Remote Patient Monitoring for Technology-Dependent Pediatric Tracheostomy Patients

Rapid Evidence and Policy Review

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Overview and Key Findings

Overview

Remote patient monitoring (RPM) allows healthcare professionals to review patient health information digitally. This can be done either asynchronously, meaning the data is transmitted, received, and reviewed at different times, or synchronously, where data is shared in real-time. This process is facilitated by various connected devices that continuously record and transmit clinical data readings as they occur. RPM programs, including those for technology-dependent pediatric tracheostomy patients, may also involve periodic scheduled and unscheduled real-time synchronous telehealth visits to allow for outpatient follow-up, as well as virtual assistance or coaching (e.g., tracheostomy tube installation, cleaning) for family caregivers.

In 2022, the Centers for Medicare & Medicaid Services broadened its reimbursement coverage for digital patient care monitoring by introducing remote therapeutic monitoring (RTM) codes. RTM codes are distinct from RPM codes in that RTM codes allow for monitoring the musculoskeletal and respiratory systems, as well as tracking patient adherence to and response to therapy. Louisiana Medicaid is researching the feasibility of a RPM program that targets pediatric tracheostomy patients.

For this report, researchers from the Center for Evidence-based Policy reviewed the published literature, evaluating comparative evidence on the use of RPM for technology-dependent pediatric tracheostomy patients. We also searched for relevant clinical guidelines from major medical organizations about the monitoring of pediatric patients receiving mechanical ventilation in the home. To identify RTM and RPM coverage criteria, we reviewed policy documents from five state Medicaid programs (Alabama, Mississippi, Texas, North Carolina, and Virginia) and conducted interviews with Medicaid program staff in four of those states. We also spoke to subject matter experts from Maine and Utah Medicaid and the American Medical Association. In addition, we conducted a comprehensive review of policy sources.

Key Findings

Published Evidence Findings

Overview

- Three studies met the inclusion criteria for this report: one United States (U.S.) randomized controlled trial (RCT), one Italian cohort study, and one Italian case-control study.
    - Studies were generally small, of moderate to high risk of bias, and had short follow-up durations. Due to the risk of bias ratings and the scarcity of comparative evidence, the findings of these studies should be interpreted with caution.
    - Participants were predominantly medically complex children with neuromuscular conditions.
    - The RPM technology used in each study varied from handheld devices capturing images, heart rate, and temperature data to ventilators with integrated RPM capabilities that allowed for cloud-based management of patient data (e.g., oxygen parameters).

Feasibility

- Telehealth consultations ranged from 31 to 73 calls across studies, including scheduled and unscheduled calls (three studies).

    - The majority of calls were successful, but some difficulties due to pairing issues or video freezing were reported (one study; U.S. RCT).
- Clinicians were able to successfully address exacerbations and develop a clinical plan with caregivers in the majority of episodes (three studies).
    - The majority of exacerbations occurred in low-severity patients and could be managed at home with nonphysicians (one study; Italian case-control).

Adverse Events

- In general, studies did not report specific adverse events that necessitated the need for higher-level care.
    - No critical or life-threatening event occurred (one study; Italian cohort) and there was no difference between groups in the number of exacerbations (one study; Italian case-control).

Healthcare Service Use

- Findings were mixed, but generally, RPM patients had lower rates of hospitalization, including intensive care unit admission (two studies), but higher rates of emergency department and acute office visits than control patients (one study; U.S. RCT).
- In the U.S. RCT, 67% of RPM patients remained out of the hospital while 44% of control patients remained out of the hospital.

Cost and Cost Savings

- Calculated cost rates yielded a $44,751.65 total ($9,425 per patient) cost savings for RPM (one study; U.S. RCT).
    - Fewer hospitalization days contributed to an overall lower cost rate despite a greater number of acute office and telehealth visits.
- Seven RPM telehealth visits led to $58,300 in potential direct cost savings by preventing the equivalent of three emergency department visits, three outpatient visits, and a three-week intensive care unit stay (one study; U.S. RCT).

Satisfaction and Quality of Life

- Clinicians were satisfied with RPM, citing the ability to provide detailed instructions to caregivers, specialist consultations, and outpatient follow-up (one study; U.S. RCT).
- Caregivers were similarly satisfied with RPM, citing comfort with technology and ease of use, the level of communication between hospital and home, and increased ease of decision-making (two studies).
    - However, there was no significant difference in caregiver burden based on the Caregiver Burden Inventory score (one study; Italian case-control).

Clinical Practice Guidelines

- Three recommendations from the American Thoracic Society (ATS; 2016) and Canadian Thoracic Society (CTS; 2017) guidelines are relevant to the monitoring of children with home mechanical ventilation:
    - An awake and alert-trained home caregiver should be the first line of monitoring (CTS recommendation: Consensus).

- A pulse oximeter should be used for monitoring as opposed to solely using cardiopulmonary monitoring or ventilator alarms (ATS recommendation: Conditional [very low-quality evidence]; CTS recommendation: 1C [strong recommendation, low-quality or very low-quality evidence]).
- Technology-enabled video monitoring or other modalities may be used to communicate with a patient's healthcare team (CTS recommendation: Consensus).

Policy Findings

Commercial

- Anthem, Blue Cross Blue Shield of Michigan, Blue Cross and Blue Shield of North Carolina, and Cigna have coverage policies for RPM and RTM.
  - None of the commercial plans explicitly mention tracheostomy patients as targeted populations.
  - Cigna specifies medical conditions for RPM and RTM, including chronic obstructive pulmonary disease, diabetes, and heart failure.

Medicaid

- Medicaid programs in Alabama, Mississippi, North Carolina, Texas, and Virginia cover RPM billing codes.
- None of the five state Medicaid programs reviewed explicitly included pediatric tracheostomy patients as a targeted population for RPM or RTM in their policies.
- However, both Texas and Virginia Medicaid coverage criteria do include specific references to oxygen- or ventilator-dependent children, although Texas Medicaid does not cover any of the RTM Current Procedural Terminology (CPT) codes.

Medicare

- As of November 2023, Medicare does not have local coverage determinations or a national coverage determination for RPM or RTM.
- Medicare Administrative Contractors held a committee meeting in February 2023 to discuss the evidence related to RPM and RTM devices and ultimately decided to not create formal coverage policies.
  - As a result, Medicare coverage determinations for RPM and RTM are made on a case-by-case basis.

Barriers to RPM Adoption

- Medicaid program officials have noted limited use of RPM codes.
- Reasons for this include a lack of clinician buy-in because of reimbursement rates and administrative burden.
  - Clinicians argue that reimbursement rates for RPM codes are not adequate to cover costs associated with acquiring, setting up, and maintaining RPM technology and equipment.
- Piecemeal payer coverage of RPM is also a barrier to obtaining clinician interest in the codes. While Medicaid programs tend to cover the codes, commercial payers do not, and Medicare coverage determinations are made on a case-by-case basis.
- For Medicaid enrollees themselves, other barriers to adoption include inadequate internet access, particularly in rural regions, a preference for in-person nursing over RPM, technological literacy issues, and language barriers for non-English speakers.

State Medicaid Efforts to Examine Return on Investment

- We found limited evidence on the impact of RPM on expenditures and outcomes for Medicaid enrollees.
- Texas Medicaid was the only key informant state that has evaluated RPM use.
  - While emergency room visits decreased as a result of RPM, there were increases in outpatient and pharmacy claims.
- Other state Medicaid programs reviewed have not audited the use of RPM to determine cost savings or other outcomes.

Conclusion

RPM and RTM services have shown potential for enhancing the care and management of some patients, particularly those with chronic conditions. However, there are few published studies of RPM for technology-dependent pediatric tracheostomy patients, and those that do exist are small, of short duration, and have concerning methodological limitations. Similarly, there are few clinical practice guideline recommendations about the monitoring of technology-dependent pediatric tracheostomy patients receiving care in the home. Additionally, our research found that none of the commercial plans or state Medicaid programs specifically name tracheostomy patients, either adults or children, as targeted patient populations in their RPM and RTM policies. Additional research is needed to quantify the clinical and cost-effectiveness of RPM for other patient populations, including technology-dependent pediatric tracheostomy patients.

