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TITLE: Evaluation of Telemedicine Spirometry Testing for Veterans with ALS (E-TEST VA)

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14. ABSTRACT

Background: Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative condition characterized by weakness of skeletal muscles, including the diaphragm which is responsible for breathing. The effect of this weakness on decreasing lung function is evaluated every 3 months following the diagnosis of ALS with serial breathing tests (spirometry), conducted at clinic visits. Policies adopted by the Veterans Health Administration (VHA) and local governments during the COVID-19 pandemic limited the ability to provide routine in-person evaluation and testing. To continue serving patients, VA and non-VA ALS clinics expanded the use of video telehealth visits to maintain continuity. Additionally, some clinics have been able to take advantage of telehealth spirometry devices to monitor patient lung function remotely. We sought to evaluate the quality of tests produced, patient and provider satisfaction, and costs/savings of using these devices among patients with ALS in order to better understand patient and provider opinions regarding telehealth and determine if this would be an appropriate form of telehealth to integrate into ongoing ALS care following the pandemic.

Methods: We are currently conducting a prospective mixed methods study at two ALS multidisciplinary clinics located at Rocky Mountain Regional VA in Denver, Colorado and VA Puget Sound in Seattle, Washington. After enrollment patients perform three spirometry tests, one in clinic (standard of care), one study with the portable spirometer supervised by study staff, and a final portable spirometer study that is unsupervised. The study was designed to minimize impact on patient care, as both sites were already performing in-facility and supervised home spirometry. Patients also complete a survey outlining costs related to transportation and testing as well as satisfaction with the spirometer device and tolerance of uncertain results produced by the device. Providers in both clinics, involved in performing or interpreting these tests are being interviewed about their experience with the device as well. Finally, we are performing a cost-consequence analysis to model local and national costs of program implementation using survey results and VA administrative data.

Results: We are completing data collection from the 45 patients that are enrolled in the study. Additionally, we are completing data analysis for the six staff qualitative interviews and costing information collected for Aim 3. Finally, we have been approved for a No Cost Extension to allow for adequate time to finish collecting Veteran spirometry, survey, and interview results. Thirteen patients are completely done with all parts of the study. Five patients have completed all parts of the study that they are able/willing to do. Twenty-two patients are still being followed by the study team. Five patients are considered lost to follow-up. More details on enrollment and study progress can be found below in Diagram 1 (pg.10).

Conclusions: Preliminary data analysis of the staff qualitative data has shown some of the following themes: most patients with ALS were able to use the device independently or with assistance from their home caregiver; both VA medical centers (VAMCs) were able to problem solve with patients to send results to the clinic; providers felt that spirometry tests were accurate and reliable and could reduce the burden of equipment maintenance, testing, and in-person clinic time; concerning results were evaluated in clinic and patients received appropriate follow-up treatment as indicated. As part of preliminary data analysis of the cost-consequence analysis, we have completed an inventory and process maps to identify the different resources and related costs to the VA healthcare system of three testing modalities: 1. Remote without supervision, 2. Remote with supervision, and 3. In-person at a VA clinical facility. Further, the team has identified that remote testing may reduce barriers for completing quarterly pulmonary function tests (PFTs), due to the incremental travel costs (e.g., special transportation needs and caregiver time) entailed if ALS patients visit VA clinics specifically for this assessment. Estimates of the current level of testing and related costs vs. the expected costs of testing to meet higher testing frequency recommendations for all VA ALS under the three modalities is in progress. Data analysis for the spirometry results and Veteran survey has yet to be started. Qualitative analysis is ongoing as data collection continues. Staff qualitative data will be triangulated with Veteran interviews to explore convergence and divergence across themes.

15. SUBJECT TERMS None listed.

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1. Introduction

Amyotrophic lateral sclerosis (ALS) is a progressive neurodegenerative condition characterized by skeletal muscle weakness and loss of function that is due to loss of upper and lower motor neurons throughout the central nervous system. While around 10% of cases may be inherited in an autosomal dominant pattern, the remaining 90% are classified as sporadic in onset with an unclear etiology. For unknown reasons, the incidence of ALS in the Veteran population exceeds that of those without military service, leading to the Department of Veterans Affairs to classify it as a fully service-related condition. The most common type of onset is “Non-Bulbar” with focal distal muscle weakness, dyscoordination, or atrophy which then spreads to involve more diffuse muscle groups. The less common type, occurring in about 30% of cases, presents predominantly with changes in voice, speech clarity, or swallow function and is termed “Bulbar onset.”¹ Due to the heterogeneity of presentation, patients typically experience symptoms for 9-24 months prior to the time of diagnosis. While most patients live for 20-48 months following diagnosis, the disease trajectory varies substantially from one individual to another.²⁻⁴ Progressive deterioration of the respiratory system primarily due to increasing diaphragm paralysis is often one of the most troubling and burdensome symptoms for patients with ALS and their caregivers.^{5,6} Eventually, pneumonia and respiratory failure are responsible for up to 80% of deaths among patients with ALS.^{7,8} A recent study suggests three separate phenotypes of respiratory decline in ALS: Slow progressor, Rapid progressor, and Stable low.⁹ Rapid progressors (40% of patients with ALS) have normal pulmonary function at the time of diagnosis but decline to 50% predicted within 18 months. Slow progressors (15%) have normal function at the time of diagnosis and maintain normal pulmonary function for at least 3 years. Stable low patients (45%) have abnormally low pulmonary function at the time of diagnosis and see only modest declines in the following 3 years. Failure to recognize rapid trajectories of decline in functional status and respiratory disease experienced by different patients can lead to delays in initiating therapies if using regularly scheduled (e.g., quarterly) clinical assessments.⁹ These delays in care can expose patients to unnecessary risk of disease progression or complication.

The management of ALS is predominantly supportive, with few medications and interventions that can affect outcome. However, non-invasive positive pressure ventilation (NIV) and airway clearance and lung expansion with a cough assist device (CAD) can decrease the rate of lung function decline, the risk of pneumonia, and can improve quality of life among individuals with ALS.¹⁰⁻¹² When used > 4 hours per day, NIV can even provide survival benefits, particularly in patients with non-bulbar onset disease who experience shortness of breath when lying flat (orthopnea) or have daytime elevation in carbon dioxide (hypercapnia).^{10,13,14} CAD and NIV therapies are initiated for patients with ALS once their lung function declines below a pre-determined threshold that suggests their respiratory muscles have been significantly affected by ALS.^{10,12} Lung function is typically monitored every 1.5-3 months following the diagnosis of ALS with serial breathing maneuvers called spirometry, conducted at clinic visits. These maneuvers are performed into an airflow transduction device called a spirometer, that measures a volume of exhaled air known as a forced vital capacity (FVC). A FVC that is measured to be below 80% of a predicted value, generated using patient age, height, gender and race is considered abnormal.^{10,15,16} In our Multidisciplinary ALS clinic (MDC) at the Rocky Mountain Regional VA Medical Center (RMR VAMC), patients are initiated on NIV and CAD once respiratory muscle function is abnormally weak (defined by FVC<80% predicted). This practice is based on a review of current evidence rather than current payer requirements of the Centers for Medicare and Medicaid Services (FVC <50% predicted) which drive care decisions for patients receiving care outside of the VA system. Earlier initiation (as judged by FVC) of NIV can improve adherence to this therapy in ALS, further supporting the importance of a serial spirometry monitoring program.^{17,18}

Policies adopted by the VA and local governments during the COVID-19 pandemic limited the ability to provide routine in-person evaluation and testing. In response, there has been greatly expanded use of alternate means evaluation including video conference and telehealth services, which are being used about 18 times more frequently in the VA system now than in the spring of 2020.¹⁹ However, these types of visits do not typically allow for diagnostic testing such as spirometry. In addition, aerosol generating procedures such as spirometry currently require an extra trip to the medical center to perform COVID-19 PCR testing several days before the MDC visit. As regular interval spirometry testing is important for patients with ALS to help determine trend, prognosis, and need for expansion of therapies, this inability to provide testing represents a disservice to this population.²⁰

Although patients with ALS and their caregivers greatly appreciate the convenience of MDCs, concerns about travel still exist, usually centered around geography, weather, and mobility.²¹ While in-person evaluation remains essential periodically for occupational, physical, and respiratory therapy evaluation, our ALS clinics have expanded use of video visits to increase access to care and reduce travel burden for our patients with ALS when able. We have also purchased telehealth portable spirometer devices that can interface with a patient's smartphone or tablet and upload pulmonary function test results to the cloud for clinicians to retrieve and review. The Spirobank Smart Spirometer we have employed claims to be the "simplest device for cost effective spirometry" and has a user-friendly application with real-time results. The device meets International Organization for Standardization (ISO) 26782, the standards that all facility-based spirometers must meet, as well as the American Thoracic Society/European Respiratory Society (ATS/ERS) 2019 spirometry guidelines for volume measurement. A report is generated with acceptability grading, flow volume loops, and a diagram showing the results in relation to lower limits of normal.²² We have been providing these to most patients, regardless of pulmonary symptoms or prior pulmonary function test results and have been asking them to perform maneuvers every 8-10 weeks or with any change in symptoms. The results are stored on the patient's smartphone or tablet and remain available for their own review of their trend over time. Pulmonary providers have been reviewing these test results to evaluate disease trajectory and determine an appropriate time to initiate NIV and cough assist. However, it remains unclear if these results are accurate and reliable in the ALS population without telehealth coaching or support. In patients with motor neuron disease, remote spirometry has been demonstrated to be sensitive and specific to detect FVC values less than 50% predicted when coached in real time via video telehealth with a respiratory therapist.²³ However this same study found that the sensitivity is lower when using the higher values (FVC > 80%) that are used for prescription of NIV in our and other VA MDCs, which likely confer more patient benefit and are more patient centered. Additionally, it is not known how accurate these devices measure forced vital capacity when not consistently coached in real time with a respiratory therapist, or whether performance of this testing modality is associated with patient demographics, social determinants of health, or functional status (as measured by the ALS Functional Rating Scale [ALSFRS-R]).²⁴

Patients with other pulmonary conditions, not resulting from neuromuscular weakness have demonstrated both the capacity to produce highly reliable tests and to be satisfied with the technology, however findings from these prior studies suggest that a tailored approach to re-training and troubleshooting is needed. Among patients with Idiopathic Pulmonary Fibrosis (IPF), a disease commonly manifesting declines in FVC over time, daily non-monitored home spirometry was found to correlate with values obtained in hospital or clinic settings. The resultant rate of decline was highly informative of prognostic factors including mortality and other outcomes.²⁵ A more recent and larger study of patients with IPF confirmed correlation between at-home and clinic-measured FVC values, but estimation of the rate of FVC decline was less reliable when measured at home.²⁶ A study in patients with asthma using a mobile spirometry system showed that while an initial training session on the proper performance of spirometry was adequate for many patients, around 1/3rd of their population required retraining to achieve reliable, reproducible results. Satisfaction with the portable spirometer used was high with 90% rating it useful and user-friendly.²⁷

These data suggest a home spirometry program for patients with ALS is feasible. We hypothesize that patients will prefer home spirometry compared with scheduled in-facility testing as this will provide patients and their providers with greater awareness of their disease progression without requiring the complicated arrangements and physical discomfort required to travel to urban clinics or medical centers. Additionally, as there are often long travel distances to receive standard in-facility spirometry, initiation of a home-based intervention in this cohort has great potential to decrease costs.

Significance:

Our proposed evaluation will characterize the accuracy, patient satisfaction and costs of a home-based spirometry program compared to gold-standard spirometry. This information will allow key-stakeholders in Veterans Health Administration and non-VA health systems to evaluate wider implementation of home spirometry programs for ALS centers – beyond the two Veterans Health Administration "hub" sites in Denver and Seattle.

Veterans are more likely to be diagnosed with ALS than patients who never served in the military. As we are a large Veterans Affairs facility with a relatively large population of patients diagnosed with ALS, we are well suited to provide multidisciplinary care to these patients with community support and frequent follow

up to allow for successful implementation and evaluation of this program. If successful, collaboration within our network of ALS providers in the VA system could lead to the ability to implement such a program on a larger scale to help the largest single population of ALS patients in the United States. Demonstration of a successful program in our health system has the potential to inform changes in care for other large health systems and among healthcare payers including Medicare.

Additionally, we anticipate that patient advocacy groups such as the ALS Association (ALSA) who we meet with regularly to discuss individual patients in our multidisciplinary clinics, will be interested in disseminating findings of our study whether supporting home spirometry or not. ALSA representatives frequently visit the clinics of ALS providers and have many resources available to patients who have the disease. Regardless of findings, the work proposed in this study will add to the discussion of high-quality, patient- centered, and home-based care for ALS during the ongoing COVID-19 pandemic and well beyond.

