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Use of Remote Cardiorespiratory Monitoring is Associated with a Reduction in Hospitalizations for Subjects with COPD

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Background: Chronic obstructive pulmonary disease (COPD) is prevalent and results in high healthcare resource utilization. The largest impact on health status and proportion of healthcare costs in COPD are related to hospitalizations for acute exacerbations. Accordingly, the Centers for Medicare & Medicaid Services have advocated for remote patient monitoring (RPM) to aid in chronic disease management. However, there has been a lack of evidence for the effectiveness of RPM in reducing the need for unplanned hospitalizations for patients with COPD.

Methods: This pre/post study was a retrospective analysis of unplanned hospitalizations in a cohort of COPD subjects started on RPM at a large, outpatient pulmonary practice. The study included all subjects with at least one unplanned, all-cause hospitalization or emergency room visit in the prior year, who had elected to enroll in an RPM service for assistance with clinical management. Additional inclusion criteria included being on RPM for at least 12 months and a patient of the practice for at least two years (12 months pre- and post-initiation of RPM).

Results: The study included 126 subjects. RPM was associated with a significantly lower rate of unplanned hospitalizations per patient per year (1.09 ± 0.07 versus 0.38 ± 0.06, $P<0.001$).

Conclusion: Unplanned, all-cause hospitalization rates were lower in subjects started on RPM for COPD when compared to their prior year. These results support the potential of RPM to improve the long-term management of COPD.

Keywords: COPD, exacerbations, hospitalizations, admissions, remote patient monitoring, physiology

Introduction

Chronic obstructive pulmonary disease (COPD) has an estimated global prevalence of 11.7% and is the third leading cause of death worldwide.[1] Acute exacerbations of chronic obstructive pulmonary disease (AECOPD) are associated with significant rates of hospitalization and accelerated disease progression, leading to greater patient disability.[2,3]

Many interventions aim to reduce exacerbation frequency and hospitalizations.[4] These include pharmacologic and nonpharmacologic therapies.[5] If identified and treated early, COPD exacerbations can often be managed on an outpatient basis with the use of bronchodilators, antibiotics, and oral steroids.[6,7] Nonpharmacologic therapies include long-term oxygen therapy,[8] pulmonary rehabilitation,[9,10] and home non-invasive ventilation.[11] Identifying AECOPDs early, however, requires overcoming multiple challenges including a heightened awareness of symptoms and a demonstrated ability to coordinate provider examination and care, including pharmacologic intervention. Experience shows that patients are often slow or loathe to self-report symptoms that indicate an emerging AECOPD.[12,13]

To pre-identify exacerbations, physiologic and spirometric measures have been used including changes in pulse rate, peripheral oxygen saturation, blood pressure, body temperature, forced expiratory volume in the first second (FEV1), and respiratory rate.[14] However, devices currently available and commonly used by COPD patients, such as spirometers and

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pulse oximeters, may be inadequate to accurately pre-identify AECOPDs.[15] While research has demonstrated the potential for remote patient monitoring (RPM) to pre-identify exacerbations,[16] there is a lack of real-world evidence showing that this method can improve outcomes. The objective of this study was to determine whether RPM, with sustained use and a protocol that allows for timely medical intervention in respiratory subjects, would improve healthcare resource utilization in a COPD cohort.

Methods

Study Design and Participants

This study included a retrospective analysis of data collected from subjects at a large outpatient pulmonology practice in a mid-Atlantic metropolitan city of the United States between May 2019 and February 2022. At this clinic, patients who were candidates for RPM had been offered voluntary participation in a service tailored to chronic respiratory disease patients (Spire Health, San Francisco, CA, USA). They continued regular follow-ups with their pulmonologists and received usual care according to the direction of their primary pulmonary physician for their COPD. The study compared chart data from each patient's initial 12 months of the intervention to their own chart data 12 months prior, for a total of 24 months of chart data per patient.

Inclusion criteria for the present study included a clinical diagnosis of COPD (COPD, chronic bronchitis, obstructive lung/airways disease, or emphysema), subscribed to RPM for at least 12 months as of February 28, 2022, full electronic medical records (EMR) at the site in question for one year before and one year after the start of RPM, and at least one all-cause ER visit or unplanned hospitalization in the year prior to enrollment. All such patients were included in the analysis. Patients with less than 12 months of exposure to the intervention were not included.