Section 1 – Background

Remote patient monitoring (RPM) has been gradually gaining traction in the U.S. healthcare system for several years, with use increasing substantially during the COVID-19 pandemic.[1] RPM enables clinicians to access patients' health data through digital means, either asynchronously, with data received later, or synchronously in real time using connected devices to track clinical readings as they happen.[2] RPM has shown some signs of clinical benefit for various patient populations, particularly those dealing with chronic conditions or recovering from hospitalization.[3] For instance, RPM may benefit patients with cardiac conditions by continuously tracking vital signs like heart rate and blood pressure to manage conditions like congestive heart failure and hypertension, reducing the likelihood of readmissions.[3]

In recent years, the Centers for Medicare & Medicaid Services (CMS) has finalized payment for seven RPM codes.[4] These include Current Procedural Terminology (CPT) codes 99453, 99454, 99091, 99457, and 99458.[4] This decision was based on the fact that the CPT code descriptors do not specify that clinical staff must perform RPM services.[4] The adoption of RPM spiked between 2019 and 2022, with a 1,294% increase in RPM claim volume.[1] This significant increase can be attributed to the urgent need for remote monitoring during the COVID-19 pandemic.[1]

In 2022, CMS expanded reimbursement of digital monitoring of patient care with the introduction of remote therapeutic monitoring (RTM) codes.[5] These CPT codes include 98975, 98976, 98977, 98980, and 98981.[5] RTM codes differ from RPM codes in that they are used to primarily track musculoskeletal and respiratory systems, therapy adherence, and therapy response, aiming to assess the effectiveness of interventions by healthcare professionals.[5] RPM codes, conversely, concentrate on monitoring physiological parameters like weight, blood pressure, pulse oximetry, and respiratory flow rate, with a focus on chronic conditions such as hypertension, diabetes, and heart disease.[5]

Both code sets enable reimbursement for educating patients on remote care management platforms, monitoring platform alerts, direct messaging with clinicians, and data collection concerning therapy response and functional outcomes.[5] However, RTM codes can be billed by a broader range of healthcare professionals, including physical therapists, occupational therapists, speech-language pathologists, and clinical psychologists.[5] RPM codes are largely billed by physicians, physician assistants, and nurse practitioners.[5] RTM permits self-reporting by patients, providing a broader scope of data collection.[5]

The Louisiana State Legislature's House Resolution 107, introduced by Representative Aimee Adatto Freeman in the 2023 Regular Session, urges and requests the Louisiana Department of Health to study the feasibility of funding a remote monitoring program for technology-dependent children.[6] Louisiana Medicaid was specifically interested in determining the feasibility of developing a remote monitoring program for technology-dependent pediatric tracheostomy patients as a result of both House Resolution 107 and an increase in requests for such a program.

This report reviews the published evidence on the use of RPM for technology-dependent pediatric tracheostomy patients and recommendations from major clinical practice guideline organizations. This report also explores whether payers, including other state Medicaid programs, are using RPM or RTM as a way to monitor pediatric tracheostomy patients receiving mechanical ventilation in the home.

The following key questions and parameters guided our research.

Subsection 1.1 – Key Questions (KQ)

KQ1. What is the clinical evidence for the effectiveness or harms of using RPM for pediatric tracheostomy patients?

   a. What are the positions of major clinical guideline organizations on RPM for pediatric tracheostomy patients?

KQ2. What coverage policies do payers use to cover RPM for pediatric tracheostomy patients?

   a. What are barriers to implementation (e.g., implementation cost [return on investment], technology challenges [inherent to devices and tech-savviness of members], additional education necessary for caregivers to use RPM data)?

Subsection 1.2 – Populations, Interventions, Comparators, Outcomes, and Study Designs (PICOS) Parameters

Populations

Technology-dependent pediatric tracheostomy patients receiving care in the home.

Interventions

RPM technology that transmits data automatically or allows a person to submit their data through a secure website, smartphone, or other digital device, including services that employ RPM data and provide virtual assistance or coaching (e.g., tracheostomy tube installation, cleaning).

Comparators

- Continuous (24/7) in-person care (e.g., skilled nursing).
- No specific intervention.

Outcomes

- Cost and cost savings.
- Adverse events necessitating the need for higher-level care (e.g., pneumonia, aspiration).
- Mortality.
- Healthcare service use (e.g., readmission, emergency department visits).
- Caregiver quality of life.

Study Designs

- Randomized controlled trials.
- Prospective comparative observational studies.
- Clinical guidelines from major medical organizations.

Subsection 1.3 – Methods

To address KQ1, we conducted a review of evidence resources (e.g., Ovid MEDLINE, Cochrane Library) for relevant published literature. We also searched for relevant clinical guidelines from major medical organizations (e.g., the American Academy of Pediatrics, the American Thoracic Society). One researcher reviewed the title, abstract, and full-text documents and conducted risk of bias assessments for each included study. To address KQ2, we searched DuckDuckGo to find published reports about state-based

remote patient monitoring and remote therapeutic monitoring. We also reviewed policy documents from five state Medicaid programs that cover RPM and RTM services (Alabama, Mississippi, North Carolina, Texas, and Virginia), including Medicaid program fee schedules, governing statutes, regulations, provider manuals, and policy guidance. We interviewed state Medicaid program staff from four of these states (Alabama, Mississippi, Texas, and Virginia) to better understand approaches to covering RPM and RTM services; staff from North Carolina were not available for an interview. Additionally, we spoke to subject matter experts from Maine and Utah Medicaid offices and the American Medical Association. Additional details on the methods used to develop this report are included in Appendix A.

Subsection 1.4 – Related Center Resources

Ruppel L, Chapman S, King VJ. *Remote patient monitoring: evidence and coverage policies*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University; 2021.

Section 2 – Findings

Published Evidence

We identified 143 publications from our database searches. Three studies met inclusion criteria and were included in this report (Table 1): one moderate risk of bias (RoB) RCT conducted in the U.S., one high RoB Italian cohort study, and one moderate RoB Italian case-control study. Studies were rated as moderate to high RoB due to unclear allocation concealment (one study), lack of blinding (two studies), short length of follow-up (two studies), no adjustment for confounding variables (two studies), and potential conflicts of interest (one study). Due to the RoB ratings and the scarcity of comparative evidence, the findings of these studies should be interpreted with caution. All included studies were small, with fewer than 100 participants in each.[7-9] Two studies, the U.S. RCT and the Italian cohort study,[7,8] had a short follow-up period (three to four months), while the Italian case-control study had a longer two-year follow-up.[9]

The included studies evaluated the use of RPM and telehealth consultations in medically complex technology-dependent children and young adults, although not all participants underwent invasive mechanical ventilation (Table 1).[7-9] Participants had severe neuromuscular or developmental disabilities, with common conditions including Duchenne muscular dystrophy, spinal muscular atrophy types 1 and 2, and congenital myopathy (Table 1; Appendix B, Table B1).[7-9] One study, the Italian case-control study, stratified findings by patients' clinical severity, which was defined according to their daily ventilatory requirement (low severity < 12 hours, moderate severity > 12 hours and < 20 hours, high severity > 20 hours).[9] Participants were young, with an average age ranging from 9 to 16 years across the three studies.[7-9] In the U.S. RCT, approximately three-quarters of all participants were on public insurance.[7] The RPM technology used in each study varied from handheld devices capturing images, heart rate, and temperature data to ventilators with integrated RPM capabilities that allowed for cloud-based management of patient data (e.g., oxygen parameters) (Table 1). All studies also included telehealth consultations for RPM patients (two studies)[7,9] or all patients (one study).[8] Additional study characteristics are available in Appendix B, Table B1.

Table 1. Characteristics of Included Studies

Author, Year Study Design Sample Size Location	Population	RPM-Telehealth Technology
Notario, 2019[7] RCT N = 24 U.S.	Medically complex children ages one month to 18 years • Medical complexity: three or more body systems requiring active management; technology dependent or needed full support to complete ADL; moderate to severe neuromotor or intellectual disabilities • Tracheostomy alone: approximately 12%	Tyto-Home • FDA-cleared handheld, mobile device designed to capture and transmit ear, throat, and skin images; heart and lung auscultations (including heart rate); and temperature by infrared transdermal thermometer. Paired with an iOS tablet. • Caregivers used the device for noninvasive medical examinations

Author, Year Study Design Sample Size Location	Population	RPM-Telehealth Technology
	• Tracheostomy with ventilator dependence: approximately 33%	in the home guided by a remote clinician. Intervention group also received scheduled telehealth visits.
Onofri, 2021[8] Cohort N = 21 Italy	Medically complex children less than 18 years of age • Medically complex: one or more complex chronic condition • Long-term ventilation (noninvasive or invasive mechanical ventilation for at least three months) • Invasive mechanical ventilation: 13% RPM group vs. 54% non-RPM group	Ventilators equipped with RPM • Astral 100, Astral 150, Lumis 150 (AirView web platform); Trilogy, Garbin (Linde HealthView web platform); and Vemo (e- servicing by Eove web platform) • RPM data include adherence to ventilation (days of use and hours of therapy), air leaks, pressure, and flow waveforms; oxygen parameters (by pulse- oximeter); AHI and ODI Intervention and control groups received weekly teleconsultations by video call.
Trucco, 2019[9] Case-control N = 96 Italy	Children and young adults with neuromuscular disease • Disease onset at less than 18 years of age • Most patients had DMD (29%), SMA 1 (17%), SMA 2 (19%), or CM (19%) • Invasive ventilation: 15% RPM group vs. 4% non-RPM group	Teox Pro • Detects and transmits SpO_2 and heart rate, breathing pattern, and airway pressure TN Facile-Care • Detects and transmits SpO_2 and heart rate Intervention group also received a tablet that allowed real-time video calls.

