

One Health Surveillance for Zoonotic SARS-CoV-2 Events

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Statement A

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- Goal of data collection
 - To collect epidemiological data on zoonotic SARS-CoV-2 events to provide context for understanding the prevalence of linked human and animal infections and roles of animals in zoonotic SARS-CoV-2 transmission
 - To guide state, tribal, local and territorial health officials conducting a standardized One Health based epidemiological investigation when an animal with suspected or confirmed SARS-CoV-2 infection is identified
 - To describe zoonotic transmission dynamics and natural history of SARS-CoV-2
 - To inform guidance and recommendations, as well as surveillance directives for future emerging infectious diseases.
- Methods to be used to collect
 - Two standardized data collection tools were developed in consultation with federal partners (FDA, USDA/APHIS, DOD, NIH, USGS) and state partners (state public health veterinarians, state animal health officials, and wildlife health officials). These data collection tools were administered under the PRA OMB Waiver for COVID-19. Therefore, groups have routinely collected and submitted these data, and are supportive of ongoing data collection for zoonotic SARS-CoV-2 events. These data are being collected as the potential zoonotic transmission events and presumptive/confirmed cases are identified. Data are submitted to HHSProtect, which is used as CDC's secure online surveillance and data repository for COVID-19 and other pathogens.
- The subpopulation to be studied
 - N/A – No human population is to be studied
- How data will be analyzed
 - Data will be aggregated and analyzed weekly using R statistical programming language to generate tables and data visualizations. Information for analysis and interpretation will include the number of responders, states represented, and epidemiological including animal exposure history, clinical signs, and risk factors for zoonotic potential of SARS-CoV-2 infection in humans and animals. All data will be aggregated for presentation to public health partners and publications – there will be no personally identifiable information shared outside of secure HHSProtect servers.

PART A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Zoonotic SARS-CoV-2 Event Form:

This is a new Information Collection Review (ICR). CDC requests a 3-year approval for data collection.

Although it is now well established that SARS-CoV-2 is a zoonotic virus (i.e., can be spread between people and animals), little information exists on the prevalence or likelihood of zoonotic transmission events. Currently, reporting of zoonotic SARS-CoV-2 transmission events is not systematically reported. Without this crucial information, however, interpreting data on SARS-CoV-2 infection in animals, especially the overall contribution of zoonotic transmission to the spread of COVID-19, is incomplete. The information gathered using this surveillance mechanism will provide insight into the role of animals in SARS-CoV-2 transmission and will also provide context for understanding prevalence of linked human and animal infections throughout the nation.

Positive SARS-CoV-2 animal samples must be confirmed by National Veterinary Services Lab (NVSL); however, without the proposed surveillance mechanism, data on linked human and animal transmission events which yield negative results would not be tracked at the national level. CDC and USDA guidance recommends state-level health authorities, namely state public health veterinarians and state animal health officials, are involved in approving and coordinating animal SARS-CoV-2 testing. These officials are therefore the primary target audience for this surveillance form, in addition to Tribal, local and territorial health authorities. The Zoonotic SARS-CoV-2 Event form includes questions intended to improve our understanding of the number of cases state officials are asked to consult upon regarding SARS-CoV-2 testing for potential zoonotic transmission events, the proportion of those events that are tested for SARS-CoV-2, and corresponding relevant epidemiological data (epidemiological links to other cases of SARS-CoV-2 in people or animals, clinical signs, etc.), results, etc. This form will fill a needed gap over the next three years.

In addition to the primary reason for the Zoonotic SARS-CoV-2 Event form, it will also be used to replace paper-based reporting for CDC-funded research. Currently, CDC's One Health Office has funded surveillance and research at sites throughout the nation. This surveillance form will be used to report all linked human and animal testing for SARS-CoV-2 to CDC that is occurring through funded surveillance activities, including the status and circumstances for testing. This will relieve the requirement for less secure reporting such as paper-based reporting forms sent through email.

More broadly, we expect this form may be generalized in the future to encapsulate surveillance for other zoonotic respiratory viruses. This surveillance form therefore offers the opportunity to test and iterate upon surveillance mechanisms prior to the advancement of a broader surveillance system.

