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Telehealth Centers
of Excellence

Implementation Science

Telehealth Toolkit

NATIONAL TELEHEALTH CENTER of EXCELLENCE

The purpose of this toolkit is to guide interdisciplinary clinical and research teams engaged in implementation of telehealth innovations to design and conduct dissemination and implementation evaluations, including research projects and quality improvement initiatives.

Contents

The toolkit includes 10 sections to guide comprehensive, multifaceted, dynamic evaluations. This resource can be used as a manual to walk you through the steps to design and carry out a telehealth evaluation and can be used as a general resource.

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Contents

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SECTION 1

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SECTION 2

About MUSC Telehealth Center of Excellence

The Medical University of South Carolina (MUSC) Center for Telehealth was designated a National Telehealth Center of Excellence (COE) by HRSA in 2017. The role of the Center of Excellence is to fill important gaps in the national telehealth landscape through a combination of ongoing regional and national collaborations, as well as proactive dissemination of telehealth research and resources. MUSC leverages unique qualities as an academic medical center to rigorously research, evaluate and disseminate telehealth initiatives and promising practices.

The MUSC Center for Telehealth received this designation because of its successful telehealth programs with high annual volumes, substantial service to rural and medically underserved populations and financial sustainability. MUSC's Center for Telehealth has nearly 20 years of experience providing telehealth, and currently offers over 100 unique telehealth services to nearly 350 sites across South Carolina and directly to patients' homes.

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SECTION 3

About This Toolkit

Introduction

History of the Field

The field of implementation science has grown at a rapid pace to address the significant research-to-practice gaps we observe in the translation of scientific evidence into practice and policy.[1,2] Despite tremendous advances in the development and testing of treatments, interventions and innovations that improve patient, clinician and systems-level outcomes, many of these innovations are delayed in reaching practice.[3,4] The implementation science field tackles this challenge and seeks to ultimately disseminate, implement, sustain and scale evidence-based interventions, practices and policies in a timely fashion.[1,5] Implementation science researchers have designed qualitative and quantitative methods to study dissemination and implementation (D&I) research questions.

What is Implementation Science?

Implementation Science is the study of methods to promote the integration of research findings into healthcare policy and practice.[3,6] D&I research aims to accelerate the timely translation of evidence-based research findings to practice and policy by designing studies to better understand how interventions, practices and innovations are launched and executed in specific settings. While **dissemination studies** focus on the targeted distribution of information and materials to advance the spread of evidence about interventions and innovations to a target audience, **implementation studies** focus on understanding implementation processes and outcomes, and identifying effective strategies for integrating evidence-based practices and innovations within a setting.[3,6]

Examples of Dissemination and Implementation Research Studies

- Evaluating the natural spread of an innovation in a specific setting.
- Understanding the mechanisms underlying an intervention's success or failure.
- Characterizing key barriers/facilitators to intervention uptake.
- Developing and testing strategies to optimize adoption, uptake or sustainability of an evidence-based practice.
- Identifying needed adaptations for scaling an intervention to a new setting or population.

Application of Implementation Science Principles in the Evaluation of Telehealth Programs

As the field of telehealth has grown at a rapid pace into new settings and care contexts, questions arise about how to best disseminate new telehealth practices, characterize determinants of successful telehealth implementation and refine optimal strategies for improving the reach and quality of telehealth care in various settings. Principles of implementation science can be used to guide systematic evaluations of telehealth practices and programs. Results can be used to inform more effective and efficient implementation processes and outcomes, and thus improve quality of telehealth care practices.

Common Questions About Conducting Telehealth Implementation Evaluations

Below are common questions about the value of using implementation science principles to conduct telehealth evaluations as well as general resources needed, and how to conduct these evaluations.

Why use D&I principles to guide the evaluation of telehealth programs?

+ To provide a systematic approach to understanding telehealth outcomes and processes.
+ To demonstrate the value of your program.

How can rigorous D&I methods help my team improve telehealth practices?

+ Can identify challenges and successes in telehealth delivery.
+ Allows your team to use data on implementation challenges to design strategies to improve telehealth delivery.

How can my team translate observations in practice into a strong evaluation plan?

+ Close monitoring of your pilot phase can guide implementation strategies when your program goes live.
+ Tracking outcomes and observations over time can provide valuable data for funders, administrators and other stakeholders.

What is the time burden for conducting a D&I evaluation study?

+ It is important to balance rigorous, multi-level methods with the resources you have available for evaluation.
+ May require technology and evaluation staff to develop tools, administer surveys, conduct interviews and monitor tracking data.

Audience for This Toolkit

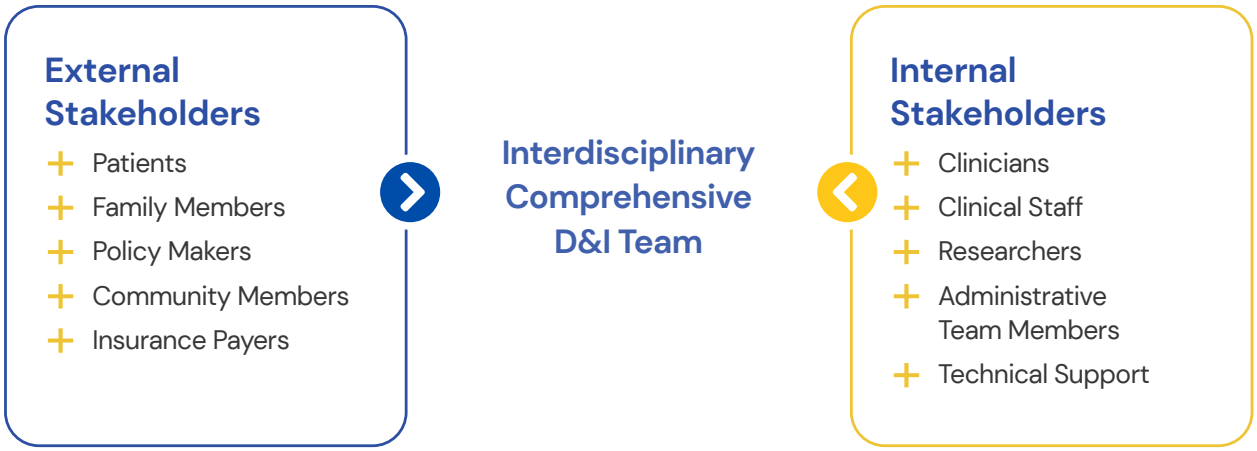
Settings and Modalities for D&I Evaluation

D&I evaluation is valuable to all types of telehealth programs including, but not limited to: outpatient video visits, in-patient and remote monitoring programs, store and forward visits, school-based telehealth and telehealth in the context of clinical research.

Participants in D&I evaluation

D&I evaluation of telehealth programs should include a comprehensive set of interdisciplinary collaborators:

- **Internal:** Internal participants can include clinicians, clinical staff, researchers, clinical administrative team members, technical support and any key stakeholders involved in the adoption and ongoing implementation processes of a telehealth program.
- **External:** Evaluation can also include external stakeholders such as patients, family members, policy makers, community members and payers.



