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A qualitative evaluation of a remote medical monitoring system for COVID-19 patients in Australia

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Title of Manuscript:

A qualitative evaluation of a remote medical monitoring system for COVID-19 patients in Australia

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ABSTRACT

Background

Many COVID-19 patients are discharged home from hospital with instructions to self-isolate. This reduces the burden on potentially overwhelmed hospitals. The Royal Melbourne Hospital (RMH) Home Monitoring Programme (HMP) is a new model of care for COVID-19 patients which chiefly tracks pulse oximetry and body temperature readings.

Objective

To evaluate the feasibility and acceptability of the HMP from a patient perspective.

Design, settings and participants

Of 46 COVID-19 patients who used the HMP through RMH during April to August 2020, 16 were invited to participate in this qualitative evaluation study; all accepted, including six health care workers. Attempts were made to recruit a gender-balanced sample across a range of COVID-19 severities and comorbidities. Participants completed a brief semi-structured phone interview discussing their experience of using the HMP.

Outcomes measure and analysis

A thematic analysis of interview data was conducted. Feasibility was defined as the HMP's reported ease of use. Acceptability was considered holistically by reviewing emerging themes in the interview data.

Results

Clinical deterioration was recognised as it occurred enabling prompt intervention. All participants reported a positive opinion of the HMP, stating it was highly acceptable and easy to use. Almost all participants said they found using it reassuring. Patients frequently mentioned the importance of the monitoring clinicians as an information conduit. The most commonly suggested improvement was to monitor a greater breadth of symptoms.

Conclusions

The HMP is highly feasible and acceptable to patients. This model of care could potentially be implemented on a mass-scale to reduce the burden of COVID-19 on hospitals. A key benefit of the HMP is the ability to reassure patients they will receive suitable intervention should they deteriorate while isolating outside of hospital settings.

ARTICLE SUMMARY

Strengths and limitations of this study

- The Royal Melbourne Hospital Home Monitoring Programme (HMP) is a new, scalable, automated model of care for COVID-19 patients which chiefly tracks pulse oximetry and body temperature readings.
- As well as describing the HMP, we provide the first qualitative description worldwide of the
 patient experience of undertaking monitoring while isolating at home.
- Attempts were made to recruit a gender-balanced sample across a range of COVID-19 severities and comorbidities.
- Interviews, transcription, and thematic analysis were performed by a single researcher, who
 identified when thematic saturation had occurred and when recruitment should therefore
 cease.
- The reliance on a single researcher's perception and clinician-led recruitment introduces the possibility of bias, however thematic saturation was noted.

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Competing Interests: None declared

INTRODUCTION

Health systems, including hospitals and intensive care departments, have become overwhelmed in areas severely affected by the COVID-19 pandemic.¹ COVID-19 symptoms range from mild to severe. The time from symptom onset to severe symptoms presenting is, on average, 8 to 10 days. COVID-19 complications may require hospitalisation to treat and may become life threatening. ² In Australia, community and health care associated transmission has occurred, with 30,274 cases of COVID-19 reported by 15 June 2021, including 910 deaths, since the first case was confirmed almost seventeen months previously.³ By far, the majority of this burden has occurred in Victoria, Australia, with 20,676 COVID-19 cases (68% of the national case total) and 820 deaths (90% of the national death total).⁴

There are various models of care available for monitoring COVID-19 patients. Many patients who present to emergency services may be diagnosed and discharged home with instructions to self-isolate, monitor symptoms, and to return to hospital only if significantly unwell. For some patients, the clinical course remains mild, with further medical intervention not required. However, a subset of patients who do not require urgent inpatient hospital admission at the initial clinical review may deteriorate or die during their illness.[9] COVID-19 patients considered by assessing clinicians to not require hospitalisation may be instructed to use a home-based monitoring system while self-isolating. Home-based monitoring systems track signs and symptoms to identify if a patient deteriorates and requires hospitalisation. Previous reports indicate home-based monitoring can avoid unnecessary hospitalisations, reducing the likelihood of overwhelming hospitals and reducing the risk of nosocomial transmission, as well as providing a much more cost-effective alternative to inpatient care. Despite these advantages, concerns regarding home-based monitoring systems have been raised in regards to patient safety and privacy.

The aim of this study was to evaluate the feasibility and acceptability of the Royal Melbourne Hospital (RMH) Home Monitoring Programme (HMP) from a patient perspective. This information will ultimately inform refinements to this new model of care for COVID-19 patient management, with an eye to maximising acceptability to patients.

METHODS

Study design

This was a prospective cohort study with a qualitative evaluation component.

Ethics approval was granted by the RMH Human Research Ethics Committee (QA2020073).

This study is reported in accordance with COREQ guidelines. 10

Study setting and population

This study was undertaken at the Royal Melbourne Hospital (RMH), a quaternary care hospital in Melbourne, Victoria, Australia. More than 60,000 adults present at the Emergency Department (ED) per annum and around half require hospital admission.¹¹

All patients attending the ED or COVID-19 assessment clinic at RMH were screened for HMP eligibility. Eligible patients were adults aged over 17 years-old who were self-isolating in Victoria and had laboratory confirmed SARS-CoV-2 infection. Patients who were considered well enough to be sent home were assessed for risk of deterioration, with low-, moderate- and high-risk patients identified. Low-risk patients who were well at discharge and were considered unlikely to deteriorate were advised to follow up with their usual general practitioner or return to hospital as needed. Moderate-risk and high-risk patients were offered enrolment in the HMP. This risk assessment was conducted by clinicians using the matrix presented in Appendix 1, which considered patient age, comorbidities, and supports.

Home Monitoring Program Intervention

The HMP was established de-novo and used pre-existing hospital information technology infrastructure, finger-tip pulse oximeters (inHealth: ARTG ID: 321974) and personal-use oral digital thermometers (MT-518). A bespoke open-source mobile-health software solution was built to facilitate the HMP via mobile phone and wireless technologies. The technical specifications for this software have previously been published.^{12 13}

After enrolment, patients were given monitoring packs. During the monitoring period, patients received twice daily prompts via short message service (SMS) reminders to measure and report their pulse rate, temperature and oxygen saturation (termed 'observations'). Abnormal vital signs, or symptom base indicators of clinical deterioration, triggered automated clinical advice to be sent to patients and flagged the supervising clinician, who provided e-health services and arranged transfer for hospital admission if required (Figure 1).

Clinical alert and MET call threshold criteria were customisable depending on pre-existing medical conditions. Default values are described in the supplementary table.

Survey content and administration

Patients at least 60-days post HMP discharge were recruited into a formal evaluation of the program following a routine phone consultation with a clinician. When recruiting, attempts were made to achieve a gender balance, and include patients across a range of COVID-19 severities, age groups and comorbidities.

Qualitative HMP evaluation data were collected during semi-structured phone interviews. Invited participants were interviewed once. A pilot study was not conducted. All interviews were conducted by JO (PhD - Public Health; Postdoctoral Fellow - University of Melbourne). Participants had no prior knowledge of, or relationship with, the interviewer. Interviews were conducted privately in the interviewer's office. Participants were informed that the interviewer had no prior involvement with the HMP and was independent from RMH. Informed verbal consent to participate was provided. Interview questions were planned a priori. The interview guide (Appendix 2) was created by the interviewer using suggestions from two clinicians experienced in treating COVID-19. Both clinicians and the interviewer had experience in qualitative health systems research and had published scientific research in this area. The interviewer sought to cover each participant's overall experience of the HMP, its ease of use, positive and negative aspects, potential improvements and whether participants would recommend the HMP to someone with COVID-19 in a similar situation to their own. Participants were free to comment in other areas. Participants were able to speak until they indicated they had nothing further to add. Interview times varied according to the speed at which participants volunteered information, the amount of information volunteered, and participants' time restraints. Interviews were recorded using a Dictaphone. Any notes made during the interview were not included in the analysis.

Recruitment ceased when the interviewer felt that thematic saturation had occurred.

Data analysis

A grounded theory approach was used to analyse interview data. Interviews were transcribed by the interviewer using Trint ™ with automated transcriptions manually edited with reference to the audio recording.¹⁴ Participants did not review the interview transcripts or provide feedback on findings. Interview transcripts were holistically analysed on Nvivo by the interviewer.¹⁵ The interviewer assigned tags to perceived themes under the headings of HMP experience, ease of HMP use, and potential HMP improvements. A saturation point was reached when no new codes were generated

while reviewing the transcripts. A single registry of codes was created. A thematic analysis occurred using the code register data which was loosely based around questions asked during the interview.

Where an issue was addressed by multiple participants, the proportion who responded in the same way (for example, with agreement) was reported in a semi-quantitative manner.

All patients who enrolled in the HMP had quantitative data entered and extracted from the RMH REDCAP database, aggregated, and reported using descriptive statistical analysis. These data included the patient's age, gender, co-morbidities, clinical course during COVID-19, reason for HMP discharge and outcome at 60-days post HMP discharge.

RESULTS

Home Monitoring Programme Enrolment, Events and Outcome

Forty-six patients were enrolled in the HMP from April 7, 2020 to August 21, 2020. The evaluation component recruited from a population with a significant burden of comorbid diseases (Table 1).

Table 1: Home Monitoring Program Population enrolled from 7 April to 21 August 2020, Royal Melbourne Hospital, Victoria, Australia

Characteristics		
	Median	Interquartile range
Age (years)	45.8	36.8-61.6
	Number of Home Monitoring	Proportion
Sex	Programme patients	(%)
Male	20	43.5
Female	26	56.5
Comorbidity Burden		
Single Comorbidity	19	41.3
2 Comorbidities	6	13.0
3 Comorbidities	3	6.5
4 Comorbidities	1	2.2
Any	29	63.0
Comorbidity Frequency		
Diabetes	10	21.7
Pulmonary Disease	9	19.6
Hypertension	8	17.4
Ischemic Heart Disease	3	6.5
Immunosuppression	3	6.5
Smoker	3	6.5
Pregnancy	2	4.3
Obesity	2	4.3
Other	8	17.4
Total	46	100.0

The median number of self-reported observations submitted by patients through the HMP was 16 (equating to 8 days of observation) with a range of 1 - 28 observations.

Over one-third of patients had an episode of documented oxygen desaturation, however significant episodes of hypoxia were less common. Automated pyrexia management advice was generated for just under 10% of patients (Table 2).

Table 2: Summary of clinical deterioration events occurring among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

	Pat	ients	Total triggers for clinical review
	n	%	n
Pulse Rate			
Clinical Review	2	4.3	2
MET call	4	8.7	6
Oxygen Saturation			
Clinical Review	16	34.8	39
MET Call	3	6.5	5
Body temperature			
Automated Advice	4	8.7	6

MET Call: Medical Emergency Team call. Marked physiological derangement.

Clinical Review: Modest physiologic derangement.

Clinical events resulted in supervising clinician notification and planned ED attendance for 10/46 (22%) patients. No patients had ED attendances that were not facilitated though the HMP. Following ED presentation, one patient required general ward admission, and two patients were admitted to ICU. Following discharge from the HMP, one patient deteriorated and died following rehospitalisation with COVID-19 complications.

Program Evaluation

Sixteen of 32 patients who completed the 60-day follow up were invited to be interviewed and all consented with no withdrawals. Interviews ranged from 4 to 13 minutes. The median duration was 7.5 minutes.

