RESOURCE TOOLKIT:

COVID@Home Monitoring for Primary Care

Implementing home monitoring for COVID-19 patients through primary care

March 17, 2021

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Introduction

During the COVID-19 pandemic, Hamilton Primary Care Leadership (including the McMaster University Department of Family Medicine) created the HFAM.ca website to support primary care resource sharing for Hamilton Family Medicine (HFAM) teams. Their model for monitoring patients with COVID-19 at home through primary care to optimize care for their patients was inspiring and led to the creation of this toolkit.

Purpose of This Document

This toolkit was created to be shared with primary care teams across Ontario to help them treat COVID-19 patients directly in the community. Using the best evidence pathways available through the HFAM website (HFAM.ca), this toolkit will provide the following information to help your team implement a remote home monitoring system for your COVID-19 patients:

1. Clinical content and suggested best practice pathways for primary care that will safely support COVID-19 patients in their home

2. Quality improvement building blocks that may be used in planning and sustaining a monitoring program within your setting

Rationale for Home Monitoring in Primary Care

Primary care is essential in the context of the COVID-19 crisis to help manage unexpected surges in demand on the health system and to maintain continuity of care for affected patients.[1] Implementing systematic COVID-19 monitoring programs in primary care creates the opportunity to provide optimized care for patients who do not need immediate hospital attention but may be at high risk of developing serious symptoms. For example, primary care monitoring may assist in early detection of pneumonia or asymptomatic hypoxia, allowing patients to receive appropriate, more intensive medical care sooner—before invasive measures are required.

If patients are admitted to hospital, primary care monitoring can also improve the transition from hospital back home by providing continuity of care for medically stable patients who require continued short-term oxygen support in terms of oxygen monitoring, continued oxygen provision (where appropriate), and oxygen weaning.

This toolkit is meant to provide guidance on leading practices and tools and resources for primary care providers or other teams who wish to support this work. Remote monitoring of COVID-19 patients in the community can be considered an extended model of primary care that can be ready to unburden hospital services that may become overwhelmed. It includes resources to support clinicians in establishing this type of program and a review of possible implementation steps.

> **Note:** There are currently 29 technology-based remote monitoring programs supporting patients with COVID funded throughout the province of Ontario with various local models (e.g., hospital-based COVID assessment centre models) and regional models (leveraging home and community care, and community paramedicine). If you want to learn more about a remote monitoring programs in your region and how you can work in collaboration to support your patients, please reach out to your regional digital lead (see Appendix A for a list of contacts).

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[1] Organization for Economic Co-operation and Development (OECD). Strengthening the frontline: How primary health care helps health systems adapt during the COVID-19 pandemic. Paris: OECD; 2021 Feb 10 [cited 2021 Mar 2]. Available from: https://read.oecd-ilibrary.org/view/?ref=1060_1060243-snyxeld1ii&title=Strengthening-the-frontline-How-primary-health-care-helps-health-systems-adapt-during-the-COVID-19-pandemic

Target Patient Population

For the purposes of this toolkit, we have categorized community-dwelling COVID-19 patients into three categories:

Group 1: Community-dwelling patients who have tested positive for COVID-19 and the primary care practice has received a notification. They may have risk factors that make them more vulnerable to serious illness and require increased monitoring beyond the advice public health can provide.

Group 2: Community-dwelling patients prefer to have their care needs met in the home setting, whose goals of care do not align with transfer to hospital, and where a palliative approach to care is being used. These patients require increased monitoring but also may require oxygen for management of symptoms and connection to additional supports to ensure they are able to remain at home.

Group 3: Community-dwelling patients who have tested positive for COVID-19 and have been hospitalized but are now stable and can be discharged earlier from hospital or directly from the emergency department if monitoring by primary care is continued. This can include patients who required continued oxygen provision and is planning an eventual weaning in the home setting, continued oxygen saturation monitoring, medication management (e.g., steroids) and/or intravenous (IV) fluids.

For the purposes of this toolkit, we will be focusing on Group 1 and Group 2 patients. Primary care models may be able to serve Group 3 patients once they have successfully rolled out to Group 1 and Group 2 patients in their practice, and if they have good relationships with other partners in their health care ecosystem.

COVID@Home Primary Care Monitoring Models

Table 1 outlines the suggested primary care monitoring models for Group 1 and Group 2 patients.

Table 1: Suggested Primary Care Monitoring Models for Group 1 and Group 2 COVID-19 patients

Primary Care Monitoring Models		
	Group 1 Patients	**Group 2 Patients**
Intent	• Provide safety net that reduces unnecessary ED visits • Ensure objective decision making regarding escalations for additional care	• Improve quality of care for patients with serious life-limiting illness • Care for COVID-19 patients on a palliative care pathway who require oxygen for symptom management
Activities of Care Team	• Triage and monitor oxygen saturation • Monitor symptoms through patient self-monitoring, patient education on management, and an action plan for "red flag" symptoms • Virtual primary care "ward rounds"/ check-ins with frequency determined by patient risk level (see Monitoring and Follow-up section of the HFAM website for risk assessment and monitoring frequency recommendations)	• Triage and monitor oxygen saturation • Monitor symptoms through patient self-monitoring and patient education • Manage oxygen and other medications • Virtual rounding/check-ins, as needed
Clinical Plan	• IV fluids and oxygen are not "started" on patients in this group • If patient condition worsens, they are sent to ED	• Oxygen provision, IV medications, and/or IV fluids/hypodermoclysis can be started if required • If patients condition worsens, goals of care are reviewed again, and external supports put in place if patient wishes to remain at home
Required Equipment and Human Resources	• Pulse oximetry monitors • Primary care physician **and/or** staff for monitoring (may include nursing and/or paramedicine, depending on setting)	• Oxygen saturation monitors, oxygen provision as required for hypoxia (see HFAM.ca pathway for targets) • Primary care physician or most responsible physician and other staff as clinically indicated for monitoring (e.g., may include respiratory therapy, if indicated and if available, home care nursing, or paramedicine)

Abbreviations: ED, emergency department; HFAM, Hamilton Family Medicine team; IV, intravenous

> **Note:** It is important for primary care teams to provide protocol-based care and fail-proof escalation pathways. If technologically-driven remote processes are used, low-tech back-up options should be readily available should technologies fail.

