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Assessment of Home-based Monitoring in Adults with Chronic Lung Disease

An Official American Thoracic Society Research Statement

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Abstract

Background: There is increasing interest in the use of home-based monitoring in people with chronic lung diseases to improve access to care, support patient self-management, and facilitate the collection of information for clinical care and research. However, integration of home-based monitoring into clinical and research settings requires careful consideration of test performance and other attributes. There is no published guidance from professional respiratory societies to advance the science of home-based monitoring for chronic lung disease.

Methods: An international multidisciplinary panel of 32 clinicians, researchers, patients, and caregivers developed a multidimensional framework for the evaluation of home-based monitoring in chronic lung disease developed through consensus using a modified Delphi survey. We also present an example of how the framework could be used to evaluate home-based monitoring using spirometry and pulse oximetry in adults with asthma, bronchiectasis/cystic fibrosis, chronic obstructive pulmonary disease, and interstitial lung disease.

Results: The PANACEA framework includes seven domains (test Performance, disease mANAgement, Cost, patient Experience, clinician Experience, researcher Experience, and Access) to assess the degree to which home-based monitoring assessments meet the conditions for clinical and research use in chronic lung disease. Knowledge gaps and recommendations for future research of home spirometry and pulse oximetry in asthma, bronchiectasis/cystic fibrosis, chronic obstructive pulmonary disease, and interstitial lung disease were identified.

Conclusions: The development of the PANACEA framework allows standardized evaluation of home-based monitoring in chronic lung diseases to support clinical application and future research.

Keywords: home-based monitoring; home spirometry; pulse oximetry; chronic lung disease

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A data supplement for this article is available via the Supplements tab at the top of the online article.

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Overview

Home-based monitoring holds promises to improve the access, quality, and experience of care for patients with chronic lung disease and could also improve endpoint collection and safety monitoring in clinical trials. With technology improvement, there has been rapid development of remote monitoring of key assessments in chronic lung disease that are critical for disease monitoring and therapeutic decisions. In this research statement, we *1*) present a multidimensional framework for the evaluation of home-based monitoring in chronic lung disease in clinical and research settings; and *2*) summarize existing literature using the framework to identify knowledge gaps and develop research recommendations for home spirometry and pulse oximetry in adults with chronic lung disease.

Key conclusions and recommendations include:

- The PANACEA framework provides a structured approach for evaluating the degree to which home-based monitoring assessments meet the conditions for clinical and research use in chronic lung disease.
- The PANACEA framework consists of seven domains, with a total of 7 essential and 21 desirable items: test performance, disease management, cost, patient experience, clinician experience, researcher experience, and access.
- Essential items for the PANACEA framework are test validity, test reliability, utility for disease assessment/monitoring, test cost to patients, result availability to patients, patient safety with performing the test, and need for digital health literacy for patients. These items should be prioritized in the assessments of home-based monitoring in chronic lung disease.
- Research recommendations for home spirometry in chronic lung disease
  Study settings
  - Evaluate home spirometry in different resource settings
  - Evaluate home spirometry in patients of different backgrounds in terms of digital health literacy, socioeconomic status, and geographical distribution

  Study aims
  - Evaluate performance (validity, reliability, responsiveness, interpretability) and usability of various commercially available and new home spirometers
  - Compare home spirometry to in-laboratory spirometry for patient monitoring and prognostication
  - Evaluate the role of home spirometry as part of a program in disease management and patient outcomes compared with conventional patient care
  - Evaluate home spirometry as a secondary outcome in clinical trials
  - Evaluate the optimal frequency and technical supports required for home spirometry testing
  - Evaluate measures to improve patient acceptability, adherence, and experience for long-term home spirometry
  - Evaluate cost-effectiveness and impact on healthcare delivery with the incorporation of home spirometry into routine clinical care
- Research recommendations for pulse oximetry in chronic lung disease
  Study settings
  - Evaluate home oximetry in different resource settings
  - Evaluate home oximetry in people of different backgrounds in terms of digital health literacy, socioeconomic status, and geographical distribution
  - Evaluate home oximetry in people with a range of skin pigmentation

  Study aims
  - Evaluate performance (validity, reliability, responsiveness, interpretability) and usability of various commercially available and new home oximeters, including wearable sensors and mobile applications
  - Define specific subsets of patients who would derive benefits from home oximetry
  - Compare home oximetry to oxyhemoglobin saturation measurements using 6-minute-walk testing for patient monitoring and prognostication
  - Evaluate the role of home oximetry as part of a program in disease management and patient outcomes compared with conventional patient care
  - Define optimal parameters and the minimal clinical important difference as cutoff values of home oximetry for patient care
  - Evaluate home oximetry as a secondary outcome of oxygenation status assessment in clinical trials
  - Evaluate clinical utility of home oximetry for the assessment,

prescription, and monitoring of oxygen therapy
  - Evaluate clinical utility of home oximetry for monitoring during home-based exercise and pulmonary rehabilitation
  - Evaluate the optimal frequency and monitoring duration required for home oximetry
  - Evaluate measures to improve patient acceptability, adherence, and experience for long-term home oximetry
  - Evaluate cost-effectiveness and impact on healthcare delivery with the incorporation of home oximetry into routine clinical care
- Factors affecting health equity should be considered in the implementation of home-based monitoring for clinical and research settings of chronic lung disease.

PANACEA

Panacea is the daughter of Asclepius, the god of medicine, and Epione, the goddess of soothing. Panacea is the goddess of universal remedy, embodying the eternal quest for a "cure-all." Also, for modern medical applications such as e-health and home monitoring, the allure of panacea exists. Yet, its pursuit reveals complexities, as described in this manuscript, reminding us to carefully consider limitations.

Introduction

The care of patients with chronic lung diseases has traditionally required in-person visits to clinical settings to complete assessments of health status. The requirement for in-person visits for clinical and research purposes imposes substantial patient burden, particularly for those with limited mobility or socioeconomic resources, those with caregiving or other such responsibilities, or those who need to travel substantial distances. Although home assessments are available for selected health services and by primary care physicians, only interval visits can be provided, with limited availability because of the constraints of healthcare resources. Assessment at a single clinical appointment provides a snapshot of patient health that may not be representative of overall health, particularly in conditions with health impacts that wax and wane over time. Regular and more frequent monitoring of different aspects of health status could provide a more complete picture of health trajectories and detect intercurrent problems, such as acute exacerbations.

These considerations have fueled interest in home-based monitoring for people with chronic lung diseases. Home-based monitoring includes handheld devices, such as spirometers; pulse oximeters; wearables, such as smart watches or step counters; smartphone apps to monitor symptoms; electronic inhaler monitors; and remote or virtual exercise tests. However, wide variation exists in the technical specifications, support requirements, and patient and clinician acceptability of these home-based monitoring possibilities, with uncertainties about their validation process and healthcare and research workflow redesign. In addition, the need for access to technology, reliable internet service or mobile data plans, and digital literacy could perpetuate or exacerbate health inequities. Conversely, they also offer opportunities for improved patient engagement in clinical care, for decentralization of clinical trials by improving access beyond academic centers, and for marginalized populations with difficulties attending regular hospital visits (1). The shift to telemedicine during the coronavirus disease (COVID-19) pandemic because of infection control restriction has accelerated the priority of home-based monitoring as an alternative approach for symptom and physiological monitoring in chronic lung disease for patient care and research.

Large-scale and effective integration of home-based assessments for clinical or research purposes may therefore require careful consideration of test performance and other attributes that could affect implementation in clinical and research settings. Although existing tools are available to evaluate digital health technologies for a specific type of home monitoring (2, 3) and with a specific focus on either clinical (4, 5) or research use (6), there are two main issues. First, many tools are specific to a particular type of home monitoring. Although there are many different types of home monitoring tests and devices, they have shared features and common requirements for clinical and research applications. In addition, it is common for them to be used as a bundle. Hence, having different assessment tools for various types of home monitoring makes it impractical to implement. Second, some existing tools lacked the involvement of diverse perspectives, particularly patient and caregiver representatives, in their development.

