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Title	A virtual care model for outpatients diagnosed with COVID-19
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Reviewer 1	Dena Schanzer
Institution	Public Health Agency of Canada, Infectious Disease and Emergency Preparedness Branch
General comments (author response at end of document)	<p>In this manuscript the authors describe the characteristics of the first 50 cases of COVID-19 confirmed at Sunnybrook Hospital in Toronto. Sunnybrook Hospital is a fully affiliated teaching hospital of the University of Toronto, with a focus on ground-breaking research on patient care. Sunnybrook has a large staff of scientists and clinician-scientists.</p> <p>As patients initially have mild symptoms, they were sent home to self-monitor while waiting for test results. The authors initiated a virtual care feasibility pilot study with the primary aims to follow-up with at least 90% of the outpatients from Sunnybrook diagnosed with COVID-19, and to reduce unplanned transfers to hospital in these patients to less than 10% by using their extended outreach protocol, COVIDEO.</p> <p>This study describes patient characteristics. However, the pilot protocol for virtual care was not compared to the standard of care. This study did not evaluate quality improvement of the pilot protocol as suggested by the manuscript type. There are many omissions of critical information, however the sample size seems to be much too small for the patient descriptions, and a comparison group for the standard of care is not available.</p> <ol style="list-style-type: none"> 1. The authors did not describe how their pilot protocol differed from the standard of care, or protocols put in place for patients diagnosed elsewhere. Public health websites suggest that all patients will be contacted by public health (as a standard of care). 2. The authors included the first 50 cases, but only followed-up for the full course of the illness with about half of the cases. Trying to analyse this data could create a bias (more complex statistical techniques such as time-to-event or survival analyses could be used). 3. The authors found that 1 out of 6 cases who were transferred back to the hospital was unplanned. Seems like there is room for improvement in the protocol. Based on this one unplanned transfer, the authors note that “symptom management without physical examination may not be sensitive enough to anticipate all cases of clinical deterioration” and recommend that “to account for this we have subsequently introduced mini-home oxygen saturation monitors into the program.” This looks a potentially important finding that is mostly hidden in manuscript. 4. Abstract: What are the challenges to providing patient counseling and support surrounding their diagnosis, or re-assessment in the event of clinical deterioration? Results should correspond to the stated objectives. The main finding appears to be that 1 out of 6 transfers to hospital was unplanned. Perhaps the objective should be restated to assess the pilot protocol! (ie remove the sections on patient characteristics, unless related to the pilot protocol). 5. The intro should focus on your project. The challenges with patient counseling should be described. Given the long delays in confirmation, shouldn't all suspected cases be assessed while waiting, especially as delays grew to more than a week for results? This sentence from the interpretation section could be placed in the intro as it

	<p>seems to explain your motivation: “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.” However, it looks like this priority is taking a back seat now due to lack of testing capacity in Ontario. With testing limited to hospitalized patients, it would seem that most patients will have unplanned transfers to hospital!</p> <p>6. The objective of describing your experience with the first 50 patients managed using COVIDEO does not seem relevant. The sample size seems much too small for this objective and is not linked to quality improvement. The bulk of the cases were for people at higher risk of infection who were advised to get tested in order to self-isolate and reduce the initial spread. Any description of the first 50 cases would require details of testing criteria in order to interpret any of the symptom data.</p> <p>7. The use of non-standard acronyms should be limited. I am not sure of the point of detailing the public health structure. If there is a reason, this needs to be discussed in context to the objectives of the project.</p> <p>8. Please check the reason given for ethics approval not being required. There may be standing ethics approval in place at the hospital for specific research, but the reason given should agree with existing ethics approval and MOUs at that hospital, and the relevant document should be stated. Usually there are limitations put on researchers about the level of data that can be reported. Usually cell sizes less than 5 can not be reported.</p> <p>9. The authors set up a hypothesis test for a change in demographic characteristics over time. Whether the change from travel to health care workers over the first 4 weeks is statistically significant does not seem to be important. The hypothesis is not consistent with your study objectives: the sample size is too small and testing criteria are not discussed. If this information is useful, reporting this as part of surveillance would likely be more appropriate. It is also worth noting that the report of percentages and 95% confidence intervals is more informative than p-values.</p> <p>10. Only half of the first 50 cases were signed off of further follow-up by the end of the study. This negates the sample size calculations.</p> <p>11. Change in protocol to include mini-home oxygen saturation monitoring seems vitally important!</p> <p>12. Is your protocol for virtual surveillance still viable given the increase in the number of cases, the lack of testing in persons with mild symptoms, the high false negative rate (estimated at approximately 30%)? Is it scalable?</p>
Reviewer 2	Jennifer Grant
Institution	Vancouver Coastal Health
General comments	<p>Thank you for thinking of publishing this practical approach to discharged COVID patients while we are still early in the epidemic. There are a few things that might help readers have a better understanding of your context, and thus how it fits with theirs.</p> <p>1. What were the testing recommendations at different time-points. You mention they change, but it is not clear who is and who is not tested. This would be helpful to know for jurisdiction with different testing criteria.</p> <p>2. Given the relatively restricted testing criteria in many areas (not sure if this was the case in T.O.) were there patients who came in, were not tested, and returned with COVID?</p>