How to Use This Toolkit

Purpose of toolkit

The goal of this toolkit is to guide interprofessional telehealth teams and stakeholders to design and conduct D&I evaluations of telehealth interventions and programs.

Specifically, the purpose is to provide an overview for how to design a comprehensive, structured, step-by-step plan to evaluate D&I processes and outcomes of an existing telehealth program. This plan will include a multi-disciplinary team of key stakeholders and will facilitate teamwork and communication in planning, designing and carrying out the evaluation. The process will be dynamic and adapted to meet changing healthcare and organizational needs.

The results may include assessing and summarizing outcomes related to your telehealth program, identification of barriers and facilitators to telehealth implementation processes and outcomes, or identification of gaps in reach, with the overall goal to improve delivery and sustainability of evidence-based telehealth interventions.

D&I evaluation is an evolving field and there are other published resources for general D&I evaluations. This toolkit will link to existing resources where applicable and more importantly, will supplement the existing resources with telehealth-specific strategies.

Sections of the implementation science toolkit

The toolkit is organized to guide stakeholders to design a D&I evaluation plan by the following domains:

Refine research question

- Understanding mechanisms underlying intervention success or failure.
- Characterizing key barriers/facilitators to intervention uptake.
- Developing and testing strategies to optimize adoption, uptake or sustainability of an evidence-based practice.
- Identifying needed adaptations for scaling an intervention to a new setting or population.

Determine study design

- Outline evaluation design.

Define implementation outcomes of interest

- Determine key outcomes of interest.

Select guiding implementation science frameworks

- Process models.
- Determinant models.
- Evaluation framework.

Develop data collection tools and measures

- Implementation tracking log.
- Site surveys.
- Staff surveys.
- Qualitative interviews with stakeholders.

Select Implementation Strategies

The majority of the toolkit's sections can be considered evaluation or research steps using implementation science principles. The final step in the toolkit, selecting implementation strategies, is unique as it is not relevant to all evaluations but is an important element of implementation. This last section may be relevant for teams evaluating the effects of varied implementation strategies for your telehealth program, or alternatively, after you complete a study that identifies barriers and facilitators to implementation. This can lead to making recommendations for implementation strategies to overcome those barriers or capitalize on those facilitators.

Each domain included in the toolkit contains introductory materials, practical questions to guide your team, telehealth-specific considerations and examples and key articles and resources.

Teams can use the toolkit as a guide and follow through the sections one by one or they may instead want to use different parts of the toolkit as a resource, acknowledging that the D&I evaluation process can be bi-directional and cyclical.

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SECTION 4

Refining Your Research Question

Introduction

A critical first step to designing your project is to refine your research question. The development, planning, launch and maintenance of a program, innovation or practice is a multi-step process, and your team may have a variety of different research questions. It is important to refine the question you will study as all other research planning steps will depend on a clear research question. Using a group process and including all the stakeholders who have a perspective on your program is important.

Practical Questions for Your Team

- What phase are you in with developing and launching your innovation/intervention?
- Have you observed challenges in the planning, implementation or sustainment of your innovation/intervention?
- What are the primary gaps in the literature about the treatment or practice under study?
- What results are most important to your stakeholders (e.g., patients, families, clinicians, administrators, funders)?
- What timeline and resources do you have in place to conduct your study?

Example research question domains

Are you interested in:

- Evaluating the natural spread of an innovation?
- Understanding the mechanisms underlying intervention success or failure?
- Characterizing key barriers/facilitators to intervention uptake?
- Evaluating the impact of intervention dose on improvements in outcomes?
- Developing and testing strategies to optimize implementation or sustainability of an evidence-based practice?
- Evaluating the effects of implementation strategies (e.g., marketing, training, incentives) on the use of an evidence-based practice?
- Identifying needed adaptations for scaling an intervention to a new setting or population?

Telehealth-Specific Considerations

There are multiple potential research questions when studying the implementation of telehealth programs that can vary based on progress of your team in the development and implementation of a telehealth service. The Telehealth Service Implementation Model®[1,2] assists teams in framing telehealth-specific implementation science research questions. The original model includes three main components for the telehealth service strategy, including telehealth service design, transition and operations.

Telehealth Implementation Model (TSIM™)

In the telehealth service design phase, teams design the scope of the service and consider a variety of planning details (e.g., develop a common architecture, draft operational protocols, customize test scripts, consider technology and training needs and navigate legal and credentialing issues). In the service transition phase, teams move from the planning phase to preparing to go live. This phase may include things like training and piloting the service. The final phase is telehealth service operations where the program is in place and teams are monitoring volume, quality and managing any challenges that occur in practice. These processes can be mapped to implementation science research questions that align with your program's status. For example, before launching a program, your site may benefit from conducting a needs assessment to aid in the telehealth service design phase. In the service transition phase, you may benefit from collecting pilot data to help guide refinement of protocols and resources. Finally, in the telehealth service operations phase, you may evaluate implementation outcomes, barriers and facilitators to successful implementation and/or needed resources (e.g., training) to support implementation and sustainment of practices.

Telehealth Research Questions and Considerations

Below are various scenarios telehealth teams may face when refining a research question, and study considerations are highlighted.

Is your team considering the development of a new telehealth program to meet a need in your health system or community?

POTENTIAL RESEARCH QUESTIONS

- What are the gaps in care delivery that could be addressed with a new telehealth program?
- What are the unmet needs that can be addressed with a new telehealth program?
- What infrastructure is in place to support a telehealth program?

STUDY CONSIDERATIONS

- A needs assessment can be a good starting place for telehealth programs to evaluate key stakeholders' perceptions and existing resources to guide and support the development of a new program.
- A readiness assessment can provide data to guide strategies to address existing barriers and needs as the program is launched.

Have you observed variability in the adoption of an existing telehealth program?

POTENTIAL RESEARCH QUESTIONS

- What are the primary barriers and facilitators to adoption of your program?

STUDY CONSIDERATIONS

- Ask who are the primary stakeholders who need to adopt your program.
- Consider examining the experiences of low, medium and high adopters.

Have you observed variability in the reach of an existing telehealth program?

POTENTIAL RESEARCH QUESTIONS

- What are the primary barriers and facilitators to reaching your target population?

STUDY CONSIDERATIONS

- Ask who you are reaching successfully with the program and why.
- Consider who you are missing with your program and why.

Have you observed variability in successful implementation of a telehealth program?

POTENTIAL RESEARCH QUESTIONS

- What are the primary barriers and facilitators to implementing the program?
- Why are some sites successful and others not?

STUDY CONSIDERATIONS

- Consider methods for monitoring the fidelity of program delivery (i.e., the degree in which a telehealth program was delivered as intended) and any adaptations that are made in practice.
- Define a clear metric for implementation for your study (i.e., how is successful implementation defined?).

What are the benefits and costs of your telehealth program?

