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Incorporating systems-level stakeholder perspectives into the clinical trial design of school-supervised asthma therapy

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Abstract

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Declaration of interests
The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Statement: The data that support the findings of this study are available on request from the corresponding author, [MT]. The data are not publicly available due to their containing information that could compromise the privacy of research participants.

Rationale: Few evidence-based public health interventions are adopted in practice, in part due to a disconnect between the outcomes measured in clinical trials and the outcomes important to stakeholders that determine implementation in real-world practice. AsthmaLink is a school-supervised asthma therapy program which partners pediatric providers, school nurses, and families. To inform the design of a cluster randomized controlled trial of AsthmaLink, we elicited systems-level stakeholder input.

Methods: Maximum variation sampling was used to recruit 18 stakeholders to participate in semi-structured interviews that were recorded, transcribed, and open coded: Department of Public Health officials (n=4), school officials (n=4), pediatric practice managers (n=3), health insurance officials (n=4), and legislators (n=3). Thematic analysis was used to identify common themes related to stakeholder priorities for clinical trial design and perceived barriers to AsthmaLink adoption.

Results: Stakeholder groups identified common priorities for the clinical trial design, including examination of the extent to which AsthmaLink (1) reduces health care utilization, (2) is cost effective (2) addresses health disparities, (3) reduces school absenteeism, and (4) educates families about asthma. Stakeholder groups reported potential barriers to AsthmaLink adoption, including challenges pertaining to (1) securing resources, staffing, and reimbursement, (2) variability across school districts, and (3) standing out amidst multiple programs vying for resources.

Conclusions: Systems-level stakeholder input informed refinements to the clinical trial design of a school-supervised therapy program including outcome and implementation measures and choice of study population. Incorporating systems-level stakeholder perspectives into clinical trial design is critical to achieve adoption of evidence-based interventions into practice.

Keywords

stakeholder engagement; clinical trial design; childhood asthma; implementation

1. Introduction

Childhood asthma remains a significant public health challenge in the United States,[1] with the majority of morbidity due to poor adherence to a daily preventive inhaler.[2,3] School-supervised asthma therapy is a strategy which improves asthma medication adherence and health outcomes for children in research settings.[4–6] Yet, it has not been widely implemented. This is in part due to a disconnect between the outcomes measured in previous trials of school-supervised therapy and the outcomes important to “systems-level” stakeholders[7–10], i.e. stakeholders that lead the systems within which an intervention operates. These systems-level stakeholders, (public health officials, legislators, payers, school administrators and clinic directors) ultimately determine adoption of community-clinical interventions in practice, yet their perspectives are rarely incorporated into clinical trial design.

We developed AsthmaLink™ as a real-world application of school-supervised asthma therapy in central Massachusetts. In AsthmaLink™ pediatric providers identify and enroll children into the program. These providers communicate with and send orders to school nurses who then supervise daily asthma therapy. (Figure 1) A preliminary retrospective

study showed that children enrolled in AsthmaLink™ experienced fewer emergency room visits, hospital admission and less rescue medication use.[11] Based on this pilot evaluation, we are developing a clinical trial to prospectively evaluate AsthmaLink™.

We sought to examine the perspectives of systems-level stakeholders to inform clinical trial design and ultimately facilitate the translation of AsthmaLink™ into clinical practice.

2. Methods

2.1 Overview

AsthmaLink™ is a program developed to ensure children aged 6–18 years take their daily asthma medicine with supervision at school. We interviewed systems-level stakeholders to elicit their perspectives on the clinical trial design.

2.2 Stakeholder Recruitment

Maximum variation sampling was used to capture a diversity of perspectives from stakeholders.[12] Between 2019–2020, we approached the following stakeholder groups in Massachusetts via telephone or email: Department of Public Health (DPH) officials (n=6), legislators (n=3), health insurance officials (n=4), school officials (n=4), and pediatric practice leaders (n=3). Interviews were performed with new stakeholders until thematic saturation was reached, defined as the point at which further observations and analysis revealed no new themes.[13]A fact sheet was reviewed with each participant prior to obtaining consent. No compensation was provided to participants. This study was approved by the Institutional Review Board at the University of Massachusetts Medical School.

2.3 Interview Guide

Semi-structured interview guides were developed for each stakeholder group to elicit each group's priorities and perspectives on the design of a clinical trial evaluating AsthmaLink™. We asked these stakeholders what data and outcomes they would need to see from a clinical trial to support AsthmaLink. For example, health insurance officials were asked: "What would you need from a research study to see value in a program like AsthmaLink™ to lead you to want to fund it or reimburse for it?"

