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Research

A Virtual Care Model for Outpatients Diagnosed with COVID-19

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Running Title: COVID-19 outpatient virtual care

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Abstract

Background: The majority of individuals with COVID-19 present initially with a mild illness and are typically discharged home to self-isolation while diagnostic tests are pending. In the subset of outpatients whose tests subsequently return positive for COVID-19, there are challenges to providing patient counseling and support surrounding their diagnosis, or re-assessment in the event of clinical deterioration.

Methods: COVID-19 Expansion to Outpatients (COVIDEO) was a virtual care feasibility pilot study developed through an intra-disciplinary collaboration between Microbiology, Infectious Diseases (ID), and Infection Prevention and Control at Sunnybrook Health Sciences Centre (SHSC), and Toronto Public Health. The primary aims of this project were to provide ID assessments to at least 90% of outpatients from SHSC diagnosed with COVID-19 using COVIDEO, and to reduce unplanned transfers to hospital in these patients to less than 10%.

Results: From March 1 to March 27, 2020, 50 persons under investigation assessed at SHSC and discharged home to self-isolation tested positive for COVID-19. All 50 (100%) outpatients were successfully assessed by ID using COVIDEO. Of those served by COVIDEO, 32 (64%) patients were assessed using the Ontario Telemedicine Network platform; the remainder were assessed by telephone. Six (12%) patients demonstrated a change in clinical status requiring transfer to hospital; only one transfer was unplanned.

Interpretation: With the imminent expectation of widespread escalation of the pandemic, COVIDEO represents a tool that can assist clinicians in providing high-quality care to patients diagnosed with COVID-19 while keeping physical assessments within the healthcare system to a minimum.

Introduction

In December 2019, an outbreak of acute respiratory illness secondary to a novel coronavirus (SARS-CoV-2) originated in Wuhan, China. As of April 4, 2020, coronavirus disease (COVID-19) has caused a global pandemic resulting in more than 1,000,000 cases and close to 57,000 deaths (1). This pandemic has placed immense, and in some cases overwhelming, strain on healthcare systems around the world.

The majority of individuals with COVID-19 present initially with a mild illness and do not require hospitalization (2). After initial assessment and sample collection, these patients are typically discharged home to self-isolation while results of diagnostic tests are pending. This approach is critical to reducing the burden on the healthcare system and limiting spread of COVID-19 to other vulnerable patients and staff in hospital (3). However, in the subset of outpatients whose tests subsequently return positive for COVID-19, there are challenges to providing patient counseling and support surrounding their diagnosis, or re-assessment in the event of clinical deterioration.

To address this gap, we developed COVID-19 Expansion to Outpatients (COVIDEO), a virtual care feasibility pilot study aimed at providing ongoing care to outpatients with COVID-19. The benefits of virtual care to improve accessibility to infectious diseases consultation and assessments has been increasingly recognized (4). For instance, guidelines now recognize virtual care as a complementary tool to monitor safety and response to therapy in those receiving outpatient parenteral antibiotic therapy (5,6).

Given the availability of fixed broadband or mobile internet access to 99% of Canadian households (7), we hypothesized that COVIDEO could be safely used for outpatient

management of COVID-19. In this report, we describe our experience with the first 50 patients managed using COVIDEO. Given the accessibility of virtual care platforms, this model of care would be rapidly scalable by other practitioners and institutions. With the imminent expectation of widespread escalation of the pandemic, this represents a tool that can assist clinicians in providing high-quality care to COVID-19 patients while keeping physical assessments within the healthcare system to a minimum.