The primary endpoint was unplanned, all-cause hospitalizations per subject. Secondary endpoints included unplanned cardiopulmonary hospitalizations, respective lengths of stay, ER visits, outpatient pulmonary visits, systemic corticosteroid use, adherence to RPM, and time-to-visit (RPM escalation to provider visit).

Ethical standards for patient data confidentiality were performed in compliance with the principles stated in the Declaration of Helsinki. The study was approved by the Western Institutional Review Board (00000533) and registered on ClinicalTrials.gov (NCT05518981). A waiver of informed consent was granted due to the retrospective nature of the data retrieval. All subjects separately consented to RPM as part of their enrollment.

Intervention

The RPM service includes an FDA-cleared remote physiologic monitor validated for clinical accuracy[17] and adherence[18] among COPD patients, and currently in active use at practices around the United States. It is tailored to chronic respiratory disease patients, utilizing a system that includes three components: undergarment-adhered cardiorespiratory sensors (Figure 1), an in-home hub (Figure 2), and web-based clinical dashboard (not shown). The RPM service's physiologic monitors are a set of six proprietary, skin-safe devices that include sensors[19] for intermittent photoplethysmography for pulse, continuous respiratory force, and tri-axis accelerometers for activity. Each set lasts over 12 months and does not require recharging. They are designed to remain adhered to the inner waistband of undergarments through the washer/dryer. The proprietary respiration sensor senses the entire respiratory waveform continuously, providing granular coverage of respiratory behavior when undergarments are worn.

The sensors communicate wirelessly and passively with a dedicated data transmission hub, offering patients minimal feedback except for their current respiratory rate, pulse rate, duration worn, and total steps taken for the day. The hub sends data securely via Wi-Fi or a cellular connection to a cloud-based dashboard used by the clinical team.

The clinical dashboard is monitored seven days a week by clinical liaisons (CL), which vary in accreditation but in this study were comprised of respiratory therapists and registered nurses with clinical experience in pulmonary disease. The dashboard displays notifications based on sustained elevation of respiratory and pulse rates starting at 10% and 20% over rolling baselines, respectively. Notifications are also triggered when rates exceed the absolute thresholds of 35 brpm (breaths per minute) and 135 bpm (beats per minute). Each patient's thresholds are adjusted based on input from the clinical team. Low quality physiologic data are automatically excluded by the notification algorithms.

Figure 1 The sensors included in the RPM service are adhered to undergarments to address the burden involved in maintaining a clip-on or wrist-worn sensor, without requiring skin-adhesion.

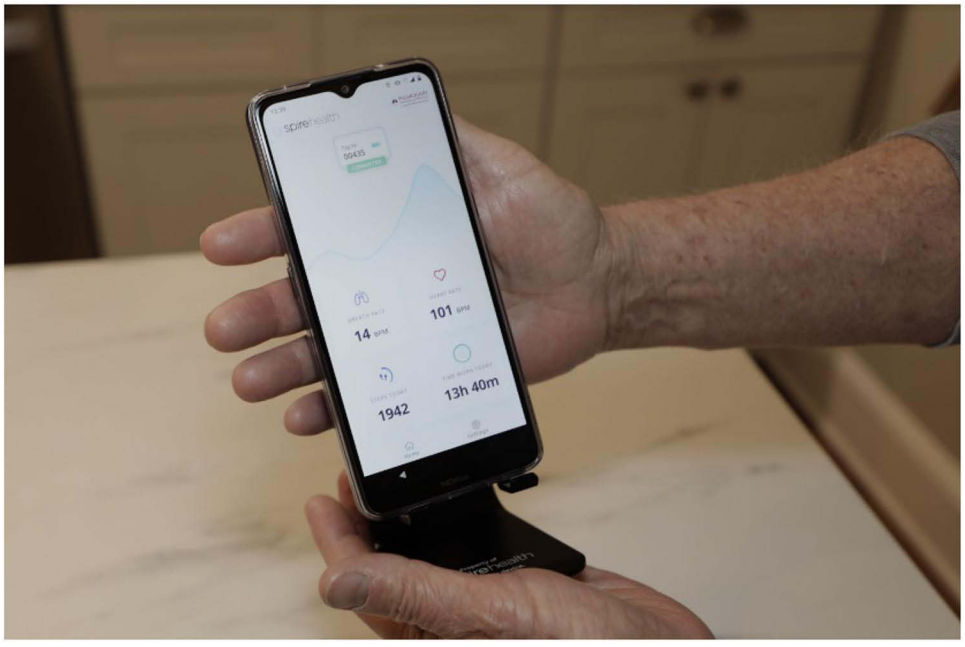

Figure 2 The hub passively captures sensor data and securely transmits it to the cloud. It provides limited feedback to patients.