2.4 Analysis

Interviews were audio recorded, transcribed, and open coded using Dedoose Version 8.3.45 (2021),[14] a qualitative analysis software. We used thematic analysis to examine the interviews according to two constructs (defined as the main issues recognized and presented in the data[15]): stakeholder priorities for clinical trial design and perceived challenges to AsthmaLink™ adoption. Within these constructs, researchers looked for alignment in themes across multiple stakeholder groups.

The themes that aligned across two or more stakeholder groups within each construct are shown below. Qualitative analysis methods similar to those used in this study have been described in our prior work.[16]

3. Results

3.1 Participant Characteristics

Of 20 stakeholders contacted, 18 (90%) agreed to participate in the key informant interviews and 2 (10%) were unable to be reached. We chose to interview stakeholders that were critical to real-world implementation of AsthmaLink. DPH officials (n=4) included leaders in early education and school-based health. Health insurance officials (n=4) included leaders in child health payment. School officials (n=4) included one superintendent, a district-level school nurse supervisor, and two principals from local elementary schools. Legislators (n=3) included policymakers at the city and state levels. Pediatric practice leaders (n=3) included one physician director and two practice managers.

3.2. Constructs

3.2.1. Stakeholder Priorities for Clinical Trial Design—Stakeholder groups agreed on five major themes as priorities for the clinical trial design of AsthmaLink™ These were: 1) reducing healthcare utilization (n=16), 2) establishing cost-effectiveness (n=12) 3) addressing health disparities (n=13), 4) reducing school absenteeism (n=8), and 5) educating families about asthma (n=11). (See Table 1 for additional illustrative quotes).

- Reducing healthcare utilization

  "If you had a legitimate study, which it sounds like you do, that shows that you avoided even one emergency room visit, I mean it's compelling."

  – Health insurance official

- Establishing cost-effectiveness

  "But then you juxtapose that cost [of AsthmaLink]…so the figures will become really important. What's the cost of sending that kid to the ER? Five times that cost? Seven times?"

  – Legislator

- Addressing health disparities

  "This is the sort of thing that you really hope will happen and we know that asthma is such a prevalent problem among children of poverty, that if we can deal with that in an evidence-based way, boy, we're going to come a long way in terms of making a difference for these children."

  – Legislator

- Reducing school absenteeism

  "We know that absenteeism greatly decreases when the asthma is managed properly. So, especially when you're looking at schools, that's one of the things that you want to make sure is being recorded."

  – DPH official

"My concern is the absenteeism for students who have asthma that most likely can be controlled."

- School Administrator

- Educating families about asthma

"I would say…underusage of medication puts up a huge backlog in healthcare because there's a compliance issue in the home… we found that a lot of the patient's were not educated, so working with them to establish the importance of regular maintenance and making sure that the child actually got that."

– Pediatric practice manager

3.2.2. Perceived Challenges to AsthmaLink™ Adoption—Stakeholder groups reported three challenges to AsthmaLink™ adoption: 1) securing resources, staffing, and reimbursement, 2) variability across school districts, and 3) standing out amidst multiple programs (Table 1).

- Securing resources, staffing and reimbursement

"Where's the incentive for programs to be providing health services as an additional burden to their services without any additional financial or staffing incentives for it?"

– DPH official

"I mean…what usually stops programs and initiatives that are functioning to continue, is funding."

– Legislator

- Variability across school districts

"I think that's…a little bit hard because each school district is its own thing and they all run a little differently."

– Health insurance official

- Standing out amidst multiple programs

"Its hard to stand out from other programs…so I would go to another high risk…gateway city that has a huge need, where you can get some data really on what percentage of the children have asthma…and try to get the highest percentage you can to participate in your study…then you'd get buy-in."

– Legislator

3.3. Clinical Trial Refinements

Based on stakeholder input, the following refinements will be incorporated into the clinical trial design:

1. We will add new study outcomes: health care utilization (emergency room visits and hospitalizations for asthma); cost and relative health benefits of program (through cost-effectiveness measures that have been validated); school absences (through school nurse and caregiver report); level of family's understanding of asthma (through surveys assessing asthma knowledge).
2. We will enhance recruitment of study participants from low-income and minority populations by developing culturally/literacy sensitive recruitment material and through targeting school districts in "gateway" cities with high asthma prevalence rates.
3. We will measure resources, staffing, time, administrative burden and reimbursement required by participants.
4. We will observe policies and practices for medication administration specific to the state and school districts studied.
5. We will collect data on competing programs within pediatric practices and schools that require similar resources to AsthmaLink™.

