The SIP Study:
Simultaneously Implementing Pathways for Improving Asthma, Pneumonia, and Bronchiolitis Care for Hospitalized Children

Study Protocol

National Clinical Trial (NCT) Identified Number: NCT05206695
Principal Investigator: Sunitha Kaiser, MD MSc
Sponsor: University of California, San Francisco
Grant Number: R33HL157804
Funded by: National Heart, Lung, and Blood Institute
Version Number: v.1.6
September 11, 2025

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A Introduction

A1 Study Abstract

Asthma, pneumonia, and bronchiolitis are the top causes of childhood hospitalization in the US, leading to over 350,000 hospitalizations and ≈$2 billion in costs annually. **Poor guideline adoption by clinicians contributes to poor health outcomes for children hospitalized with these respiratory illnesses**, including longer recovery time/hospital stay, higher rates of transfer to intensive care units, and increased risk of hospital readmission.

General hospitals, such as community hospitals, primarily provide care for adults but also provide care for >70% of hospitalized children nationally. Unlike dedicated children's hospitals, community hospitals face unique challenges to achieving guideline adoption and high-quality care for children, including less access to pediatric services and limited resources for pediatric care and quality improvement.

Pathways have been shown to improve clinicians' adoption of evidence-based practices/guidelines and health outcomes for children in community hospitals. Pathways are simple, visual diagrams that guide clinicians step-by-step through the evidence-based care of a specific medical condition (accessed via paper or electronically). Most hospitals implement pathways for a single medical condition at a time, but Seattle Children's Hospital developed an intervention for simultaneously implementing multiple pathways for multiple pediatric conditions. This intervention led to sustained improvements in guideline adoption, decreases in length of stay, and decreases in costs. **This multi-condition pathway intervention has not yet been studied in community hospitals, which face unique implementation barriers.**

Our objective is to identify and test pragmatic and sustainable strategies for implementing the multi-condition pathway intervention for children hospitalized with asthma, pneumonia, or bronchiolitis in community hospitals. In Aim 1, we will conduct a pragmatic, cluster-randomized trial in 36 community hospitals (1:1 randomization to intervention vs. wait-list control) to determine the effects of the multi-condition pathway intervention. Our primary outcome will be **adoption** of 2 evidence-based practices for each condition over a sustained period of 2 years. We will also determine length of stay, ICU transfer, and readmission. During implementation, we will measure **fidelity** (use of implementation strategies as intended) in hospitals receiving the intervention. In Aim 2, we will use multi-level models to determine if these strategies are associated with guideline adoption (measured in Aim 1). Our expected outcomes will be a comprehensive understanding of how to pragmatically and sustainably implement the multi-condition pathway intervention in community hospitals and an assessment of its effects. These outcomes will have an important positive impact by providing evidence on an intervention that can leverage implementation resources by tackling multiple pathways and rapidly improve care and outcomes for children with respiratory illnesses.

A2 Primary Hypothesis

Our hypothesis is that the multi-condition pathway intervention will be associated with significantly greater increases in adoption of evidence-based practices compared to control (standard care/practice).

B Background

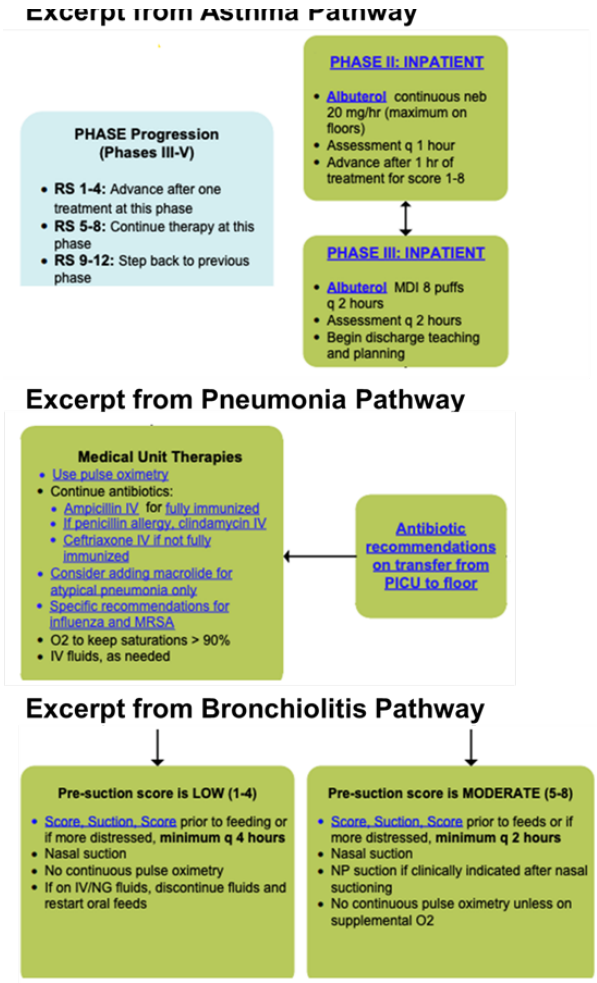
B1 Prior Literature and Studies

Overview of Prior Literature:

Asthma, pneumonia, and bronchiolitis are the top 3 causes of childhood hospitalization.[1,2] An estimated 370,000 children are hospitalized each year in the US for these conditions, leading to ≈$2 billion in direct healthcare costs.[1,2]

Tremendous delays and barriers to clinicians' guideline adherence lead to poor health outcomes for hospitalized children. Clinicians face many challenges adhering to guidelines (e.g., lack of familiarity, low confidence in ability to adhere),[3] and these challenges cause up to 17-year delays in achieving high guideline adherence.[4] There is unnecessary variability in guideline adherence and health outcomes for children in hospital settings across a wide range of conditions, including respiratory illnesses. Even after adjusting for clinical severity, there is significant heterogeneity across hospitals in children receiving recommended medications, having prolonged length of stay and associated high costs, being transferred to intensive care units, and being readmitted to the hospital.[5-8]

Figure 1.
Multi-condition Pathway Intervention: Clinicians select the appropriate pathway based on the child's illness



Pathways are a critical tool for improving guideline adherence and outcomes. Guidelines are lengthy and difficult to access and review efficiently while providing clinical care. Pathways are visual, step-by-step diagrams that are accessed via paper or electronically (Figure 1). They facilitate quick, easy guidance on evidence-based practices. Rigorous studies, including randomized-controlled trials, have shown single-condition pathways improve guideline adherence in children's and community hospitals (Table 1).[9-21] These studies illustrate the current state of low guideline adherence, but also show: 1) pediatric asthma pathways increase use of recommended medications, and decrease unnecessary tests and medications, length of stay, costs, and hospital readmissions;[9,13,16,17,19-21] 2) pediatric pneumonia pathways increase appropriate antimicrobial use, and decrease radiation exposure, surgical procedures, and readmissions;[10,15,18] and 3) pediatric bronchiolitis pathways decrease unnecessary tests and medications, length of stay, costs, and readmissions.[11,12,14] Pathways also have the potential to improve current disparities[22,23] in pediatric respiratory illness care and outcomes by standardizing care for all children.[24]

Recently, Seattle Children's Hospital developed an intervention that required similar implementation resources (e.g., clinician time, support for electronic integration) to simultaneously implement multiple pathways for multiple conditions. This intervention

demonstrated improvements in clinicians' guideline adherence comparable to those described for single-condition pathway implementation, and these results were sustained.[9-12,25-27]

Table 1. Baseline Adherence to Evidence-Based Practices & Increases Associated with Single-Condition Pathways

	Evidence-Based Practice	Rationale	Baseline Adoption	Absolute Increase
Pneumonia	Administration of narrow-spectrum antibiotic in hospital	Reduces antibiotic-associated side effects and emergence of multi-resistant organisms	32%	+ 30%
	No prescription of macrolide antibiotic at discharge	Reduces antibiotic-associated side effects and emergence of multi-resistant organisms	62%	+ 27%
Asthma	Prescription of ICS for children ≥5 years	ICS (daily or just when using rescue inhaler) prevents future severe exacerbations	70%	+20%
	Use of metered-dose inhalers (MDIs)	MDIs are cost-effective, promote asthma education, and promote asthma control.	43%	+ 25%
	Placement of an asthma pathway order	Use of a pathway associated with decreased LOS, costs	56%	+ 8%
Bronchiolitis	No administration of albuterol during admission*	Bronchodilators do not reduce symptoms or length of stay	54%	+ 13%
	Avoidance of chest radiographs	Radiography leads to unnecessary radiation exposure and costs	55%	+9

Simultaneously implementing pathways for multiple conditions is a higher-value approach– this approach leverages similar resources to potentially achieve sustained improvements in guideline adherence and health outcomes for more children more efficiently (compared to single-condition pathway implementation).