	<p>2a. How many COVID tests were done and what was the positivity rate?</p> <p>3. Were there patients who tested positive who had a previously negative test, why did they come back for further testing?</p> <p>4. Is there a mechanism (e.g. employee health programme) to manage employees? If so, what was its role.</p> <p>5. You discuss sustainability . . . it would be helpful to know how long was spent with each patient, and how many patients could be reasonably managed by a single ID physician.</p> <p>6. The patients that didn't use the video platform, what were the barriers to use? Was there a difference in efficacy between phone and video?</p> <p>7. You mention that your interventions "reduced anxiety" while that seems intuitively reasonable, it would be nice to have an indication of how that was assessed or measured.</p> <p>8. The graphs do not come across well on black and white. If the aim is to publish in black and white, please change the colours so that the shades are distinguishable or use patterns instead (e.g. cross hatching).</p>
Reviewer 3	William Gardner
Institution	Children's Hospital of Eastern Ontario, Psychiatry, Ottawa, Ont.
General comments	<p>I am skeptical of the claim that internet or broadband is available to 99% of Canadian households. Similar claims made for the US have been called into serious question by reports from Microsoft that there are extensive regions where no actual broadband use is observable in the data. Above all, I don't believe that 99% of Canadian households can afford the service. COVIDEO would still be justified without such a strong claim.</p> <p>"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." Has any further follow-up been done to check whether these decisions were correct?</p> <p>Can you say more about why 36% did not or could not use video service? What would have been lost if all had been done by phone?</p> <p>"Thirdly, marginalized populations who may not have access to a phone or internet, in particular those who are underhoused, may be challenging to manage." This is an exceptionally important point. Please say more about who these patients will be, how many you think there are, and what needs to be done to deliver services to them.</p> <p>I am glad to see this service and applaud the authors for getting the news out ASAP. That said, their QI methods only allow evaluation of a few of the relevant questions. I would like to see more discussion of what should be studied in future research. What are the alternative methods for following these patients? Is COVIDEO efficient and effective compared to those alternatives?</p>

Author responses are below:

