# Attachment 10. Justification for the Addition of Disease-Specific Data Elements

208 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for 16 conditions: Anthrax, Brucellosis, Campylobacteriosis, Cholera, Cryptosporidiosis, Hansen's Disease, Leptospirosis, Melioidosis, Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19), 2019 Novel Coronavirus Disease (COVID-19), *S*. Paratyphi Infection, *S*. Typhi Infection, Salmonellosis, Shiga toxin-producing Escherichia Coli (STEC), Shigellosis, and Vibriosis. Names, descriptions, value set codes (the answer list for coded data elements from CDC vocabulary server (PHIN VADS) which can be accessed at http://phinvads.cdc.gov), and justification for the addition of these new data elements are below:

| *Anthrax: 25 Data Elements* | |
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| The impetus/urgency for CDC to add data elements for this condition | • To allow Bacterial Special Pathogens Branch (BSPB) to conduct enhanced domestic surveillance for anthrax due to the potential for *Bacillus anthracis* to be used as a bioweapon, the likelihood for severe illness; and the potential need to distribute antitoxin, other medical supplies, and materiel support from federal assets. <br> • To aid in identifying other individuals who may be at risk of infection and to identify an area of potential exposure, information about route of infection, occupation, sources of exposure, and location of potential exposures is needed. The source and location exposure data elements also will inform if the source is naturally acquired or is a potentially intentional spore release. <br> • Treatment type and hospital testing will guide decisions on whether additional medical countermeasures are needed to be deployed to hospitals and understand severity of disease. <br> • To help with determining specific risk factors for severe illness, which will aid with case triage algorithms to ensure people at greater risk can be seen more rapidly for treatment. <br> • All source and location exposure data elements will only be asked for cases that are naturally acquired (domestically or internationally), and for the first cases during an intentional spore release to identify the exposure area. Once the exposure area is defined, these additional questions will not be asked unless a case does not have any known associations with the known exposure area. |

| Data Element Name | Data Element Description | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| Route of Infection | Suspected primary route of infection at time of evaluation (select all that apply): | TBD | 1 |

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| | | | |
|---|---|---|---|
| International Destination(s) of Recent Travel | List all international destinations (country) traveled during the 14 days prior to illness onset | PHVS_Country_ISO_3166-1 | 2 |
| Travel State | List all domestic destinations (state) traveled to during the 14 days prior to illness onset | PHVS_State_FIPS_5-2 | 2 |
| Public Transportation Route | Specify public transportation route (e.g. name/number) | N/A | 3 |
| Date Using Public Transportation | Specify date(s) using public transportation | N/A | 3 |
| Exposure Source | Indicate the type of exposure the patient had in the 14 days prior to illness onset. | TBD | 1 |
| Type of Animal Exposure | Types of exposure to animal. | TBD | 3 |
| Animal Type | If exposure type is Animal contact, specify animal the subject had contact with in the 14 days prior to illness onset. If the subject had contact with multiple animals complete separate repeating groups for each one. | TBD | 2 |
| Lab Name | If worked in a clinical, microbiological, or animal research laboratory, specify lab. | N/A | 2 |
| Contact Type | If linked to confirmed case or contact with similar illness or sign and symptoms, indicate type of contact. | TBD | 2 |
| Location of Contact | If linked to confirmed case or contact with similar illness or sign and symptoms, indicate geographic location where contact occurred (e.g. city, country, state). | N/A | 2 |

| Illicit Drug Specify | If subject had contact with illicit drugs, specify the name or type of the drug. | N/A | 2 |
|---|---|---|---|
| Location Name | Location name of place or event. | N/A | 2 |
| Location Address | Location address of place or event (e.g. country, city, state, county.) | N/A | 3 |
| Attendance Date | List all date(s) of event or place attendance. | N/A | 2 |
| Locations Routinely Visited | Specify the name of a place that was routinely visited in the 14 days prior to illness onset, such as a place of worship, volunteer, gym, etc. | N/A | 3 |
| Time of Day | List the time period during the day when the place was visited | TBD | 3 |
| Date of last dose | Date last received anthrax vaccine | N/A | 2 |
| Post-exposure or Treatment | Indicates if medication received is for post-exposure or anthrax treatment. | TBD | 1 |
| Alcohol use frequency | In the past 30 days, how often does the patient take alcoholic drinks? | TBD | 3 |
| Alcohol use quantity | On the days when the case patient drank, about how many drinks did the case patient drink on average? | N/A | 3 |
| Hospital Procedure | If subject was hospitalized, were any of the following procedures or treatments done? | TBD | 3 |
| Diagnostic Test Findings | Results from procedures or treatments done in the hospital. | TBD | 3 |