This research statement presents the development of a framework to support multidimensional decision making for home-based monitoring in chronic lung disease based on input from an international multidisciplinary panel of clinicians, researchers, and patient and caregiver representatives. Subsequently, as a first test case, we used this framework to evaluate current literature on home spirometry and pulse oximetry in adults with chronic lung disease to identify knowledge gaps and develop research recommendations.

Methods

Committee Composition

The co-chairs proposed and assembled an international multidisciplinary panel with experience in remote monitoring that included patients, caregivers, clinicians, and researchers in pulmonary medicine, primary care, physiotherapy, and nursing. Committee members also had proficiency in evidence-based medicine, health equity, and implementation science. Panel members were selected for complementary clinical or research expertise and lived experiences in performing and using remote monitoring, with representation from different chronic lung diseases, while ensuring diversity in sex, geography, disciplines, and career stages. This was reviewed and approved by the American Thoracic Society (ATS) Assembly on Clinical Problems and Documents Development and Implementation Committee. Conflicts of interest were disclosed and managed according to the ATS policies and procedures.

All committee meetings were conducted via virtual web conferences. A steering committee was formed consisting of the co-chairs and co-leads for each subcommittee, who oversaw the work of six subcommittees (Online Supplement 1): *1*) evidence-based medicine, which oversaw the literature search and screening; *2*) health equity, which oversaw considerations of health disparities with using home-based monitoring; and *3*) four disease-based subcommittees that reviewed the literature relevant to home-based monitoring with spirometry or pulse oximetry (asthma; bronchiectasis/cystic fibrosis [CF]; chronic obstructive pulmonary disease [COPD]; and interstitial lung disease [ILD]).

Development of a Framework to Evaluate Home-based Monitoring for Chronic Lung Disease

The primary objective was to develop a multidimensional PANACEA (test *p*erformance, disease m*ana*gement, *c*ost, *e*xperiences, *a*ccess) framework to evaluate home-based monitoring tests that represented the interests of patients and caregivers, clinicians, and researchers.

We used a three-step approach to develop the PANACEA framework (Figure 1):

1. Preliminary work based on existing literature led the co-chairs to develop domains and items of the framework that were potentially relevant;
2. Two rounds of a modified Delphi survey that included the full committee to rate the domains (a particular dimension for the evaluation of home-based monitoring tests in chronic lung disease) and items (parameters or characteristics that are used to measure the various aspects of a dimension) using a 7-point Likert scale (1 = very unimportant, 7 = very important). Domains and items were defined *a priori* as "essential" if the median score was 6 (important) or 7 (very important) with an interquartile range of 0 and "desirable" for a median score 6 or 7 with an interquartile range of 1; otherwise, items were considered "neither essential nor desirable"; and
3. Discussions to review survey findings.

More details are presented in Online Supplement 2 (methods used in Steps 1 and 2), Online Supplement 3 (results), and Online Supplement – Modified Delphi Survey Rounds 1 and 2.

Literature Search and Evaluation for Application of the PANACEA Framework

A secondary objective was to demonstrate an example of how the PANACEA framework could be used to evaluate studies about home-based spirometry and oximetry in asthma, bronchiectasis/CF, COPD, and ILD. These chronic lung diseases were chosen because of their substantial health burden and the pressing need for evaluation after the rapid adoption of telemedicine since the COVID-19 pandemic. To this end, we conducted a literature search of Ovid MEDLINE, EMBASE, and CINAHL for publications between 2000 and May 2023 to identify relevant studies. Committee members were asked to propose additional relevant literature. Relevant studies were reviewed, with data being synthesized narratively for summaries. Results of this second objective were intended to identify knowledge gaps that could be used to develop research recommendations. The full search strategies and study

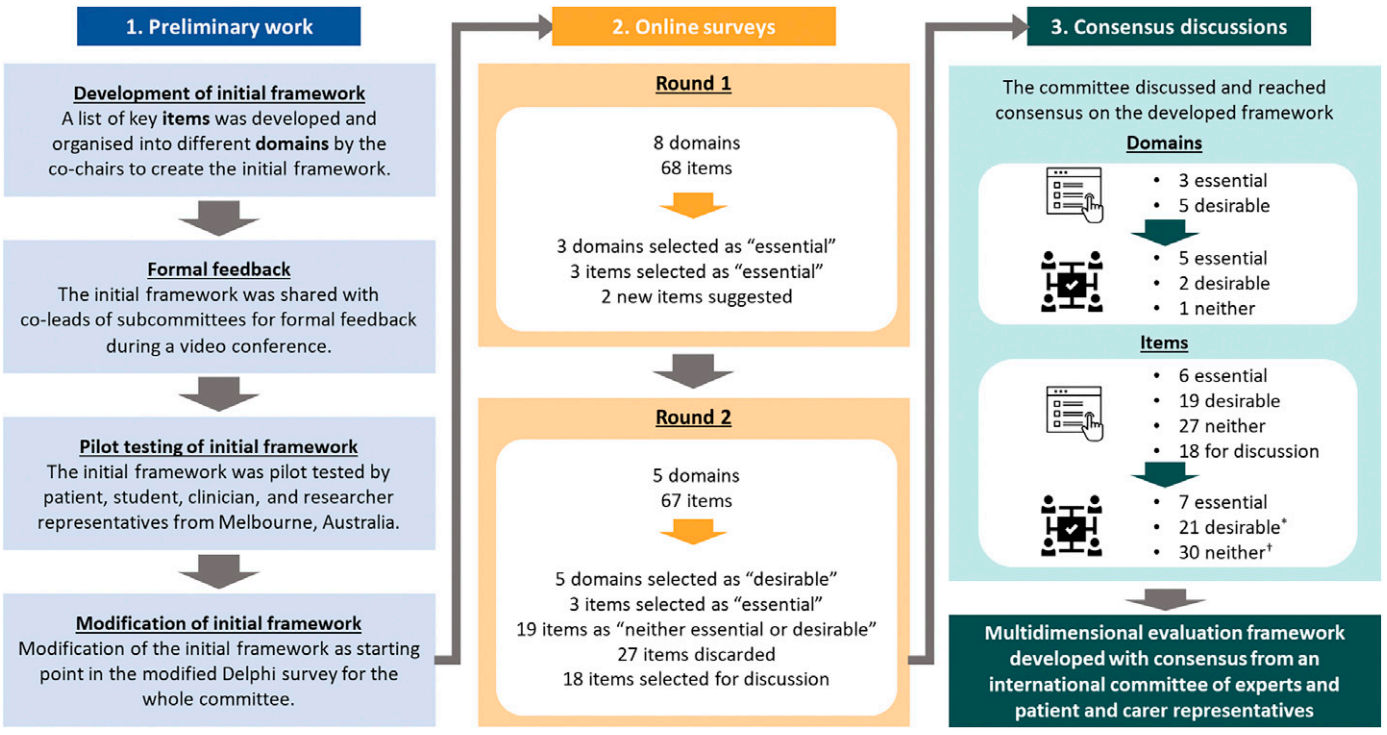

Figure 1. Steps in developing the multidimensional evaluation framework for assessment of home-based monitoring tests in chronic lung disease. *Two desirable items were considered overlapped with an essential item. After discussion, it was decided to combine into a single essential item. †Ten items under the health outcome domain were discarded (*see* Online Supplement 2 for details).

selection criteria are described in Tables E1 and E2 in the online supplement, respectively.