<p>1. The authors did not describe how their pilot protocol differed from the standard of care, or protocols put in place for patients diagnosed elsewhere. Public health websites suggest that all patients will be contacted by public health (as a standard of care).</p>	<p>Because this program was initiated early in the pandemic, there was no established medical 'standard of care' for outpatients diagnosed with COVID-19. Although all patients are contacted by public health, they are limited in their ability to provide</p>	<p>Introduction</p>
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	<p>medical advice surrounding their infection, and are unable to contact all patients in a timely fashion during local surges in cases.</p> <p>We chose to address this potential gap of healthcare proactively by introducing virtual physician assessments to this patient population. We have clarified this in the Introduction (paragraph 2)</p>	
<p>The authors included the first 50 cases, but only followed-up for the full course of the illness with about half of the cases. Trying to analyse this data could create a bias (more complex statistical techniques such as time-to-event or survival analyses could be used).</p>	<p>We have reframed the manuscript to describe a feasibility study rather than a pilot project. The focus has therefore shifted towards describing the model in detail and the lessons learned, and removing any mention of hypothesis testing, sample size determination or tests of significance.</p>	<p>Throughout manuscript</p>
<p>3. The authors found that 1 out of 6 cases who were transferred back to the hospital was unplanned. Seems like there is room for improvement in the protocol. Based on this one unplanned transfer, the authors note that “symptom management without physical examination may not be sensitive enough to anticipate all cases of clinical deterioration” and recommend that “to account for this we have subsequently introduced mini-home oxygen saturation monitors into the program.” This looks a potentially important finding that is mostly hidden in manuscript.</p>	<p>We have dedicated a paragraph in the Interpretation section to outlining challenges to this virtual care model. We have elaborated on the challenge of dyspnea and hypoxemia monitoring.</p>	<p>Interpretation section, paragraph 3</p>
<p>Abstract: What are the challenges to providing patient counseling and support surrounding their diagnosis, or re-assessment in the event of clinical deterioration? Results should correspond to the stated objectives. The main finding appears to be that 1 out 6 transfers to hospital was unplanned. Perhaps the objective should be restated to assess the pilot protocol! (ie remove the sections on patient characteristics, unless related to the pilot protocol).</p>	<p>We have reframed the manuscript to describe a feasibility study rather than a pilot project. The focus has therefore shifted towards describing the model in detail and the lessons learned, and removing any mention of hypothesis testing, sample size determination or tests of significance.</p>	<p>Throughout manuscript</p>
<p>The intro should focus on your project. The challenges with patient counseling should be described. Given the long delays in confirmation, shouldn't all suspected cases be assessed while waiting, especially as delays grew to more than a week for results? This sentence from the interpretation section could be placed in the intro as it seems to explain</p>	<p>We have reframed the manuscript to describe a feasibility study rather than a pilot project. The focus has therefore shifted towards describing the model in detail and the lessons learned, and removing any mention of hypothesis testing, sample size determination or tests of significance.</p>	<p>Throughout manuscript</p>

<p>your motivation: “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.” However, it looks like this priority is taking a back seat now due to lack of testing capacity in Ontario. With testing limited to hospitalized patients, it would seem that most patients will have unplanned transfers to hospital!</p>	<p>Appreciating the limited capacity of our healthcare system and our infectious diseases team, we opted to focus our care model on patients who tested positive for COVID-19, as these patients were felt to benefit the most from counseling and monitoring.</p> <p>Testing for COVID-19 is not limited to hospitalized patients. We have summarized the testing criteria used at our institution and how it has evolved over time in the Methods section (paragraph 1).</p>	
<p>The objective of describing your experience with the first 50 patients managed using COVIDEO does not seem relevant. The sample size seems much too small for this objective and is not linked to quality improvement. The bulk of the cases were for people at higher risk of infection who were advised to get tested in order to self-isolate and reduce the initial spread. Any description of the first 50 cases would require details of testing criteria in order to interpret any of the symptom data.</p>	<p>We have reframed the manuscript to describe a feasibility study rather than a pilot project. The focus has therefore shifted towards describing the model in detail and the lessons learned, and removing any mention of hypothesis testing, sample size determination or tests of significance.</p> <p>We feel that other institutions would benefit from learning about our experiences with implementing a virtual care model for this population.</p>	<p>Throughout manuscript</p>
<p>The use of non-standard acronyms should be limited. I am not sure of the point of detailing the public health structure. If there is a reason, this needs to be discussed in context to the objectives of the project.</p>	<p>All suggested abbreviations have been removed. We have chosen to keep the COVIDEO abbreviation as this is the name of our virtual care program. Since the focus of this manuscript has shifted towards describing our care model, we have retained information related to public health structure.</p>	<p>Throughout manuscript</p>
<p>Please check the reason given for ethics approval not being required. There may be standing ethics approval in place at the hospital for specific research, but the reason given should agree with existing ethics approval and MOUs at that hospital, and the relevant document should be stated. Usually there are limitations put on researchers about the level of data that can be reported. Usually cell sizes less than 5 can not be reported.</p>	<p>Sunnybrook Research Institute uses the Ethics Review-Self Assessment Tool (ER-SAT) to determine whether a project requires REB approval. Using ER-SAT, this project does not require REB review. We have modified the language in the ethical approval section based on recommendations from our institutional REB.</p>	<p>Ethics Approval subsection of Methods section</p>
<p>The authors set up a hypothesis test for a change in demographic characteristics over time. Whether the change from</p>	<p>We have reframed the manuscript to describe a feasibility study rather than a pilot project. The focus has</p>	<p>Throughout manuscript</p>

