

GenIC Clearance for CDC/ATSDR
Formative Research and Tool Development
Supporting Statement B

**Formative Research with Clinicians for the Development of Quantitative Metrics to
Improve Antibiotic Prescribing Behavior in the Outpatient Setting**

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The purpose of this study is to conduct formative research to inform the development of metrics and benchmarking to improve antibiotic use in the pediatric ambulatory setting. The research results will be used to design the metrics to be used in the future to assess antibiotic prescribing stewardship across the Children’s Hospital of Philadelphia (CHOP) ambulatory care network.

This research utilizes a qualitative approach; therefore, no statistical methods will be used to guide the sampling or analysis of data. The study sample will be a nonprobability-based purposeful sample. Therefore, the results are not generalizable to the general population. We intend to conduct 4 distinct focus groups with 6 participants each. We will conduct focus groups at 4 geographically diverse pediatric primary care practices in the CHOP ambulatory network: a large urban academic practice, a large suburban practice, a shore practice, and a small rural practice. These sites have been purposefully selected because they serve distinct patient populations and represent diverse organizational structures and cultures. Our sample will be comprised of physicians and nurse practitioners since they are authorized to prescribe antibiotics.

Study Population

The audience for this research will be pediatricians, pediatric nurse practitioners and those leading antimicrobial stewardship programs in ambulatory settings.

B2. Procedures for the Collection of Information

The University of Pennsylvania and CHOP will be responsible for the collection of all study information. 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 (Attachment C) 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.

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 (Attachment D) on the metrics and benchmark to get feedback on how to best display the data and a note-taker 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 from the focus group guide (Attachment A) 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.

No personally identifiable information will be collected as part of this formative research. Respondents will provide data on their position title and the number of years they have been in practice. All focus group questions focus on the antibiotic prescribing metric and general perceptions of barriers and facilitators to judicious antibiotic prescribing in the ambulatory pediatric setting. These questions do not request any personally identifiable information. Data

will be audio recorded and hand written notes will be taken. Audio data will be stored in an encrypted, password protected server at the University of Pennsylvania. It will be professionally transcribed by a transcriptionist who has signed a privacy agreement. Audio files will be destroyed after they have been transcribed. All data will be de-identified and used internally at CHOP to inform future research and implementation efforts. We anticipate completing all focus groups within 4 months of OMB approval.

B3. Methods to Maximize Response Rates and Deal with No Response

To maximize response rate we will attempt to schedule the focus groups during an already-scheduled meeting in order to accommodate clinician schedules. We will get approval from the practice manager and will work with them to find this time.

B4. Test of Procedures or Methods to Be Undertaken

To estimate the burden of data collection, our study team has reviewed the focus group guide to ensure that no extraneous questions are being asked. Based on the expertise of the qualitative methodologist on the team (Dr. Julia E. Szymczak), we estimate that our burden estimate most closely resembles a maximum average burden.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

No statistical methods are used in this study. It is a qualitative study. The study has been designed by Dr. Szymczak, a medical sociologist and qualitative methodologist with extensive experience conducting studies on the antibiotic prescribing behavior of clinicians using interviews and ethnographic techniques. Data will be gathered by Ms. Brandi Muller, MA, who is trained as a medical anthropologist and works as Dr. Szymczak's primary data collector and analyst.

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