The RPM clinical monitoring protocol includes a "risk assessment" (Table 1) phone call 24–48 hours after notification of physiologic deviation(s). Patients who fail the risk assessment were escalated to the practice for an in-person or virtual visit. Where possible, CLs scheduled patients directly by using the site's practice management system. In months where no risk assessment calls were necessary, CLs performed a generic "monthly check-in" call to address any operational issue with the RPM service, changes in insurance, and to elicit patient-reported events.

Table 1 The Risk Assessment Script

1	These past two days, are you more short of breath than usual?
2	These past two days, are you having more sputum than usual?
3	These past two days, have you noticed any changes in the color of your sputum?
4	Do you have any new concerns about your breathing?
5	Would you like me to make an appointment with your doctor?

Notes: The risk assessment is administered to patients by clinicians, post-notification of physiologic deviations. Patients who reported 'Yes' to any of the questions were escalated to their provider.

Data Collection

EMR data of the period 12 months prior to and 12 months post-initiation of the intervention were coded and analyzed. Hospital notes and discharge summaries from the local hospital network were routinely imported into the EMR system as part of the practice's care. Thus, data collection included both clinic and all available hospital notes as source documents.

EMR records were reviewed and labeled by a rater with the goal of identifying reliable information about subject, encounters, and hospitalizations. The rater was trained with the research team for over 10 hours with an additional 110 hours of practice alongside weekly review by the site pulmonologist. The rater reviewed each of the subject's encounter records, subject correspondence notes, and physician notes chronologically to search for references to hospitalizations and ER visits.

"Hospitalizations" included all acute, unplanned hospital admissions. "Cardiopulmonary" events were determined based on the treating provider's documentation referencing a respiratory or cardiovascular finding such as chest pain, shortness of breath, or pneumonia. Adherence to remote monitoring, captured automatically by the RPM platform, was calculated as the proportion of days during the intervention period where physiological sensors were worn for at least 8 hours.

Statistical Analysis

To compare differences between pre- and post-initiation periods for the discrete variables, a paired Wilcoxon Signed Rank test (non-normal) was used. The Kolmogorov–Smirnov (KS) statistical test was used to test normality (see Appendix A for results). Because length of stay data was not available for all hospitalizations depending on the data source, sample sizes were unequal, and the Wilcoxon Rank Sum test was used to compare length of stay data. A two-sided *P*-value of <0.05 was considered statistically significant. Statistical analysis was conducted using the *SciPy* Python package (version 1.8.1, 2022).

Results

126 subjects were identified who fit the inclusion criteria. At the time of analysis, all patients were included who met the inclusion criteria. No patients were excluded from the analysis. The baseline characteristics of the study participants are summarized in Table 2.

Healthcare Resource Utilization

Hospital Admissions

The number of all-cause hospitalizations in the cohort decreased 65.0%, from 137 to 48 (see Figure 3). On a per-patient basis, there was a significant difference pre-initiation to post-initiation (1.09 ± 0.07 to 0.38 ± 0.06, $P<0.001$). On average, the length of stay during all-cause hospitalizations was 0.60 days shorter post-initiation but the difference was not statistically significant (5.77 ± 0.86 to 5.06 ± 1.80 days, $P=0.612$) (Table 3).

