Validated Interview and Survey of Outpatient Clinicians on Antibiotic Stewardship Interventions

Request for OMB approval of a New Information Collection

June 2, 2020

Supporting Statement A

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- **Goal of the study:** To assess knowledge, attitudes, and practices related to antibiotic prescribing among clinicians after implementation of a year-long Urgent Care stewardship initiative. We will assess if the interventions within the stewardship initiative were acceptable, appropriate, and feasible and will continue to benefit patients beyond the implementation period. These interventions are adapted specifically for the Urgent Care setting from the Core Elements of Outpatient Antibiotic Stewardship designed by CDC.
- **Intended use of the resulting data:** To inform key stewardship stakeholders within our own organization and to publish generalizable information that can aid in design of global implementation of similar stewardship projects in similar outpatient settings.
- **Methods to be used to collect:** Semi-structured interviews and validated survey instrument based on results from the semi-structured interview.
- **The subpopulation to be studied:** We would like to study 30 clinicians practicing in Intermountain Healthcare's InstaCare and KidsCare Urgent Care clinics in Utah between 7/1/2019 and 6/30/2020. In addition, we are proposing a small sample (n=10 clinicians) from other ambulatory service lines at Intermountain and a small sample of clinicians from the University of Utah's Urgent Care network.
- **How data will be analyzed:** Qualitative analysis software will be used with interview transcripts and notes taken in the field. The software can identify themes from the data to help understand the mindset of clinicians with relation to antibiotic prescribing and how they might respond to interventions. Survey data and prescribing rates will be analyzed to determine relationships and to explain resulting outcomes after implementation of the stewardship initiative.

1. Circumstances Making the Collection of Information Necessary

CDC is requesting approval for one year for a new information collection.

Inappropriate antibiotic prescribing is a major driver of antibiotic resistance which is an urgent national and global health threat. Additionally, inappropriate antibiotic prescribing contributes to avoidable adverse drug events that cause substantial harms to patients. Most antibiotic prescribing originates in traditional outpatient settings such as physician offices and emergency departments and at least 30% of these prescriptions are completely unnecessary. Over the past decade there has been rapid growth in non-traditional outpatient settings including Urgent Care clinics. Recent evidence shows that when compared to traditional office settings, inappropriate antibiotic prescribing is substantially higher in Urgent Care clinics making this an important priority for antibiotic stewardship.

Although a strong body of evidence exists about many types of outpatient stewardship interventions with proven effectiveness, there remain several important knowledge, applicability, and feasibility gaps. First, most outpatient stewardship interventions have focused on traditional primary care settings. Second, those interventions that have been developed and funded through research studies were unable to sustain their effects once the resources were removed. The design, development, and evaluation of durable stewardship interventions addressing the unique setting of Urgent Care clinics is an important area of unmet need.

Recognizing this opportunity, with support from CDC, Intermountain Healthcare (hereafter, named Intermountain) has undertaken the development and implementation of a system-wide stewardship program in Urgent Care **(UC)**. Intermountain has a long-standing commitment to and expertise in implementation of system-wide quality improvement interventions aimed at reducing unwarranted practice variation and cost. Intermountain includes a large network of 39 Urgent Care clinics throughout Utah with a patient volume exceeding 1 million encounters annually. As part of our CDC contract, we recently published a study highlighting problems of inappropriate antibiotic use throughout our UC system. In collaboration with CDC we have developed and recently implemented a multi-faceted antibiotic stewardship program for UC clinics using the framework of the CDC's Core Elements of Outpatient Stewardship. As part of the development of this program, we previously conducted a series of 9 clinician interviews focusing on knowledge, attitudes and practices related to antibiotic prescribing. This was our baseline data. In order to ensure that our program is practical, effective and sustainable, it is now necessary to conduct follow-up interviews with clinicians to determine if there are changes from the baseline clinician perspectives after the implementation of the interventions. Further, to enhance the generalizability of this feedback it will be necessary to expand from our baseline sample size to include 1) clinicians who have and have not made changes in their prescribing practices over the course of the intervention; and 2) clinicians who have not received any stewardship interventions to compare results. Authorizing legislation (Attachment 1) comes from "Combatting Antimicrobial Resistance" section of the Public Health Service Act (42 U.S.C. 247d5).

