

Attachment 9. Justification for the Addition of Disease-Specific Data Elements

107 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for 4 conditions: 2019 Novel Coronavirus (COVID-19), Carbon Monoxide (CO) Poisoning, Congenital Syphilis, and STD (not congenital). 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:

COVID-19: 46 Data Elements

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 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. Nationwide disease surveillance is necessary to provide consistent case identification and classification, measure the potential burden of illness, characterize the epidemiology of medically attended and moderate to severe COVID-19 in the United States, detect community transmission, and 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)
COVID-19 ID	ID to link all case information on patient	N/A	1
Interviewer Last Name	Last name of interviewer	N/A	1
Interviewer First Name	First name of interviewer	N/A	1
Interviewer Organization	The affiliation or organization of the interviewer.	N/A	1
Interviewer Telephone	Telephone number of interviewer	N/A	1
Interviewer Email	Email of interviewer	N/A	1
Probable Classification Reason	If probable case classification status, provide reason for classification.	TBD	1

Process for Case Identification	Under what process was the case first identified?	TBD	1
DGMQID	If EpiX notification of traveler, provide the DGMQID.	N/A	1
Positive Collection Date	Date of first positive specimen collection.	N/A	1
Hospital Translator	If hospitalized, was a translator required?	PHVS_YesNoUnknown_CDC	1
Translator Language	If translator required in the hospital, specify which language?	TBD	1
Intensive Care Unit Admittance	Was patient admitted to an intensive care unit (ICU)?	PHVS_YesNoUnknown_CDC	1
ICU Admission Date	If patient was admitted to an ICU, provide the admission date.	N/A	1
ICU Discharge Date	If patient was admitted to an ICU, provide the discharge date.	N/A	1
Housing Type	Select the best description of where the patient lived at the time of illness onset.	TBD	1
Health Care Worker	Is the patient a health care worker in the U.S.?	PHVS_YesNoUnknown_CDC	1
Health Care Worker Job Type	If patient is a health care worker, select their occupation. If other, specify in text.	TBD	1
Health Care Worker Job Setting	If patient is a health care worker, select their job setting. If other, specify in text.	TBD	1
Exposure of Interest	In the 14 days prior to illness onset, did the patient have any of the following exposures? Select all that apply.	TBD	1
State of Travel Exposure	If domestic travel outside of state of normal residence, specify the state.	N/A	1
Country of Travel Exposure	If patient traveled internationally, specify country.	N/A	1
Cruise Ship or Vessel	If exposed on a cruise ship or vessel, specify the name of the cruise ship.	N/A	1

Workplace Critical Infrastructure	If the patient was exposed at their workplace, is the workplace critical infrastructure?	PHVS_YesNoUnknown_CDC	1
Workplace Exposure	If workplace exposure, specify the workplace setting (e.g., long term healthcare setting, hospital, grocery store)	TBD	1
Animal Case	If an animal with confirmed or suspected COVID-19, specify the animal.	N/A	1
Type of Contact with COVID-19 Case	If the patient had contact with a known COVID-19 case, specify the type of contact.	TBD	1
Contact with U.S. COVID-19 Case	Was this person a U.S. case?	TBD	1
COVID-19 Case Identifier	If patient had contact with a known COVID-19 case, specify the COVID-19 ID(s).	N/A	1
Clinical History Collection Mechanism	Select which mechanisms were used for the collection of the clinical course, symptoms, past medical history and social history.	TBD	1
Symptomatic	Symptoms present during course of illness.	TBD	1
Symptoms Resolved	Did the patient's symptoms resolve?	TBD	1
Clinical Symptoms	Indicate the symptoms associated with this illness.	TBD	1
Clinical Symptoms Indicator	Indicator for each symptom.	PHVS_YesNoUnknown_CDC	1
Diagnostic	Select the diagnostic tests that were performed.	TBD	1
Diagnostic Result	Indicator for each diagnostic test result.	TBD	1
Treatment	Indicate the treatment received.	TBD	1
Treatment Indicator	Indicator for each treatment.	N/A	1
Days of Mechanical Ventilation	If patient received mechanical ventilation intubation, specify the total days of treatment.	N/A	1
Underlying Risk Factors	Specify any of the underlying medical conditions and/or risk behaviors.	TBD	1

Underlying Risk Factors Indicator	Indicator for each medical condition and risk behaviors.	PHVS_YesNoUnknown_CDC	1
Chronic Disease	If other chronic diseases, please specify.	N/A	1
Underlying Condition	If other underlying condition, please specify.	N/A	1
Risk Behavior	If other underlying risk behavior, please specify	N/A	1
Disability	If disability (neurologic, neurodevelopmental, intellectual, physical, vision or hearing impairment, please specify.	N/A	1
Psychological or Psychiatric Condition	If psychological or psychiatric condition, please specify.	N/A	1