Cardiopulmonary hospitalizations decreased 63.6%, from 88 to 32. On a per-patient basis, there was a significant difference pre-initiation to post-initiation (0.70 ± 0.08 to 0.25 ± 0.05, $P<0.001$). On average, the length of stay during

Table 2 Baseline Characteristics of Subjects

Parameter	Value
Age, years, mean (SD)	73.8 (9.3)
Females, *n* (%)	72 (57.1%)
Body mass index, kg/m2, mean (SD)	28.2 (7.5)
FEV1 (within 5y), % predicted (post-bronchodilator when available), mean (SD)	59.5 (21.3)[a]
Supplemental oxygen use, *n* (%)	59 (46.8%)
Active smoker, *n* (%)	27 (21.4%)
Depression, *n* (%)	35 (28.0%)
African American, *n* (%)	28 (23.7%)[b]
Comorbidities:	
Atrial fibrillation, *n* (%)	22 (17.5%)
Congestive heart failure, *n* (%)	24 (19.0%)
Hypertension, *n* (%)	85 (67.5%)
Diabetes, *n* (%)	43 (34.1%)
Sleep apnea, *n* (%)	51 (40.5%)
Stroke or cerebrovascular accident, *n* (%)	15 (11.9%)
Interstitial Lung Disease (ILD), *n* (%)	2 (1.6%)
History of any cancer, *n* (%)	36 (28.6%)
Thyroid disease, *n* (%)	21 (16.7%)
Coronary artery disease, *n* (%)	27 (21.4%)

Notes: [a]N=109. [b]N=118.

cardiopulmonary hospitalizations was 1.28 days shorter post-initiation of RPM but the difference was not statistically significant (6.74 ± 1.40 to 5.46 ± 1.63, P=0.097). Table 4 presents greater detail on the hospitalization endpoints.

ER Visits

All-cause ER visits decreased 44.3%, from 61 to 34. On a per-patient basis, there was a significant difference pre-initiation to post-initiation (0.48 ± 0.07 to 0.27 ± 0.09, P<0.001). Cardiopulmonary ER visits decreased 44.4%, from 36 to 20. On a per-patient basis, there was a significant difference pre-initiation to post-initiation (0.29 ± 0.05 to 0.16 ± 0.06, P=0.002).

Total outpatient pulmonary provider visits increased 13.2%, from 532 to 602. On a per-patient basis, there was a significant difference pre-initiation to post-initiation (4.22 ± 0.24 to 4.78 ± 0.28, P=0.038). The total number of prescribed steroid courses increased 3.4%, from 116 to 120. On a per-patient basis, there was a non-significant difference pre-initiation to post-initiation (0.92 ± 0.13 to 0.95 ± 0.14, P=0.589). We also observed a significant difference pre-initiation to post-initiation in the average number of steroid courses prescribed per office visit (0.17 ± 0.02 to 0.14 ± 0.02, P=0.026).

Among subjects who had at least 1 hospital admission pre-initiation of RPM, 79.4% experienced a reduction in hospitalizations, 10.8% had the same number, and 9.8% experienced an increase (Figure 4). All patients with frequent prior admissions (ie, ≥3 in the 12 months prior to enrollment) experienced a reduction after RPM was started.

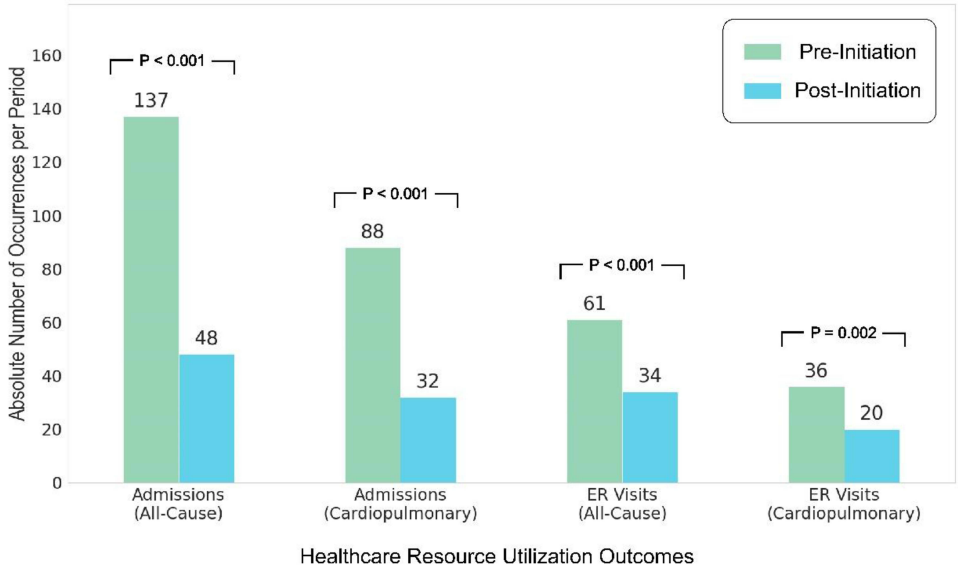

Figure 3 Healthcare resource utilization outcomes pre- to post-initiation of RPM. Each bar is labeled with the absolute number of events.