Community hospitals face unique challenges in pediatric quality improvement (QI) efforts and pathway implementation. General hospitals, such as community hospitals, care for >70% of hospitalized children,[2] but face unique and formidable barriers in pediatric QI efforts compared to dedicated children's hospitals. Dedicated children's hospitals have resources explicitly devoted to improving and sustaining clinicians' guideline adherence and high-quality care for children (e.g., QI staff, data collection systems, support for electronic health record [EHR] modifications). Community hospitals primarily provide care to adults, and as a consequence, pediatric QI efforts have limited access to such QI resources.[28,29] Additionally, community hospitals have less availability of pediatric-focused staff (e.g., emergency physicians, respiratory therapists, nurses) and services (e.g., pediatric intensive care units), low volumes of pediatric patients, and more varied staffing models for pediatric units.[2,30] These and other factors contribute to substantially different uptake and effectiveness of pediatric QI interventions, lower adherence to pediatric guidelines, and differences in health outcomes for children in community hospitals.[31-34] Reflective of these barriers, we found community hospitals have lower utilization of pediatric pathways (asthma pathway use 44% vs. 75% in community vs. children's hospitals).[9]

Community hospitals may be able to overcome these barriers and achieve rapid, widespread improvements in guideline adherence and health outcomes across the full spectrum of care. Our group and others have demonstrated that community hospitals can successfully overcome these barriers and implement pathways for a single condition at a time,[9-11] and our preliminary data indicates the multi-condition pathway intervention is feasible and acceptable in community hospitals (see Details on Prior Literature, below).

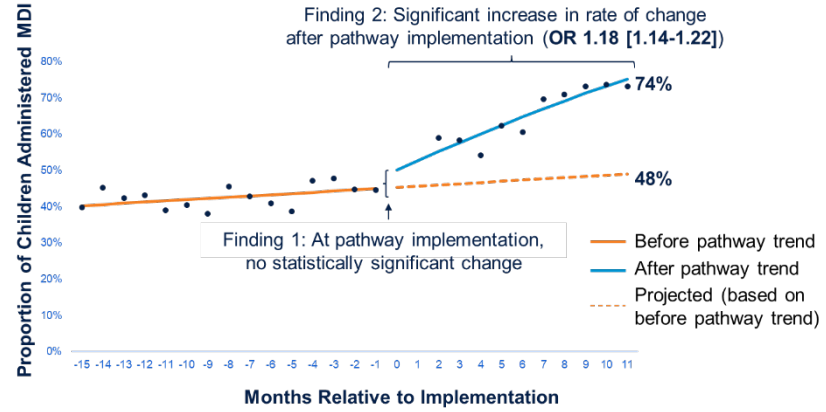
Details on Prior Literature: The preliminary studies described below provide evidence that: **#1)** the multi-condition pathway intervention tested in Seattle Children's Hospital can rapidly, broadly, and sustainably improve care quality for hospitalized children; **#2)** single-condition pathways can be successfully implemented and improve care quality for children in community hospitals; and **#3)** the multi-condition pathway intervention is feasible, acceptable, and appropriate in community hospitals.

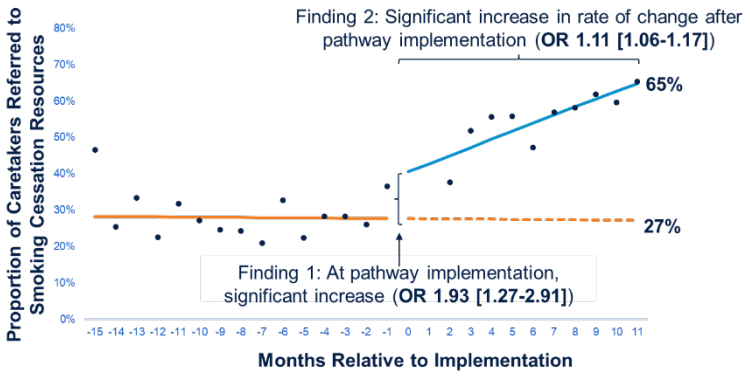
#1) As mentioned above, Seattle Children's Hospital developed an intervention to simultaneously implement multiple pathways for multiple conditions. This multi-condition pathway intervention (pathways and key implementation strategies) demonstrated significant improvements in clinicians' guideline adherence, length of stay, and costs that were comparable to those described for single-condition pathway implementation, and these results were sustained over 5 years.[9-12,25-27]

#2) PIPA (Pathways for Improving Asthma Care): We successfully implemented and tested a pediatric asthma pathway intervention (single condition: asthma) in both children's and community hospitals using a hybrid effectiveness-implementation study design,[9] which is also proposed here**.** The PIPA study included 85 hospitals from around the US– 40 children's hospitals and 45 community hospitals.

PIPA Study- Effectiveness: Figure 2 illustrates our prior study findings. In our evaluation of effectiveness,[9] we found pathways improved use of metered-dose inhalers (MDIs) during hospitalizations. MDIs are recommended by guidelines because they are more cost-effective and have fewer side effects than nebulizers,[35,36] and MDI use promotes asthma education and better chronic asthma control.[37-39] We also found pathways improved rates of referral of caretakers to smoking cessation resources– this is recommended by evidence-based guidelines because secondhand tobacco exposure worsens asthma outcomes in children.[35,40,41] We evaluated sustainability in community hospitals, and we found improvements in both of these outcomes were sustained over 2 years. In addition, we found an 8% decrease in length of hospital stay for children who had pathway orders placed in the EHR.[9] This study illustrates the effectiveness of asthma pathways (single-condition) in community hospitals. In Aim 1, we propose to build on this prior single-condition pathway work by determining the effectiveness of the multi-condition pathway intervention, specifically in community hospitals.

Figure 2. Guideline Adherence Before and After Pediatric Asthma Pathway Implementation





Other prior studies indicate single-condition pathways for pneumonia and bronchiolitis are also effective in community hospitals. A 2017 study by Parikh et. al. that included a total of 48 hospitals (n=3802) demonstrated signficant

improvements in use of narrow-spectrum antibiotics and avoidance of uneccessary macrolide antibiotics with pediatric pneumonia pathway implementation.[10] A 2016 study by Ralston et. al. that included 21 hospitals (n=1869) demonstrated significant improvements in avoidance of uneccessary bronchodilators and corticosteroids, as well as decreased length of stay with bronchiolitis pathway implementation.[11]

PIPA Study- Quantitative Evaluation of Implementation Strategy Utilization: During the PIPA study, we prospectively collected quantitative data on the utilization of key implementation strategies (via monthly survey of local implementation leaders and field visits).[42] We found that site leaders conducted an average of 6 audit and feedback meetings with clinicians and 4 Plan-Do-Study-Act (PDSA) cycles over 12 months at each site. Over 90% of hospitals that completed the study reported successful integration of pathways into the EHR. This study illustrates the feasibility of our proposed implementation strategies and our team's experience with collecting prospective data on the utilization of implementation strategies (proposed in Aim 2). In Aim 2, we propose to build on this prior work by determining if these strategies are associated with increases in guideline adherence.

PIPA Study- Qualitative Evaluation of Barriers and Facilitators of Implementation: Our team was the first to identify barriers, facilitators, contextual factors that influence pediatric asthma pathway implementation (single condition) in community hospitals.[29] We found significant barriers included developing consensus on evidence-based practices, obtaining the needed QI resources, and training adult-focused clinicians (e.g., respiratory therapists). Facilitators included engaging a multi-disciplinary implementation team and devising solutions with external QI facilitators.[29]

#3) We conducted a survey of implementation leaders from all 36 community hospitals recruited for this proposal using validated instruments,[43] including the "Feasibility of Intervention Measure" (sample question: "This intervention seems easy to use"). Our results indicate high feasibility (mean score 4.1/5), high acceptability (mean score= 4.4/5), and high appropriateness (mean score 4.3/5) of the multi-condition pathway intervention. Scores ranged from 4 ("agree") to 5 ("completely agree") on all survey items.

B2 Rationale for this Study

Our proposal addresses critical gaps that prevent achievement of broad-scale improvements in care and outcomes for all hospitalized children (Table 2). We know single-condition pathways improve guideline adoption and health outcomes across a variety of settings.[9-21] Simultaneous implementation of pathways for multiple conditions has been successfully demonstrated in 1 children's hospital.[12,22-24] However, this intervention has not yet been studied in community hospitals, which face unique implementation barriers (Table 2, Box D).[28,29]

Table 2. Critical Gap in Prior Research

	Children's Hospitals	Community Hospitals
Single-Condition Pathway Interventions[9-21]	A: Tested, effective	B: Tested, effective
Multi-Condition Pathway Intervention[12,22-24]	C: Tested, effective	**D: GAP IN PRIOR RESEARCH**

Understanding how to successfully implement the multi-condition pathway intervention in community hospitals will fill a critical knowledge gap that can enable broad-scale improvements in guideline adoption and health outcomes for hospitalized children across a wide range of common conditions.[25,44]

C Study Objectives

C1 Primary Aim

We will determine the effects of the intervention compared to control via chart reviews of children hospitalized with asthma, pneumonia, or bronchiolitis. Our primary outcome will be **adoption** of evidence-based practices[35,40,45,46] (2-3 for each condition) over a sustained period of 2 years (e.g., use of narrow-spectrum antibiotics for pneumonia). We will also determine length of stay, ICU transfer, and readmission/emergency revisit.

C2 Secondary Aim

We will measure **fidelity** (use of implementation strategies as intended[25,47]) via monthly surveys of site leaders and field visits to intervention hospitals. We will use multi-level models to determine if these strategies are associated with guideline adoption (measured in Aim 1/primary aim). If the intervention is successful, we will use these and other study findings to create and disseminate an implementation toolkit.

