GenIC Clearance for CDC/ATSDR

Formative Research and Tool Development

Supporting Statement A

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

OMB number 0920-1154

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Contact:
Colleen Brouillette
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333
Phone: (404) 718-1616
Email: mfi3@cdc.gov

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LIST OF ATTACHMENTS

- **Goals of the study:** To develop quantitative metrics to improve antibiotic prescribing for Acute Respiratory Tract Infections (ARTIs) that incorporates primary care pediatric prescribers perceptions and preferences of stewardship metrics.

- **Intended use of the resulting data:** The data will be used to develop quantitative metrics to assess primary care pediatric antibiotic prescribing

- **Methods to be used to collect data:** We will conduct a qualitative study using a series of focus groups to understand prescribing clinician perceptions about the barriers to judicious prescribing for ARTIs, their thoughts stewardship metrics and benchmarks, ideas for possible interventions and feedback on intervention mock-up metrics. We will conduct these focus groups in four practices in the Children's Hospital of Philadelphia (CHOP) primary care network: a large urban academic practice, a large suburban practice, a shore practice, and a small rural practice.

- **The subpopulation to be studied:** We will recruit 6 prescribing clinicians (physicians and nurse practitioners) to participate in each focus group and will aim to include individuals who have been in practice for varying amounts of time.

- **How data will be analyzed:** All focus group transcripts will be uploaded to NVivo 12 data analysis software for management and coding. Dr. Szymczak will work with a qualitative study coordinator to code the transcripts using standard methods of inductive theory building and the constant comparative method to identify patterns in the data.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests Office of Management and Budget (OMB) approval for a new genIC entitled "Formative Research with Clinicians for the Development of Quantitative Metrics to Improve Antibiotic Prescribing Behavior in the Outpatient Setting." The goal of this formative research, conducted through a CDC contract issued to the Children's Hospital of Philadelphia (CHOP), is to inform the development of quantitative metrics as the first phase of a larger study to estimate the impact of antibiotic harms due to unnecessary antibiotic use in children with Acute Respiratory Tract Infection (ARTIs).

Antibiotic resistance is a major global public health threat. CDC estimates that 2 million people are infected with antibiotic resistant infections each year, and at least 23,000 die as a result.[1] The primary modifiable driver of antibiotic resistance is antibiotic use. Data from other countries suggest that an estimated 85-95% of antibiotic use occurs in the outpatient setting[2] and among all age groups, young children have historically had the highest rate of antibiotic use per capita. [3] Appropriate antibiotic use in children is critical to limit the development of antibiotic resistance and prevent antibiotic-associated harms in children. CDC educational efforts have targeted improving antibiotic use for children since the mid-1990s, and outpatient pediatric antibiotic prescribing rates have declined by 13% from 2011 to 2015.[4] However, more improvements are needed, as CDC estimated that in 2010-11 at least 29% of outpatient antibiotic use in children was unnecessary.[5]

ARTIs are the most common indication for antibiotic prescribing to children, and a significant proportion are unnecessary. Diagnosis of bacterial ARTIs, which drives antibiotic prescribing, varies considerably across clinicians**.** In general, antibiotic treatment is recommended only for bacterial ARTIs, while viral ARTIs should not be treated with antibiotics.

A major challenge for clinicians, however, is distinguishing between ARTIs of viral and bacterial etiology as they have overlapping presentations. As a result, bacterial ARTIs may be over diagnosed, which in turn leads to unnecessary antibiotic use. Identifying and quantifying unnecessary prescribing due to over diagnosis is challenging because an antibiotic prescription and a bacterial diagnosis code are usually paired. In previous work in the CHOP primary care network, antibiotic prescribing for children diagnosed with viral infections was uniformly low across 29 practices. However, the frequency with which bacterial ARTIs were diagnosed varied widely across practices and clinicians (e.g. a nearly a 20-fold differences in rates of sinusitis diagnosis), and these bacterial diagnoses nearly always received antibiotic prescriptions.[6-8] Thus, in order to see further improvements in antibiotic prescribing for US children, antibiotic stewardship efforts are needed to improve diagnostic practices of common bacterial ARTIs, such as acute otitis media and acute sinusitis.

Antimicrobial stewardship programs (ASPs) promote judicious prescribing through evidence-based interventions.[9,10] Guidelines for the implementation of ASPs have highlighted the importance of evidence-based interventions and quantitative metrics.[11,12] The Centers for Disease Control and Prevention (CDC) includes "tracking and reporting" as one of the four core elements of outpatient stewardship.[13] ASP interventions have typically not addressed diagnosis rates and potential over-diagnosis of bacterial ARTIs. Because diagnosis rates for bacterial ARTIs have been shown to vary widely across practices and clinicians,[7] and these diagnoses almost invariably lead to antibiotic prescriptions, reducing over-diagnosis of bacterial ARTIs might represent the most important target for outpatient antimicrobial stewardship interventions. Thus, a metric for benchmarking the relative rate of bacterial diagnosis and antibiotic prescribing within the denominator of *all* ARTIs is critical for addressing this key driver of antibiotic

overuse and would allow for a more accurate estimate of the public health impact of harms associated with unnecessary antibiotic use.