4. Discussion

In this study, systems-level stakeholders identified priority areas for the clinical trial design of AsthmaLink™. This input has prompted changes to trial design. With these changes, the clinical trial is now aligned with and informed by the stakeholders that help determine real-world implementation of this intervention.

While end-user input has been increasingly incorporated into the design of pediatric asthma trials, qualitative studies have largely been limited to clinicians, patients, and families.[17–19] Previous studies have examined the perspectives of families, and clinicians to inform the design of pediatric asthma trials.[16,18,19] Integrating these types of input has driven researchers to focus on more patient-centered outcomes, like symptom-free days, functional status, and exacerbations. [17,19] However, few trials have considered the priorities and concerns of system-level stakeholders who are critical for the adoption and sustainability of evidence-based strategies after they are tested in clinical trials. [20,21]

We believe that engaging systems-level stakeholders into clinical trial design can help to increase intervention participation, secure reimbursement, and create policy change that facilitates uptake and promotes sustainability of evidence-based interventions. During clinical trial design, we recommend eliciting input from systems-level stakeholders critical to the implementation of interventions to facilitate adoption of research-tested interventions.

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Highlights:

- First study to engage systems-level stakeholders in clinical trial design
- Engaged legislators, payers, public health officials and clinical/school leaders
- Systems-level stakeholder input informed changes to clinical trial design
- Stakeholder engagement can facilitate real-world adoption of research interventions