Methodology

Sunnybrook Health Sciences Centre (SHSC) is a 627-bed academic tertiary care centre located in Toronto, Ontario. On January 25, 2020, the first Canadian imported case of COVID-19 was diagnosed at SHSC (8). In anticipation of the growing number of patients diagnosed with COVID-19 at SHSC, COVID-19 Expansion to Outpatients (COVIDEO) was a virtual care feasibility pilot study developed through an intra-disciplinary collaboration between Microbiology, Infectious Diseases, and Infection Prevention and Control (IP&C) at SHSC, and Toronto Public Health (TPH) (Figure 1). All positive COVID-19 tests at SHSC or the SHSC Assessment centre were notified to IP&C who then subsequently notified the Infectious Diseases (ID) physician. The communication process between IP&C and the ID physician took place 7 days per week. All inpatients diagnosed with COVID-19 were assessed by the ID physician on call who followed the patient upon discharge using COVIDEO. All outpatients diagnosed with COVID-19 at SHSC were contacted by an ID physician for assessment and counseling using the Ontario Telemedicine Network (OTN) virtual care platform. OTN is a government-funded, non-profit, organization that currently serves as the primary platform for virtual care services in Ontario (9). Advancements in OTN technology now allow physicians to perform virtual care

visits with patients in their home through their personal devices (personal computer or mobile device) without the need for travel to a telemedicine studio. Patients who were unable or declined the use of OTN were assessed by telephone. COVIDEO care was maintained through a rotating weekly schedule among four ID physicians.

Standardized intake and assessment forms were developed to assess each patient (Supplement 1). In addition to exposure his45-6tory, comorbidities and a review of systems, a functional assessment consisting of ambulation and exercise capacity were used to detect any impending deterioration in respiratory status. In patients deemed stable, follow-up ID assessments were conducted on a weekly basis, at minimum, until clearance by TPH. In the intervening period, patients were also contacted by their TPH case worker by telephone, with ID being notified with any concerns. Patients who were deemed to require more frequent follow up were contacted up to twice a day; the exact schedule of follow-up was at the discretion of the most responsible ID physician based on clinical judgment and guided by the patients' clinical status. In the event of clinical deterioration requiring hospital transfer, the ID physician coordinated with IP&C, TPH, and the hospital emergency department triage or COVID-19 ward to ensure that transportation and admission to hospital was completed in a controlled and safe manner. The decision to sign off a patient from further COVIDEO follow-up was based on physician determination that there had been clear clinical improvement and no remaining risk of future deterioration. COVIDEO was launched on March 1, 2020.

The primary aims of this project were to provide ID assessments to at least 90% of outpatients from SHSC diagnosed with COVID-19 using COVIDEO, and to reduce unplanned transfers to hospital in these patients to less than 10%. We aimed for rapid dissemination, and so selected a sample size of 50 patients which would be sufficient to estimate these target

proportions with a margin of error of 9% and 95% confidence. Since the primary focus of this project was to improve the quality of care provided to outpatients with COVID-19, this study was exempted from research ethics approval.

Results

From March 1 to March 27, 2020, 50 persons under investigation (PUIs) assessed at SHSC and discharged home to self-isolation tested positive for COVID-19. During the same time period, 13 PUIs were admitted to SHSC who tested positive for COVID-19. All 50 (100%) outpatients were successfully assessed by ID using COVIDEO. Of those served by COVIDEO, 32 (64%) patients were assessed using the OTN platform; the remainder were assessed by telephone. The median (IQR) age of the patients was 40 (30.5, 59.5) years and 26 (52%) had travelled in the preceding 14 days. The most common presenting symptoms were cough (68%), fatigue (64%) and myalgia (42%). Demographic and clinical characteristics of these outpatients diagnosed with COVID-19 are summarized in Table 1.

Patient recruitment increased over time, with 3 enrolled within the first week, 18 in the second week, 13 in the third week, and 16 in the fourth week (Figure 2). Even within the short initial timespan of this intervention (first 50 patients enrolled within 27 days), there were already substantial shifts in demographic characteristics over time. The second half (as compared to the first half) of the cohort were less likely to report a travel history (18/25 vs 8/25, p=0.004), and more likely to be healthcare workers (3/25 vs 14/25, p=0.001).