Nine of the 16 were female and seven were male. The median age was 44.5 years (range: 26-68 years). Six participants self-identified as healthcare workers when asked by the interviewer.

Four participants were assessed at ED while they were using the HMP, all of whom resumed using the HMP once discharged.

Nine participants (56%) had no comorbidities. The most common comorbid state was pulmonary disease/moderate-to-severe asthma. One participant had three separate comorbid conditions. Two participants were pregnant while using the HMP.

Patient experience of the Home Monitoring Programme

All 16 participants reported a positive or very positive perception of the HMP, despite most also mentioning very negative experiences of COVID-19.

When discussing COVID-19 generally, considerable suffering due to symptoms and aggravating comorbidities were often mentioned. Distress and confusion regarding unclear public health directives and lack of contact with public health authorities was discussed by several participants. Confusion around having to report to multiple, non-integrated, systems while in isolation was noted by several participants. Some participants commented that they were required to report to regional public health authorities, their workplace, the isolation hotel and the HMP, often while feeling very tired and unwell.

Feeling reassured knowing that physicians were monitoring participants remotely and would ensure they received help if they deteriorated frequently emerged as a theme, including among patients with comorbidities and pregnant patients.

A few participants reported their family members felt reassured by their involvement in the HMP. Knowing participants could contact the monitoring clinicians if they had questions or concerns was a frequently cited source of reassurance.

Altruistic attitudes around avoiding burdening the health system were quite frequently observed. A few participants reported that the HMP empowered them by enabling them to know whether to go into hospital. They discussed feeling unwell, but not 'knowing if it was bad enough to go into hospital' and feelings of guilt around visiting the ED, 'Not wanting to overwhelm the system' or 'put a healthcare worker at risk [of infection]'. One participant stated: 'It [the HMP] gave me control.'

All participants reported that they felt the HMP was highly acceptable. None reported finding multiple daily prompts during their isolation intrusive. Perceptions of harm averted from the HMP were frequently discussed.

A few participants identified the monitoring clinicians as an important information conduit outside of their clinical role by providing advice about when they might be released from mandatory isolation, and providing updates on the COVID situation and public health response generally. One participant discussed being able plan how much food he would need during his isolation following a conversation with a monitoring clinician.

All participants reported that they found the HMP extremely easy to use. No issues with the pulse oximeters were noted, and almost all thought inputting data was extremely easy, except one participant who reported difficulty using the sliding scales on multiple electronic devices.

Two participants noted occasions when they received a follow-up call from a HMP clinician which was not actually required; once when a typo was entered into the temperature reading, and once

when the participant measured their temperature having just come out of a hot shower. Detailed participant quotations may be seen in Appendix 3.

Criticisms and potential improvements

About half the participants indicated that they could not think of any possible improvements to the HMP.

The most common criticism, mentioned by several participants, was that only a few signs (temperature and blood oxygen) were formally monitored. Monitoring a greater number and breadth of conditions was the most commonly suggested improvement, such as incorporating monitoring of the respiratory rate, pain levels, neurological and gastrointestinal symptoms. Concerns that people with atypical, or more severe symptoms, could be missed by the HMP were expressed. One participant felt there was an overreliance on the HMP, and consequently felt they had not received a full clinical assessment. A few participants mentioned that incorporating monitoring of comorbid conditions would have been an improvement. Detailed criticisms and suggestions may be seen in Appendix 3.

All participants said that they would recommend using the HMP. Almost all said they would recommend it to someone in their situation with COVID-19.

DISCUSSION

We report the successful rapid development, implementation and evaluation of a COVID-19 home monitoring system in Melbourne, Australia, during the global COVID-19 pandemic. The HMP demonstrated episodes of hypoxia were relatively common in our cohort. Clinical deterioration was recognised as it occurred, with patients recalled to hospital for assessment and/or admission. This model of care harnessed existing health information-technology infrastructure and has potential to be implemented on a mass-scale, should health system capacity become overwhelmed. Important design considerations inbuilt into the HMP set a low technical hurdle for participants to engage with, met requirements for cybersecurity, and were sufficiently agile and capable of a short concept to implementation cycle. When developing the HMP, consideration was given to the need to minimise face-to-face contact between healthcare workers and patients.

The HMP was highly acceptable and feasible from the perspective of a patient isolating outside of hospital settings, and it provided them with an important source of reassurance. An unexpected finding concerned the importance of the monitoring clinicians as an information conduit in the absence of accessible public health authorities (who themselves were overwhelmed by the outbreak). Any mass-implemented HMP should ensure that the staff involved are able to answer questions about COVID-19 and the public health response. Such a HMP could perhaps incorporate routine monitoring of other signs and symptoms. The HMP provided a low-cost patient care solution, which only required the use of the patient's smartphone and an internet connection. It is important that overreliance on a HMP does not occur, and patients presenting to ED are assessed as thoroughly as possible. A HMP should be routinely evaluated from a clinician and a patient perspective, with refinements implemented promptly – including refinements to help meet the needs of less typical patients.

Children and youth aged less than 18 years were excluded, and no adults aged over 68 years participated. It should be noted that participation required some proficiency in using a smartphone and reasonable English language skills. Interviews, transcription, and analysis were performed by a single researcher, who identified when thematic saturation had occurred and when recruitment should therefore cease. This reliance on a single researcher's perception introduces the possibility of bias. A further source of potential bias occurred when the monitoring clinicians identified patients to recruit, however it was made clear to participants that the interviews were confidential and the interviewer had no involvement in HMP development or implementation, or in patient care. Including more participants may have led to new themes emerging, however thematic saturation was noted. Participant recruitment was halted due to practical elimination of community

transmission of COVID-19 within Victoria, Australia. This limited our ability to report on the relationship between subjective and objective markers of clinical deterioration, however our findings highlight a high frequently of desaturation episodes. Next steps include scalability assessments for mass-scale roll out of a HMP, should this become useful, and larger studies to assess economic and clinical outcomes. Refining a HMP to meet the needs of culturally and linguistically diverse patients and elderly patients is important as they may be less comfortable using an internet-based electronic system.

Conclusions

Currently stable patients at moderate- and high-risk of COVID-19 complications may benefit from a HMP if they are discharged home to isolate. The HMP was highly feasible and acceptable to participants. This model of care could be implemented on a mass-scale to reduce the COVID-19 burden on hospitals. Key benefits of the HMP were its ability to reassure patients that they would receive suitable intervention should their health deteriorate while in isolation, and the ability of the monitoring clinicians to provide information and advice to isolating patients.

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Figure 1. Home monitoring programme flow diagram

Table 1: Home Monitoring Program Population enrolled from 7 April to 21 August 2020, Royal Melbourne Hospital, Victoria, Australia

Table 2: Summary of clinical deterioration events occurring among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

Supplementary Table. Summary of comorbid states among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

Appendix 1: Risk Matrix

Appendix 2. Interview guide

Appendix 3. Patient experience of using the Home Monitoring Programme

AUTHOR CONTRIBUTIONS

JO drafted the study protocol and the manuscript and refined these documents following several rounds of feedback from co-authors. JO collected data, performed the analysis and write up findings. AM critically reviewed successive versions of the manuscript and guidance on the interpretation of data.

MD performed recruitment, critically reviewed successive versions of the manuscript and provided guidance on the interpretation of data.

MP critically reviewed successive versions of the manuscript provided guidance on the interpretation of data.

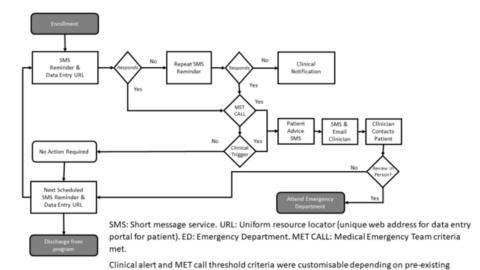
JK conceived of the study, performed recruitment, critically reviewed successive versions of the manuscript and study protocol and provided guidance on the interpretation of data.

DATA STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information in Appendix 3.

PATIENT OR PUBLIC INVOLVEMENT

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.



Home monitoring programme flow diagram

medical conditions. Default values are described in the supplementary material.

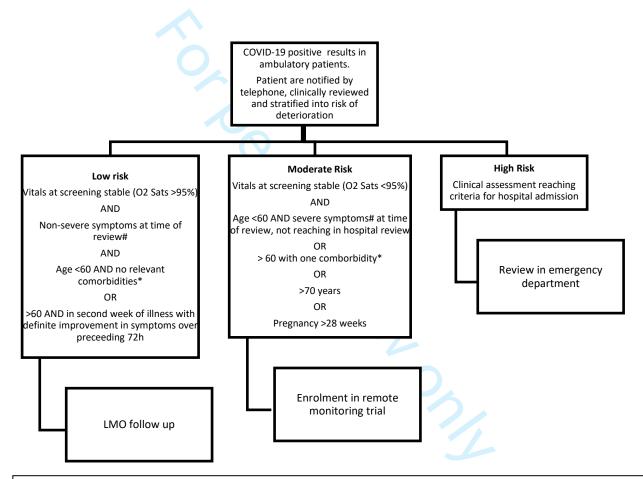
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Appendix 1: Risk Matrix Criteria for risk stratification

Low risk: Discharge for follow up with local medical officer (LMO)

Medium risk: Royal Melbourne Hospital Home Monitoring System

High risk: Inpatient admission



* Relevant comorbidities: Hypertension, Type 1 and Type 2 diabetes, history of cardiovascular disease or cerebrovascular disease, Malignancy with treatment (chemotherapy, radiotherapy or biological therapy in the preceding 3 months), pulmonary disease (severity of asthma – daily preventer), immunosuppressed (20mg or more of prednisolone, disease modifying medication, biologicals or transplant medication)

Rating any one of the following symptoms currently as severe: fever, cough, headache, muscle aches, sore throat or chest tightness

O2 sats – oxygen saturation

RMH Home Monitoring System Evaluation

Interview Guide - Version 1.0; Dated 4 Sep 2020

Hi (name), my name is ______. I work at the University of Melbourne. I'm calling to invite you to have a brief interview with me to discuss your experience of using the Royal Melbourne Hospital home monitoring systems while you had COVID-19.

• Is this a good time talk?

(If YES)

Great, thank you. Participating in this interview is completely voluntary, if you choose not go ahead with the interview then there won't be any adverse consequences at all. You're free to decline any questions and you can end the interview at any point. Any information you give me is confidential. The interview notes and research findings will be written up in a way that will not identify you to anybody.

If you would like to proceed with the interview it will be recorded, but I can stop the recording at any time you choose.

Would you be happy to proceed with an interview now?

(If YES)

Great, thank you. Please let me know if you would like me to pause the recording at any point.

- First of all I'd just like ask if you are a health care worker?
- And how old are you?

Thanks.

- I understand you developed COVID-19 and you went to the Royal Melbourne Hospital. You were discharged and invited to use their home monitoring system. Is that right?
- Did you go back to hospital for COVID at any point while you were sick?
- And have you recovered from COVID now?
- What was your experience of using the RMH Home Monitoring System?

Prompts: what worked well, what did not work well? How acceptable was using the RMH Home Monitoring System for you?

Prompts: was the system easy to use? How did you find getting the SMS prompts?