POTENTIAL RESEARCH QUESTIONS

- What are the costs of a telemedicine program?
- Are there differences in clinical outcomes in those receiving telemedicine compared to those receiving in-person care?

STUDY CONSIDERATIONS

- Review whether you will have access to historical data for comparison of benefits and costs.
- Capture the perspectives of healthcare administrators/leaders who can define value for the system.

What would it take to sustain your telehealth program long-term?

POTENTIAL RESEARCH QUESTIONS

- What capacity does the site have to continue implementing the program over time?
- What resources are needed to continue program delivery over time?

STUDY CONSIDERATIONS

- Consider current interventionists' perspectives on their capacity for sustainability.
- Depending on your timeline, you could study the natural course of your telehealth program after the funding period is over.

Are you interested in adapting an existing telehealth program to reach a new population or for delivery in a new setting?

POTENTIAL RESEARCH QUESTIONS

- What modifications in content, timing, delivery modality and setting are needed to reach a new population and/or deliver your program in a new setting and why?[3]

STUDY CONSIDERATIONS

- Consider your team's capacity to monitor adaptations occurring in varied domains.
- Gather data from those receiving and delivering the intervention.

Telehealth-Specific Example: Refining Your Research Question

Background

Perinatal Mood and Anxiety and Substance Use Disorders are common and involve significant morbidity and mortality.[4,5,6] Despite evidence-based treatment availability, multiple barriers exist to care delivery. Our telemedicine team developed a program for patients to access specialty perinatal psychiatrists in the context of their local OB/GYN and primary care office. Because our telemedicine team observed variability in program implementation across clinics in the community setting, we wanted to develop a research question to learn from our experiences to ultimately improve the service.

Refining Our Research Question

Using an interdisciplinary team approach with telehealth leaders and clinicians, we used a group process with discussion groups and meetings with stakeholders to refine our research question. Telehealth program stakeholders (administrators, physician leaders, physician and nurse team members at the central telehealth site and in community clinics) ultimately decided to focus on gaining a better understanding of community clinics' experiences with the telehealth program, to guide best practices for supporting successful implementation of the service.

Research Question

The objective of this study was to characterize barriers and facilitators to implementing a mental health and substance use disorder telemedicine program in community obstetric and pediatric clinics.[7,8]

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SECTION 5

Determining Study Design

Introduction

A variety of traditional and non-traditional study designs[1] can be selected for your D&I study and will be chosen based on your research question and your evaluation resources. Implementation studies often require flexible methods to monitor and assess real-life, complex experiences from the perspective of multiple stakeholders.[2] A mixed method approach using both quantitative and qualitative strategies is often appropriate to offer an in-depth examination of implementation processes and their determinants.

Study Design and Methods Considerations

- **Qualitative designs** may be useful for the early stage of your implementation study to examine perceptions about and experiences with implementation.
- **Mixed methods designs**[3] include:
  - The convergent parallel design in which quantitative and qualitative data collection and analysis are completed concurrently but separately, and then results are merged for comparison and interpretation.
  - The explanatory sequential design in which quantitative data collection and analysis are completed first and then qualitative data collection and analysis are the next step; qualitative results can offer a more in-depth explanation of quantitative results.
  - The exploratory sequential design in which qualitative data collection and results are completed first and used to guide quantitative data collection plans.
- **Observational designs** (i.e., cohort and cross-sectional studies) may be appropriate for monitoring the implementation of a new practice and observing changes over time and experiences in stakeholders.
- **Experimental designs** may be appropriate for testing a new clinical intervention or a set of implementation strategies. Experimental designs may include randomized controlled trials, pragmatic trials and stepped-wedge cluster trials.[4]
- **Effectiveness-implementation hybrid designs**[5] study both effectiveness and implementation concurrently.
  - A hybrid type I design primarily focuses on testing a clinical intervention but concurrently monitors implementation.
  - A hybrid type II design focuses equally on testing a clinical intervention and implementation strategies.
  - A hybrid type III design primarily focuses on testing implementation strategies while concurrently monitoring or observing clinical outcomes.

Practical Questions for Your Team

- What design will allow you to answer your primary research question?
- Who will you share your research results with (e.g., your funders, hospital administrators, community, clinicians, patients)?
- Do you have an in-house database that can be used to support data collection and administration of surveys?
- Do you have the ability to pull data directly from your electronic medical record?
- Do you have staff on your team who have committed time to carry out data collection and analysis, (e.g., sending surveys and reminders, cleaning data, performing chart reviews, conducting interviews, analyzing data)?
- What types of outcomes are you able to track (e.g., system, process, clinician patient, family)?
- Who are the important stakeholders touched by the program whose perspectives you should include (e.g., patients, family, clinicians, clinic champions, health system leaders)?
- Do you have existing retrospective data, or will you be collecting data prospectively?

Telehealth-Specific Considerations

A cross-sectional study may be appropriate if your team wants to summarize implementation outcomes (e.g., number of telehealth visits completed) or examine the relationships between implementation and clinical, demographic or setting characteristics (e.g., is the number of telehealth visits associated with clinic type, patient's age, race, sex or diagnosis?) at one point in time.

A longitudinal cohort study may be appropriate as your team launches new telehealth practices to monitor barriers, facilitators and processes in real time. For example, if your team is launching a new telehealth program in a new setting, you may choose a prospective observational design to track milestones, outcomes and barriers over time in the pilot period so your team can use results to guide any needed changes.

A qualitative study may be appropriate if your team has observed challenges in the adoption of new telehealth practices in a particular setting (e.g., primary care) but do not know what the challenges are. Qualitative interviews offer the opportunity to work closely with clinicians and other key stakeholders to discuss their experiences and results can be hypothesis-generating for next steps. A qualitative approach may also be beneficial if your team is interested in considering the capacity for sustaining telehealth services in the future by gathering feedback from clinicians, administrators and others about resource and team needs to maintain telehealth service delivery over time.

If your team has a well-established telehealth program and you want to test its effects on clinical outcomes, you may plan a randomized controlled trial. You can test the

effects of your telehealth program on targeted outcomes in comparison to a control group (i.e., sites without the telehealth program). Depending on how established your telehealth program is and what preliminary data you have about its effects, you may want to consider a hybrid design in which you concurrently test clinical effects and implementation strategies.

Telehealth-Specific Example: Determining Study Design

Background

Remote patient monitoring (RPM) to support diabetes management is an increasingly used method of telemedicine in which data obtained at the point-of-care are transmitted for remote clinician viewing and action.[6] Diabetes has been the focus of many RPM interventions, with patients achieving sustained reductions in hemoglobin A1c during and after participation.[7] An RPM program was established in 2016 to support diabetes management in South Carolina via remote patient monitoring.[8] Over time, the telemedicine team observed variability in clinic success in the program implementation outcomes of enrollment, data submission and patient monitoring. The team wanted to better understand clinic experiences to guide improved implementation.