RPM Utilization

Adherence, where an adherent day was one where the sensors were worn ≥8 hours per 24 hours, among patients remained high (Figure 5) with most patients being adherent ≥90% of the 12-month post-initiation period. Adherence waned over time (Figure 6) but the overall adherence per patient was 88.6% ± 1.1% of days.

Pre-initiation of RPM, there were 532 outpatient office visits to the pulmonology practice in the cohort. There were 70 more office visits during the post-initiation period; 52 office visits occurred as a direct result of an RPM escalation. Of these, the mean time-to-visit (escalation to office visit) was 2.8 ± 0.3 days.

Discussion

While the study design and timing introduced limitations and biases, the study setting, magnitude of the effect, intervention novelty, and support for a proposed mechanism motivates future research. To our knowledge, this is one of the first real-world studies which assesses the impact of a disease management program leveraging longitudinal and passive cardiorespiratory RPM on healthcare resource utilization in a COPD cohort. Both hospitalization and ER visits

Table 3 Differences in Healthcare Utilization per Patient Pre- and Post-Initiation of RPM

Parameter	Pre-Initiation	Post-Initiation	Percent Change	*P*-value
Hospitalizations (all-cause)	1.09 ± 0.07	0.38 ± 0.06	−65.0% ± 8.9%	<0.001
Hospitalizations (all-cause) length of stay	5.77 ± 0.86[a]	5.00 ± 1.8[b]	−13.3% ± 25.3%	0.612
Hospitalizations (cardiopulmonary)	0.70 ± 0.08	0.25 ± 0.05	−63.6% ± 13.1%	<0.001
Hospitalizations (cardiopulmonary) length of stay	6.74 ± 1.40[c]	5.46 ± 1.63[d]	−19.0% ± 29.6%	0.097
ER visits (all-cause)	0.48 ± 0.07	0.27 ± 0.09	−44.3% ± 24.4%	<0.001
ER visits (cardiopulmonary)	0.29 ± 0.05	0.16 ± 0.06	−44.4% ± 27.4%	0.002
Pulmonary outpatient visits	4.22 ± 0.24	4.78 ± 0.28	13.2% ± 8.7%	0.038
Prescribed steroid courses	0.92 ± 0.13	0.95 ± 0.14	3.4% ± 20.3%	0.589

Notes: Data are presented as mean ± SE. The ± values for percent change are derived from the standard error of differences between the pre- and post-initiation groups. [a]N=78. [b]N=34. [c]N=57. [d]N=24.

Table 4 Descriptive Statistics of Hospitalizations, All-Cause and Cardiopulmonary

Parameter	Pre-Initiation	Post-Initiation	*P*-value
All-cause hospitalizations			<0.001
Mean ± SD	1.09 ± 0.07	0.38 ± 0.06	
Median (25%, 75%)	1 (1, 1)	0 (0, 1)	
Range	0–5	0–3	
Total Occurrences	137	48	
Cardiopulmonary hospitalizations			<0.001
Mean ± SD	0.70 ± 0.08	0.25 ± 0.05	
Median (25%, 75%)	1 (0, 1)	0 (0, 0)	
Range	0–5	0–3	
Total Occurrences	88	32	

were significantly lower during the intervention period (both all-cause and cardiopulmonary). It is also possible to see utilization shifts (ie, from hospital to office visits) that point to a justifiable mechanism of change. The study duration was adequate, at 24 months, to account for seasonal variation and to assess longer-term outcomes. An indication that the program was well-received is the sustained device adherence rate during the intervention period. By having subjects serve as their own control group in a pair-wise analysis, the pre- and post- groups were automatically well-matched. For these reasons, the reduction in hospitalization demonstrated in the intervention group appears to be clinically significant.