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|---|---|---|---|
| Treatment Type | Listing of treatment or medical intervention the subject received for this illness. | TBD | 3 |
| Treatment Type Indicator | Indicate if treatment was administered. | PHVS_YesNoUnknown_CDC | 3 |

| **Brucellosis: 9 Data Elements** | |
|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • To allow Bacterial Special Pathogens Branch (BSPB) to conduct enhanced domestic surveillance for brucellosis.<br>• Monitoring *Brucella* spp.-related exposures and infections is important, due to the pathogen's select agent status and the potential for the pathogen to cause severe illness.<br>• To allow for appropriate follow-up and monitoring of exposures to *Brucella* spp. in laboratory and occupational settings which can lead to infection.<br>• To help BSPB learn more about risk factors for brucellosis, track cases' treatment to reduce the risk of relapse, identify situations where others may have been exposed (and potentially identify case clusters), and track exposure events to mitigate the risk of developing brucellosis.<br>• To help BSPB update recommendations for case and exposure monitoring, inform outreach activities, and target health communications to populations that are at higher risk of being exposed to *Brucella*. |

| Data Element Name | Data Element Description | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| Physician Name | Name of the physician or clinician who diagnosed and/or treated the subject | N/A | 3 |
| Physician Phone | Phone number of the patient's clinician/provider of care | N/A | 3 |
| Treatment Drug Indicator | Were antimicrobials prescribed or administered to the subject for this illness or following an exposure? | PHVS_YesNoUnknown_CDC | 2 |
| Antibiotic dose units | Dose units of the antimicrobial prescribed or administered | PHVS_UnitsOfMeasure_CDC | 2 |
| Medication Stop Date | What was the date that the case patient stopped taking antimicrobials | N/A | 3 |

| International Destination(s) of Recent Travel | List all international destination (country) traveled to during six months before symptom onset or diagnosis | PHVS_Country_ISO_3166-1 | 1 |
|---|---|---|---|
| Travel State | List all domestic destination (state) traveled to during six months before symptom onset or diagnosis. | PHVS_State_FIPS_5-2 | 2 |
| Travel County | List all intrastate destination (county) traveled to during six months before symptom onset or diagnosis. | PHVS_County_FIPS_6-4 | 3 |
| Specimen Collected Prior to Therapy | Was the specimen for culture collected prior to antimicrobial therapy? | PHVS_YesNoUnknown_CDC | 2 |

| *Campylobacteriosis: 1 Data Element* | | | |
|---|---|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodbore and Diarrheal Diseases Message Mapping Guide (FDD MMG). Routine linking between lab and epi data is fundamental to outbreak response and epidemiologic analysis. | | |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority[1]** |
| PulseNet ID | State lab ID submitted to PulseNet | N/A | 1 |

| *Cholera: 2 Data Elements* | | | |
|---|---|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG). Routine linking between lab and epi data is fundamental to outbreak response and epidemiologic analysis. | | |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority[1]** |

| PulseNet ID | State lab ID submitted to PulseNet | N/A | 1 |
|---|---|---|---|
| WGS ID Number | Whole Genome Sequencing (WGS) ID Number | N/A | 1 |

| *Cryptosporidiosis: 2 Data Elements* | | | |
|---|---|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG). Routine linking between lab and epi data is fundamental to outbreak response and epidemiologic analysis. | | |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority[1]** |
| CryptoNet ID | Unique CryptoNet ID (formed by concatenating [Case Year]-[State Lab ID]-[Specimen Type]-[Reporting State]-[Reporting Country]) where Specimen Type is: ES for Environmental, HS for Human, or AS for Animal. | N/A | 1 |
| WGS ID Number | Whole Genome Sequencing (WGS) ID Number | N/A | 1 |
| *Hansen's Disease: 5 Data Elements* | | | |
| The impetus/urgency for CDC to add data elements for this condition | • To improve CDC's understanding of Hansen's disease epidemiology<br>• To identify challenges to diagnoses<br>• To possibly prevent further transmission and lifelong disability given the increase in disease incidence and lack of information related to type of leprosy, family or household contacts, treatment received, or even history or previous diagnosis that is currently received via current notifications to CDC | | |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority[1]** |
| Location of Initial Diagnosis | Indicate the location of the initial diagnosis of Hansen's Disease | PHVS_LocationofInitialDiagnosis_Hansen | 3 |