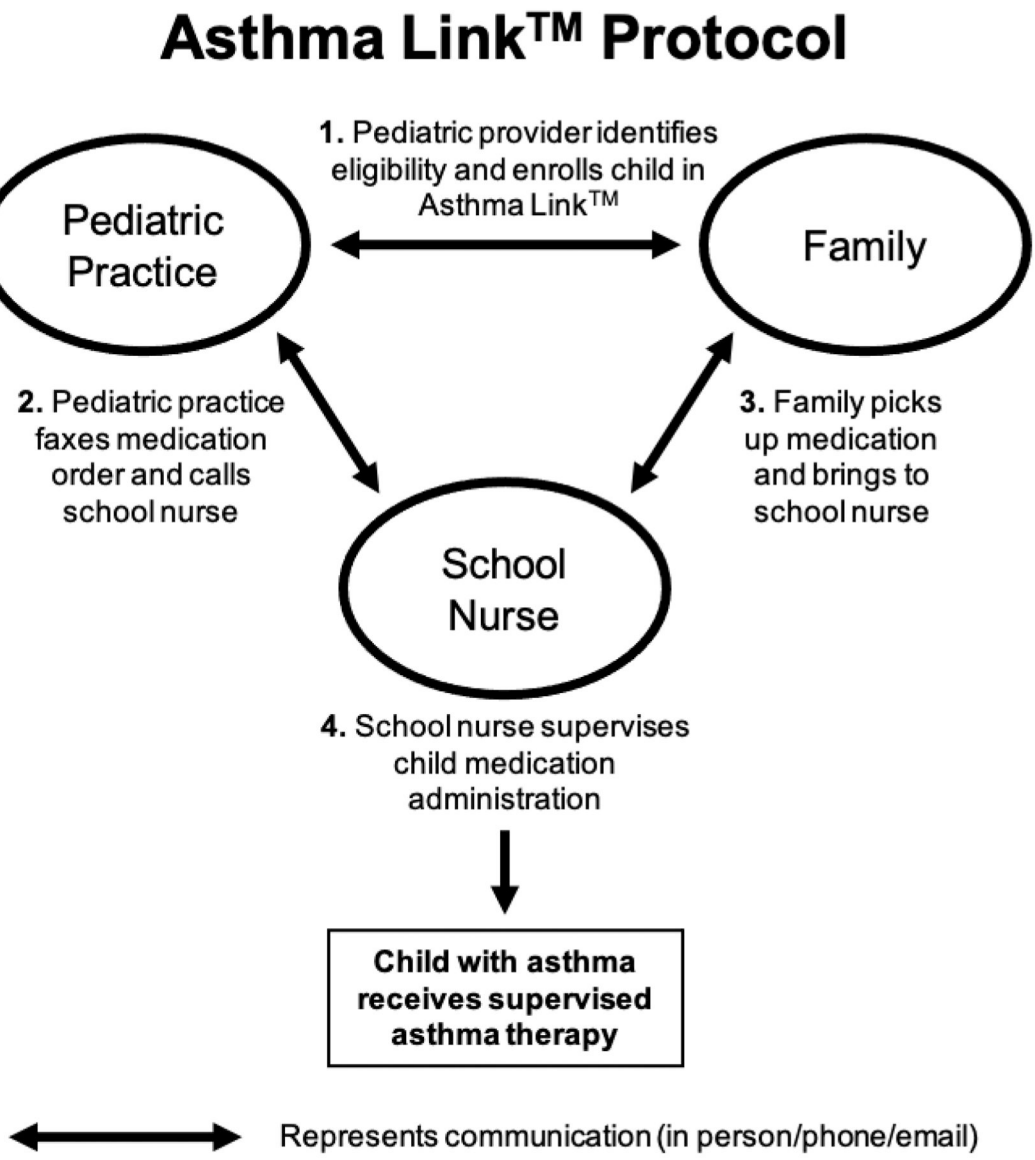

Figure 1.
AsthmaLink™ protocol.

Table 1.

AsthmaLink™ Clinical Trial Design Changes Resulting from Stakeholder Input

Participant					Priorities	Illustrative Quotes	Refinements to Clinical Trial Protocol
PH	**HI**	**SA**	**L**	**PM**			
•	•	•	•	•	Reducing health care utilization	*"It only makes sense if you can keep the child out of the emergency room or out of the hospital."* - Public Health Official	New trial outcomes: Emergency room visits and hospital admissions
•	•		•		Establishing cost effectiveness	*"Any level, whether it's pediatrics, gerontology, substance use, diabetes - any place that we can find an area where it's exactly as you're saying, highly effective and low cost and everybody perks up for sure."* - Legislator	New trial outcomes: Cost and relative health benefit of program
•	•	•	•		Addressing health disparities	*"The issue with asthma is something really important and we need some people to talk about the disparities among different cultures, and I think it is something that people would definitely get onboard… People of disparity and health access is a conversation that needs to be had, which we ignore."* -Legislator	Create culturally and literacy sensitive recruitments materials Ensure recruitment of low-income and minority study participants
•	•	•			Reducing school absenteeism	*"We know that absenteeism greatly decreases when the asthma is managed properly. So, especially when you're looking at schools, that's one of the things that you want to make sure is being recorded."* - Public Health Official *"I think if we could, you know, offer treatment at school for kids and keep them in school and keep them healthier, that's our obligation to do it."* - School Administrator	New trial outcomes: School absences through school nurse report and caregiver report
•			•	•	Educating families about asthma	*"I think it's super important that education and support is out there and measured for all of the families and children with asthma."* -Pediatric Practice Manager	New trial outcomes: Family asthma education
PH	**HI**	**SA**	**L**	**PM**	**Challenges**	**Illustrative Quotes**	**Refinements to Clinical Trial Protocol**
•	•	•	•	•	Securing resources, staffing, and reimbursement		New trial outcomes: resources, staffing, time

						"Do the school nurses have the capacity? Do they have the training from an operational standpoint?" - Health Insurance Official *"Come September or when the kids start back to school, it's gonna be mayhem here and that's when the kids are gonna ask for scripts for their inhalers and that's when it's gonna be tough."* - Pediatric Practice Manager	and reimbursement required by participants during intervention execution
•	•				Variability across school districts	*"I think that's a challenge that's a little bit hard because each school district is its own thing and they all run a little differently."* -Health Insurance Official *"I sometimes describe it as the wild west out there because it's super variable from program to program. Programs are not required to administer medication."* -Public Health Official	New consideration: Observe policies and practices specific to school district studied, compare to other districts
•	•		•		Standing out amidst multiple programs	*"I mean I hear about initiatives every week that people are focusing on. They are all really good. This one sounds absolutely compelling. So, I think a barrier would just be figuring out how to get on the radar amidst all of these other great programs that are being looked at."* - Health Insurance Official	New consideration: Collect data on other programs requiring resources within the systems

Key: **PH** = Public Health Officials; **HI** = Health Insurance Officials; **SA** = School Administrators; **L** = Legislators; **PM** = Pediatric Practice Managers