Request for genIC Approval

CHOP - Antibiotic Use Metric and Tool Development

CIO:

PROJECT TITLE: A Novel Metric for Benchmarking Antibiotic Use to Inform Outpatient Stewardship

PURPOSE AND USE OF COLLECTION:

Antibiotics are, by far, the most common medication dispensed for children. The majority of these antibiotics are prescribed for acute respiratory tract infections (ARTIs). Antibiotic use is the leading cause of emergency department (ED) visits for drug-related adverse events in children and is associated with the emergence of antimicrobial resistance. Infections with resistant bacteria lead to increased morbidity, mortality, and costs.

The Centers for Disease Control and Prevention (CDC) includes "tracking and reporting" as one of the four core elements of outpatient stewardship. Appropriate quantitative metrics are essential to fully describe the problem, design interventions, and assess improvement in ambulatory antibiotic prescribing. For outpatient ARTIs, previous stewardship interventions have largely focused on reducing antibiotic prescribing for specific viral diagnoses and optimizing the selection of antibiotics for bacterial infections. These interventions have not addressed diagnosis rates of bacterial ARTIs. Because diagnosis rates for bacterial ARTIs have been shown to vary widely across practices and clinicians, and these diagnoses almost invariably lead to antibiotic prescriptions, reducing the over-diagnosis of bacterial ARTIs represents an important target for antimicrobial stewardship interventions. Thus, we are seeking to get feedback for the development of a metric for benchmarking the relative rate of bacterial diagnosis and antibiotic prescribing within the denominator of all ARTIs.

We designed an education intervention to improve antibiotic prescribing for ARTIs that incorporates primary care pediatric prescriber perceptions and preferences. Focus groups will be designed to (1) elicit prescriber perceptions of our benchmark rate and preferences for its integration into an educational and clinical intervention (2) elicit prescriber feedback on the intervention and suggestions for improvement. The purpose of the focus groups is to elicit prescriber feedback to improve the engagement and acceptance of prescribers with the stewardship metrics.

DESCRIPTION OF RESPONDENTS:

We will conduct focus groups with primary care pediatric prescribers (physicians and nurse practitioners) at four practices in the Children's Hospital of Philadelphia (CHOP) pediatric primary care network.

CERTIFICATION:

I certify the following to be true:

- 1. The collection is voluntary.
- 2. The collection is low-burden for respondents and low-cost for the Federal Government.
- 3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
- 4. Information gathered will not be used to substantially inform influential policy decisions.
- 5. The study is not intended to produce results that can be generalized beyond its scope.

Name: Julia E. Szymczak, PhD

To assist review, please answer the following questions:

Personally Identifiable Information:

- 1. Is personally identifiable information (PII) collected? [] Yes [X] No
- 2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [] Yes [] No
- 3. If Applicable, has a System or Records Notice been published? [] Yes [X] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [] Yes [X] No

BURDEN HOURS

Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
Physicians	Focus Group Script	16	1	1	16
Nurse Practitioners	Focus Group Script	8	1	1	8
	Total	24			24

FEDERAL COST: Not applicable.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? [X] Yes [] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

We will utilize a purposive sampling approach to assemble 4 focus groups comprised of prescribing clinicians who work in the CHOP ambulatory care setting. Our respondents are physicians and nurse practitioners who are employed by CHOP. We aim to conduct 4 focus groups of approximately 6 participants in each, for a total of 24 respondents. We will purposively sample by occupation role and will attempt to include at least 4 physicians and 2 nurse practitioners per focus group.

We will use CHOP ambulatory practice provider lists to identify eligible respondents and obtain their work email address. Within one month of receiving OMB approval, we will send a recruitment email to each eligible individual inviting them to participate in a focus group at their practice. They will be made aware that participation is voluntary. Once we have a critical mass of potential respondents we will work with administrative staff at the practice to schedule the focus group during lunch or another period of time in which a regularly-scheduled all staff meeting is held.

Sampling method description

The sample will include a combination four primary care settings: 1 large urban academic practice, 1 large suburban practice, 1 small rural practice, and 1 shore practice. We have purposefully selected practices that vary by location, size and demographics of the community served.

Administration of the Instrument

1.	How will you collect the information? (Check all that apply)			
	[] Web-based or other forms of Social Media			
	[] Telephone			
	[X] In-person			
	[] Mail			
	[] Other, Explain – via email / Word documents			

2. Will interviewers or facilitators be used? [X] Yes [] No

The focus groups will be led by a trained facilitator who will state focus group ground rules, ask questions and keep the focus group on task. The facilitator will be joined by the study PI who will give a presentation on the metric and benchmark and a note-taker who will make notes about the dynamics of the focus group and will manage the audio recording of the focus group session.

We will ask a series of questions intending to encourage clinicians to reflect on the barriers to judicious prescribing for ARTIs in their setting. Then, we will have the study PI give a brief presentation on our metric, benchmark, and rationale for the intervention. The focus group facilitator will elicit feedback from participants on the material presented. Then, we will have participants brainstorm possible educational interventions that incorporate these data and the information they shared on barriers to judicious prescribing.

Please make sure all instruments, instructions, and scripts are submitted with the request.

• Attachment A: Focus Group Script

Attachment B: IRB Determination Letter