Document Development

The co-chairs collated writings from each subcommittee and drafted the initial version of the manuscript, which was then disseminated to the full committee for iterative revision and approval. The final manuscript was peer reviewed and approved by the ATS Board of Directors.

Results

Section 1: The PANACEA Framework for Multidimensional Evaluation of Home-based Monitoring in Chronic Lung Disease

The PANACEA framework consists of seven domains with a total of 7 essential and 21 desirable items (Figure 2 and Table 1). The domains are test performance, disease management, cost, patient experience, clinician experience, researcher experience, and access. Each domain includes one or more items that could be used to evaluate the device for remote monitoring. The domains and items are categorized as essential when they are strongly recommended across all settings, or desirable when they are suggested depending on local resources and the purpose of testing.

Section 2: Applying the PANACEA Framework for Home Spirometry in Chronic Lung Disease

Spirometry is conventionally conducted under supervision in clinical laboratories using specialized equipment in accordance with established technical standards (7). Commercially available lower-cost portable spirometers with features such as associated apps, online data storage, and/or real-time wireless data transmission have become available for use in patient homes for clinical and research purposes. Home-based spirometers offer the potential for frequent serial measurements of lung function. We used the PANACEA framework to evaluate home spirometry described in peer-reviewed publications. Different spirometers were used in the studies within and across the disease areas (Figure E1 and Table E3), with key device characteristics described in Figure 3. A summary of key findings from the literature review of peer-reviewed publications of home spirometry is presented to demonstrate application of the PANACEA framework, with detailed findings described in Tables E4 and E5. Table 2 presents the research recommendations of home spirometry evaluation in chronic lung diseases.

Asthma. Fourteen studies evaluated home spirometry in 4,040 adult participants with asthma. Results of additional analyses of spirometry data from two studies (8, 9) were subsequently reported in two separate publications. Thus, a total of 16 publications were reviewed. Of the 15 unique studies, 9 were observational studies (10–18) and 2 were randomized controlled trials (RCTs) that included home monitoring of spirometry versus no home monitoring as part of the intervention (8, 19). The report from one of the RCTs also included results of a separate pre/post home monitoring

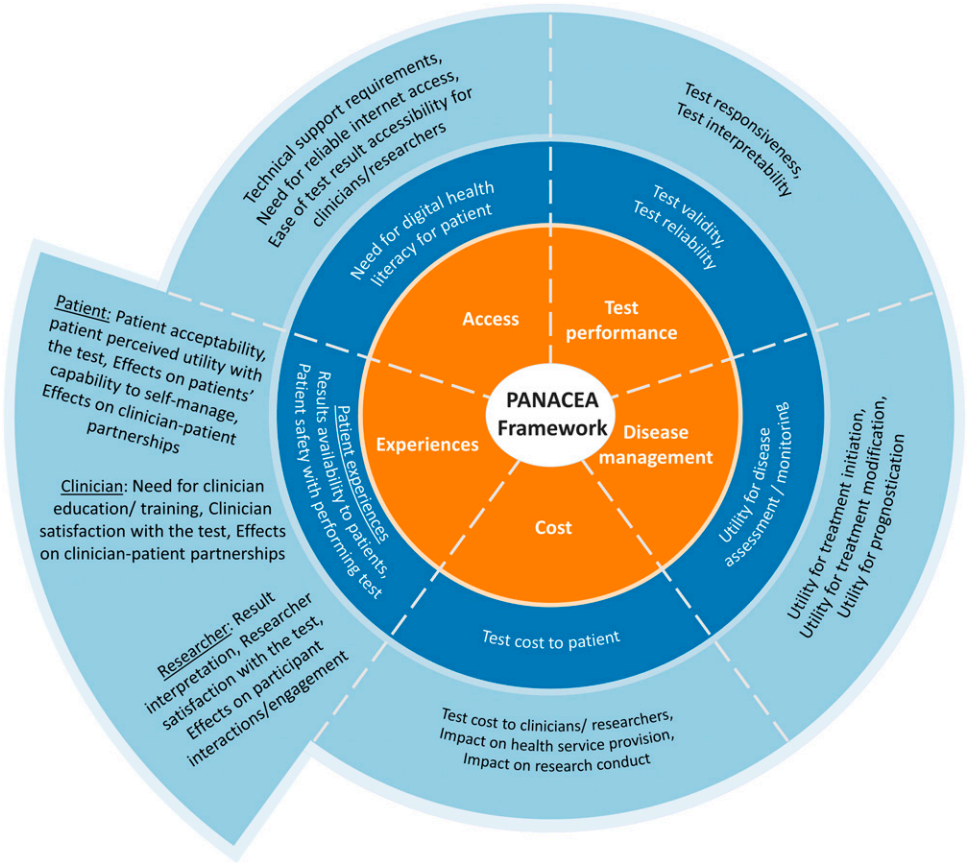

Figure 2. The multidimensional evaluation framework for home-based monitoring tests in chronic lung disease.

Table 1. The PANACEA Framework Domains and Items for Home-based Monitoring Tests in Chronic Lung Disease

Essential Items	Guidance for Evaluation
Test performance domain	
Test validity: How well the test measures what it is supposed to measure	For comparison against a reference standard test performed at the same time or within a short interval: • Calculation of variance/differences in measurements • Intraclass correlation coefficients • Pearson or Spearman correlation • Bland and Altman plots
Test reliability: How well the test provides consistent measurements when it is performed twice or more	For repeated measurements using the same test under the same test condition within a short interval: • Calculation of variance/differences in measurements • Intraclass correlation coefficients • Coefficient of variation • Pearson or Spearman correlation • Bland and Altman plots
Disease management domain	
Utility for disease assessment/monitoring: Extent to which the test results inform disease severity and course	• Evaluation against known parameters for disease severity, progression, and acute exacerbation: Pearson or Spearman correlation • Qualitative research with experienced patients, caregivers, clinicians, and researchers
Cost domain	
Test cost to patients: Cost associated with patient access to the test, including reimbursement	• Reporting of potential test cost for patients in nonresearch settings (e.g., cost for self-purchasing, availability of reimbursement) Qualitative research with experienced patients, caregivers, clinicians, and researchers
Patient experiences domain	
Results availability to patients: Whether patients have the option to access results without going through a healthcare professional	• Description of test data recording or patient access for test results in the Methods section of a manuscript • Provision of technical specification for a device as part of the study protocol • Qualitative research with experienced patients, caregivers, clinicians, and researchers
Patient safety with performing the test: Whether performing the test can affect patients' mental or physical well-being, including causing adverse events	• Qualitative research with experienced patients, caregivers, clinicians, and researchers • Evaluation of patient well-being and adverse events (such as health-related quality of life, anxiety, respiratory symptoms, and syncope) as outcomes
Access domain	
Need for digital health literacy for patients: Level of knowledge about technological expertise and capacity to use the computer required for patients	• Description of required patients' digital capability for performing test and data recording/reporting as study eligibility criteria in the Methods section of a manuscript • Qualitative research with experienced patients, caregivers, clinicians, and researchers
Desirable Items	**Examples**
Test performance domain	
Test responsiveness: How well the test detects a change	• For comparison against changes detected using a reference standard test performed at the same time or within a short interval: Pearson or Spearman correlation • For repeated measurements using the same test under the same test condition over a longer period of time: standardized effect size, standardized response mean • For evaluation of changes to a known effective intervention: calculation of variance/differences in measurements
Test interpretability: Ease of assigning meaning (e.g., disease severity, significance of changes, availability of normal range) to test measurements	• Establishment of thresholds for minimal important changes and detection of nonmeaningful results • Qualitative research with experienced patients, caregivers, clinicians, and researchers
Disease management domain	
Utility for treatment initiation: Extent to which the test results inform clinicians' decision to start treatment	• Evaluation of initiation of treatments based on the test results for chronic disease state or acute exacerbation: calculation of variance/differences • Qualitative research with experienced clinicians • Evaluation of modification of treatments based on the test results for chronic disease state or acute exacerbation: calculation of variance/differences