The median (IQR) time from viral swab collection to first COVIDEO assessment was 2 (1, 2) days. Of the 26 patients who were signed off from further COVIDEO follow-up at the time

of this manuscript, the median (IQR) time from first COVIDEO assessment to sign-off was 12.5 (8.75, 16) days. The care trajectory for each of the 50 patients assessed in our study is summarized in Figure 3.

Six (12%) patients demonstrated a change in clinical status requiring transfer to hospital (Table 2); only one transfer was unplanned. Four out of the 6 patients were admitted to hospital. The reasons for transfer included changes in respiratory status (3/6), chest pain (1/6), relative hypotension (1/6), and need for isolation due to ongoing hemodialysis (1/6). As of April 4, 2020, 1/50 (2%) patients were admitted to intensive care, and 0/50 (0%) had died.

Discussion

Implementation of a virtual care model for monitoring outpatients diagnosed with COVID-19 was effective in providing care and counseling for patients in self-isolation. The use of virtual care in medicine has become an attractive mitigation strategy to minimize unnecessary patient travel to healthcare institutions for medical care. Through a collaborative approach, we have demonstrated that this model can also be successfully utilized in outpatients diagnosed with COVID-19 under self-isolation.

COVIDEO allows healthcare providers to plan for a safe and controlled hospital transfer in those demonstrating signs of clinical deterioration (12% in our cohort). Prior experiences with the SARS epidemic have highlighted that uncontrolled hospitalizations of acutely deteriorating patients (due to lack of adherence to infection control procedures) significantly increases the risk of nosocomial transmission (10). Use of COVIDEO also allowed the ability to assess household contacts for symptoms and initiate appropriate investigations and contact tracing through TPH in

an effort to reduce community spread. As the burden on TPH has increased, the COVIDEO service has been able to inform the patient of their positive diagnosis within 24 hours of receipt of lab notification, allowing for timely notification and confirmation of required self-isolation procedures.

Patients generally found COVIDEO to be an important and helpful service. There is a tremendous degree of anxiety and uncertainty that can accompany a diagnosis of COVID-19. Having a physician provide frequent reassessment, and education around the various manifestations of illness, expected clinical course, and which symptoms should prompt concern, tended to alleviate anxiety. Physicians providing COVIDEO care were able to emphasize and elaborate on self-isolation procedures for patients and their household contacts, even prior to their being contacted by TPH. In addition, all patients were instructed on how to reach either their most responsible ID physician, or the ID physician on-call, at any time. Having relatively easy access to a physician 24 hours a day, 7 days a week, provided an additional level of reassurance.

Health care workers comprised 34% of COVIDEO patients and this was primarily because of the changes in local testing criteria that prioritized health care workers self-identifying with symptoms for testing in order to mitigate nosocomial transmission. It is important to note that in this early cohort, the majority of these cases were related to importation from travel to areas with community transmission, with some also related to local community transmission; none were related to nosocomial exposure.

There are several limitations to COVIDEO. First and most importantly, as the number of patients diagnosed with COVID-19 increase exponentially (Figure 1), this model will inevitably become more time and labour intensive. However, we feel that COVIDEO could be sustainable,

scaled and adapted for use by other primary care providers to manage outpatients diagnosed with COVID-19, potentially through a rotating roster of physicians or nurse practitioners linked to assessment centres providing testing and willing to provide continuity of care for the duration of illness for individual patients. Importantly, for those physicians, and residents, who may not be able to assist in direct care of individuals with confirmed or suspected COVID-19 due to underlying comorbidities, this virtual care platform may provide them with an opportunity to contribute to COVID-related care in a safe, yet impactful, way. Secondly, due to the implementation of COVIDEO early in the pandemic to improve the quality of care, no baseline or comparator data was available to evaluate its incremental impact on outcomes. We plan to formally evaluate our intervention using a quasi-experimental study design once we have accumulated a large enough cohort. Thirdly, marginalized populations who may not have access to a phone or internet, in particular those who are underhoused, may be challenging to manage. In addition, the short timeframe between viral swab collection and first COVIDEO assessment was dependent on a rapid turnaround time for COVID-19 testing at our institution. Settings where COVID-19 test result reporting is delayed may attenuate the benefits of early assessments in reducing unplanned transfers to hospital. Lastly, symptom management without physical examination may not be sensitive enough to anticipate all cases of clinical deterioration; to account for this we have subsequently introduced mini-home oxygen saturation monitors into the program.