Abbreviations. ADL: activities of daily living; AHI: Apnea-Hypopnea Index; CM: congenital myopathy; DMD: Duchenne muscular dystrophy; FDA: U.S. Food and Drug Administration; ODI: Oxygen Desaturation Index; RCT: randomized controlled trial; RPM: remote patient monitoring; SMA 1: spinal muscular atrophy type 1; SMA 2: spinal muscular atrophy type 2; SpO_2: blood oxygen.

Subsection 2.1 – Feasibility

In the U.S. RCT, telehealth visits were attempted in 73 encounters and telehealth device connection was successful in the majority (92%) of these attempted encounters (Box A).[7] In 18% of attempts, connection was established with some reported difficulty, including device pairing issues or video freezing during the encounter.[7] In four encounters, the telehealth device failed to connect; however, in more than 92% of uses, ease of use, image, and sound quality were considered acceptable.[7] Clinicians were able to develop a clinical plan in 97% of visits based on available telemedicine data.[7]

Box A. Feasibility Findings

Telehealth consultations ranged from 31 to 73 calls across studies, including scheduled and unscheduled calls (three studies).

- The majority of calls were successful, but some difficulties due to pairing issues or video freezing were reported (one study; U.S. RCT).

Clinicians were able to successfully address exacerbations and develop a clinical plan in the majority of episodes (three studies).

- The majority of exacerbations occurred in low-severity patients and could be managed at home with nonphysicians (one study; Italian case-control).

Sources. Notario, 2019[7]; Onofri, 2021[8]; Trucco, 2019.[9]
Abbreviations: RCT: randomized controlled trial.

A total of 31 teleconsultations were conducted in the Italian cohort study.[8] During these teleconsultations, study personnel detected suboptimal ventilatory therapy in six cases (19%), including five RPM patients and one non-RPM patient.[8] The reported issues concerned episodes of headaches and morning sleepiness, secretions, considerable desaturations, patient-device asynchrony, and poor ventilator adherence.[8] After teleconsultations, study personnel changed ventilation parameters (i.e., increased inspiratory or expiratory positive airway pressure, changed inspiratory and expiratory triggers, increased backup respiratory rate) for RPM patients using the web platforms, and successfully improved the condition of all but one patient.[8] Additional details are available in Appendix B, Table B2.

In the Italian case-control study, there was a median of nearly 62 scheduled calls (interquartile range [IQR], 53.5 to 68 calls) per patient throughout the RPM trial.[9] There were a total of 26 unscheduled calls made by caregivers during the study period.[9] Reasons for unscheduled calls included an increased amount of upper airway secretions without fever (12 calls), reports of respiratory infections with fever and increased secretions (nine calls), sore throat (two calls), increased difficulty breathing (two calls), and nausea (one call).[9] Of the 26 unscheduled calls, 15 episodes were managed at home: 10 were managed entirely by nonphysicians with the supervision of the on-site physician, and five were initially managed by nonphysicians, but because of their incomplete resolution, were then managed by the medical team.[9] There were 59 exacerbations detected by the combination of both overnight monitoring and scheduled calls: 36 in low-, 16 in moderate-, and seven in high-severity patients.[9] The majority (48; 81.4%) of exacerbations were resolved with home management: 30 in low- (83.3%), 11 in moderate- (68.8%), and seven in high-severity patients (100%).[9] Exacerbations occurring in low- and moderate-severity patients were managed almost entirely (28 of 30, and eight of 11) by the combination of nonphysicians with medical advice and supervision.[9] Exacerbations occurring in high-severity patients were resolved by the on-site medical team both by directly contacting patients and caregivers and prescribing antibiotics and by discussing the therapeutic approach with the patient's primary care provider or pediatrician.[9]

Subsection 2.2 – Adverse Events

The U.S. RCT did not report specific adverse events.[7] In the Italian cohort study, no critical or life-threatening events occurred in either group and none of the patients required a hospital admission due to worsening of clinical conditions (Box B).[8] In the Italian case-control study, there were no significant differences in the number of exacerbations that occurred in the RPM group throughout the study period (*P* = .48; Appendix B, Table B2).[9] However, RPM patients experienced significantly fewer respiratory infections than they had experienced before enrolling in the RPM intervention (11 vs. 24; *P* = .04) and were lower overall than the number of exacerbations in control patients (53 total; 24 in low-, 12 in moderate-, and 17 in high-severity patients).[9]

Box B. Adverse Event Findings

Few studies reported specific adverse events that necessitated the need for higher-level care.

- No critical or life-threatening events occurred in the Italian cohort study.
- In the Italian case-control study, there was no difference between groups in exacerbations, but RPM patients had fewer respiratory infections than control patients did.
- The U.S. RCT did not report specific adverse events.

Sources. Notario, 2019[7]; Onofri, 2021[8]; Trucco, 2019.[9]
Abbreviations: RCT: randomized controlled trial; RPM: remote patient monitoring.

Subsection 2.3 – Healthcare Service Use

In the U.S. RCT, five patients in the RPM intervention group required nine hospitalizations, while five patients in the control group accounted for six hospitalizations.[7] The rate of intensive care unit (ICU) hospitalization (0.77 vs. 1.14) and pediatric floor hospitalization (0.32 vs. 0.67) was lower for the intervention group compared with the control group (Box C).[7] However, the rate of emergency department (ED) visits (0.12 vs. 0.06) and acute office visits (0.17 vs. 0.14) was higher for the intervention group than the control group.[7] Ultimately, 67% of the intervention group remained out of the hospital while 44% of the control group remained out of the hospital.[7] Additional details on resource use are available in Appendix B, Table B2.

Box C. Healthcare Service Use Findings

Findings were mixed, but generally, RPM patients had lower rates of hospitalization, including ICU admission (two studies), but higher rates of ED and acute office visits than control patients had (one study; U.S RCT).

In the U.S. RCT, 67% of RPM patients remained out of the hospital while 44% of control patients remained out of the hospital.

The Italian cohort study did not report this outcome.

Sources. Notario, 2019,[7] and Trucco, 2019.[9]
Abbreviations: ED: emergency department; ICU: intensive care unit; RCT: randomized controlled trial; RPM: remote patient monitoring.

In the Italian case-control study, out of the 59 episodes, 11 (18.6%) required hospitalization, two (3.4%) of which were emergency admissions (both occurring in moderate-severity patients), while nine (15.2%) were admissions to the ward (six occurring in low-severity and three in moderate-severity patients).[9] Emergency admissions included both high-intensity and ICU admissions.[9] RPM patients had significantly fewer emergency admissions during the RPM trial than they had before the RPM trial (two vs. 12; *P* < .05), while ward admissions were not significantly lower during the RPM trial than before the trial (nine vs. 12; *P* > .05).[9] Nearly 40% of exacerbations in controls required hospitalization.[9] Therefore, hospital admissions in RPM patients were also significantly fewer than in control patients (11 vs. 21; *P* = .03). However, a comparison of ward and emergency admissions

between RPM patients and control patients did not achieve statistical significance (nine vs. 15 ward [*P* = .4] and two vs. six emergency admissions [*P* = .08]).[9] RPM patients were hospitalized for a total of 108 days compared with 219 days for control patients, and RPM patients had a significantly lower median duration in days than control patients had (six vs. seven; *P* = .03).[9]

Subsection 2.4 – Cost and Cost Savings

Cost and Cost Savings

Only one study, the U.S. RCT, reported outcomes related to cost (Box D). This study reported both direct costs and cost rates (direct cost of encounter multiplied by the visit rate) per encounter type over the four-month study period (Appendix B, Table B2).[7] Calculated cost rates yielded $44,751.65 total ($9,425 per patient) cost savings for the RPM intervention group.[7] While the intervention group had a greater number of acute office and telehealth visits than the control group had, the intervention group had a lower number of hospitalization days, which contributed to the overall lower cost rate.[7] Seven telehealth visits were reported as having prevented in-person visits, including three ED visits, three outpatient visits, and an ICU hospitalization.[7] Study authors noted that the ICU hospitalization that was prevented would typically have resulted in a three-week ICU stay based on previous experience.[7] Based on the direct cost for the ED visits, acute outpatient visits, and 21 days in the ICU, the prevented services resulted in approximately $58,300 in potential direct cost savings.[7] Additional details on cost outcomes are available in Appendix B, Table B2.

Box D. Cost and Cost Savings Findings

Calculated cost rates indicated $44,751.65 total ($9,425 per patient) cost savings for RPM (one study; U.S. RCT).