Knowledge to be Gained:

This research will evaluate home spirometry as a useful tool in decentralizing high- quality multidisciplinary ALS care from urban medical centers to the patient's home. Spirometry is a necessary procedure to characterize disease progression and facilitate shared decision-making with patient's regarding initiation of non-invasive ventilation therapies, feeding-tube placement, and advance care planning. However, it may not be necessary to require that patients travel substantial distances and with great deal of physical, mental, emotional, and financial costs to undergo this testing. Additionally, providing patients with spirometry testing equipment will allow them to perform tests whenever they feel like there has been a change in their symptoms or quality of life. This could lead to earlier identification of a clinically important change that could be addressed by their providers. This is important because breathing difficulties create a large amount of suffering in patients with ALS. Multiple therapies are available to relieve this suffering, once identified, including cough assist or non-invasive ventilation, to improve clearance of secretions and ease of breathing, respectively. The trend of spirometry may have impacts on prognosis estimates and may improve urgency of, and timing to, discussion and completion of advanced directives to be sure our patient's wishes are honored.

2. Keywords

Veterans Health Administration, Amyotrophic lateral sclerosis (ALS), telehealth, pulmonary function test, lung function, cost-effectiveness, mixed-methods

3. Accomplishments

What were the major goals of the project?

We have adjusted the timeline in the table below to include the no-cost extension year.

Specific Aims 1-3 – Preparation and Enrollment	Timeline	Task completion	Date task completed/ Date anticipated being finished
	Months	%	
Major Task 1: Study Preparation			
Refine eligibility criteria, exclusion criteria, screening protocol	0-1	100	5/26/2022
Finalize consent form & human subjects protocol	0-1	100	5/26/2022
Coordinate with Sites for COMIRB and VA Puget Sound Health Care System institutional review board (IRB) review	1-3	100	8/24/2022
Submit amendments, adverse events and protocol deviations as needed	As Needed	Ongoing	<i>Ongoing until end of study</i>
Coordinate with sites for annual IRB report for	Annually	Ongoing	<i>Ongoing until end of</i>

continuing review			<i>study</i>
<i>Milestone Achieved: Local IRB approval at RMR VAMC and Seattle VAMC (SVAMC)</i>	3	100	8/24/2022
Formalize list of existing Denver-Seattle Center of Innovation (COIN) staff to be paid with study funds	0-3	100	4/19/2022
Orient staff on roles in the project. All staff will be existing COIN staff, no new hires	0-3	100	9/20/2022
<i>Milestone Achieved: Research staff identified and oriented</i>	3	100	9/20/2022
Major Task 2: Patient Enrollment			
Identify all patients currently receiving care in RMR VAMC and SVAMC ALS MDCs (n=90-100)	3-4	100	3/1/2023
Discuss study with patients during quarterly MDC visit and obtain approval to consent	3-6	100	11/07/2023
Consent existing patients for study	3-8	100	11/07/2023
Ongoing coordination with clinic to identify newly diagnosed patients (n=0-20)	3-18	100	11/1/2023
Ongoing consent of newly diagnosed patients	3-18	100	11/07/2023
<i>Milestone Achieved: All patients enrolled in study</i>	18	100	12/15/2023
Specific Aim 1: Evaluate overall test performance characteristics of unsupervised home-based spirometry compared with in-laboratory testing and evaluate patient and disease characteristics associated with testing quality			
Major Task 3: Patients Trained on Spirometry Device			
Patients contacted, during study enrollment to determine if they have a working home spirometry device.	3-18	100	11/07/2023
Patients without working device are provided with home spirometer device	3-18	100	12/1/2023
All patients will receive a one-time training from a respiratory therapist on correct use	3-18	99	<i>Ongoing</i>
Repeat process for newly diagnosed patients	3-24	99	<i>Ongoing</i>
<i>Milestone Achieved: All patients trained on correct device use</i>	24	99	<i>Ongoing</i>
Major Task 4: Complete Study Spirometry			
Confirm in-facility spirometry during ALS MDC clinic as part of standard care or within 3 months of study enrollment if not planned during MDC visit.	3-24	82	<i>Ongoing</i>
Complete in-facility spirometry	3-24	82	<i>Ongoing</i>
Schedule date and time for home testing, within 30 days of in-facility test	3-24	91	<i>Ongoing</i>
Patients perform home spirometry test on scheduled day	3-24	91	<i>Ongoing</i>
Confirm test information successfully uploaded to telehealth platform	3-24	91	<i>Ongoing</i>
Complete spirometry studies for newly diagnosed patients	3-24	91	<i>Ongoing</i>
<i>Milestone Achieved: All patients complete home and in-facility spirometry</i>	24	91	<i>Ongoing</i>
Major Task 5: Evaluate Spirometry Studies			
Abstract test results to study form to standardize appearance	3-25	91	<i>Ongoing</i>
Review and score batched study spirometries	6, 9, 12,	91	<i>Ongoing</i>

for all existing patients	18, 25		
Review studies for newly diagnosed patients	9, 12, 18, 25	91	Ongoing
<i>Milestone Achieved: All spirometries will be evaluated for test quality</i>	25	91	Ongoing with goal of completing in February
Major Task 6: Additional Data Acquisition and Analysis			
Patients are contacted to complete ALSFRS-R and DALS-15	3-24	91	Ongoing
Comorbidities and demographics identified through CDW	3-24	91	Ongoing
Create and evaluate regression models to evaluate test quality once data collection complete	25-29	0	Not yet started
<i>Milestone achieved: Data collection and analysis complete</i>	33	75	Ongoing
Major Task 7: Interview Patients			
Finalize patient and provider interview guides	1-3	100	2/21/2022
Patients will complete initial survey	3-25	91	Ongoing
Identify patients for interviews	6-30	100	12/1/2023
Identify RT and nursing staff for interviews	3-9	100	2/13/2023
Conduct initial interviews with patients and staff	6-30	65	Ongoing
Conduct 6 month follow up surveys with patients with fewer than 6 months of experience at time of enrollment	9-30	62	Ongoing
<i>Milestone Achieved: Data collection completed</i>	30	62	Ongoing
Major Task 8: Qualitative Data Analysis			
Initial independent coding	9-30	60	Ongoing
Establish team coding consensus	11-30	75	Ongoing
Subsequent coding of all interviews including identification of themes	13-30	60	Ongoing
Summarize themes and characterize thematic differences between subgroups	20-32	60	Ongoing
Write manuscript and disseminate to stakeholders	22-36	25	Ongoing
<i>Milestone Achieved: Data analysis completed</i>	36	25	Ongoing
Specific Aim 3 – Conduct a cost-consequence analysis of a home-based pulmonary function testing program for patients with ALS as compared with in laboratory testing program in the VA health care system.			
Major Task 9: Cost Data Collection and Analysis			
Confirm costs of all components of in-facility pulmonary function testing	18-26	80	Ongoing
Confirm cost of staff time spent performing tests and supporting patients with home devices	18-22	100	12/1/2023
Identify number of smart devices and types provided to patients for use of home spirometers	18-22	100	12/1/2023
Identify common travel modalities for in-person MDC visits and/or in-facility spirometry tests	18-26	91	Ongoing
Abstract charts to identify consequence costs	18-26	90	Ongoing
Create national dataset to estimate system wide costs and consequences of expanding home spirometry	18-22	100	12/1/2023
Summarize data and perform analysis	21-26	80	Ongoing
Major Task 10: Disseminate to key	27	30	Ongoing

stakeholders and operations partners			
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What was accomplished under these goals?

Major Task 1: Study preparation

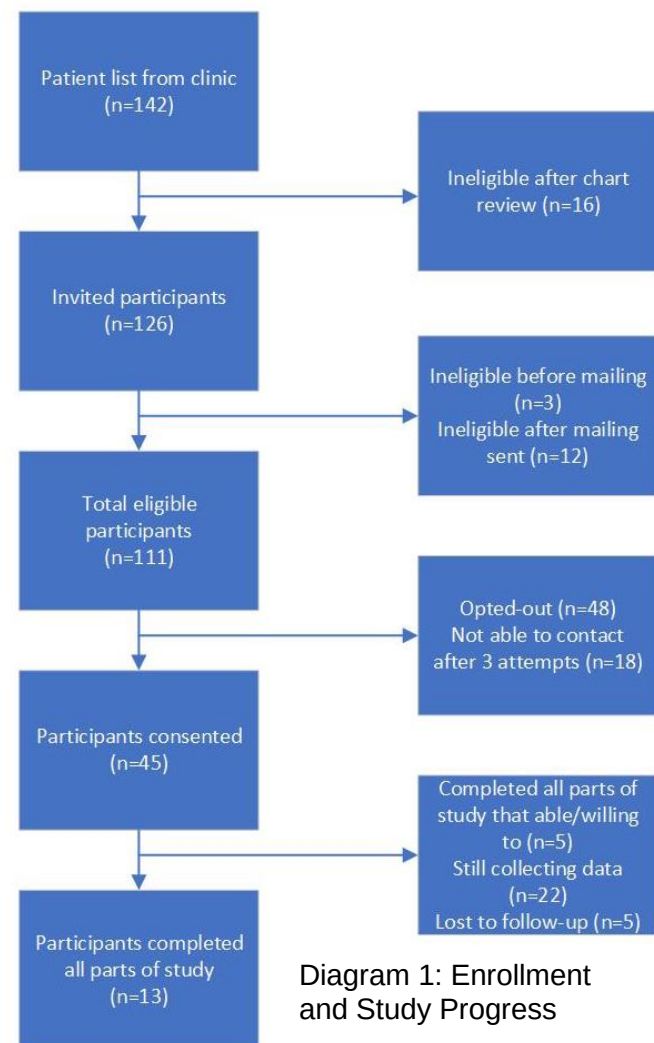
As previously reported, we received all our final approvals to begin the study at Rocky Mountain Regional (RMR) Veterans Administration Medical Center (VAMC) on 7/20/2022. We received final approvals from Puget Sound VAMC on 8/11/2022. Final approval from HRPO was granted on 9/14/2022. Union approval was given on 09/26/2022 which was the final approval needed to begin participant recruitment.

Since the last annual report, the study was approved for continuation by Colorado Multiple Institutional Review Board (COMIRB) and RMR Research & Development (R&D) on 04/25/2023. Puget Sound did not require any ongoing continuing review processes. OHRO continuing review was approved 04/26/2023. The next continuing review period will be before 04/24/2024. The study team is currently preparing the required documents.

Major Task 2: Patient enrollment

As previously reported, initial enrollment began in October 2023, and we had approximately 22 patients we were actively following, with at least 55 more patients that needed to be mailed an invite. No patients had completed the study. Recruitment had been delayed initially due to delays with receiving regulatory approvals as well as a higher number of opt outs than anticipated.

Currently we have completed all recruitment efforts for the study to allow appropriate time to collect and analysis study data. Diagram 1 provides a complete breakdown of participant enrollment and progress within the study. We ended the study having mailed to 126 patients that were believed to be eligible to participate in the study. Three of those participants ended up not actually being eligible and unanticipated problems were submitted to COMIRB and R&D at continuing review. Twelve patients became ineligible after the initial mailing. Common reasons were that they had passed away after eligibility review was done; that they were not planning to continue care at either RMR or Puget Sound ALS clinics; or that they were in the process of getting a trach. Of those mailed, 45 patients were consented into the study. As of 1/1/2023, 22 of the 45 patients consented were still having data collected from them. Thirteen patients have completed all parts of the study. Five patients have completed all parts of the study that they were willing/able to do. Primary reasons that patients have not been able to complete all parts: they declined one or more parts of the study, they had a serious decline in health after consent, or they passed away after consent. Five patients have been considered lost to follow-up because at some point after the consent visit the study team has been unable to contact them despite the above reasons.



Overall, the number of study participants was lower than originally anticipated. As reported previously this was due to a higher than anticipated opt out rate. Reasons for potential participants to opt out continued to be that they were too worn out from keeping up with ALS care; no longer doing spirometry; live too far from a medical facility that can do spirometry; and having too many complications from other illnesses. For future studies we will plan to offer participation incentives (e.g., gift cards) and engage with partner community organizations (e.g., the ALS Association or ALS United) to improve likelihood of participation.

Major Task 3: Patients Trained on Spirometry Device

During the last reporting period, we had determined only those that had not done spirometry with a handheld device in the last 6 months needed an orientation visit. Fifteen participants in the study received an orientation. Only one study participant still needs this orientation. We anticipate this will be done before February 2024.

