guidelines.
- If positive cases are being communicated to external parties, this should be done via virtual communication tools (e.g., email or digital platform, if secure and in compliance with HIPAA regulations).

Guidance surrounding the collection and storage of test results is severely lacking, and consensus was not found in many areas of consideration associated with this topic. This is likely because policies are frequently modified and can vary significantly depending on the province or jurisdiction.[12] Although each jurisdiction provides guidance as to whether results are to be reported to municipal or provincial bodies,

guidelines are lacking on whether pharmacies should maintain their own records.

Jurisdictional guidelines also vary significantly on whether pharmacists can facilitate access to outpatient therapeutics and antivirals. For example, the ability of pharmacists to initiate nirmatrelvir/ritonavir (Paxlovid) varies by province.[29,30] Relevant to results of this application, in April 2022, Quebec became the first Canadian jurisdiction to grant pharmacists the authority to prescribe nirmatrelvir/ritonavir (Paxlovid) to patients in a "test-to-treat" model, of which point-of-care antigen testing was a valid method of diagnosis[31]; other provinces have since implemented a similar system.[32-34] The ability for pharmacists to test and treat in the same environment creates an opportunity for pharmacies to fill a gap by providing a connection between point-of-care testing and accessing appropriate therapies.[35] Further, encouraging regular testing in high-risk populations minimizes the delay between testing and treatment, lowers the risk of hospitalization and reduces health care costs.[36]

The SARS-CoV-2/COVID-19 pandemic has forced health systems to rethink the way that our health care system delivers and rations care. Our consensus framework model is intended to extend beyond SARS-CoV-2 testing and serve as a blueprint for the implementation of other pharmacy-led screening and diagnostic services, which can include testing for strep throat, urinary tract infections, and metabolic panels. These testing modalities already exist in the marketplace; however, a few factors limit scale of adoption. One such factor is the "test-to-treat" model, whereby the inherent value to the patient is timely access to therapeutics (if appropriate and necessary) in the same visit and/or same pharmacy environment. Several provinces have regulations in place that allow specific pharmacy personnel to perform point-of-care tests in a community pharmacy setting. Authorized and trained pharmacy employees collect blood samples from patients and assist them with the management of their medication and treatment of their chronic diseases. For example, Ontario announced that point-of-care testing for glucose, hemoglobin A1C, lipids and prothrombin time (PT) and international normalized ratios (INR) can be performed in community pharmacies.[37,38] This algorithm provides a standardized and practical implementation model for pharmacies across Canada.

Conclusion

Our national panel of subject matter experts used the modified Delphi process to develop new standardized guidelines and an implementation framework to follow when performing SARS-CoV-2 RDTs in a pharmacy setting. Simple modifications to questions between voting rounds allowed our experts to clearly agree and align on many topics, highlighting the power of the Delphi or modified Delphi method for finding agreement on process. The recommendations and guidance developed from the 2 rounds of questions will provide knowledge, awareness and confidence for pharmacies to safely and effectively assess and test patients for SARS-CoV-2. Using community pharmacies to test for and treat SARS-CoV-2 will alleviate some of the burdens that are overwhelming acute care facilities in Canada and improve access for many patients. By receiving reliable test results, patients will know to quarantine or isolate as well as obtain access to treatment if necessary. The adaptable model of care described by these guidelines will ensure that pharmacy employees can provide these services to their communities safely and effectively. ■

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