One Health Case Investigation Form for Animals with SARS-CoV-2:

Currently, most animal samples that test positive for SARS-CoV-2 are confirmed by the United States Department of Agriculture (USDA) National Veterinary Services Lab (NVSL) and are reported to the World Organization for Animal Health (OIE). However, the information collected is largely restricted to information on the animal case, including animal species, number of affected animals, and clinical signs. Richer epidemiological data, including the routes that animals become exposed to SARS-CoV-2 and potential transmission events back to people, are needed to better understand the zoonotic potential of SARS-CoV-2, whether transmission is becoming sustained among animal populations, and the public health risks that infected animals may pose. Through this data collection tool, state and local public health and animal health officials will be able to use a standardized approach to collect epidemiological data while conducting One Health epidemiologic investigations over the tool's expected reporting lifespan of three years.

CDC and USDA guidance recommends state-level health authorities, namely state public health veterinarians and state animal health officials conduct follow-up investigation if and when an animal is identified as positive for SARS-CoV-2. These officials, in addition to other state, Tribal, local, and territorial (STLT) collaborators conducting research or surveillance within their jurisdiction are therefore an appropriate target audience for this surveillance form. This form involves voluntary reporting from STLT health officials conducting epidemiological investigations to enter case information and return it to CDC. This tool was designed by CDC staff at the request of STLT partners.

These data will be used to describe the transmission dynamics and natural history of SARS-CoV-2 infection. Specifically, this tool will assist in collecting and compiling data to better understand the

zoonotic potential of SARS-CoV-2 from humans or other sources, and the role animals infected with SARS-CoV-2 may play in onward transmission to humans or other animals.

2. Purpose and Use of Information Collection

Zoonotic SARS-CoV-2 Event Form:

The data collected from this tool will assist in the enumeration of consultations by state and local authorities regarding potential zoonotic transmission events, the proportion that are tested for SARS-CoV-2 and furthermore, the prevalence of SARS-CoV-2 among animal populations. Data collected will be used to investigate what role animals play in the zoonotic transmission of SARS-CoV-2 with humans and other animals.

One Health Case Investigation Form for Animals with SARS-CoV-2:

The data collected from this tool will provide rich epidemiological data to understand the zoonotic potential of SARS-CoV-2 to spread among human and animal populations. The aggregation of data regarding animal demographics, animal health, laboratory diagnostics, animal exposure and risk of transmission on national level, provide a more detailed understanding of the natural history and transmission dynamics of SARS-CoV-2 that cannot be achieved at a state or local level. The insights provided by this tool will refine guidance and recommendations, identify high-risk exposures and transmission events, and advance surveillance directives for future emerging zoonotic diseases.

3. Use of Improved Technology and Burden Reduction

Both standardized forms were developed in consultation with federal partners (FDA, USDA/APHIS, DOD, NIH, USGS) and state partners (state public health veterinarians, state animal health officials, and wildlife health officials). Data entry is conducted as the potential zoonotic transmission events and presumptive/confirmed cases are identified. Data are reported and stored in HHSProtect, CDC's secure online surveillance and data repository for COVID-19 and other pathogens.

4. Efforts to Identify Duplication and Use of Similar Information

CDC's One Health Office led development of these forms in consultation with federal partners (FDA, USDA/APHIS, DOD, NIH, USGS) and state partners (state public health veterinarians, state animal health officials, and wildlife officials); these groups will continue to be engaged throughout the duration of this work to ensure that data collection efforts in this space are not duplicated. Additionally, aggregate data and analyses/results will be shared with federal and state partners through calls and webinars, and potentially through scientific publication and guidance, to ensure that data and results are shared in a timely and appropriate manner.

Efforts have been made to identify duplication and use of similar information. USDA has a [website](#) that provides basic information on the number of animals that have tested positive for SARS-CoV-2 in the United States. This website includes a species breakdown of SARS-CoV-2 positive animals and the diagnostic methods resulting in confirmation of a positive result. However, this website does not include information on animals that have tested negative for SARS-CoV-2 or >90% of the epidemiological data collected through the One Health Case Investigation Form for Animals with SARS-CoV-2. Additionally, USDA APHIS is aggregating diagnostic testing data submitted by the National Animal Health Laboratory Network (NAHLN), which represents an unknown percentage of SARS-CoV-2 testing for animals. Data from private labs, university research laboratories, veterinary schools, state labs not affiliated with NAHLN, and CDC-funded or independent

active surveillance sites are all conducting SARS-CoV-2 testing in animals that are not included in [USDA APHIS's](#) data aggregation efforts. Therefore, the data collected from the questionnaire presented here would complement data being collected by USDA APHIS.