Major Task 4: Complete Study Spirometry

As of the last reporting period only 3 participants had completed all tasks related to spirometry. 3 participants had completed a part of the spirometry tasks. Eight participants had spirometry scheduled. Four participants were waiting to be scheduled for their regular ALS appointments which included an in-facility spirometry. The study team had been working through the best way to schedule and get spirometry results.

As of 1/1/2024, 34 participants have completed all tasks related to spirometry. Five participants have completed a part of the spirometry tasks. Three patients still need to have spirometry scheduled which we anticipate will be scheduled in January 2024 and completed by March 2024. 3 participants have no spirometry results due to only completing the survey and interview part or because they were lost to follow-up before any spirometry tests were completed.

Major Task 5: Evaluate Spirometry Studies

As of the last reporting period, only one batch of spirometries had been deidentified and sent to Dr. Borg to be graded. Dr. Borg had not yet returned them with grades.

Currently, Dr. Borg has only one batch of spirometry left to grade which will be done after all spirometry tests have been collected. We anticipate all spirometry will be graded by mid-March of 2024. During this reporting timeline, the study team made changes to how spirometry quality was graded. Drs. Griffith and Graustein worked together to develop a scale for grading the FVC, FEV1, and flow volume loop (FVL) quality. Grading for the FVC and FEV1 followed the suggested grading scale set-up by the American Thoracic Society (ATS) standards. They also implemented a scale for the FVL to capture additional information about acceptability of test quality when an insufficient number (<3) of maneuvers were completed, as ATS standards only apply when all three tests are available.

Major Task 6: Additional Data Acquisition and Analysis

Previously in the last report, we were collecting the ALSFRS-R score and DALS-15 score for all participants within 30 days of in-facility spirometry completion. We also were developing code to identify comorbidities from the Corporate Data Warehouse (CDW) and beginning chart abstraction.

As of 1/1/2024, 40 participants have ALSFRS-R scores abstracted and 39 participants have DALS-15 scores abstracted. Some ALSFRS-R scores are missing because they weren't or haven't been collected yet clinically. DALS-15 scores will be collected once spirometry tests are collected unless participant declines to answer questions.

As of 1/1/2024, the study's programmer has been working on creating a new dataset of comorbidities for all the participants in the cohort, as well as all other Veterans treated in the VA system with ALS. We created a similar dataset in May 2023 and presented our analysis of these at two conferences: Academy Health Annual Research Meeting in Seattle, WA in June 2023 and VA Research Day in Denver, CO in September 2023. The new dataset increased specificity of our inclusion criteria as, after conducting individual chart review audits of included patients, we determined some patients included in the original cohort were only seen a single time for ALS evaluation and were not ultimately diagnosed with ALS. Results of this updated evaluation are currently submitted for presentation at the 2024 Annual Meeting of the American Academy of Neurology.

Major Task 7: Complete Patient Surveys and Interviews

Previously in the last report, we had not started doing any patient interviews but were working on refining the interview guide and process. We had completed all the staff interviews but hadn't started analysis.

As of 1/1/2024, we have collected 39 initial patient surveys, 17 six-month follow-up surveys, and 14 patient interviews. We have implemented different methods of data collection related to the patient interviews to allow them to be more inclusive. This includes sending the questions beforehand to participants in an electronic survey. We have found that this has helped to cut down on time needed for the actual interview. We anticipate completing all the initial patient surveys by mid-February of 2024. Six-month follow-up surveys and patient interviews will be collected into the no cost extension period. We anticipate that all data will be collected by August 2024.

Major Task 8: Qualitative Data Analysis

Previously reported, the qualitative team had an analytic plan for the staff interviews and was working on looking at manuscript and abstract options.

Since the last reporting period, we have done preliminary analysis on all the collected staff interviews (n=6), submitted abstracts about this data to four different conferences, and presented a national Cyberseminar about qualitative methods used in this project. For the staff interviews, we were interested specifically in talking with staff that worked primarily with patients with ALS for their respiratory care. Six staff members agreed to participate out of the eight that were eligible between the two VAMCs. Using Atlas.ti 22, the qualitative staff performed data analysis by coding all six staff interviews independently and then finalizing coding through team consensus. Overarching themes that emerged from the data were: respiratory therapists (RTs) facilitated appropriate telehealth spirometry use by extensively training patients and caregivers in-person and/or through telehealth, and on an ongoing basis as needed; most patients with ALS were able to use the device independently or with assistance from their home caregiver; both VAMCs were able to problem solve with patients to send results in time for their in-person appointments; providers felt that spirometry tests were accurate and reliable and could reduce the burden of equipment maintenance, testing, and in-person clinic time; and concerning results were evaluated in clinic and patients received appropriate follow-up treatment as indicated. Abstracts on these findings were submitted and accepted for poster presentations at: Academy Health's Annual Research Meeting, Colorado Pragmatic Research in Health conference, Rocky Mountain Regional VA Research Day, and American Association of Respiratory Care Congress meeting. Additionally, the qualitative team with the help of a speech language pathologist, presented a Cyberseminar focused on how to adapt qualitative interviews to individuals with dysarthria. This Cyberseminar was presented national through the Health Science Research and Development (HSR&D) platform and had more than 150 attendees.

Additionally, the qualitative staff have started coding for the Veteran interviews that have already been collected and transcribed. Future analysis of staff qualitative data will include triangulating findings with Veteran interviews. *A priori* codes have been selected to focus on key aspects of Veteran experience for triangulation as well as building new themes from the analysis. Manuscripts are planned to disseminate these findings including topics such as uncertainty around telehealth spirometry, communication with people with speech difficulties, and convergent, divergent, and points of tension in themes across and within staff and Veteran interviews.

Major Task 9: Cost Data Collection and Analysis

As previously reported, the study team had been working on developing code to abstract cost variables from CDW data to determine appropriateness and costs of expanding this program nationally in the VA system. The team had also used chart abstraction to help identify needed variables and process mapping.

Since the last reporting period, the study team has completed process mapping and has identified most costing variables through either CDW pulls or chart abstraction. This process took several iterations to refine exactly what variables are best to describe what the team was looking for and the best timelines to focus on. The study team under the guidance of Dr. Radcliff, who is an experienced health economist, is in the final stages of consolidating costing data and completing the cost analysis. An initial finding thus far is that remote testing may reduce barriers for completing quarterly pulmonary function tests (PFTs), due to the incremental travel costs (e.g., special transportation needs and caregiver time) entailed if ALS patients visit VA clinics specifically for this assessment. The team also has begun drafting an outline of a manuscript that we hope to submit for publishing around April or May.

Major Task 10: Disseminate to Key Stakeholders and Operations Partners

Previously reported was that the study team had been talking with additional ALS clinics about potential involvement in this research study as well as the study team submitting three abstracts to upcoming conferences.

Since the last reporting period, the study team determined that it was not feasible with the time left in the study to add additional sites to boost recruitment. However, discussions with other ALS clinics are continuing to discuss opportunities around new research proposals related to telespirometry for ALS patients. All three abstracts previously mentioned were accepted for poster presentations and were presented at the respective conferences by study staff. An additional two abstracts were submitted, selected and presented as posters at VA Research Day and one other abstract was selected but not presented at the American Association of Respiratory Care Congress meeting. As previously mentioned above under the qualitative data

analysis section, the study team presented a national Cyberseminar focused on how to adapt qualitative interviews to individuals with dysarthria.

Currently the study team is working on submitting an abstract to the American Academy of Neurology meeting that will be held in April 2024. Additionally, the study team has outlined multiple manuscripts to disseminate findings. We are currently focusing on two manuscripts while awaiting completion of data collection. One is derived from our cost analysis being performed for Aim 3 and one will disseminate our lessons learned about qualitative data collection and analysis methods when conducting research with patients who suffer from difficulty speaking clearly, known as dysarthria.

Conclusion: Our major accomplishments this reporting period have been completing recruitment efforts and most of the initial data collection, completing the staff qualitative interview preliminary analysis, completing most of the cost analysis data collection through data pulls from CDW, and the multiple poster presentations and the Cyberseminar that were disseminated.

What opportunities for training and professional development has the project provided?

- This project has provided training for multiple new research staff and created an opportunity to provide training to qualitative researchers across the VA system. During this reporting period, the study was selected as a good orientation opportunity for two new VA research staff members at the Rocky Mountain Regional VA Medical Center - a biostatistician and programmer. Additionally, our study PI, qualitative methodologist and qualitative analysis conducted a national VA Cyberseminar training for VA qualitative analysts and methodologists on how to engage individuals with dysarthria in qualitative work and evaluate data collected from these individuals.

How were the results disseminated to communities of interest?

- As previously reported we disseminated the preliminary results of this study at Academy Health, the largest health services research conference; Colorado Pragmatic Research in Health Conference, a national conference for clinical, translational, and public health research audiences; Rocky Mountain Regional VA Research Day, local presentation of ongoing research happening at the medical center that allows Veterans and local staff to see results; and HSR&D Cyberseminar; a series hosted by the Qualitative Methods Learning Collaborative ([I'm not drunk, I'm not stupid, it's ALS!: How to Include People with Speech Limitations in... \(va.gov\)](#)). Finally, we have presented our results on multiple occasions to local ALS Association leadership through quarterly care collaboration conferences held at RMR VAMC – answering questions and identifying opportunities for local dissemination.

What do you plan to do during the next reporting period to accomplish goals?

- Aim 1:
 - Complete initial data collection from consented patients
 - Complete data analysis of spirometry data
 - Disseminate results through abstracts and papers
- Aim 2:
 - Complete Veteran interviews and 6-month surveys
 - Analyze Veteran interviews and surveys
 - Disseminate results through abstracts and papers
- Aim 3:
 - Refine completed data pull for any last cost variables
 - Complete analysis of cost data
 - Disseminate results through abstracts and papers

4. Impact

What was the impact on the development of the principal discipline(s) of the project?

- Pulmonary providers caring for patients with ALS and other neuromuscular diseases will have data regarding the accuracy of home testing with and without technician supervision. Along with patient preference and cost data, this service could be rapidly expanded among appropriate patients, adding an effective, patient-centered and cost-effective tool in caring for these complex patients.

What was the impact on other disciplines?

- Findings of this study will have applicability, particularly related to cost and patient preferences relevant to the expansion of other telehealth services among patients with severe functional limitation. Additionally, our evaluation of chronic comorbidities suffered by individuals with ALS will have the potential to inform adaptation of American Academy of Neurology guidelines that outline ideal multidisciplinary care for people with ALS. Beyond individuals with the specific diagnosis of ALS, we anticipate that our findings will also push for the inclusion of people with communication (e.g., dysarthria) and functional limitations (e.g., paralysis) in development of guidelines for chronic conditions managed by specialties other than pulmonary medicine.

What was the impact on technology transfer?

- Nothing to report

What was the impact on society beyond science and technology?

- We hope that by publishing and disseminating research related to ALS we will increase awareness of this disease and hope for patients, beyond the VA, living with this disease.

5. Changes/Problems

Changes in approach and reasons for change

- Amendments 1 through 6 in Table 1 and 1 in Table 2 have been previously reported during the last annual report. Since the last reporting period, only minor amendments have been made to the original protocol at the Denver location and none have been made in Seattle. These amendments were approved by Colorado Multiple Institutional Review Board (COMIRB) and the Rocky Mountain Regional (RMR) VA's Research and Development Committee or by Puget Sound Institutional Review Board and Research & Development Committee.

Table 1: Amendments submitted to COMIRB and RMR Research and Development Committee

Amendment number	Approval date (COMIRB/R&D)	Reason for amendment
1	8/5/2022 8/9/2022	This amendment was to adapt study to be more in line with clinical practice and additional needs that were learned after the initial submission. For example, making orientation to the Spirobank spirometer optional if done guided spirometry with a respiratory therapist for clinical care in last 6 months. Also added multiple recruitment or contact documents that were not initially submitted due to oversight such as a study completion letter or email with instructions on collecting electronic consent.
2	8/29/2022 9/15/2022	This amendment included updating study documents with the new study phone number. As well as, strengthening the effectiveness of the cost analysis by adding data components being collected to include a national data set. Additional data was also identified as being useful for cost analysis such as encounter data related to ALS care. Finally outlined changes to study data storage; added that data would be stored in VINCI workspace and in the SQL database on the OIT server.
3	10/03/2022 10/26/2022	This amendment added that COVID 19 test may be required to complete spirometry according to hospital policy and the risks associated with that. Clarified the data collection timeline for the cohort and national dataset.
4	11/16/2022 11/17/2022	This amendment added the Dyspnea in ALS (DAL-15) questionnaire. This score is part of the data collection; however, clinically it is only being collected in Denver. Study staff will have to ask questions to those patients that are in Seattle. Also added more details and documents related to spirometry testing requirements and to make accommodations for participants to have help from care givers.