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|---|---|---|---|
| Medication Stop Date | What was the date that the case patient stopped taking antimicrobials | N/A | 2 |
| Post-exposure or Treatment | Indicates if medication received is for post-exposure or Hansen's treatment. | TBD | 2 |
| Post-Exposure Prophylaxis Medication | If answer is yes to the previous question regarding household contacts of the patient receiving prophylaxis, please specify PEP | N/A | 2 |
| History of Treatment for Latent or Active TB | Does the case patient have a history of being on treatment for latent or active TB? | PHVS_YesNoUnknown_CDC | 3 |

| *Leptospirosis: 5 Data Elements* | |
|---|---|
| The impetus/urgency for CDC to add data elements for this condition | <ul><li>To better understand the clinical presentation and severity of leptospirosis cases in the U.S., which will in turn help: evaluate and revise, if necessary, the U.S. case definition for leptospirosis, inform improved identification of leptospirosis cases by clinicians, and help quantify the burden and outcome of leptospirosis cases in the U.S.</li><li>To identify adverse effects of leptospirosis in pregnant patients and their fetus/neonate</li><li>To identify potential hotspots for leptospirosis exposure/infection by linking exposure types with exposure location</li><li>To detect emerging risk factors/risk groups for leptospirosis in the U.S.</li><li>To clarify the questions in the case report form and improve the quality and usefulness of the data collected to better inform public health practice</li><li>To inform CDC recommendations on leptospirosis case identification and management, control and prevention, and inform local outreach and prevention efforts</li></ul> |

| Data Element Name | Data Element Description | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| Patient Address City | Patient Address City | N/A | 2 |
| Immunocompromised Associated Condition or Treatment | If the patient has an immunosuppressive condition, specify the condition. | N/A | 3 |

| Days Missed Due to Illness | Number of days of work or school the patient missed due to this illness? | N/A | 3 |
|---|---|---|---|
| Container Lid | If the subject had contact with well water, cistern water, or rainwater collected in a drum or other container, did the well, cistern or other container have a lid? | PHVS_YesNoUnknown_CDC | 3 |
| Rodent Location | Where did the subject see rodents or evidence of rodents? | TBD | 3 |

| *Melioidosis: 103 Data Elements* | |
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| The impetus/urgency for CDC to add data elements for this condition | • Although *B. pseudomallei* is a Tier 1 overlap Select Agent, melioidosis is not nationally notifiable. Consequently, CDC receives reports from jurisdictions on a voluntary basis.<br>• The disease is most commonly associated with areas of Southeast Asia and Northern Australia but predicted to have a wider global distribution. Most cases reported in the United States are those who have traveled to endemic areas, but the CDC has recently identified cases of melioidosis from travel within the Americas and in areas outside these historically known endemic regions.<br>• CDC recently identified the first documented transmission of *B. pseudomallei* from a freshwater aquarium to a human.<br>• The proposed additional data elements are necessary to improve understanding of the risk factors for as well as the temporal and geographic occurrence of melioidosis, and aid in facilitating its prevention and control. |

| Data Element Name | Data Element Description | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| State or Local Public Health Laboratory/LRN POC- Name | Name of the laboratory person who is the lab POC for this investigation | N/A | 1 |
| State or Local Public Health Laboratory/LRN POC- Phone number | Phone number of the laboratory person who is the lab POC for this investigation | N/A | 1 |
| State or Local Public Health Lab/LRN POC Email Address | Email address of person who is reporting cases to CDC | N/A | 1 |
| State or Local Public Health Lab/LRN  POC- Affiliation | Affiliated Facility of the state LRN/lab POC | N/A | 1 |