5. Impact on Small Businesses or Small Entities

Data for the surveillance pipelines are submitted by state and local public health officials. The activities required to collect information for the forms aligns with their appointed duties in order to prevent the duplication or increase of work required for data collection. CDC One Health Office provides respondents with several resources to assist in the collection and entry of data in HHS Protect to lessen the burden and allow the continuation of data reporting.

6. Consequences of Collecting Information Less Frequently

Currently, epidemiological information regarding animals infected with SARS-CoV-2 is limited and is siloed among individual entities. The aggregation of this data is vital for the understanding of the zoonotic potential of SARS-CoV-2 from humans or other sources as well as the role of infected animals in onward transmission to humans and other animals. The absence of this data collection will result in knowledge gaps that do not currently estimate the public health risk of SAR-CoV-2 in both animal and human populations.

7. Special Circumstances Relating to 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. This is a new ICR request. Two 60-day Federal Register Notices were published in the Federal Register on Friday, August 13th, 2021, Vol. 86, No. 154, pp. 44722-44723, and pp. 44726-44727. One public comment was received for CDC-2021-0080, and no public comments were received for CDC-2021-0081. The comment was non-substantive (Att. D). CDC replied to the commentor via email.
- B. Consultation

No outside parties were consulted on the collection of animal testing and epidemiological data for the One Health Office.

9. Explanation of Any Payment or Gift to Respondents

CDC's One Health Office will not provide remuneration or incentives to participants.

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

No Personal Information (PII) is being collected in these surveillance forms. The National Center for Emerging and Zoonotic Infectious diseases has reviewed this proposed collection and determined that the Privacy Act does not apply. No PII is being collected as part of this project. The data collected will be stored on a secure electronic CDC server with limited access.

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

No information will be collected that are of a personal or sensitive nature or require IRB approval.

12. Estimates of Annualized Burden Hours and Costs

Zoonotic SARS-CoV-2 Event form

The data collected will be used to improve our understanding the prevalence of potential zoonotic events and the prevalence of SARS-CoV-2 in animal populations. This information has not previously been collected and data collection procedures are in align with data management systems currently existing in state and local health departments to maximize standardization across sites and minimize the burden on responders. The estimated time burden is 80 responders x 400 responses each (extrapolation from previously collected data) x 0.25hrs per response = 8,000 hours.

One Health Case Investigation Form for Animals with SARS-CoV-2

Over 10 respondents will be involved. An estimated 50 respondents will complete the one-hour case investigation form 20 times. This brings the total estimated burden to 1,000 hours per year.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State, tribal, local, and territorial health officials	Zoonotic SARS-CoV-2 Event Form	80	400	0.25	8,000
State, tribal, local, and territorial health officials	One Health Consultation Form	>50	20	1	1,000
Total		130			9000

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

There will be no direct costs to the respondents other than their time to complete the Zoonotic SARS-CoV-2 Event Form and/or the One Health Case Investigation Form for Animals with SARS-CoV-2.

14. Annualized Cost to the Government

There is no annualized cost to the government for the data reporting in this project.

15. Explanation of Program Changes or Adjustments

This is a new ICR request. This work previously qualified for and was granted a statutory waiver for the 21st Century Cures Act- Sec. 3087 (Public Health Emergency).

16. Plans for Tabulation and Publication and Project Time Schedule

Data from the pipelines are aggregated and analyzed weekly for presentation on calls with local, state and federal partners. Plans for publications are being developed in an effort to share valuable insights with the public health community.

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

No exemption is being requested. The display of the expiration date is appropriate.

18. Exceptions to Certification for Paper Reduction Act Submissions

There are no expectations to the certifications.

Attachments

- A. Authorizing legislation
- B. Published 60-day FRN (CDC-2021-0080)
- C. Published 60-day FRN (CDC-2021-0081)
- D. Public Comment
- E. Collection Instrument: One Health Case Investigation Form for Animals with SARS-COV-2
- F. Collection Instrument: Zoonotic SARS-CoV-2 Event Form
- G. Case Investigation Data Dictionary
- H. Zoonotic SARS-CoV-2 Event Form Data Dictionary
- I. 60-Day FRN
- J. NRDs