

TechFlash: At-home remote monitoring of COVID-19 patients

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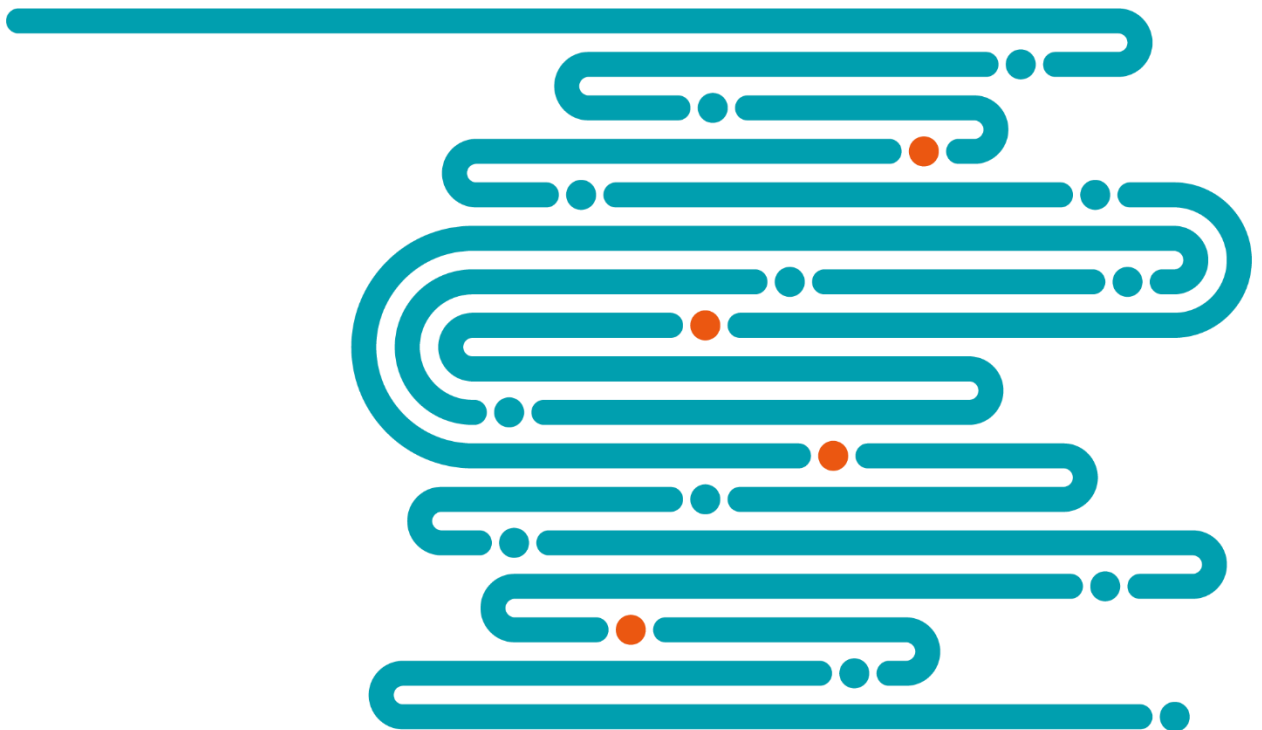


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This report comprises a review of abstracts identified through a search of the recent biomedical literature and does not constitute a comprehensive analysis. The report focus is on clinical evidence and outcomes.



For more information, contact Joe Cummings, PhD, at joe.cummings@vizientinc.com

Technology overview and status

Remote monitoring (RM) uses various at-home medical devices to collect information on targeted physiologic signs and symptoms. The collected clinical data is then digitized and transmitted through telecommunication technology to healthcare providers. Remote monitoring is intended to provide earlier recognition of actionable data; thereby potentially reducing morbidity, mortality, emergency department (ED) utilization and hospitalization. During the COVID-19 pandemic, RM provides an added advantage of limiting potential exposure to and/or spread of the SARS-CoV-2 virus by keeping patients at-home.