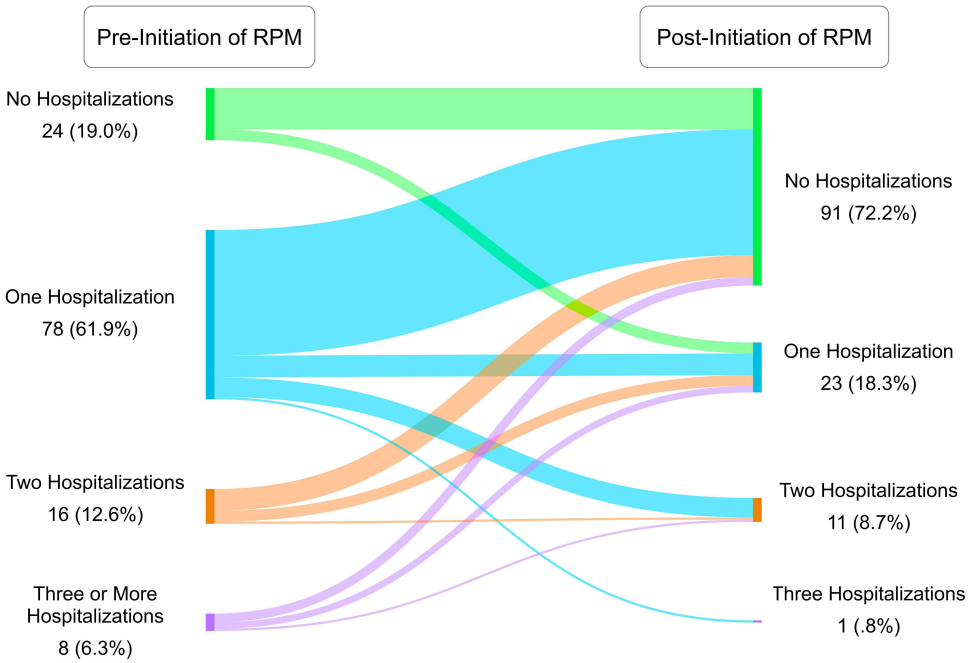

Figure 4 Sankey graph where colored bins on the left represent groups of patients who experienced 0, 1, 2, or 3+ all-cause hospitalizations pre-initiation of RPM. The ribbons represent the flow of those patients to a bin representing the number of hospitalizations they experienced in the 12 months post-initiation. The numbers indicate numbers of patients in that subgroup.