(*Continued*)

Table 1. (*Continued*)

Desirable Items	Examples
Utility for treatment modification: Extent to which the test results inform clinicians' decision to change treatment	• Qualitative research with experienced clinicians
Utility for prognostication: Extent to which the test results inform future risk of adverse outcomes (e.g., exacerbations, mortality)	• Evaluation of association of test results in predicting future adverse health outcomes (e.g., exacerbations and mortality): linear, logistic, and Cox regression • Qualitative research with experienced clinicians
Cost domain	
Test cost to clinicians/researchers: Cost associated with providing the test for clinicians/researchers, including reimbursement	• Reporting of potential test cost for clinicians in nonresearch settings or researchers in research settings (e.g., cost for equipment purchasing and set-up, availability of reimbursement for clinical settings) • Qualitative research with experienced clinicians and researchers
Impact on health service provision: Extent to which the test affects health service provision (e.g., resource allocations, development of infrastructure)	• Description of changes in health service provision, including health economics • Implementation evaluation of facilitators and barriers for the test performance • Qualitative research with experienced clinicians and researchers
Impact on research conduct: Extent to which the test affects research conduct (e.g., clinical trial access)	• Description of changes in research conduct, such as clinical trial efficiency • Implementation evaluation of facilitators and barriers for the test performance • Qualitative research with experienced clinicians and researchers
Patient experiences domain	
Patient acceptability: Patients' ease and comfort level with performing the test	• Test adherence and discontinuation rates • Qualitative research with experienced patients, caregivers, clinicians, and researchers • Questionnaires to evaluate patients' satisfaction
Patient-perceived utility with the test: Patients' perceived usefulness of the test	• Qualitative research with experienced patients and caregivers
Effects on patients' capability to self-manage: Impact of performing the test on patient's ability to manage their lung disease and seek medical help	• Evaluation of self-efficacy in disease management • Qualitative research with experienced patients, caregivers, clinicians, and researchers
Effects on clinician–patient partnerships: Patients' impression of their involvement with the treating team with performing the test in clinical care	• Qualitative research with experienced patients and caregivers
Clinician experiences domain	
Need for clinician education/training: Level of education/training required for clinicians to provide test	• Description of required clinicians' digital capability for performing test and data recording/reporting in the Methods section of a manuscript • Qualitative research with experienced clinicians
Clinician satisfaction with the test: Clinicians' perceived usefulness of the test	• Qualitative research with experienced clinicians • Questionnaires to evaluate clinicians' satisfaction
Effects on clinician–patient partnerships: Clinicians' perceived quality of interactions or relationships with patients by performing the test	• Qualitative research with experienced clinicians
Researcher experiences domain	
Result interpretation: Ease of using the test results as meaningful and/or validated trial outcomes	• Evaluation of the degree of missing and/or invalid data • Availability of analytic methods for large dataset/big data • Composite of test performance parameters
Researcher satisfaction with the test: Researchers' perceived usefulness of the test	• Qualitative research with experienced researchers • Questionnaires to evaluate researchers' satisfaction
Effects on participant interactions/engagement: Researchers' perceived quality of interactions/engagement with participants during clinical trials or other research activities with providing the test	• Qualitative research with experienced researchers
Access domain	
Ease of test result accessibility for clinicians/researchers: Extent to which the test result can be readily accessed by clinicians/researchers	• Description of test data recording or clinician/researcher access for test results in the Methods section of a manuscript • Qualitative research with experienced clinicians and researchers
Technical support requirements: Extent to which the test requires ready access to technical support for patients and clinicians/researchers (e.g., troubleshooting for device failure)	• Description of the degree of technical support availability for performing test and data recording/reporting in the Methods section of a manuscript • Provision of technical support availability for performing test and data recording/reporting as part of the study protocol • Qualitative research with experienced patients, caregivers, clinicians, and researchers

(*Continued*)

Table 1. (*Continued*)

Desirable Items	Examples
Need for reliable internet access: Need to have reliable internet access as part of the test	• Description of the degree of meaningful internet connectivity (e.g., regular access, sufficient data, and fast connection) for performing test and data recording/reporting in the Methods section of a manuscript • Qualitative research with experienced patients, caregivers, and healthcare professionals

Together with the PANACEA framework, guidance and checklists for different research methods should be used for the study design and reporting: the CONSORT (Consolidated Standards of Reporting Trials) for randomized trials, the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) for observational studies, the STARD (Standards for Reporting Diagnostic Accuracy) for diagnostic/validation studies, the SRQR (Standards for Reporting Qualitative Research) or COREQ (Consolidated Criteria for Reporting Qualitative Research) for qualitative studies, the SQUIRE (Standards for Quality Improvement Reporting Excellence) for quality improvement studies, and the CHEERS (Consolidated Health Economic Evaluation Reporting Standards) for economic equation.

study (19). Three studies included home spirometry as an endpoint in an RCT without its evaluation as part of the intervention (9, 20, 21).

Six out of seven essential items of the PANACEA framework were reported in at least one study (Figure 4 and Tables E4 and E5). None of the studies reported the cost of home-based spirometers. Test performance for home spirometry focused on FEV_1 measurements, with limited data suggesting good validity and reliability, with the tendency of lower measurements using home spirometry. Availability of results to patients together with familiarity with technology or access to a smartphone were commonly reported. There was limited reporting about the effects on disease management and adverse events. Of the 21 desirable items of the framework, 15 were evaluated (Tables E4 and E5). The most reported desirable item was patient acceptability of home spirometry using different methodologies, including qualitative interviews and proxy assessments such as protocol adherence. This was followed by responsiveness of home spirometry, which was often evaluated against pharmaceutical interventions in clinical trials, and patient experiences on the utility, self-management capability, and interactions with their healthcare professionals. Data transfer of home spirometry measurements to healthcare professionals or researchers often required mobile phone or internet access, which resulted in missing data in a small minority with no other reported technology-related problems. The remaining evaluated desirable items in asthma were each reported in one or two studies.

The wide range of home spirometry devices used precluded meaningful analyses comparing findings across devices. Another major limitation was that test performance was a primary objective in only a few studies, one of which included only five participants (11), with varying intervals between home and in-laboratory assessments that could be affected by diurnal variation in patients with asthma. There was substantial heterogeneity in how various items were assessed across studies, and home spirometry was often a component of a multicomponent intervention, limiting the ability to evaluate home spirometry in isolation.

Bronchiectasis/CF. Eleven studies, including 747 adult patients and 28 healthcare professionals, evaluated home spirometry in CF: eight observational studies (22–29), one RCT (30), and two qualitative studies (one with patients [31] and one with healthcare professionals [32]). The eight observational studies included two conducted as part of a comprehensive digital home monitoring program (23, 24), one comparing home and in-laboratory spirometry (29), one comparing supervised and unsupervised home spirometry (27), two comparing home monitoring and usual care (22, 28), and two patient surveys (25, 26). There were no relevant studies of non-CF bronchiectasis identified.

Six of seven essential items of the PANACEA framework were evaluated in two to four studies, with none assessing costs of tests (Figure 4 and Tables E4 and E5). Nevertheless, the limited data showed satisfactory validity and reliability for home spirometry in CF, with utility for disease assessment and monitoring for pulmonary exacerbation as part of a comprehensive program. Results were often accessible to patients, with data transmission and digital skills being required for some. Eleven of the 21 desirable items of the framework were evaluated, with patient acceptability being the most reported (Tables E4 and E5). The utility of remote monitoring programs that incorporated home spirometry to guide treatment and management of pulmonary exacerbation in CF was evaluated. Various modes were used for clinicians' and researchers' access to home spirometry results. Reimbursement concerns, clinician training and satisfaction, and effects on clinician–patient partnerships were rarely reported.