5	12/22/2022 12/22/2022	This amendment was to make minor modifications to recruitment and study materials to clarify instructions. Also added more options for Veterans to reach study team. Finally, adjusted staff interview guide to better answer research question.
6	2/21/2023 3/15/2023	This amendment was focused on expanding the data collection timelines so that we can be more accommodating to patients with ALS. For example, being able to collect in facility test within 30 days of home spirometry vs the previous timeline that the test had to be collected in the next 30 days which delayed data collection for some participants. Additionally, we adjusted study emails to be able to remove need for encryption, and we added the ability to complete interview questions before actual interview with staff. Both of these changes increase accessibility to participate.
7	5/4/2023 5/11/2023	This amendment focused on our making dataset not de-identified, adding a key information statement to the consent form and to make the cohort be with those that were living as of March 1, 2019.
8	12/01/2023 12/7/2023	This amendment focused on adding the Environmental Justice Index data which is a publicly available data set from the CDC. This data will be used adjacent to the area deprivation index (ADI) score. This amendment also gave the study team flexibility in the qualitative data collection and analysis by adding matrix analysis and changing total number of qualitative interviews from 24 qual to 40.

Table 2: Amendments submitted to Puget Sound IRB and RMR Research and Development Committee

Amendment number	Approval date	Reason for amendment
1	9/15/2022	Updated data storage locations that were originally described. Also updated HIPAA waiver. Submitted updated documents that were approved by COMIRB for acknowledgement.

Actual or anticipated problems or delays and actions or plans to resolve them

- As of 1/1/2024, the study team had documented 13 adverse events (See Table 3). We have had a total of 5 unanticipated problems, one of which happened in the current reporting period (See Table 4). The study applied for a one-year no cost extension to allow for more time to finish the final survey and interview data collection as well as sufficient time for data analysis and dissemination. Ultimately this extension was needed because of initial delays in starting recruitment in year 1 due to not receiving regulatory approvals in a timely manner. Additionally, recruitment was lower than anticipated, so the study team extended recruitment efforts until December 2023 with plans to do data collection during the no cost extension year. This resulted in recruiting an additional 9 patients into the study.

Table 3: Adverse events (AEs)

AE number	Study id number	Date discovered	Details	Expected ness	Related ness	Serious ness	Date reported to COMIRB	Date reported to HRPO
1	1013	5/4/2023	Patient had a rash; went to the ER. Admitted for sepsis. Discharged home	Unexpect ed	Not related	Serious	Not reported until continuing	Not reported until continui

			from hospital.				review	ng review
2	1018	5/21/2023	Patient lost balance and fell on nose, requiring the stitches for face laceration. Discharged home from ER.	Unexpected	Not related	Not Serious	Not reported until continuing review	Not reported until continuing review
3	1017	6/13/2023	Patient was found unresponsive at home by spouse. Patient passed away before reaching hospital	Unexpected	Not related	Serious	6/14/23; instructed that this event should be on continuing review since not related	6/15/23; instructed that this event should be on continuing review
4	1100	7/27/2023	Patient reported falling from wheelchair. Went to ER and got x-rays and a CAT scan. Discovered that patient had a hairline fracture on the femur above the knee. Patient was discharged with a splint and pain medication from Hospital same day.	Unexpected	Not related	Not serious	Not reported until continuing review	Not reported until continuing review
5	1050	8/14/2023	Patient admitted to hospital for progressive ALS symptoms. The patient was found to be non-responsive to verbal and tactile stimuli. Patient declared deceased.	Unexpected	Not related	Serious	Not reported until continuing review	Not reported until continuing review
6	1010	11/14/2023	Patient went to ER with complaints of respiratory arrest and diagnosed with pneumonia, sepsis, and elevated brain natriuretic peptide level. Patient received a tracheostomy, treated with multiple antibiotics, and discharged to	Unexpected	Not related	Serious	Not reported until continuing review	Not reported until continuing review

			nursing facility.					
7	1111	11/21/2023	Patient had aspiration episode and was admitted to hospital. Currently improving but working on placement in facility due to changes in living situation.	Unexpected	Not related	Serious	Not reported until continuing review	Not reported until continuing review
8	1018	11/21/2023	Patient went to urgent care for an episode related to neck pain and shooting pain from the neck to the hands. Got an MRI and was determined to have degenerative changes. Taking over-the-counter pain medication and doing PT/OT.	Unexpected	Not related	Not serious	Not reported until continuing review	Not reported until continuing review
9	1016	11/28/2023	Patient was hospitalized for cardiac arrest and sepsis due to pneumonia. Required trach placement and mechanical ventilation. Has since been taken off mechanical ventilation and is stable. Looking to be discharged to a skilled nursing facility	Unexpected	Not related	Serious	Not reported until continuing review	Not reported until continuing review
10	1068	11/29/2023	During in facility appointment, the patient reported a rash on his left leg (amputated) after he received a new stump sleeve. Rash is likely due to heat rash, excessive moisture, and/or sensitivity to fragrance in soap used to clean gel liner. Patient was educated on the use of fragrance-free dish soap for	Unexpected	Not related	Not Serious	Not reported until continuing review	Not reported until continuing review

			cleaning gel liner.					
11	1024	12/6/2023	Patient lost balance and fell forward, striking head and face on the tile. Patient went to the ER and was diagnosed with closed head injury with forehead hematoma, right knee contusion and hypokalemia. Wounds were cleaned, and oral potassium was given and discharged home.	Unexpected	Not related	Not Serious	Not reported until continuing review	Not reported until continuing review
12	1024	12/20/2023	Patient went to the ER with complaints of worsening right flank pain and hematuria and was diagnosed with an infection in her urine. Patient was provided with antibiotics for a urinary tract infection and discharged.	Unexpected	Not related	Not Serious	Not reported until continuing review	Not reported until continuing review
13	1105	12/20/2023	Patient was evaluated at ER for having a hard time focusing and worsening dizziness when moving from side to side. Diagnosed with benign paroxysmal positional vertigo. Discharged in a stable condition.	Unexpected	Not related	Not Serious	Not reported until continuing review	Not reported until continuing review

Table 4: Unanticipated problems (UAPs)

UAP number	Date of UAP	Description	Outcome and Changes implemented	Date submitted to COMIRB	Date submitted to HRPO
1	12/8/2022	Sent unencrypted email to participant	Incident reported to privacy. Privacy determined no breach was caused. Implemented encrypting email first before typing message.	12/12/2022	12/13/2022
2	1/9/2022	Invitation sent to	Patient was contacted that	4/28/2023:	3/31/2023:

		ineligible Veteran. Veteran did not have ALS diagnosis but had been seen in ALS clinic.	since doesn't have ALS diagnosis, they are not eligible at this time. Implemented a more robust search for ALS diagnosis instead of going off if seen in ALS clinic; no corrective action required by COMIRB	Submitted during continuing review	Submitted in annual report
3	1/24/2022	Invitation sent to ineligible Veteran	Patient was deceased at time of mailing. Date of death is difficult to find in chart for patients; however, recent system update to the chart seems to have resolved this; no corrective action required by COMIRB.	4/28/2023: Submitted during continuing review	3/31/2023: Submitted in annual report
4	2/2/2022	Invitation sent to ineligible Veteran	Patient was deceased at time of mailing. Date of death is difficult to find in chart for patients; however, recent system update to the chart seems to have resolved this; no corrective action required by COMIRB.	4/28/2023: Submitted during continuing review	3/31/2023: Submitted in annual report
5	10/11/2023	Patient testing outside protocol-outlined timeline	Patient was asked by study staff to complete a spirometry test on their own by a study staff member even though it was past the five-day window for collecting the test outlined in the protocol. The study staff member was retrained on the timeline of data collection.	Not required to submit until continuing review	Did not submit due to reporting guidelines recommendations

Changes that have a significant impact on expenditures

- We had a significant period of time when Ms. Smith was covering both the biostatistician and programmer roles which saved the study money. There also were a few months after Ms. Smith left that the role of biostatistician was open while we waited to bring Mr. Rogers onto the protocol. Additionally, we have not spent as much as budgeted on Dr. Radcliff's and Ms. Lane's salary, equipment, or transcription. The leftover money has been pushed forward to cover staff time in the No Cost Extension year.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

- None to report

Significant changes in use or care of human subjects

- None to report

Significant changes in use or care of vertebrate animals

- None to report

Significant changes in use of biohazards and /or select agents.

- None to report

6. Products

Publications, conference papers, and presentations

- 6 accepted abstracts (all abstracts have been added as Appendices)
 - 5 were actually presented as posters
- 1 Cyberseminar
 - Calder, A., Griffith, M., Lee, M. 2023 October 12. I'm not drunk, I'm not stupid, it's ALS!: How to Include People with Speech Limitations in Research.
https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=6418&Seriesid=113. Accessed 01/17/2024.

Websites or other internet sites

- None to report

Technologies or techniques

- None to report

Inventions, patent applications and/or licenses

- None to report

Other Products

- None to report

7. Participants & Other Collaborating Organizations

What individuals have worked on the project

Name of individuals who have had change or been added to staff	Project Role	Researcher Identifier	Nearest person month worked	Contribution to Project	Funding Support
Amber Lane	Research Coordinator	0000-0001-6018-5148	3	Ongoing regulatory; oversaw research assistant; manages different teams, qualitative and quantitative; database creation and maintenance (REDCap and Access); staff recruitment	W81XWH-22-1-0077
Dustin Rogers	Biostatistician	0009-0003-4370-3830	1	Created analytic plan; attend quantitative team meetings; creating tables from programmer data and cleaning data in preparation of beginning analysis.	W81XWH-22-1-0077
Susan Kim	Programmer	0009-0006-0523-6727	1	Built code for pulling data from CDW; checked data collection methods; built SQL database; attended quantitative team meetings	W81XWH-22-1-0077

Name of individuals that	Project Role
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have had no change since last reporting period	
Matthew Griffith	Co-Principal Investigator
Cari Levy	Co-Principal Investigator
Andrew Graustein	Co-Investigator
Bryan Borg	Co-Investigator
Maryam Tahmasbi Sohi	Co-Investigator
Kristina Crothers	Co-Investigator
Summer Huang	Research Assistant
Rachel Johnson	Qualitative Methodologist
Marcie Lee	Qualitative Analyst
Pramod Khanal	Chart abstracter
Tiffany Radcliff	Consultant

Name of individuals that no longer work on project	Project Role	Reason left project
Qing Shao	Former Programmer	Left the VA
Karen Albright	Former Qualitative Methodologist	Left the VA
Emily Gamm	Former Qualitative Analyst	Received other funding
Shelby Smith	Former Biostatistician	Left the VA

Has there been a change in the active other support of the PD/PI or senior/key personnel since the last reporting period?

- Nothing to report

What other organizations were involved as partners?