As the pandemic has evolved, the overall epidemiology of patients diagnosed with COVID-19 has transitioned from predominantly imported cases in individuals healthy enough to travel, to community-transmission. The utility of COVIDEO may become more relevant, particularly as older patients, or patients with chronic medical illness are sent home for self-

isolation after their initial presentation to the healthcare system. The changing demographic of patients followed in COVIDEO is also reflective of institutional decisions that have been made around prioritizing tests and rationing limited testing capacity to sicker patients as well as individuals who work in professions (e.g. health care, or long term care facilities) that are "high risk" for outbreak or institutional spread.

The exponential increase and rapidly changing demographic of patients in this COVIDEO cohort is a microcosm of the rapidly progressing pandemic in Canada and globally. It is difficult to predict the final toll of COVID-19, but it appears that virtual care may be a feasible way to manage patients with mild to moderate symptoms in their own homes. This approach serves to reassure patients, offers early detection of clinical deterioration, and helps lessen the burden on strained acute care facilities.

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Table 1. Characteristics of the first 50 outpatients diagnosed with COVID-19 managed with COVIDEO

Characteristic	No. (%)
Demographic characteristics	
Age (years, IQR)	44 (30.5, 59.5)
Sex (% male)	33 (66.0)
Median time from symptom onset to healthcare assessment (days, IQR)	3 (1.5, 5.0)
Recent Travel within 14 days of symptom onset	26 (52.0)
Austria	3
Canada (within country)	2
Cayman Islands	1
Colombia	1
Dominican Republic	1
Egypt	2
England	1
Germany	1
Iran	3
Japan	1
Peru	2
Switzerland	1
United Arab Emirates	2
United States	10
Healthcare worker	17 (34.0)
Community acquisition	9
Recent Travel within 14 days of symptom onset	8
Nosocomial acquisition	0
Pregnant	0
Co-morbidities	
Asthma	3 (6)

Cardiac disease	1 (2)
Chronic hematologic disease	2 (4)
Chronic kidney disease	2 (4)
Chronic lung disease	1 (2)
Chronic neurologic disease	1 (2)
Diabetes	3 (6)
HIV	0
Hypertension	11 (22)
Malignancy	5 (10)
Malnutrition	0
Moderate to severe liver disease	0
Obesity	1 (2)
Rheumatic Disorder	1 (2)
Smoker	5 (10)
Symptomatology	
Abdominal pain	8 (16)
Adenopathy	0
Anorexia	21 (42)
Arthralgia	5 (10)
Chest pain	7 (14)
Chills or Rigors	18 (36)
Confusion	1 (2)
Conjunctivitis	3 (6)
Cough	34 (68)
Depression and anxiety	9 (18)
Diarrhea	15 (30)
Dyspnea	10 (20)
Fatigue/malaise	32 (64)
Fever	19 (38)
Headache	22 (44)
Hemoptysis	0

Insomnia	13 (26)
Myalgia	21 (42)
Nausea and vomiting	10 (20)
Otalgia	5 (10)
Pharyngitis	19 (38)
Rash	0
Rhinorrhea	13 (26)
Sputum production	16 (32)
Wheezing	2 (4)
Investigations	
Bloodwork drawn	13 (26)
Median white blood cell count (x 10^9/liter)	4.9
Median lymphocyte count (x 10^9/liter)	0.9
Chest x-ray completed	15 (30)
Abnormal chest x-ray findings	11
Bilateral infiltrates	7