- Fewer hospitalization days contributed to an overall lower cost rate despite a greater number of acute office and telehealth visits.

Seven RPM telehealth visits led to $58,300 in potential direct cost savings due to preventing the equivalent of three ED visits, three outpatient visits, and a three-week ICU stay (one study; U.S. RCT).

Sources. Notario, 2019.[7]
Abbreviations: ED: emergency department; ICU: intensive care unit; RCT: randomized controlled trial; RPM: remote patient monitoring.

Subsection 2.5 – Clinician Satisfaction and Caregiver Quality of Life

The U.S. RCT evaluated clinician and caregiver satisfaction with a survey using a four-point Likert response scale.[7] Clinicians reported being very satisfied with the use of the telehealth device during encounters (median, 4.0; IQR, 4.0 to 4.0), noting specific benefits, including the ability to provide detailed instructions (e.g., gastrostomy tube insertion), in-home care for posthospitalization visits, specialist consultation, and scheduled outpatient follow-up visits (Box E).[7] Throughout the study period, caregivers reported being very satisfied (median, 4.0; IQR, 3.5 to 4.0) and very comfortable (median, 4.0; IQR, 3.5 to 4.0) with the use of the telehealth device, rating it very easy to use (median, 3.0; IQR, 3.0 to 4.0).[7] Parents noted that the ability to interact with the clinician through telehealth reduced their worries about having their child stay at home.[7]

In a three-item questionnaire, parents and caregivers in the Italian case-control study reported being highly satisfied with RPM and the level of communication between home and the hospital.[9] Out of 48 parents, 10 (21%) considered the program "good" and the remaining families (38/48; 79%) considered it "very good."[9] RPM was considered "very easy" to use by 34 parents (71%), while 14 (29%) found it "easy" to use.[9] None of the parents considered RPM to be difficult to use.[9] There was no significant difference in the median Caregiver Burden Inventory score before and after the RPM trial (32.5 vs. 35.5; *P* = .06).[9] Higher Caregiver Burden Inventory scores are indicative of greater caregiver burden.[10] However, parents and caregivers anecdotally reported increased ease in decision-making and improved communication with the on-site healthcare professionals.[9]

Box E. Satisfaction and Quality of Life Findings

☑ Clinician satisfaction with RPM (one study; U.S. RCT)
- Ability to provide detailed instructions to caregivers, specialist consultations, and outpatient follow-up

☑ Caregiver satisfaction with RPM (two studies)
- Comfort with technology and ease of use
- Level of communication between hospital and home
- Increased ease of decision-making

☒ No difference in caregiver burden based on Caregiver Burden Inventory score (one study; Italian case-control).

Sources. Notario, 2019,[7] and Trucco, 2019.[9]
Abbreviations: RCT: randomized controlled trial; RPM: remote patient monitoring.

Section 3 – Ongoing Studies

In our research, we identified one relevant ongoing study listed in ClinicalTrials.gov. The Transitions to Long-term In-Home Ventilator Engagement (TtLIVE) trial will evaluate the effect of using the aTouchAway RPM platform for children and adults newly initiated on home mechanical ventilation, in conjunction with the following care elements[11]:

- Virtual home visits,
- Customizable care plan,
- Clinical workflows that incorporate reminders, completion of symptom profiles, and telemonitoring,
- Digitally secure communication via messaging, audio, and video calls, and
- A resource library including print and audiovisual material.

The primary completion date of the TtLIVE trial was March 2023, and a publication may be soon forthcoming.[11] Of note, the TtLIVE trial plans to enroll 440 participants, which would be a substantially greater sample size than the three available studies included in this report.[11] Therefore, the findings of the TtLIVE trial may markedly shift the evidence base. Additional study details are available in Appendix C.

Section 4 – Clinical Practice Guidelines

We identified two clinical practice guidelines that are relevant to monitoring technology-dependent pediatric tracheostomy patients in the home: the 2016 American Thoracic Society (ATS) Clinical Practice Guideline on Pediatric Chronic Home Invasive Ventilation and the 2017 Canadian Thoracic Society (CTS) Clinical Practice Guideline on Pediatric Home Mechanical Ventilation.[12,13]

Three recommendations are relevant to the monitoring of children with home mechanical ventilation (Table 2; Box F)[12,13]:

- An awake and alert trained caregiver should be the first line of monitoring (CTS recommendation)
- A pulse oximeter should be used for oxygen saturation monitoring as opposed to solely using cardiopulmonary monitoring or ventilator alarms (ATS and CTS recommendation)
- Technology-enabled video monitoring or other modalities may be used to communicate with a patient's healthcare team (CTS recommendation)

Table 2. Clinical Practice Guideline Recommendations

Recommendation	Strength of Recommendation
An awake and alert **trained caregiver** 24 hours a day and seven days a week should be the first line of monitoring for a child receiving home mechanical ventilation	Canadian Thoracic Society Rating: Consensus
Use a **pulse oximeter** to monitor children with home mechanical ventilation as opposed to using a cardiorespiratory (e.g., electrocardiogram or chest wall movement) monitor or solely using ventilator alarms	American Thoracic Society Rating: Conditional • GRADE Quality of Evidence: very low Canadian Thoracic Society Rating: 1C • Interpretation: strong recommendation, low-quality or very low-quality evidence
Use **technology-enabled video monitoring or other technology-enabled modalities** for communication with a patient's healthcare team	Canadian Thoracic Society Rating: Consensus

Sources. Amin, 2017,[12] and Sterni, 2016.[13]
Abbreviation. GRADE: Grading of Recommendations Assessment, Development, and Evaluation.

Box F. Guideline Strength of Recommendation Ratings

ATS rates the strength of recommendations as either *strong* or *conditional*. Briefly, interventions with strong recommendations are those that should be provided to individuals in most clinical situations, whereas interventions with conditional recommendations are those that may not be appropriate in all clinical situations, and where decision aids and stakeholders (e.g., individuals, clinicians, policymakers) discussions may be necessary to determine the appropriateness of applying the intervention. ATS also uses the GRADE methodology to assess the quality of the published evidence and evaluate the strength of the recommendations.

CTS grades the strength of their recommendations from 1A (strong recommendation, high-quality evidence), which indicates an intervention may be applied to most patients in most clinical situations, to 2C (weak recommendation, low-quality or very low-quality evidence), which indicates other alternatives to an intervention may be equally reasonable. Consensus recommendations are those in which no evidence was available and the guideline committee made a recommendation when consensus among the members was reached.

Additional details on clinical practice guideline strength of recommendation ratings are available in Appendix D.

Sources. Amin, 2017,[12] and Sterni, 2016.[13]
Abbreviations. ATS: American Thoracic Society; CTS: Canadian Thoracic Society; GRADE: Grading of Recommendations Assessment, Development, and Evaluation.

Small, indirect studies and expert consensus suggest that ventilator alarms may not always function correctly and may not adequately alert to accidental decannulation (removal of tracheostomy tube) or ventilator disconnection.[12,13] During ventilator disconnection, the ventilator hub may be sufficiently obstructed by the patient or by bedding material, creating enough back pressure to not trigger the alarms.[12] In addition, when a child has an accidental decannulation, a sufficient drop in pressure may not occur depending on the ventilator settings and characteristics (i.e., pressure and flow).[12] This is more likely with tracheostomy tubes used in children than those used for adults because the tubes used in children have a smaller internal diameter (i.e., < 5 mm) and higher resistance.[12,13] Furthermore, hypoxemia is more likely to be an early indicator of airway obstruction or equipment malfunction leading to inadequate ventilation in infants and children.[12,13] Standard home cardiorespiratory monitors that detect heart rate and chest wall movement will only provide alerts if there is an absence of respiratory movement or associated bradycardia.[13] Bradycardia occurs as a downstream complication of a serious respiratory event, which makes patient resuscitation more difficult.[12,13]

CTS recommends that technology-enabled video monitoring or other technology-enabled modalities and support should be used for communication with the patient's healthcare team to reduce family caregiver anxiety, provide symptom support, promote troubleshooting of equipment challenges, and reduce unscheduled provider visits.[12] ATS notes that additional studies examining the role of telemedicine and RPM in the care of chronically ventilated children are necessary, specifically when investigating the usefulness of these technologies concerning patient outcomes and equipment troubleshooting.[13]

Section 5 – Payer Coverage Policies

Subsection 5.1 – Commercial Payers

We reviewed commercial payer coverage policies for Anthem, Blue Cross Blue Shield of Michigan, Blue Cross and Blue Shield of North Carolina, and Cigna related to both RPM and RTM.