Telemedicine with virtual visits conducted through video, phone and text messaging have dramatically increased during the pandemic.¹⁻³ RM can significantly add value to these virtual visits by providing another layer of information beyond symptoms.⁴ RM provides objective data, trends over time and continued connection to the patient beyond the scheduled visit to enable timely intervention if conditions change. This functionality has allowed RM to fill a role in the management of acute infectious disease patients.⁵⁻⁸

Recognizing the potential value of RM in the care of COVID-19 patients, both the Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS) issued policies to facilitate RM throughout the duration of the public health crisis. The FDA [guidance](#) provides flexibility in the marketing of previously approved monitoring devices for use in COVID-19 patients in the home setting. Similarly, CMS issued [policies](#) that removed previous restrictions and allowed payment for RM use in new patients and settings. The CMS changes specifically allowed for use in acute patients, rather than just chronic patients.

Notably, the surge of patients coming to hospitals during the pandemic created significant issues around capacity and supplies. To cope, many hospitals applied Centers for Disease Control (CDC) [guidelines](#) that suggest most patients testing positive for COVID-19 and with only mild symptoms can safely recover at-home. In fact, one large retrospective Chinese study found that the majority of COVID-19 patients (~81%) may fall into this category.⁹ Prospectively identifying the patients who can be managed at-home, however, is a diagnostic challenge because rapid respiratory deterioration is a notable characteristic of COVID-19.

During the pandemic, many hospitals have reported the use of RM to manage mildly symptomatic COVID-19 positive patients and to monitor certain high-risk patients in the home setting.¹⁰⁻¹⁶ For example, patients presenting in the ED with mild symptoms not requiring immediate hospitalization may be given portable sensors, like pulse oximeters and thermometers, and instructions for set-up and use. They are then enrolled in programs for daily monitoring, 24/7 nurse hotlines and regular follow-up with virtual care. Similarly, patients receiving positive test results while at-home can get expedited home delivery of sensors with appropriate levels of follow-up communication and care. This type of program can also be used to monitor post-discharge recovering COVID-19 patients.¹⁷

The technology for RM has undergone rapid expansion in recent years as it has been developed for use in various chronic diseases, like heart failure, diabetes, chronic obstructive pulmonary disease and others.¹⁸ These chronic disease management RM programs can be readily adapted to acute COVID-19 patients. For example, some commercial electronic health records (EHRs) have modules that can be adapted for COVID-19. There are also standalone software programs developed for RM and companies that can provide complete turn-key RM programs. Features of RM platforms may include: mechanisms to provide educational information, input of patient reported outcomes from designed questions, manual or automatic digitization of physiologic data, asynchronous upload, interactive chat features, capability for video visits and emergency call functions.¹⁹

In general, RM technology must have the capability to acquire, transmit (intermittent or continuous), store and facilitate analysis of relevant clinical parameters.²⁰ There are many ways, however, to accomplish these tasks. Processes and technologies that are the most reliable and user-friendly may be critical for at-home adherence to data collection, better outcomes and long-term patient satisfaction.

Data transmission may be accomplished through multiple methods, including internet, telephone, email, SMS text messaging and/or smartphone apps. In simplest form, metrics may be logged by the patient on paper and then reported to a nurse during a phone call. The nurse then manually enters the value into the EHR. Other reported technologies utilize structured phone support with automated questions that the patient answers by pressing a number on the phone keypad or by replying to automated interactive texts. Some other technologies may require the patient to manually input data into a form on a web portal. More advanced remote technologies may automatically capture and transmit pertinent clinical data into the EHR. Some RM devices may have their own built-in telecommunication or internet capability and sometimes a tablet computer may be provided as part of the management program.

Notably, the information technology (IT) associated with RM is currently undergoing rapid growth in parallel with the rapid advances overall in digital technology, mobile communications, high speed networks and wireless technologies. In particular, there is a rapidly growing trend for RM devices that utilize mobile smart phone technologies for data capture and transfer.²¹⁻²³ Smart phone enabled technologies, also known as mHealth technologies, include numerous currently available apps and associated physiologic sensors.