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| Case origin/type | Is this a human or animal case? | TBD | 1 |
| Country of travel destination | Choose a country for each destination | PHVS_Country_ISO_3166-1 | 2 |
| International Region | Enter region (list multiple if applicable) | N/A | 3 |
| Dates of International Travel | Enter dates of travel (multiple if applicable) | N/A | 2 |
| Contact with soil or water in International travel destination | Was the subject contact with soil or water during this visit? | PHVS_YesNoUnknown_CDC | 2 |
| Specific location of exposure for International Travel | If yes to Question above, indicate specific location of exposure | N/A | 3 |
| Other close contacts with same soil/water exposures (International Travel) | If yes to Question above, indicate whether other close contacts also had the same soil/water exposure | PHVS_YesNoUnknown_CDC | 3 |
| Number of close contacts (International Travel) | If yes to Question above, list the total number of close contacts | N/A | 3 |
| Relationship (International Travel) | If yes to Question above, select relationship to subject (select all that apply) | TBD | 3 |
| Significant weather or environmental events during this visit (International Travel) | Were there any significant weather or environmental events during this visit? | PHVS_YesNoUnknown_CDC | 2 |
| Specific weather or environmental events (International Travel) | If yes to Question above, select all weather/environmental events | TBD | 3 |
| Contact with soil or water in melioidosis-endemic areas | Has subject ever been in contact with soil or water in melioidosis-endemic areas? | PHVS_YesNoUnknown_CDC | 2 |
| Contact with soil or water in melioidosis- | If yes, date of contact in YYYYMM format. | N/A | 2 |

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| endemic areas service Date | | | |
| Travel within U.S. but >50 miles from residence | Did the subject travel 50 miles or more outside his or her normal residence but within the U.S. 30 days prior to onset? | PHVS_YesNoUnknown_CDC | 2 |
| State | Choose a state each destination | PHVS_State_FIPS_5-2 | 2 |
| City/town | Please indicate city/town (list multiple if applicable) | N/A | 3 |
| Dates of Travel | Enter dates of travel | N/A | 2 |
| Contact with soil or water in travel destination | Was the subject contact with soil or water during this visits? | PHVS_YesNoUnknown_CDC | 2 |
| Specific location of exposure | If yes to Question above, indicate specific location of exposure | N/A | 3 |
| Other close contacts with same soil/water exposures | If yes to Question above, were there other close contacts also had the same soil/water exposure | PHVS_YesNoUnknown_CDC | 3 |
| Number of close contacts | If yes to Question above, list the total number of close contacts | N/A | 3 |
| Relationship | If yes to Question above, select relationship to subject (select all that apply) | TBD | 3 |
| Significant weather or environmental events during this visit | Were there any significant weather or environmental events during this visit? | PHVS_YesNoUnknown_CDC | 2 |
| Specific weather or environmental events | If yes to Question above, select all weather/environmental events | TBD | 3 |

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|---|---|---|---|
| Travel (in the last 10 years) | In the 10 years before symptoms onset, did the patient travel outside of the continental U.S. or to an area in the U.S. where the endemicity is possible | PHVS_YesNoUnknown_CDC | 2 |
| Country of travel destination (in the last 10 years) | Choose a country for each destination | N/A | 2 |
| Region of travel in last 10 years | Enter region (list multiple if applicable) | N/A | 2 |
| Dates of Travel (in the last 10 years) | Enter dates of travel | N/A | 2 |
| Contact with soil or water in travel destination (in the last 10 years) | Was the subject contact with soil or water during this visit? | PHVS_YesNoUnknown_CDC | 2 |
| Specific location of exposure (in the last 10 years) | If yes to Question above, indicate specific location of exposure | N/A | 3 |
| Other close contacts with same soil/water exposures (International Travel) | If yes to Question above, indicate whether other close contacts also had the same soil/water exposure | PHVS_YesNoUnknown_CDC | 3 |
| Number of close contacts (International Travel) | If yes to Question above list the total number of close contacts | N/A | 3 |
| Relationship (International Travel) | If yes to Question above, select relationship to subject (select all that apply) | TBD | 3 |
| Significant weather or environmental events during this visit (International Travel) | Were there any significant weather or environmental events during this visit? | PHVS_YesNoUnknown_CDC | 2 |
| Specific weather or environmental events (International Travel) | If yes to Question above, select all weather/environmental events | TBD | 2 |