2. **Purpose and Use of Information Collection**

The purpose of collecting this data is to assess knowledge, attitudes, and practices related to antibiotic prescribing among clinicians after implementation of a year-long Urgent Care stewardship initiative. We will assess if the interventions within the stewardship initiative were acceptable, appropriate, and feasible and will continue to benefit patients beyond the implementation period. We will collect information using two methods. One, we will conduct semi-structured, in-person interviews with a sample of 40 clinicians. Virtual interviews will be performed instead in the event that it is inadvisable to perform in-person interviews due to health and safety concerns related to the COVID-19 pandemic situation. This sample will include 9 clinicians from our original qualitative study to determine changes in perceptions over time from this baseline. In addition, we are proposing to sample an additional 31 clinicians to ensure that we do not introduce unnecessary bias and limit generalizability of the deep contextual information that would put our results at risk with a smaller sample size. Second, we will disseminate a validated survey to all UC clinicians employed by Intermountain. We expect about 250 clinicians to respond to our survey. The information gained from these two methods of information collection will be used to refine, enhance and improve our stewardship program while allowing us to more deeply understand the unique environment and barriers found in UC clinics.

See Attachment 3 for the information about the data collection instruments.

3. Use of Improved Information Technology and Burden Reduction

Audio recording will reduce burden on interviewers and participants to collect and transcribe data in real-time. A transcription service will be used to generate a written transcript of interviews for analysis. Information technology would reduce the burden on the study team, allowing for greater efficiency in the time spent collecting information from the public. Atlas.ti is a platform that will be used to analyze the transcripts from interviews for themes, which will serve as a basis for designing interventions. We will disseminate the survey electronically and record the participants responses. Semi-structured interviews and surveys are designed to only solicit information that will be used to explore clinician knowledge, attitudes, and practices of antibiotic prescribing and explain outcomes after implementation of the stewardship initiative. No extraneous data will be collected for objectives other than what has been reported.

4. Efforts to Identify Duplication and Use of Similar Information

A literature review revealed no information regarding the design and effectiveness of antibiotic stewardship initiatives in UC clinics. Additionally, little is known about strategies that are needed to ensure sustainability of stewardship interventions in any outpatient setting. Even with the rapid increase in the number of Urgent Care clinics nationally, contextual data pertaining to Urgent Care settings is woefully unavailable and few other health systems have a large, mature UC network such as Intermountain that would be suitable for sampling from. Data obtained from other outpatient settings would not fit our proposed purpose, due to the unique characteristics (such as clinician variability) and interventions that have been implemented in Urgent Care. The CDC's need for Urgent Care specific data, at this level of detail, can't be met through any prior information collected for these or any other purposes. CDC is not aware of the availability of any similar information that serves these purposes or needs.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Previously interviewed clinicians will be re-interviewed only one time. Newly interviewed clinicians will be interviewed once. We will only ask for one validating survey to be completed per clinician. Our aim is to ensure no duplicative or unnecessary information is requested so as to minimize burden on the public.

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 the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on February 10, 2020, vol. 85, No. 27, pp. 7556 (Attachment 2). CDC did not receive public comments related to this notice.

B. Intermountain Healthcare is performing this work as a subcontractor through the SHEPheRD funding mechanism agreement between CDC and the University of Utah. The work is expected to take place from 2020 to 2022.

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9. Explanation of Any Payment or Gift to Respondents

No incentive will be provided to respondents for participation.