Targeted Populations

None of the commercial plans reviewed explicitly named tracheostomy patients, either adults or children, as targeted patient populations in their policies.[14,15-17] Cigna was the only commercial payer to detail medical conditions to which RPM and RTM would be limited.[14] Those include chronic obstructive pulmonary disease (COPD) patients as well as those with diabetes or heart failure.[14] Anthem and both Blue Cross Blue Shield plans had broader coverage policies for any patient for which a clinician feels such services are medically necessary.[15-17] Anthem also explicitly notes that RPM and RTM should not be primarily used for convenience and should be for individuals at risk due to their medical condition, unable to access regular outpatient care, and requiring enhanced monitoring.[15]

Criteria for RPM and RTM Devices

All of the payers reviewed required that any device used for RPM and RTM meet the U.S. Food and Drug Administration (FDA) definition of a medical device.[14-17] Cigna explicitly notes that the devices must be prescribed and administered by a board-eligible or board-certified medical provider or subspecialist (e.g., cardiologist, pulmonologist, endocrinologist), nurse practitioner, or physician assistant. Physiologic data are electronically collected and automatically uploaded for analysis and interpretation.[14]

Blue Cross Blue Shield of Michigan further details that the devices should be noninvasive and have the potential to be connected to a wireless network through Bluetooth, Wi-Fi, or cellular connection.[16] Covered devices should also transmit a patient's measurements directly to their clinician, or a monitoring company affiliated with their clinician.[16] Such devices may include wearable, handheld, or stationary in-home units and digital interfaces or clinical electronic thermometers, electrocardiographs, cardiac monitors, or pulse oximeters.[16]

Subsection 5.2 – Medicare

Medicare has no local coverage determinations (LCDs) or national coverage determination for RPM or RTM as of November 2023.[18] In February 2023, six out of the seven Medicare Administrative Contractors (MACs) convened a multijurisdictional contractor advisory committee meeting to discuss the current state of evidence related to RPM and RTM medical devices.[19] Typically, contractor advisory committee meetings are convened before the release of a preliminary LCD, which outlines the specific conditions or criteria governing the Medicare coverage of healthcare items and services within a particular geographic region.[20,21] In May 2023, two of the MACs informed stakeholders they were not planning to issue LCDs for these products, but no formal rationale was released.[21] The other five MACs have issued no announcements as to whether or not they would issue LCDs for RTM and RPM devices.[21] As a result, fee-for-service Medicare coverage determinations of RPM and RTM are made on a case-by-case basis.[21]

Subsection 5.3 – Medicaid

We reviewed Medicaid RPM coverage policies from Alabama, Mississippi, North Carolina, Texas, and Virginia Medicaid. Our review found that while all five Medicaid programs covered RPM billing codes, Alabama and Texas Medicaid did not cover any of the RTM CPT codes (98975, 98976, 98977, 98980, and 98981).[22,23]

Prior Authorization

Commonalities exist across all five state Medicaid programs in terms of prior authorization criteria for RPM.[24-30] Clinicians in each state must conduct an assessment to determine whether RPM services are appropriate for individual patients.[24-30] This assessment takes into consideration the patient's behavioral, physical, and cognitive capabilities to participate safely in RPM.[24-30] Secondly, patient consent is a universal requirement.[24-30] Billing clinicians are obliged to obtain and document the patient's consent for RPM services, which includes informing patients about the service's availability, any applicable cost sharing, and their right to terminate the service.[24-30] Four of the states reviewed (Mississippi, North Carolina, Texas, and Virginia) explicitly require that devices used for RPM meet the FDA's definition of a medical device and that these products must be able to transmit real-time data.[25-30] Alabama, Texas, and Virginia Medicaid have duration authorization policies for RPM.[24,27,28,30] Alabama Medicaid requires all claims for RPM services to be filed within one year of the date of service.[24] Texas and Virginia Medicaid authorize RPM for ventilator or oxygen-dependent children for six months.[27,28,30] After this initial authorization period, enrollees can seek reauthorization depending on their adherence to their RPM care plan.[30] Texas Medicaid did not outline reauthorization criteria in their manuals.[27,28]

Clinicians Able to Bill for RPM

Medicaid programs in four of the states (Alabama, Mississippi, North Carolina, and Texas) allow nonphysician practitioners to bill for RPM, though the specifics vary.[24-26,28] Alabama Medicaid and Mississippi Medicaid specifically mention physician assistants and nurse practitioners,[24,25] Texas Medicaid extends this to include registered nurses and clinical nurse specialists,[27,28] and North Carolina Medicaid further broadens the scope to include psychiatric nurse practitioners and certified nurse midwives.[26]

Alabama Medicaid uniquely also requires clinicians to enter into a memorandum of understanding specific to RPM before they can offer such services to their patients.[24] The memorandum of understanding outlines the financial and medical responsibilities of both parties.[24] Requirements for RPM providers include statewide service provision, meeting clinical staffing requirements, providing interactive audio and video technology monitoring equipment to recipients, accepting electronic referrals, conducting in-home assessments, transmitting recipient data in real-time, promptly reviewing and reporting on data, offering 24/7 access to healthcare professionals, developing patient-centered care plans, maintaining compliance, and facilitating program graduation when appropriate.[24] Alabama Medicaid notes these requirements ensure the effective delivery of RPM services and the provision of high-quality care to recipients.[24]

Target Populations

The eligibility criteria for RPM across the five states' Medicaid programs reviewed emphasize the importance of medical necessity for RPM services and the need for the services to be appropriate and effective for the patient's condition.[24-30] None of the state Medicaid programs reviewed explicitly

mention pediatric tracheostomy patients as a target population for these services.[24-30] However, relevant to Louisiana Medicaid's request, Texas and Virginia Medicaid coverage criteria explicitly mention children with either an oxygen or ventilator dependence.[24,27-30] However, officials from both states said they were not aware of RPM specifically being requested for pediatric tracheostomy patients (Texas Medicaid staff, Virginia Medicaid staff, informal interviews). In Mississippi, COPD patients are one of the populations eligible for RPM services.[25] Mississippi Medicaid does not outline additional severity criteria COPD patients must meet to receive RPM services in its billing guidelines, including whether the patient needs to be oxygen or ventilator-dependent.[25] Tracheostomies can be used as part of the treatment for COPD patients[31]; however, state officials said they were also not aware of tracheostomy patients using RPM benefits (Mississippi Medicaid staff, personal communication). The only respiratory-related population explicitly targeted by Alabama Medicaid is pediatric asthma patients (Alabama Medicaid staff, personal communication).[24] Alabama Medicaid officials noted that target populations are determined in part on patient demand (Alabama Medicaid staff, personal communication). Alabama Medicaid also works with the University of South Alabama's Center for Strategic Health Innovation to identify Medicaid patients eligible for RPM services.[32]

RPM Educational Requirements for Caregivers and Patients

Each state Medicaid program reviewed covers CPT codes used for RPM device set-up and training.[24-30] In Texas, Medicaid officials refer to RPM as telemonitoring (Texas Medicaid staff, personal communication).[28] They state that educating and training Medicaid enrollees, as well as providing and maintaining the necessary telemonitoring equipment, falls under the responsibility of either a home health agency or the outpatient hospital that delivers these services (Texas Medicaid staff, personal communication). Virginia Medicaid's coverage documents are unique in that they detail a member's choice and education program.[29] This effort targets all patients receiving telehealth services, not just RPM and RTM specifically.[29] Under its program, Medicaid enrollees receive information about telehealth usage, the voluntary nature of telehealth services, and clarification that they can refuse this treatment modality without jeopardizing future care or benefits.[29] Efforts to respect privacy and confidentiality are also discussed.[29]

Section 6 – Barriers to Widening Use of RTM and RPM Services

For this section, we conducted a literature review to determine what if any programmatic barriers there are to implementing RTM and RPM efforts. We also spoke to Medicaid officials in key informant states of Mississippi, Texas, and Virginia as well as Medicaid staff from Maine and Utah. We also spoke to a subject matter expert from the American Medical Association. We found that the use of RTM and RPM codes is often low for various factors, including clinician buy-in, a changing regulatory landscape around remote monitoring billing codes broadly, and socioeconomic factors faced by patients.

Subsection 6.1 – Clinician Buy-In

In the background section of this report, we noted that there has been an uptick in the use of RPM codes; however, the use of these codes has been limited to a minority of medical practices nationally (American Medical Association staff, personal communication).[1] For instance, only 25% of member

practices are currently using RPM, according to a Medical Group Management Association state poll from June 2022.[1] Lack of clinician buy-in has been attributed to two main factors: reimbursement rates and the administrative burden imposed on clinicians who seek to bill remote monitoring codes.[1]

Reimbursement Rate Concerns

Clinicians have raised worries that the average reimbursement rate for remote monitoring codes is not adequate for further adoption of these services (American Medical Association staff, personal communication). National reimbursement rates for RPM CPT codes range from $18.84 to $48.93 for services like initial setup and ongoing physiologic monitoring.[33] Average RTM CPT code rates range between $19 and $55 for services such as initial setup, respiratory system monitoring, and treatment management.[33] Those rates can be a barrier to offering remote monitoring as an option to patients (Maine Medicaid staff, personal communication). Clinicians point to several key challenges, including the upfront costs associated with acquiring and setting up RPM technology and equipment (Maine Medicaid staff, personal communication). Additionally, ongoing expenses related to the maintenance and upkeep of RPM systems pose a significant financial burden (Maine Medicaid staff, Virginia Medicaid staff, personal communication).