C3 Rationale for the Selection of Outcome Measures

Our primary outcome will be adoption of evidence-based practices. We selected 7 evidence-based practices (Table 1),[35,40,45,46] based on the following criteria: 1) there are low baseline rates and significant variability in adoption of the practice in community hospitals,[9-11] 2) pathways are associated with significantly increased adoption of the practice,[9-11,15,19,27] and 3) improved adoption is associated with improvements in patient-centered outcomes, such as length of stay or hospital readmission.[9,11-17,19,27,48] Secondary study outcomes will include length of hospital stay in hours, transfer to an intensive care unit, and 30-day hospital readmission or emergency revisit. These outcomes align with national quality measures, including the PRIMES guideline adoption measures,[72,74] and the National Quality Forum-endorsed 30-day pediatric respiratory illness readmission measure.[49]

D Investigational Intervention

D1 Clinical Data to Date

General hospitals, such as community hospitals, care for >70% of hospitalized children[2] but face unique barriers in efforts to improve care quality for children. Our prior work demonstrated that community hospitals have lower utilization of pediatric pathways (asthma pathway use 44% in community hospitals versus 75% in children's hospitals)[9] and face unique barriers to pathway implementation, including delays in integrating pathway content into the electronic health record (EHR), less quality improvement (QI) infrastructure and support, and fewer resources prioritized for pediatric care.[28,29] However, our group and others have demonstrated that community hospitals can overcome these barriers and successfully implement pathways for a single condition at a time (Table 1 in B1 Prior Literature and Studies).[9-11]

Recently, Seattle Children's Hospital developed an intervention that required similar implementation resources (e.g., clinician time, support for electronic integration) to simultaneously implement multiple pathways for multiple conditions. This intervention demonstrated improvements in guideline adoption, length of stay, and costs comparable to those described for single-condition pathway implementation, and these results were sustained.[9-12,25-27]

D2 Risk/Benefits

Risks
This proposed research involves a cluster-randomized controlled trial of a multi-condition pathway intervention in general/community hospitals (1:1 randomization to intervention vs. wait-list control). The pathway intervention is designed to provide clinicians with step-by-step guidance on the evidence-based care of children hospitalized with asthma, pneumonia, or bronchiolitis. The pathway intervention provides decision support to clinicians to promote current standards of care; the intervention does not involve any new therapies or diagnostic tests in participants.

For Aim 1/primary aim, chart reviewers will extract data from electronic health records into REDCap (Research Electronic Data Capture), a secure electronic data management tool. Reviewers will obtain a list of eligible patients (based on ICD-10 primary diagnosis codes), and this list will be destroyed after data entry into REDCap. No Protected Health Information will be collected for this study. The data recorded in REDCap will include the patient's age, sex, need for supplemental oxygen on admission, race, primary insurance type, prior prescription of an inhaled corticosteroid, and presence of any other comorbidities. Data collection will also include our outcomes of interest, including evidence-based care practices, length of hospital stay, transfer to intensive care (yes/no), and 30-day hospital readmission or emergency revisit (yes/no). For Aim 2, data on use of implementation strategies (e.g., audit and feedback meetings) and potential unintended negative consequences of implementation will be collected via monthly surveys entered into REDCap. These data will specify hospital/study site.

No Protected Health Information will be collected in any part of this study. To ensure confidentiality and compliance with the Health Insurance Portability and Accountability Act (HIPAA), all data and records will be kept confidential, all data will be stored on secure servers maintained by UCSF (see below), and access will be restricted to members of the IRB-approved research team. Any paper documents generated in the execution of this study will be stored in a locked filing cabinet in a locked office. Only the investigative team will have access to this information. Data collected through this research will be used only for the purposes discussed in this application.

All research data, including that within REDCap, will be stored within UCSF MyResearch. MyResearch is a secure, HIPAA-compliant desktop environment hosted on servers at the UCSF Data Center. The MyResearch environment is hosted on 6 Dell PowerEdge R710s and 1 Dell EqualLogic SAN array, which are located inside a locked rack at the Data Center. There are two layers of physical redundant Juniper firewalls that protect the servers and SAN. The MyResearch environment utilizes VM Ware View Virtual Desktop, which must be logged into using UCSF Active Directory credentials. The servers are locked inside a rack locked with a combination lock. The rack is in a data center secured by two sets of locked doors with an air lock and unlocked via a biometric device. To reach the rack, one must progress through the two sets of locked doors and through an Operations Desk area which is staffed 24x7. The rack itself has a security camera mounted on it and is tied into the central security camera system to ensure that the feed is monitored 24x7. Study data will be stored in Dr. Kaiser's group network folder in the remote MyResearch environment, where only the research team members are able to view the data and this access is audited. This folder is physically located in a data store on the SAN in the locked rack, and study staff will only access it through the VMWare remote desktop. Network traffic between MyResearch and the UCSF campus network traverses an SSL VPN tunnel in encrypted format.

The potential risks to the participants in this research will be no more than minimal risk. There are minor risks to privacy of individuals or confidentiality of data. The minimal risks of this study will be mitigated by strict adherence to proper data management and protection policies.

Benefits
Children hospitalized with respiratory illnesses may benefit from the intervention through improvements in clinicians' adherence to evidence-based practices. Better guideline adherence may reduce time to recovery/hospital stay, risk of transfer to intensive care, and risk of hospital readmission. Clinicians who participate in implementation data collection (Aim 2) will not directly benefit from participating in these research activities. In the long term, patients/children and families, clinicians, and administrators stand to benefit from participating in this research as they and their families continue to receive care in the participating sites (after implementation of pathways).

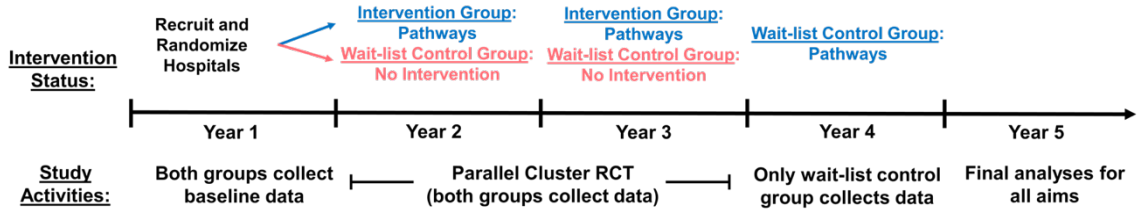
E Study Design

E1 Overview and Study Design

The multi-condition pathway intervention was previously studied at a 1 dedicated, free-standing children's hospital.[25] We propose to implement and test this intervention in a diverse sample of community hospitals across the US. We will conduct a type 3 hybrid effectiveness-implementation trial, in which the primary goal is evaluating implementation and a secondary goal is determining effects on clinical outcomes.[50] For Aim 1, we will conduct a cluster-randomized trial of the multi-condition pathway intervention in community hospitals (1:1 randomization to intervention versus wait-list control), and we will implement the intervention using the well-established mentored implementation framework.[47] We will determine effects of the intervention compared to control via chart reviews of children hospitalized with asthma, pneumonia, or bronchiolitis. Our primary outcome will be **adoption** of 2-3 evidence-based practices[35,40,45,46] for each condition over a sustained period of 2 years. During implementation, we will measure **fidelity** (use of implementation strategies as intended[25,47]) and in Aim 2 we will use multi-level models to determine if these strategies are associated with guideline adoption.

Design: A parallel, cluster-randomized trial best addresses seasonal variation in outcomes for these respiratory illnesses by providing a concurrent control group and collecting data over 5 respiratory viral seasons, 3 seasons prior to implementation and 2 seasons after implementation. We will stratify hospital randomization by geographic region (e.g., Northeast) to help ensure the effects of seasonal variation are similar across intervention and control groups. Figure 3 shows the study timeline. In Year 1, we will recruit and randomize hospitals to intervention versus wait-list control, and chart reviewers will collect baseline data (before implementation). In Year 2, we will begin implementation in the intervention hospitals. Hospitals in the wait-list control arm will wait/not implement pathways until Year 4.

Figure 3. Study Timeline



E2 Subject Selection

2.a Inclusion and Exclusion Criteria

The study sample will include children admitted to the inpatient pediatric wards of study hospitals for asthma, pneumonia, or bronchiolitis during the study period. We will identify eligible children using ICD-10 codes that were developed and validated as part of the NHLBI-funded PRIMES Studies (Pediatric Respiratory Illness Inpatient Measurement System, R01HL121067 and R01HL088503).[48,51] For asthma, codes include J4520, J4521, J4522, J4530, J4531, J4532, J4540, J4541, J4542, J4550, J4551, J4552, J45901, J45902, J45990, J45991, or J45998. For pneumonia, codes include J13, J14, J150, J151, J1520, J15211, J15212, J1529, J153, J154, J155, J156, J157, J158, J159, J160, J168, J17, J180, J181, J182, J188, J189 (focused on bacterial pneumonia). For bronchiolitis, codes include J210, J211, J218, J219. Inclusion and exclusion criteria and rationale are outlined in Table 3. Chart reviewers at each hospital will review all eligible admissions each month, to a maximum of 10 per condition of interest (total 30 admissions per month, randomly selected).