- None to report

8. Special Reporting Requirements

Collaborative awards

- Nothing to report

Quad chart

- Nothing to report

9. Appendices

Appendix 1: References

1. Brown RH, Jr., Al-Chalabi A. Amyotrophic Lateral Sclerosis. *N Engl J Med*. 2017;377(16):1602.
2. Longinetti E, Fang F. Epidemiology of amyotrophic lateral sclerosis: an update of recent literature. *Curr Opin Neurol*. 2019;32(5):771-776.
3. Chio A, Logroscino G, Hardiman O, et al. Prognostic factors in ALS: A critical review. *Amyotroph Lateral Scler*. 2009;10(5-6):310-323.
4. Thakore NJ, Lapin BR, Pioro EP, Pooled Resource Open-Access ALSCTC. Trajectories of impairment in amyotrophic lateral sclerosis: Insights from the Pooled Resource Open-Access ALS Clinical Trials cohort. *Muscle Nerve*. 2018;57(6):937-945.
5. Brizzi KT, Bridges JFP, Yersak J, et al. Understanding the needs of people with ALS: a national survey of patients and caregivers. *Amyotroph Lateral Scler Frontotemporal Degener*. 2020;21(5-6):355-363.
6. Nicholson K, Murphy A, McDonnell E, et al. Improving symptom management for people with amyotrophic lateral sclerosis. *Muscle Nerve*. 2018;57(1):20-24.
7. Corcia P, Pradat PF, Salachas F, et al. Causes of death in a post-mortem series of ALS patients. *Amyotroph Lateral Scler*. 2008;9(1):59-62.
8. Spataro R, Lo Re M, Piccoli T, Piccoli F, La Bella V. Causes and place of death in Italian patients with amyotrophic lateral sclerosis. *Acta Neurol Scand*. 2010;122(3):217-223.
9. Ackrivo J, Hansen-Flaschen J, Jones BL, et al. Classifying Patients with Amyotrophic Lateral Sclerosis by Changes in FVC. A Group-based Trajectory Analysis. *Am J Respir Crit Care Med*. 2019;200(12):1513-1521.
10. Vitacca M, Montini A, Lunetta C, et al. Impact of an early respiratory care programme with non-invasive ventilation adaptation in patients with amyotrophic lateral sclerosis. *Eur J Neurol*. 2018;25(3):556-e533.
11. Andrews JA, Meng L, Kulke SF, et al. Association Between Decline in Slow Vital Capacity and Respiratory Insufficiency, Use of Assisted Ventilation, Tracheostomy, or Death in Patients With Amyotrophic Lateral Sclerosis. *JAMA Neurol*. 2018;75(1):58-64.
12. Khamankar N, Coan G, Weaver B, Mitchell CS. Associative Increases in Amyotrophic Lateral Sclerosis Survival Duration With Non-invasive Ventilation Initiation and Usage Protocols. *Front Neurol*. 2018;9:578.
13. Ackrivo J, Hsu JY, Hansen-Flaschen J, Elman L, Kawut SM. Noninvasive Ventilation Use Is Associated with Better Survival in Amyotrophic Lateral Sclerosis. *Ann Am Thorac Soc*. 2021;18(3):486-494.
14. Bourke SC, Tomlinson M, Williams TL, Bullock RE, Shaw PJ, Gibson GJ. Effects of non-invasive ventilation on survival and quality of life in patients with amyotrophic lateral sclerosis: a randomised controlled trial. *Lancet Neurol*. 2006;5(2):140-147.
15. Quanjer PH, Stanojevic S, Cole TJ, et al. Multi-ethnic reference values for spirometry for the 3-95-yr age range: the global lung function 2012 equations. *Eur Respir J*. 2012;40(6):1324-1343.
16. Graham BL, Steenbruggen I, Miller MR, et al. Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. *Am J Respir Crit Care Med*. 2019;200(8):e70-e88.
17. Gruis KL, Brown DL, Schoennemann A, Zebarah VA, Feldman EL. Predictors of noninvasive ventilation tolerance in patients with amyotrophic lateral sclerosis. *Muscle Nerve*. 2005;32(6):808-811.
18. Pinto A, de Carvalho M, Evangelista T, Lopes A, Sales-Luis L. Nocturnal pulse oximetry: a new approach to establish the appropriate time for non-invasive ventilation in ALS patients. *Amyotroph Lateral Scler Other Motor Neuron Disord*. 2003;4(1):31-35.
19. Shane L. VA telehealth options here to stay, secretary vows. 2021; <https://www.militarytimes.com/news/pentagon-congress/2021/06/23/va-telehealth-options-here-to-stay-secretary-vows/>. Accessed June 29, 2021.
20. Andrews JA, Berry JD, Baloh RH, et al. Amyotrophic lateral sclerosis care and research in the United States during the COVID-19 pandemic: Challenges and opportunities. *Muscle Nerve*. 2020;62(2):182-186.
21. Schellenberg KL, Hansen G. Patient perspectives on transitioning to amyotrophic lateral sclerosis multidisciplinary clinics. *J Multidiscip Healthc*. 2018;11:519-524.
22. Spirobank Smart. 2021; <https://www.spirometry.com/prodotti/spirobank-smart/>. Accessed June 29, 2021.
23. Geronimo A, Simmons Z. Evaluation of remote pulmonary function testing in motor neuron disease. *Amyotroph Lateral Scler Frontotemporal Degener*. 2019;20(5-6):348-355.

24. Cedarbaum JM, Stambler N, Malta E, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. BDNF ALS Study Group (Phase III). *J Neurol Sci.* 1999;169(1-2):13-21.
25. Russell AM, Adamali H, Molyneaux PL, et al. Daily Home Spirometry: An Effective Tool for Detecting Progression in Idiopathic Pulmonary Fibrosis. *Am J Respir Crit Care Med.* 2016;194(8):989-997.
26. Noth I, Cottin V, Chaudhuri N, et al. Home spirometry in patients with idiopathic pulmonary fibrosis: data from the INMARK trial. *Eur Respir J.* 2021.
27. Kupczyk M, Hofman A, Koltowski L, et al. Home self-monitoring in patients with asthma using a mobile spirometry system. *J Asthma.* 2021;58(4):505-511.

Appendix 2: Staff interview guide

Evaluation of Telemedicine Spirometry Testing for Veterans with ALS (E-TEST VA) Staff Interview Guide

Interviewer Name:

Interview date:

Start time:

Initial interview date:

End time:

Hello [Dr./Mr./Ms. interview participant name], thank you for taking time to speak with me today.

My name is [interviewer name]. I am with a research team interested in understanding how you use home spirometry devices in your patients with ALS. These findings will be used to understand which patients would be most likely to benefit from home spirometry, allowing the VA and other healthcare systems to expand the program to other sites. Your responses will be kept confidential, and you will not be identified in any reports or publications.

The call will take approximately 30 to 40 minutes.

Your participation in this interview is voluntary. You can stop the interview at any time and let us know if you'd rather not answer a particular question. Do you have any questions?

In order to make sure we capture all of the information you give us, we would like to record this call. The audio-file for the recording will be uploaded to a restricted access file on the VA intranet immediately after we complete this interview. The audio file will be saved anonymously. We may transcribe the recording, and your name will be removed from any transcripts. We are interested in what you have to say, so we want you to speak freely. Is this okay with you?

If yes, turn the recording on. Confirm if it's ok to record.

Would it be ok if we contact you with any follow up questions after we review your responses?

Grounded prompts: If responses are limited or require clarification, probes may be used to illicit more detailed responses. Probes should use words or phrases presented by the participant using one of the following formats:

1. What do you mean by_____?
2. Tell me more about_____.
3. Give me an example of_____.
4. Tell me about a time when_____.
5. Who_____?
6. When_____?

Bolded questions are key domains to ask if provider time is limited

1. To start, can you tell me your title and role within the [site name] ALS clinic?

Optional Probes:

1. How long have you been in this role? How long have you been with the VA?

(PRISM: Organizational Perspective)

2. **What is your clinic's current process for spirometry testing?** (PRISM: Organizational Perspective)
 - a. How did the COVID-19 pandemic change your clinic's procedure for spirometry testing?
(PRISM: Implementation and Sustainability Infrastructure)
 - b. Do you have different processes for testing new patients compared with returning patients?

Thank you. Now we are going to ask you some questions about your familiarity with the home spirometer device and about your patients' usage of the home spirometer device.

3. **How long have you been using the home spirometer device with your patients?**

(PRISM: Organizational Perspective)

- c. Approximately how many times have you supervised a home spirometry test?
4. What training did you receive on the home spirometer before providing it to patients? (PRISM: Implementation and Sustainability Infrastructure)
 - d. If yes, when was that first training?
 - e. If yes, have you received any further training since then?
 - f. Are you able to access information about the device like a manual or FAQ?
 - g. What types of information or training would you have liked to receive?
 - h. If you wanted more training, who would you contact?
5. **What types of patients with ALS would you use home testing with?** (PRISM: Patient Characteristics)
6. **What is your confidence level that patients can perform home spirometry tests on their own?**
(PRISM: Patient Characteristics)
 - i. What assistance is available to patients for home spirometry (i.e., technical assistance/support, testing assistance, etc.)? (PRISM: Patient perspective)
 - j. What assistance would you like to be available to patients for home spirometry (i.e., technical assistance/support, testing assistance, etc.)? (PRISM: Implementation and Sustainability Infrastructure)
7. **In your opinion, how has the use of the at home spirometer impacted patient experience?**
(PRISM: Organizational Perspective)
 - k. What benefits do patients have with using the device in their home (i.e., difficulty performing the test, technology, getting results, etc.) (PRISM: Patient perspective)
 - l. What challenges do patients have with using the device in their home (i.e., difficulty performing the test, technology, getting results, etc.) (PRISM: Patient perspective)

- m. How do you address potential challenges?
 - n. How does this patient experience compare to the patient experience you have observed in the pulmonary function lab or clinic?
8. How has the use of the home spirometer impacted the patient's burden of care? (PRISM: Organizational characteristics)
- o. How has the use of home spirometer reduced burden of care?
 - p. How has the use of home spirometer increased burden of care?
9. **How has the shift towards home spirometry affected your workload (i.e. testing, issuing orders, reviewing test results, etc.)?**
- q. Do you do any coaching/training involving the home spirometer with patients?
 - r. If yes:
 - How much time did you spend performing spirometry prior to introducing home-based spirometry?
 - o How much time moving, calibrating and cleaning equipment?
 - o How much time performing tests?
 - o How much time retrieving or forwarding results?
 - How much time do you spend with at home spirometry?
 - o How much time do you spend orienting or training patients to use the device initially? Do you spend additional time orienting patients with each subsequent test?
 - o How much time do you spend conducting testing?
 - o How much time do you spend retrieving and forwarding results?
 - o How much time do you spend providing technical support outside of scheduled testing or how many calls about trouble shooting do you receive each week?
 - o How many additional home visits do you make each week because of home spirometry testing?
 - If any, how much time do you spend traveling?
 - If this adds on any time to previously scheduled home visits, how much time does it add?

Thank you for your responses. Now we are going to ask you questions about your opinion of the home spirometer

10. **Overall, what do you think about the spirometer's functionality?** (PRISM: Organizational perspective)
- s. What do you think about the spirometer's reliability? Probe: Why or why not
 - t. What do you think about the spirometer's accuracy? Probe: Why or why not
 - u. What do you think about the trustworthiness of the results? Probe: Why or why not
11. In your opinion, what do you think your patients think about the spirometer's functionality? (PRISM: Patient perspective)
- v. What do you think patients think about the trustworthiness of the results? Probe: Why or Why

not

12. In your opinion are there risks in allowing patients to do testing at home? (PRISM: Patient characteristics)

- w. Would you say benefits of using this device at home out weight the risks of a potentially uncertain result?

13. If a home test shows that a patients lung function has significantly worsened from the prior test, would you recommend additional testing? Why or why not? (PRISM: Organizational characteristics)

Finally, we would like to ask you a few questions about future use of the home spirometer.

14. If you could change anything about the at home spirometer, what would it be? (PRISM: Implementation and Sustainability Infrastructure)

- x. What would you change about the current process related to the at home spirometer?
- y. Would you like the device better if it did not require a smartphone or device? Probe: Why or why not?

15. Would you like home testing as an option for any other medical conditions? Probe: why or why not (PRISM: Implementation and Sustainability Infrastructure)

- z. What other health conditions would you want at home testing for?

16. Is there anything else you would like to tell us about the device or home testing in general?

17. Do you have any questions for us?

Thank you for your time and for sharing your insight during this interview

Appendix 3: Patient interview guide

Evaluation of Telemedicine Spirometry Testing for Veterans with ALS (E-TEST VA) Patient Interview Guide

Hello [Dr./Mr./Ms. interview participant name], thank you for taking time to speak with me today.

My name is [interviewer name]. I am a member of the E-TEST VA research study team. We are interested in understanding how you use your home spirometry device to measure your lung function. We are also interested in understanding how you respond to uncertain results, like those which may come from a potentially inaccurate home test. These findings will be used to understand which patients would be most likely to benefit from home spirometry, allowing the VA and other healthcare systems to expand the program to other sites. Your responses will be kept confidential, and you will not be identified in any reports or publications.

The call will take approximately 30 to 60 minutes. If you feel fatigued during the interview, we can stop and take a break or schedule to continue the interview at another time.

[For those that completed the optional questions before interview] Thank you for completing the questions that we sent before this interview. Today we will focus on any follow-up questions we may have based on your answers.

Your participation in this interview is voluntary. You can stop the interview at any time and let us know if you'd rather not answer a particular question. If it would make you more comfortable, you can have someone you consider to be a caregiver present. Do you have any questions?

In order to make sure we capture all of the information you give us, we would like to record this call. The audio-file for the recording will be uploaded to a restricted access file on the VA intranet immediately after we complete this interview. The audio file will be saved anonymously. We may transcribe the recording, and your name will be removed from any transcripts. We are interested in what you have to say, so we want you to speak freely. Is this okay with you?

If yes, turn the recording on. Confirm if it's ok to record.

