

National Surveillance for *Candida auris*

Request for OMB approval of a New Information Collection

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Supporting Statement A

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- **Goal of the study:** The goal of the National Surveillance for *C. auris* Cases is to monitor burden to guide public health action and ultimately prevent morbidity and mortality from *C. auris*.
- **Intended use of the resulting data:** In coordination with the states/jurisdictions that submit data, we plan on sharing, presenting, and publishing findings to the general public on the burden of *C. auris* in the United States.
- **Methods to be used to collect:** Voluntary case-based reporting
- **The subpopulation to be studied:** Patients with laboratory confirmed *Candida auris*
- **How data will be analyzed:** Descriptive analysis

1. Circumstances Making the Collection of Information Necessary

This is a new request, and the length of time requested is for 3 years.

Candida auris (*C. auris*) is an emerging healthcare-associated fungal pathogen associated with high mortality and antifungal resistance. The incidence of *C. auris* cases has continued to increase globally and in the United States. Most cases are the result of healthcare transmission and have mortality estimates between 30-60%.

C. auris can asymptomatically colonize the skin and other body sites, which contributes to potential spread and increases patients' risk of clinical infections. *C. auris*' persistence on the skin has been linked to an increased risk in the development of *C. auris*-related bloodstream infections in adults and pediatric cases. These clinical infections can be severe and invasive and are associated with high mortality.

Cases of *C. auris* are nationally notifiable, as of 2018 for clinical cases and 2023 for screening cases.

C. auris is a nationally notifiable condition and reportable in many jurisdictions. It is reported through the National Notifiable Diseases Surveillance System (NNDSS) and is approved under OMB Control Number 0920-0728. Cases identified through positive clinical specimens or colonization screening (with testing performed by public health, clinical, or commercial labs) based on the CSTE

case definition are reported by laboratories or healthcare facilities to the local or state health department. Our program seeks to supplement the *C. auris* case data collected through NNDSS by capturing pertinent information on these cases with the goal to monitor burden to guide public health action and ultimately prevent morbidity and mortality from *C. auris*.

Data from National Surveillance of *C. auris* Cases can have several high-level applications, such as identifying longitudinal and geographic trends in burden and characterizing high-risk settings for case identification.

Authorizing legislation is Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

2. Purpose and Use of Information Collection

The goal of the project is to monitor burden and to guide public health action and ultimately prevent morbidity and mortality from *C. auris*.

In coordination with the states/jurisdictions that submit data, we plan on sharing, presenting, and publishing findings to the general public on the burden of *C. auris* in the United States.

C. auris is a nationally notifiable condition and reportable in many jurisdictions. Cases identified through positive clinical specimens or colonization screening (with testing performed by public health, clinical, or commercial labs) based on the CSTE case definition are reported by laboratories or healthcare facilities to the local or state health department. Information collected for each case from reporting laboratories or healthcare facilities through case investigations by local/state health departments will be submitted to CDC using REDCap.

The information collected will supplement the data collected through NNDSS and will include basic information about patient demographics (e.g., age, sex, location of residence, case type), specimen information (e.g., specimen type, date of collection), location and healthcare facility of specimen collection, and mortality (Attachment 4).

The subpopulation to be studied is people with *C. auris* testing performed in health care facilities in the United States.

The data will be analyzed in coordination with the states/jurisdictions that submit data. Examples of analyses include descriptive analyses of case counts, stratified by case type, geographic area, and specimen collection year. More advanced modeling and linking with other data sources may be done in the future to assess associations of facility characteristics with facility burden and trends over time.

3. Use of Improved Information Technology and Burden Reduction

The collection involves the use of technology, specifically data management databases, such as REDCap and DCIPHER, to record and report cases. 100% of responses are to use the technology to collect responses. Only the minimum amount of information necessary for data collection is requested.

4. Efforts to Identify Duplication and Use of Similar Information

Basic information about patient demographics (e.g., age, sex, location of residence, case type, specimen information (e.g., specimen type, date of collection), location and healthcare facility of specimen collection, and mortality data will be collected for each case identified using information obtained from reporting laboratory or through case investigations routinely conducted by local/state health departments for multi-drug resistant organisms, including *C. auris*.

The data that we plan to collect with this instrument is different than other instruments that collect data on *C. auris*. Although NNDSS collects information on *C. auris*, it does not collect certain specific, pertinent information that is relevant to *C. auris*. For example, NNDSS does not collect case type, which is used to differentiate between screening and clinical cases. NNDSS also does not collect ARLN specimen ID, which is important for linking our case-based data to our lab-based data. Additionally, NNDSS does not collect more nuanced details on specimen source site and collection date. These are important for our understanding of *C. auris* epidemiology. Finally, NNDSS does not collect information

on collection site (i.e., collection state, type, ID). These data elements are not added to NNDSS because of the framework of the NNDSS system.

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

Since *C. auris* is a healthcare acquired infection and subsequently, transmitted in healthcare facilities, it is important to gather this type of information to get a better understanding on both the epidemiology and transmission behaviors among and between these high-risk environments. Having this level of information helps in outbreak response and in developing guidance for specific facility types.

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 October 1, 2024, vol. 89, pp. 190 (Attachment 2). CDC received one non-substantive public comment related to this notice (Attachment 3).

B. No consultations outside of CDC occurred.

9. Explanation of Any Payment or Gift to Respondents

No incentives provided to respondents.

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 included as part of this submission (Attachment 5).

Data will be kept private to the extent allowed by law.

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 not research involving human subjects. IRB approval is not required (Attachment 6).

Justification for Sensitive Questions

No planned sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Currently, there are 52 state and local health departments who we have been in contact about *C. auris* reporting case-based surveillance. The 340 is the average number of cases that each jurisdiction will report. Based on an average of approximately 5 minutes to fill out the form that is only 30 questions (some of which are conditional and so would not populate), the total burden hours calculated is 1,473 hours a year.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
State and local health departments	MDB Candida auris	52	340	5/60	1,473
Total					1,473

B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State and local health departments	MDB Candida auris	1,473	\$39.13	\$57,638.49
Total				\$57,638.49

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

The estimated total cost to the Federal Government for this project is \$20,800 over a one-year period of data collection.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
Managing data and communication with states	\$20,800 (10 hours a week of work across 52 weeks at an hourly wage rate of \$40).

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

As this is a surveillance project, the data collection timeline is indefinite.

Project Time Schedule	
Activity	Time Schedule

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.

Attachments

1. Authorizing Legislation
2. 60-Day FRN
3. Public Comment and Response
4. Information Collection instrument
5. Privacy Impact Assessment
6. Human Subjects Determination Memo