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| Specify other or abscess for "specimen source" | If abscess or other specimen selected, please specify | N/A | 2 |
| Date of LRN confirmation, if applicable | Enter Date of Confirmation by LRN | N/A | 3 |
| AST Request | Is the jurisdiction requesting AST on the isolate | TBD | 3 |
| Dates of Hospitalization | Give reporting jurisdiction ability to enter multiple hospitalizations if needed | N/A | 2 |
| Pneumonia/pleural effusion | Did the subject have pneumonia/pleural effusion | PHVS_YesNoUnknown_CDC | 2 |
| Skin/soft tissue infections | Did the subject have skin/soft tissue infection | PHVS_YesNoUnknown_CDC | 2 |
| Genitourinary infection | Did the subject have genitourinary infection | PHVS_YesNoUnknown_CDC | 2 |
| Neurologic infection | Did the subject have neurologic infection | PHVS_YesNoUnknown_CDC | 2 |
| Pericardial effusion | Did the subject have pericardial effusion | PHVS_YesNoUnknown_CDC | 2 |
| Bone or joint infection | Did the subject have bone/joint infection | PHVS_YesNoUnknown_CDC | 2 |
| Internal abscesses | Did the patient have internal abscesses | PHVS_YesNoUnknown_CDC | 2 |
| Select or specify location of abscesses | If yes, for internal abscesses, please select all that apply | TBD | 2 |
| Additional notes describing abscesses | If yes for internal abscesses, additional notes  (number, location of abscesses) | N/A | 2 |
| Septic Shock | Did the subject have septic shock | PHVS_YesNoUnknown_CDC | 2 |
| Bacteremia | Did the subject have bacteremia | PHVS_YesNoUnknown_CDC | 2 |
| Date antimicrobial Treatment ended | Indicate the date antimicrobial treatment ended | N/A | 2 |

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| Liver disease | Does subject have liver disease | PHVS_YesNoUnknown_CDC | 2 |
| Excess alcohol abuse | Does subject have history chronic alcohol abuse? | PHVS_YesNoUnknown_CDC | 2 |
| Chronic granulomatous disease | Does the subject have chronic granulomatous disease? | PHVS_YesNoUnknown_CDC | 2 |
| Malignancy | Does the subject have malignancy? | PHVS_YesNoUnknown_CDC | 2 |
| Systemic lupus erythematous | Does the subject have systemic lupus erythematous? | PHVS_YesNoUnknown_CDC | 2 |
| Prior splenectomy | Does the subject have a history of prior splenectomy | PHVS_YesNoUnknown_CDC | 2 |
| Immunosuppressing drugs | Is the subject on any immunosuppressing medication | PHVS_YesNoUnknown_CDC | 2 |
| Other immunocompromising condition | Does the patient have any other immunocompromising conditions | PHVS_YesNoUnknown_CDC | 2 |
| Patient's Occupation | What is the patient's occupation | N/A | 2 |
| Recreational Gardener | Is the patient a recreational gardener? | PHVS_YesNoUnknown_CDC | 2 |
| Is this case part of a cluster? | Is this case part of a cluster? | PHVS_YesNoUnknown_CDC | 3 |
| Exposure to Iguanas | In the 30 days prior to symptoms onset did the patient own or have direct contact with an iguana? | PHVS_YesNoUnknown_CDC | 2 |
| Type of Iguana | Indicate type of iguana if yes to previous question | N/A | 2 |
| Type of exposure | Indicate type of exposure if yes to exposure to iguana | TBD | 2 |
| If owned, how acquired | If owned an iguana, indicate how case patient acquired | TBD | 2 |
| Location of purchase or where acquired | Location of purchase/where acquired (name of river, lake, | N/A | 2 |