Would it be ok if we contact you with any follow up questions after we review your responses?

Grounded prompts: If responses are limited or require clarification, probes may be used to illicit more detailed responses. Probes should use words or phrases presented by the participant using one of the following formats:

7. What do you mean by_____?
8. Tell me more about_____.
9. Give me an example of_____.
10. Tell me about a time when_____.
11. Who_____?
12. When_____?
13. Tell me in one or two words, [question]
14. Tell me in a few words, [question]
15. Offer options of potential answers in yes or no format

For interviewer: The bolded question probes are the key domains to focus on.

For those that sent in written responses prior to the interview:

- i. Use the probes above to drill into specific parts of the response
- ii. Check to ensure that the domains are covered in the response
- iii. Clarify any missing domains or unclear responses
- iv. If there is time and interest, explore additional unbolded questions below

Interview Questions

1. Thank you again for agreeing to participate. To start with, I'd like to hear a little bit about you.

How many years did you serve in the military? Which branch or branches of service?

Thank you for that information and thank you for your service.

Optional Probes:

2. When were you diagnosed with ALS?

Now we are interested in learning more about your use of the at home spirometer.

3. How did you decide whether you wanted to do at home spirometry? (PRISM: External Environment)

4. What training have you received about using the home spirometer device? (PRISM: Implementation and Sustainability Infrastructure)

- a. If any, when was that first training?
- b. If any, have you received any further training since then?
- c. Do you have access to additional information about the device like a manual or FAQ?
- d. If none, what types of information or training would you have liked to receive
- e. If you wanted more training, who would you contact?

5. What is your confidence level that you can perform spirometry at home? (PRISM: Patient Characteristics)

- a. What support is available to you (i.e., technical support, testing support, etc.)? (PRISM: Patient perspective)
- b. What support would you like to be available to you (i.e., technical support, testing support, etc.)? (PRISM: Implementation and Sustainability Infrastructure)

6. What challenges do you have with using the spirometer at home (i.e., difficulty performing the test, technology, getting results, etc.) (PRISM: Patient perspective)

- a. How do these challenges compare to the tests you complete in person at the pulmonary

function lab or clinic? (PRISM: Organizational perspective)

7. Overall, what do you think about the spirometer's functionality? (PRISM: Organizational perspective)
 - a. What do you think about the spirometer's reliability? Probe: Why or why not
 - b. What do you think about the spirometer's accuracy? Probe: Why or why not
 - c. What do you think about the trustworthiness of the results? Probe: Why or why not
8. In your opinion, how has the use of the at home spirometer impacted your patient experience? (PRISM: Organizational Perspective)
 - a. How does this compare to the experience you have had in person at the pulmonary function lab or clinic?
9. **How has the use of the home spirometer made it easier to get care (i.e., travel time, appointment times, etc.) or has it? (PRISM: Organizational characteristics)**
10. Are there some patients with ALS that you think are a better fit for home testing than others?
11. Do you trust the results of your testing with this device? Do you think your doctors trust the results from this device? Why or why not? (PRISM: Organizational perspective)
12. **How would you feel if the home testing showed a worsening of your condition? What would you do? (PRISM: Organizational characteristics)**
13. What would your doctors do if your home testing showed a worsening of your condition? (PRISM: Organizational characteristics)

If your device showed a worsening of your condition, but when you were re-tested in clinic your results were the stable, would you feel differently about the device?
14. Would you say that being able to do tests when you want to is worth the risk of an uncertain result?
15. **What should be changed about doing home spirometry? (PRISM: Implementation and Sustainability Infrastructure)**
 - a. Would you like the device better if it did not require a smartphone or device? Probe: Why or why not?
 - b. If you could change anything about the device, what would it be?
16. Would you like home testing as an option for any other medical conditions? Why or why not?

(PRISM: Implementation and Sustainability Infrastructure)

a. What other conditions would you want at home testing for?

17. Is there anything else you would like to tell us about the device or home testing in general?

18. Do you have any questions for us?

Thank you for your time and for sharing your insight during this interview

Appendix 4: Baseline survey

E-TEST VA Veteran Questionnaire in REDCap

Study id #: _____

Date survey completed: _____

Thank you for your participation in our study. First, we would like to ask about your current usage of and experiences with the Spirobank Smart spirometer device. Along with a few questions describing how long it takes and how you typically get to your regular ALS appointments.

Background

How long have you had the Spirobank Smart spirometer?

- ☐ Less than a month
- ☐ 1-2 months
- ☐ 3-4 months
- ☐ 5-6 months
- ☐ 7-8 months
- ☐ 9-10 months
- ☐ 11-12 months
- ☐ More than 12 months
- ☐ Decline to Answer

Did you receive training on how to use the device?

- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Decline to Answer

Have you had to call the VA staff or the device company for technical support?

- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Decline to Answer

Approximately how many times have you used the Spirobank Smart spirometer to complete an at home spirometry test? (Include tests done with or without a respiratory therapist)

- ☐ Never
- ☐ 1 time
- ☐ 2 times
- ☐ 3 times
- ☐ 4 times
- ☐ 5 times
- ☐ 6 times
- ☐ 7 times
- ☐ 8 times
- ☐ 9 times
- ☐ 10 times
- ☐ More than 10 times
- ☐ Unsure
- ☐ Decline to Answer

How long does it typically take you to complete the at-home spirometry test when you have coaching from a respiratory therapist? (Include the time it takes you/your caregiver to set up the appointment, set up the device, do the test, and report your results)

- ☐ I never get coaching from a respiratory therapist
- ☐ 0-14 mins
- ☐ 15-29 mins
- ☐ 30-44 mins
- ☐ 45-59 mins
- ☐ 60-74 mins
- ☐ 75-89 mins
- ☐ 90+mins
- ☐ Decline to answer

How often have you completed an at-home spirometry test without coaching from a respiratory therapist?

- ☐ Never
- ☐ 1-2 times
- ☐ 3-4 times
- ☐ 5-10 times
- ☐ More than 10 times
- ☐ Unsure
- ☐ Decline to Answer

[Individuals who selected any answer other than “Never” or “Decline to Answer” will be given this question]

How long does it typically take you to complete the at-home spirometry test when you do not have coaching from a respiratory therapist? (Include the time it takes you/your caregiver to set up the appointment, set up the device, do the test, and report your results)

- ☐ 0-14 mins
- ☐ 15-29 mins
- ☐ 30-44 mins
- ☐ 45-59 mins
- ☐ 60-74 mins
- ☐ 75-89 mins
- ☐ 90+mins
- ☐ Decline to answer

How do you typically travel to your regular ALS appointments?

- ☐ Personal Car
- ☐ Shared Vehicle (e.g., Shuttle)
- ☐ Bus
- ☐ Rideshare Service
- ☐ Other
- ☐ Decline to Answer

[Individuals who selected Other will be given this question]

If you selected Other in the above question, please describe:

How much extra time do you spend getting ready on days with in-person ALS appointments at the Medical Center (i.e., travel time, time grooming/dressing for appointment, etc.) versus a typical day:

- ☐ 0-14 mins
- ☐ 15-29 mins
- ☐ 30-44 mins

- ☐ 45-59 mins
- ☐ 60-74 mins
- ☐ 75-89 mins
- ☐ 90+mins
- ☐ Decline to answer

Did you buy any technology in order to use the Spirobank Smart spirometer device?

- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Decline to answer

[Individuals that select yes will be prompted to answer the next question; individuals selecting No or Unsure or Decline to answer will not see this question]

What technology did you buy in order to use the Spirobank Smart spirometer?

- ☐ Tablet (e.g., iPad, Samsung tablet, Google Edge)
- ☐ Smartphone (e.g., iPhone, Android)
- ☐ Modem/Broadband equipment
- ☐ Computer
- ☐ Other
- ☐ Decline to answer

[Individuals who selected Other will be given this question]

If you selected Other in the above question, please describe:

Did you receive any technology from the VA in order to use the Spirobank Smart spirometer device?

- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Decline to answer

[Individuals that select yes will be prompted to answer the next question; individuals selecting No or Unsure or Decline to answer will not see this question]

What technology did you receive in order to use the Spirobank Smart spirometer?

- ☐ Tablet (e.g., iPad, Samsung tablet, Google Edge)
- ☐ Smartphone (e.g., iPhone, Android)
- ☐ Modem/Broadband equipment
- ☐ Computer
- ☐ Other
- ☐ Decline to answer

[Individuals who selected Other will be given this question]

If you selected Other in the above question, please describe:

Second, we would like to understand your current satisfaction with your portable Spirobank Smart spirometer device. These questions were modified from the Patient Satisfaction and Preference Questionnaire for Inhalation Devices.

Device Satisfaction

Have you ever used the Spirobank Smart spirometer device to perform spirometry testing?

- ☐ Yes
- ☐ No

☐ Decline to answer

[Individuals selecting “no” will skip the following questions up to the final section]

Overall feeling of blowing into device	Very Dissatisfied				Very Satisfied			
	1	2	3	4	5	6	7	Decline to answer
Breath goes into the device when exhaled	1	2	3	4	5	6	7	Decline to answer
Lungs are able to empty completely into the device	1	2	3	4	5	6	7	Decline to answer
Works reliably	1	2	3	4	5	6	7	Decline to answer
Ease of completing a test	1	2	3	4	5	6	7	Decline to answer
Using the spirometer	1	2	3	4	5	6	7	Decline to answer
Speed test is completed	1	2	3	4	5	6	7	Decline to answer
Instructions for use	1	2	3	4	5	6	7	Decline to answer
Size of device	1	2	3	4	5	6	7	Decline to answer
Durability of device	1	2	3	4	5	6	7	Decline to answer
Ease of cleaning device	1	2	3	4	5	6	7	Decline to answer
Ease of holding during use	1	2	3	4	5	6	7	Decline to answer
Convenience of transport and storage	1	2	3	4	5	6	7	Decline to answer
Overall satisfaction	1	2	3	4	5	6	7	Decline to answer

Third, we would like to learn about your comfort with using home tests. Since home tests could produce uncertain results when compared with tests performed in our clinic, we are also going to ask you about how well you react to uncertainty to understand how you use your spirometry device. These questions are modified from the short-form Intolerance of Uncertainty Scale.

Use of New Technologies

Unforeseen events upset me greatly.	Not at all like me			Entirely Like Me		
	1	2	3	4	5	Decline to Answer
It frustrates me not having all the information I need.	1	2	3	4	5	Decline to Answer
One should always look ahead so as to avoid surprises.	1	2	3	4	5	Decline to Answer
A small, unforeseen event can spoil everything, even with the best of planning.	1	2	3	4	5	Decline to Answer
I always want to know what the future has in store for me.	1	2	3	4	5	Decline to Answer
I can't stand being taken by surprise.	1	2	3	4	5	Decline to Answer
I should be able to organize everything in advance.	1	2	3	4	5	Decline to Answer
Uncertainty keeps me from living a full life.	1	2	3	4	5	Decline to Answer
When it's time to act, uncertainty paralyses me.	1	2	3	4	5	Decline to Answer
When I am uncertain, I can't function very well.	1	2	3	4	5	Decline to Answer
The smallest doubt can stop me from acting.	1	2	3	4	5	Decline to Answer

I must get away from all uncertain situations.	1	2	3	4	5	Decline to Answer
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Finally, we have a few demographics questions.

What is the highest level of education you have completed?

- ☐ Less than a high school diploma
- ☐ High school diploma, GED or equivalent
- ☐ Associate degree
- ☐ Bachelor's degree
- ☐ Master's degree
- ☐ Doctorate
- ☐ Decline to answer

What is your current marital status?

- ☐ Single (never married)
- ☐ Married
- ☐ Domestic Partnership
- ☐ Divorced
- ☐ Widowed
- ☐ Decline to answer

What is your current employment status?

- ☐ Employed full-time (40+ hours a week)
- ☐ Employed part-time (less than 40 hours a week)
- ☐ Unemployed (currently looking for work)
- ☐ Unemployed (not currently looking for work)
- ☐ Student
- ☐ Retired
- ☐ Self-employed
- ☐ Decline to answer

What is your household income?

- ☐ Below \$20,000
- ☐ \$20,000-\$30,000
- ☐ \$30,000-\$40,000
- ☐ \$40,000-\$50,000
- ☐ \$50,000-\$60,000
- ☐ \$60,000-\$70,000
- ☐ \$70,000-\$80,000
- ☐ \$80,000-\$90,000
- ☐ \$90,000-\$100,000
- ☐ \$100,000-\$110,000
- ☐ \$110,000-\$120,000
- ☐ \$120,000-\$130,000
- ☐ \$130,000-\$140,000
- ☐ Over \$140,000
- ☐ Decline to answer

Thank you for completing our surveys. If you have any questions, please feel free to reach out to a study team member at 720 857 5613. We may ask you to complete these same surveys again in approximately 6 months.