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

CDC's Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. A Privacy Impact Assessment is not required for this information collection because it does not collect individually identifiable information (IIF) or Personally Identifiable Information (PII).. All data will be stored in secured electronic files at CDC's and/or a contractor's office and will be accessible only to staff directly involved in the project. All members of the project are bound by institutional and federal data privacy rules, which are reviewed and affirmed on a regular basis. Data files will be retained for a period of no more than three years and then destroyed. After three years, the documents and multimedia recordings will be deleted.

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

Institutional Review Board (IRB)

NCEZID's Human Subjects Advisor has determined that information collection is research involving human subjects. IRB approval is required.

Prior information collection was reviewed and approved by the performing institution's IRB. See Attachment 4 for a copy of the cover letter.

Justification for Sensitive Questions

There are no planned sensitive questions such as those related to religious beliefs, political affiliation, or self-incrimination

12. Estimates of Annualized Burden Hours and Costs

Two forms of information collection will take place: a semi-structured interview following the guide submitted with this request; and the survey submitted with this request. Each collection will take place once. The interviews will take place in-person or virtually and the surveys will be distributed and completed through REDCap, a research electronic data capture system. Burden is estimated from our pilot work of interviews with 9 respondents at baseline, and burden did not vary widely among this cohort.

A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Urgent Care Clinician	Interview Guide	40	1	1	40
Urgent Care Clinician	Survey	250	1	40/60	167
Total					207

B. Estimated Annualized Burden Costs

Hourly wage rate determined from averaging the following hourly mean wages from Bureau of Labor Statistics (May 2018):

- 29-1062 Family and General Practitioners – Outpatient Care Centers: $105.51/hr
- 29-1071 Physician Assistants – Outpatient Care Centers: $56.15/hr
- 29-1171 Nurse Practitioners – Outpatient Care Centers: $56.04/hr

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Urgent Care Clinician	Interview Guide	40	72.57	$2902.80
Urgent Care Clinician	Survey	167	72.57	$12119.19
Total				$15021.99

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

Cost estimate of $35,420 provided by lead qualitative analyst based on figures from prior work.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
Support staff (Lead Analyst @ 260 hours)	$15,600
Support staff (Research coordinator or qualitative analyst @ 240 hours)	$5520
Support staff (research coordinator or data analyst @ 160 hours)	$7200
Transcription Service (contractor @ 20 hours)	$2100
Publication Fees in Open Access Journal (x2)	$5000

15. Explanation for Program Changes or Adjustments

This is a new request.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Information Collection	July 2020 – July 2021
Report Completion	July 2021 – October 2021
Publication	November 2021

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

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

1. Stenehjem, E., Wallin, A., Fleming-Dutra, K.E., Buckel, W.R., Stanfield, V., Brunisholz, K.D., Sorensen, J., Samore, M.H., Srivastava, R., Hicks, L.A. & Hersh, A.L. (2020). Antibiotic Prescribing Variability in a Large Urgent Care Network: A New Target for Outpatient Stewardship. *Clinical Infectious Diseases, 70*(8), 1781-1787. https://doi.org/10.1093/cid/ciz910
2. Brunisholz, K.D., Stenehjem, E., Hersh, A.L., Wallin, A., Carmichael, H., Allen, T.L., Wolfe, D., Knighton, A.J., Belnap, T. & Srivastava, R. (2020). Antibiotic Prescribing in Urgent Care: Implementing Evidence-Based Medicine in a Rapidly Emerging Health Care Delivery Setting. *Q Manage Health Care, 29*(1), 46-47. https://doi.org/10.1097/QMH.0000000000000242
3. Brunisholz, K.D., Hersh, A.L., Stenehjem, E., Richards, A., Wallin, A., Carmichael, H., Stanfield, V., Willis, P., Samore, M., & Srivastava, R. (2020). Antibiotic Prescribing in Urgent Care Settings: The Relationship Between Implementation Barriers and Antibiotic Use for Respiratory Conditions. Manuscript in preparation.

Attachments

1. Authorizing Legislation
2. 60-Day FRN
3. Information Collection instrument
4. IRB Approved Consent
5. Data Collection Recruitment E-mail Templates