| | park, or location of pet store, for example) | | |
|---|---|---|---|
| Exposure to Pet Fish | In the 30 days prior to symptoms onset did the patient own or have direct contact with pet fish? | PHVS_YesNoUnknown_CDC | 2 |
| Type of pet fish | Indicate type of pet fish if yes to previous question | N/A | 2 |
| Type of exposure | Indicate type of exposure if yes to exposure to pet fish | TBD | 2 |
| If owned, how acquired | If owned a pet fish, indicate how case patient acquired | TBD | 2 |
| Location of purchase or where acquired | Location of purchase/where acquired (name of river, lake, park, or location of pet store, for example) | N/A | 2 |
| Exposure to Aquatic Plants | In the 30 days prior to symptoms onset did the patient own or have direct contact with aquatic plants? | PHVS_YesNoUnknown_CDC | 2 |
| Type of aquatic plant | Indicate type of aquatic plant if yes to previous question | N/A | 2 |
| Type of exposure | Indicate type of exposure if yes to exposure to aquatic plants | TBD | 2 |
| If owned, how acquired | If owned aquatic plant, indicate how case patient acquired | TBD | 2 |
| Location of purchase or where acquired | Location of purchase/where acquired (name of river, lake, park, or location of pet store, for example) | N/A | 2 |
| Exposure to Other Animals | In the 30 days prior to symptoms onset did the patient own or have direct contact with other animals | PHVS_YesNoUnknown_CDC | 2 |
| Type of "Other Animal" | Indicate type of other animal if yes to previous question | N/A | 2 |

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|---|---|---|---|
| Type of exposure | Indicate type of exposure if yes to exposure to "other animal" | TBD | 2 |
| If owned, how acquired | If owned "other animal", indicate how case patient acquired | TBD | 2 |
| Location of purchase or where acquired | Location of purchase/where acquired (name of river, lake, park, or location of pet store, for example) | N/A | 2 |
| Laboratory exposures identified | Were potential laboratory exposures identified in this investigation | PHVS_YesNoUnknown_CDC | 1 |
| Name of Facility (Exposures) | Name of facility/hospital where exposures were identified | N/A | 2 |
| City/town (Exposures) | City of facility where exposures were identified | N/A | 2 |
| State (Exposures) | State where the facility where the exposures were identified | PHVS_State_FIPS_5-2 | 2 |
| Number of laboratorians exposed | Total number of laboratory personnel exposures | N/A | 1 |
| High Risk | Number of laboratory personnel with high-risk exposures | N/A | 2 |
| Low Risk | Number of laboratory personnel with low-risk exposures | N/A | 2 |
| Minimal Risk | Number of laboratory personnel with minimal exposures | N/A | 2 |
| Date of Exposure | For each laboratory personnel, date of exposures | N/A | 2 |
| Risk Factors | Does the laboratory personnel have risk factors for melioidosis | TBD | 2 |
| Laboratory Activity | Select activity that resulted in exposure | TBD | 2 |

| | | | |
|---|---|---|---|
| Risk Category | For each laboratory personnel and each activity, select risk category | TBD | 2 |
| Serologic Monitoring | Did the laboratory personnel undergo serologic monitoring | TBD | 2 |
| Received post-exposure prophylaxis | Did the laboratory personnel receive post-exposure prophylaxis | TBD | 2 |
| Reported Symptoms (lab exposures) | Did the laboratory personnel report symptoms within 21 days of exposure | TBD | 2 |
| Onset Date (lab exposure) | If the laboratory personnel reported symptoms, please provide onset date | N/A | 2 |
| Describe Symptoms | If the laboratory personnel reported symptoms, describe | N/A | 2 |

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| ***Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19): 44 Data Elements*** | |
| The impetus/urgency for CDC to add data elements for this condition | <ul><li>To allow the CDC COVID-19 response to conduct enhanced domestic surveillance Multisystem inflammatory syndrome in children (MIS-C) which was first identified in April 2020 and was reported out of the UK. This new but severe condition has temporal association with SARS-CoV-2. Due to the urgency in collecting these cases to learn more about this condition a national surveillance system was rapidly developed.</li><li>This new syndrome does not have a diagnostic test and relies on the CDC MIS-C case definition for diagnosis. Due to the reliance on the case definition the data elements listed below need to be completed on the case report form to gather the necessary details to decide if a case meets the case definition or not.</li><li>Obesity has been shown as a comorbidity for SARS-CoV-2 so we are collecting related data elements, this allows us to learn more about a potential link with obesity and increased risk of MIS-C.</li><li>To assist with determination of timeline from COVID-19 to MIS-C to better determine the course of illness. Determination of which children are at risk for MIS-C and those that have MIS-C which specific risk factors lead to severe illness. This will allow for more rapid diagnosis, and treatment of MIS-C.</li></ul> |

