

The place of telemonitoring in managing COVID-19

This is an ongoing review compiled to reflect the balance of evidence for monitoring COVID-19 in the community. Comments and questions to Brian McKinstry, Emeritus Professor of Primary Care eHealth, The University of Edinburgh, brian.mckinstry@ed.ac.uk

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Summary

In many countries, most people who contact health services with suspected COVID-19 symptoms are asked to self-isolate at home. Although they are advised to recontact health services if their symptoms worsen, there is often little structured follow-up. However, a significant proportion of these patients will experience relatively rapid deterioration while self-isolating. Some of these experience very low oxygen saturations with little in the way of breathlessness. Certain groups such as the elderly and those with underlying medical conditions are at particular risk of deterioration. Other groups (NHS staff, BAME, and obese patients) are known to particularly delay presentation. There is increasing evidence, however, that early detection of deterioration and treatment is associated with improved outcomes.

Telemonitoring, where patients self-monitor and report their symptoms and physiological readings electronically to their clinician, has been widely used in long-term condition management. Its use is rapidly being stepped up world-wide in the management of self-isolating elderly and vulnerable people in the COVID-19 pandemic. However, telemonitoring can also be used in the management of suspected high-risk COVID-19 patients to detect early signs of deterioration that may require further assessment or hospitalisation and to encourage them to make contact. (See figure 1 for proposed Scottish system). Several observational studies support the use of telemonitoring of symptoms and pulse oximetry and suggest high levels of patient and clinician satisfaction with the process.

Background

Coronavirus disease 2019 (COVID-19) is a new disease whose natural history is still incompletely understood. However, it is known that some patients who were initially not seriously unwell later develop severe disease requiring hospital admission, with a sub-set of these eventually needing intensive care.¹ In the early stages of the COVID-19 pandemic in Italy, hospitals in Lombardy were quickly overloaded with patients resulting in significant hospital-acquired infections.² This experience was also repeated in UK settings.³ Safely keeping people out of hospital will remain important as the pandemic develops.

However, it has become clearer that early treatment is associated with better outcomes.⁴ An analysis of early data from Jiangsu province in China suggested that early intervention reduced death rates (<1%) in comparison with Hubei Province (4.3%) where treatment was started later.⁵ Likewise in South Korea analysis of data showed that later presentation was associated with poorer outcomes,⁶ and countries such as Singapore which had a policy of early admission to hospital had a very low fatality rate.⁷

Most of the lung injury in COVID-19 is due to inflammation.⁸ Hypoxia itself is pro-inflammatory so it is likely that early oxygen therapy should reduce inflammation. In addition, in severely ill patients, the use of steroids^{9,10} has been shown to reduce the death rate. In addition early, general supportive therapy such as early appropriate rehydration helps prevent acute kidney injury.¹¹ Early identification of deterioration is important to permit appropriate therapy.

The elderly and those with underlying medical conditions are at particular risk of deterioration.¹² Other groups (NHS staff, BAME, and obese patients) are known to particularly delay presentation.¹³

High death rates in those admitted to hospital in the UK has raised concerns that in some cases admission to hospital may be happening too late for treatment to be effective, and have led to calls for more active monitoring to detect early deterioration in these at risk groups and encourage them to attend.¹⁴ Analysis of NHS England data suggest that early treatment could lead to an absolute reduction the death rate of between 3 and 5%.

Recently research carried out by Inada-Kim et al., which is yet to be peer reviewed, but published in medRxiv is an analysis of how oxygen saturation and measurements of other vital signs correlate to patient outcomes in COVID-19 patients conveyed by ambulance to hospital by the South Central Ambulance Service in England. The aim was to investigate if clinical deterioration can be predicted with simple community physiological monitoring. They demonstrated that even relatively small reductions of oxygen saturation (95% and below) were associated with significant increases in mortality.¹⁵

However, an unpublished study in Northern Ireland set in carehomes showed that in what could be assumed to be a debilitated population a reading of 95% was relatively common occurring in 13/69 patients over a 10 day period. This group as others (for example with chronic lung disease) may requires a different triggering level from most patients.¹⁶