Study Objectives

The objectives of this study were to 1) characterize clinic delivery strategies for a South Carolina RPM program and 2) examine barriers and facilitators to program implementation in underserved and/or low-income community settings.[9]

Selection of Study Design

We used a team process to identify the best study design for this research. As the program had been in place for several years, the team had existing data (e.g., enrollment numbers, clinical outcomes) that could be included. As we wanted to understand clinician and clinic experiences over time, we decided to also collect data at the clinic and provider levels prospectively. We wanted to collect data from multiple stakeholders at the patient, clinician, clinic and system levels. For these reasons, after a 6-month planning phase in which we discussed multiple potential study designs and the strengths and limitations of each, we selected a prospective, parallel convergent mixed methods design with TACM-2 clinical data from the electronic medical record, clinic champion surveys and qualitative interviews with clinician team members.

Illustration of Types of Study Design

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SECTION 6

Defining Implementation Outcomes of Interest

Introduction

Implementation outcomes are critical to monitor in D&I studies to describe implementation processes and assess implementation effects and costs. Implementation outcomes are differentiated from and can serve as "intermediate" outcomes to clinical effectiveness (service) and system (client) outcomes. Proctor et al. describe that in order to be successful in regard to clinical and system outcomes (service or client outcomes), a new treatment must be implemented favorably.

Eight implementation outcomes, as defined by Proctor et al. (2011),[1] include:

- Acceptability
- Adoption
- Appropriateness
- Cost
- Feasibility
- Fidelity
- Penetration
- Sustainability

Each outcome's level of analysis (e.g., individual provider/consumer, organization/environment), relevant implementation stage and measurement examples are provided.[1] See telehealth-specific considerations section below.

Practical Questions for Your Team

- How many outcomes will be included in the study?
- What is the study level of analysis (e.g., individual provider/consumer, organization/environment)?
- What stage of implementation are you interested in (e.g., early, mid, late)?
- What does your implementation outcome mean in your clinical context and setting (e.g., what does adoption mean in the context of a rural primary care clinic?)

Telehealth-Specific Considerations

Below illustrates implementation outcomes and considerations with examples of telehealth related definitions adapted from Proctor et al.[1]

Acceptability

The perception among telehealth stakeholders (e.g., patients, families, clinicians, administrators) that a telehealth service is acceptable or satisfactory.

- Individual provider or individual consumer level.
- Early, ongoing or late stage in telehealth service delivery.

Adoption

The initial decision to "take on" a telehealth program within an organization.

- Individual provider or organization level.
- Early to mid stage.

Appropriateness

The fit and compatibility of a telehealth service within an existing organization or environment to reach a target population.

- Individual provider or consumer; organization or setting level.
- Early, mid or ongoing stage.

Cost

The costs of implementing a telehealth program or the cost-effectiveness of the program.

- Provider or institution level.
- Early to mid to late stage.

Feasibility

An indicator of the fit of a telehealth program in workflows of a particular setting.

- Individual provider, organization or setting level.
- Early stage (during adoption).

Fidelity

A measure of whether the steps of a telehealth program are delivered as intended and planned.

- Individual provider level.
- Early to mid stage.

Penetration

The integration of a telehealth service into routine practice.

- Organization or setting level.
- Mid to late stage.

Sustainability

A measure of long-term integration and sustained usability of a telehealth service within an organization, environment and/or target population.

- Administrator or organization or setting level.
- Late stage.

Telehealth-Specific Example: Defining Implementation Outcomes of Interest

School-based telehealth asthma evaluation: Measuring fidelity, feasibility, acceptability

Background

Asthma is a common chronic condition in children that causes a large burden on families and disproportionately affects people in underserved areas.[2] School-based telehealth asthma programs have been shown to be cost-effective in improving patient outcomes related to asthma[3,4,5]; however, implementation of these programs is challenging due to ongoing barriers. Our study question was to characterize school-based telehealth asthma program delivery experiences and examine barriers and facilitators to telehealth program implementation.[6,7]

Selecting Implementation Outcomes

Because operating a school-based telehealth asthma program is dependent on an interprofessional team (e.g., physician, respiratory therapist, school nurse, school administrator, teacher, tele-presenter) and multiple concurrent and sequential steps and guidelines, we chose to include fidelity as an outcome to measure whether the program was delivered as intended. By measuring fidelity, we could identify which implementation processes were challenging for school nurses and staff to complete and why, in order to help maximize program delivery. As this program is incorporated into a routine school day, we also chose to measure feasibility and acceptability. We assessed feasibility and acceptability" among school nurses--who already have full workdays with routine duties--and among school administrators, teachers, the telehealth program team, patients and their families.

Implementation Outcomes Chosen

Fidelity, Feasibility, Acceptability

Fidelity was defined as the degree to which the school-based telehealth asthma program was delivered as intended; this included completing the steps for program setup, identifying children for the program, consenting processes, nurse training, technology, referrals and carrying out visits.

Feasibility was defined as nurse and school team perceptions about the extent to which the program could be successfully conducted in the school setting.

Acceptability was defined as nurse and school team perceptions of the degree to which the program was satisfactory to the school team, students and families.

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SECTION 7

Selecting Guiding Implementation Science Frameworks

Introduction

Choosing the implementation science frameworks, models and theories to guide your evaluation is an integral part of D&I science.

It is important to understand the differences in theories, models and frameworks[1]:

- A **theory** is explanatory and predictive, and specifies relationships between and among variables. A theory is typically not content-specific.
- A **model** is similar to a theory but is more detailed and solely descriptive; it can be used to guide the implementation process.
- A **framework** is descriptive and content-specific and often is used to identify factors related to implementation outcomes.

In this section we use the term framework broadly to encompass theories, models and frameworks. In general, frameworks:

- Provide guidance and structure for the entire evaluation process, from project development to analysis and dissemination.
- Allow inclusion of all relevant contextual factors and implementation strategies.
- Provide standardized feedback for the implementation process.

Types of frameworks[1]:

- **Process Framework**: guides the process of implementation; includes action frameworks which also offer implementation strategies.
- **Determinant Framework**: specifies types of barriers and facilitators to implementation outcomes.
- **Evaluation Framework**: includes components or domains of implementation that can be evaluated to determine implementation success.

Existing resources to guide selection of frameworks

Selecting Frameworks

Selecting frameworks for D&I research can be a complex process and includes identifying key constructs of interest, relevant levels of the Social Ecologic Framework (SEF),[2,3] D&I focus area (i.e., dissemination, implementation or both) and whether the framework has been utilized in similar settings or clinical areas.

Some existing implementation science frameworks have published corresponding validated data collection measures for specific framework domains. These existing data collection tools can be adapted to meet individual study domains and needs. Please see data collection tools/measures section in this toolkit (Section 8) for additional information on developing data collection tools for your project.