Table 2. Characteristics of outpatients diagnosed with COVID-19 managed with virtual care subsequently transferred back to hospital

Characteristic	No. (%)
Number of patients transferred to hospital	6 (12)
Age of transferred patients (years, IQR)	61 (56.5, 64.75)
Sex of transferred patients (% male)	5 (83.3)
Median time from diagnosis to transfer (days, IQR)	4 (2.25, 6.5)
Number of patients admitted to hospital	4 (8)
Number of patients admitted to ICU	1 (2)

Figure 1. COVIDEO process map

ED = Emergency Department, ID = Infectious Diseases, IP&C = Infection Prevention and Control, TPH = Toronto Public Health

Figure 2. Case count for the 50 outpatients diagnosed with COVID-19 assessed by COVIDEO

The vertical dotted line signifies a change to COVID-19 testing criteria at SHSC in response to increasing case counts.

Figure 3. Care trajectory for the 50 outpatients diagnosed with COVID-19 assessed by COVIDEO up until April 2, 2020.

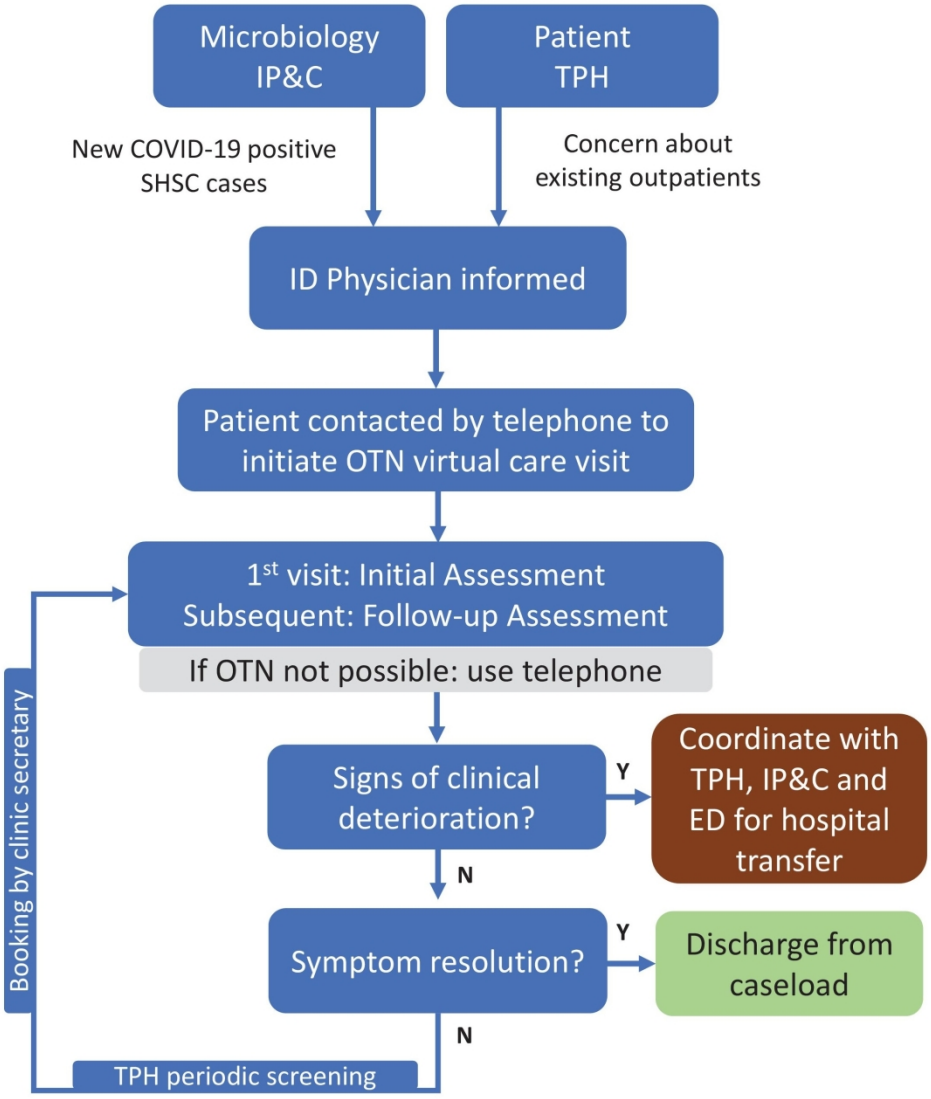

Figure 1. COVIDEO process map

ED = Emergency Department, ID = Infectious Diseases, IP&C = Infection Prevention and Control, TPH = Toronto Public Health

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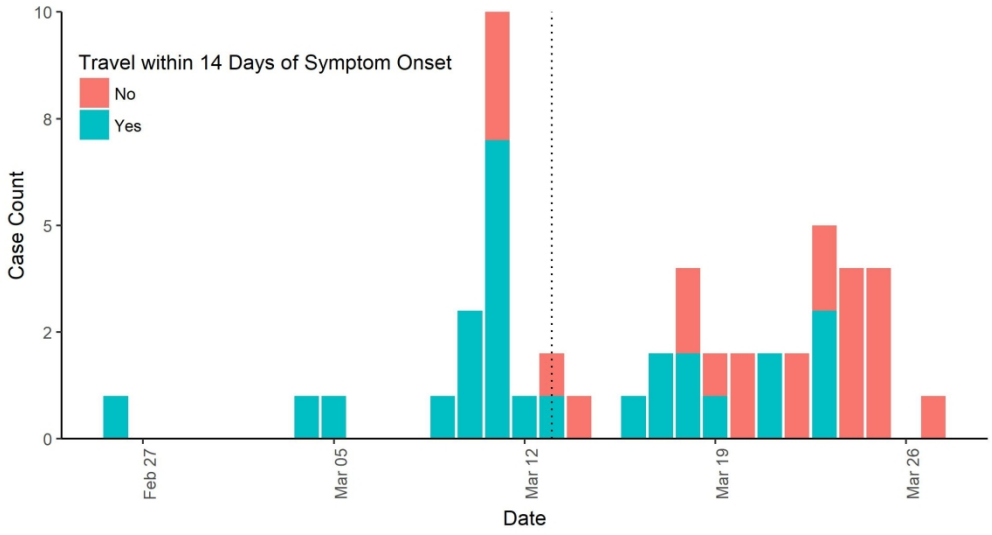

Figure 2. Case count for the 50 outpatients diagnosed with COVID-19 assessed by COVIDEO