Clinical and Escalation Pathways

The HFAM.ca website includes links to all of the required tools and information for clinical and escalation pathways (including patient information and electronic medical record [EMR] templates), and the site is updated regularly as COVID-19 evidence evolves.

Clinical Pathways for Groups 1 and 2 COVID-19 Patients

Clinical recommendations for both acute COVID patients (Group 1) and those patients whose goal of care are consistent with palliating at home (Group 2) are available at the links below:

- **Group 1 (acute COVID-19 patients):** Hamilton Family Medicine Pathway for Assessment, Diagnosis and Management of COVID

- **Group 2 (patients who have goals of care which align with taking a palliative approach to care and who have indicated they do not wish to be transferred to hospital):** Hamilton Family Medicine Pathway for Group 2 COVID-19 Patients

Please see the Quality Improvement section for a high-level example of a possible clinical pathway for Group 1 and Group 2 COVID-19 patients.

Figure 1 shows a possible disease course for COVID-19 through three phases of the virus. The disease course is important to consider when thinking about the optimal time to start and stop active monitoring for patients. Anticipate that symptoms peak at 8 to 12 days after symptom onset and expect to monitor patients from 0 to 14 days or longer, depending on the individual's disease trajectory. (These details are included in the operationalised pathway; see "Monitoring and Follow-up/Risk Stratify Patient" in the HFAM pathway).
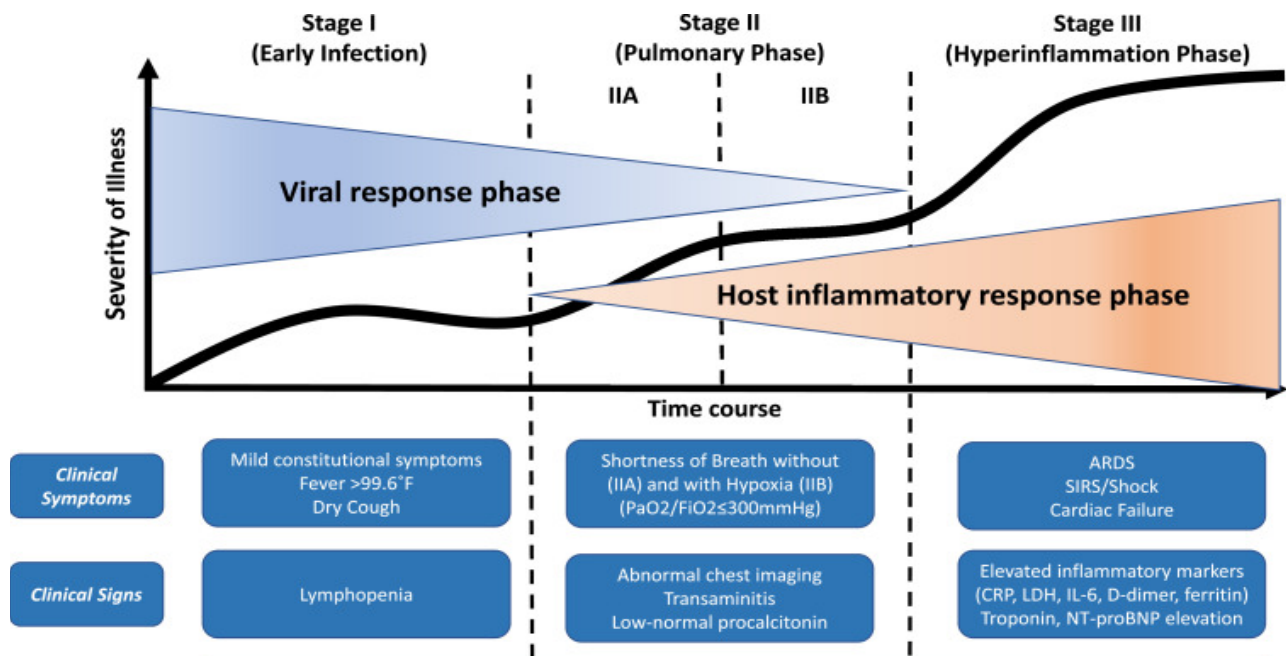
Figure 1: Possible disease course of COVID-19[2]

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[2] Siddiqi HK, Mehra MR. COVID-19 illness in native and immunosuppressed states: A clinical-therapeutic staging proposal. *J Heart Lung Transplant*. 2020; 39(5): 405–7.

Key Safety Factors and Escalation Pathways

In setting up *COVID@Home* monitoring systems, the following factors are **key** to ensuring patient safety:

1. Appropriate assessment of COVID severity, including risk assessment and risk stratification

2. Clear escalation pathways if patient experiences any "red flags" or their risk level changes

3. Quick access for patients to a clinical provider 24 hours a day, 7 days a week (or guidance on what to do if they can not reach their providers)

Risk Stratification

A [risk stratification table](#) is available from the HFAM webpage. It can be found under "Monitoring and Follow-up-Risk Stratify Patient tab" on the HFAM clinical pathway.

> **Note:** Please visit the [HFAM website](#) frequently as information is constantly updated to reflect the latest evidence and best practice.