Detecting deterioration can be challenging. Many patients present with pronounced arterial hypoxaemia yet without proportional signs of respiratory distress or sense of breathlessness. Dyspnoea was reported by only 18.7% of hospitalised patients in one reported series.¹⁷ Additionally, in some patients with very low CO₂ due to hyperventilation, there is a shift to the left of the oxygen dissociation curve and normal oxygen saturation (SaO₂) can be maintained in the presence of very low arterial oxygen pressure (PaO₂). It is important therefore to consider both symptoms of breathlessness and SaO₂ when detecting deterioration in COVID-19.¹⁸

A recent Delphi exercise based in UK primary care,¹⁹ involving 72 clinicians, set out to develop an early warning score for deterioration in COVID-19. The authors suggested the following to be valuable in predicting deterioration : pulse, shortness of breath or respiratory rate, trajectory of breathlessness, pulse oximeter reading (with brief exercise test if appropriate) or symptoms suggestive of hypoxia, temperature or fever symptoms, duration of symptoms, muscle aches, new confusion, shielded list and known risk factors for poor outcome. They suggest a scoring system, the sensitivity and specificity of which is yet to be assessed.

Managing COVID-19 by telemonitoring

Proactive telemonitoring has the potential to identify deterioration early, and hence improve the patient's eventual outcome. Telemonitoring systems can have built-in triggers which offer automatic

advice to encourage people to seek help by phone or videolink if responses indicate significant deterioration.

Telemonitoring has been adopted in several locations world-wide. As yet there are few published papers and no randomised controlled trials (RCT). Two RCTs are currently planned in the USA²⁰ and another in Norway.²¹ The first aims to report in April and the second in December 2020, too late to inform implementation in Scotland. However two papers have been published one from the Netherlands²² and one from Minnesota USA²³ which describe the early experience of two monitoring systems. In addition there is unpublished work from Kaiser Permanente using a traditional telemonitoring system in Southern California and NHS England which used oximetry with regular telephone calls.

(Silven et al)²² a paper from the Netherlands, is largely a description of how patients are enrolled and use the devices (thermometer, BP meter, oximeter), the arrangement for support services, integration with current systems and how patients re discharged and equipment returned. Of 55 patients enrolled in the system no adverse events occurred and 5 of these 50 were subsequently admitted to hospital due to deterioration. Both patients and health care providers viewed the use of the system positively. The article ends with recommendations for further development of the system including the need for face-to-face recruitment, agreed selection criteria, target protocols, integration with clinical work-flow, privacy and ethical considerations and the need for evaluation.

(Annis et al)²³ from Minnesota USA provides an early evaluation of a similar system. Implementation was aided by a history of telemonitoring in the area. Recruitment was on the basis of suspected COVID. They describe results from 3701 patients enrolled in three versions of the system, the first two being symptom monitoring only. In the third version 657 patients were offered the opportunity to use pulse oximeters (most similar to the proposed Scottish system) of whom 347 (54%) activated the system and 345 continued to use it. Over 10 days these 347 produced 524 alerts requiring first responder action. Reassuringly workload from the system was low. Satisfaction was high. Figures on hospitalisation were given for the total sample of 2255/3701 patients who returned data in all three versions. Of these 91 has an emergency visit and 13 were admitted to hospital. These figures need to be interpreted with some caution as testing rates were low and many patients may not have had COVID.

In as yet unpublished work from England the NHS @home team tested a simple “virtual ward” model (COVID Care@Home) to support at risk groups by making pulse oximeters available for home testing of oxygen saturations levels and linking the individual by regular telephone call to a clinical team. Three pilot sites were stepped up to test clinical pathways, and data was evaluated by Imperial College from both the pilots and additional models being operated across the country. The work considered if remote monitoring pathways are safe and effective for COVID-19 patients, and whether earlier recognition, escalation, admission and treatment of deteriorating patients could save lives.

They recruited higher risk patients base on age >65, or under 65 + BAME, underlying co-morbidities, learning difficulty and high risk professions.