How might your experience of using the RMH Home Monitoring System be improved?

Prompts: were there any aspects of the system that were intrusive or annoying?

 How likely would you be to recommend the RMH Home Monitoring System to a friend or family member who was in your situation with COVID-19?

Prompts: Why?

- Is there anything in particular you felt RMH did well for you while you had COVID?
- Is there anything you feel that RMH could have done better?

Appendix 3. Patient experience of using the Home Monitoring Programme

All 16 participants reported a positive or very positive perception of the HMP, despite most also mentioning very negative experiences of COVID-19.

When discussing COVID-19 generally, considerable suffering due to symptoms and aggravating comorbidities were often mentioned. Distress and confusion regarding unclear public health directives and lack of contact with public health authorities was discussed by several participants. Confusion around having to report to multiple, non-integrated, systems while in isolation was noted by several participants. Participants commented that they were required to report to regional public health authorities, their workplace, the isolation hotel and the HMP, often while feeling very tired and unwell.

Feeling reassured through being involved in the HMP frequently emerged as a theme. This was mentioned by most participants, including some with serious comorbidities and two who were pregnant. One participant mentioned they liked '...knowing what my body was doing.' Many participants reported feeling reassured knowing that physicians were monitoring them remotely and would ensure they received help if they deteriorated.

'It gave a complete peace of mind... it was my comfort actually.'

'I felt quite safe knowing I was being monitored.'

A few participants reported their family members felt reassured by their involvement in the HMP. Knowing participants could contact the monitoring clinicians if they had questions or concerns was a frequently cited source of reassurance.

A few participants reported that the HMP empowered them by enabling them to know whether or not they needed to go into hospital. They discussed feeling unwell, but not 'knowing if it was bad enough to go into hospital' and feelings of guilt around visiting the ED, 'Not wanting to overwhelm the system' or 'put a healthcare worker at risk [of infection]' prior to enrolment in the HMP. One participant stated:

'It gave me control.'

Altruism around avoiding burdening the health system were quite frequently observed.

'It's good to see that people have been looking at creative ways to... prevent potentially overwhelming the health system [by creating the HMP].'

All participants reported that they felt the HMP was highly acceptable. No participants reported finding the multiple prompts through it each day during their isolation intrusive. These prompts requested a temperature reading and pulse oximetry value.

Perceptions of averted harm due to the HMP were frequently discussed. Participants made statements like:

'I'm not sure what would have happened if the doctor hadn't called the ambulance...'

'It probably saved my life.'

A few participants identified the monitoring clinicians as an important information conduit outside of their clinical role.

'I was on hold to the Department of Health for an hour, but being able to talk to the doctor was good.'

The monitoring clinicians were able to provide advice about when participant might be released from their mandatory isolation, and provide updates on the COVID situation and public health response generally.

"...when the health system is overwhelmed, participating in [the HMP]... was really positive because it provides another point of reference and support."

Another participant discussed being able plan how much food he would need during his isolation following a conversation with a monitoring clinician. Several participants described monitoring clinicians as an important source of support.

'[The] team were so supportive... even just chatting and listening.'

Detailed criticisms and potential improvements to the Home Monitoring System

Concerns that people with atypical or more severe symptoms could be missed by the HMS were expressed.

'I never had... [formally monitored symptoms]... but I had a 10 out of 10 headache that made me want to punch a wall. I added a note [in the HMS] saying I was in a lot of pain and... [the clinician] contacted me and said, 'We'll get you an ambulance'. So you can deteriorate on it but... there is a safety net.'

One participant was concerned that cough wasn't monitored, stating that cough can lead to a stroke. A few participants mentioned that incorporating monitoring of comorbid conditions would have been an improvement.

One participant felt there was an overreliance on the HMS, which meant that they had not been fully assessed, saying:

'I feel the service at Emergency [RMH ED] ended up lacking because I was sent straight into the monitoring system and sent home.... There were no blood tests or even listening to my chest.'

This participant indicated they felt the seriousness of their illness had been somewhat trivialised, laughing

'If we can control COVID like this, why can't we just produce lots of oximeters and monitor it this way?'

Several participants had household members who had also COVID-19 and were enrolled in the HMS at the same time as they were. One participant mentioned having the ability to tell the monitoring clinicians that they were worried about a family member in this situation, and get help looking after them, would have been valuable. Several participants mentioned that having the ability to use a HMS for other conditions, unrelated to COVID-19, would be useful.

'Having a system [like this] in place in which people can avoid overwhelming the health system... would be great' or to avoid '...dragging yourself into the hospital or the clinic... with chronic pain.'

One participant mentioned that the sliding scales used to report symptom severity were 'glitchy' and frustrating to use. They suggested that entering numbers corresponding to the e.g. breathlessness score would have resolved this.

Another participant reported having difficulty accessing wireless internet access in her isolation facility and not being able to use the internet through any other source, which meant she could only upload her HMS data in a certain part of her room.

One participant mentioned that although they were comfortable using the thermometer, others may benefit from being provided with instructions on how to use it and keep it clean.

A few participants mentioned the monitoring clinicians need to be aware of their role as an information conduit.

'They actually might be the most important health professional reference point that's available... it would be great to put that a little bit more in the foreground.'

A few participants suggested making a more personal connection through the HMS, such as a video call to check in during the patient's isolation.

Supplementary Material

Supplementary Table 1. Summary of comorbid states among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

	Number of participants	Proportion of participants (%)
No comorbidities	9	56.3
Pulmonary disease /	3	
Moderate to severe asthma		18.8
Immunosuppressed	1	6.3
Diabetes and Chronic Lung	1	
Disease and Hypertension		6.3
Pregnancy	2	12.5
Total	16	100.0

Supplementary Table 2. Number of comorbid states among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

Number of comorbidities	Number of participants affected	Proportion of participants (%)
3	1	6.3
2	0	0.0
1	6	37.5
0	9	56.3
Total	16	100.0

Clinical alert triggers

The software replicated hospital-based systems to identify clinical deterioration in patients based on alternations in reported vital signs.

Two thresholds were set to delineate the magnitude of departure from normal physiology, and to differentiate the urgency of clinical response: Clinical Alert and MET Call. The software allocated default values for each vital sign threshold at registration. Clinical alert and MET call threshold criteria were customisable depending on pre-existing medical conditions (eg. Oxygen desaturation could be set lower in patients with pre-existing lung disease).

The following were default values, which were used for most patients:

- Temperature 38.0 degrees Celsius: Fever management advice
- Oxygen Saturations <95%: Clinical Alert
- Oxygen Saturation: < 90% Met Call
- Heart Rate <50: Clinical Alert
- Heart Rate >130: Met Call

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on
Damain 1. Dagaanah taan			Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with	3	What experience of training and the researcher have:	
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer	'	goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
interviewer characteristics	0	e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design		e.g. bias, assumptions, reasons and interests in the research topic	
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory	9	grounded theory, discourse analysis, ethnography, phenomenology,	
and meory		content analysis	
Participant selection		Content analysis	
Sampling	10	How were participants selected? e.g. purposive, convenience,	1
Sampling	10	consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail,	
Method of approach	11	email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
	15	now many people refused to participate of dropped out; keasons;	
Setting of data collection	1.1	Where was the data collected? or a home clinic workplace	
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non- participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	
Description of Sample	10	data, date	
Data collection		uata, uate	
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot	
interview guide	"	tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	20	What was the duration of the inter views or focus group?	
		Was data saturation discussed?	
Data saturation Transcripts returned	22		
Transcripts returned	23	Were transcripts returned to participants for comment and/or wonly - http://bmlopen.bml.com/sire/about/guidelines.xhtml	

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Topic	Item No.	Guide Questions/Description	Reported on
			Page No.
		correction?	
Domain 3: analysis and			
findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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BMJ Open

A remote COVID-19 monitoring system for patients at the Royal Melbourne Hospital, Victoria, Australia: A qualitative evaluation

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A remote COVID-19 monitoring system for patients at the Royal Melbourne Hospital, Victoria, Australia: A qualitative evaluation

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ABSTRACT

Background

Many COVID-19 patients are discharged home from hospital with instructions to self-isolate. This reduces the burden on potentially overwhelmed hospitals. The Royal Melbourne Hospital (RMH) Home Monitoring Programme (HMP) is a model of care for COVID-19 patients which chiefly tracks pulse oximetry and body temperature readings.

Objective

To evaluate the feasibility and acceptability of the HMP from a patient perspective.

Design, settings and participants

Of 46 COVID-19 patients who used the HMP through RMH during April to August 2020, 16 were invited to participate in this qualitative evaluation study; all accepted, including six health care workers. Attempts were made to recruit a gender-balanced sample across a range of COVID-19 severities and comorbidities. Participants completed a brief semi-structured phone interview discussing their experience of using the HMP.

Outcome measures and analysis

A thematic analysis of interview data was conducted. Feasibility was defined as the HMP's reported ease of use. Acceptability was considered holistically by reviewing themes in the interview data.

Results

The HMP allowed clinical deterioration to be recognised as it occurred enabling prompt intervention. All participants reported a positive opinion of the HMP, stating it was highly acceptable and easy to use. Almost all participants said they found using it reassuring. Patients frequently mentioned the importance of the monitoring clinicians as an information conduit. The most suggested improvement was to monitor a broader set of symptoms.

Conclusions

The HMP is highly feasible and acceptable to patients. This model of care could potentially be implemented on a mass-scale to reduce the burden of COVID-19 on hospitals. A key benefit of the HMP is the ability to reassure patients they will receive suitable intervention should they deteriorate while isolating outside of hospital settings.

ARTICLE SUMMARY

Strengths and limitations of this study

- The Royal Melbourne Hospital Home Monitoring Programme (HMP) is a new, scalable, automated model of care for COVID-19 patients which chiefly tracks pulse oximetry and body temperature readings.
- As well as describing the HMP, we provide one of the first qualitative descriptions of patients' experiences of using the HMP.
- Attempts were made to recruit a gender-balanced sample across a range of COVID-19 severities and comorbidities.
- Interviews, transcription, and thematic analysis were performed by a single researcher, who
 identified when thematic saturation had occurred and when recruitment should therefore
 cease.
- The reliance on a single researcher's perception and clinician-led recruitment introduces the possibility of bias, however thematic saturation was noted.