Escalation Pathways for Red Flags

It is key that an escalation pathway for patient presenting with "red flag" symptoms (including hospital referral) is mapped out and agreed upon with all partners before commencing with the pathway with your clinic or group. *COVID@Home* monitoring systems should consider using [process mapping](#) to ensure decision points and pathways are clear to all team members involved as well as patients.

Common "red flags" that should trigger an escalation pathway to the emergency department may change as evidence is updated. Current "red flags" can be found at the following webpages:

- [Assessment, Diagnosis and Management of COVID page](#) of the HFAM website
  - In "History" tab and "When to Refer to the ED" tab

- [COVIDCare@Home clinical assessment tool](#) from Women's College Hospital

These "red flags" should be clear to all providers in your clinic and included as triggers in escalation pathways.

> **Tip:** In Hamilton, a specific rapid access advice line to secondary care physicians was made available to support patients who do not need transfer to hospital, but where secondary care advice would be useful. This may be a helpful support to set up in your own area.

Clinical Considerations

Oxygen Provision

Prior restriction to oxygen therapy qualifications and funding are being waived during the pandemic.

> **Note for users outside the Hamilton area:** These pathways from HFAM include VitalAire and ProResp Order Forms for oxygen provision. You may have relationships with a different oxygen provider in your area. **A full list of oxygen providers can be found HERE**. If you are working with another oxygen provider, please confirm this provider can rapidly initiate home oxygen, if needed, including on weekends to map your local requirements.

Oxygen Saturation Monitoring

The following three pulse oximetry monitors are available from the Ministry of Health:

- Thermor BIOS 11PO Oximeter — Operator's Manual
- ChoiceMMed MD300C20 — Operator's Manual
- ChoiceMMed MD300C29 — Operator's Manual can be found in Appendix B (not available online)

The above monitors can be requested from the ministry via this link. Please consider the size of the population you are serving and the incidence of COVID-19 in your community when determining quantities for ordering.

> **Public Health Guidance:** Pulse oximeters should be cleaned with approved alcohol wipes and then ordered by return date in storage. Public Health advice suggests this cleaning plus a 24-hour "rest period" before re-allocating to protect those handling devices for the patient.

EMR Integration

A template for this clinical pathway has been created for several electronic medical record (EMR) platforms, including OSCAR, TELUS, and Accuro. The development of the OSCAR template was led by Dr. Dee Mangin, Professor and Associate Chair of Research, McMaster Department of Family Medicine and her colleagues. The TELUS and Accuro EMR templates were adapted by the North York Family Health Team. Links to all three templates can be found here.

The purpose of the template is to better support primary care in comprehensive monitoring of patients who have tested positive for COVID-19, enabling early and effective intervention, and wherever possible, reducing demand on our hospitals. The tool may also be used as a monitoring template for patients discharged from hospital after initial management of COVID. The eForm links to best practice information for assessing and managing COVID-related illness that has been curated by our Department and made available for download on the Hamilton Family Medicine (HFAM) website.

Tools for the OSCAR EMR can be found below:

- [OSCAR COVID Community Ward Monitoring Record](#) eForm
- [Report by Template](#) (For optimal performance, it is recommended that you add an index to the database; instructions provided in the link)

> **If you are a client of Well EMR Group:** You can email help@oscarprodesk.ca to have the tools added to your system.

FOR TELUS

Custom TELUS EMR forms can be found at this link: [Telus PS Custom Forms on COVID-19 Positive Patient Tracking Tool for Telus PS Suite](#)

FOR ACCURO

Follow the same steps you would in downloading other templates (e.g., [Quality Standards placemats](#)) or patient forms. Follow these four easy steps:

1. Go To Tools $\Rightarrow$ Forms editor
2. Click Tools $\Rightarrow$ Publish/Download
3. Use the keyword "Ontario Health" or "COVID@Home" to search
4. Download the form

Please contact support@QHRtech.com for support.

Assigning Staff Roles

It can be helpful to assign specific roles to staff to ensure that all patients are well monitored. Table 2 provides an example of how responsibilities can be divided.

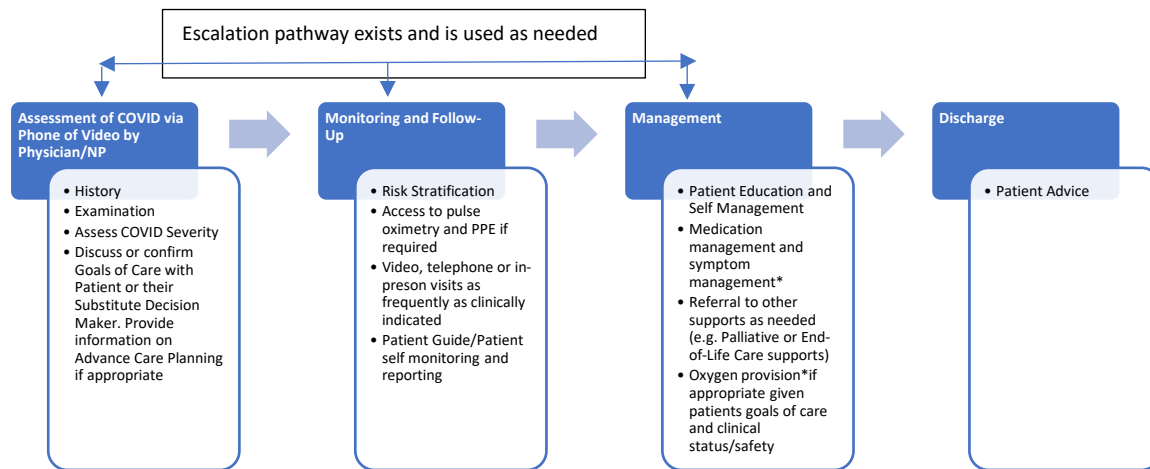**Table 2: Sample Assignment of Roles and Responsibilities**