There are a number of published online resources as well as publications that can assist in the process for D&I framework selection:

- The *University of Washington D&I Toolkit* provides a comprehensive list of types of models and frameworks, specific examples and corresponding published literature. [4]
- The *Dissemination & Implementation Models in Health: Interactive Webtool* is a website that guides a researcher and/or practitioner through an entire framework selection process to best fit the project needs. All frameworks are categorized by D&I category, SEF level and construct. This tool has tabs for 'Plan, Select, Combine, Adapt, Use, Measure' and within each tab on the webtool, there is background information and steps to follow to select a framework, combine and adapt frameworks and identify existing measures to fit the contextual factors identified in the framework.[5]
- *Theory, Model, Framework and Comparison and Selection Tool* (T-CaST) is an interactive framework selection webtool that has fillable worksheets for researchers and practitioners to rate frameworks for best selection. These worksheets allow implementation researchers or clinicians to rate a potential framework for an individual study based on the characteristics of usability, testability, applicability and acceptability.[6]
- A literature review by *Tabak et al. (2012)* lists D&I frameworks based on D&I classification, level of SEF and construct flexibility (broad to operational), including references for each framework.[7]

Practical Questions for Your Team

- What is the research question? Are you planning to study implementation determinants and/or processes, or are you planning to evaluate implementation outcomes?
- What are the relevant constructs to consider: factors internal to your setting, factors external to your setting or other types of factors?
- Does one framework include all relevant constructs, or do frameworks need to be combined/adapted?
- What type of framework is best for the scope of the project?
- What level(s) of the SEF are pertinent to your project? (Individual, organization, community, system)
- Has the framework been utilized successfully in similar content areas or settings?
- Are validated measures available for framework constructs?

Many of these questions can be answered with assistance from the previously noted framework selection resources.

Telehealth-Specific Considerations

The evaluation of telehealth program outcomes and processes can be guided by a variety of different conceptual frameworks as outlined below. A process framework can help examine the steps involved in the process of implementing a telehealth program, from early exploration through planning, launch and sustainment. A determinant framework can help identify and explain barriers and facilitators in delivery of a specific telehealth service. Finally, an evaluation framework can assess telehealth implementation outcomes within a variety of environments. In selecting a framework for the evaluation of telehealth interventions, it is important to consider the study type, research question, relevant constructs to include, timeline for data collection, need for one framework or multiple frameworks, relevant levels of SEF to consider and if the framework has been utilized successfully in similar environments, realizing that all questions may not be applicable to each project.

Example Telehealth Research Areas

1. Describe the process of telehealth implementation into practice

EXAMPLE STUDY QUESTION

- What are optimal implementation strategies for successful adoption/sustainability of your telehealth program?

FRAMEWORK CONSIDERATIONS

Action frameworks are process frameworks that also offer implementation strategies, typically in a series of phases or steps.

POTENTIAL FRAMEWORK TYPE

Process Framework

- Exploration, Preparation, Implementation, Sustainment (EPIS).[8,9]
- Iowa Model (Action).[10]
- Knowledge to Action (Action).[11,12]

2. Explain barriers and facilitators to telehealth implementation outcomes

EXAMPLE STUDY QUESTION

- What are the primary barriers and facilitators to the adoption of your program?
- What are primary barriers and facilitators to reaching your target population?
- What are primary barriers and facilitators to implementing the program as planned?

FRAMEWORK CONSIDERATIONS

Determinants frameworks do not describe how change takes place; they are typically multi-level to include domains related to several relevant stakeholders and/or potential influences on implementation; these frameworks encompass an entire system for evaluation.

POTENTIAL FRAMEWORK TYPE

Determinants Framework

- Consolidated Framework for Implementation Research (CFIR).[13]
- Promoting Action on Implementation Research in Health Services (PARIHS). [14]

3. Evaluate telehealth implementation to describe or determine success, based on chosen implementation outcomes

EXAMPLE STUDY QUESTION

- Why are some sites successful in telehealth implementation and others not?

FRAMEWORK CONSIDERATIONS

It is ideal to identify implementation outcomes of interest prior to choosing an evaluation framework; also note that some process and determinant frameworks also evaluate implementation outcomes.

POTENTIAL FRAMEWORK TYPE

Evaluation Framework

- Reach Effectiveness Adoption Implementation Maintenance (RE-AIM).[15,16]
- Predisposing, Reinforcing, Enabling Constructs in Educational Diagnosis and Evaluation-Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development (PRECEDE-PROCEED). [17]

Telehealth-Specific Example: Selecting a Guiding Implementation Science Framework

School-based telehealth asthma evaluation: Adapted EPIS Framework.

Background

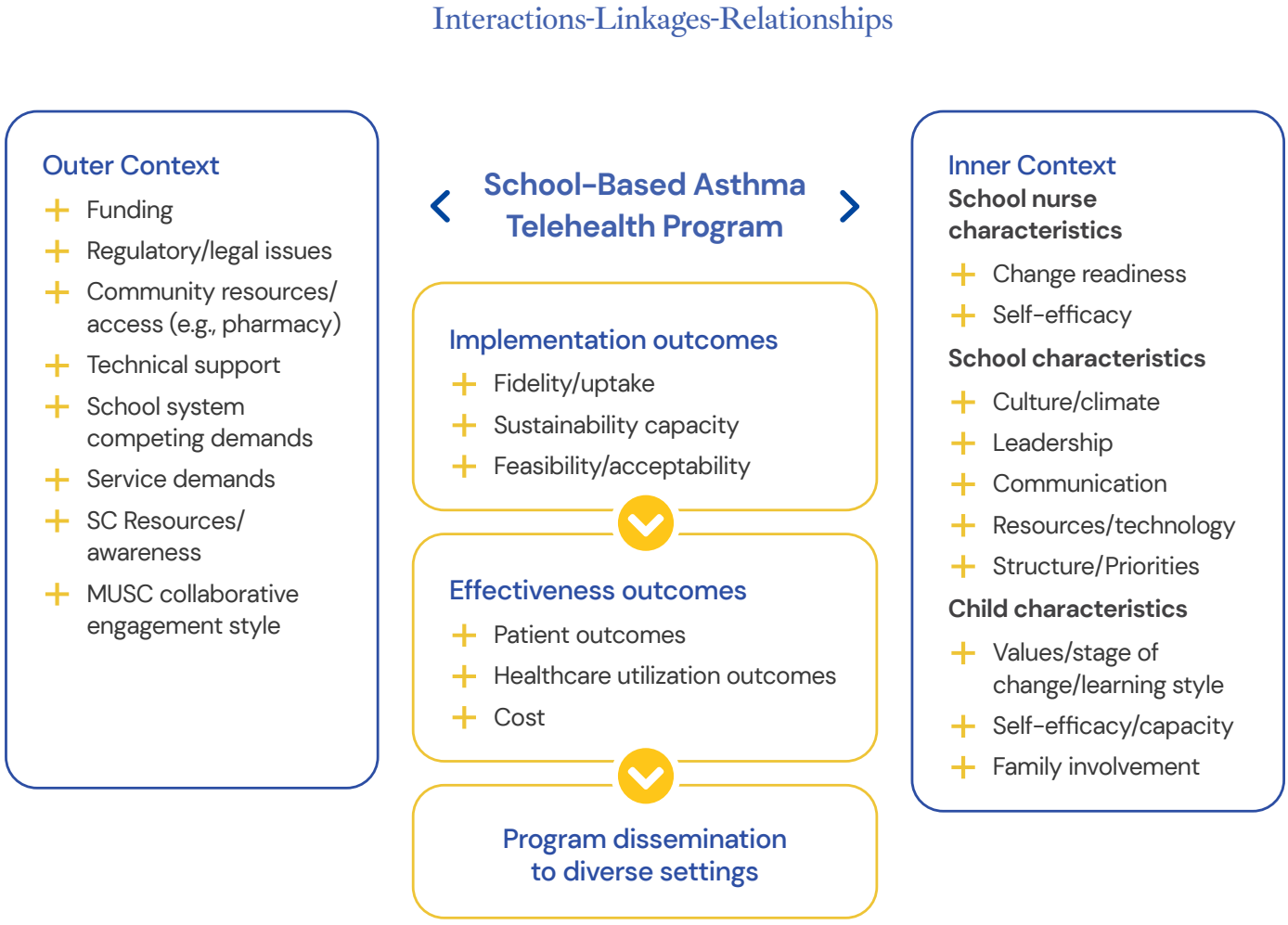
Asthma is common in children and disproportionately underserved populations.[18] Research shows that school-based telehealth asthma programs are cost-effective and improve asthma outcomes.[19,20,21] Implementation of telehealth programs in the school setting can be challenging due to student, family, teacher and school nurse barriers. Our study question was to characterize school-based telehealth asthma program delivery experiences and examine barriers and facilitators to telehealth program implementation. [22,23]