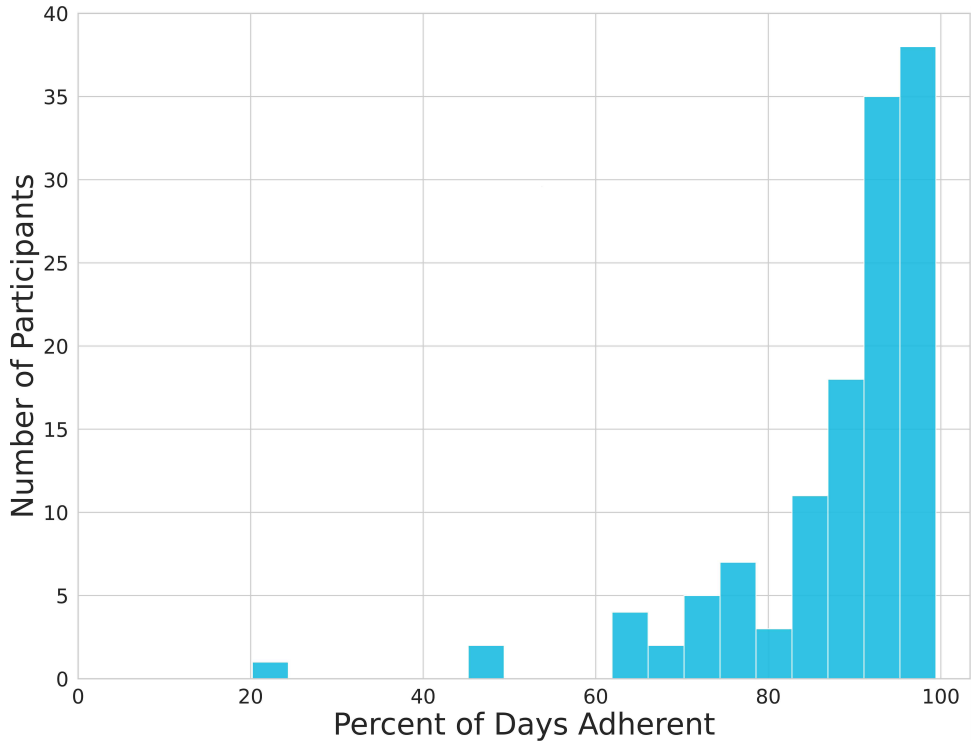

Figure 5 The mean RPM adherence values of the individual participants in the cohort across all months post-initiation of RPM.

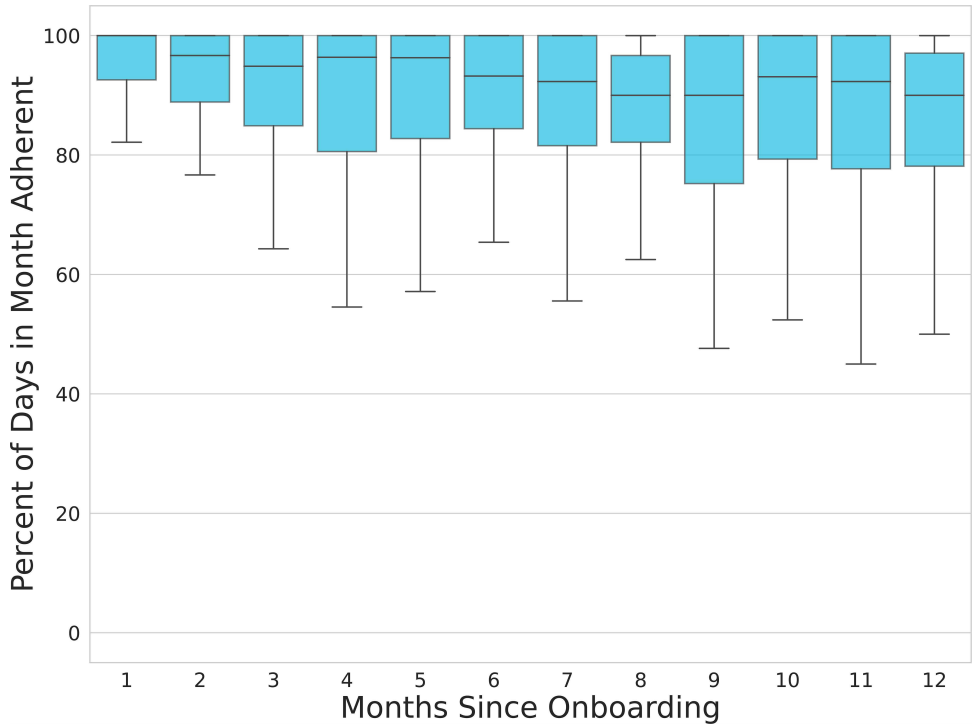

Figure 6 Boxplots showing the distribution of adherence rates to RPM for each month post-initiation. For each month, adherence is calculated as the proportion of days in which sensors were worn ≥8 hours.

The study's main finding was a significant reduction in hospitalizations associated with the initiation of RPM. The reason for this effect is likely multi-faceted. We hypothesize that RPM may have led to subjects being treated earlier for exacerbations than they may have otherwise, which has been shown to improve outcomes.[7] Proactive engagement with

subjects due to the identification of physiologic changes as well as frequent phone contact with subjects likely helped identify medical problems, COPD or otherwise, earlier and encouraged compliance with best practices, such as medication adherence. Finally, the contact and knowledge that they were being monitored likely helped subjects feel more connected to their provider, reducing anxiety[20] and easing care-seeking in the time of clinical deterioration. All these factors, individually or together, have the potential to reduce acute care visits.

Adherence of wearable RPM devices has been a concern, particularly in chronic diseases that require long-term monitoring. Yet, the participants of this study had high adherence; despite receiving no incentive other than the prospect of improved medical care, adherence to the garment-adhered devices was high, averaging ~90% per month. We attribute this in part to the device form factor, which aims to reduce burden compared to traditional wearable devices that require regular charging and maintenance.