Role	Options to Source	Responsibilities
Remote monitoring of patients	• Clinic physicians or NPs • Larger groups may also organise to deliver remote monitoring for a local area (e.g., community health centres, family health teams)	• Initial assessment and risk stratification • Communication with monitoring team members • Review patients regularly and provide patients information and education
On-the-ground clinicians *(most primary care patient monitoring does not require any in-home staff)*	• Respiratory therapy from oxygen vendors • Home care nurses • Family health team nursing staff • Community paramedicine • Primary care providers	• Perform home visits, if indicated • Support patient and families • Communicate findings to lead most responsible physician (e.g., physician, NP, etc.)
Patients and Substitute Decision Makers	• Not applicable	• Provide consent to participate in assessment and treatment if program provided outside their usual primary care setting (e.g., technology-based remote monitoring programs) • Allow on-the-ground providers access (into the home) as required • Agree to use virtual tools as needed • Access to home internet or cell phone with data if apps are being used for video visits or monitoring or any phone for "low tech" monitoring via telephone • Participate in self monitoring activities and data entry
Infection Prevention and Control Expertise	• Public health • Regional hubs • Hospital partners	• Support to team regarding IPAC practices for visiting patient in the home, instructions for caregivers in the home, and cleaning procedures for equipment
General Internal Medicine, Emergency Department physicians, Palliative Care Specialists	• Hospital partner (local hospital or tertiary care centre)	• Provide advice regarding COVID treatment and escalation of care as needed • Help develop direct care advice and pathway from community to hospital
Volunteers	• Local community groups	• Assist with delivery and pick up of oxygen saturation monitors when they are no longer needed by patients • Ensure IPAC advice is followed (e.g., appropriate distancing, hygiene, and PPE use)

Abbreviations: IPAC, infection prevention and control; NP, nurse practitioner; PPE, personal protective equipment

A Quality Improvement Approach to Implementation

Sample Mapping of a Clinical Pathway

Stakeholders may use the following sample clinical pathway (Figure 2) or map out their own (as long as best evidence/best practice is followed). Consider indicating which team members are involved in each activity and any tools or resource which will be used at each step.

Escalation pathway exists and is used as needed

Assessment of COVID via Phone of Video by Physician/NP
- History
- Examination
- Assess COVID Severity
- Discuss or confirm Goals of Care with Patient or their Substitute Decision Maker. Provide information on Advance Care Planning if appropriate

Monitoring and Follow-Up
- Risk Stratification
- Access to pulse oximetry and PPE if required
- Video, telephone or in-preson visits as frequently as clinically indicated
- Patient Guide/Patient self monitoring and reporting

Management
- Patient Education and Self Management
- Medication management and symptom management*
- Referral to other supports as needed (e.g. Palliative or End-of-Life Care supports)
- Oxygen provision*if appropriate given patients goals of care and clinical status/safety

Discharge
- Patient Advice

*clinical decision making based on best-evidence – COVID science evolving rapidly requiring practitioners to stay up to date

Figure 2: Sample clinical pathway for Group 1 and Group 2 COVID-19 patients (based on the HFAM clinical pathways)

Pre-Implementation Activities

Readiness Assessment Questions

Before implementing a quality improvement (QI) change, it is important to conduct a readiness assessment. The following are prompting questions to help you understand factors that will affect your ability to implement provision of different levels of comprehensive COVID care for patients at home:

1. Do I have the human resource capacity and flexibility to do the different levels of this work (including monitoring over the weekends)?

2. Does my team have experience with previous QI initiative or projects? Were these successful?

3. Does my team have relationships with other parts of the system that can be leveraged for this program to work at different levels of intensity (e.g., the ability to provide monitoring consultations and access to a pulse oximeter for Group 1 patients, or the ability to refer to oxygen suppliers, community paramedicine, home and community care, hospital emergency department (ED)/virtual ED or hospital general internal medicine programs, palliative care resources, etc. for palliative or Group 2 patients)?

4. Do I have access, or can I get access to the technology required to run this type of program (e.g., virtual care technology [including phone visits], a place to document patient statuses, an agreed upon way to communicate with other team members)?

5. For Group 2 patients, are all key stakeholders aware of the change? If not, how will you make them aware of this change?

6. Do the team members/stakeholders understand the purpose and demonstrate a willingness to support this initiative?

7. Do our team members currently have the education and skills needed to support this initiative? If not, when, where, and how will they get them?

Implementation Activities

The following checklists help guide the implementation of your *COVID@Home* remote monitoring system.

Implementation Checklist 1 (QI and Change Management Perspective):

- ☐ Identify a leader or champion
- ☐ Engage all team members who will support this initiative
- ☐ Review the pre-implementation readiness assessment questions with the team and brainstorm mitigation strategies for areas of deficit or change ideas around items as needed
- ☐ Identify scope (which patients to enroll first for plan-do-study-act [PDSA] cycles)
- ☐ Create a process to share education, tools, and resources to prepare for new monitoring
- ☐ Plan for a way to integrate toolkit contents, especially clinical pathways, into workflow (test on PDSA group)
- ☐ Brainstorm ways to use other resources, aids, innovative thinking, or partnerships to promote effective skills, knowledge, and confidence among all team member (which will improve patients' satisfaction and safety)
- ☐ Evaluate use and benefits of this model of care

Implementation Checklist 2 (Operational Perspective)

Do I have the following in place?