Table 3. Study Inclusion/Exclusion Criteria

Inclusion Criteria:
Primary diagnosis of asthma AND age >2 to <18 years-old at time of admission to the hospital
Primary diagnosis of pneumonia AND age >2 months and <18 years at time of admission to the hospital
Primary diagnosis of bronchiolitis AND age <2 years at time of admission to the hospital
Exclusion Criteria and Rationale:
Secondary diagnosis of SARS-CoV-2 (due to lack of evidence-based guidelines on management)
Transfer in from or out to an inpatient facility (due to inability to accurately determine length of hospital stay)
Pre-existing chronic lung disease (other than asthma), cardiovascular disease, airway anomalies, immunodeficiency, or neurologic disorders*

*The pathway intervention excludes these children because it is intended for routine management of the targeted respiratory conditions, not for children who are critically ill or have underlying chronic illness

2.b Subject Recruitment Plans and Consent Process

Data will be collected via chart review, as described above. Data collection will occur a minimum of 30 days after a patient is discharged from the hospital. No recruitment is required for this data collection process. In line with prior studies,[9-11] we were granted waiver of consent by the UCSF IRB. An IRB may waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects

This proposal meets criteria for minimal risk, as the intervention seeks to improve clinicians' adherence to current standard of care, and no PHI will be collected.

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects

This study involves no procedures for which written consent is normally required outside of the research context. It is unlikely that patients and their families would consider that this waiver has the potential to cause adverse consequences for their privacy, welfare, or general well-being. There is no collection of Protected Health Information planned, therefore collecting Protected Health Information in order to document informed consent increases the risk of privacy breach associated with this study.

(3) The research could not practicably be carried out without the waiver or alteration

It would not be practicable to perform the research (as it has been defined in the protocol by its specific aims and objectives) if consent was required for the following reasons:

a. Scientific validity would be compromised if consent was required. The sample size required is so large that including only those patients for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.

b. The disclosure of the study purpose as part of the consent process could impact the behavior of the staff caring for patients with respiratory illnesses, so that the results will not be meaningful.

c. There is a risk of creating additional threats to privacy by having to link data that is otherwise free of identifiers in order to contact patients' families to seek and document consent.

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2.c Randomization Method and Blinding

We will cluster-randomize participating hospitals to 2 different intervention start dates as described above in "E1 Overview and Study Design." Patients, families, and clinicians will be unblinded to the exposure to the intervention. Study analysts will be blinded as to intervention status.

2.d Risks and Benefits

See above section "D2 Risks/Benefits."

2.e Early Withdrawal of Subjects

Early withdrawal is not applicable in this study, as all study data is collected at one time point, after a hospitalization.

E3 Study Intervention

3.a Description

The multi-condition pathway intervention consists of pathways clinicians select from to guide the care of children with asthma, pneumonia, or bronchiolitis (Figure 1). Our overall implementation plan integrates the implementation strategies outlined in the prior single-center study of the intervention[25] and implementation strategies specified for mentored implementation, a well-established framework for multi-site implementation of healthcare interventions.[47] Our prior research on asthma pathway implementation in community hospitals demonstrated the importance of these strategies.[29] For instance, audit and feedback was critical to motivating clinicians and overcoming practice change inertia. Implementation strategies occurring during this R33 phase include:

- Audit and feedback: Chart reviewers at each site will collect data (described below in "Data Collection"). We will use these data to produce monthly run charts/performance reports on the

proportion of eligible patients with pathway-based order sets accessed (process measure) and guideline adoption outcomes (Table 1). Reports will contain hospital-specific performance and aggregate performance across all intervention sites. Local implementation teams will hold monthly meetings with all clinicians and staff involved in the care of children with respiratory illnesses. In the meetings, they will use these reports to review local performance.
- PDSA cycles: Local implementation teams will review clinical workflows in relation to current performance and plan PDSA cycles, in which teams identify and test workflow changes to improve performance.[52] PDSA cycles facilitate progressive, structured, and iterative change.
- Integration of pathway content into electronic order sets: In order to promote sustainability, local implementation teams will integrate guidance on evidence-based practices into electronic order sets. The Core Investigator Team will provide these teams order set templates to guide this process and mentors will support site leaders in planning and addressing barriers.
- Mentor meetings/facilitation: Monthly meetings of the mentors and implementation teams will involve: 1) reviewing performance reports on adoption of evidence-based practices, 2) developing project plans with key milestones/targets and monitoring progress, and 3) planning PDSA cycles.
- Learning Collaborative: Monthly mentor calls will periodically involve implementation leaders from all 2-3 sites the mentor is assisting. These group calls will facilitate cross-site problem solving and sharing of insights on barriers and facilitators of implementing the multi-condition pathway intervention.

3.b Method for Assigning Subjects to Intervention Groups

We will cluster-randomize participating hospitals to 2 different intervention start dates as described above in "E1 Overview and Study Design." All children hospitalized after a hospital's intervention start date will be considered "exposed" to the intervention.

3.c Fidelity Monitoring

During the first 12 months of intervention implementation, we will collect data via monthly electronic survey of local implementation leaders. Surveys will measure utilization (yes/no) of implementation strategies[25] in the prior month. Each month, mentors will verbally verify these yes/no survey responses (during scheduled mentor meetings). In addition, during scheduled field visits to sites in month 4 after start of the intervention period, mentors will visually verify the integration of pathways into electronic order sets. Surveys will inquire about prior or concomitant interventions to improve pediatric respiratory illness care quality. Surveys will also collect quantitative estimates of the monthly time costs of implementation for local implementation leaders; and qualitative, free-text responses on any unintended negative consequences of implementation.

3.d Prior and Concomitant Interventions

See above section "E3 3.c Fidelity Monitoring."

F Study Procedures

F1 Screening for Eligibility

See above section "E2 2.a Inclusion and Exclusion Criteria."

F2 Data Collection/Study Outcome Measurement

Chart reviewers at each hospital will collect data through monthly chart review of the electronic health records of enrolled patients. All hospitals (both intervention and wait-list control) will collect baseline data in Year 1 and then continue data collection in Years 2-3, while intervention hospitals implement pathways and control hospitals continue to wait. Only wait-list control hospitals will collect data in Year 4, when they implement the intervention. We will collect data on the outcomes described in Table 1 as well as several patient characteristics known to be associated with the severity of these respiratory illnesses in children (see below in "Primary Analysis").

Dr. Kaiser and the UCSF Project Manager will train chart reviewers at each study site based on the Medical Record Abstraction Quality Assurance and Control Framework.[53] Principles of the framework include: 1) quality assurance– prospective actions taken such as abstractor training, standard procedures, and job aids to assure adequate accuracy, and 2) quality control– measurement of error or discrepancy rates and use of the measurements to guide adjustments to controllable inputs to the abstraction process, such as abstraction tools, procedures, and training. A second chart reviewer will review a subset of charts (10%) each month at each site for quality control, providing feedback to the primary reviewer, Dr. Kaiser, and the UCSF Project Manager about any discrepancies (to facilitate additional training).

Reviewers will enter data into the REDCap electronic database, accessible from all study sites. To maximize data quality, we will use REDCap data validation algorithms, which restrict input to plausible values and check for potentially erroneous outliers. The UCSF Project Manager will check for suspicious or missing data weekly and contact chart reviewers to make any needed corrections. We will store all data securely (see Protection of Human Subjects, Facilities). Our team has extensive experience using these methods of chart reviewer training and quality control/assurance in community hospitals.[9,54] For any issues with REDCap, our central study team should be contacted (SIP@ucsf.edu).

SHM will create a project website in which all project materials will be stored in the WorkZone platform. All site leaders and chart reviewers will be provided individual usernames and passwords to access this website at anytime throughout the study. The SHM team can be contacted to help with access (sthompson@hospitalmedicine.org). Project materials will include chart review training and reference materials (including site-specific REDCap data entry links), the multi-condition pathway implementation toolkit, performance reports, mentor/facilitator meeting notes, educational videos, and project timeline.

F3 Safety Monitoring and Serious Adverse Event Reporting

The Data and Safety Monitoring Plan for this grant application incorporates the Policies on Data and Safety Monitoring specified by the Department of Pediatrics at the University of California, San Francisco.

Monitoring the Progress of the Study

The progress of the study will be monitored by the Data Safety Monitoring Board (DSMB) on a semi-annual basis. The DSMB chair is Dr. Eyal Cohen, and additional members include Dr. Stephen Teach and Dr. Matthew Hall. On a semi-annual basis, the Project Leaders (Drs. Kaiser, Auerbach, Gonzales, McCulloch, and Howell), the Project Manager, and Project Analyst will prepare a written report on the progress of the study including data on enrollments, comparison

of target to actual enrollment, overall status of the study patients, information on race/ethnicity and sex, and information on any serious adverse events. Following review of these reports, the DSMB will recommend any modifications that are required to enhance recruitment and retention of study patients. Participating hospitals each have designated safety officers as well, who will help ensure the safety of participants. This protocol presents minimal risks to participants and interim analyses of trial outcomes are not considered crucial for the protection of human subjects.

- Overview of the DSMB

The purpose of the DSMB is to provide the oversight and monitoring necessary to ensure the safety of the study participants and the validity and integrity of the trial data. The study governance provided by the DSMB is distinct from the review and approval by an Institutional Review Board (IRB) or any independent adjudication committee. The members of the DSMB have relevant expertise in the operational, medical, and biostatistical aspects of a clinical trial. The DSMB will advise the principal investigator (PI) and the study sponsor (NHLBI) regarding the continuing safety of study participants, the ongoing validity and scientific merit of the trial and whether or not the study should continue.