Appendix 5: Follow up survey

E-TEST VA Veteran Questionnaire in REDCap

Study id #: _____

Date survey completed: _____

Thank you for your participation in our study. First, we would like to ask about your current usage of and experiences with the Spirobank Smart spirometer device. Along with a few questions describing how long it takes and how you typically get to your regular ALS appointments.

Background

How long have you had the Spirobank Smart spirometer?

- ☐ Less than a month
- ☐ 1-2 months
- ☐ 3-4 months
- ☐ 5-6 months
- ☐ 7-8 months
- ☐ 9-10 months
- ☐ 11-12 months
- ☐ More than 12 months
- ☐ Decline to Answer

Did you receive training on how to use the device?

- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Decline to Answer

Have you had to call the VA staff or the device company for technical support?

- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Decline to Answer

Approximately how many times have you used the Spirobank Smart spirometer to complete an at home spirometry test? (Include tests done with or without a respiratory therapist)

- ☐ Never
- ☐ 1 time
- ☐ 2 times
- ☐ 3 times
- ☐ 4 times
- ☐ 5 times
- ☐ 6 times
- ☐ 7 times
- ☐ 8 times
- ☐ 9 times
- ☐ 10 times
- ☐ More than 10 times
- ☐ Unsure
- ☐ Decline to Answer

How long does it typically take you to complete the at-home spirometry test when you have coaching from a respiratory therapist? (Include the time it takes you/your caregiver to set up the appointment, set up the device, do the test, and report your results)

- ☐ I never get coaching from a respiratory therapist
- ☐ 0-14 mins
- ☐ 15-29 mins
- ☐ 30-44 mins
- ☐ 45-59 mins
- ☐ 60-74 mins
- ☐ 75-89 mins
- ☐ 90+mins
- ☐ Decline to answer

How often have you completed an at-home spirometry test without coaching from a respiratory therapist?

- ☐ Never
- ☐ 1-2 times
- ☐ 3-4 times
- ☐ 5-10 times
- ☐ More than 10 times
- ☐ Unsure
- ☐ Decline to Answer

[Individuals who selected any answer other than “Never” or “Decline to Answer” will be given this question]

How long does it typically take you to complete the at-home spirometry test when you do not have coaching from a respiratory therapist? (Include the time it takes you/your caregiver to set up the appointment, set up the device, do the test, and report your results)

- ☐ 0-14 mins
- ☐ 15-29 mins
- ☐ 30-44 mins
- ☐ 45-59 mins
- ☐ 60-74 mins
- ☐ 75-89 mins
- ☐ 90+mins
- ☐ Decline to answer

How do you typically travel to your regular ALS appointments?

- ☐ Personal Car
- ☐ Shared Vehicle (e.g., Shuttle)
- ☐ Bus
- ☐ Rideshare Service
- ☐ Other
- ☐ Decline to Answer

[Individuals who selected Other will be given this question]

If you selected Other in the above question, please describe:

How much extra time do you spend getting ready on days with in-person ALS appointments at the Medical Center (i.e., travel time, time grooming/dressing for appointment, etc.) versus a typical day:

- ☐ 0-14 mins
- ☐ 15-29 mins
- ☐ 30-44 mins

- ☐ 45-59 mins
- ☐ 60-74 mins
- ☐ 75-89 mins
- ☐ 90+mins
- ☐ Decline to answer

Did you buy any technology in order to use the Spirobank Smart spirometer device?

- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Decline to answer

[Individuals that select yes will be prompted to answer the next question; individuals selecting No or Unsure or Decline to answer will not see this question]

What technology did you buy in order to use the Spirobank Smart spirometer?

- ☐ Tablet (e.g., iPad, Samsung tablet, Google Edge)
- ☐ Smartphone (e.g., iPhone, Android)
- ☐ Modem/Broadband equipment
- ☐ Computer
- ☐ Other
- ☐ Decline to answer

[Individuals who selected Other will be given this question]

If you selected Other in the above question, please describe:

Did you receive any technology from the VA in order to use the Spirobank Smart spirometer device?

- ☐ Yes
- ☐ No
- ☐ Unsure
- ☐ Decline to answer

[Individuals that select yes will be prompted to answer the next question; individuals selecting No or Unsure or Decline to answer will not see this question]

What technology did you receive in order to use the Spirobank Smart spirometer?

- ☐ Tablet (e.g., iPad, Samsung tablet, Google Edge)
- ☐ Smartphone (e.g., iPhone, Android)
- ☐ Modem/Broadband equipment
- ☐ Computer
- ☐ Other
- ☐ Decline to answer

[Individuals who selected Other will be given this question]

If you selected Other in the above question, please describe:

Second, we would like to understand your current satisfaction with your portable Spirobank Smart spirometer device. These questions were modified from the Patient Satisfaction and Preference Questionnaire for Inhalation Devices.

Device Satisfaction

Have you ever used the Spirobank Smart spirometer device to perform spirometry testing?

- ☐ Yes
- ☐ No

☐ Decline to answer

[Individuals selecting “no” will skip the following questions up to the final section]

Overall feeling of blowing into device	Very Dissatisfied				Very Satisfied			
	1	2	3	4	5	6	7	Decline to answer
Breath goes into the device when exhaled	1	2	3	4	5	6	7	Decline to answer
Lungs are able to empty completely into the device	1	2	3	4	5	6	7	Decline to answer
Works reliably	1	2	3	4	5	6	7	Decline to answer
Ease of completing a test	1	2	3	4	5	6	7	Decline to answer
Using the spirometer	1	2	3	4	5	6	7	Decline to answer
Speed test is completed	1	2	3	4	5	6	7	Decline to answer
Instructions for use	1	2	3	4	5	6	7	Decline to answer
Size of device	1	2	3	4	5	6	7	Decline to answer
Durability of device	1	2	3	4	5	6	7	Decline to answer
Ease of cleaning device	1	2	3	4	5	6	7	Decline to answer
Ease of holding during use	1	2	3	4	5	6	7	Decline to answer
Convenience of transport and storage	1	2	3	4	5	6	7	Decline to answer
Overall satisfaction	1	2	3	4	5	6	7	Decline to answer

Finally, we would like to learn about your comfort with using home tests. Since home tests could produce uncertain results when compared with tests performed in our clinic, we are also going to ask you about how well you react to uncertainty to understand how you use your spirometry device. These questions are modified from the short-form Intolerance of Uncertainty Scale.

Use of New Technologies

Unforeseen events upset me greatly.	Not at all like me			Entirely Like Me		
	1	2	3	4	5	Decline to Answer
It frustrates me not having all the information I need.	1	2	3	4	5	Decline to Answer
One should always look ahead so as to avoid surprises.	1	2	3	4	5	Decline to Answer
A small, unforeseen event can spoil everything, even with the best of planning.	1	2	3	4	5	Decline to Answer
I always want to know what the future has in store for me.	1	2	3	4	5	Decline to Answer
I can't stand being taken by surprise.	1	2	3	4	5	Decline to Answer
I should be able to organize everything in advance.	1	2	3	4	5	Decline to Answer
Uncertainty keeps me from living a full life.	1	2	3	4	5	Decline to Answer
When it's time to act, uncertainty paralyzes me.	1	2	3	4	5	Decline to Answer
When I am uncertain, I can't function very well.	1	2	3	4	5	Decline to Answer
The smallest doubt can stop me from acting.	1	2	3	4	5	Decline to Answer

I must get away from all uncertain situations.	1	2	3	4	5	Decline to Answer
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Thank you for completing our survey. If you have any questions, please feel free to reach out to a study team member at 720 857 5613. We may reach out in the next few weeks to invite you to take part in a phone interview about your experience using the Spirobank Smart spirometer.

Appendix 6: Dyspnea in ALS-15 (DAL5-15) survey

[Intro to survey] We are interested in learning about your shortness of breath also known as dyspnea in the past two weeks. You can skip any question or stop the survey at any time. Do you have any questions before we get started?

In the past two weeks,

- 1) I experienced mild shortness of breath
 0. Never
 1. Sometimes
 2. Always
- 2) I experienced severe shortness of breath
 0. Never
 1. Sometimes
 2. Always
- 3) I was often short of breath
 0. Never
 1. Sometimes
 2. Always
- 4) I had shortness of breath when sitting still
 0. Never
 1. Sometimes
 2. Always
- 5) I had shortness of breath when exercising
 0. Never
 1. Sometimes
 2. Always
- 6) I felt anxious about my breathing
 0. Never
 1. Sometimes
 2. Always
- 7) I was afraid of being unable to breathe or suffocating
 0. Never
 1. Sometimes
 2. Always
- 8) I woke up at night with shortness of breath
 0. Never
 1. Sometimes
 2. Always
- 9) My breathing difficulties limited my activities around the house
 0. Never
 1. Sometimes
 2. Always
- 10) Due to the shortness of breath and its consequences, I felt isolated from other people
 0. Never
 1. Sometimes

2. Always

11) Keeping up with my breathing exhausted me

- 0. Never
- 1. Sometimes
- 2. Always

12) My shortness of breath was a problem

- 0. Never
- 1. Sometimes
- 2. Always

13) I had to cancel or avoid activities that I like to do, because of my breathing

- 0. Never
- 1. Sometimes
- 2. Always

14) I found it difficult to cough up my phlegm

- 0. Never
- 1. Sometimes
- 2. Always

15) I avoided lying flat because of my shortness of breath

- 0. Never
- 1. Sometimes
- 2. Always

Appendix 7: Accepted Abstract Submissions

Appendix 7a: Colorado Pragmatic Research in Health

Title: Qualitative Evaluation of a Respiratory Therapist-Led VA Telehealth Spirometry Program for ALS using the Practical Robust Implementation and Sustainability Model

Authors: Marcie Lee, MA, MPH,¹ Amber Lane, BS,¹ Summer Huang, BS,¹ Emily Gamm, LCSW,^{1,2} Rachel Johnson-Koenke, PhD, LCSW,^{1,2} Matthew Griffith, MD, MPH^{1,3}

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Background: Individuals who have served in the military have a higher risk of Amyotrophic Lateral Sclerosis (ALS). ALS is a neurodegenerative condition characterized by progressive skeletal muscle weakness and impacts function, including pulmonary function. Recognizing trajectories of pulmonary decline can lead to initiation of therapies that can slow disease progression, prevent complications, or provide comfort for the patient. Spirometry is used to routinely monitor lung function to determine prognosis and therapy needs. The implementation of a pilot Telehealth Spirometry Program for ALS patients was accelerated during the COVID pandemic due to challenges with in-person spirometry testing. We used the Practical Robust Implementation and Sustainability Model (PRISM) to inform the ongoing implementation and evaluation of the program. PRISM helps to identify factors needed to implement a successful program and to measure success.

Setting: We are evaluating the Telehealth Spirometry Program for ALS at two Veteran Affairs Medical Centers (VAMCs), the Rocky Mountain Regional VAMC and Puget Sound VAMC.

Methods: PRISM-informed semi-structured interviews were conducted with staff and providers including respite to assess implementation between November 2022 and February 2023. Audio recordings were transcribed verbatim, checked for accuracy, and analyzed in ATLAS.ti v23. We used thematic inquiry analysis and directed content analysis methods.

Results: Staff (n=6) found implementation of telehealth spirometry to be effective in monitoring respiratory decline in patients with ALS. RTs facilitated appropriate spirometry use by extensively training patients and caregivers in-person and through telehealth. Most patients with ALS were able to use the device independently or with assistance from their home caregiver however some required additional instruction and time to get used to the technology and process. Both VAMCs worked through challenges with patients to send results in time for their in-person appointments. Providers including RT perceived telehealth spirometry testing as accurate and reliable and could reduce the patient's in-person clinic time for patients who are physically able to form a mouth seal on the device. If patient spirometry measurements were notably lower than previous levels, RTs initiated appropriate follow-up testing and treatment as well as education for patients.

Discussion: PRISM informed our evaluation by highlighting organizational factors such as ongoing technical support that were essential to making this telehealth program successful. Staff reported that having telehealth spirometry measures were helpful for monitoring pulmonary function. Additionally, staff reported that overall patients responded positively and could use the device independently or with caregiver support with continued training and support. These results could inform the development of other telehealth spirometry programs (e.g. lung cancer screening). Telehealth spirometry programs such as this should consider organizational factors such as ongoing program support to be implemented successfully.