A 2022 survey by Texas Medicaid that targeted in-network clinicians and medical facilities found that 83% of responders did not offer remote monitoring as a service for patients.[34] The primary reasons included concerns over reimbursement and lack of resources to maintain monitoring programs, with one survey respondent stating that they felt there would be no return on investment for offering such services.[34] Billing for RPM services requires investment in unique workflows and IT platforms that clinicians may either be unable or unwilling to make given the current payer landscape for these codes (Virginia Medicaid staff, personal communication). Furthermore, some patients require multiple training sessions to effectively use the RPM equipment, and the responsibility to provide this training falls on clinicians (Maine Medicaid staff, personal communication).

A 2018 JAMA research article noted that professional billing costs can account for approximately 14.5% of the total expenses for primary care practices. The medical billing process involves multiple steps, including patient registration and insurance verification, followed by the patient-provider encounter and medical coding. All of these steps add up to annual billing costs for primary care physicians which are estimated at $99,581 per physician, based on billing costs of $20.49 per visit and an estimated total of 4,860 visits annually.

Differences Across Payer Types

Related to reimbursement, there is piecemeal payer coverage for these codes, which may limit clinicians' interest in adopting these codes (Virginia Medicaid staff, personal communication). As of September 2023, 37 state Medicaid programs provide reimbursement for RPM,[35] while most commercial payers do not reimburse for the codes and Medicare lacks a formal national coverage determination or LCD policies for the codes.[1,21]

Further, Medicare's billing requirements can differ from those in place for Medicaid programs (Texas Medicaid staff, personal communication). Payer nonalignment on remote monitoring billing guidelines can create a more uncertain and laborious billing experience for clinicians to navigate (Virginia Medicaid staff, personal communication). For instance, Medicare requires a prior-established patient-provider relationship before initiating remote monitoring services, and it requires clinicians to bill for RPM device

setup and patient education (CPT code 99453). CMS also requires that devices must transmit 16 days' worth of patient-generated health data before 99453 and 99454 can be billed. Of the five state Medicaid programs reviewed, only North Carolina and Virginia Medicaid have both of these requirements explicitly outlined in their billing guidelines.[26,30]

Texas Medicaid's coverage of home telemonitoring services predated CMS's codes and guidelines by five years, which meant it had its billing codes and policies in place before Medicare (Texas Medicaid staff, personal communication). The majority of beneficiaries who receive telemonitoring services in Texas are dual-eligible recipients, and since their codes do not exactly align with Medicare, crossover claims are a challenge (Texas Medicaid staff, personal communication).

Subsection 6.2 – Patient-Related Factors

Medicaid enrollees face several challenges in using RPM, with issues varying across states. A critical barrier is the lack of access to reliable internet, especially in rural areas (Utah Medicaid staff, personal communication).[36] Additionally, officials in Mississippi indicate that Medicaid home-bound enrollees with complex medical conditions may prefer in-person private duty nursing over RPM (Mississippi Medicaid, personal communication). Moreover, Texas clinicians have highlighted issues with patients' ability to use RPM equipment, citing concerns about technological literacy as a barrier.[34] In North Carolina, a 2023 evaluation of telehealth use among Medicaid enrollees, including the use of RPM, found a disparity in usage among different ethnic groups, with lower usage among Black and non-White Hispanic populations.[37] Particularly for Hispanic patients, language barriers may lead to lower adoption rates.[37]

Section 7 – State Efforts to Examine Return on Investment Related to RPM Use

For this section, we interviewed Medicaid officials to examine what the return on investment has been for offering remote monitoring as a covered benefit.

Limited Evidence of Impact of RPM on Expenditures and Outcomes

Of the five state Medicaid programs reviewed, Texas Medicaid is the only one that has published an evaluation that specifically examines its experience with remote monitoring among Medicaid enrollees and whether any savings have been realized. Its analysis found that the number of enrollees using telemonitoring grew by approximately 1,188% (from 1,506 in 2014 to 19,404 in 2021), while program spending for these services increased by about 3,511% (from $900,000 in 2014 to $32.5 million in 2021).[38] The net effect of home telemonitoring is an increase in total medical spending related to outpatient visits by $345 and pharmacy spending by $61 per client per month, indicating that it enhances client-clinician interactions, leading to faster responses to therapy needs and reduced inpatient admissions.[39]

In Alabama, RPM is jointly funded and overseen by both the state's Medicaid agency and its department of public health.[40,41] Annual reports released by the Alabama Department of Public Health indicate that the number of home-bound Medicaid enrollees receiving RPM hovered around 1,600 between fiscal years 2019 and 2021.[40,41] The reports note that the goal of offering RPM is to decrease exacerbation

episodes, urgent care visits, hospital admissions, and costs.[40,41] However, these reports do not quantify progress on any of those metrics.[40,41]

An interviewee from Mississippi Medicaid noted that the agency has not audited the use of RPM to determine savings or improved quality outcomes (Mississippi Medicaid staff, personal communication). However, a 2022 research paper issued by the University of Mississippi found that RPM led to patients experiencing notable improvements in their diabetes management, including an average reduction of two points in hemoglobin A1c levels, weight loss, and enhanced self-care knowledge after 12 months of nurse coaching and diabetes education via electronic tablets.[42] The paper examined patients in Mississippi across payer types, including Medicaid.[42]

Section 8 – Discussion

RPM and RTM services have shown some potential in enhancing the care and management of patients, particularly those with chronic conditions. There have been few published studies of RPM for technology-dependent pediatric tracheostomy patients, but the studies that do exist suggest the potential of RPM to provide enhanced monitoring of patients and caregiver support. However, these studies are small, of short duration, and have concerning methodological limitations. Similarly, there are few clinical practice guideline recommendations on the monitoring of technology-dependent pediatric tracheostomy patients receiving care in the home. Guidelines recommend direct caregiver monitoring and the use of pulse oximetry as first- and second-line options.

Our research found that none of the commercial plans or state Medicaid programs specifically name tracheostomy patients, either adults or children, as targeted patient populations in their policies. Although certain conditions relevant to tracheostomy, such as COPD, were included in some payer policies, there was no explicit mention of pediatric tracheostomy patients. This indicates a gap in the knowledge and a potential area for future exploration, especially given the potential benefits of RPM and RTM in this patient group.

Clinicians have also expressed concerns about the administrative demands and uncertain financial returns of RPM in the context of current reimbursement structures. Differences in payer guidelines and the lack of alignment on RPM policies between Medicare and Medicaid also present challenges. Patient-related factors like limited internet access and technology literacy also impede RPM use.

Evaluation of the return on investment and impact of RPM remains limited. Few Medicaid programs audit the use of RPM codes to determine cost savings or improved outcomes. Texas Medicaid, one of the few to perform such an evaluation, found there was an increase in spending on outpatient and pharmacy claims for patients receiving RPM services.

These findings were echoed in a 2022 systematic review of 34 studies that evaluated the cost-effectiveness of RPM for chronic disease management compared with usual care.[43] Most studies found that RPM can improve health outcomes for patients with chronic conditions such as hypertension, COPD, and heart failure.[43] However, RPM often increases upfront healthcare costs due to the need for monitoring equipment and services.[43] Several cost-utility analyses found RPM to be cost-effective for hypertension management, as it has the potential for greater cost savings in the long run by preventing costly health events through early detection of health declines.[43] However, additional research is

needed to quantify the clinical and cost-effectiveness of RPM for other patient populations, including technology-dependent pediatric tracheostomy patients.

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Appendix A. Full Evidence Tables

Table A1. Characteristics of Included Studies

Author, Year Study Design Risk of Bias Location NCT Number	Intervention Comparator Population Overview	Demographics	Time Period Data Source
Notario, 2019[7] RCT Moderate U.S. NCT02849938	Intervention group: participants who received the Tyto-Home telehealth device • n = 15 participants • Tyto-Home is an FDA-cleared, handheld, mobile device designed to capture and transmit ear, throat, and skin images; heart and lung auscultations (including heart rate); and temperature by infrared transdermal thermometer. The device is paired with an iOS tablet for wireless network transmission of a live-interactive connection. • Caregivers used the device to facilitate noninvasive medical examinations in the home guided by a remote clinician. • Intervention group also had scheduled telehealth visits for routine care such as postdischarge care and follow-up for a particular concern.	Intervention vs. Control Age (mean y, SD): 8.81 (5.74) vs. 9.32 (6.67) Female (%): 46.7 vs. 66.7 Non-White (%): 46.7 vs. 77.8 Public insurance (%): 73.3 vs. 77.8 Tracheostomy alone (%): 13.3 vs. 11.1 Tracheostomy with ventilator-dependence (%): 33.3 vs. 33.3 Number of diagnoses (mean, SD): 10.0 (3.40) vs. 11.0 (3.71) Number of specialists (mean, SD): 5.87 (1.51) vs. 5.55 (1.87)	Four-month follow-up Data included clinician encounter device usability; caregiver satisfaction; and encounter type, purpose, and cost.