- ☐ Access to an evidence-based risk assessment tool, which includes "red flags" for escalation
- ☐ For Group 2 patients: a process for rapid assessment of oxygen needs with a vendor and rapid delivery of equipment and 24/7 access to respiratory therapy
- ☐ Process in place for timely initial assessment (in-person or virtual) by nurse practitioner or physician
- ☐ Process or partnerships in place to deploy human resources for monitoring oxygen saturation and other clinical indicators virtually and/or in-person (also on weekends)
- ☐ Education materials for patients developed and ready for distribution
- ☐ Secure place to document patient
- ☐ Communication pathway or tool for interprofessional team members
- ☐ Process in place for delivery, pick up and cleaning of pulse oximetry monitors (if not done by oxygen vendor)
- ☐ Escalation pathway or "fast track corridor" in place with hospital partner
- ☐ Process for providing after-hours contact to patients in distress
- ☐ Clear criteria for discharge

Implementation Checklist 2 is by no means an exhaustive list of steps a team may take to initiate a remote monitoring system but does provide some "big bucket" items that require consideration and action for implementation to be successful.

Model for Improvement

Several QI tools and resources can be found on Ontario Health's Quorum page under the QI Tools and Resources Tab. Using the Model for Improvement in Figure 3 can help you know what you want to improve and allow you to test a change before you attempt to implement it on a larger scale. Since we already have evidence or best practices, developing change ideas is much easier! You may need to think about what the "gaps" are between your current practice and the ability to meet these best practices. Your change ideas will be developed around finding ways to embed this new standard of practice into your current workday/workflows.
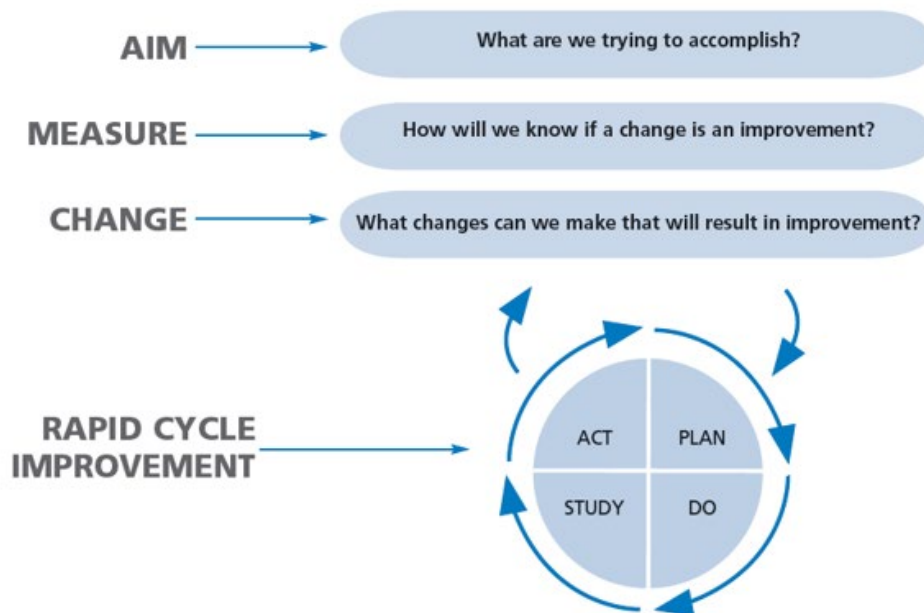
Figure 3: Model for Improvement

The Plan-Do-Study-Act (PDSA) tool will help you set up a small test of change using the principles provided in this resource toolkit. This helps to minimize risk and increase provider confidence in using new practices. If unsuccessful, you can tweak or modify as needed and try it again. If successful, you can continue to widen the scale. See Figure 4 for an example of a completed PDSA worksheet after one test cycle.

PDSA: Plan-Do-Study-Act TOOL

Test Topic: Develop process of COVID+	Cycle #:	Date:

PLAN

The purpose of this cycle is to: ❑ Develop ❑ Test ❑ Implement

What questions do you want to answer?	What are your predictions?
Can I develop a process to montior my COVID+ patients who have risk factors that make them more vulnerable to serious ilness and who may need increased monitoring? Can I test this process on a small group of patients?	Yes - with support from my hospital partners and some community services Yes - I can try this with the next three COVID+ patients that are identified in my practice

Plan to collect data to answer your questions:

What data will be collected?	How? (checklist, chart audit)	Who? (name or role)	When? (times, dates – be specific)	Where? (unit, area, charts)
# of patients monitored per month # staff members educated on new processes	EMR	admin	pull data at end of each month	using PC in back office

List tasks necessary to set up test:

What? (specific task)	How? (checklist, chart audit)	Who? (name or role)	When? (times, dates – be specific)	Where? (unit, area, – be specific)
Download COVID Community Ward monitoring form into my EMR Educate staff on new model and process Connect with community para-medicine and Home and Community Care Contacts re: assistance with monitoring	electronic discuss at next staff meeting and set aside extra time e mail and follow up phone call	front desk staff physician QI specialist	by Feb 20th Feb 21st at staff meeting by Feb 20th	electronic virutally on Zoom by phone from home

Figure 4: Sample Completed PDSA Worksheet

Discussion

Enablers and Barriers Teams Can Expect

The following are lists of considerations and topics for discussion with your team and/or stakeholders as you develop your *COVID@Home* monitoring system.

Enablers

What are possible facilitators to implementation and how can we incorporate these?

- Clear instructions for patients
- Ease of clinical pathway into workflow
- Having time available to implement this model
- Interdisciplinary approach to implementation

Barriers

What are possible barriers to implementation and how can be mitigate them?

- Not enough time or staff to implement
- Uncertainty of process owner
- Necessary resources unavailable
- Model does not fit into our current workflow
- Patient guides and education not accessible to those non-English reading/speaking
- Uncertainty around which billing codes to use/financial renumeration

Additional Resources

A list of remote home monitoring contacts can be found in Appendix A. The Operator's Manual for pulse oximetry monitor MD300C29 can be found in Appendix B. Additional resources to help support the implementation of your *COVID@Home* monitoring system in primary care can be found in Appendices C and D.