<p>travel to health care workers over the 1st 4 weeks is statistically significant does not seem to be important. The hypothesis is not consistent with your study objectives: the sample size is too small and testing criteria are not discussed. If this information is useful, reporting this as part of surveillance would likely be more appropriate. It is also worth noting that the report of percentages and 95% confidence intervals is more informative than p-values.</p>	<p>therefore shifted towards describing the model in detail and the lessons learned, and removing any mention of hypothesis testing, sample size determination or tests of significance.</p>	
<p>Only half of the first 50 cases were signed off of further follow-up by the end of the study. This negates the sample size calculations.</p>	<p>We have reframed the manuscript to describe a feasibility study rather than a pilot project. The focus has therefore shifted towards describing the model in detail and the lessons learned, and removing any mention of hypothesis testing, sample size determination or tests of significance. We have included an additional sentence to highlight that a subset of patients continued to be followed by the COVIDEO program at the time of data collection (Results section, paragraph 2)</p>	<p>Throughout manuscript</p>
<p>Change in protocol to include mini-home oxygen saturation monitoring seems vitally important!</p>	<p>We have dedicated a paragraph in the Interpretation section to outlining challenges to this virtual care model. We have elaborated on the challenge of dyspnea and hypoxemia monitoring.</p>	<p>Interpretation section, paragraph 3</p>
<p>Is your protocol for virtual surveillance still viable given the increase in the number of cases, the lack of testing in persons with mild symptoms, the high false negative rate (estimated at approximately 30%)? Is it scalable?</p>	<p>We acknowledge in our limitations paragraph that this feasibility study does this address sustainability or scalability. However, we feel that this model could serve as a useful template for other institutions who are looking for a model for providing outpatient care to COVID-19 patients. To date, over 180 patients have been enrolled in COVIDEO, and the model remains viable. We plan to formally evaluate this model once a large enough sample has been attained.</p>	<p>Interpretation section, Limitations subsection</p>
<p>1. What were the testing recommendations at different time-points.</p>	<p>The testing criteria for COVID-19 have rapidly changed throughout</p>	<p>Methods section, paragraph 1</p>

<p>You mention they change, but it is not clear who is and who is not tested. This would be helpful to know for jurisdiction with different testing criteria.</p>	<p>the pandemic. We have provided a general description on how testing has changed in the Methods section.</p> <p>Further elaboration regarding the testing criteria is beyond the scope of this paper.</p>	
<p>2. Given the relatively restricted testing criteria in many areas (not sure if this was the case in T.O.) were there patients who came in, were not tested, and returned with COVID?</p>	<p>We are unable to specifically comment on this possibility because we have not collected data pertaining to this scenario. We hope to provide a more detailed epidemiologic study once enough patients have been cared for by this program.</p>	N/A
<p>2a. How many COVID tests were done and what was the positivity rate?</p>	<p>We are unable to specifically comment on this because accrual into our program occurs at the point of positive test, and we have not collected data pertaining to patients tested in the emergency department, hospital or assessment centre that are negative for COVID19.</p>	N/A
<p>3. Were there patients who tested positive who had a previously negative test, why did they come back for further testing?</p>	<p>We have identified patients who have tested positive after a previously negative test. The indication for repeating testing is typically worsening symptoms. We hope to provide a more detailed epidemiologic study once enough patients have been cared for by this program.</p>	N/A
<p>4. Is there a mechanism (e.g. employee health programme) to manage employees? If so, what was its role.</p>	<p>There is an occupational health department which in conjunction with infection prevention and control facilitates testing, performs contact tracing and provides guidance on when to return to work. Medical advice and care is not provided by these departments.</p> <p>Healthcare workers who were diagnosed with COVID-19 at our institution were included in the COVIDEO program and were treated the same as other non healthcare worker outpatients diagnosed with COVID-19.</p>	N/A
<p>5. You discuss sustainability . . . it would be helpful to know how long was spent with each patient, and how many patients could be reasonably managed by a single ID physician.</p>	<p>We acknowledge in our limitations paragraph that, by definition, this early feasibility study cannot address long-term sustainability. The first 50 patients were cared for by 4 ID physicians. Care was handed over from week to week.</p>	Interpretation section, Limitations subsection