Author, Year Study Design Risk of Bias Location NCT Number	Intervention Comparator Population Overview	Demographics	Time Period Data Source
	Comparator group: standard care • n = 9 participants • Patients were referred to an in-person encounter if an examination was needed. Children with medical complexity and their caregivers participating in a pediatric complex care program at a single institution in the U.S. Midwest. Children were ages one month to 18, had at least one English-speaking parent, and had in-home Wi-Fi connectivity. Children in the complex care program had three or more body systems requiring active management, were technology-dependent or needed full support to complete activities of daily living, and had moderate to severe neuromotor or intellectual disabilities. Participants were randomized with stratification based on tracheostomy status.		
Onofri, 2021[8] Cohort High Italy	Intervention group: patients who received ventilator telemonitoring • n = 8 Comparator group: patients who did not receive ventilator telemonitoring • n = 13 Participants were medically complex children (< 18 years of	Telemonitored patients vs. nontelemonitored patients Age (mean y, SD): 12.6 (5.49) vs. 10.7 (7.12) Female (%): 37.5 vs. 30.8 Race/ethnicity: NR Invasive mechanical ventilation (%): 12.5 vs. 53.8 Diagnosis (%): • Down syndrome: 12.5 vs. 7.7 • Obesity: 12.5 vs. 0	Three-month follow-up (March 2020 to May 2020) Data provided by the platforms include adherence to ventilation (days of use and hours of therapy), air leaks, pressure, and flow waveforms (among others). In addition to that, AirView and Eove platforms allow the

Author, Year Study Design Risk of Bias Location NCT Number	Intervention Comparator Population Overview	Demographics	Time Period Data Source
	age with one or more complex chronic conditions) on long-term ventilation (noninvasive or invasive mechanical ventilation for at least three months). Patients in both groups were on a waiting list for a planned hospital admission during COVID lockdown between March 2020 and May 2020. All patients received weekly teleconsultations by video call during the study period conducted via a platform specific to the region. Nine different models of ventilators were used by study participants: Astral 100, Astral 150, Lumis 150, and Elisee 150, manufactured by ResMed; Trilogy and Garbin, manufactured by Philips Respironics; Vemo 150, manufactured by Eove; Vivo 60, manufactured by Breas; Puritan Bennet 560, manufactured by Covidien; Monnal t50, manufactured by AirLiquide. Of these devices, only a few can be equipped with telemonitoring: Astral 100, Astral 150, Lumis 150 (AirView web platform); Trilogy, Garbin (Linde HealthView web platform); and Vemo (e-servicing by Eove web platform). Twelve patients in the cohort had the	• Parenchyma diseases: 12.5 vs. 0 • Metabolic diseases: 25.0 vs. 0 • Neuromuscular diseases: 0 vs. 38.4 • Prader-Willi Syndrome: 0 vs. 7.7 • Central nervous system diseases: 37.5 vs. 46.2	reading of oxygen parameters, with the connection of a pulse-oximeter by the patient's family. AirView alone provides additional information such as the Apnea- Hypopnea Index (AHI) and the Oxygen Desaturation Index (ODI) and allows remote changes in the ventilator setting.

Author, Year Study Design Risk of Bias Location NCT Number	Intervention Comparator Population Overview	Demographics	Time Period Data Source
	ventilator equipped with telemonitoring.		
Trucco, 2019[9] Case-control Moderate Italy	Intervention group: patients who received telemonitoring • n = 48 • Telemonitoring devices used were: Teox Pro (detects and transmits SpO_2 and heart rate, breathing pattern, and airway pressure), TN Facile-Care (detects and transmits SpO_2 and heart rate) as well as a home tablet that allowed real-time video calls. Comparator group: age- and disease-matched controls who did not receive telemonitoring • n = 48 Participants were home-ventilated neuromuscular disease young patients (disease onset < 18 years). Participants were recruited from 3 centers in Italy (Genoa, Alessandria, and Catania). Consecutive patients followed by the three centers who met inclusion criteria were enrolled. The control population was age- and disease-matched to the intervention population and were those whose parents or patients themselves withheld consent for the telemonitoring trial or	Cases vs. controls Age (mean y, IQR): 16.4 (8.9-22.1) vs. 15.0 (9.2-21.5) Female (%): 37.5 vs. 25.0 Age at start of home ventilation (median, IQR): 12.6 (4.5-17.5) vs. 13.9 (6.2-17.1) Hours of home ventilation (median, IQR): 10.5 (8.0-16.0) vs. 8.0 (8.0-13.0) Invasive ventilation (%): 14.6 vs. 4.2 Telemonitoring duration in months (median): 2.0 vs. NA Number of previous hospital admissions: • 0: 32.3 vs. NR • 1: 10.4 vs. NR • 2: 7.3 vs. NR Presence of scoliosis (%): 70.8 vs. 80.8 Diagnosis (%): • DMD: 29.2 vs. 29.2 • SMA 1: 16.7 vs. 16.7 • SMA 2: 20.8 vs. 18.8 • SMA 3: 0 vs. 2.1 • CM: 18.8 vs. 18.8 • LGMD: 4.2 vs. 4.2 • CMD: 2.1 vs. 2.1 • Mitochondrial encephalopathy: 2.1 vs. 2.1 • Guillain-Barre: 2.1 vs. 2.1 • Peripheral neuropathy: 4.2 vs. 4.2	September 15, 2014 to September 15, 2016

Author, Year Study Design Risk of Bias Location NCT Number	Intervention Comparator Population Overview	Demographics	Time Period Data Source
	were approached for participation when all devices were already allocated.		

Abbreviations. BPD: bronchopulmonary dysplasia; CM: congenital myopathy; CMD: congenital muscular dystrophy; CPD: chronic pulmonary disease; CRF: chronic respiratory failure; DMD: Duchenne muscular dystrophy; FDA: U.S. Food and Drug Administration; FSH: fascioscapulohumeral; IHMV: invasive home mechanical ventilation; IQR: interquartile range; LGMD: limb girdle muscular dystrophy; NR: not reported; SMA 1: spinal muscular atrophy type 1; SMA 2: spinal muscular atrophy type 2; SMA 3: spinal muscular atrophy type 3.

Table A2. Outcomes of Included Studies

Author, Year Study Design Risk of Bias Location NCT Number	Outcomes
Notario, 2019[7] RCT Moderate U.S. NCT02849938	Encounter data for cases when a telehealth visit was desired (n encounters, %, *P* value) Intervention vs. Control • Type of encounter (*P* < .01) ○ Phone: 2/73 (3%) vs. 11/12 (92%) ○ Electronic message: 0/73 vs. 1/12 (8%) ○ Scheduled telehealth visit: 58/73 (79%) vs. 0/12 ○ Unscheduled telehealth visit: 13/73 (18%) vs. 0/12 • Who did the clinician interact with (*P* = .006) ○ Clinician/legal guardian: 67/73 (92%) vs. 7/12 (64%) ○ Home health nurse: 4/73 (5%) vs. 3/12 (27%) ○ Other: 2/72 (3%) vs. 2/12 (18%) • Chief concern for the encounter (*P* = .008) ○ Respiratory/ENT: 34/43 (79%) vs. 4/12 (33%) ○ Fever or acute illness symptoms: 1/43 (9%) vs. 1/12 (8%) ○ Seizure or neurologic symptoms: 1/43 (2%) vs. 0/12 ○ Medical technology or equipment: 4/43 (9%) vs. 1/12 (8%) ○ Other: 8/43 (19%) vs. 7/12 (58%) ○ Practice visit + clinical question: 5/73 (7%) vs. 0/12 ○ Practice visit only: 30/73 (41%) vs. 0/12 Feasibility of connectivity (n, %) Premodification month vs. observation months • Not able to get a connection: 0/23 (0) vs. 4/50 (8.0%) • Connection obtained but was problematic: 15/23 (65.2%) vs. 9/50 (18.0%) • Connection worked great: 8/23 (34.8%) vs. 37/50 (74.0%) Resource use and costs (No. of visits, direct cost [$], visit rate [count/group n x months], cost rate [costs for visits x visit rate] in $) Intervention Group: • Acute office visit: 10, $1,840.00, 0.167, $307.28 ○ Premodification month: 4 (visits) ○ Observation months: 6, $1,104.00, 0.100, $110.40 • Telehealth visit: 43, $7,912.00, 0.717, $131.93 ○ Premodification month: 15 (visits) ○ Observation months: 28, $5,152.00, 0.467, $85.93 • ED visit: 7, $13,741.00, 0.117, $1,607.70 ○ Premodification month: 1 (visit) ○ Observation months: 6, $11,778.00, 0.100, $1,177.80 • Hospitalization days-pediatric floor: 19, $34,752.00, 0.317, $11,016.38 ○ Premodification month: 1 ○ Observation months: 18, $32,923.00, 0.300, $9,876.90 • Hospitalization days-ICU: 46, $113,574.00, 0.767, $87,111.26 ○ Premodification month: 9 (visits) ○ Observation months: 37, $91,353.00, 0.617, $56,364.80 • Total costs without telehealth visits: $163,907.00 (direct cost), $100,042.62 (cost rate)