Once the RM data is transmitted, it must be read and analyzed. The data may be automatically flagged for further analysis if values exceed certain pre-programmed thresholds. Technologies that employ machine learning (ML) and artificial intelligence (AI) are also becoming more common for these tasks. ML is a form of sophisticated computer modeling that excels at pattern recognition in large datasets without the need for preprogrammed thresholds. As more and more data from multiple parameters are collected, these automated approaches may be critical to sift through the data in a timely manner. Regularly scheduled caregiver review of remotely collected data is also necessary.

The sensors used for RM are probably the most varied component. They must be safe, simple to operate and accurate. RM devices intended for medical decision-making and diagnostic support should have relevant FDA approval to ensure they meet accuracy standards. Those devices included in the FDA policy for at-home use during the COVID-19 crisis include electronic thermometers, electrocardiogram (ECG) software, cardiac heart rate (HR) monitors, pulse oximetry (SpO₂), non-invasive blood pressure (BP) measurement, respiratory rate (RR) devices and electronic stethoscopes. Direct-to-consumer marketed sensors should also have relevant FDA clearance. As is the case for many different supplies during the pandemic, there may be sporadic shortages of these devices, especially for the consumer products.

Sensors for RM can involve intermittent monitoring of a user-initiated device. An example of this would be daily temperature monitoring using a thermometer, a clip-on fingertip pulse oximeter or a blood pressure cuff. Continuous non-invasive sensors measuring an array of vital signs are also available. These sensors may be on “wearables”, like watches, rings, bracelets, necklaces and adhesive patches.²⁴ Continuous devices may be better at measuring trends over time and at capturing relevant events not occurring during once daily monitoring. Of note, continuous sensors for RM are also used in the hospital setting to help avoid repeated exposure and utilization of personal protective equipment (PPE) by healthcare staff.

A key focus for optimizing use of RM is determining which parameters to measure and how often they should be measured. Parameters with clear targets or thresholds directly applicable in evidence-based treatment algorithms are expected to result in the best outcomes.

Virtually every physiologic parameter pertinent to COVID-19 can potentially be collected via RM.²⁵ The vital signs of HR, RR, BP and temperature are readily measured and useful for COVID-19 monitoring. For example, a high breathing rate and elevated temperature are well-established characteristics of active COVID-19 infection. In addition, pulse rate may increase as a compensatory mechanism and hypertension is a known risk factor for COVID-19 severity. Measurement of oxygen saturation may be a useful indicator of COVID-associated lung involvement even in the absence of other hallmark symptoms, as indicated by the phenomenon of the “happy hypoxic.”²⁶ Audio sensors for real-time evaluation of lung sounds to detect pneumonia and for measurement of symptomatic coughing frequency have also been reported. Long-term RM of COVID-19 patients may also use digital home spirometers to assess lung function changes over time.

RM apps also typically collect periodic qualitative data on COVID-19 symptoms like cough, difficulty breathing, fatigue, body aches, headache, loss of taste or smell, sore throat, congestion, nausea, vomiting and diarrhea. These data may also be analyzed for trends and triggers for more in-depth follow-up.

Technology significance

Virtual health/telemedicine is a disruptive technology transforming the way healthcare is delivered during the COVID-19 crisis.²⁷⁻³⁰ But for telemedicine to reach its full potential, the means to remotely obtain objective patient physiologic data is needed that is comparable to measurements collected in the clinic or hospital. Thus, RM is a critical component of telemedicine when it is intended for use in lieu of in-person healthcare.

Most hospitals and clinicians have either begun using telemedicine for the first time or greatly expanded their utilization of telemedicine services for all types of patients. Expanded usage has occurred in both urgent and non-urgent settings.² Because of the high prevalence, morbidity and mortality associated with COVID-19, any strategy used in these patients is potentially very high-impact.