| | | Data elements will allow for better characterization of MIS-C, potentially leading to an update of the case definition and more streamlined diagnosis. • All health departments have set up their reporting databases to align with the requested data elements for streamlined reporting and standardization of reporting. | | |
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| Data Element Name | Data Element Description | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| MIS ID | Multisystem inflammatory syndrome identifier. | N/A | 1 |
| Health Department ID | Health Department identifier. | N/A | 1 |
| NCOV ID | COVID-19 identifier (if available) | N/A | 1 |
| Abstractor name | Name of person compiling medical records and/or interviews. | N/A | 1 |
| Date of abstraction | Date of abstraction | N/A | 1 |
| Temperature if fever | Fever >38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours | N/A | 1 |
| Inflammation laboratory markers | Laboratory markers of inflammation (including, but not limited to one or more; an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin), | TBD | 1 |
| Signs and symptoms | Evidence of clinically severe illness requiring hospitalization, with multisystem (>2) organ involvement. | TBD | 1 |
| Signs and symptoms indicator | Indicator for associated sign and symptom | PHVS_YesNoUnknown_CDC | 1 |

| No alternative plausible diagnosis | Is there no alternative plausible diagnosis? | PHVS_YesNoUnknown_CDC | 1 |
|---|---|---|---|
| SARS-COV-2 test | Positive for current or recent SARS-COV-2 infection (select all applicable tests) | TBD | 1 |
| Symptom onset within 4 weeks of exposure | COVID-19 exposure within the 4 weeks prior to the onset of symptoms | PHVS_YesNoUnknown_CDC | 1 |
| Date of symptom onset | If yes, date of first exposure within the 4 weeks prior | N/A | 1 |
| Height | Height specified in inches | N/A | 1 |
| Weight | Weight in pounds | N/A | 1 |
| Body Mass Index | Body Mass Index | N/A | 1 |
| Patient Epidemiological Risk Factors | Underlying medical conditions or risk behaviors for the case patient. | TBD | 1 |
| Patient Epidemiological Risk Factors Indicator | Provide a response for each value in the risk factors value set. | PHVS_YesNoUnknown_CDC | 1 |
| Type of complication | Complications associated with the illness being reported | TBD | 1 |
| Type of complication indicator | Provide a response for each complication. | PHVS_YesNoUnknown_CDC | 1 |
| ICU Admission Date | If admitted to the ICU, ICU admission date | N/A | 1 |
| Days in ICU | Number of days in ICU | N/A | 1 |
| Patient outcome | Patient outcome | TBD | 1 |
| Preceding COVID-like illness | Did the patient have preceding COVID-like illness? | PHVS_YesNoUnknown_CDC | 1 |
| Date of onset of preceding COVID-like illness | If yes, date of onset of preceding illness | N/A | 1 |

| | | | |
|---|---|---|---|
| Fever | Fever ≥ 38.0°C | PHVS_YesNoUnknown_CDC | 1 |
| Date of fever onset | Date of fever onset | N/A | 1 |
| Highest temperature | Highest temperature © | N/A | 1 |
| Number of days febrile | Number of days febrile | N/A | 1 |
| Clinical finding | Clinical finding | TBD | 1 |
| Clinical finding indicator | Provide a response for each clinical finding. | PHVS_YesNoUnknown_CDC | 1 |
| Treatment Type | Listing of treatment or medical intervention the subject received for this illness | TBD | 1 |
| Treatment type indicator | Provide a response for each treatment type. | PHVS_YesNoUnknown_CDC | 1 |
| Vasoactive medications | Specify vasoactive medications | TBD | 1 |
| Immune modulators | Specify immune modulators treatment | TBD | 1 |
| Antiplatelets | Specify antiplatelets treatment | TBD | 1 |
| Anticoagulation | Specify anticoagulation treatment | TBD | 1 |
| Echocardiogram | Select any echocardiogram that apply. | TBD | 1 |
| Max coronary artery Z-score | If coronary artery aneurysms, state max coronary artery Z-score. | N/A | 1 |
| Cardiac dysfunction | If cardiac ventricular dysfunction, specify type. | TBD | 1 |
| Mitral regurgitation | Specify type of mitral regurgitation. | TBD | 1 |
| Date of coronary artery aneurysm | Date of first test showing coronary artery aneurysm or dilatation. | N/A | 1 |