The vertical dotted line signifies a change to COVID-19 testing criteria at SHSC in response to increasing case counts.

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Figure 3. Care trajectory for the 50 outpatients diagnosed with COVID-19 assessed by COVIDEO up until April 2, 2020.

Initial Assessment

Date of Video OTN Assessment:

Demographics	
Name	
Age	
Sex	F M Not known
Pregnant	Y N
HCW	Y N Site of Exposure:

Onset of Symptoms	
Symptom onset date of first symptom	DD/MM/YYYY
Symptom onset date of first fever (>38.0)	DD/MM/YYYY
Date of COVID Test Positive	DD/MM/YYYY
Travel in the 14 days prior to first symptom onset	Y N
If Yes: Country	
City/Geographic Area	
Dates of Travel	DD/MM/YYYY- DD/MM/YYYY
Other comments:	

Past Medical History / Comorbidities		
	Y/N	Notes
Cardiac disease		
Chronic lung Disease		
Asthma		
Smoker		
Chronic kidney disease		
Moderate or severe liver disease		
Chronic neurological issues		
Malignancy		
Chronic hematologic disease		
HIV		
Diabetes		
Hypertension		
Rheumatic disorder		
Malnutrition		
Obesity		
Other comments:		

Medications:	
Antivirals	
Other antimicrobials	
Other medications	

Allergies:	Y N Notes:

Social History		
	Y/N	Notes
Other residents in household		
ADLs intact at baseline?		
IADLs intact at baseline?		