With the right RM technology, it may be possible to improve patient outcomes, increase quality of care and reduce costs. Potential advantages of RM in COVID-19 patients include:

- Expedient patient isolation
- Reduced potential for disease transmission
- Increased hospital bed capacity with reduced PPE consumption
- Better patient contact, communication and education
- Provision of objective, supplemental disease indicators
- More rapid intervention when needed
- Improved patient satisfaction

On the other hand, despite the high potential of RM there are still many unproven assumptions about its acceptability, evidence quality and outcomes. This is typical of an emerging technology in the early stages of dissemination and particularly expected for one rapidly implemented as a crisis strategy. In addition, there are significant ever-present barriers common to telemedicine in general that apply here as well. These may include choice of technology, medico-legal issues, cybersecurity and privacy concerns, high costs,

inadequate reimbursement, equitable access and lack of face-to-face interaction. Addressing these barriers may be the key to safe, effective, and cost-effective longer-term adoption of RM in acute care.

Current practice and alternatives

Most COVID-19 patients can be managed in the home or outpatient setting.³¹ The initial management decision, however, should be made by a trained clinician on a case-by-case basis.³² Some alternatives to at-home self-management include nurse home visits, hospitalization or non-traditional care sites, like field hospitals, dedicated COVID-19 nursing facilities and even options like repurposed hotels, gyms or stadiums equipped to manage COVID-19 patients.

In addition to clinical presentation, the appropriateness of at-home care requires assessment of the patient's mental and physical limitations, social support factors and home environment. At-home patients need to be able to understand and escalate care as needed. Isolation and infection prevention standards must also be rigorously followed in the home. Secondary caregivers, such as family members, who can monitor status, provide food and other necessities of daily living and assist with communications are also very important.

At-home COVID-19 patients with mild symptoms and no risk factors may self-manage with instructions provided on when to initiate further care. A communication channel such as a 24/7 nurse hotline may be sufficient at this stage. Based on risk stratification, more involved at-home care management plans may involve provision of self-assessment tools, coordinated outreach from clinicians and telehealth (phone or video) visits for evaluation and regular follow-up.³³ The frequency of follow-up may also be risk stratified. For collection of physiologic data, in-person evaluation such as at the ED or urgent care clinic, may be used as needed. Structured care should continue until resolution of symptoms and throughout the following isolation period.

Regular at-home monitoring of physiologic parameters may also be accomplished by motivated and competent patients without a formal RM program using a "bring your own device" approach. However, this type of system may be sporadic and associated with inconsistent logging and reporting of values. Further, monitoring equipment may not be standardized and may have varying levels of accuracy and different types of monitors (e.g., pulse oximetry) may not be available. In addition, the cost of at-home monitors and supplies may be paid for by the patient in these scenarios; thus, reducing the likelihood that they will be available. This informal paradigm also does not usually have the healthcare infrastructure and procedures needed for rigorously handling the remotely collected physiologic data.

Clinical evidence summary

The [Medline/PubMed](#) bibliographic database, [MedRxiv](#) preprint server for health sciences, Google COVID-19 [Research Explorer](#) and [ClinicalTrials.gov](#) database of registered clinical studies were searched in June 2020 to identify clinical evidence on the use of RM in COVID-19 patients. Because of the rapidly evolving nature of the pandemic, gray literature sources were also used to identify RM trends and practices.

At this point in time, the clinical evidence for RM in COVID-19 patients consists mostly of anecdotal reports from various hospitals across the country.¹⁰⁻¹⁶ A few more detailed, rapid publications are also available.³⁴⁻³⁶ As expected, the available evidence at this time is of generally low quality and limited by study design, incomplete follow-up, few controls and lack of rigorous peer-review. Nonetheless, it is typical of the overall state of evidence for treatment and patient management strategies developed under crisis conditions.

The University of Minnesota Fairview Health reported use of an RM system with 2,255 COVID-19 patients enrolled in March and April 2020.³⁴ The COVID-19 platform was modified from software originally developed for enhanced recovery after surgery (ERAS) patient management. Conversion and roll-out of the program was reportedly accomplished in about two weeks. The platform provided educational materials, daily check-in questions regarding symptoms, care escalation protocols and an upgrade to include assessment of at-home pulse oximetry data. In a one-month span, the system was used for 2,303 alerts and 4,613 sent messages and resulted in 13 hospital admissions (median six days after enrollment) and 91 ED visits. Study authors concluded that the system was a safe and effective approach for at-home management of COVID-19 patients. High patient satisfaction with the system was reported for 74% of 300 survey respondents.