- DSMB Membership and Chair

The ability of the DSMB to provide additional assurance of participant safety and scientific validity depends on the appropriate selection of its Board members. The DSMB will be composed of Board members with expertise in pediatrics, pediatric respiratory illnesses, pediatric hospital care, quality and safety, and clinical trials. The DSMB will have a designated Chair. The role of the DSMB Chair is to provide leadership on administrative and scientific issues. The chair will: facilitate discussions on trial related topics; integrate differing points of view from the Board members; and establish a consensus on recommendations to the study sponsor.

Any concerns noted will be brought to the attention of the DSMB Chair who will take appropriate action. The DSMB will review on a semi-annual basis the reports prepared by the study PI, statistician, and programmer/analyst on the progress of the project, including: data on enrollments; comparison of target to actual enrollment; overall status of the study participants; information on race/ethnicity; gender; and serious adverse events. The DSMB will also determine whether additional effort is required to foster the progress of the study, and whether serious adverse events were immediately reported to the UCSF Committee on Human Research and dealt with appropriately. The DSMB will determine whether the study should continue, be terminated, or be modified based on observed beneficial or adverse effects.

- DSMB Responsibilities

Prior to implementation of the trial, the DSMB will evaluate the study design, review informed consent documents and plans for recruitment, adherence, interventions, data quality and safety monitoring. At periodic intervals during the course of the trial, the responsibilities of the DSMB are to:

- Evaluate the progress of the study, including, adequacy and timeliness of participant recruitment, adherence to the interventions protocol, data quality and timeliness, participant safety, and other factors that can affect study outcome;
- Consider factors external to the study when relevant information, such as scientific developments, may have an impact on the safety of the participants or the ethical conduct of the trial;
- Ensure data integrity;
- Ensure confidentiality of data and the results of monitoring;

- Report to the study sponsor and investigators on the scientific progress of the trial and the safety of participants;
- Make recommendations to the study sponsors and Investigators and Institutional Review Boards on continuation, termination, or other modifications of the trial.

- DSBM Process

The DSMB will meet semi-annually by videoconference. Agendas for the meetings will be developed by the PI and the DSMB Chair. The first meeting should take place before initiation of the study to discuss protocol, interventions, safety measures and to establish guidelines for monitoring. Following the initial meeting, the DSMB should meet semi-annually. An emergency meeting of the DSMB may be called at any time by the Chair or study sponsor should questions of participant safety arise.

DSMB meetings will consist of an open and a closed session. The open session may be attended by investigators and study sponsor staff, and they should always include the principal investigator and the study biostatistician. Issues discussed at the open session will include conduct and progress of the study, recruitment, adherence with the visit and interventions protocols, data quality and timeliness, problems encountered and aggregate outcome data. The closed session will be attended only by DSMB members and appropriate study sponsor staff representative(s), but others may attend if requested by the DSMB. All discussion at the closed session is completely confidential.

Should the DSMB decide to issue a recommendation to terminate or alter the study protocol, a full vote of the DSMB will be required. In the event of a split vote, a simple majority vote will rule and a minority report should be appended. The DSMB will review the protocol of approved and funded studies ancillary to the study, but they will not review the conduct and outcomes of these studies.

- DSMB Recommendations

The DSMB Chair will prepare minutes of the open and closed sessions, including any recommendations for changes in the study protocol that are approved by the Board and sent to study sponsor. The study sponsor Project Scientist will distribute minutes of the open session to the Principal Investigators within four weeks of each meeting. The minutes of each DSMB closed session should conclude with a recommendation to continue, terminate or alter the study. A recommendation to terminate the study or alter the study protocol may be made by the DSMB at any time by majority vote. Such recommendations will be transmitted to the study sponsor. Recommendations of the DSMB that are accepted by the study sponsor will be transmitted by the Project Scientist to the Principal Investigator as rapidly as possible. In the event of a split vote in favor of continuation, a minority report should be included in the regular DSMB closed report.

Plans for Assuring Compliance with Requirements Regarding the Reporting of Serious Adverse Events

This trial intervention consists of clinical pathways that remind clinicians of current standards of care. It does not involve experimental treatments or diagnostic tests. Given the nature of this intervention, serious adverse events (SAEs) have been defined and will be monitored as follows. SAEs are defined as: 1) events that lead to patient harm/morbidity (reported via hospital safety/incident reporting systems), or 2) death/mortality. Local Project Leaders at participating hospitals will be notified to contact the UCSF Core Study Team immediately should SAEs occur, and they will also be contacted monthly throughout the trial period via survey to inquire about any SAEs. If any SAEs are reported, the PI and Project Manager are responsible for reporting to

the Core Investigator Team, DSMB, and the UCSF Human Subjects Committee within 48 hours. The Core Investigator Team, DSMB, local Project Leader, and Local Safety Officers will then use root cause analysis (RCA) methods to review any events to determine attribution to the SIP intervention. A central tenet of RCA is to identify underlying problems that increase the likelihood of errors while avoiding the trap of focusing on mistakes by individuals. RCA thus uses the systems approach to identify both active errors (errors occurring at the point of interface between humans and a complex system) and latent errors (the hidden problems within health care systems that contribute to serious adverse events).

G Statistical Plan

G1 Sample Size Determination and Power

For sample size calculations, we used an alpha of 0.05, effect size estimates based on prior literature (see Table), and intra-class correlation coefficients (ICCs) specific to each outcome. ICCs were calculated based on our baseline period data (12-month period prior to trial intervention). We identified 40 hospital sites, and we accounted for up to 20% drop out of hospitals over the course of the trial (n=32 hospitals). We found that with volumes of 10 children with asthma, 15 children with pneumonia, and 15 children with bronchiolitis per year per hospital, we have >80% power to detect previously reported effect sizes in mean adherence to these evidence-based practice measures. If 32 hospitals (80%) remain from the 40 hospitals we have enrolled, we will have estimated minimal sample size of 3,840 admissions in the study (32 hospitals X 40 admissions per year X 3 years [1-year baseline and 2-year intervention period]).

G2 Analysis Plan and Statistical Methods

Primary Outcome:

Our primary outcome will be mean adherence to the 7 evidence-based practices of focus (in aggregate, Table 1). In our primary analysis, we will compare changes in mean adherence to evidence-based practices from the baseline to intervention period between the pathway intervention and control groups (difference-in-differences analysis). This design best addresses the seasonal variation in outcomes for the target respiratory illnesses by providing a concurrent control group and collecting data over 5 respiratory viral seasons, including three seasons prior to implementation and 2 viral seasons/years after implementation.

The unit of analysis is each patient, who will have 2-3 of the evidence-based practices applicable to their care during the hospitalization. We will analyze the primary outcome, mean adherence, using multi-level linear regression models. We will include hospital-specific random effects to account for clustering within hospitals. We will include patient-level covariates that have been associated with severity of respiratory illnesses: age,[55,56] sex,[56] need for supplemental oxygen on admission,[57] and prior prescription of an inhaled corticosteroid (applies only to admissions for asthma).[78,79] We will also include hospital-level covariates including hospital size, teaching status, and geographic region. We will not include clustering effects by clinician, because multiple clinicians are commonly involved in a patient's care during a hospital admission. We will exclude data from months 1-3 of the implementation period from all analyses to allow for intervention implementation. However, we will collect outcome data throughout the intervention period to help guide implementation efforts.

Secondary Outcomes:
Secondary outcomes will include adherence for each evidence-based practice, length of hospital stay in hours, transfer to intensive care, and 30-day hospital readmission or emergency

revisit. We will analyze secondary outcomes using multi-level regression models with hospital-specific random effects and the same hospital and patient characteristics included in the primary outcome analysis (see above). We will analyze each evidence-based practice using linear regression, length of stay using gamma regression, and transfer to intensive care and 30-day hospital readmissions/emergency revisits using logistic regression.

Subgroup Analyses:
For our primary outcome, we will perform exploratory subgroup analyses to understand effects by different subgroups: 1) hospital type [community hospital, nested children's hospital], and 2) additional demographic characteristics [race, ethnicity, primary language, and primary insurance]. We will conduct these analyses to quantify and understand effects sizes across these important subgroups. We will also test interaction terms to see if any differences in effect sizes by subgroup are significant.

Sensitivity Analyses:
In our primary analysis, we will adjust for patient age, sex, need for supplemental oxygen, and prior prescription of inhaled corticosteroid (applies only to admissions for asthma). In a sensitivity analysis, we will incorporate additional demographic factors including race, ethnicity, primary language, and primary insurance [proxy for socioeconomic status]. This will be done to make sure our effects are robust even if these covariates were imbalanced by randomization. Additionally, we will examine an "all-or-nothing" outcome across all conditions (asthma, pneumonia, and bronchiolitis), where we analyze if all 2-3 evidence-based practices that apply for a given admission were adhered to or not. Although our difference-in-differences approach should account for differential adherence to evidence-based practices before the intervention, if we find significant discrepancy in baseline adherence in control versus intervention hospitals such that we would be concerned about floor/ceiling effects (limited ability to improve), we will perform an additional sensitivity analysis in which we formally incorporate mean adherence to evidence-based practices at baseline/before the intervention at the hospital level into our models. Lastly, we have also collected prospective data on intervention fidelity and interventions that could lead to potential contamination in the control arm. If we find low fidelity in the intervention arm or potential contamination in control arm hospitals, we will also incorporate these data into a sensitivity analysis.