All studies of home spirometry in CF were conducted in high-income countries, with additional limitations of single-center design or enrolling a small number of participants. Furthermore, a few studies were conducted in the pre-CFTR (CT transmembrane conductance regulator) modulator era. Patient lung function and symptoms have changed significantly in recent years with the advent of highly effective CFTR modulator therapies, which may reduce the relevance of findings from previous studies in contemporary care. Participant characteristics were not provided in two observational studies, which may have included pediatric participants with different support requirements (23, 24).

COPD. Twenty-one studies evaluated 3,998 adult participants with home spirometry in COPD. Of these, six studies (33–38) had nine additional publications with analyses related to home spirometry. Thus, a total of 30 publications were reviewed. Home monitoring using spirometry often included other assessments and components (e.g., teleconsultation, patient education, and COPD action plans). Spirometry was evaluated as the principal component of interest in 16 studies (33–36, 38–49), whereas it was incidental to other components (such as home pulmonary rehabilitation) in three studies (37, 50, 51). There was one validation study against in-laboratory spirometry (14) and one

A

	Key lung function parameters measured						Provision of test quality feedback	Associated app platform	Instructional video/App by developer	Test result interpretation
	FEV_1	FVC	FEV_1/FVC	FEF 25-75	FEV_6	PEF				
AioCare	X	X	X	X		X	X	X	X	X
Air Next	X	X	X	X	X	X	X	X	X	
Ambulatory mSpirometer	X	X	X	X	X	X	X	X	X	
Asma-1-monitor	X					X	X		X	X
Asthma Monitor 3	X					X	X			
EasyOne	X	X	X	X	X	X	X		X	
Lung Monitor S	X				X		X		X	X
Micro spirometer	X	X	X	X	X	X	X			X
MicroDiaryCard	X					X	X			
Microlife PF100	X					X				X
Model V2120	X	X	X	X	X	X	X			
mySpiroSense	X	X	X	X	X	X	X	X	X	X
PiKo-1	X				X	X	X			X
Spirobank Smart	X	X	X	X	X	X	X	X	X	X
SpiroHome	X	X		X		X	X	X		X
SpiroPro	X	X		X		X				X
Spirotel	X	X		X		X			X	
Vivisol One Flow	X	X		X		X				

B

	Device types				Provision of test quality feedback*	Associated app platform	Instructional video by developer
	Fingertip oximeter	Handheld oximeter	Portable sleep monitor	Comprehensive telemonitor system			
Cloud DX Connected Health Kit				X		X	X
Contec CMS50D	X						X
Docobo® Health HUB (Nonin 3831-001)				X			
HomMed				X			
Nonin 3230	X				X	X	
Nonin 8500M		X			X		
Nonin 9500 Onyx†	X				X		
Nonin 9550/9560 Onyx II	X				X		
Palmsat 2500		X			X		X
SAS2100			X				
Spirotel				X			X
TeleMedCare				X			
Tuffsat		X			X		

Figure 3. Key characteristics of devices used in studies of (*A*) home spirometry and (*B*) pulse oximetry in chronic lung disease. Only home spirometry and pulse oximetry devices used in completed published studies were included. In addition, several studies did not provide device names for home spirometry and pulse oximetry used. Device information was obtained from publications and developers' websites. *Provision of feedback when the finger is not placed properly in the device and/or pulse quality. †Nonin 9500 Onyx has been replaced by Nonin Onyx Vantage 9590. FEF 25–75 = forced expiratory flow between 25% and 75% of vital capacity; FEV_6 = forced expiratory volume in 6 seconds; PEF = peak expiratory flow.

Table 2. Recommendations for Future Research of Home Spirometry in Chronic Lung Diseases

Areas Requiring Additional Research
Study settings
Evaluate home spirometry in different resource settings
Evaluate home spirometry in patients of different backgrounds in terms of digital health literacy, socioeconomic status, and geographical distribution
Study aims
Evaluate performance (validity, reliability, responsiveness, interpretability) and usability of various commercially available and new home spirometers
Compare home spirometry to in-laboratory spirometry for patient monitoring and prognostication (e.g., frequent home-based vs. interval office-based spirometry to identify and risk-stratify patients for respiratory exacerbations)
Evaluate the role of home spirometry as part of a program in disease management and patient outcomes compared with conventional patient care
Define optimal parameters and the minimal clinical important difference as cutoff values of home spirometry for patient care
Evaluate home spirometry as a secondary outcome in clinical trials
Evaluate the optimal frequency and technical supports required for home spirometry testing
Evaluate measures to improve patient acceptability, adherence, and experience for long-term home spirometry
Evaluate cost-effectiveness and impact on healthcare delivery with the incorporation of home spirometry into routine clinical care

Some recommendations may be more relevant for specific types of chronic lung diseases.

long-term prospective study (52). The included studies were clinical trials and observational cohorts, with few having qualitative and cost assessments.

Of the seven essential items of the PANACEA framework, six items were reported in at least one study (Figure 4 and Tables E4 and E5). Most studies evaluated the utility and safety of remote or telemonitoring programs with inbuilt alert notifications based on prespecified thresholds for home spirometry and other assessments for disease management. Availability of results for home spirometry and the requirement of familiarity with technology varied depending on the platforms used for delivering remote or telemonitoring programs. Very few studies assessed test performance of home spirometry in patients with COPD, suggesting satisfactory validity and reliability. None evaluated the test cost to patients. Sixteen of the 21 desirable items of the framework were evaluated (Tables E5 and E6). The utility of remote or telemonitoring programs with home spirometry in predicting or identifying the need for treating acute exacerbation of COPD varied across studies. There was high patient acceptability of home spirometry as part of remote or telemonitoring programs, with positive views about the usefulness and ease of testing. Most platforms for delivering remote or telemonitoring programs allowed automated data transmission of different assessments, including home spirometry, for access by clinicians and researchers, with reported technical support availability in selected ones. Although some monitoring platforms required telephone lines only, others needed reliable internet. Changes to clinician workloads were evaluated in a small number of studies, such as the provision of clinical reviews either remotely or in person.

Most studies of home spirometry in COPD were conducted in high-income countries, with more than one-third having fewer than 50 patients and high dropout rates in some. Given that the vast majority of studies of COPD evaluated home spirometry in the context of multicomponent remote or telemonitoring programs, the value of home spirometry as an individual component is uncertain.

ILD. Nineteen studies, including a total of 1,334 adult patients and 207 clinicians, evaluated home spirometry in ILD: 14 observational studies either as part of a comprehensive digital home monitoring program (53–59) or in comparison to in-laboratory spirometry (14, 60–65); 3 RCTs, with 1 specifically evaluating a home monitoring program (66) and 2 as clinical trial outcomes (67, 68); 1 qualitative study of patients (69); and 1 international clinician survey of home monitoring including home spirometry (70).

All seven essential items of the PANACEA framework were evaluated in at least one study (Figure 4 and Tables E4 and E5). Several studies reported good validity of FVC measurements using home spirometry against in-laboratory spirometry cross-sectionally at baseline and during follow-up between 1 and 12 months, with reduced correlation for longitudinal changes. Reliability of home spirometry was assessed with repeated measurements within days to weeks. Home spirometry results were often made available to patients in varying formats, such as recordings on the device or digital platforms, with some reported physical symptoms with test performance and conflicting impacts on psychological well-being. Digital health literacy requirement and associated patient cost were barriers for use of home spirometry, although detection of FVC changes could be informative for disease monitoring. Sixteen out of the 21 desirable items of the framework were evaluated, with patient acceptability, patients' perceived test utility, and ease of clinicians' and researchers' access for test result being commonly evaluated (Tables E5 and E6). Considerations raised regarding home spirometry use included test cost to clinicians and researchers together with associated training need, availability of clinicians' feedback, trial outcome interpretation with outlier measurements, and patients' internet access.