- Initial standardised assessment
- Pulse oximeter, diary and supporting materials

- “Check-in” phone call at days 2, 5, 7, 10 and 12: standard script
- 24/7 access to advice and support
- Follow-up call at 14 days to “discharge” from the service

Key findings

- **COVID care@home is safe and reports positive patient experience.** The proposed assessment and treatment pathways, with associated assumptions on oxygen saturations and safety netting recommendations, are correct. Remote monitoring pathways can be set up in 3-4 weeks. We also have a defined the target patient group.
- **However, the benefits are not yet proven.** Due to the reduction in case numbers during the pilot period it was only possible to include 1,338 patients in the pilots, and it was challenging to identify a reliable comparator group. COVID-related mortality was rare in the monitored population (1.8%). As a result, it was not possible to demonstrate a significant difference in rates of hospital attendance or all-cause mortality, however there are other indicators of benefit.(unspecified)
- **COVID care@home has strong clinical support,** and is being implemented piecemeal in many areas of England. There are additional benefits in terms of the wider COVID response, integration with other services and public reassurance. These slides set out the proposed model of care and plans for implementation.

USA , S California, Kaiser Permanente: In a meeting in June with Digital Health Innovation and the TEC COvid Response group, members of the clinical team from KP in Southern California described a telemonitoring system they had set up to manage acute COVID at home. This consisted of a traditional telemonitoring system which alerted clinicians if symptoms or physiological parameters (temperature and pulse oximetry)were breached, backed up by daily phone calls. The full results are not yet available, but in personal correspondence (14/10/20) the reported that since April they have enrolled >4000 patients, physician engagement has been robust, they have used the system for early discharge and to monitor home oxygen therapy. They believe that patients are being safely managed at home with no reduction in care levels.

Implementing telemonitoring in people with suspected or proven COVID-19

The best way to deliver telemonitoring will vary according to local care pathways and infrastructure, but all implementations have to address common challenges including usability, choice of which data to collect, devices and data transmission, and evaluation and optimisation.

Data collection and devices (see table 1): Early data from the pandemic identified important predictors of serious disease including symptoms such as increasing breathlessness and high fever, and physiological metrics, such as pulse rate and oxygen saturation (SpO₂) easily measured by low-cost devices. Raised respiratory rate, a strong predictor of poor outcomes, is more challenging to measure remotely,^{24,25} but, recently, pulse-oximeters which can estimate respiratory rate using the photoplethysmography (PPG) waveform and its amplitude variation^{26,27} have become available. During the COVID-19 pandemic, there have been supply-chain difficulties for medical devices including pulse oximeters, as worldwide demand has soared. This means that safe methods for

collecting, cleaning and re-using equipment will be necessary. Along with data for immediate decision-making on the need for re-assessment, there is an opportunity to collect data to help characterise the natural history of the illness, contribute to future predictive algorithms and identify potential participants for mechanistic research, and clinical trials.

Usability: Systems should be selected that are as simple as possible for clinicians to deploy and explain to patients, for patients (or their carers) to interact with, and for clinicians to access data they send back. Unnecessary features or complexity will reduce adoption, scale-up and spread.²⁸

Data transmission: Ideally, systems should work across a range of mobile phones, tablets and computers, and touch tone phones and link to health service systems using open standards so that the service obtains timely robust data which are critical to managing workload. Telemonitoring systems that require patients to subscribe using their own smartphones or tablet PCs, or that use closed-access data systems, could exclude more vulnerable older and poorer people who are less likely to have a smartphone or internet access.²⁹

Setting triggers for symptom and physiological measurements: As evidence accumulates it is becoming clearer which patterns of symptoms or SpO₂ levels are the best markers of early deterioration, so initial alert levels are based on expert clinical judgement¹⁹ and extrapolation from other conditions and on national advice.³⁰ Linkage of telemonitoring data to outcomes (reassessment, admission to hospital, need for respiratory support or ICU, death) will allow tailoring of alert thresholds to the condition.