Fidelity/Aim 2 Analysis:
We will summarize the degree of utilization of implementation strategies aggregated over 12 months (e.g., mean number of audit and feedback episodes) and time costs of implementation using descriptive statistics. We will link data on hospital-level utilization of implementation strategies to hospital-level data on changes in mean adherence to evidence-based practices from the baseline to intervention period. We will use multi-level linear regression models to determine associations between degree of utilization of implementation strategies and changes in adherence by testing for interactions between the strategies and time. We will include hospital-specific random effects to account for clustering within hospitals. We will use the same patient-level and hospital-level covariates for these models as described in the primary analysis.

G3 Missing Outcome Data

We will monitor for missingness throughout the study as described above in "F2 Data Collection/Study Outcome Measurement." We will determine overall proportion of missingness of each co-variate and outcome variable and, if any variable is missing in >5% of participant records, we will apply multiple imputation methods. We will report all missingness and analytic strategies to address missingness in any publications or reports.

G4 Unblinding Procedures

Patient, families, and clinicians will be unblinded to the intervention throughout the study. The DSMB and study team will work in concert to review study progress and any adverse events as described above in "F3 Safety Monitoring and Serious Adverse Event Reporting." If the DSMB determines unblinding of the DSMB, study team, and/or study analyst is needed at any time, this will be done.

H Data Handling and Record Keeping

H1 Confidentiality and Security

See above section, "D2 Risks/Benefits" for a detailed description of data confidentiality and security procedures.

H2 Training

See above section "F2 Data Collection/Study Outcome Measurement" for a detailed description of chart reviewer training methods.

H3 Case Report Forms and Source Documents

All study data will be collected from participating hospitals' electronic health records and entered into case report forms within the UCSF REDCap database as described above in "F2 Data Collection/Study Outcome Measurement."

H4 Records Retention and Data Sharing

Data generated under this project will be administered in accordance with the policies of the University of California San Francisco (UCSF) and NIH/NHLBI. The proposed research will generate quantitative and qualitative data from community hospitals that care for children hospitalized with respiratory illnesses. Aim 1 generates quantitative data about adherence to evidence-based practices in the care of these conditions as well as patients' length of hospital stay, transfer to intensive care, and hospital readmissions/emergency department revisits. Aim 2 generates a combination of qualitative and quantitative data about the multi-condition pathway implementation process. The Final Research Data (the dataset necessary to document and support research findings) will be made available for sharing after the main research findings from the final data set have been accepted for publication in a peer-reviewed journal. Prior to sharing, data will be redacted to strip all direct identifiers of hospitals (no identifiers of patients/individuals will be collected).

I Study Monitoring, Auditing, and Inspecting

I1 Study Monitoring Plan

See details in above section "F3 Safety Monitoring and Serious Adverse Event Reporting."

I2 Auditing and Inspecting

See details in above section "F3 Safety Monitoring and Serious Adverse Event Reporting."

J Study Administration

J1 Organization and Participating Centers

Figure 3. Organizational Structure

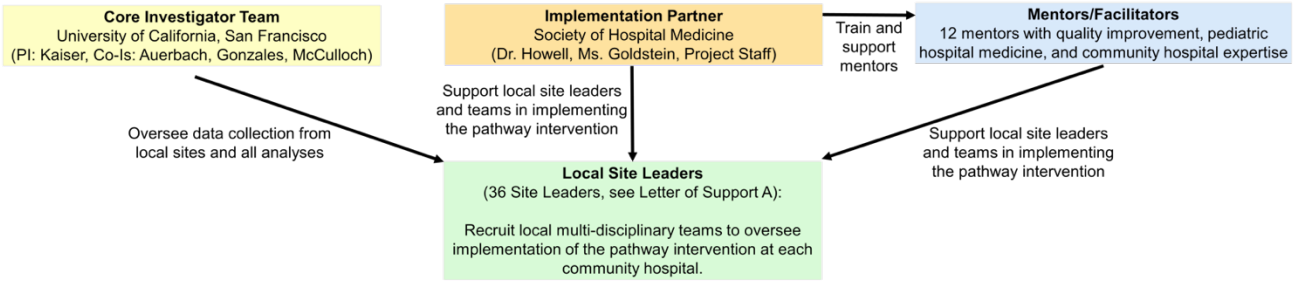


Figure 3 displays the organizational structure for the proposed study. Our proposed interdisciplinary Core Investigator Team at the University of California, San Francisco will oversee all aspects of the proposed research. Members include Sunitha Kaiser, MD MSc (PI), Andrew Auerbach, MD MPH (Co-I), Ralph Gonzales, MD MSPH (Co-I) and Charles McCulloch, PhD (Co-I). The team is supported by Project Manager Yeelen Edwards, MSc.

A team from Society of Hospital Medicine will oversee all aspects of implementation using the mentored implementation framework.[47] SHM team members include Dr. Eric Howell, Ms. Jenna Goldstein, and Sara Thompson.

We have also recruited local site leaders from community hospitals (participating centers). These leaders are physicians with QI expertise. They will recruit multidisciplinary implementation teams at each site that will assist in identifying barriers, refining the intervention, and overseeing implementation at participating sites. Expert QI mentors/facilitators will support these local teams.

We have also assembled a multidisciplinary National Advisory Board that will help guide successful completion of the proposed grant. These 8 members include Dr. Casey Lion, Dr. Michael Cabana, Dr. Kavita Parikh, Dr. Shawn Ralston, Dr. Christopher Landrigan, Dr. Judy Shaw, Dr. Leonard Bacharier. Several advisory board members hold leadership roles with our dissemination partners, and they will advise us on how best to provide these organizations with the needed information on the intervention for future dissemination and replication. Our 5 dissemination partners are the leading national organizations involved in the care of hospitalized children.

Sunitha Kaiser, MD MSc	Yeelen Edwards, MSc	Jenna Goldstein, MA
Principal Investigator, who handles all scientific and clinical inquiries related to the study	UCSF Project Manager, who leads all administrative and logistical aspects of the study	SHM Project Manager, who leads all aspects of Mentored Implementation of the intervention

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J2 Funding Source and Conflicts of Interest

The funding source for the study is the National Heart, Lung, and Blood Institute. The PI and Co-Is have no conflicts of interest relevant to this proposal to disclose.

J3 Subject Stipends or Payments

None.

J4 Study Timetable

Timeline: Year 1

Study Month	1	2	3	4	5	6	7	8	9	10	11	12
Hire UCSF Project Manager and staff	■	■										
Complete the UCSF Single IRB approval process	■	■	■									
Recruit community hospitals and randomize to intervention versus wait-list control groups				■	■	■						
Issue reliance agreements and data use agreements (if needed) for each participating site				■	■	■	■	■	■			
Train chart reviewers at each site, then reviewers enroll participants/perform baseline chart review				■	■	■	■	■	■			
Assess organizational readiness for change					■	■	■					
Finalize plans for implementation strategies, operationalizing the implementation framework, and skills development (to occur during Mentor University)									■			
Finalize the unit of intervention, comparison groups, and outcome measures (with targets)									■			
Plan elements of the implementation strategy designed to foster sustainability and re-use									■			
Finalize study infrastructure and documents (e.g., data safety monitoring plans, informed consent documents, study protocol)							■	■	■	■		
Conduct mentor/facilitator monthly meetings with sites (discuss performance, identify targets, plan implementation efforts)									■	■	■	■
Conduct meetings with Dr. Kaiser, UCSF Project Manager, and UCSF staff (weekly)	■	■	■	■	■	■	■	■	■	■	■	■
Conduct meetings with Dr. Kaiser, UCSF Project Manager, UCSF staff, and SHM team (bi-weekly)	■	■	■	■	■	■	■	■	■	■	■	■
Conduct meetings with Dr. Kaiser, UCSF Project Manager, UCSF staff, SHM team, and other Core Investigators (monthly)	■	■	■	■	■	■	■	■	■	■	■	■
Conduct meetings with Dr. Kaiser, UCSF Project Manager, UCSF staff, SHM team, other Core Investigators, and National Advisory Board (quarterly)			■			■			■			■

Timeline: Years 2-5

Study Quarter	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16
Aim 1: Intervention hospitals implement intervention and perform chart review*		25%		50%		75%		100 %								
Aim 1: Control hospitals wait to implement, but perform chart review*		25%		50%		75%		100 %								
Aim 1: Control hospitals implement intervention and continue chart review																
Aim 1: Analyze data (cluster RCT)																
Aim 1: Prepare manuscript (cluster RCT)																
Aim 1: Analyze data (effects in wait-list group)																
Aim 1: Prepare manuscript (effects in wait-list group)																
Aim 2: Collect data (surveys, field visits)																
Aim 2: Analyze data (with Aim 1 data)																
Aim 2: Prepare manuscript																
Develop a plan to support sustainability beyond the research study																
Close out study																
Develop implementation toolkit (if intervention is successful)																
Disseminate findings +/- toolkit																
Conduct meetings with Dr. Kaiser, UCSF Project Manager, and UCSF staff (weekly)																
Conduct meetings with Dr. Kaiser, UCSF Project Manager, UCSF staff, and SHM team (bi-weekly)																
Conduct meetings with Dr. Kaiser, UCSF Project Manager, UCSF staff, SHM team, and other Core Investigators (monthly)																
Conduct meetings with Dr. Kaiser, UCSF Project Manager, UCSF staff, SHM team, other Core Investigators, and National Advisory Board (quarterly)																

* Percentages within timeline boxes indicate cumulative enrollment in the cluster RCT

K Publication Plan

We have engaged the 5 leading national organizations involved in the care of hospitalized children in dissemination efforts (see Letters of Support J-N). These include the Society of Hospital Medicine (SHM, national organization representing over 40,000 hospitalists), the American Academy of Pediatrics (national organization of 67,000 pediatricians, pediatric medical subspecialists, and pediatric surgical specialists), the Pediatric Research in Inpatient Settings Network (pediatric hospitalist network representing over 120 hospitals and 400 pediatric hospitalists in the US and Canada), America's Hospital Essentials (national network of over 300 safety-net hospitals), and the National Improvement Partnership Network (national quality improvement network that includes hospitals in 20 states).