Funding statement: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors

Competing Interests: None declared

INTRODUCTION

Hospitals and intensive care departments, have, at times, become overwhelmed in areas severely affected by the COVID-19 pandemic.¹ In Australia, community and health care associated transmission has occurred. As at 6 December 2021, there are currently over 18,700 active COVID-19 cases in Australia. Melbourne, Victoria has experienced the highest disease burden of any Australian city.² COVID-19 symptoms range from mild to severe. In patients with severe COVID, the mean time from symptom onset to severe symptoms presenting is, on average, 8 to 10 days. COVID-19 complications may require hospitalisation to treat and may become life threatening.⁴

Due to the variable clinical course, there are several models of care available for monitoring COVID-19 patients. Many patients who present to emergency services may be diagnosed and discharged home with instructions to self-isolate, monitor symptoms, and to return to hospital only if significantly unwell. For some patients, the clinical course remains mild, with further medical intervention not required. However, a subset of patients who do not require urgent inpatient hospital admission at the initial clinical review may deteriorate or die during their illness. These patients may develop rapid hypoxemia and silent hypoxia, which can potentially be detected through a monitoring system.⁵ COVID-19 patients considered by assessing clinicians to not require hospitalisation may be offered a home-based monitoring system while self-isolating. Home-based monitoring systems track signs and symptoms, particularly blood oxygen saturation, to identify if a patient deteriorates and requires hospitalisation. Systems described in the literature include phone or video based clinical assessment/s of isolating patients, email links to surveys collecting biometric and symptom data, and mobile phone-based web applications. At a minimum, symptom data, pulse oximetry and body temperature readings are generally included, in addition to providing a mechanism enabling patients to discuss concerns with a clinician. When certain thresholds are met, further follow-up, including emergency department referrals are triggered. 6-11 Previous reports indicate home-based monitoring can avoid unnecessary hospitalisations, reducing the likelihood of overwhelming hospitals and reducing the risk of nosocomial transmission, as well as providing a much more cost-effective alternative to inpatient care. 6-10 12-15 A number of evaluations report high levels of user satisfaction (67-100%).⁷⁻⁹ Despite these advantages, concerns regarding home-based monitoring systems have been raised in regards to patient safety and privacy. 16

The aim of this study was to evaluate the feasibility and acceptability of the Royal Melbourne

Hospital (RMH) Home Monitoring Programme (HMP) from a patient perspective. This information

will ultimately inform refinements to this new model of care for COVID-19 patient management, with an eye to maximising acceptability to patients.



METHODS

Study design

This was a prospective cohort study with a qualitative evaluation component which used a constructivist approach.

Ethics approval was granted by the RMH Human Research Ethics Committee (QA2020073). This study is reported in accordance with COREQ guidelines.¹⁷

Study setting and population

This study was undertaken at the Royal Melbourne Hospital (RMH), a quaternary care hospital in Melbourne, Victoria, Australia. More than 80,000 adults present at the Emergency Department (ED) per annum and around half require hospital admission.¹⁸

All patients attending the ED or COVID-19 assessment clinic at RMH were screened for HMP eligibility. Eligible patients were adults aged over 17 years-old who were self-isolating in Victoria and had laboratory confirmed SARS-CoV-2 infection. Patients who were considered well enough to be sent home were assessed for risk of deterioration, with low-, moderate- and high-risk patients identified. Low-risk patients who were well at discharge and were considered unlikely to deteriorate were advised to follow up with their usual general practitioner or return to hospital as needed. Moderate-risk and high-risk patients were offered enrolment in the HMP. This risk assessment was conducted by clinicians using the matrix presented in Appendix 1, which considered patient age, co-morbidities, and supports.

Home Monitoring Program Intervention

The HMP was established de-novo and used pre-existing hospital information technology infrastructure, finger-tip pulse oximeters (inHealth: ARTG ID: 321974) and personal-use oral digital thermometers (MT-518). A bespoke open-source mobile-health software solution was built to facilitate the HMP via mobile phone and wireless technologies. In summary, patients were enrolled into the program via a hyperlink to a RedCAP form. The form captured demographic and clinical data. After enrolment, patients were given monitoring packs. During the monitoring period, patients received twice daily automated prompts via short message service (SMS) reminders to measure and report symptoms, pulse rate, temperature and oxygen saturation (termed 'observations'). Abnormal vital signs triggered automated clinical advice to be sent to patients and flagged the supervising clinician, who provided e-health services and arranged transfer for hospital admission if required (Figure 1).

Clinical alert and MET call threshold criteria were customisable depending on pre-existing medical conditions. Default values are described in the supplementary table. Detailed technical specifications for this software, and all associated documentation have previously been published.^{19 20}

Interview guide content and administration

Patients were recruited into a formal evaluation of the program following their routine 60-day post HMP discharge phone consultation with a clinician. Recruitment was conducted at this point to coincide with routine re-contacting and allow patients time to recover and reflect on their experiences. When recruiting, attempts were made to achieve a gender balance, and include patients across a range of COVID-19 severities, age groups and comorbidities. Qualitative HMP evaluation data were collected during semi-structured one-on-one phone interviews. Invited participants were interviewed once. A pilot study was not conducted. All interviews were conducted by JO (PhD - Public Health; female; Postdoctoral Fellow - University of Melbourne). Participants had no prior knowledge of, or relationship with, the interviewer. Interviews were conducted via a phone call from the interviewer's office. Participants were informed that the interviewer had no prior involvement with the HMP and was independent from RMH. Informed verbal consent to participate was provided. Interview questions were planned a priori. The semistructured interview guide (Appendix 2) was created by the interviewer using suggestions from two clinicians experienced in treating COVID-19. Both clinicians and the interviewer had experience in qualitative research and interviewing for health systems research. The interviewer sought to cover each participant's overall experience of the HMP, its ease of use, positive and negative aspects, potential improvements and whether participants would recommend the HMP to someone with COVID-19 in a similar situation to their own. Participants were free to comment in other areas. Participants were able to speak until they indicated they had nothing further to add. Interview times varied according to the speed at which participants volunteered information, the amount of information volunteered, and participants' time restraints. Interviews were recorded using a Dictaphone. Any notes made during the interview were not included in the analysis. We aimed to interview 10-20 people across a range of demographic and clinical characteristics. This sample size was practical given the study team's timeframes and resources. Recruitment ceased when the interviewer felt that thematic saturation had occurred.

Data analysis

Quantitative data for all patients enrolled in the HMP were extracted from the RMH REDCAP database, aggregated, and reported using descriptive statistical analysis. These data included the

patient's age, gender, co-morbidities, clinical course during COVID-19, reason for HMP discharge and outcome at the routine clinical assessment 60-day post HMP discharge.

A inductive thematic analysis was used to analyse interview data.²¹ Interviews were transcribed by the interviewer using Trint ™ with automated transcriptions manually edited with reference to the audio recording.²² Participants did not review the interview transcripts or provide feedback on findings. Interview transcripts were holistically analysed on Nvivo by the interviewer.²³ The interviewer assigned codes and subcodes to data, and grouped these according to perceived themes. A virtual whiteboard (miro.com) was used to identify unique and common themes. A saturation point was reached when no new codes were generated while reviewing the transcripts. A single registry of codes was created. Illustrative quotes, corrected for grammar, are provided.

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Home Monitoring Programme Enrolment, Events and Outcome

Forty-six patients were enrolled in the HMP from April 7, 2020 to August 21, 2020. The evaluation component recruited from a population with a significant burden of comorbid diseases (Table 1).

Table 1: Home Monitoring Program Population enrolled from 7 April to 21 August 2020, Royal Melbourne Hospital, Victoria, Australia

Characteristics		
	Median	Interquartile range
Age (years)	45.8	36.8-61.6
	Number of Home Monitoring	Proportion
Sex	Programme patients	(%)
Male	20	43.5
Female	26	56.5
Comorbidity Burden		
Single Comorbidity	19	41.3
2 Comorbidities	6	13.0
3 Comorbidities	3	6.5
4 Comorbidities	1	2.2
Any	29	63.0
Comorbidity Frequency	\sim	
Diabetes	10	21.7
Pulmonary Disease	9	19.6
Hypertension	8	17.4
Ischemic Heart Disease	3	6.5
Immunosuppression	3	6.5
Smoker	3	6.5
Pregnancy	2	4.3
Obesity	2	4.3
Other	8	17.4
Total	46	100.0

The median number of self-reported observations submitted by patients through the HMP was 16 (equating to 8 days of observation) with a range of 1 - 28 observations.

Over one-third of patients had an episode of documented oxygen desaturation, however significant episodes of hypoxia were less common. Automated pyrexia management advice was generated for just under 10% of patients (Table 2).

Table 2: Summary of clinical deterioration events occurring among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

	Patients		Total triggers for clinical review
	n	%	n
Pulse Rate			
Clinical Review ¹	2	4.3	2
MET call ²	4	8.7	6
Oxygen Saturation			
Clinical Review ¹	16	34.8	39
MET Call ²	3	6.5	5
Body temperature			
Automated Advice	4	8.7	6

Clinical Review: Modest physiologic derangement.

MET Call: Medical Emergency Team call. Marked physiological derangement.

Clinical events resulted in supervising clinician notification and planned ED attendance for 10/46 (22%) patients. No patients had ED attendances that were not facilitated though the HMP. Following ED presentation, one patient required general ward admission, and two patients were admitted to ICU. Following discharge from the HMP period, one patient deteriorated and died following rehospitalisation with COVID-19 complications.

Program Evaluation: Description of participants

Sixteen of 32 patients who completed the 60-day follow up were invited to be interviewed and all consented with no withdrawals. Interviews ranged from 4 to 13 minutes. The median duration was 7.5 minutes.

Nine of the 16 participants were female and seven were male. The median age was 44 years (range: 26-68 years). Six participants self-identified as healthcare workers when asked by the interviewer.

Four participants were assessed at ED while they were using the HMP, all of whom resumed using the HMP once discharged.

Nine participants (56%) had no comorbidities. The most common comorbid state was pulmonary disease/moderate-to-severe asthma. One participant had three separate comorbid conditions. Two participants were pregnant while using the HMP.

All 16 participants praised the HMP, despite many also mentioning very unpleasant experiences of having COVID-19. All participants recommended using the HMP, with almost all (N=14; 88%) saying they would recommend it to someone in their situation with COVID-19.

Key themes

Theme 1. "It gave a complete peace of mind"

Almost all of the participants mentioned they felt reassured knowing that medical staff were monitoring their health remotely while they were isolating with COVID-19. Participants described having peace of mind knowing that they deteriorated, help would be provided. This theme was particularly strong among patients with severe COVID-19, those with serious comorbidities, and those who were pregnant. Participants who required hospitalisation while isolating frequently discussed perceptions of harm averted through using the HMP. Around half the participants described being contacted by a HMP clinician following data entry in the HMP app. In a small minority of cases, the participant had entered data incorrectly and this contact was not warranted, but in other cases, HMP clinicians facilitated a transfer to hospital, with participants saying they were extremely grateful to have received this help.

"It [the HMP] probably saved my life. It was quite frightening knowing how sick I was getting.

It showed me when I de-sated and needed help." HMP013, female, aged 45 years, hospitalised twice using HMP

Participants discussed feeling comforted by seeing their temperature readings and oxygen saturation results. They used this information to assess the severity of their illness.

"It gave a complete peace of mind and reassurance that I could follow where my body was. It was my comfort actually." HMP001, female, aged 35, not hospitalised using HMP

Five participants spoke about the HMP facilitating contact with clinicians when they were concerned about symptoms that were not monitored using with the pulse oximeter or thermometer, such as severe pain, and receiving help.

"I added a note [to the HMP] saying I was in a lot of pain and that was when [the clinician] contacted me and said, 'We'll get you an ambulance'. So you can deteriorate on it but... there is a safety net".

HMP003, female, aged 65 years, hospitalised once using HMP.

As well as feeling reassured themselves, two participants spoke about how their loved ones felt reassured knowing they were using the HMP.