Choosing the Framework

Once our study question was established, we used an interdisciplinary team approach to include pediatricians, telehealth program administrators, school nurses and researchers to work together to identify applicable levels of the SEF[2,3] for this study. Through a set of focus groups with the telehealth group and multiple group brainstorming sessions, we determined that all levels of the SEF (individual, organization, community, system) and a mix of factors internal and external to the school setting were relevant to our evaluation. We were interested in exploring both the process of implementation and barriers and facilitators to implementation, so we decided to utilize an adapted version of the EPIS[8,9] framework, as this framework is classified as both a process and determinants framework and includes

multi-level contextual factors. We adapted the constructs and measures based in this framework to meet the specific details of our school-based telehealth asthma program evaluation.

Framework Chosen: School-based telehealth asthma framework (adapted from the EPIS framework)



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SECTION 8

Developing Data Collection Tools and Measures

Introduction

After identifying study outcomes of interest, selecting a framework and outlining study design, the next steps in a D&I study would entail developing data collection tools and measures. There are established validated and reliable tools in the literature that can be mapped to study outcomes and constructs and adapted as needed to meet individual study needs.

Things to consider when selecting or developing data collection tools and measures[1]:

- Data collection should be driven by study aims and guided by study framework and existing literature.
- Established D&I frameworks typically are associated with applicable tools that map to outcomes and constructs within the framework.
- All factors in a model or framework do not need to be included in each study; an interdisciplinary study team should identify specific applicable domains and measures to include based on the study objectives.
- There are different measures for implementation outcomes and constructs.
- Reliability and validity of measures are important to consider.
- Tools can be adapted and/or combined to meet study aims.
- Feasibility and practicality of data collection can be based on time, cost and length of tools.

Types of Measures[1]

Quantitative

Typically used when a theory already exists; utilizes instrument to measure outcomes or constructs; surveys are most common.

Self Report

To glean direct participant perceptions; most commonly used data collection in implementation studies; may have bias.

Observation

May have higher level of feasibility but outcomes of interest need to be observable; examples include a site survey that defines organizational structural characteristics or an implementation tracking log that tracks completion of implementation outcome milestones.

Administrative

Existing data that can inform outcomes; may have lower burden but may not be available for study needs.

Qualitative

Typically used to develop theory and expand upon quantitative data; interviews or focus groups are most common.

As noted in Section 7 of the toolkit (Selecting a Guiding Implementation Science Framework), some implementation frameworks in the literature have published corresponding validated data collection tools or measures for some constructs. After identifying a guiding conceptual framework, it is ideal to identify the corresponding measures for that framework and/or additional measures as needed. These measures can be adapted to meet study domains and needs; see examples in section below for available data collection tools for several D&I frameworks and other resources in this area.

Framework

Exploration, Preparation, Implementation, Sustainment (EPIS) Framework[2]

- The EPIS site provides background information on the framework, including definitions of the phases and constructs.
- This site offers links to quantitative measures that correspond with framework constructs and outcomes; there are also citations for published literature that has used these existing tools.

Consolidated Framework for Implementation Research (CFIR)[3]

- The CFIR site offers background information on the framework, including definitions of constructs.
- It also offers links to quantitative and qualitative measures to correspond to each construct.
- Please note CFIR measures focus on applicable constructs related to implementation and not specifically implementation outcomes.

Measuring Factors Affecting Implementation of Health Innovations: A Systematic Review of Structural, Organizational, Patient, Provider and Innovation Level Measures[4]

- A comprehensive literature review created an implementation framework with five types of factors: structural, organizational, patient, provider and innovation. This review identified all applicable measures for these factors and thus provides an easy-to-use reference guide.

Dissemination and Implementation Models in Health[5]

- This webtool provides a table of relevant implementation constructs and links to existing measures.

Society for Implementation Research Collaboration (SIRC) Instrument Review Project[6]

- This repository of instruments contains descriptions and links to implementation tools, mapped to CFIR constructs (available for SIRC members only).

Implementation Outcome Repository[7]

- The repository includes the psychometric and methodological quality of 55 tools as well as usability rating. Tools are categorized by six implementation outcomes[8]:
  - Acceptability
  - Feasibility
  - Appropriateness
  - Adoption
  - Penetration
  - Sustainability

Practical Questions for Your Team

- What data collection methods are feasible? What resources do you have for data collection (e.g., staff committed to administering surveys, conducting interviews, completing data analysis)?
- What existing data collection tools exist in literature, based on chosen study framework, outcomes and constructs of interest?
- What is the setting for the study?
- Who are the ideal respondents and sample size?
- What is the timeline for data collection?

Telehealth-Specific Considerations

After a study team defines the research question and selects a framework, the next step is to identify data tools and measures. For example, if a team is interested in examining the barriers and facilitators to adoption of a telehealth program, and has selected the CFIR to guide the study, this can help guide the selection of data measures. The study team can consider CFIR framework domains related to the intervention, outer setting, inner setting, individuals and implementation process for applicable measure selection. CFIR provides online data measure repositories to identify validated tools to meet data collection needs.

Example Data Tools and Measures for Telehealth Domains

Below are select CFIR examples of telehealth study domains and definitions with potential data tools and measures.

Intervention Characteristics

RELATIVE ADVANTAGE

Stakeholder perceptions of the advantage a telehealth program has over previous practices.