Appendix A: List of Current Remote Monitoring Programs and Contacts

Region	Ontario Health Team (OHT)	Lead Organization	Remote Patient Monitoring (RPM) Technology	Regional Digital Health Lead Contact
Central	Hills of Healthwaters Collaborative	Headwaters Health Care Centre-LIVE	Community Paramedicine RPM-Ideal Life	OH-Central_DigitalVirtual@ontariohealth.ca
	Western York Region	Mackenzie Health-LIVE	EPIC-Healthy Planet-One Care plan MYCare COVID-output	
East	Scarborough, Durham, Peterborough, Northumberland, Kawartha Lakes	Central East LHIN Home and Community Care-LIVE	Vivify Go+	OH-East_DigitalVirtual@ontariohealth.ca
	Ottawa and Ottawa East OHTs	Champlain LHIN Home and Community Care	Vivify Go+	
	Lanark Leeds Grenville OHT	Brockville General Hospital	aTouchAway-(Aetonix)	
	Rural Hastings, Quinte OHT's	Bellville Quinte West Community Health Centre	Raziel (Ideal Life), aTouchAway	
	Frontenac, Lennox, Addington OHT	Lennox and Addington County General Hospital	aTouchAway- (Aetonix)	
North		Thunder Bay Regional Health Sciences Centre-LIVE	Vivify Go	OH-North_DigitalVirtual@ontariohealth.ca
		Sudbury EMS-LIVE	Raziel (Ideal Life)	
		Cochrane EMS	Raziel (Ideal Life)	
		Parry Sound EMS and West Perry Sound Health Centre-LIVE	Raziel (Ideal Life)	
		Superior North EMS (Thunder Bay)	Raziel (Ideal Life)	
		Maamwesying North Shore Community Health Services	Vivify Go	
Toronto	East Toronto OHT	Michael Garron Hospital-LIVE	Vivify Go	OH-Toronto_DigitalVirtual@ontraiohealth.ca
	Mid West Toronto OHT	University Health Network-LIVE	UHN-RCOVID app	
		Women's College Hospital-LIVE	WCH-EPIC/Zoom/RCOVID-Care Companion	
	North Toronto OHT	Sunnybrook Health Sciences Centre-LIVE	Phone/video	
		Baycrest Hospital-LIVE	Vivify Go	
	North Western Toronto OHT	Humber River Hospital -LIVE	Healix	
	North York Health Partners OHT	North York General Hospital	Vivify Go	
	West Toronto	Unity Health Toronto LIVE	Phone/email/Zoom	
West	Brandford-Brant	County of Brant, Town of Paris, Township	Raziel (Ideal Life)	OH-West_DigitalVirtual@ontariohealth.ca
	Burlington	Burlington Family Health Team-LIVE	Aetonix	
	Chatham-Kent	Chatham-Kent Health Alliance-LIVE	Vivify Go	
	Guelph Area	The Corporation of the City of Guelph-LIVE	Vivify Go, Raziel (Ideal Life)	
	Hamilton OHT	St. Joseph's Healthcare Hamilton-LIVE	Cloud DX, EPIC	
		Hamilton Health Sciences	Cloud DX	
	10+ OHTs in West Region	South West LHIN Home and Community Care-LIVE	Vivify Go	
	Western (London and Middlesex)	London Health Sciences Centre-LIVE	Phone	

Fingertip Pulse Oximeter

ChoiceMMed

## USER MANUAL

General Description

Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO_2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO_2 level.

Measurement Principle

Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO_2.

Diagram of Operation Principle
1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube
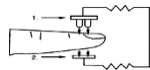
Precautions For Use

1. Before use, carefully read the manual.
2. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
4. Do not use the fingertip pulse oximeter in an MRI or CT environment.
5. Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the fingertip pulse oximeter in an explosive atmosphere.
7. The fingertip pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
8. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
9. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
10. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
11. This equipment complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
12. Portable and mobile RF communications equipment can affect medical electrical equipment
13. This equipment is not intended for use during patient transport outside the healthcare facility.
14. This equipment should not be used adjacent to or stacked with other equipment.
15. It may be unsafe to：
—use accessories、detachable parts and materials not described in the instructions for use
—interconnect this equipment with other equipment not described in the instructions for use
—disassemble, repair or modify the equipment
16. These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
17. When the signal is not stable, the reading may inaccurate. Please do not reference.
Rx only: "Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner."

Contraindication

It is not for continuous monitoring.

Inaccurate measurements may be caused by

1. Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive patient movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Low hemoglobin.

Product Features

1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. Dual color OLED displays SpO_2, PR, Pulse bar, and waveform.
4. Level 1-10 adjustable brightness.
5. 6 display modes.
6. 2pcs AAA-size alkaline batteries; battery-low indicator.
7. When it shows "Finger out", the pulse oximeter will power off automatically in 8 seconds.
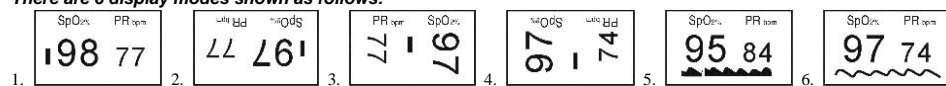
Intended Use

The Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homecare.
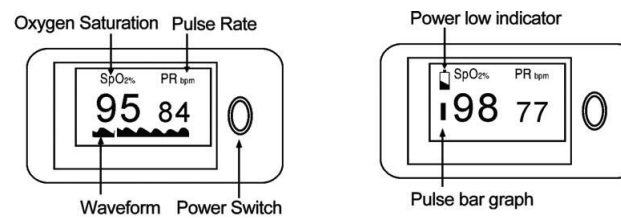
Operation Instructions

1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the pulse oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
5. Read the data from the display screen
6. Press the power switch for longer than one second, will adjust the brightness of the oximeter. There are 10 levels of brightness. The default is level four.