There is a need to increase clinician acceptability of ASP interventions. A frequently cited barrier to the implementation of ASP interventions is prescribing clinician resistance. [14,15] A study at CHOP found, for example, that clinicians who had recently participated in an ASP intervention that utilized audit and feedback of individual prescribing data expressed skepticism and a lack of trust in the data used to generate their feedback reports. These findings underscore how important it is to secure clinician confidence in the measurement system and prescribing guidelines before implementing an ASP intervention to boost credibility of audit data, increase motivation to change and reduce dysfunctional behavior. Understanding how prescribing clinicians perceive an intervention and modifying the intervention based on this feedback is critical to securing engagement.

Thus, CDC is funding this project to develop a metric and a benchmark for the relative rate of bacterial diagnosis and antibiotic prescribing within the denominator of *all* ARTIs among children with the goal of determining how best to utilize this benchmark in clinician feedback as an intervention to improve antibiotic use.

2. Purpose and Use of Information Collection

The purpose of this part of the study is to conduct formative research to inform the development of metrics and benchmarking that will be used in a larger study of antibiotic use in the pediatric ambulatory setting. The research results will be used to design the metrics and benchmarks for their future implementation across the CHOP ambulatory care network. This research is formative and not intended to produce generalizable knowledge that will be consumed in a scholarly context. All information collected as part of the formative research will

be used to inform metric development and provide input into a dissemination and implementation strategy of the newly developed metric as an antibiotic stewardship intervention.

3. Use of Improved Information Technology and Burden Reduction

The study will consist of in-person data collection through participation in a focus group. All data will be provided verbally and recorded by the study team. The focus group script was designed to include the minimum number of items required to assess prescriber perceptions of metrics and benchmarks.

4. Efforts to Identify Duplication and Use of Similar Information

No nationally recognized, standardized metrics for pediatric ambulatory prescribing for all ARTIs, including both bacterial and viral, exist. The formative research described here will inform the broader use of these metrics in both education and antimicrobial stewardship efforts.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

This GenIC request will be for a focus group. There are no legal obstacles to reduce burden. The present study will provide primary data needed to address the goals of this formative research. If the study was not conducted, information needed to inform the development of our metric in pediatric ambulatory care would not be gathered.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies

CDC published a Federal Register Notice on this generic clearance on July 16, 2016 (Vol. 81, No. 137, pp. 46680-46682). No additional public comment period is required for the current submission.

9. Explanation of Any Payment or Gift to Respondents

No incentives will be provided for participation in this study.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

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.

Respondents will be informed that their participation is voluntary and that data will not be analyzed or presented in such a way that their individual practice will be identifiable.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

<u>IRB Approval</u>

This project has been deemed non-research quality improvement by the CHOP IRB. The determination letter is included as Attachment B.

<u>Justification for Sensitive Questions</u>

No sensitive questions will be asked as part of this information collection. The focus group guide is included as Attachment A.

12. Estimates of Annualized Burden Hours and Costs

Exhibits 12.1 and 12.2 provide details about the estimates of annualized burden hours and costs. We anticipate conducting 4 distinct focus groups with 6 participants in each. The focus group will take 1 hour of time. Total burden hours are 24.

Bureau of Labor Statistics data (https://www.bls.gov/oes/current/oes_nat.htm#29-0000) were used to estimate the hourly wage rate for general pediatricians and nurse practitioners for the purposes of this generic request. Total annualized cost to respondents is $1856.

Exhibit 12.1 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**

Exhibit 12.2 Annualized Cost to Respondents

Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physicians	Focus Group Script	16	$90.16	$1442.56
Nurse Practitioners	Focus Group Script	8	$51.68	$413.44
	Total			$1856.00

13. Estimate of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents or record keepers other than their time.

14. Annualized Costs to the Government

This formative research is part of a larger contract from CDC, awarded to CHOP, which has a total cost to the government of $488,971.00. Additionally, a CDC Medical Officer SME will be providing technical expertise at 2.5% FTE (1 hour per week) and a CDC COR at 2.5% FTE for the whole contract. The total contract is $488,971.00, and this formative research is $720.00.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
GS-14 Medical Officer	$4943
GS-13 CDC COR	$2248
Federal Personnel Subtotal	$7191
Project Contract	$720
Total	**$7911**

15. Explanation for Program Changes or Adjustments

No change in burden is requested as this is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data from the focus groups will be transcribed within 2 weeks. The transcripts will be uploaded into NVivo 12 qualitative data analysis software, accessible only to project staff. Data will be analyzed by study Co-Investigator Dr. Julia Szymczak and her study coordinator Ms.

Brandi Muller. We will aggregate common themes and report them back to the rest of the study team in a brief written document outlining findings and recommendations. We will not submit any manuscripts for publication arising from this formative research. The findings will be used internally to drive the creation of antibiotic prescribing metrics and benchmarks, which can be used in future studies of antimicrobial stewardship efforts.

Key events are described in Exhibit 16.1.

Exhibit 16.1 Project Activities and Time Schedule

Activity	Time Schedule
Begin recruitment	1 month after OMB approval
Complete formative research	4 months after OMB approval
Report of findings and recommendations completed	6 months after OMB approval

Of note, additional formative research, in the form of one follow-up focus group, is planned as part of this larger project. The follow-up focus group will be submitted for OMB approval as a separate service delivery package, as the purpose of that focus group will be to receive feedback on the developed metric, benchmark, and communications materials.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date in not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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