The University of Iowa Hospitals and Clinics reported using an EHR based system to triage potential COVID-19 patients.¹⁰ RM includes a blood pressure cuff and pulse oximeter delivered to the patient's home with nurse follow-up. By early April, they had reported managing 90 total patients with five admitted to the hospital and 30 still being monitored.

An Australian public health system based in Sydney reported using a previously existing virtual care system developed for palliative care and chronic care monitoring to manage COVID-19 patients.³⁵ In about a 3-week period in March 2020, 162 patients were enrolled for at-home monitoring. Technology, including a pulse oximeter and temperature patch, were delivered to the patient's home after enrollment. RM included RR, SpO₂, HR and temperature measured three times per day and recorded in the EHR and clinician video check-in twice per day. Care escalation was reported in five patients resulting in four ED visits and three subsequent hospitalizations. No deaths were reported in monitored patients.

The Cleveland Clinic reported usage of at-home monitoring in 878 COVID-19 patients in March and April 2020 using a custom built EHR module using the Epic **MyChart** Care Companion platform.³⁶ Daily monitoring includes clinician telephone outreach and use of an app with patient-entered data on symptoms, as well as pulse oximetry and temperature when available. Hospital admission was reported in 132 patients at a median of eight days from symptom onset. Further follow-up of outcomes is planned.

Atrium Health in Charlotte reported COVID-19 RM using home delivered kits including a blood pressure cuff, pulse oximeter and thermometer.¹¹ Mount Sinai Health System in New York repurposed an RM platform originally developed for stroke.¹⁵ Their **platform** uses a smart device-enabled app to track symptoms, temperature and pulse oximetry. St. Luke's University Health Network in Pennsylvania has partnered with pulse oximetry manufacturer **Masimo** to provide smart device-enabled RM in a variety of hospital and non-traditional settings including the home.¹⁶

OSF Health Care in Illinois developed an RM program using various care escalation levels.¹⁴ Technology kits include thermometers, pulse oximeters and blood pressure cuffs. The COVID-19 RM program has now been extended statewide with funding from the state government and RM services provided by various regional hubs.

In March 2020, Providence health system reported enrolling more than 700 COVID-19 patients in a program using at-home monitoring.¹² An external software platform (**Xealth**[®]) is utilized for integrating virtual health into the clinical workflow and the EHR and another third-party platform (**Twistle**) is used to automate communication and collect RM data from thermometry and pulse oximetry. The combined system was reportedly implemented in less than four days.

Financial issues

RM for at-home management of acute COVID-19 patients is predicated on reducing disease spread and increasing hospital bed capacity. From a societal perspective, the indirect and hidden costs associated with these advantages are deemed to be much greater than the direct costs associated with RM. More rigorous comparative financial analysis, however, are not yet available.

RM may incur costs for the sensors, associated information technology (if provided) and telecommunication fees. Device costs can be as low as \$5 to \$10 for a digital thermometer and \$20 to \$30 for a fingertip pulse oximeter or blood pressure cuff. At the low-end, these devices are not typically connected to IT and require manual data logging. Continuous connected sensors and wearables can cost on the order of \$100 per parameter. Some RM systems provide tablet computers with pre-loaded apps with IT costs around \$200 to \$400. Utilization of the patients' smart phone with free downloadable apps may minimize some IT costs.

Hospital infrastructure costs are also associated with RM. Servers, web portals, data storage, cybersecurity and other IT are needed, with costs depending on the size of the program. Hospitals with existing RM programs may incur fewer costs associated with incrementally adding COVID-19 capabilities. In addition, there may be costs associated with internal software development or modification, purchase of off-the-shelf software or fees for external platforms and program management.

The labor costs associated with staff used to enroll patients, provide education, conduct daily check-in and communications, monitor and/or enter data and respond to queries may be the largest cost associated with RM. Staff costs can run ~\$50 to \$100/patient/month depending on tasks, time required, local factors and program scale. Automating tasks like enrollment and data entry, using chatbots to respond to queries and provide education and using AI for data analysis could minimize some operating costs. Use of medical staff repurposed from other hospital service lines, who may be underutilized due to pandemic-associated issues, has been reported.