| | | | |
|---|---|---|---|
| Abdominal imaging type | Type of abdominal imaging (ultrasound, CT) | TBD | 1 |
| Chest imaging type | Type of chest imaging (chest x-ray, CT) | TBD | 1 |

| *2019 Novel Coronavirus Disease (COVID-19): 3 Data Elements* | |
|---|---|
| The impetus/urgency for CDC to add data elements for this condition | Introduction of SARS-CoV-2, the virus that causes 2019 novel coronavirus disease (COVID-19), into the United States has resulted in the need for national notifiable disease surveillance to assist in understanding the transmission and epidemiology of the disease in U.S. jurisdictions. Public health agencies are investigating reported respiratory illnesses and identifying infected people (cases) through laboratory testing. These data elements are necessary: <br>• To provide consistent case identification and classification, measure the potential burden of illness <br>• To characterize the epidemiology of medically attended and moderate to severe COVID-19 in the United States <br>• To detect community transmission <br>• To inform public health response to clusters of illness and efficacy of population-based non-pharmaceutical interventions on the epidemic |

| Data Element Name | Data Element Description | Value Set Code | CDC Priority (New) |
|---|---|---|---|
| Primary Language | What's case's primary language? Please indicate for both hospitalized and not hospitalized cases. | PHVS_Language_ISO_639-2_Alpha3 | 2 |
| Information Source for Data | Clinical information collected from which source(s)? Check all that apply | PHVS_DataReportingSource_COVID-19 | 3 |
| Did Underlying Condition(s) Exist | Did they have any underlying medical conditions and/or risk behaviors? | PHVS_YesNoUnknown_CDC | 1 |

| *S. Paratyphi Infection: 2 Data Elements* | |
|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG). |

| | | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| **Data Element Name** | **Data Element Description** | | |
| PulseNet ID | State lab ID submitted to PulseNet | N/A | 1 |
| WGS ID Number | Whole Genome Sequencing (WGS) ID Number | N/A | 1 |

| *S. Typhi Infection: 2 Data Elements* | |
|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG). Routine linking between lab and epi data is fundamental to outbreak response and epidemiologic analysis. |

| | | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| **Data Element Name** | **Data Element Description** | | |
| PulseNet ID | State lab ID submitted to PulseNet | N/A | 1 |
| WGS ID Number | Whole Genome Sequencing (WGS) ID Number | N/A | 1 |

| *Salmonellosis: 1 Data Element* | |
|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG). Routine linking between lab and epi data is fundamental to outbreak response and epidemiologic analysis. |

| Data Element Name | Data Element Description | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| PulseNet ID | State lab ID submitted to PulseNet | N/A | 1 |

| *Shiga toxin-producing Escherichia Coli (STEC): 1 Data Element* | | | |
|---|---|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG). Routine linking between lab and epi data is fundamental to outbreak response and epidemiologic analysis. | | |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority[1]** |
| WGS ID Number | Whole Genome Sequencing (WGS) ID Number | N/A | 1 |

| *Shigellosis: 1 Data Element* | | | |
|---|---|---|---|
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG). Routine linking between lab and epi data is fundamental to outbreak response and epidemiologic analysis. | | |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority[1]** |
| PulseNet ID | State lab ID submitted to PulseNet | N/A | 1 |
| *Vibriosis: 2 Data Elements* | | | |
| The impetus/urgency for CDC to add data elements for this condition | • The proposed data elements are necessary to facilitate linking between laboratory data submitted to the CDC (including whole-genome sequencing data) and enhanced case-patient data transmitted per the Foodborne and Diarrheal Diseases Message Mapping Guide (FDD MMG). Routine linking between lab and epi data is fundamental to outbreak response and epidemiologic analysis. | | |

| Data Element Name | Data Element Description | Value Set Code | CDC Priority[1] |
|---|---|---|---|
| PulseNet ID | State lab ID submitted to PulseNet | N/A | 1 |
| WGS ID Number | Whole Genome Sequencing (WGS) ID Number | N/A | 1 |