These partners have all committed to disseminate our study findings via organizational websites, e-mail listservs, social media (e.g., Twitter), newsletters, and national seminars. If the multi-condition pathway intervention is effective, we will assemble an implementation toolkit for dissemination by these national organizations. The toolkit will contain all necessary materials for future implementation efforts, including a brief/overall summary of our findings; the multi-condition pathways; details about mentored implementation; educational seminar materials; specifications on measuring evidence-based practice adoption outcomes; and guidance on implementation strategies, barriers and facilitators, and adaptions to the intervention. SHM will distribute this toolkit, and prior SHM projects have each had 400-800 downloads of such toolkits and widespread use. Also, the American Academy of Pediatrics will consider using this toolkit to support a future national project to scale the multi-condition pathway intervention more broadly to hospitals across the country (as they have done in several prior successful projects). In addition, we will share order sets via the Agency for Healthcare Research and Quality's Clinical Decision Support Repository.

We will also seek to publish our findings in peer-reviewed manuscripts, present them at academic meetings, and present them to national, regional, and local clinician, health administrator, and QI audiences. Our Core Investigator Team has experience with the rapid publication of research findings and have collaborated on prior research publications. In addition, there are a number of resources at UCSF to support dissemination, including a network of affiliated community hospitals, the Clinical and Translational Science Institute's (CTSI) consultation services on scientific writing and dissemination, and CTSI's Communications Team.

L Attachments

L1 Informed consent documents

We were approved for waiver of consent for Aim 1. For Aim 2, we have provided the consent document as Appendix A.

L2 Data Collection Instrument

The chart review data collection instrument is provided as Appendix B.

M References

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Appendix A: Consent Form

UCSF University of California San Francisco
IRB NUMBER: 20-30418
IRB APPROVAL DATE: 07/14/2021

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE IN RESEARCH

Study Title: The SIP Study: Simultaneously Implementing Pathways for Improving Asthma, Pneumonia, and Bronchiolitis Care for Hospitalized Children

This is a research study, and you do not have to take part. The researcher, Dr. Sunitha Kaiser from the Department of Pediatrics will explain this study to you. If you have any questions, you may ask the researcher.

You are being asked to take part in this study because you have been leading efforts to implement pathways to guide asthma, pneumonia, and bronchiolitis care.

In this study, the researchers are doing a survey to learn more about the pathway implementation process. The National Heart, Lung, and Blood Institute (of the National Institutes of Health) is paying for this research. About 18 people will participate in this study.

What will happen if I take part in this study?

If you agree to be in this study, you will complete surveys online. You will be asked to complete one survey now. You will also be asked to complete a follow-up survey in a month's time, and another survey each subsequent month for the first year of the pathway implementation period at your hospital. The surveys ask about the pathway implementation and quality improvement activities that have occurred at your hospital. It will take you about 10 minutes to complete each survey.

How will my information be used?

Researchers will use your information to conduct this study. Once the study is done using your information, we may share it with other researchers so they can use it for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Are there any risks to me or my privacy?

Some of the survey questions may make you feel uncomfortable or raise unpleasant memories. You are free to skip any question.

We will do our best to protect the information we collect from you. Information that identifies you will be kept secure. The survey itself will not include details that directly identify you, such as your name or address. Please do not put this information on your survey. The completed surveys will be kept secure and separate from information that identifies you. Only a small number of researchers will have direct access to completed surveys. If this study is published or presented at scientific meetings, names and other information that might identify you will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Heart, Lung, and Blood Institute (of the National Institutes of Health)
- Representatives of the University of California

Are there benefits?

There is no benefit to you. The survey results will be used for research.

Can I say "No"?

Yes, you do not have to complete a survey. If you choose not to be in this study you will not lose any of your regular benefits, and you can still receive medical care from UCSF.

Are there any payments or costs?

You will not be paid for completing the survey. There are no costs to you.

Who can answer my questions about the study?

You can talk with the study researcher about any questions, concerns, or complaints you have about this study. Contact the study researcher(s) Dr. Sunitha Kaiser at 415-476-3392.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814

CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY.

You have may request a copy of this consent to keep.

If you wish to participate in this study, please click "Yes" and we will begin the survey. By consenting to complete the initial survey, you are also agreeing to complete subsequent monthly surveys for the first year of the implementation period.

Appendix B: Chart Review Tool

SIP Chart Review Tool

Please use this tool for review of charts of children ADMITTED to your hospital (inpatient or observation status) with a PRIMARY DIAGNOSIS OF ASTHMA, PNEUMONIA, or BRONCHIOLITIS. Please review all charts for each calendar month up to a maximum of 10 charts per month for each of these conditions.

This chart is being reviewed for [hospital_name].

Hospital Name

- ◯ CA UCLA Medical Center
- ◯ CA Adventist Health White Memorial
- ◯ CA Marin Health Medical Center
- ◯ CA Kaiser Oakland Medical Center
- ◯ CA Rady Children's at Sharp Grossmont Hospital
- ◯ CA Kaiser Permanente Orange County
- ◯ CA Community Regional Medical Center
- ◯ CA John Muir
- ◯ CANADA Childrens Hospital, Health Science Centre, Shared Health Inc.
- ◯ CO SkyRidge/North Suburban Hospital
- ◯ FL Tampa General Hospital
- ◯ FL Tallahassee Memorial Hospital
- ◯ FL St. Mary's Medical Center/Palm Beach Children's
- ◯ FL Sarasota Memorial Hospital
- ◯ IL University of Illinois Hospital
- ◯ IL University of Chicago Comer Children's Hospital
- ◯ IL Northwestern Lake Forest Hospital
- ◯ IL MacNeal Hospital
- ◯ MD University of Maryland Baltimore Washington Medical Center
- ◯ MI St. Joseph Mercy Ann Arbor
- ◯ MN Fairview Ridges Hospital
- ◯ MO CoxHealth
- ◯ MT Billings Clinic
- ◯ NC Vidant Medical Center
- ◯ NC Duke University Medical Center
- ◯ NJ Hackensack University Medical Center
- ◯ NY Bronx Care Health Systems
- ◯ NY New York Presbyterian Queens
- ◯ NY Mount Sinai Beth Israel
- ◯ NY Brookdale University Hospital One Brooklyn Health
- ◯ OR OHSU Health: Hillsboro Medical Center
- ◯ PA York Wellspan
- ◯ Puerto Rico Hima San Pablo Caguas
- ◯ TX Baylor Scott & White Healthcare McLane Children's Medical Center
- ◯ TX University of Texas Medical Branch
- ◯ TX Texas Children's Hospital- The Woodlands
- ◯ TX Texas Children's Hospital - West Campus
- ◯ TX St. David's Children's Hospital
- ◯ VA Augusta Health
- ◯ VA University of Virginia Children's Hospital
- ◯ WA Sacred Heart Children's Hospital
- ◯ WA Mary Bridge Children's Hospital
- ◯ WV Ruby Memorial Hospital
- ◯ WV Hoops Family Children's Hospital

What is the patient's primary diagnosis for this hospital admission? (use report)

The primary diagnosis may be listed in the discharge summary as "discharge diagnosis" or marked as the "principal" problem in the problem list.

- ◯ Asthma
- ◯ Pneumonia
- ◯ Bronchiolitis

CONFIRMING ELIGIBILITY

Does this patient meet BOTH inclusion criteria? (use report)

Inclusion Criteria:
1) Age 2-17 years
2) Primary Diagnosis of Asthma

◯ Yes
◯ No

Does this patient meet BOTH inclusion criteria? (use report)

Inclusion Criteria:
1) Age 3 months-17 years
2) Primary Diagnosis of Pneumonia

◯ Yes
◯ No

Does this patient meet BOTH inclusion criteria? (use report)

Inclusion Criteria:
1) Age < 2 years
2) Primary Diagnosis of Bronchiolitis

◯ Yes
◯ No

From where was the patient admitted to your inpatient unit?

This may be documented in the History of Present Illness (HPI) section of the History & Physical note.