Selecting patients for monitoring: Decisions as to who should be monitored will depend on the scale of the pandemic and the availability of resources. People at higher risk of admission should be offered monitoring. Two UK based risk calculators are available both based on UK patient outcome data.

COVID-AGE³¹ summarises vulnerability to COVID for different combinations of risk factors including age, sex and ethnicity and various health problems. It works by “translating” the risk associated with each factor into years which are added to (or subtracted from) an individual’s actual age. This then gives a single overall measure of vulnerability. It can be used in people with no underlying medical conditions or multiple medical conditions. One measure combines all of an individual’s risk factors with their actual age. Vulnerability is considered very high if the combined age is ≥ 85 , high 70-84, moderate 50-69 and low < 50 . There is an online applet to calculate risk.

QCOVID³² makes use of primary care datasets linked to COVID outcomes. It takes into account a wider range of factors than COVID-AGE and includes post-code and deprivation data. There is the potential to link this to individual GP patient data to calculate an individual overall risk of death or serious outcome.

Evaluation and optimisation: COVID-19 requires a rapid implementation at scale of a new kind of telemonitoring. There needs to be awareness of the potential risks of telemonitoring, such as over-reliance on physiological parameters by inexperienced clinicians, poor adherence to self-monitoring, or faulty equipment. For example, the afore mentioned significance of changes in SpO₂ in the context of COVID-19 is uncertain. Younger people, for example, are able to initially maintain SpO₂ through increased respiratory effort and the associated left shift of the dissociation curve due to

hypocapnea, but are then at risk of rapid decompensation and deterioration ,³³ alongside the emerging reports that others experience only mild breathlessness despite a very low SpO₂.³⁴ A normal SpO₂ in the presence of breathlessness may or may not therefore be misleading. Asking the patient to exercise (for example, a 1-minute brisk walk back and forth in their room) followed by re-measurement may demonstrate desaturation in borderline patients and could be reassuring if stable, but this is not certain. Respiratory rate measurement when it becomes readily available should be helpful in the interpretation of SpO₂. Any implementation therefore needs to be within an evaluative framework which examines impact on workload, utility to clinicians, usability, acceptability to patients and equity of access. In particular, rapid feedback of evaluation findings will be needed to modify and optimise the intervention, considering the value of different components of any intervention, and modify them as required (for example, by altering trigger levels for advice, and removing those elements that are not found to be predictive of deterioration or are clinically unhelpful).

Further research

In order to maximise the effectiveness of self-isolation but ensure that those who need hospital assessment and treatment are rapidly identified and referred, we must urgently carry out observational studies. We need to understand the natural history of progression, confirm which types of data are most useful and develop prediction tools to identify reliably those needing escalation of care, as well as identify participants for drug trials. Electronic collection of time-stamped telemonitoring data can facilitate the development of predictive algorithms³⁵ [15,16], which, in turn, can be used continuously to improve processes, define what helps and what does not, and rapidly devise systems which are implementable at large scale.