"The greatest value.. was for other people in my life to know... I wasn't an invisible and isolated person who may die and not be found for days. ...they found it very reassuring knowing that I was being monitored..." HMP005, male, aged 45 years, not hospitalised using HMP

Theme 2. HMP clinicians as an important information conduit

The benefits of having good communication with the HMP clinicians while isolating were often raised. In addition to appreciating their ability to answer clinical questions, the HMP clinicians were identified as an important information conduit outside of their clinical role. Participants discussed feeling distressed while experiencing having great difficulty contacting public health authorities to receive advice. In this absence, HMP clinicians provided advice about when participants might be released from mandatory isolation and provided updates on the COVID situation and the Victorian public health response.

"I live by myself so I was in isolation for that whole period and their [the Health Department's] lack of communication was distressing. What I was able to do was call the [HMP clinicians]... get some kind of prediction about when I might get a release and how many days of food I needed to plan."

HMP005, male, aged 45 years, not hospitalised using HMP

Theme 3: A highly acceptable supplement to clinical care

Considerable suffering due to COVID-19 symptoms and aggravating comorbidities were often mentioned. Many participants discussed the HMP supplementing their clinical care and enabling them to isolate outside of hospital settings. A strong theme around participants not wanting to present to hospital unless they really had to in order to avoid burdening the health care system and posing a transmission risk to staff was observed.

"It's good to see that people have been looking at creative ways to... prevent potentially overwhelming the health system, it [the HMP] was a good idea." HMP007, male, aged 68 years, not hospitalised using HMP

One participant felt there was an overreliance on the HMP and they had not received a full clinical assessment at RMH ED. They indicated they felt the seriousness of their illness had been trivialised.

"It [HMP] was excellent... but I feel the service at Emergency ended up lacking because I was sent straight into the monitoring system and sent home. [Laughing] If we can control COVID like this, why can't we just produce lots of oximeters and monitor it this way?' HMP011, female, aged 33 years, not hospitalised using HMP

All participants reported they felt using the HMP was highly acceptable. None said they found the multiple daily data entry prompts intrusive at all, even when feeling very unwell as they understood the importance of regular data entry. This came in spite of feeling overwhelmed having to report to multiple systems, often whilst unwell, such as to the Department of Health and to their workplace. All participants said they found the HMP extremely easy to use. No issues with the pulse oximeters were noted, and all thought inputting data was extremely easy, except one participant who reported difficulty using the sliding scales on multiple electronic devices.

Many participants highly praised the quality of clinical care they had received while at RMH and from the RMH HMP clinicians.

"I thought every aspect of my visit there from the first day to the ward was just absolutely phenomenal. I sent them a complimentary feedback afterwards." HMP001, female, aged 35, not hospitalised using HMP

Theme 4. Criticisms and potential improvements

About half the participants indicated that they could not think of any possible improvements to the HMP.

The most common criticism was that only a few signs (temperature and blood oxygen) were formally monitored. Monitoring a greater number and breadth of symptoms and signs was the most commonly suggested improvement, including respiratory rate, pain levels, neurological and gastrointestinal symptoms. Concerns that people with atypical, or more severe symptoms, could be missed by the HMP were expressed. Four participants mentioned that incorporating monitoring for comorbid conditions would have been an improvement. One participant suggested modifying the HMP and applying it to other conditions besides COVID-19.

One participant was frustrated by a lack of quality internet connection in her isolation facility which made it harder for her to use the HMP. Another emphasised the need for HMP clinicians to

understand their importance as an information conduit when public health authorities are unresponsive.

"It would be great to put that [communication role] a little bit more in the foreground so that the people who are running it are aware that they actually might be the most important health professional reference point that's available. HMP005, male, aged 45 years, not hospitalised using



DISCUSSION

We report the successful rapid development, implementation and evaluation of a COVID-19 home monitoring system in Melbourne, Australia, during the global COVID-19 pandemic. The HMP demonstrated episodes of hypoxia were relatively common in our cohort. Clinical deterioration was recognised as it occurred, with patients recalled to hospital for assessment and/or admission. This model of care harnessed existing health information-technology infrastructure and has potential to be implemented on a mass-scale to protect hospital capacity. Important design considerations inbuilt into the HMP set a low technical hurdle for participants to engage with, met requirements for cybersecurity, and were sufficiently agile and capable of a short concept to implementation cycle. When developing the HMP, consideration was given to the need to minimise face-to-face contact between healthcare workers and patients.

The HMP was developed extremely quickly over approximately 2 weeks in February 2020 in response to reports of COVID-19 community transmission internationally. It utilised readily available, configurable software such as REDCAP, which enabled prompt implementation once ethical and administrative requirements were met. The HMP was highly acceptable and feasible from the perspective of a patient isolating outside of hospital settings, and it provided them with an important source of reassurance. An unexpected finding identified the importance of the monitoring clinicians as information conduits in the absence of accessible public health authorities (who themselves were overwhelmed by the outbreak). Any mass-implemented HMP should ensure that the staff involved are able to answer questions about COVID-19 and the public health response. Such a HMP might incorporate routine monitoring of other signs and symptoms, including heart rate and peak expiratory flow as implemented by a similar Brazilian system. However increasing data entry may make it more difficult for patients to comply with the system.⁷ The HMP provided a low-cost patient care solution, which only required the use of the patient's smartphone, an internet connection and the cost of posting the oximeter and thermometer back to RMH. The HMP was similar to several home-based monitoring systems developed in other countries that successfully facilitated early assessment of deteriorating patients and reported high levels (≥67%) of user satisfaction. 7-9 A HMP should be routinely evaluated from a clinician and a patient perspective, with refinements implemented promptly – including refinements to help meet the needs of less typical patients.

Children and youth aged less than 18 years were excluded, and no adults aged over 68 years participated. It should be noted that participation required some proficiency in using a smartphone and reasonable English language skills. Interviews, transcription, and analysis were all performed by

a single researcher, who identified when thematic saturation had occurred and when recruitment should therefore cease. This reliance on a single researcher's perception introduces the possibility of bias. A thematic analysis with multiple contributors was not possible due to the time constraints of the study team, however preliminary themes were discussed in regular study team meetings and were refined based on feedback. A further source of potential bias occurred when the monitoring clinicians identified patients to recruit, however it was made clear to participants that the interviews were confidential and the interviewer had no involvement in HMP development or implementation, or in patient care. Including more participants may have led to the identification of new themes, however thematic saturation was noted. The brevity of some interviews limited the depth and richness of the data generated (especially for the briefest interview which was only four minutes), however participants were allowed to speak until they indicated they had nothing more to say.

Patient recruitment into the HMP was halted due to practical elimination of community transmission of COVID-19 within Victoria, Australia. This limited our ability to report on the relationship between subjective and objective markers of clinical deterioration, however our findings highlight a high frequently of desaturation episodes.

Next steps include scalability assessments for mass-scale roll out of a HMP, should this become useful, and larger studies to assess economic and clinical outcomes. Refining a HMP to meet the needs of culturally and linguistically diverse patients and elderly patients is important as they may be less comfortable using an internet-based electronic system.

Conclusions

Currently stable patients at moderate- and high-risk of COVID-19 complications may benefit from a HMP if they are discharged home to isolate. The HMP was highly feasible and acceptable to participants. This model of care could be implemented on a mass-scale to reduce the COVID-19 burden on hospitals. Key benefits of the HMP were its ability to reassure patients that they would receive suitable intervention should their health deteriorate while in isolation, and the ability of the monitoring clinicians to provide information and advice to isolating patients.

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Figure 1. Home monitoring programme flow diagram

Table 1: Royal Melbourne Hospital Home Monitoring Program Population enrolled from 7 April to 21 August 2020

Table 2: Summary of clinical deterioration events occurring among the Royal Melbourne Hospital Home Monitoring population

Supplementary Table. Summary of comorbid states among the Royal Melbourne Hospital Home Monitoring population

Appendix 1: Risk Matrix

Appendix 2. Interview guide

AUTHOR CONTRIBUTIONS

JO drafted the study protocol and the manuscript and refined these documents following several rounds of feedback from co-authors. JO collected data, performed the analysis and write up findings. AR critically reviewed successive versions of the manuscript and guidance on the interpretation of data.

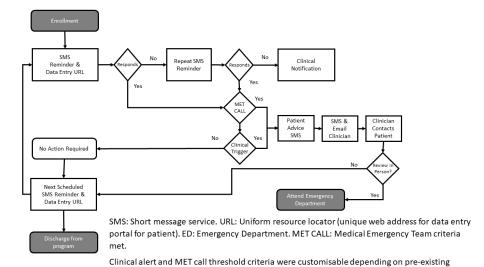
MD performed recruitment, critically reviewed successive versions of the manuscript and provided guidance on the interpretation of data.

MP critically reviewed successive versions of the manuscript provided guidance on the interpretation of data.

JK conceived of the study, performed recruitment, critically reviewed successive versions of the manuscript and study protocol and provided guidance on the interpretation of data.

DATA AVAILABILITY STATEMENT

No additional data are available.



Home monitoring programme flow diagram $54x30mm (600 \times 600 DPI)$

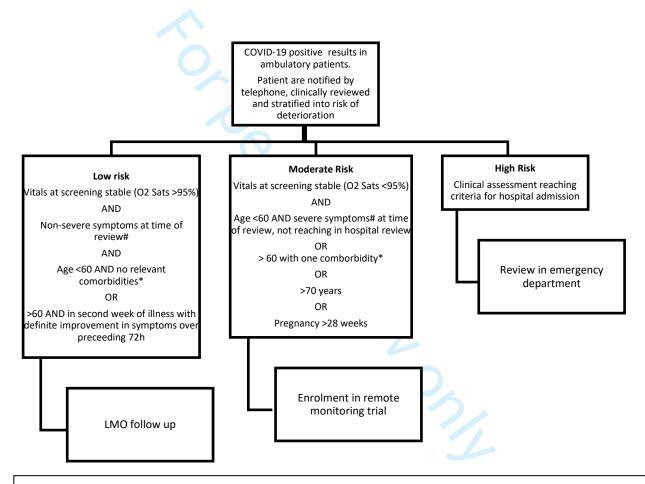
medical conditions. Default values are described in the supplementary material.

Appendix 1: Risk Matrix Criteria for risk stratification

Low risk: Discharge for follow up with local medical officer (LMO)

Medium risk: Royal Melbourne Hospital Home Monitoring System

High risk: Inpatient admission



* Relevant comorbidities: Hypertension, Type 1 and Type 2 diabetes, history of cardiovascular disease or cerebrovascular disease, Malignancy with treatment (chemotherapy, radiotherapy or biological therapy in the preceding 3 months), pulmonary disease (severity of asthma – daily preventer), immunosuppressed (20mg or more of prednisolone, disease modifying medication, biologicals or transplant medication)

Rating any one of the following symptoms currently as severe: fever, cough, headache, muscle aches, sore throat or chest tightness

O2 sats – oxygen saturation

Interview Guide - Version 1.0; Dated 4 Sep 2020

RMH Home Monitoring System Evaluation

Hi (name), my name is ______. I work at the University of Melbourne. I'm calling to invite you to have a brief interview with me to discuss your experience of using the Royal Melbourne Hospital home monitoring systems while you had COVID-19.

Is this a good time talk?

(If YES)

Great, thank you. Participating in this interview is completely voluntary, if you choose not go ahead with the interview then there won't be any adverse consequences at all. You're free to decline any questions and you can end the interview at any point. Any information you give me is confidential. The interview notes and research findings will be written up in a way that will not identify you to anybody.