The majority of prior research investigating remote management of COPD falls into the larger umbrella of telemedicine and telemonitoring.[21–23] These remote monitoring solutions often place a high technological burden on an aging patient population with potential barriers to care such as technology anxiety and difficulty in collecting data manually.[24,25] Furthermore, the efficacy of telehealth solutions in COPD populations has yet to be fully demonstrated and has yielded mixed results.[26] The reduction in hospitalizations we observed indicates that passive physiologic sensing may improve upon prior methods and we attribute this to its low patient burden, high adherence rates, and to the benefits of continuous monitoring of parameters directly relevant to AECOPDs (ie, respiration), which may allow for earlier detection of exacerbations.

However, the intervention at hand is not remote monitoring alone – it included low-burden and continuous physiologic monitoring, clinical monitoring, and escalation followed by timely response by providers. In support of this mechanism, we observed a significant increase in the number of pulmonary outpatient visits but not courses of steroids. On average, the duration from RPM escalation to provider visit was less than 3 days. This key point supports the conclusion that healthcare resource utilization was shifted from higher acuity (ie, hospital and ER) to lower acuity areas (ie, outpatient visits).

This study has several limitations. First, the behavioral changes exhibited by COPD patients during the COVID-19 pandemic may influence the number of events in both arms and in unknown directions and magnitudes. It has been reported that at a population level, fewer hospitalizations for AECOPD were observed during the initial phase of the pandemic.[27,28] In this study, the treatment period began after COVID-19 "lockdown" periods, with the earliest participants starting May 15, 2020 and local, state-mandated lockdowns ending May 8, 2020. Second, subjects served as their own controls and were not randomized into the intervention. This may present a selection bias of subjects who were referred and subsequently elected to enroll and remain in the intervention. Third, as a commercially available RPM service, there were insurance coverage and expense factors that may have impacted their decision to enroll, potentially introducing further selection bias. Fourth, survivorship bias[29] may have influenced the results in that only patients who remained alive and continued RPM for at least a year were included. Finally, it is possible the difference in events observed in this study could be affected in part by a regression to the mean;[30] without a randomized and contemporaneous control group, the true expected counterfactual rate of acute events in the post period is unknown.

Another limitation is that the study was conducted at a single large pulmonary practice, one with the capacity to do both in-person and telemedicine visits. Additionally, the RPM program used was well-integrated into the EHR and the practice management system. These factors allowed subjects to have rapid access to the providers and outpatient visits. It is possible other clinics would be unable to match this rapidity of service. However, given the importance of early management of AECOPDs, such early medical intervention is a primary goal of care.

The results from this study are preliminary evidence of improved clinical outcomes. The shift observed to less acute care also suggests support for earlier intervention as a proposed mechanism. This research would benefit from further validation using study designs that allow for causal inference, such as a randomized controlled trial.

Conclusion

All-cause and cardiopulmonary hospitalization rates were significantly lower in subjects started on RPM for COPD during the year after initiation when compared to the year prior. This improvement was paralleled by reductions in all-

cause and cardiopulmonary ER visits. At the same time, the number of office visits increased significantly, suggesting that RPM was redirecting care to less expensive and less burdensome settings. These results support the potential of RPM to improve the long-term management of COPD and reduce acute healthcare utilization. While the study design and timing carry limitations, including the impact of the COVID-19 pandemic, the results justify further investigation into the potential benefits of RPM for the management of COPD.

Abbreviations

COPD, chronic obstructive pulmonary disease; AECOPD, acute exacerbation of COPD; FEV1, forced expiratory volume in the first second; RPM, remote patient monitoring; EMR, electronic medical record; CL, clinical liaison; brpm, breaths per minute; bpm, beats per minute; KS, Kolmogorov–Smirnov.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis, and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Neema Moraveji, Ashley Hendricks, Richard Murray, and Robert K Teresi are employees of Spire Health. In addition, Neema Moraveji has a patent (system for physiological monitoring) issued to Spire Health. Richard Murray is currently the Board Chair of the Asthma and Allergy Foundation of America (AAFA). Michael Polsky receives financial support from Spire Health. Diego J Maselli reports personal fees from GSK, AstraZeneca, Sanofi/Regeneron, and Amgen, outside the submitted work. The authors have no other conflicts of interest to disclose for this work.

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