The majority of studies of home spirometry in ILD were conducted in high-income countries and were primarily single-center studies, with fewer than 50 patients for most observational studies. Although a good number of studies evaluated validity and reliability of home spirometry, there were varying intervals between in-laboratory and home spirometry tests and different technical specifications, such as number of blows, test frequency and prompts, and feedback provision, which can affect study findings.

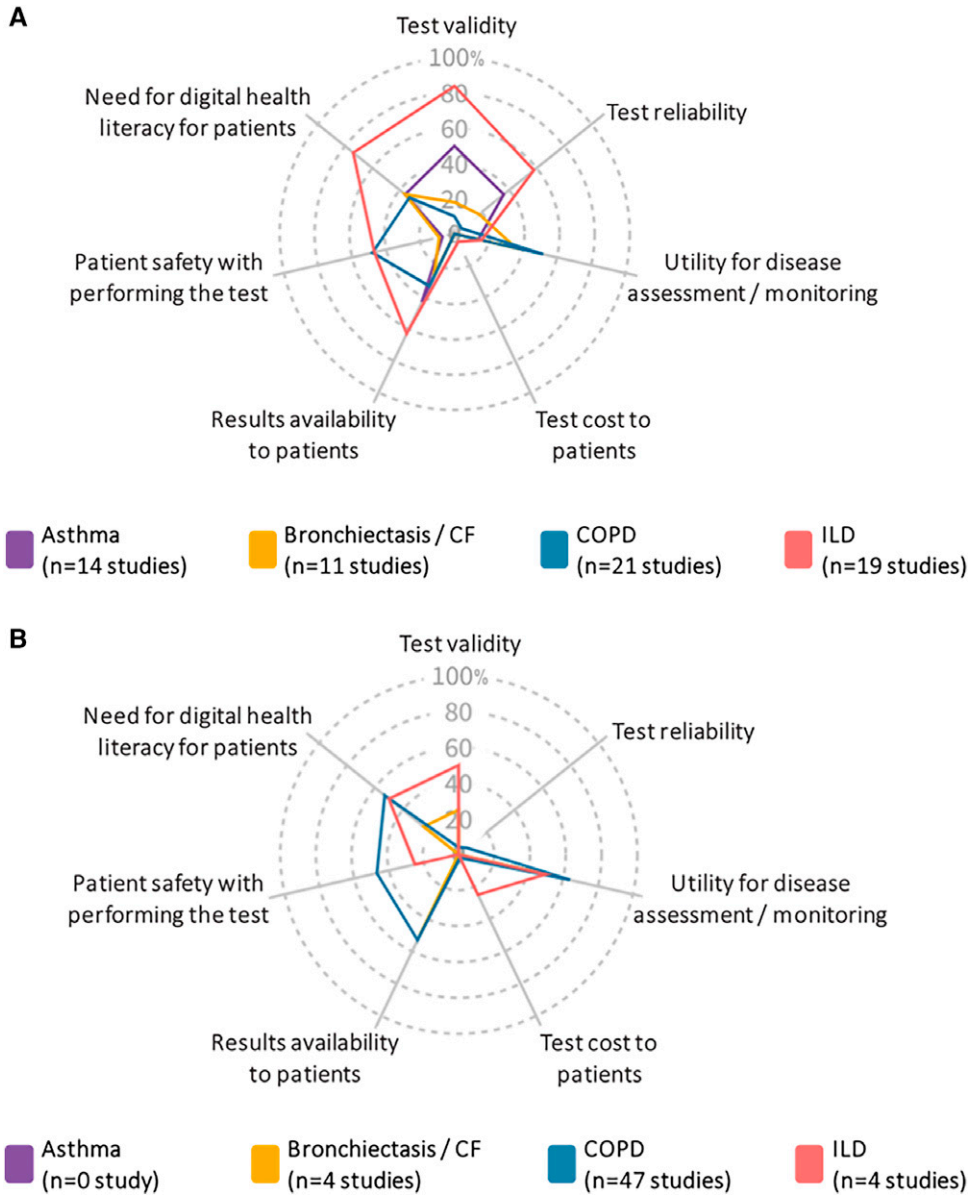

Figure 4. Studies evaluating the PANACEA framework essential items for (*A*) home spirometry and (*B*) pulse oximetry in asthma, bronchiectasis/CF, COPD, and ILD. Presented as percentages of the total number of studies for each disease area. CF = cystic fibrosis; COPD = chronic obstructive pulmonary disease; ILD = interstitial lung disease.

Section 3: Applying the PANACEA Framework for Home Pulse Oximetry in Chronic Lung Disease

Different types of devices have been developed for pulse oximetry monitoring, which can be broadly categorized into the conventional pulse oximeters of different portability and costs that rely on transmission and absorption of different light wavelengths, with newer wearable devices and mobile applications measuring light reflection (71–73). Pulse oximetry is routinely performed in various healthcare settings and has also been used by patients for self-monitoring because of its low cost and ease of use. However, there is increasing awareness that pulse oximeters are an indirect measure of arterial blood saturation with inherent inaccuracy. Of note, there is mounting evidence that darker skin pigmentation can affect the accuracy and reliability of pulse oximetry (74, 75); the potential for measurement errors across different levels of skin pigmentation was not specifically addressed in the peer-reviewed publications included in the current report. Other patient (e.g., dyshemoglobinemia, severe anemia, low perfusion, motion artifacts) and environmental (e.g., ambient light, electromagnetic or electrosurgical sources) factors also contribute to the inaccuracy of pulse oximetry (75). Herein, we review current evidence of home oximetry for four major chronic lung diseases using the PANACEA framework. Various pulse oximeters were used in the studies across the disease areas (Figure E2 and Table E6), with key device characteristics

Table 3. Recommendations for Future Research of Home Oximetry in Chronic Lung Diseases

Areas Requiring Additional Research
Study settings
Evaluate home oximetry in different resource settings
Evaluate home oximetry in people of different backgrounds in terms of digital health literacy, socioeconomic status, and geographical distribution
Evaluate home oximetry in people with a range of skin pigmentation
Study aims
Evaluate performance (validity, reliability, responsiveness, interpretability) and usability of various commercially available and new home oximeters, including wearable sensors and mobile applications
Define specific subsets of patients who would derive benefits from home oximetry
Compare home oximetry to Sp_{O_2} measurements using 6MWT for patient monitoring and prognostication
Evaluate the role of home oximetry as part of a program in disease management and patient outcomes compared with conventional patient care
Define optimal parameters and the minimal clinical important difference as cutoff values of home oximetry for patient care
Evaluate home oximetry as a secondary outcome of oxygenation status assessment in clinical trials
Evaluate clinical utility of home oximetry for the assessment, prescription, and monitoring of oxygen therapy
Evaluate clinical utility of home oximetry for monitoring during home-based exercise and pulmonary rehabilitation
Evaluate the optimal frequency and monitoring duration required for home oximetry
Evaluate measures to improve patient acceptability, adherence, and experience for long-term home oximetry
Evaluate cost-effectiveness and impact on healthcare delivery with the incorporation of home oximetry into routine clinical care

Definition of abbreviations: 6MWT = 6-minute-walk test; Sp_{O_2} = oxyhemoglobin saturation.
Some recommendations may be more relevant for specific types of chronic lung disease.

described in Figure 3. Key findings from the literature review are presented to demonstrate application of the PANACEA framework, with detailed findings described in Tables E7 and E8. Research recommendations of home oximetry evaluation in chronic lung diseases are presented in Table 3.