	We would estimate that the assessments required 20-30min on average, but we are prefer not to comment on the duration of each patient assessment in the manuscript as this data was not collected.	
6. The patients that didn't use the video platform, what were the barriers to use? Was there a difference in efficacy between phone and video?	We have dedicated a paragraph in the Interpretation section to outlining challenges to this virtual care model, as well as the additional value of using video over phone. This study was not designed to evaluate the differences in telemedicine modality on patient outcomes.	Interpretation section, Paragraph 3
7. You mention that your interventions "reduced anxiety" while that seems intuitively reasonable, it would be nice to have an indication of how that was assessed or measured.	This observation was based on physician experience interacting with patients. We have acknowledged this as a limitation in a subsequent paragraph and have elaborated on future plans to study this formally.	Interpretation section, Limitations subsection
8. The graphs do not come across well on black and white. If the aim is to publish in black and white, please change the colours so that the shades are distinguishable or use patterns instead (e.g. cross hatching).	We have modified Figure 3 to improve the readability.	Figure 3
I am skeptical of the claim that internet or broadband is available to 99% of Canadian households. Similar claims made for the US have been called into serious question by reports from Microsoft that there are extensive regions where no actual broadband use is observable in the data. Above all, I don't believe that 99% of Canadian households can afford the service. COVIDEO would still be justified without such a strong claim.	As part of our major revisions to shift the focus of this manuscript on the model of care, we have removed this sentence.	Introduction
"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." Has any further follow-up been done to check whether these decisions were correct?	Patients are given the infectious diseases contact information or instructed to return to our institution if there are further symptoms or concerns. At the time of data collection, those patients who were signed-off have not developed any clinical deterioration. Given that the focus of this manuscript has shifted towards describing the model rather than a formal evaluation, we have not included this additional information in the manuscript.	N/A
Can you say more about why 36% did not or could not use video service? What would have been lost if all had been done	We have dedicated a paragraph in the Interpretation section to outlining challenges to this virtual care	Interpretation section, Paragraph 3

<p>by phone?</p>	<p>model, as well as the additional value of using video over phone. This study was not designed to evaluate the differences in telemedicine modality on patient outcomes.</p>	
<p>"Thirdly, marginalized populations who may not have access to a phone or internet, in particular those who are underhoused, may be challenging to manage." This is an exceptionally important point. Please say more about who these patients will be, how many you think there are, and what needs to be done to deliver services to them.</p>	<p>We have not accumulated a large enough cohort to be able to describe the characteristics of this population. We have included an additional sentence which provides a suggestion as to how to help provide care to this population.</p>	<p>Interpretation section, Limitations subsection</p>
<p>I am glad to see this service and applaud the authors for getting the news out ASAP. That said, their QI methods only allow evaluation of a few of the relevant questions. I would like to see more discussion of what should be studied in future research. What are the alternative methods for following these patients? Is COVIDEO efficient and effective compared to those alternatives?</p>	<p>We have reframed the manuscript to describe a feasibility study rather than a pilot project. The focus has therefore shifted towards describing the model in detail and the lessons learned, and removing any mention of hypothesis testing, sample size determination or tests of significance.</p> <p>We address our plans for a formal evaluation of our cohort in the Limitations paragraph.</p>	<p>Interpretation section, Limitations subsection</p>