After turning on the Oximeter, each time you press the power switch, the Oximeter will switch to another display mode. There are 6 display modes shown as follows:

1. 98 77 2. 97 77 3. 97 77 4. 97 74 5. 95 84 6. 97 74

Front Panel

Oxygen Saturation   Pulse Rate

95 84

Waveform   Power Switch

Power low indicator

98 77

Pulse bar graph

The pulse bar less than 30% indicates signal inadequacy and the displayed SpO_2 and pulse rate value is potentially incorrect.

Battery Installation

1. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
2. Slide the battery door cover horizontally along the arrow shown as the picture.

Notes:
✧ Please remove the batteries if the pulse oximeter will not be used for long periods of time.
✧ Please replace the battery when the power indicator starting flickering.
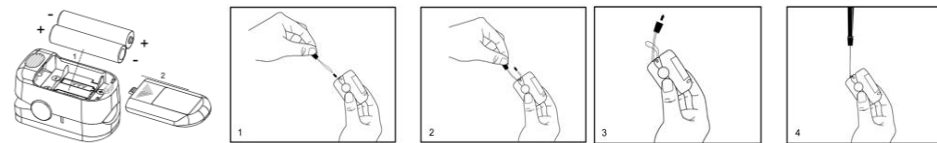
Using the Lanyard

1. Thread thinner end of the lanyard through the hanging hole.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.

⚠ **Warnings!**
✧ Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
✧ Do not hang the lanyard from the device's electrical wire.
✧ Please notice that the lanyard which is tied to the oximeter may cause strangulation due to excessive length.

Maintenance and Storage

1. Replace the batteries in a timely manner when low voltage lamp is lighted.
2. Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
3. Remove the batteries if the oximeter is not operated for a long time.
4. It is best to store the product in -25℃~+70℃ and ≤93% humidity.
5. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning the fingertip pulse oximeter
Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.
Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.
The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.

The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:
● An error in the *Possible Problems and solutions* is displayed on screen.
● The oximeter cannot be powered on in any case and not the reasons of battery.
● There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.
Disinfecting
The applied parts touching the patients' body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.
Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter before disinfecting it.
CAUTION: Never use EtO or formaldehyde for disinfection.

Specifications

1. Display Type
OLED display

2. SpO_2
Display range: 0%~100%
Measurement range: 70%~100%
Accuracy: 70%~100%±2%; 0%~69% no definition
Resolution: 1%

Note: A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (**SpO_2**) of the sensors is compared to arterial hemoglobin oxygen (**SaO_2**) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the **SpO_2** range of 70%~100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment‐Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
A functional tester is used to measure how accurately Fingertip Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy.
The model of functional tester is Index2 FLUKE simulator and the version is 2.1.3.

3. Pulse Rate
Display range: 0bpm~250bpm
Measure range: 30bpm~250bpm
Accuracy: 30bpm~99bpm, ±2bpm; 100bpm~250bpm, ±2%
Resolution: 1bpm

4. Probe LED Specifications

	Wavelength	Radiant Power
RED	660±3nm	3.2mw
IR	905±10nm	2.4mw

NOTE: The information about wavelength range can be especially useful to clinicians.

5. Power Requirements
Two AAA alkaline Batteries
Power consumption: Less than 40mA

6. Environment Requirements
Operation Temperature: 5℃~40℃
Storage Temperature: -25℃~+70℃
Ambient Humidity: 15%～93% no condensation in operation; ≤93% no condensation in storage/transport
Atmosphere pressure: 70kPa~106kPa

7. Equipment data update period
As shown in the following figure. Data update period of slower average is 8s.
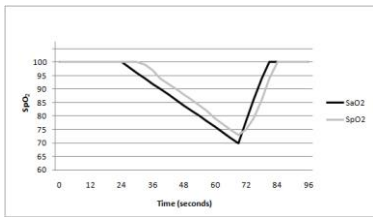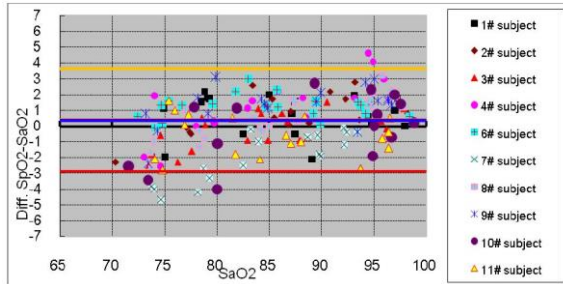
8. Classification

According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
According to the degree of protection against electric shock: TYPE BF APPLIED PART, (applied part: the rubber hole of the device);
According to the degree of protection against ingress of water: IP22
According to the mode of operation: CONTINUOUS OPERATION

Clinical Study Summary

The following details are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot of data is shown as following:

ARMS Value Analysis Statement

Item	90--100	80--<90	70--<80
#pts	78	66	63
Bias	1.02	0.40	-0.48
ARMS	1.66	1.46	1.93

Bland-Altman Plot Graphic

Declaration

Requirement – Test	Result/Comments	Verdict
Clause 7 - Emissions		
Classification	--	—
Class A or B ....:	Class B	—
Group 1 or 2 ....:	Group 1	—
CISPR 11, 14-1, 32 or ISO 7137 ....:	CISPR 11	—
Conducted RF Emissions ....:	N/A	N/A
Radiated RF Emissions ....:	--	P
Disturbance Power (if applicable)....................:	N/A	N/A
Harmonic Distortion per IEC61000-3-2 (Class A, B, C, D):	N/A	N/A
Voltage Fluctuations and Flicker per IEC61000-3-3 ....:	N/A	N/A
Clause 8 - Immunity		
Electrostatic Discharges ....:	IEC 61000-4-2	P
Radiated RF EM Fields and Proximity Wireless fields .....:	IEC 61000-4-3	P
Electrical Fast Transients and bursts ....:	IEC 61000-4-4	N/A
Surges ....:	IEC 61000-4-5	N/A
Conducted Disturbances, induced by RF fields ....:	IEC 61000-4-6	N/A
Voltage Dips and Interruptions ....:	IEC 61000-4-11	N/A
Rated Power-frequency Magnetic Field ....:	IEC 61000-4-8	P