◯ Other area/unit of your hospital (e.g., emergency room, intensive care unit)
◯ Outpatient office/facility
◯ Another hospital's emergency room
◯ Another hospital's inpatient units (e.g., ward, ICU)
◯ Other
◯ Unknown

Does this patient meet ANY of the following exclusion criteria? (use Problem List or History and Physical note)

1) Active/current diagnosis of SARS-CoV-2 (COVID-19)
2) Co-morbid conditions predisposing to severe or recurrent respiratory illness:
- Chronic lung disease (e.g. cystic fibrosis, restrictive lung disease, bronchopulmonary dysplasia, lung dysplasia/hypoplasia)
- Congenital or acquired heart disease
- Airway issues (e.g. vocal cord paralysis, tracheomalacia, tracheostomy dependent)
- Immunodeficiency or chemotherapy
- Neurological disorders (e.g., congenital, neuromuscular, quadriplegia/quadriparesis)

◯ Yes
◯ No

Chart Number (use report)

Remember to review all eligible charts, to a max of 10 per condition per month.

PATIENT DEMOGRAPHICS

Data cycle inpatient admit order was placed (use report)

- ◯ Cycle 2
- ◯ Cycle 3
- ◯ Cycle 4
- ◯ Cycle 5
- ◯ Cycle 6
- ◯ Cycle 7
- ◯ Cycle 8
- ◯ Cycle 9
- ◯ Cycle 10
- ◯ Cycle 11
- ◯ Cycle 12
- ◯ Cycle 13

Year inpatient admit order was placed (use report)

- ◯ 2019
- ◯ 2020
- ◯ 2021
- ◯ 2022
- ◯ 2023
- ◯ 2024
- ◯ 2025

What is the patient's sex? (use report)

- ◯ Male
- ◯ Female

What is the patient's age in YEARS at admission? (use report)

- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7
- ◯ 8
- ◯ 9
- ◯ 10
- ◯ 11
- ◯ 12
- ◯ 13
- ◯ 14
- ◯ 15
- ◯ 16
- ◯ 17

What is the patient's age in YEARS at admission? (use report)

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7
- ◯ 8
- ◯ 9
- ◯ 10
- ◯ 11
- ◯ 12
- ◯ 13
- ◯ 14
- ◯ 15
- ◯ 16
- ◯ 17

What is the patient's age in MONTHS at admission? (use report)

- ◯ 0
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6
- ◯ 7
- ◯ 8
- ◯ 9
- ◯ 10
- ◯ 11
- ◯ 12
- ◯ 13
- ◯ 14
- ◯ 15
- ◯ 16
- ◯ 17
- ◯ 18
- ◯ 19
- ◯ 20
- ◯ 21
- ◯ 22
- ◯ 23

What is the patient's race? (select all that apply, use report)

- ☐ African
- ☐ African American or Black
- ☐ Alaska Native
- ☐ American Indian
- ☐ Asian
- ☐ Hawaiian
- ☐ Indian
- ☐ Middle Eastern
- ☐ Pacific Islander
- ☐ Sudanese
- ☐ White
- ☐ Two or More Races
- ☐ Other
- ☐ Unknown

What is the patient's ethnicity? (use report)

- ◯ Hispanic/Latino
- ◯ Non-Hispanic
- ◯ Unknown

What the patient's primary language? (use report)

- ◯ English
- ◯ Spanish
- ◯ French
- ◯ Chinese
- ◯ Tagalog
- ◯ Other
- ◯ Unknown

What is the patient's primary health insurance type? (use report)

- ◯ Public insurance (e.g., Medicaid, Medicare, Children's Health Insurance Program/CHIP)
- ◯ Private insurance (e.g., Blue Shield, group health plan, commercial)
- ◯ Self pay
- ◯ Other (e.g., Tricare)
- ◯ Unknown

QUALITY MEASURES

Was prescription of inhaled corticosteroids (ICS; e.g., fluticasone, budesonide) PRIOR to this hospital admission documented anywhere in the patient chart?

This may be documented in the History of Present Illness (HPI) or "Home Medications" sections of the H&P, or it may be documented in the Medication Reconciliation process. We are interested in whether the child was ever PRESCRIBED ICS in the past, as a marker of chronic asthma severity. Please mark "Yes" if it was ever prescribed, even if you are concerned that the patient was not compliant with taking ICS.

◯ Yes
◯ No

Was an asthma pathway or asthma protocol order placed for this patient?

◯ Yes
◯ No

Was the first inpatient bronchodilator order via metered-dose inhaler (MDI)?

Find the time stamp of the "admit to inpatient" order. Find the first bronchodilator order done with/just after the "admit to inpatient" order or first bronchodilator order by an inpatient provider. Select "Yes" if this order was via MDI.

If bronchodilator orders are continued/carried over from the emergency department, please select "Yes" if the continued order is via MDI. If a pathway/protocol is ordered that guides bronchodilator dosing, please find the first inpatient bronchodilator the patient was administered using the Medication Administration Record and select "Yes" if it was given via MDI.

◯ Yes
◯ No

At what dosing frequency was bronchodilator via metered-dose inhaler (MDI) FIRST ordered?

Find the first bronchodilator order via MDI using the Order History, and select the dosing frequency at which it was ordered. If an asthma pathway/protocol is ordered instead of a specific frequency of MDI dosing, please mark the shortest interval at which the pathway/protocol allows MDI to be administered (e.g., Q1, Q2).

◯ Q1
◯ Q2
◯ Q3
◯ Q4
◯ MDI administered only as a single/one time dose
◯ No bronchodilator via MDI ordered
◯ Other

Please describe "Other"

_____

Was this patient prescribed any inhaled corticosteroids (e.g., fluticasone, budesonide) at HOSPITAL DISCHARGE?

Please refer to the discharge orders. Select "yes" for new prescriptions at discharge or discharge instructions to continue previously prescribed inhaled corticosteroids.

◯ Yes
◯ No

What type of antibiotic was first ordered in the inpatient setting?

Find the time stamp of the "admit to inpatient" order. Find the first antibiotic order done with/just after the "admit to inpatient" order or the first antibiotic order by an inpatient provider. Specify what type of antibiotic was ordered.

◯ Narrow-spectrum antibiotic (only includes ampicillin, amoxicillin, or penicillin G)
◯ Other antibiotic
◯ No antibiotics were ordered in the inpatient setting

Did this patient have a documented reason for not ordering narrow-spectrum antibiotics?

Please refer to the History and Physical Note to find documentation of reasons. Reasons may include incomplete immunization for age, failure of narrow-spectrum antibiotics, severe or complicated pneumonia (e.g., with empyema), infection with an organism not susceptible to narrow-spectrum antiobiotics (e.g., staph), allergy to penicillin, or local high-level penicillin resistance.

◯ Yes
◯ No

Did this patient have macrolide antibiotics (e.g., azithromycin, erythromycin, clarithromycin) ordered during the inpatient hospitalization or at hospital discharge?

Please check the Order History and Discharge Orders for any macrolide antibiotic orders and mark "Yes" if found. If macrolide antibiotics were ordered in the emergency room but discontinued inpatient, mark "No."

◯ Yes
◯ No

Did this patient have POSITIVE mycoplasma testing (e.g., IgM, PCR)?

Please check the Lab Results for any positive mycoplasma testing.

◯ Yes
◯ No

Did this patient have any bronchodilators (e.g, albuterol, salbutamol, epinephrine) ordered at any time?

Please check the Order History for any bronchodilator orders and mark "Yes" if ordered (even if only PRN/as needed).

◯ Yes
◯ No

In which setting/s were bronchodilators ordered? (select all that apply)

Review the Order History and use "admit to inpatient" order timestamp or ordering provider to help determine setting.

☐ Emergency Department
☐ Inpatient Unit
☐ Other/Unknown

Did this patient have chest radiography ordered?

Please check the Order History for any bronchodilator orders and mark "Yes" if ordered.

◯ Yes
◯ No

In which setting/s was chest radiography ordered? (select all that apply)

Review the Order History and use "admit to inpatient" order timestamp or ordering provider to help determine setting.

☐ Emergency Department
☐ Inpatient Unit
☐ Other/Unknown

Did this patient receive supplemental oxygen anytime during the hospitalization?

Please use the Medication Administration Record or Vital Sign Documentation to see if the patient received oxygen.

◯ Yes
◯ No

HEALTH OUTCOMES

Was this patient transferred FROM your hospital's acute/general inpatient unit to an intensive care unit for higher level of care? (use report)

◯ Yes
◯ No

What was this patient's disposition from the hospital? (use report)

◯ Discharged home
◯ Transferred to another facility
◯ Died/death
◯ Other

Length of inpatient stay in HOURS: (use report)

Use the time stamp of the "admit to inpatient" and "discharge patient" orders and this LINK to calculate, rounding down to the nearest hour. For example, if "admit to inpatient" order was placed at 23:30 on 7/17/2022 and "discharge patient" order was placed at 08:15 on 7/19/2022, length of stay= 32 hours.

Was this patient seen in your hospital emergency department within 30 days of discharge for any reason? (use report)

Chart review should begin a minimum of 1 month after the month of interest/review (e.g., begin reviewing charts for July 2022 no earlier than September 1, 2022).

◯ Yes
◯ No

Was this patient readmitted to your hospital (can be via ED) within 30 days of discharge for any reason? (use report)

Chart review should begin a minimum of 1 month after the month of interest/review (e.g., begin reviewing charts for July 2022 no earlier than September 1, 2022).

◯ Yes
◯ No