If you would like to proceed with the interview it will be recorded, but I can stop the recording at any time you choose.

Would you be happy to proceed with an interview now?

(If YES)

Great, thank you. Please let me know if you would like me to pause the recording at any point.

- First of all I'd just like ask if you are a health care worker?
- And how old are you?

Thanks.

- I understand you developed COVID-19 and you went to the Royal Melbourne Hospital. You were discharged and invited to use their home monitoring system. Is that right?
- Did you go back to hospital for COVID at any point while you were sick?
- And have you recovered from COVID now?
- What was your experience of using the RMH Home Monitoring System?

Prompts: what worked well, what did not work well? How acceptable was using the RMH Home Monitoring System for you?

Prompts: was the system easy to use? How did you find getting the SMS prompts?

How might your experience of using the RMH Home Monitoring System be improved?

Prompts: were there any aspects of the system that were intrusive or annoying?

 How likely would you be to recommend the RMH Home Monitoring System to a friend or family member who was in your situation with COVID-19?

Prompts: Why?

- Is there anything in particular you felt RMH did well for you while you had COVID?
- Is there anything you feel that RMH could have done better?

Supplementary Material

Supplementary Table 1. Summary of comorbid states among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

	Number of participants	Proportion of participants (%)
No comorbidities	9	56.3
Pulmonary disease /	3	
Moderate to severe asthma		18.8
Immunosuppressed	1	6.3
Diabetes and Chronic Lung	1	
Disease and Hypertension		6.3
Pregnancy	2	12.5
Total	16	100.0

Supplementary Table 2. Number of comorbid states among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

Number of comorbidities	Number of participants affected	Proportion of participants (%)
3	1	6.3
2	0	0.0
1	6	37.5
0	9	56.3
Total	16	100.0

Clinical alert triggers

The software replicated hospital-based systems to identify clinical deterioration in patients based on alternations in reported vital signs.

Two thresholds were set to delineate the magnitude of departure from normal physiology, and to differentiate the urgency of clinical response: Clinical Alert and MET Call. The software allocated default values for each vital sign threshold at registration. Clinical alert and MET call threshold criteria were customisable depending on pre-existing medical conditions (eg. Oxygen desaturation could be set lower in patients with pre-existing lung disease).

The following were default values, which were used for most patients:

- Temperature 38.0 degrees Celsius: Fever management advice
- Oxygen Saturations <95%: Clinical Alert
- Oxygen Saturation: < 90% Met Call
- Heart Rate <50: Clinical Alert
- Heart Rate >130: Met Call

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on
Damain 1. Dagaanah taan			Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with	3	What experience of training and the researcher have:	
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer	,	goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
interviewer characteristics	0	e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design		e.g. bias, assumptions, reasons and interests in the research topic	
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory	9	grounded theory, discourse analysis, ethnography, phenomenology,	
and meory		content analysis	
Participant selection		Content analysis	
Sampling	10	How were participants selected? e.g. purposive, convenience,	1
Sampling	10	consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail,	
Method of approach	11	email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
	15	now many people refused to participate of dropped out; keasons;	
Setting of data collection	1.1	Where was the data collected? or a home clinic workplace	1
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non- participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	
Description of Sample	10	data, date	
Data collection		uata, uate	
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot	
interview guide	"	tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	20	What was the duration of the inter views or focus group?	
		Was data saturation discussed?	
Data saturation Transcripts returned	22		
Transcripts returned	23	Were transcripts returned to participants for comment and/or w only - http://bmlopen.bml.com/sire/about/guidelines.xhtml	

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Topic	Item No.	Guide Questions/Description	Reported on
			Page No.
		correction?	
Domain 3: analysis and			
findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			•
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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BMJ Open

A remote COVID-19 patient monitoring system: A qualitative evaluation

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Keywords:	Public health < INFECTIOUS DISEASES, COVID-19, INFECTIOUS DISEASES, PUBLIC HEALTH

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ABSTRACT

Background

Many COVID-19 patients are discharged home from hospital with instructions to self-isolate. This reduces the burden on potentially overwhelmed hospitals. The Royal Melbourne Hospital (RMH) Home Monitoring Programme (HMP) is a model of care for COVID-19 patients which chiefly tracks pulse oximetry and body temperature readings.

Objective

To evaluate the feasibility and acceptability of the HMP from a patient perspective.

Design, settings and participants

Of 46 COVID-19 patients who used the HMP through RMH during April to August 2020, 16 were invited to participate in this qualitative evaluation study; all accepted, including six health care workers. Attempts were made to recruit a gender-balanced sample across a range of COVID-19 severities and comorbidities. Participants completed a brief semi-structured phone interview discussing their experience of using the HMP.

Outcome measures and analysis

A thematic analysis of interview data was conducted. Feasibility was defined as the HMP's reported ease of use. Acceptability was considered holistically by reviewing themes in the interview data.

Results

The HMP allowed clinical deterioration to be recognised as it occurred enabling prompt intervention. All participants reported a positive opinion of the HMP, stating it was highly acceptable and easy to use. Almost all participants said they found using it reassuring. Patients frequently mentioned the importance of the monitoring clinicians as an information conduit. The most suggested improvement was to monitor a broader set of symptoms.

Conclusions

The HMP is highly feasible and acceptable to patients. This model of care could potentially be implemented on a mass-scale to reduce the burden of COVID-19 on hospitals. A key benefit of the HMP is the ability to reassure patients they will receive suitable intervention should they deteriorate while isolating outside of hospital settings.

ARTICLE SUMMARY

Strengths and limitations of this study

- The Royal Melbourne Hospital Home Monitoring Programme (HMP) is a new, scalable, automated model of care for COVID-19 patients which chiefly tracks pulse oximetry and body temperature readings.
- As well as describing the HMP, we provide one of the first qualitative descriptions of patients' experiences of using the HMP.
- Attempts were made to recruit a gender-balanced sample across a range of COVID-19 severities and comorbidities.
- Interviews, transcription, and thematic analysis were performed by a single researcher, who
 identified when thematic saturation had occurred and when recruitment should therefore
 cease.
- The reliance on a single researcher's perception and clinician-led recruitment introduces the possibility of bias, however thematic saturation was noted.

Funding statement: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors

Competing Interests: None declared

INTRODUCTION

Hospitals and intensive care departments, have, at times, become overwhelmed in areas severely affected by the COVID-19 pandemic.¹ In Australia, community and health care associated transmission has occurred. As at 6 December 2021, there are currently over 18,700 active COVID-19 cases in Australia. Melbourne, Victoria has experienced the highest disease burden of any Australian city.² COVID-19 symptoms range from mild to severe. In patients with severe COVID, the mean time from symptom onset to severe symptoms presenting is, on average, 8 to 10 days. COVID-19 complications may require hospitalisation to treat and may become life threatening.⁴

Due to the variable clinical course, there are several models of care available for monitoring COVID-19 patients. Many patients who present to emergency services may be diagnosed and discharged home with instructions to self-isolate, monitor symptoms, and to return to hospital only if significantly unwell. For some patients, the clinical course remains mild, with further medical intervention not required. However, a subset of patients who do not require urgent inpatient hospital admission at the initial clinical review may deteriorate or die during their illness. These patients may develop rapid hypoxemia and silent hypoxia, which can potentially be detected through a monitoring system.⁵ COVID-19 patients considered by assessing clinicians to not require hospitalisation may be offered a home-based monitoring system while self-isolating. Home-based monitoring systems track signs and symptoms, particularly blood oxygen saturation, to identify if a patient deteriorates and requires hospitalisation. Systems described in the literature include phone or video based clinical assessment/s of isolating patients, email links to surveys collecting biometric and symptom data, and mobile phone-based web applications. At a minimum, symptom data, pulse oximetry and body temperature readings are generally included, in addition to providing a mechanism enabling patients to discuss concerns with a clinician. When certain thresholds are met, further follow-up, including emergency department referrals are triggered. 6-11 Previous reports indicate home-based monitoring can avoid unnecessary hospitalisations, reducing the likelihood of overwhelming hospitals and reducing the risk of nosocomial transmission, as well as providing a much more cost-effective alternative to inpatient care. 6-10 12-15 A number of evaluations report high levels of user satisfaction (67-100%).⁷⁻⁹ Despite these advantages, concerns regarding home-based monitoring systems have been raised in regards to patient safety and privacy. 16

The aim of this study was to evaluate the feasibility and acceptability of the Royal Melbourne

Hospital (RMH) Home Monitoring Programme (HMP) from a patient perspective. This information

will ultimately inform refinements to this new model of care for COVID-19 patient management, with an eye to maximising acceptability to patients.



METHODS

Study design

This was a prospective cohort study with a qualitative evaluation component which used a constructivist approach.

Ethics approval was granted by the RMH Human Research Ethics Committee (QA2020073). This study is reported in accordance with COREQ guidelines.¹⁷

Study setting and population

This study was undertaken at the Royal Melbourne Hospital (RMH), a quaternary care hospital in Melbourne, Victoria, Australia. More than 80,000 adults present at the Emergency Department (ED) per annum and around half require hospital admission.¹⁸

All patients attending the ED or COVID-19 assessment clinic at RMH were screened for HMP eligibility. Eligible patients were adults aged over 17 years-old who were self-isolating in Victoria and had laboratory confirmed SARS-CoV-2 infection. Patients who were considered well enough to be sent home were assessed for risk of deterioration, with low-, moderate- and high-risk patients identified. Low-risk patients who were well at discharge and were considered unlikely to deteriorate were advised to follow up with their usual general practitioner or return to hospital as needed. Moderate-risk and high-risk patients were offered enrolment in the HMP. This risk assessment was conducted by clinicians using the matrix presented in Appendix 1, which considered patient age, co-morbidities, and supports.

Home Monitoring Program Intervention

The HMP was established de-novo and used pre-existing hospital information technology infrastructure, finger-tip pulse oximeters (inHealth: ARTG ID: 321974) and personal-use oral digital thermometers (MT-518). A bespoke open-source mobile-health software solution was built to facilitate the HMP via mobile phone and wireless technologies. In summary, patients were enrolled into the program via a hyperlink to a RedCAP form. The form captured demographic and clinical data. After enrolment, patients were given monitoring packs. During the monitoring period, patients received twice daily automated prompts via short message service (SMS) reminders to measure and report symptoms, pulse rate, temperature and oxygen saturation (termed 'observations'). Abnormal vital signs triggered automated clinical advice to be sent to patients and flagged the supervising clinician, who provided e-health services and arranged transfer for hospital admission if required (Figure 1).