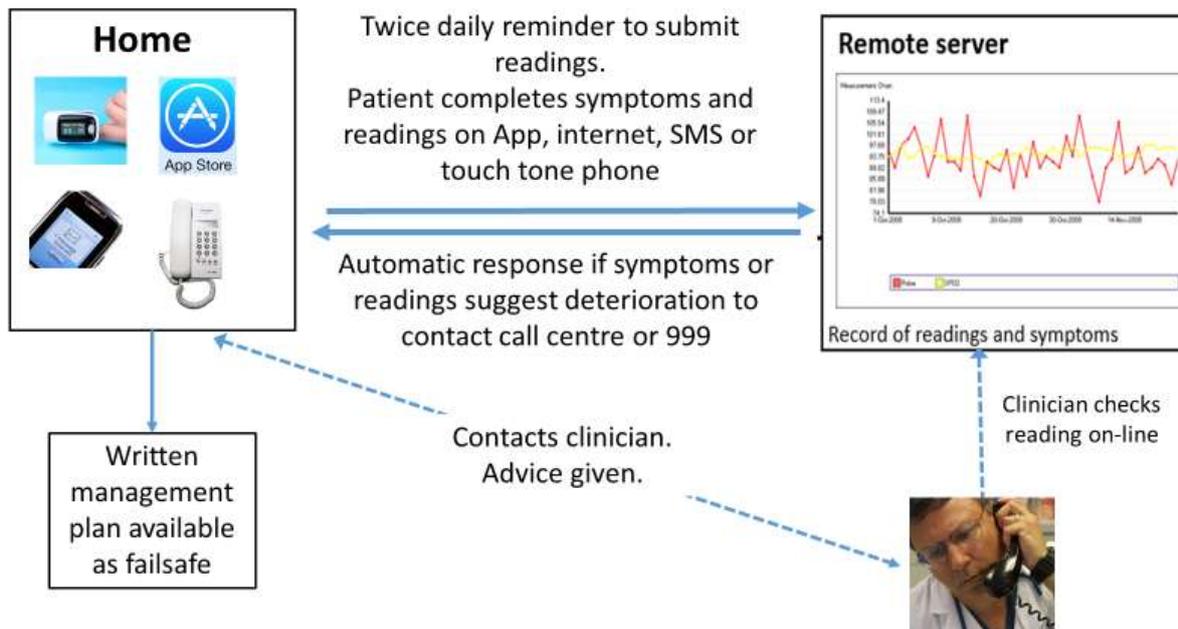
Conclusion

Routine telemonitoring of those at greater risk offers the potential to detect deterioration, and to provide regular support and advice without compromising quarantine and exposing healthcare workers to unnecessary risk.

Table 1: Types of telemonitoring data

- Regular collection of symptom data:
 - Breathlessness – At rest, on minimal activity (walking across room on the flat), and more challenging (stairs, dressing, bathing)
 - Cough
 - Fever
 - Others which may help characterise the illness (e.g. myalgia, fatigue, taste/smell, rhinorrhoea, diarrhoea, conjunctivitis)
- Physiological parameters:
 - *Using simple/commonly available devices* – pulse rate, SpO₂ (after 20 minutes seated and after 1 minute walking/sit to stand), temperature
 - *Less readily available* - respiratory rate, cardiac rhythm

Figure 1: Proposed Scottish telemonitoring system for COVID-19.



Usability: The key principle of the Scottish system is that telemonitoring has to be simple enough that it maximises the proportion of people at risk who can use it, and can be deployed with minimal training. Suspected COVID patients attending an assessment centre, who are to be discharged home, can be enrolled in the telemonitoring system, given a pack with equipment, and information on its use. Patients are advised that telemonitoring is just an aid and that any significant symptom or oximetry deterioration at any time should prompt an immediate contact for advice rather than waiting for the next routine request for data. At least once daily, records of active patients are scanned to ensure data is being sent and that appropriate action has been taken by the patient. At the end of a fortnight patients are asked to return the equipment, unless still symptomatic when the observation period is extended.

Data collection: A daily symptom diary is collected, covering change in breathlessness from the day before, current severity of breathlessness, fever, cough, and other potentially relevant symptoms. Patients are asked to record their temperature and pulse oximetry twice daily, with pulse oximetry readings at both rest (after 20 minutes seated) and after walking on the flat for one minute.

Device and data transmission: The Scottish system uses commercially available pulse oximeters, and a telemonitoring platform which will work by App, internet, SMS text or touch tone phone [14] and which is configured for secure data delivery to NHS systems. Patients are texted reminders to text symptom diaries and temperature/pulse oximetry data back to a central server which collates a report for the clinical team. Patients whose symptoms or pulse oximetry data suggest deterioration (e.g. significantly increased breathlessness at rest, SpO₂ <94% at rest or following minimal exercise in a previously well person) are advised to phone 999. Borderline oxygen saturation (94 or 95) which is lower than the previous recorded reading prompts a message to telephone for advice as does a resting pulse rate >100 beats per minute, fever of >38.0 for 5 consecutive days or any fever of >38.5.

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