Asthma. None of the studies we examined evaluated home oximetry in asthma. Chronic hypoxemia is uncommon in asthma. Nevertheless, this can develop in patients who have chronic asthma with severe airflow obstruction, during exacerbations due to ventilation–perfusion mismatch, or if there is a delay in seeking medical attention.

Bronchiectasis/CF. Four studies, including 56 patients and 22 healthcare professionals, evaluated home oximetry in CF: three observational studies either as part of a comprehensive home monitoring program (23, 24) or part of remote monitoring during 3-minute step tests (76), and one qualitative study of healthcare professionals (32). There were no studies identified in non-CF bronchiectasis.

Four of the seven essential items of the multidimensional evaluation framework were evaluated (Figure 4 and Tables E7 and E8). Limited data suggest validity of nadir oxyhemoglobin saturation measurements and their utility for disease management together with other assessments. Oximetry results were available to patients, with some needing technological familiarity for data transmission. Out of the 21 desirable items of the framework, 6 were evaluated with only one to two studies each (Tables E7 and E8). The conduct of remote step tests with oximetry monitoring was acceptable to patients. Oximetry results were accessible using dedicated software running on personal computers, with training of healthcare professionals being required. There were concerns with reimbursement for telehealth, including the need to consider the increased complexity of remote care delivery with the involvement of a multidisciplinary team.

All studies of home monitoring of pulse oximetry in CF were conducted in high-income countries, with most being a single-center design with fewer than 50 patients. Participant characteristics were not always reported (23, 24). As the studies used home oximetry either as part of telehealth devices or as a remote field test assessment tool, they provide only limited evidence about the role of home oximetry as a standalone monitoring tool in the clinical care of patients with CF.

COPD. Forty-seven studies evaluated 7,053 adult participants and 46 healthcare professionals for home oximetry in COPD. Of these, nine studies (33–36, 38, 77–80) had 19 additional publications with analyses related to home oximetry; thus, a total of 66 publications were reviewed. Pulse oximetry as part of remote or telemonitoring programs with other assessments was evaluated as the principal intervention of interest in 43 studies (33–36, 38–42, 44–47, 49, 77–103), whereas it was incidental to other interventions (such as home pulmonary rehabilitation) in two studies (51, 104). There were two studies evaluating the utility of nocturnal home oximetry (105, 106). The majority of studies were clinical trials and observational cohorts, with few having secondary reports on qualitative and cost assessments.

All seven essential items of the PANACEA framework were evaluated in at least one study (Figure 4 and Tables E7 and E8). Most studies focused on the evaluation of home oximetry as part of remote or telemonitoring programs to discern exacerbations and guide treatment changes or initiation of exacerbation management, with no impact on mental wellbeing and health-related quality of life. Home oximetry measurements were often available to patients. Limited data of validity of home oximetry showed overestimation of nocturnal desaturation when compared with home sleep study, with the reliability of home oximetry being influenced by movements during activities. Cost associated with battery replacement for oximeters could be a barrier reported by patients. Sixteen of the 21 desirable items of the framework were evaluated (Tables E7 and E8). Home oximeters as part of remote or telemonitoring programs were generally

believed to be easy to use by participants, with high acceptability, although experiences varied among clinicians and researchers as reported in a limited number of studies. Automated data transmission of home oximetry via telephone lines or internet connection was often available.

Most studies of home oximetry in COPD were conducted in high-income countries. The role of home oximetry is uncertain, as it has primarily been evaluated as part of remote or telemonitoring programs with multiple tools and components. The resources required for home oximetry as part of the studies of remote or telemonitoring raise questions about scalability into clinical practice.

ILD. Four studies including a total of 128 patients and 207 clinicians evaluated home oximetry in ILD: three observational studies, with one evaluating a mobile application with optional self-purchased home oximetry over 6 weeks (53) and two evaluating 2-day home use of a wrist-type conventional pulse oximeter (107, 108), and an international survey of clinician perspectives of home monitoring, including pulse oximetry (70).

Five out of the seven essential items of the framework were evaluated (Figure 4 and Tables E7 and E8). Validity of home oximetry assessment for desaturation against 6-minute-walk tests ranged from weak to moderate. Limited data suggested utility of home oximetry for detecting disease progression and acute exacerbation, with potential barriers of digital health literacy and test costs to patients being raised (53, 70). Six of the 21 desirable items of the framework were evaluated with only one to two studies each (Tables E7 and E8). Limited data suggest patients perceived using a home monitoring mobile application that included oximetry measurements was useful, although varying patient adherence and acceptability of the application were reported. In addition to concerns with internet access and associated test cost and training need for clinicians and researchers, missing or invalid oximetry data could affect result interpretation.

Most studies of home use of pulse oximetry in ILD were conducted in high-income countries, with some having notable exclusion criteria that limit generalizability, including significant comorbidities, such as COPD, and confirmed isolated exertional hypoxemia.

Section 4: Health Equity for Home-based Monitoring in Chronic Lung Disease

Everyone should have access to high-quality and affordable health care, a concept known as health equity (Figure 5) (109, 110). To achieve health equity, evidence-based interventions must be translated, implemented, and disseminated to marginalized populations (111). That means that home-based monitoring must address the needs of diverse populations, including those with limited digital health literacy to operate independently at home and interpret results correctly. Digital health literacy requires both personal literacy (e.g., reading and math ability) and digital literacy (e.g., cognitive, and technical skills in the use of computers, electronic communication, and software) (112, 113) to locate, understand, evaluate, and apply health information from electronic sources to a health problem (112).

Health equity also needs accessible technology. Home-based monitoring often requires data transmission necessitating access to fixed broadband networks or wireless technologies using radio signals (i.e., Wi-Fi or Bluetooth), as well as dependable, continuous, and free (public) or low-cost service plans and technology support. But even in highly wired countries like the United States, 25% of rural communities lack fixed territorial broadband (114), and approximately 5% of adults use prepaid (pay-as-you-go) cell phone services (115). The COVID-19 pandemic exposed the limits of high U.S. smartphone ownership. Limited internet access among poor and minority populations with children attending school virtually required use of free networks available in the parking lots of fast-food restaurants, public libraries, schools, and prisons in some cases (116).

Dependence on health financing from government health services or insurance plans to cover home-based monitoring costs also has the potential to negatively impact patient outcomes and opportunities for research participation (117). In low- and middle-income countries like India, where there is no universal health coverage and an immature digitalization of the national healthcare system, disparities in access (61% of men vs. 31% of women own a mobile phone and 67% of the urban population vs. 31% of the rural population has internet access [118]) only widen the digital divide, exacerbating health inequities (119). For these reasons, experts deemed access and cost to be essential framework components that would be fatal flaws in the system if not adequately addressed.