Appendix 7b: Academy Health Annual Research Meeting-Abstract 1

Primary theme Area: Aging, Disability, and End-of-Life; Secondary theme: Dissemination, implementation, and impact

Title: Opportunities for Inclusive Care for Patients with Functional Limitations: Evaluating a Telehealth Pulmonary Program for Patients with ALS

Authors: Marcie Lee, MPH,¹ Amber Lane, BS,¹ Summer Huang, BS,¹ Emily Gamm, LCSW,^{1,2} Rachel Johnson-Koenke, PhD, LCSW,^{1,2} Matthew Griffith, MD, MPH^{1,3}

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Research Objective: Individuals who have served in the military have a higher risk of Amyotrophic Lateral Sclerosis (ALS). ALS is a neurodegenerative condition characterized by progressive skeletal muscle weakness and impacts function but does not routinely affect cognitive function. Over time, ALS weakens the muscles used to breathe. Spirometry is used to routinely monitor lung function to determine trend, prognosis, and therapy needs. Patients with ALS commonly face mobility and social challenges (e.g. caregiver and transportation) that can make in facility testing potentially burdensome for patients and staff. Telehealth spirometry offers flexibility for patients and providers to monitor pulmonary function. We used the Practical Robust Implementation and Sustainability Model (PRISM) to inform the ongoing implementation and evaluation of the program in exploring program satisfaction.

Study Design: To assess the implementation of the Telehealth Spirometry Program, PRISM informed semi-structured interviews were conducted with staff and providers between November 2022 and February 2023. Audio recordings were transcribed verbatim, checked for accuracy, and analyzed in ATLAS.ti v22. We used thematic inquiry analysis and directed content analysis methods. The qualitative analysis team used an iterative approach to team consensus building.

Population Studied: We evaluated the Telehealth Spirometry Program for ALS at two multidisciplinary ALS clinics at Veteran Affairs Medical Centers (VAMCs), one in Colorado (Rocky Mountain Regional VAMC) and one in Washington (Puget Sound VAMC). A variety of roles were recruited, including physicians, nurses, and respiratory therapists (RT) that work within the ALS clinics.

Principal Findings: Staff (n=6) found implementation of telehealth spirometry to be effective in monitoring and trending the respiratory decline progress in patients with ALS. RTs facilitated appropriate telehealth spirometry use by extensively training patients and caregivers in-person and/or through telehealth, and on an ongoing basis as needed. Most patients with ALS were able to use the device independently or with assistance from their home caregiver. Both VAMCs were able to problem solve with patients to send results in time for their in-person appointments. Providers felt that spirometry tests were accurate and reliable and could reduce the burden of equipment maintenance, testing, and in-person clinic time. Concerning results were evaluated in clinic and patients received appropriate follow-up treatment as indicated.

Conclusions: PRISM informed our evaluation by highlighting organizational factors such as ongoing technical support that were essential to making this telehealth program successful. For ALS patients using telehealth spirometry, staff reported having these additional measures were helpful for patient monitoring, addressing prognosis, and initiating treatments. These results could be informative for telehealth spirometry programs for other indications (e.g., lung cancer screening) among older adults with functional limitations and other geriatric syndromes. Telehealth spirometry programs such as this should consider organizational factors such as the ongoing program support required to be implemented successfully.

Implications for Policy and Practice: These results show that telehealth-based spirometry testing could be successful and could be expanded in populations with functional limitations if provided ongoing support. Healthcare systems treating people with functional limitations would benefit from considering these types of organizational factors.

Appendix 7c: Academy Health Annual Research Meeting- Abstract 2

Primary theme Area: High cost, high need populations; Secondary theme: Aging, Disability, and End-of-Life
Title: Characterizing chronic comorbidities among patients with amyotrophic lateral sclerosis (ALS) enrolled in a large, integrated health system

Authors: Shelby Smith, MS¹, Summer Huang, BS,¹ Amber Lane, BS,¹ Andrew Graustein, MD^{2,3}, Cary Levy, MD, PhD,^{1,4} Matthew Griffith, MD, MPH^{1,4}

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Research Objective:

Amyotrophic lateral sclerosis (ALS) is a progressive, neurodegenerative condition characterized by declining respiratory function and skeletal muscle weakness. ALS primarily affects older adults (> 65) who often suffer from multiple comorbid chronic conditions at the time of, and following, their ALS diagnosis. ALS often affects speech and swallowing, contributes to psychological distress, and causes other physical and cognitive limitations that make it challenging to diagnose and treat other chronic comorbid conditions as guidelines for managing these conditions assume a baseline level of communication and functional ability. In this study, we sought to quantify the prevalence of common comorbidities among patients with ALS in order to characterize the implications these conditions have for comprehensive chronic disease care. Although previous studies have looked at specific cardiac comorbidities or assessed comorbidity burden among small groups of patients at single centers, this is the largest and most comprehensive assessment of comorbidities in this population.

Study Design:

We performed a retrospective study of patients living with ALS on 03/01/2019. Data was obtained from the Veterans Health Administration (VHA) Corporate Data Warehouse (CDW). Comorbidities were identified by ICD-10 codes associated with a care encounter, using current Elixhauser categorization.

Population Studied:

A total of 4,831 patients met inclusion criteria. The majority of patients (96%) were male with a mean age of 68y. Approximately 1/3rd (31%) lived in rural areas of the US.

Principal Findings:

Hypertension (65%), Depression or other mental health disorders (39%), Chronic Pulmonary Conditions (30%), Cerebral or Peripheral Vascular Disease (29%) and Diabetes (28%) were prevalent in nearly 1/3rd of patients in the cohort. Approximately 1 in 7 patients suffered from cancer (14%) or significant heart disease such as congestive heart failure (14%).

Conclusions:

Patients with ALS frequently suffer from chronic comorbid conditions that must be managed with daily oral, inhaled, or injected medications. Additionally, the severity of many of the conditions that we found to be common among these patients (e.g. chronic pulmonary disease and congestive heart failure) are evaluated using patient-reported symptom scores (e.g. COPD Assessment Test or New York Heart Association score) that may not be valid among adults who are not ambulatory or who have communication challenges.

Implications for Policy and Practice:

Although ALS only affects approximately 20,000 Americans, given that this condition is associated with military service and is service-connected through the VA system, these patients constitute a priority high-needs high-cost population to the VA. Understanding the prevalence of chronic comorbidities among these patients could inform integration of medical specialty providers into existing ALS multidisciplinary clinics. Given the low number of these patients and the high proportion living in rural areas, there may be opportunities to utilize telehealth to provide these patients with appropriate access to specialists such as pulmonologists, cardiologists and mental health providers who are better suited to adapt existing guidelines for disease assessment and management to patient ability.

Appendix 7d: VA Research Day- Abstract 1

Title: Opportunities for Inclusive Care for Patients with Functional Limitations: Evaluating a Telehealth Pulmonary Program for Patients with ALS

Authors: Marcie Lee, MPH,¹ Amber Lane, BS,¹ Summer Huang, BS,¹ Emily Gamm, LCSW,^{1,2} Rachel Johnson-Koenke, PhD, LCSW,^{1,2} Matthew Griffith, MD, MPH^{1,3}

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Amyotrophic Lateral Sclerosis (ALS) is a neurodegenerative condition characterized by progressive skeletal muscle weakness including the muscles used to breathe. Spirometry is used to monitor lung function to determine trend, prognosis, and therapy needs. Veterans with ALS commonly face challenges that can make infacility testing burdensome. Telehealth spirometry offers flexibility to monitor pulmonary function. We used the Practical Robust Implementation and Sustainability Model (PRISM) to inform the ongoing implementation and evaluation of the program in exploring program satisfaction.

We interviewed staff (n=6) that work within the ALS clinics to assess the implementation of the Telehealth Spirometry Program at two multidisciplinary ALS clinics (Rocky Mountain Regional VAMC and Puget Sound VAMC). PRISM informed semi-structured interviews were conducted between November 2022 and February 2023. Audio recordings were transcribed verbatim and analyzed using thematic inquiry and directed content analysis methods using team consensus.

PRISM highlighted organizational factors that were essential to success. For ALS patients using telehealth spirometry, staff reported having these additional measures were helpful for patient monitoring, addressing prognosis, and initiating treatments. These results could be informative for telehealth spirometry programs for other indications (e.g., lung cancer screening) among older adults with functional limitations and other geriatric syndromes. Future telehealth spirometry programs should consider organizational factors such as the ongoing program support. These results show that telehealth-based spirometry testing could be successful and expanded in populations with functional limitations with ongoing support. Healthcare systems treating people with functional limitations would benefit from considering these types of organizational factors.

Appendix 7e: VA Research Day- Abstract 2

Title: Characterizing chronic comorbidities among patients with Amyotrophic lateral sclerosis (ALS) enrolled in a large, integrated health system

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Amyotrophic lateral sclerosis (ALS) is a progressive, neurodegenerative condition characterized by declining respiratory function and skeletal muscle weakness. Individuals who have served in the military have a higher risk of developing ALS. ALS primarily affects older adults (> 65) who often suffer from multiple comorbid chronic conditions at the time of, and following, their ALS diagnosis. Having ALS can complicate the diagnoses, treatment, and management of those conditions. In this study, we quantified the prevalence of common comorbidities among patients with ALS in order to characterize the implications these conditions have for comprehensive chronic disease care.

We performed a retrospective study of Veterans (n=4,831) living with ALS on 03/01/2019. Data was obtained from the Veterans Health Administration (VHA) Corporate Data Warehouse (CDW). Comorbidities were identified by ICD-10 codes associated with a care encounter, using current Elixhauser categorization.

Hypertension (65%), Depression or other mental health disorders (39%), Chronic Pulmonary Conditions (30%), Cerebral or Peripheral Vascular Disease (29%) and Diabetes (28%) were prevalent in nearly 1/3rd of patients in the cohort. Approximately 1 in 7 patients suffered from cancer (14%) or significant heart disease such as congestive heart failure (14%). 33% of patients lived in rural areas of the US. Understanding the prevalence of chronic comorbidities and rurality could improve care by informing the integration of medical specialists and delivery of care (i.e., telehealth) to better suit Veterans' needs within ALS multidisciplinary clinics.

Appendix 7f: American Association of Respiratory Care Congress

Title: Qualitative Evaluation of a Respiratory Therapist (RT)-Led VA Telehealth Spirometry Program for Amyotrophic Lateral Sclerosis (ALS)

Authors: Korren Rappisi, RRT, BS¹, Marcie Lee, MA, MPH,² Amber Lane, BS,² Summer Huang, BS,² Rachel Johnson-Koenke, PhD, LCSW,^{2,3} Matthew Griffith, MD, MPH^{2,4}, Andrew Graustein, MD¹

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Background: Amyotrophic Lateral Sclerosis (ALS) is a neurodegenerative disease characterized by progressive skeletal muscle weakness that can impact pulmonary function. Recognizing pulmonary decline can lead to initiation of therapies that can slow disease progression, prevent complications, or provide comfort for the patient. Spirometry is used to monitor lung function quarterly to determine prognosis and therapy needs.

Setting: We are evaluating a telehealth spirometry program for ALS at two Veteran Affairs Medical Centers (VAMCs), the Rocky Mountain Regional VAMC and Puget Sound VAMC.

Methods: This study was approved by both the VA and the local IRB. Semi-structured interviews were conducted with staff and providers to assess implementation between October 2022 and February 2023. Interviews were audio recorded, transcribed verbatim, and analyzed in ATLAS.ti v23. We used thematic inquiry analysis and directed content analysis methods.

Results: Staff (n=6) found implementation of telehealth spirometry to be effective in monitoring respiratory decline in ALS patients. Respiratory Therapists (RTs) facilitated appropriate spirometry use by extensively training patients and caregivers in-person and through telehealth. Most patients with ALS were able to use the device independently or with assistance from their home caregiver however some required additional instruction and time to get used to the technology and process. VAMCs worked through challenges with patients to send results in time for their in-person appointments. Providers perceived telehealth spirometry testing as accurate and reliable and could reduce the burden of the in-person clinic time. If patient spirometry measurements were notably lower than previous levels, RTs initiated appropriate follow-up testing and treatment as well as education for patients.

Conclusion: Ongoing RT support is essential for successful implementation of a telehealth spirometry program. Staff reported that having telehealth spirometry measures were helpful for monitoring pulmonary function. Additionally, staff reported that overall patients responded positively and could use the device independently or with caregiver support with continued training and support. These results could inform the development of other telehealth spirometry programs (e.g., lung cancer screening).

Disclosures: None