Reimbursement for RM of at-home COVID-19 patients may be available depending on payer. CMS pays for RM using CPT[®] codes 99453 (initial set-up and patient education of monitoring equipment), 99454 (devices and supplies for 30 days), 99457 (RM treatment management services, first 20 minutes), 99458 (RM treatment management services, each additional 20 minutes) and 99091 (Collection and interpretation of physiologic data, minimum of 30 minutes of time, each 30 days).³⁷ Payment rates vary, but average CMS reimbursement may provide about \$21 for set-up, \$69 for devices, ~\$54 for each 20 minute period spent by a qualified health professional on interactive patient management and ~\$60 per month for data analysis and interpretation.

RM may eventually show a positive return-on-investment (ROI) in a value-based care scenario if it reduces ED visits and/or hospitalizations. For example, a typical ED visit for a respiratory infection may cost \$2,000 more than that for a patient managed in a less intensive setting.³⁸ In addition, RM could reduce the overall length of stay (LOS) and associated costs by admitting the patient only when it becomes necessary. If RM results in earlier intervention compared to non-RM patients managed at-home, it could improve clinical outcomes, lower resource utilization and improve quality of life. Future studies collecting both clinical and financial outcomes and economic modeling will be needed, however, to determine the ROI for RM.

Patient selection criteria

Patients with suspected or confirmed COVID-19 may be enrolled in an RM care management program after triage through a virtual care platform (e.g., phone, video, text), an urgent care visit or ED evaluation. Appropriate patient selection requires thorough evaluation of clinical symptoms and risk factors as well as the time course for disease onset. Subjective judgments are made regarding whether the patient has the ability to understand and competently manage their own care in the home setting.³⁵ Geographic and economic considerations may also play a role in patient selection.

Risk factors that may provide a relative contraindication to RM include those associated with the probability for developing more severe disease or death. These may include advanced age (e.g., > 65 years), uncontrolled hypertension, immunosuppression, chronic lung disease, cardiovascular disease, severe obesity, diabetes mellitus, chronic kidney disease and chronic liver disease.³³ Residence in a nursing home or long-term care facility may also require special consideration. Risk stratification may also play a role in the intensity of monitoring. While RM may be initially considered in all disease positive patients, targeted use in the most vulnerable patient populations may be the most cost-effective. Patient selection may be highly specific to local factors, like hospital capacity, resource availability and infection rates.

Future developments

There are more than 100 new and ongoing clinical studies related to COVID-19 and RM listed on the [ClinicalTrials.gov](https://clinicaltrials.gov) site. This clinical evidence development is expected to shed more light on the effect of RM on key outcomes of interest, including: ED visits, hospitalizations, LOS, mortality, readmissions and costs. A wide variety of RM technologies, sensors and physiologic parameters are also under investigation. These may help to better understand target parameters, technology acceptability, user-friendliness, compliance with monitoring and patient satisfaction.

Though well-designed and conducted trials require a significant amount of time, the pandemic has accelerated many phases of the study process, such as rapid patient enrollment and early pre-print publication of interim results. In this accelerated timeframe, more clinical data on RM may be expected throughout 2020 and early 2021.

Telemedicine has rapidly expanded into many areas of care because of the pandemic. Expanded use has been facilitated by easing of regulations and facilitation of payment for virtual health services. Many government-based rules implemented during the crisis, however, are only valid during the declared crisis period and will expire when it is over. While it is unknown what new policies or procedures will be retained, some will undoubtedly be carried forward.

Many experts expect telemedicine growth trends will accelerate rapidly in the foreseeable future, albeit with more careful planning and implementation.³⁹ Future growth is in part driven by the experiences gained during the pandemic. While before the number of clinicians using telemedicine were limited, the majority of caregivers now have used the technology and experienced its potential advantages. Further, patients may now have experience with the technology and may come to expect the enhanced access and convenience associated with telemedicine. A competitive advantage may be gained by providers using telemedicine secondary to this increase in patient demand.