Current Symptoms		
	Y/N	Notes
Fever		
Sore Throat		
Runny Nose		
Cough		
Shortness of Breath		
Chills/Rigors		
Conjunctivitis		
Ear Pain		
Sputum		
Hemoptysis		
Wheezing		
Chest Pain		
Myalgia		
Arthralgia		
Abdominal Pain		
Nausea/Vomiting		
Diarrhea		
Adenopathy		
Rash		
Fatigue/Malaise		
Headache		
Confusion		
Depression/Anxiety		

Insomnia		
Anorexia		
Other comments:		

Physical Exam		
	Y/N	Notes
Temperature		
Increased work of breathing		
Cyanosis		
Indrawing		
Walk Test		
Other comments		

Investigations	
Bloodwork	
Chest x-ray	
Microbiology	
Other comments	

Impression and Plan:

Clinical Status: Stable VS Improving VS Deteriorating

Disposition Plan: Maintain at home VS transfer to hospital

Other recommendations:

-

Name of Physician:

Toronto Public Health Contact and Number:

Follow-up Assessment

Date of Video OTN Assessment:

Demographics	
Name	
Age	
Sex	F M Not known
Pregnant	Y N
HCW	Y N Site of Exposure:

Number of days since symptom onset:	

Treatments:	
Antivirals	
Other antimicrobials	
Other medications	

Current Symptoms		
	Y/N	Notes
Fever		
Sore Throat		
Runny Nose		
Cough		
Shortness of Breath		
Chills/Rigors		
Conjunctivitis		
Ear Pain		
Sputum		
Hemoptysis		
Wheezing		
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Adenopathy		
Rash		
Fatigue/Malaise		
Headache		
Confusion		
Depression/Anxiety		
Insomnia		

Anorexia		
Other comments:		

Physical Exam		
	Y/N	Notes
Temperature		
Increased work of breathing		
Cyanosis		
Indrawing		
Walk Test		
Other comments		

Investigations	
Bloodwork	
Chest x-ray	
Microbiology	
Other comments	

Impression and Plan:

Clinical Status: Stable VS Improving VS Deteriorating

Disposition Plan: Maintain at home VS transfer to hospital

Other recommendations:

Name of Physician:

Toronto Public Health Contact and Number:

Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015

Text Section and Item Name	Section or Item Description	
Notes to authors	• The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.	**As you review the manuscript, place a checkmark in this column for each SQUIRE item that is appropriately addressed in the manuscript. Remember that not every item is necessary in every manuscript.**
Title and Abstract		
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)	Page 1
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	Page 2

Introduction	*Why did you start?*	
3. Problem Description	Nature and significance of the local problem	Page 3
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	Page 3
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	Page 3
6. Specific aims	Purpose of the project and of this report	Page 5
Methods	*What did you do?*	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	Page 4
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	Page 4-5
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	Page 5
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	Page 5
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	Page 5-6
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	Page 6

Results	*What did you find?*	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (*e.g.*, time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s). f. Details about missing data	Page 6
Discussion	*What does it mean?*	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	Page 7-8
15. Interpretation	a. Nature of the association between the intervention(s) and the outcomes b. Comparison of results with findings from other publications c. Impact of the project on people and systems d. Reasons for any differences between observed and anticipated outcomes, including the influence of context e. Costs and strategic trade-offs, including opportunity costs	Page 7-8
16. Limitations	a. Limits to the generalizability of the work b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis c. Efforts made to minimize and adjust for limitations	Page 8-9
17. Conclusions	a. Usefulness of the work b. Sustainability c. Potential for spread to other contexts d. Implications for practice and for further study in the field e. Suggested next steps	Page 9-10
Other information		
18. Funding	Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting	Page 1