Author, Year Study Design Risk of Bias Location NCT Number	Outcomes

	• Total cost with telehealth visits: $171,819.00 (direct cost), $100,174.55 (cost rate)
	
	Control Group:
	• Acute office visit: 5, $920.00, 0.139, $127.88
	  ○ Premodification month: NA
	  ○ Observation months: 5, $920.00, 0.139, $127.88
	• Telehealth visit: NA
	  ○ Premodification month: NA
	  ○ Observation months: NA
	• ED visit: 2, $3,926.00, 0.056, $219.86
	  ○ Premodification month: NA
	  ○ Observation months: 2, $3,926.00, 0.056, $219.86
	• Hospitalization days-pediatric floor: 24, $43,896.00, 0.667, $29,278.63
	  ○ Premodification month: NA
	  ○ Observation months: 24, $43,896.00, 0.667, $29,278.63
	• Hospitalization days-ICU: 41, $101,229.00, 1.139, $115,299.83
	  ○ Premodification month: NA
	  ○ Observation months: 41, $101,229.00, 1.139, $115,299.83
	• Total costs without telehealth visits: $149,971.00 (direct cost), $144,926.20 (cost rate)
	• Total cost with telehealth visits: NA

Onofri, 2021[8]
Cohort
High
Italy
	Detected problems and interventions during the study period (problem; intervention; outcome)
	Telemonitored patients
	• Ventilation problems (n = 5)
	  ○ Sleepiness in the morning; changed ventilation parameters; slight improvement in sleepiness
	  ○ Presence of secretions; recommended use of aerosol; no improvement
	  ○ Morning headache; changes of interface and ventilation parameters; fewer headaches
	  ○ Asynchrony with ventilator; changed ventilation parameters; no asynchrony
	  ○ Frequent desaturations; changed ventilation parameters; reduction of desaturations
	• Domiciliary assistance problems (n = 4)
	  ○ Consumables not supplied; intercession with local health authority; consumables regularly supplied
	  ○ Suspended physiotherapy; remote assistance by the hospital's physiotherapist; physiotherapy performed by the family after training
	  ○ Interrupted data transmission to online server (x2); intercession with technical assistance; data transmission restored
	
	Nontelemonitored patients
	• Ventilation problems (n = 1)
	  ○ Scarcely tolerated ventilation; changed interface; improvement of therapy compliance
	• Domiciliary assistance problems (n = 2)
	  ○ Technical assistance not provided; intercession with local health authority; assistance regularly provided

Author, Year Study Design Risk of Bias Location NCT Number	Outcomes
	○ Prescriptions expired; renewal of prescriptions; renewal of prescriptions Adverse events • No critical or life-threatening events occurred in patients in either group during the study. • None of the patients required an urgent admission due to the worsening of clinical conditions.
Trucco, 2019[9] Case-control Moderate Italy	RPM trial • Scheduled calls (median; 1st to 3rd quartile): 61.5 (53.5 to 68) • Total unscheduled calls: ○ 0: 32 (66.7%) ○ 1: 9 (18.7%) ○ 2: 5 (10.4%) ○ 3 to 4: 2 (4.2%) • Number of exacerbations: 59 • Number of exacerbations solved by home management: 48/59 (81.4%) • Number of exacerbations requiring antibiotics: 45/59 (76.3%) • Number of exacerbations requiring hospitalization: 11/59 (18.6%) • Number of patients with at least 1 exacerbation: 24/48 (50%) • Number of patients treated by home management: 17/24 (70.8%) • Number of patients with exacerbations requiring antibiotics: 22/24 (91.7%) • Number of admissions: 11 ○ ED/ICU: 2 ○ Ward: 9 • Length of hospital stay (days): 6 (5 to 30) Details of exacerbations in RPM patients in 4 trimesters throughout RPM trial First trimester • Exacerbations (patients) ○ 0: 37/47 (78.7%) ○ 1: 9/47 (19.1%) ○ 2 to 3: 1/47 (2.1%) • Exacerbations (n): 11 Second trimester • Exacerbations (patients) ○ 0: 36/47 (76.6%) ○ 1: 7/47 (14.9%) ○ 2 to 3: 4/47 (8.5%) • Exacerbations (n): 15 Third trimester • Exacerbations (patients) ○ 0: 33/47 (70.2%) ○ 1: 12/47 (23.4%) ○ 2 to 3: 2/47 (6.4%) • Exacerbations (n): 17 Fourth trimester • Exacerbations (patients) ○ 0: 34/39 (87.2%) ○ 1: 4/39 (10.3%)

Author, Year Study Design Risk of Bias Location NCT Number	Outcomes
	○ 2 to 3: 1/39 (2.5%) • Exacerbations (n): 8

Abbreviations. ED: emergency department; ENT: ear, nose, throat; ICU: intensive care unit; NA: not applicable; RPM: remote patient monitoring.

Appendix B. Ongoing Studies

Table B. Relevant Ongoing Studies

Study Name Trial Number Location	N Enrolled Condition(s) Age Group Study Duration	Intervention Comparison	Outcome Measures	Primary Completion Date
Transitions to LIVE (TtLIVE) NCT04180722 Ontario, Canada	• N = 440 • Newly initiated home mechanical ventilator patients • Children and adults • 12 months	• TtLIVE intervention using aTouchAway platform (Aetonix) • Usual care	• ED visits • Family caregiver reported Pearlin Mastery Scale score • Healthcare service use • Family caregiver burden • Health-related quality of life • Process measures • Cost-utility	March 2023

Sources. Amin, 2022,[11] and ClinicalTrials.gov.
Abbreviations. ED: emergency department; LIVE: Long-term in-home ventilator engagement.

Appendix C. Clinical Practice Guidelines Strength of Recommendation Ratings

American Thoracic Society

Table C1. Interpretation of Strong Versus Conditional Strength of Recommendation

User Group	Strong Recommendation	Conditional Recommendation
Patients	Most individuals in this situation would want the recommended course of action and only a few would not. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	The majority of individuals in this situation would want the suggested course of action, but many would not.
Clinicians	Most individuals should receive the intervention. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.	Understand that different choices will be appropriate for individual patients. Decision aids may be useful in helping individuals make decisions consistent with their values and preferences.
Policymakers	The recommendation can be adopted as policy in most situations.	Policymaking will require substantial debates and involvement of many stakeholders.

Source. Sterni, 2016.[13]

Canadian Thoracic Society

Table C2. Grading Recommendations

Grade of Recommendation and Description	Benefit versus Risk and Burdens	Methodological Quality of Supporting Evidence	Implications
1A/strong recommendation, high-quality evidence	Benefits clearly outweigh risks and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B/strong recommendation, moderate quality evidence	Benefits clearly outweigh risks and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C/strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risks and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher-quality evidence becomes available
2A/weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances, patients' or social values
2B/weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances, patients' or social values
2C/weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks and burden; benefits, risk and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

Source. Amin, 2017.[12]
Abbreviation. RCT: randomized controlled trial.

GRADE Quality of Evidence

The Grading of Recommendations, Assessment, Development, and Evaluation Working Group (GRADE) system defines the overall quality of a body of evidence for an outcome in the following manner:

- **High:** Raters are very confident that the estimate of the effect of the intervention on the outcome lies close to the true effect. Typical sets of studies are randomized controlled trials with few or no limitations, and the estimate of effect is likely stable.
- **Moderate:** Raters are moderately confident in the estimate of the effect of the intervention on the outcome. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is different. Typical sets of studies are randomized controlled trials with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.
- **Low:** Raters have little confidence in the estimate of the effect of the intervention on the outcome. The true effect may be substantially different from the estimate of the effect. Typical sets of studies are randomized controlled trials with serious limitations or nonrandomized studies without special strengths.
- **Very low:** Raters have no confidence in the estimate of the effect of the intervention on the outcome. The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.
- **Not applicable:** Researchers did not identify any eligible articles.

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