Clinical alert and MET call threshold criteria were customisable depending on pre-existing medical conditions. Default values are described in the supplementary table. Detailed technical specifications for this software, and all associated documentation have previously been published.^{19 20}

Patients were recruited into a formal evaluation of the program following their routine 60-day post

Interview guide content and administration

HMP discharge phone consultation with a clinician. When recruiting, the clinician requested the patient's verbal consent for the interviewer to phone them and invite them to participate. Recruitment was conducted at this point to coincide with routine re-contacting and allow patients time to recover and reflect on their experiences. Which patients were invited was at the clinician's discretion, but when recruiting, attempts were made to achieve a gender balance, and include patients across a range of COVID-19 severities, age groups and comorbidities. Qualitative HMP evaluation data were collected during semi-structured one-on-one phone interviews. Invited participants were interviewed once. A pilot study was not conducted. All interviews were conducted by JO (PhD - Public Health; female; Postdoctoral Fellow - University of Melbourne). Participants had no prior knowledge of, or relationship with, the interviewer. Interviews were conducted via a phone call from the interviewer's office. Participants were informed that the interviewer had no prior involvement with the HMP and was independent from RMH. Informed verbal consent to participate was provided. Interview questions were planned a priori. The semistructured interview guide (Appendix 2) was created by the interviewer using suggestions from two clinicians experienced in treating COVID-19. Both clinicians and the interviewer had experience in qualitative research and interviewing for health systems research. The interviewer sought to cover each participant's overall experience of the HMP, its ease of use, positive and negative aspects, potential improvements and whether participants would recommend the HMP to someone with COVID-19 in a similar situation to their own. Participants were free to comment in other areas. Participants were able to speak until they indicated they had nothing further to add. Interview times varied according to the speed at which participants volunteered information, the amount of information volunteered, and participants' time restraints. Interviews were recorded using a Dictaphone. Any notes made during the interview were not included in the analysis. We aimed to interview 10-20 people across a range of demographic and clinical characteristics. This sample size was practical given the study team's timeframes and resources. Recruitment ceased when the interviewer felt that thematic saturation had occurred.

Data analysis

Quantitative data for all patients enrolled in the HMP were extracted from the RMH REDCAP database, aggregated, and reported using descriptive statistical analysis. These data included the patient's age, gender, co-morbidities, clinical course during COVID-19, reason for HMP discharge and outcome at the routine clinical assessment 60-day post HMP discharge.

A inductive thematic analysis was used to analyse interview data.²¹ Interviews were transcribed by the interviewer using Trint ™ with automated transcriptions manually edited with reference to the audio recording.²² Participants did not review the interview transcripts or provide feedback on findings. Interview transcripts were holistically analysed on Nvivo by the interviewer.²³ The interviewer assigned codes and subcodes to data, and grouped these according to perceived themes. A virtual whiteboard (miro.com) was used to identify unique and common themes. A saturation point was reached when no new codes were generated while reviewing the transcripts. A single registry of codes was created. Illustrative quotes, corrected for grammar, are provided.

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

RESULTS

Home Monitoring Programme Enrolment, Events and Outcome

Forty-six patients were enrolled in the HMP from April 7, 2020 to August 21, 2020. The evaluation component recruited from a population with a significant burden of comorbid diseases (Table 1).

Table 1: Home Monitoring Program Population enrolled from 7 April to 21 August 2020, Royal Melbourne Hospital, Victoria, Australia

Characteristics		
	Median	Interquartile range
Age (years)	45.8	36.8-61.6
	Number of Home Monitoring	Proportion
Sex	Programme patients	(%)
Male	20	43.5
Female	26	56.5
Comorbidity Burden		
Single Comorbidity	19	41.3
2 Comorbidities	6	13.0
3 Comorbidities	3	6.5
4 Comorbidities	1	2.2
Any	29	63.0
Comorbidity Frequency	\sim	
Diabetes	10	21.7
Pulmonary Disease	9	19.6
Hypertension	8	17.4
Ischemic Heart Disease	3	6.5
Immunosuppression	3	6.5
Smoker	3	6.5
Pregnancy	2	4.3
Obesity	2	4.3
Other	8	17.4
Total	46	100.0

The median number of self-reported observations submitted by patients through the HMP was 16 (equating to 8 days of observation) with a range of 1 - 28 observations.

Over one-third of patients had an episode of documented oxygen desaturation, however significant episodes of hypoxia were less common. Automated pyrexia management advice was generated for just under 10% of patients (Table 2).

Table 2: Summary of clinical deterioration events occurring among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

	Patients		Total triggers for clinical review
	n	%	n
Pulse Rate			
Clinical Review ¹	2	4.3	2
MET call ²	4	8.7	6
Oxygen Saturation			
Clinical Review ¹	16	34.8	39
MET Call ²	3	6.5	5
Body temperature			
Automated Advice	4	8.7	6

Clinical Review: Modest physiologic derangement.

MET Call: Medical Emergency Team call. Marked physiological derangement.

Clinical events resulted in supervising clinician notification and planned ED attendance for 10/46 (22%) patients. No patients had ED attendances that were not facilitated though the HMP. Following ED presentation, one patient required general ward admission, and two patients were admitted to ICU. Following discharge from the HMP period, one patient deteriorated and died following rehospitalisation with COVID-19 complications.

Program Evaluation: Description of participants

Sixteen of 32 patients who completed the 60-day follow up were invited to be interviewed and all consented with no withdrawals. Interviews ranged from 4 to 13 minutes. The median duration was 7.5 minutes.

Nine of the 16 participants were female and seven were male. The median age was 44 years (range: 26-68 years). Six participants self-identified as healthcare workers when asked by the interviewer.

Four participants were assessed at ED while they were using the HMP, all of whom resumed using the HMP once discharged.

Nine participants (56%) had no comorbidities. The most common comorbid state was pulmonary disease/moderate-to-severe asthma. One participant had three separate comorbid conditions. Two participants were pregnant while using the HMP.

All 16 participants praised the HMP, despite many also mentioning very unpleasant experiences of having COVID-19. All participants recommended using the HMP, with almost all (N=14; 88%) saying they would recommend it to someone in their situation with COVID-19.

Key themes

Theme 1. "It gave a complete peace of mind"

Almost all of the participants mentioned they felt reassured knowing that medical staff were monitoring their health remotely while they were isolating with COVID-19. Participants described having peace of mind knowing that if they deteriorated, help would be provided. This theme was particularly strong among patients with severe COVID-19, those with serious comorbidities, and those who were pregnant. Participants who required hospitalisation while isolating frequently discussed perceptions of harm averted through using the HMP. Around half the participants described being contacted by a HMP clinician following data entry in the HMP app. In a small minority of cases, the participant had entered data incorrectly and this contact was not warranted, but in other cases, HMP clinicians facilitated a transfer to hospital, with participants saying they were extremely grateful to have received this help.

"It [the HMP] probably saved my life. It was quite frightening knowing how sick I was getting.

It showed me when I de-sated and needed help." HMP013, female, aged 45 years, hospitalised twice using HMP

Participants discussed feeling comforted by seeing their temperature readings and oxygen saturation results. They used this information to assess the severity of their illness.

"It gave a complete peace of mind and reassurance that I could follow where my body was. It was my comfort actually." HMP001, female, aged 35, not hospitalised using HMP

Five participants spoke about the HMP facilitating contact with clinicians when they were concerned about symptoms that were not monitored using with the pulse oximeter or thermometer, such as severe pain, and receiving help.

"I added a note [to the HMP] saying I was in a lot of pain and that was when [the clinician] contacted me and said, 'We'll get you an ambulance'. So you can deteriorate on it but... there is a safety net".

HMP003, female, aged 65 years, hospitalised once using HMP.

As well as feeling reassured themselves, two participants spoke about how their loved ones felt reassured knowing they were using the HMP.

"The greatest value.. was for other people in my life to know... I wasn't an invisible and isolated person who may die and not be found for days. ...they found it very reassuring knowing that I was being monitored..." HMP005, male, aged 45 years, not hospitalised using HMP

Theme 2. HMP clinicians as an important information conduit

The benefits of having good communication with the HMP clinicians while isolating were often raised. In addition to appreciating their ability to answer clinical questions, the HMP clinicians were identified as an important information conduit outside of their clinical role. Participants discussed feeling distressed while experiencing having great difficulty contacting public health authorities to receive advice. In this absence, HMP clinicians provided advice about when participants might be released from mandatory isolation and provided updates on the COVID situation and the Victorian public health response.

"I live by myself so I was in isolation for that whole period and their [the Health Department's] lack of communication was distressing. What I was able to do was call the [HMP clinicians]... get some kind of prediction about when I might get a release and how many days of food I needed to plan."

HMP005, male, aged 45 years, not hospitalised using HMP

Theme 3: A highly acceptable supplement to clinical care

Considerable suffering due to COVID-19 symptoms and aggravating comorbidities were often mentioned. Many participants discussed the HMP supplementing their clinical care and enabling them to isolate outside of hospital settings. A strong theme around participants not wanting to present to hospital unless they really had to in order to avoid burdening the health care system and posing a transmission risk to staff was observed.

"It's good to see that people have been looking at creative ways to... prevent potentially overwhelming the health system, it [the HMP] was a good idea." HMP007, male, aged 68 years, not hospitalised using HMP

One participant felt there was an overreliance on the HMP and they had not received a full clinical assessment at RMH ED. They indicated they felt the seriousness of their illness had been trivialised.

"It [HMP] was excellent... but I feel the service at Emergency ended up lacking because I was sent straight into the monitoring system and sent home. [Laughing] If we can control COVID like this, why can't we just produce lots of oximeters and monitor it this way?' HMP011, female, aged 33 years, not hospitalised using HMP

All participants reported they felt using the HMP was highly acceptable. None said they found the multiple daily data entry prompts intrusive at all, even when feeling very unwell as they understood the importance of regular data entry. This came in spite of feeling overwhelmed having to report to multiple systems, often whilst unwell, such as to the Department of Health and to their workplace. All participants said they found the HMP extremely easy to use. No issues with the pulse oximeters were noted, and all thought inputting data was extremely easy, except one participant who reported difficulty using the sliding scales on multiple electronic devices.

Many participants highly praised the quality of clinical care they had received while at RMH and from the RMH HMP clinicians.

"I thought every aspect of my visit there from the first day to the ward was just absolutely phenomenal. I sent them a complimentary feedback afterwards." HMP001, female, aged 35, not hospitalised using HMP

Theme 4. Criticisms and potential improvements

About half the participants indicated that they could not think of any possible improvements to the HMP.

The most common criticism was that only a few signs (temperature and blood oxygen) were formally monitored. Monitoring a greater number and breadth of symptoms and signs was the most commonly suggested improvement, including respiratory rate, pain levels, neurological and gastrointestinal symptoms. Concerns that people with atypical, or more severe symptoms, could be missed by the HMP were expressed. Four participants mentioned that incorporating monitoring for comorbid conditions would have been an improvement. One participant suggested modifying the HMP and applying it to other conditions besides COVID-19.

One participant was frustrated by a lack of quality internet connection in her isolation facility which made it harder for her to use the HMP. Another emphasised the need for HMP clinicians to

understand their importance as an information conduit when public health authorities are unresponsive.

"It would be great to put that [communication role] a little bit more in the foreground so that the people who are running it are aware that they actually might be the most important health professional reference point that's available. HMP005, male, aged 45 years, not hospitalised using



DISCUSSION

We report the successful rapid development, implementation and evaluation of a COVID-19 home monitoring system in Melbourne, Australia, during the global COVID-19 pandemic. The HMP demonstrated episodes of hypoxia were relatively common in our cohort. Clinical deterioration was recognised as it occurred, with patients recalled to hospital for assessment and/or admission. This model of care harnessed existing health information-technology infrastructure and has potential to be implemented on a mass-scale to protect hospital capacity. Important design considerations inbuilt into the HMP set a low technical hurdle for participants to engage with, met requirements for cybersecurity, and were sufficiently agile and capable of a short concept to implementation cycle. When developing the HMP, consideration was given to the need to minimise face-to-face contact between healthcare workers and patients.