- Key Informant Interviews

COMPLEXITY

The perceived difficulty of implementing the telehealth program into existing practice and additional time and resource burden on stakeholders.

- Key Informant Interviews

Outer Setting Factors

PATIENT DEMAND

The level of patient demand or need for the telehealth services in a specified area or organization.

- Site Survey
- Key Informant Interviews

EXTERNAL POLICIES

Clinical and/or national guidelines related to medical conditions associated with the telehealth program.

- National Reporting Databases

Inner Setting Factors

LEADERSHIP

The level of involvement and commitment of an identified leader or champion, in an organization to influence implementation of a telehealth program. This may also be a measure of leadership effect on organizational teamwork.

- Implementation Leadership Scale[9]
- AHRQ Hospital Survey on Patient Safety (Management Support Section)[10, 11]
- Key Informant Interviews

RESOURCES

The level of resources (time, space, staffing, etc.) available in an organization dedicated to initial and ongoing implementation of a telehealth program.

- Site Survey
- Key Informant Interviews

Characteristics of Individuals

READINESS FOR CHANGE

The level of commitment of individual stakeholders within an organization for implementation of a new telehealth intervention.

- Evidence-Based Practice Attitude Scale[12]
- Key Informant Interviews

KNOWLEDGE/ BELIEFS

The knowledge and beliefs of individual stakeholders within an organization to have confidence to implement a telehealth program.

- Implementation Citizenship Behavior Scale[13]

Implementation Outcomes

FIDELITY

The degree in which a telehealth program was delivered as intended.

- Implementation Tracking Log
- Key Informant Interviews

SUSTAINABILITY

The extent to which a newly developed telehealth program will be maintained over time in an organization or environment.

- Program Sustainability Assessment Tool[14]
- Key Informant Interviews

Telehealth-Specific Example: Developing Data Collection Tools and Measures

Background

Diabetes has been the focus of many Remote Patient Monitoring (RPM) interventions, with patients achieving sustained reductions in blood glucose level (i.e., hemoglobin A1c) during and after participation.[15] RPM to support diabetes management is a growing method of telemedicine in which data obtained at the point-of-care are transmitted for remote provider viewing and action.[16] Our study evaluated a RPM program that was established in 2016 to support diabetes management in South Carolina among low-income adults.[17] Based observations over time, the telemedicine team planned an evaluation to better understand clinic experiences to guide improved implementation.

Study Objectives

The objectives of this study were to 1) characterize clinic delivery strategies for a South Carolina RPM program and 2) examine barriers and facilitators to program implementation in underserved and/or low-income community settings.[18]

Framework Selected

Consolidated Framework of Implementation Research (CFIR)

Identification of Data Collection Tools and Measures

We employed an interdisciplinary team to identify all applicable domains to meet the study objectives. The applicable domains chosen for this study related to inner and outer settings, individuals and implementation processes. Measures that were selected are:

Data Collection Tools Chosen for Remote Patient Monitoring Evaluation Project

Inner setting structural characteristics

- Site Survey
- Site Electronic Medical Record Clinic Data

Inner setting

(Readiness, Barriers, Leadership, Implementation Culture)

- CFIR Inner Settings Measures
- Key Informant Interviews

Individuals (Self efficacy, Knowledge/Beliefs)

- CFIR Inner Settings Measures[19]
- Adapted Survey from prior team study[20]

Implementation Processes

- Key Informant Interviews

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SECTION 9

Selecting Implementation Strategies

Introduction

Implementation strategies are actions or techniques that can improve, speed up or enhance implementation outcomes. A strategy can be discrete (i.e., a single approach) or multi-faceted (i.e., two or more implementation strategy approaches) and can address a variety of domains and stakeholders in an environment. Selecting implementation strategies is unique from other steps in the toolkit as it is not relevant to all evaluations but is an important element of implementation. This section therefore may or may not be relevant for your evaluation.

Implementation Strategy Considerations

- Study teams can reference their selected study framework to determine appropriate domains for implementation strategies. Often, we map strategies to the barriers we are experiencing in achieving implementation outcomes.
- It is ideal to identify a few key implementation strategies for a project; it is not possible to use all defined strategies in the literature.
- Strategy selection can be guided by results from a D&I evaluation of barriers and facilitators to implementation outcomes and mapped to strategies to overcome those barriers or capitalize on those facilitators.
- Teams may be interested in testing the difference in implementation outcomes when using varied strategies.
- Strategies can and should be adapted to meet study needs.
- It is vital to document details of the implementation strategies used to understand their effects and to replicate in research or practice. Aspects to document and monitor include the following[1,2]:
  - Actor (who is delivering the implementation strategy)
  - Action (what the strategy is)
  - Action target (what the strategy targets)
  - Temporality (when)
  - Dose (how much of the implementation strategy is delivered)
  - Implementation outcome(s) affected
  - Theoretical/empirical/pragmatic justification
- The Expert Recommendations for Implementing Change Project (ERIC) identified 73 distinct implementation strategies and later grouped them into 9 clusters or themes[3,4]:
  - Evaluative and iterative strategies
  - Provide interactive assistance

- Adapt and tailor
- Develop stakeholder interrelationships
- Train and educate stakeholders
- Support clinicians
- Engage consumers
- Financial strategies
- Change infrastructure

+ To identify needed strategies, a study team can first complete a formative evaluation (i.e., utilize evaluative and iterative strategies), which is typically a mixed methods evaluation to assess domains of an environment/organization of interest. This is also known as a type of needs assessment which will identify barriers and facilitators to implementation outcomes. A team can then review available strategies and identify key implementation strategies that are feasible for study domains of interest.

Practical Questions for Your Team

+ What are the implementation outcomes that can benefit from improved implementation strategies?
+ What has worked and/or not worked previously with various implementation strategies your team has tried?
+ What types of implementation strategies are best matched to the barriers your team is experiencing with implementation?
+ Who are the key stakeholders to provide a perspective on which implementation strategies are appropriate and best suited to the setting?
+ What are key clusters of strategies which may be most effective?
+ Are adaptations needed to selected implementation strategies to better match your setting and target group?

Telehealth-Specific Considerations

An interdisciplinary telehealth study team can initially complete a needs assessment in an environment to assess readiness for implementation of a new telehealth innovation and identify key facilitators and barriers. Implementation strategies can then be matched to the team's needs. You may also have experience implementing your telehealth program already and can outline the barriers you have faced that may guide selection of implementation strategies.