Attributes of test performance and patient experiences with technology were

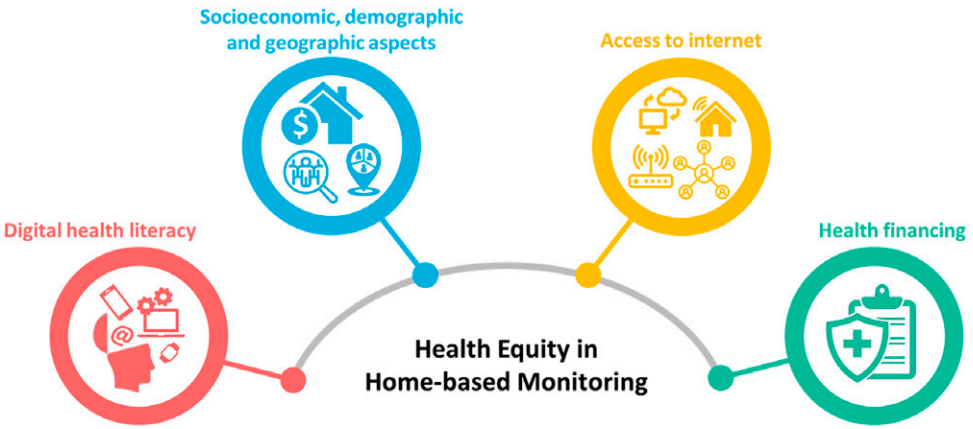

Figure 5. Factors affecting health equity in home-based monitoring.

judged desirable framework components. Test performance, such as the ease of assigning meaning to findings and understanding the significance of changes, as well as ease and comfort with test performance, are directly impacted by digital literacy. Help seeking decision-making and healthcare interactions enhanced the perceived usefulness of the test; these too are a function of digital literacy. Taken together, home-based monitoring is a scalable powerful approach that can be leveraged to promote health equity, yet more work is needed to understand its potential to improve the health of marginalized communities (120).

Section 5: Implementation Evaluation for Home-based Monitoring in Chronic Lung Disease

The items of the PANACEA checklist reflect the information required to determine if a home-based monitoring technology is suitable/ready for implementation. This not only includes technical data, and evidence of how it performs in real-life situations, but also insights in mechanisms of impact and context from a process evaluation (121). Qualitative and quantitative methods will be required to obtain comprehensive data on these contextual factors. For home-based monitoring, this includes the support needed by patients, the training and resources required by healthcare professionals, and organizational challenges that need to be overcome. Fidelity to instructions is important to ensure accuracy of measurements, but adaptations to processes may be essential to enable implementation. There is a need to distinguish core components essential to accurate, safe monitoring and features that can be adapted to suit the needs, preferences, and context. Information on uptake and reach—especially of marginalized groups—will be crucial to avoid increasing inequities.

The European Respiratory Society has recently launched the Clinical Research Collaboration CONNECT—moving multiple digital innovations toward connected respiratory care: addressing the over-arching challenges of whole systems implementation (122). CONNECT's long-term vision is of a cross-border, interoperable connected digital ecosystem. Home monitoring is clearly a component of connected respiratory care, and the PANACEA framework will inform CONNECT initiatives, such as developing a registry of respiratory technologies and defining core outcome sets of digital endpoints to support decentralized trials (6). Structuring information according to the PANACEA framework may guide selection of the optimal model of home-based monitoring in a given context (e.g., test performance, digital literacy requirements, costs to patients) and provide an evaluation framework (impact on patient care and outcomes, patient experience).

Discussion

The PANACEA framework was developed by a multidisciplinary international panel of patients, caregivers, clinicians, and researchers to systematically evaluate home-based monitoring for chronic lung disease. Using the framework, we identified several gaps based on the PANACEA framework, as presented in Tables 2 and 3, in evidence of home-based spirometry and pulse oximetry for patients with asthma, bronchiectasis/CF, COPD, and ILD. Our findings can be used to inform specific areas that would benefit from further research and development for these conditions.

A key focus of this framework is the ability to support an evaluation that is fit for purpose. Hence, the domains and items are categorized into essential and desirable for a stratified prioritization. The users may focus on essential items only in low-resource settings. Some items are linked. For example, patient acceptability of the test is a complex and versatile concept with varying influencing factors among different individuals, which may include safety with performing the test, test cost, and a multitude of others such as ease of test performance, patient- and clinician-perceived usefulness of test results, and personal beliefs and experiences. To facilitate future application of the PANACEA framework, guidance of assessment methods for each individual item is presented in Table 1. Of note, some items that have been categorized as "neither essential nor desirable" (Table E9) may be relevant depending on the intended purpose and context.

Our application of the PANACEA framework for home spirometry and oximetry in asthma, bronchiectasis/CF, COPD, and ILD highlights substantial variability in the device and study methodologies used in the existing literature. In general, validity and reliability of different home spirometry and oximetry devices in patients with these chronic lung diseases, as well as their associated cost and reported safety of test performance, are lacking. There are some uncertainties on the utility of home spirometry and oximetry for disease assessment, as they were often assessed as part of a comprehensive remote monitoring program in the studies. In addition, regular monitoring of assessment results, including home spirometry data, described as part of the research protocol for the remote or telemonitoring programs, may not be feasible in routine patient care.

Patients' digital health literacy requirements, test result accessibility, and internet access needs vary across the diverse range of devices and program delivery platforms. Health equity must be considered when implementing technology that requires smartphones, Wi-Fi, or other accessible components that may be costly to participants. Similarly, ease of use and literacy with respect to understanding instructions for use and feedback about the device are important. For home oximetry, there was no evaluation of emerging oximetry devices, such as wearable sensors and mobile applications. Clinical utility of spot versus continuous longer-term monitoring of home oximetry for oxygen therapy assessment has not been evaluated.

Although data were available for some items of the PANACEA framework, there are concerns of generalizability because of small numbers of study participants and study settings. The rapid turnover and emergence of devices for home spirometry and pulse oximetry require adequate and timely evaluation for clinical and research applications. Thus, overall recommendations for future research have been developed, with those addressing essential items of the PANACEA framework requiring prioritization. Thorough reporting of study designs, statistical analyses, study participants, and results in future research of home-based monitoring in chronic lung disease is needed to ensure methodological rigor, critical appraisal, and study replication. There are recommended reporting checklists for different study designs: the CONSORT (Consolidated Standards of Reporting Trials) for randomized trials (123), the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) for observational studies (124), the STARD (Standards for Reporting Diagnostic Accuracy) for diagnostic/validation studies (125), the SRQR (Standards for Reporting Qualitative Research) or COREQ (Consolidated Criteria for Reporting Qualitative Research) for qualitative studies (126, 127), the SQUIRE (Standards for Quality Improvement Reporting Excellence)

for quality improvement studies (128), and the CHEERS (Consolidated Health Economic Evaluation Reporting Standards) for economic evaluation studies (129). In addition, the PANACEA framework checklist (online supplement: PANACEA checklist) can be completed to provide complementary details tailored for the evaluation of home-based monitoring.

A major strength of the PANACEA framework stems from the systematic approach used in its development, with engagement of a diverse international group of stakeholders with different backgrounds, expertise, lived experiences, and perspectives. We identified gaps in existing literature on the use of home-based monitoring of spirometry and oximetry in asthma, bronchiectasis/CF, COPD, and ILD that could serve as a guide for future research. Nevertheless, expansion of the engagement to involve the wider community of patients, caregivers, clinicians, and researchers, as well as biotechnological and pharmaceutical companies and governance bodies, is needed. We invite input from other stakeholders to improve on the current framework and inform future iterations (e.g., PANACEA 2.0). Furthermore, empiric testing of the PANACEA framework is needed to test its usability across stakeholder groups. Evaluation of home-based monitoring tests using the PANACEA framework is also warranted for other chronic lung diseases, such as lung transplantation and pulmonary hypertension.

Conclusions

This research statement establishes a single tool, the PANACEA framework, that integrates different dimensions for assessing various home-based monitoring tests to facilitate its use as a tool for systematic literature review and identification of research gaps. This framework also has the potential to support future research study design and standardized reporting of different attributes of home-based monitoring devices, to incorporate into a package for assessing and/or developing telehealth services, and to facilitate governance bodies in implementing standards for home-based monitoring. With the advancement in knowledge and development of different types of home-based monitoring tests, as well as feedback and lessons from further application, the PANACEA framework can be refined over time for further improvement. ■

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