The HMP was developed extremely quickly over approximately 2 weeks in February 2020 in response to reports of COVID-19 community transmission internationally. It utilised readily available, configurable software such as REDCAP, which enabled prompt implementation once ethical and administrative requirements were met. The HMP was highly acceptable and feasible from the perspective of a patient isolating outside of hospital settings, and it provided them with an important source of reassurance. An unexpected finding identified the importance of the monitoring clinicians as information conduits in the absence of accessible public health authorities (who themselves were overwhelmed by the outbreak). Any mass-implemented HMP should ensure that the staff involved are able to answer questions about COVID-19 and the public health response. Such a HMP might incorporate routine monitoring of other signs and symptoms, including heart rate and peak expiratory flow as implemented by a similar Brazilian system. However increasing data entry may make it more difficult for patients to comply with the system.⁷ The HMP provided a low-cost patient care solution, which only required the use of the patient's smartphone, an internet connection and the cost of posting the oximeter and thermometer back to RMH. The HMP was similar to several home-based monitoring systems developed in other countries that successfully facilitated early assessment of deteriorating patients and reported high levels (≥67%) of user satisfaction. 7-9 A HMP should be routinely evaluated from a clinician and a patient perspective, with refinements implemented promptly – including refinements to help meet the needs of less typical patients.

Children and youth aged less than 18 years were excluded, and no adults aged over 68 years participated. It should be noted that participation required some proficiency in using a smartphone and reasonable English language skills. Interviews, transcription, and analysis were all performed by

a single researcher, who identified when thematic saturation had occurred and when recruitment should therefore cease. This reliance on a single researcher's perception introduces the possibility of bias. A thematic analysis with multiple contributors was not possible due to the time constraints of the study team, however preliminary themes were discussed in regular study team meetings and were refined based on feedback. A further source of potential bias occurred when the monitoring clinicians identified patients to recruit, however it was made clear to participants that the interviews were confidential and the interviewer had no involvement in HMP development or implementation, or in patient care. Including more participants may have led to the identification of new themes, however thematic saturation was noted. The brevity of some interviews limited the depth and richness of the data generated (especially for the briefest interview which was only four minutes), however participants were allowed to speak until they indicated they had nothing more to say.

Patient recruitment into the HMP was halted due to practical elimination of community transmission of COVID-19 within Victoria, Australia. This limited our ability to report on the relationship between subjective and objective markers of clinical deterioration, however our findings highlight a high frequently of desaturation episodes.

Next steps include scalability assessments for mass-scale roll out of a HMP, should this become useful, and larger studies to assess economic and clinical outcomes. Refining a HMP to meet the needs of culturally and linguistically diverse patients and elderly patients is important as they may be less comfortable using an internet-based electronic system.

Conclusions

Currently stable patients at moderate- and high-risk of COVID-19 complications may benefit from a HMP if they are discharged home to isolate. The HMP was highly feasible and acceptable to participants. This model of care could be implemented on a mass-scale to reduce the COVID-19 burden on hospitals. Key benefits of the HMP were its ability to reassure patients that they would receive suitable intervention should their health deteriorate while in isolation, and the ability of the monitoring clinicians to provide information and advice to isolating patients.

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Figure 1. Home monitoring programme flow diagram

Table 1: Royal Melbourne Hospital Home Monitoring Program Population enrolled from 7 April to 21 August 2020

Table 2: Summary of clinical deterioration events occurring among the Royal Melbourne Hospital Home Monitoring population

Supplementary Table. Summary of comorbid states among the Royal Melbourne Hospital Home Monitoring population

Appendix 1: Risk Matrix

Appendix 2. Interview guide

AUTHOR CONTRIBUTIONS

JO drafted the study protocol and the manuscript and refined these documents following several rounds of feedback from co-authors. JO collected data, performed the analysis and write up findings. AR critically reviewed successive versions of the manuscript and guidance on the interpretation of data.

MD performed recruitment, critically reviewed successive versions of the manuscript and provided guidance on the interpretation of data.

MP critically reviewed successive versions of the manuscript provided guidance on the interpretation of data.

JK conceived of the study, performed recruitment, critically reviewed successive versions of the manuscript and study protocol and provided guidance on the interpretation of data.

DATA AVAILABILITY STATEMENT

No additional data are available.

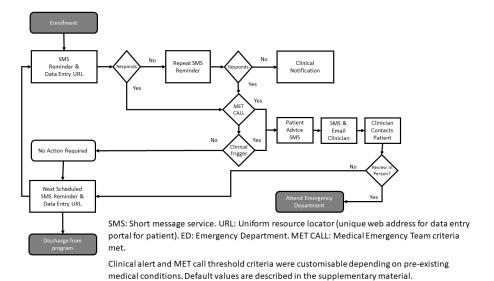


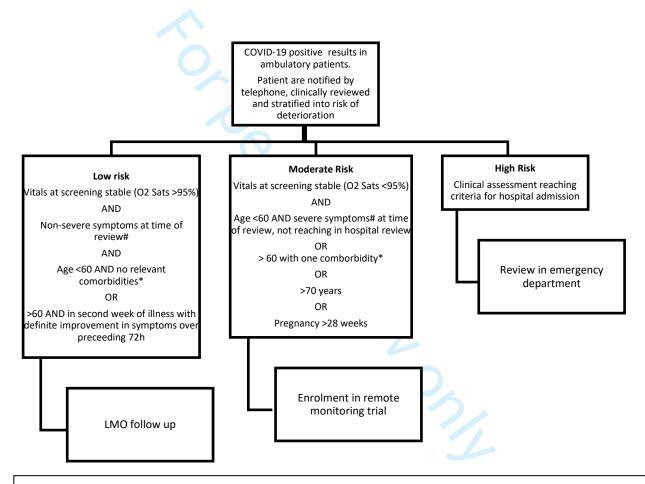
Figure 1: Home monitoring programme flow diagram 54x30mm (600 x 600 DPI)

Appendix 1: Risk Matrix Criteria for risk stratification

Low risk: Discharge for follow up with local medical officer (LMO)

Medium risk: Royal Melbourne Hospital Home Monitoring System

High risk: Inpatient admission



* Relevant comorbidities: Hypertension, Type 1 and Type 2 diabetes, history of cardiovascular disease or cerebrovascular disease, Malignancy with treatment (chemotherapy, radiotherapy or biological therapy in the preceding 3 months), pulmonary disease (severity of asthma – daily preventer), immunosuppressed (20mg or more of prednisolone, disease modifying medication, biologicals or transplant medication)

Rating any one of the following symptoms currently as severe: fever, cough, headache, muscle aches, sore throat or chest tightness

O2 sats – oxygen saturation

Interview Guide - Version 1.0; Dated 4 Sep 2020

RMH Home Monitoring System Evaluation

Hi (name), my name is ______. I work at the University of Melbourne. I'm calling to invite you to have a brief interview with me to discuss your experience of using the Royal Melbourne Hospital home monitoring systems while you had COVID-19.

Is this a good time talk?

(If YES)

Great, thank you. Participating in this interview is completely voluntary, if you choose not go ahead with the interview then there won't be any adverse consequences at all. You're free to decline any questions and you can end the interview at any point. Any information you give me is confidential. The interview notes and research findings will be written up in a way that will not identify you to anybody.

If you would like to proceed with the interview it will be recorded, but I can stop the recording at any time you choose.

Would you be happy to proceed with an interview now?

(If YES)

Great, thank you. Please let me know if you would like me to pause the recording at any point.

- First of all I'd just like ask if you are a health care worker?
- And how old are you?

Thanks.

- I understand you developed COVID-19 and you went to the Royal Melbourne Hospital. You were discharged and invited to use their home monitoring system. Is that right?
- Did you go back to hospital for COVID at any point while you were sick?
- And have you recovered from COVID now?
- What was your experience of using the RMH Home Monitoring System?

Prompts: what worked well, what did not work well? How acceptable was using the RMH Home Monitoring System for you?

Prompts: was the system easy to use? How did you find getting the SMS prompts?

How might your experience of using the RMH Home Monitoring System be improved?

Prompts: were there any aspects of the system that were intrusive or annoying?

 How likely would you be to recommend the RMH Home Monitoring System to a friend or family member who was in your situation with COVID-19?

Prompts: Why?

- Is there anything in particular you felt RMH did well for you while you had COVID?
- Is there anything you feel that RMH could have done better?

Supplementary Material

Supplementary Table 1. Summary of comorbid states among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

	Number of participants	Proportion of participants (%)
No comorbidities	9	56.3
Pulmonary disease /	3	
Moderate to severe asthma		18.8
Immunosuppressed	1	6.3
Diabetes and Chronic Lung	1	
Disease and Hypertension		6.3
Pregnancy	2	12.5
Total	16	100.0

Supplementary Table 2. Number of comorbid states among the Home Monitoring population, Royal Melbourne Hospital, Victoria, Australia

Number of comorbidities	Number of participants affected	Proportion of participants (%)
3	1	6.3
2	0	0.0
1	6	37.5
0	9	56.3
Total	16	100.0

Clinical alert triggers

The software replicated hospital-based systems to identify clinical deterioration in patients based on alternations in reported vital signs.

Two thresholds were set to delineate the magnitude of departure from normal physiology, and to differentiate the urgency of clinical response: Clinical Alert and MET Call. The software allocated default values for each vital sign threshold at registration. Clinical alert and MET call threshold criteria were customisable depending on pre-existing medical conditions (eg. Oxygen desaturation could be set lower in patients with pre-existing lung disease).

The following were default values, which were used for most patients:

- Temperature 38.0 degrees Celsius: Fever management advice
- Oxygen Saturations <95%: Clinical Alert
- Oxygen Saturation: < 90% Met Call
- Heart Rate <50: Clinical Alert
- Heart Rate >130: Met Call

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on
Damain 1. Dagaanah taan			Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
Relationship with	3	What experience of training and the researcher have:	
participants			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of	7	What did the participants know about the researcher? e.g. personal	
the interviewer	,	goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator?	
interviewer characteristics	0	e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design		e.g. bias, assumptions, reasons and interests in the research topic	
Theoretical framework			
Methodological orientation	9	What methodological orientation was stated to underpin the study? e.g.	
and Theory	9	grounded theory, discourse analysis, ethnography, phenomenology,	
and meory		content analysis	
Participant selection		Content analysis	
Sampling	10	How were participants selected? e.g. purposive, convenience,	1
Sampling	10	consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail,	
Method of approach	11	email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
	15	now many people refused to participate of dropped out; keasons;	
Setting of data collection	1.1	Where was the data collected? or a home clinic workplace	1
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non- participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic	
Description of Sample	10	data, date	
Data collection		uata, uate	
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot	
interview guide	"	tested?	
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the inter view or focus group?	
Duration	20	What was the duration of the inter views or focus group?	
		Was data saturation discussed?	
Data saturation Transcripts returned	22		
Transcripts returned	23	Were transcripts returned to participants for comment and/or w only - http://bmlopen.bml.com/sire/about/guidelines.xhtml	

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Topic	Item No.	Guide Questions/Description	Reported on
			Page No.
		correction?	
Domain 3: analysis and			
findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	
Description of the coding	25	Did authors provide a description of the coding tree?	
tree			
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	
		Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.