Possible Problems and Solutions

Problems	Possible reason	Solution
SpO₂ or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's SpO₂ value is too low to be measured	1. Retry by inserting the finger 2. There is excessive illumination 3. Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.
SpO₂ or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Excessive patient movement	1. Retry by inserting the finger 2. Be calmness
The oximeter cannot be powered on	1. No battery or low power of battery 2. Batteries might be installed incorrectly 3. The oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact with local customer service centre
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. The battery power is too low to work	1. Normal 2. Replace the batteries
"Err7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	Please contact with local customer service centre

Symbol Definitions

Symbol	Definition	Symbol	Definition
(person icon)	Type BF applied part.	⚠	Attention
IP22	Protected against dripping water.	%SpO₂	Oxygen saturation
PR bpm	Pulse rate (BPM)	(battery icon)	Low power indication
(No SpO₂ Alarm icon) SpO₂	No SpO₂ Alarm	SN	Serial No.
(storage temperature icon)	Storage temperature and relative humidity	(follow instruction icon)	Follow instruction for use
(factory icon)	Date of Manufacture	EC REP	Authorized representative in the European community
CE 0123	European union approval	(manufacturer icon)	Manufacturer's information
(WEEE icon)	Conformity to WEEE Directive		

Box Contents

1. Fingertip pulse oximeter
2. One lanyard
3. Two AAA batteries
4. One instruction manual

Applicable Models

MD300C2 MD300C21 MD300C21C MD300C22 MD300C23 MD300C25 MD300C26 MD300C29 MD300C2A MD300C2B MD300C2D MD300C2E MD300C2F MD300C2G MD300C2H MD300C2I MD300C203 MD300C21-P MD300C20

Pay attention:
- Only the device of MD300C203 is single-color OLED screen.
- Only the device of MD300C21-P has the feature of automatically power on.

Notes:
1. **The illustrations used in this manual may differ slightly from the appearance of the actual product.**
2. **The specifications are subject to change without prior notice.**

Appendix C: Learning, Education, and Training for Primary Care Providers

COVID-19 Provider Supports

- [Ontario College of Family Physicians COVID-19 Community of Practice Recordings](#)—the group meets once monthly to discuss and share perspectives on topics related to COVID-19. Recorded sessions can be accessed at the above link. In addition, the recording to our March 4 webinar can will be added to this resource when available.
- [COVID-19: Clinical Guidance for Primary Care Providers](#)—available from the Centre for Effective Practice
- [Managing COVID-19 Symptoms (including at end of life) in the Community: Summary of NICE Guidelines](#)—BMJ article
- **Resources from the Women's College Hospital (WCH) COVIDCare@Home Program:**
    - [COVID-19 Clinical Assessment Tip Sheet](#)—tip sheet for primary care providers from the Women's College Hospital COVIDCare@Home Program (originally adapted from the BMJ article [COVID-19: Remote Assessment in Primary Care](#))
    - [Additional Resources](#)
- [Virtual Care: COVID-19 Guide](#)—poster from the Ontario Medical Association and OntarioMD provides information on virtual care platforms and billing

Remote Monitoring Supports

- [Clinical Model and COVID-19 Remote Monitoring Use Cases](#)—from the Ontario Telehealth Network (Ontario Health)

- [Remote Care Management During the COVID-19 Pandemic](#)—quick reference from the Ontario Telehealth Network (Ontario Health)

Post-Acute COVID-19 Care Management

- [Long COVID: A Primer for Family Physicians](#)—editorial from the American Family Physician
- [Management of Post-Acute COVID-19 in Primary Care](#)—article from BMJ

Palliative Approach to COVID-19 Care

- [Palliative Care Resource to Support Frontline Providers during the COVID-19 Pandemic](#)—from the Ontario Palliative Care Network (Ontario Health)
- [Managing Expected Death in the Home During COVID-19](#)—from the Ontario Palliative Care Network (Ontario Health)
- [Goal of Care Conversation Guides (for patient with COVID-19)](#)—from Speak Up Ontario

Appendix D: Learning, Education, and Training for Primary Care Patients

COVID-19 Patient Supports

- [COVIDCare@Home Patient Resource for Managing COVID-19](—)—from Women's College Hospital
- [COVID Care @ Home Integrated Comprehensive Care Program Handout](—)—from a collaboration between St. Joseph's Health System, Niagara Health, and St. Joseph's Home Care
- [COVID-19 Guide for Patients](—)—from McMaster University Family Medicine and the Hamilton Family Medicine
- [COVID-19 Fact Sheet for Patients](—)—from Ontario Health West COVID-19 Remote Patient Monitoring Team
- [COVID-19 Home Monitoring Program: Timed Position Changes Instructions](—)—from the Georgian Bay Family Health Team
- [COVID-19 Symptom Timeline: Why Days 5 to 10 Are So Important](—)—from the Georgian Bay Family Health Team

Oxygen Monitoring

- [Pulse-Oximetry—Patient Instructions For Use](—)—from McMaster University Family Medicine and Hamilton Family Medicine
- [Patient At-Home Oxygen Monitoring Instructions](—)—from the Georgian Bay Family Health Team