The ongoing advances in sensor design, telecommunication technology and advanced analysis algorithms will further enable RM in a variety of settings. Ease of use and user-friendliness of technologies will improve

and contribute to increased compliance with monitoring protocols. The use of mobile phones and the availability of continuous, non-invasive wearable sensors are two megatrends expected to drive continued growth of RM.

Conclusions and recommendations

The following conclusions and recommendations are based on the material presented in this report:

- Many hospitals throughout the U.S. and worldwide have reported developing and using RM as one part of a strategy for at-home management of COVID-19 patients. This contingency strategy is intended to ease the burden on hospitals experiencing surge-related shortages in bed capacity and resources.
- Current data suggest more than 80% of COVID-19 positive patients do not require hospitalization. In addition, the average time of hospital admission is about seven days after symptom onset. Therefore, the use of RM to manage patients at-home for as long as possible is an innovative, high-impact strategy.
- RM has been previously well-established for chronic disease management. In some cases, these legacy platforms were quickly adapted for COVID-19 patients. Conversion and roll-out of RM programs were reportedly accomplished in one to two weeks for some experienced users.
- There are many different technologies and approaches reported for RM. Variations include different physiologic parameters, sensor types, data collection methods, communication mode, frequency of follow-up and educational offerings. The optimal RM strategy for COVID-19, however, has not been established.
- In its simplest form, the use of low-cost thermometers and clip-on pulse oximeters are delivered to the patient's home. Daily telephone communication between the patient and healthcare provider is used to collect the physiologic data as well as symptoms. More advanced or intensive programs may add parameters, increase automation and/or increase frequency of communication. The backend response to the collected data may be more important than the technology used to collect the data.
- The clinical evidence for safety and efficacy of RM under pandemic conditions is very limited and mostly based on clinical expertise and opinion. A significant amount of research is ongoing and should help to better establish important methodology and outcomes. Efforts should be made to update new evidence and recommendations regarding RM as it becomes available.
- RM of COVID-19 patients is not intended as a revenue generating activity; but policy changes enacted during the pandemic may provide incremental reimbursement to offset some of the costs of patient technology and program staffing. RM requires significant hospital investment in underlying IT infrastructure, equipment and overhead that is not directly reimbursable.
- Appropriate patient selection may be key to safe and effective usage of RM. The initial triage and enrollment process should be thorough and flexible. Clinical presentation and risk factors, as well as the patient's social circumstances, are important variables.
- Compliance with RM activities is another key to outcomes. Technology that is onerous may reduce compliance, hence effectiveness. On the other hand, patient satisfaction with RM may be driven by patient-centered, user-friendly and convenient technology. Other elements of RM patient satisfaction

may be derived through improved understanding about their condition, a sense of empowerment and reassurance from monitored parameters.

- Telemedicine is a disruptive technology transforming the paradigm for care delivery. Usage exploded during the pandemic but is expected to recede when the pandemic lessens. Baseline levels, however, will likely be much greater than pre-pandemic for a long period of time due to the desire of patients and providers to minimize virus exposure and risk. The rate of future growth, however, may depend on as yet undetermined factors, like permanent changes in reimbursement policy and government regulations.
- RM is a critical component as well as an evolutionary next step in the hospital-at-home care paradigm. Because of this, hospitals and health systems should be actively involved in exploring RM technology and applications. Where warranted, hospitals should proactively implement RM as a strategy to improve patient outcomes and quality of care.

Related links

ATA [resources and content](#) for telemedicine relating to COVID-19

CDC [guidelines](#) for management of patients with COVID-19

CMS [policy and regulatory](#) revisions in response to COVID-19 (April 30, 2020)

FDA [policy statement](#) on non-invasive remote monitoring during COVID-19 (revised June 2020)

Healthcare IT News [guide](#) to device and remote patient monitoring vendors

HIMSS [article](#) on remote patient monitoring for COVID-19 applications

WHO [interim guidance](#) on home care for patients with COVID-19

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Vizient, Inc.
290 E. John Carpenter Freeway
Irving, TX 75062-5146
(800) 842-5146