Example Telehealth Focused Implementation Strategies

The table below is an example of some potential identified facilitators and barriers in a clinical environment and some potential strategies to capitalize on the facilitators and overcome the barriers to improve telehealth implementation outcomes.[3]

Implementation Outcome of Interest	Identified Facilitator/ Barrier to Implementation	Potential Implementation Strategy
Acceptability Perception among telehealth stakeholders (e.g., patients, families, clinicians, administrators) that a telehealth service is acceptable or satisfactory.	+ Staff readiness, self -efficacy for change; staff perceptions of complexity of telehealth service within one's organization that would affect implementation.	+ Conduct educational meetings and educational outreach visits on benefits of telehealth intervention to organization and patients. + Distribute educational materials.
Adoption Initial decision to "take on" a telehealth program within an organization.	+ Identification of key leader or champion for the new telehealth program.	+ Recruit, designate and train for leadership. + Identify and prepare champions.
Appropriateness Fit and compatibility of a telehealth service within an existing organization or environment to reach a target population.	+ Adequate demand for new telehealth intervention. + Perceptions about complexity of telehealth program and fit into current workflows.	+ Increase demand. + Prepare patients and consumers to be active participants. + Staff trainings and structural design to fit into workflows.
Costs Costs of implementing a telehealth program or the cost-effectiveness of the program.	+ Costs of new telehealth program for needed additional resources.	+ Access new funding. + Develop resource sharing agreements between organizations. + Promote adaptability within local environment.

Implementation Outcome of Interest	Identified Facilitator/ Barrier to Implementation	Potential Implementation Strategy
Feasibility Indicator of the fit of a telehealth program in workflows of a particular setting.	+ Adequate time and resources needed for implementation.	+ Organize clinician implementation team meetings to provide dedicated time to implementation efforts. + Promote adaptability within environment for workload changes.
Fidelity Measure of whether the steps of a telehealth program are delivered as intended and planned.	+ Adequate resources, staffing and time + Staff knowledge of intervention and the steps required for implementation.	+ Promote adaptability within local environment. + Audit and provide feedback. + Use data experts. + Provide ongoing consultation.
Penetration Integration of a telehealth service into routine practice.	+ Continued staff dedication to changes needed for implementation of new program. + Continued demand for the telehealth service.	+ Provide ongoing consultation. + Intervene with patients and consumers to increase uptake.
Sustainability Measure of long-term integration and sustained usability of a telehealth service within an organization, environment and/or target population.	+ Sustained interest and demand for continued implementation of new telehealth innovations.	+ Involve patients, consumers and family members in long term implementation efforts. + Involve executive boards for long term planning.

Telehealth-Specific Example: Selecting Implementation Strategies

School-based telehealth asthma evaluation: Adapted Exploration, Preparation, Implementation, Sustainment (EPIS) framework[9,10]

Background

Asthma is a common chronic condition in children that causes a large burden on children and caregivers and disproportionately affects people in underserved areas.[5] School-based telehealth asthma programs are cost-effective in improving patient outcomes related to asthma[6,7,8]; however, implementation of these programs is challenging due to ongoing barriers. Our study question was to characterize school-based telehealth asthma program delivery experiences and examine barriers and facilitators to telehealth program implementation.[11,12]

Identification of Implementation Strategies

The School-Based Telehealth Asthma evaluation project was based on the EPIS framework. Our interdisciplinary study team utilized the framework to identify factors that may affect implementation of this program in rural schools. The team completed a mixed methods evaluation to identify barriers and facilitators to implementation of the school-based telehealth asthma program. The team completed a mixed methods evaluation to guide identification of optimal implementation strategies for the school-based telehealth asthma program.

Implementation Strategies Identified for School-Based Telehealth Asthma Evaluation Project

This evaluative and iterative strategy identified facilitators and barriers to the program as listed below in the table, and provided guidance for future program implementation strategies to improve delivery of this program in similar environments.

Facilitators	Strategy for Future Implementation	Strategy Cluster
Strong Academic Partnerships; schools reported that collaborations and guidance from the academic medical center were integral to program success.	+ Provide Clinical Supervision and Facilitation. + Conduct Educational Meetings and Ongoing Training.	+ Provide Interactive Assistance. + Train and Educate Stakeholders.

Facilitators	Strategy for Future Implementation	Strategy Cluster
Technical Assistance; schools appreciated technical assistance provided by the academic medical center to set up and continue operations of the telehealth equipment for the program.	+ Provide Clinical Supervision and Facilitation.	+ Provide Interactive Assistance.
Presence of a Program Champion; schools with a school nurse that had dedicated time, ownership and energy to lead the program had smoother implementation processes.	+ Identify and Prepare Champions.	+ Develop Stakeholder Interrelationships.
Teamwork/Communication; schools that had higher levels of teamwork and communication between nurses, administrative teams and teachers had higher uptake of the telehealth program.	+ Promote Network Weaving.	+ Develop Stakeholder Interrelationships.

Barriers	Strategy for Future Implementation	Strategy Cluster
Time; school nurses reported lack of time was a barrier to implementation of the program due to already busy and filled work days; it was necessary to adapt the program to meet time and resource needs of school nurses.	+ Promote Adaptability.	+ Adapt and Tailor to Context.
Lack of Patient/Parent Involvement; some parents of children that would benefit from the program were not engaged in participation and it was necessary to identify alternative ways to communicate with parents for improved participation.	+ Prepare Patients/ Consumers to be Active Participants. + Intervene with Patients/ Consumers to Increase Uptake.	+ Engage Consumers.

*Strategies adapted from Powell et al. (2015) and Waltz et al. (2015)

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SECTION 10

Other D&I Toolkit Resources

The toolkits listed below provide additional resources and guidance on D&I processes and research, dissemination of research findings, implementation-specific processes and evaluation research. Please see descriptions below for more detailed information on each resource.

Dissemination & Implementation Toolkits

Washington University D&I Toolkits

This interactive web toolkit provides in-depth information on D&I research, with individual sections related to conducting D&I research steps.

PCORI's Dissemination and Implementation Toolkit

This PDF toolkit provides comprehensive resources to describe steps for the processes of dissemination and implementation. The toolkit includes background information, methods for engaging stakeholders in all components of D&I steps, guidelines for dissemination and implementation of new evidence, as well as recommendations for evaluation of D&I processes.

Dissemination Toolkit

Dissemination Planning Tool (Agency for Healthcare and Research Quality)

This PDF guide describes the development steps for a dissemination plan for research findings.

Implementation Toolkits

Implementation Science Research Development Tool (King's Improvement Science)

This PDF toolkit provides a step-by-step guide for developing an implementation evaluation research project; it includes introductory information and detailed steps to follow throughout the project.

TDR Implementation Research Toolkit (USAID and WHO)

This interactive web version toolkit includes seven modules that provide guidance on developing an implementation-based research project. The modules include introductory materials and resources for each phase/step of the project, from proposal development through integrating and sustaining study findings into practice.

QUERI Implementation Guide

This PDF toolkit provides resources to guide a team through three phases of the implementation process for a new clinical program or innovation; pre-implementation, implementation and sustainment. Within each phase, there are implementation tasks for a team to accomplish and comprehensive checklists for teams to reference, prior to progressing to the next phase.

Global Alliance for Chronic Diseases – Implementation Science Toolkit

This comprehensive web version implementation library includes three sections of resources; toolkits/journals/platforms, cancer control resources, and stakeholder engagement and community participation. Each section includes individual links to corresponding online resources to provide background information and tools related to implementation.

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