CO Poisoning: 45 Data Elements

45 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for CO Poisoning. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: The data elements will contribute to enhanced surveillance efforts on the part of the CDC program and allow the program to perform additional epidemiological analyses for CO Poisoning. Tracking CO Poisoning cases in a standard manner over time will assist the program to: better understand the health consequences of CO Poisoning across the United States, learn about the effects of long-term exposures to low levels of CO, monitor trends, identify high risk groups, and determine the impact of public health policy aimed at preventing CO Poisoning. This additional data would help to better target outreach activities to those at increased risk for CO Poisoning, such as during large-scale power outages in post-disaster settings.

Data Element Name	Data Element Description	Value Set Code	CDC Priority
Primary Language	What is the patient's primary language?	PHVS_Language_ISO_639-2_Alpha3	P
Marital Status	What is the patient's current marital status?	PHVS_MaritalStatus_HL7_2x	P
Education	Indicate the highest degree or level of school completed at the time of the event.	PHVS_Education_CO	P

Poison Control Center Record	Does the patient have a poison control record indicating exposure to carbon monoxide?	PHVS_YesNoUnknown_CDC	P
Outcome of Poison Control Center Record	If patient has a poison control record, select the outcome identified in the Poison Control Center Record.	PHVS_PoisonControlCenterRecord_CO	P
Treatment Management Type	If patient has a poison control record, indicate how the care was managed.	PHVS_TreatmentSite_CO	P
Workers Compensation Record	Does the patient have a worker's compensation record with a finding, problem, diagnosis or other indication of exposure to carbon monoxide or carbon monoxide poisoning?	PHVS_YesNoUnknown_CDC	P
Type of Workers Compensation Claim	Indicate the type of claim if patient has a worker's compensation claim with a finding, problem, diagnosis or other indication of exposure to carbon monoxide or carbon monoxide poisoning.	PHVS_WorkersCompensationRecord_CO	P
Fire Related Exposure	Was the carbon monoxide exposure related to a fire?	PHVS_YesNoUnknown_CDC	P
Power Outage Event	Was the carbon monoxide exposure related to a power outage?	PHVS_YesNoUnknown_CDC	P
Extreme Weather	Was the carbon monoxide exposure related to an extreme weather event?	PHVS_YesNoUnknown_CDC	P
Extreme Weather Type	Identify the extreme weather event(s) occurring when the patient was exposed to carbon monoxide.	PHVS_ExtremeWeatherType_CO	P
Warning Announcement	Immediately before or during the extreme weather event, did patient hear or read about any warnings on the danger of carbon monoxide poisoning?	PHVS_YesNoUnknown_CDC	P
Exposure Source	If patient was physically and temporally associated with a CO-emitting source, specify the source.	PHVS_ExposureSource_CO	P
Generator Location	If the exposure source is generator, where was it placed while it was running?	PHVS_GeneratorLocation_CO	P
Generator Distance	If the exposure source was a generator, how many feet was the generator placed from the (house/attached	PHVS_GeneratorDistance_CO	P

	garage/detached garage or other location of event)?		
Carbon Monoxide Alarm Present	Patient was in a location where a carbon monoxide alarm was present.	PHVS_YesNoUnknown_CDC	P
Carbon Monoxide Alarm Sounded	The carbon monoxide alarm sounded.	PHVS_YesNoUnknown_CDC	P
Carbon Monoxide Elevated Exposure	Exposure to an elevated level of CO based on a dedicated or multi-gas meter/instrument (e.g., fire department measurement)?	PHVS_YesNoUnknown_CDC	P
Air Concentration of CO Level	Air concentration of CO Level in parts per million (PPM) at exposure site.	N/A	P
Person/Organization Taking CO Reading	If air concentration of CO level was taken, indicate the person or organization taking the CO reading.	PHVS_PersonOrgTakingReading_CO	P
Date of Reading	What was the date and time, if known, of the CO reading?	N/A	P
Exposure Site Category	Categorize the location of exposure.	PHVS_ExposureSiteCategory_CO	P
Public Site of Exposure	If a public setting where the exposure occurred, please indicate specific site.	PHVS_SiteofExposure_CO	P
Residential Site of Exposure	If a residential setting where the exposure occurred, please indicate specific site.	PHVS_ResidentialSiteofExposure_CO	P
Epi-Linked	Patient was present and exposed in the same event as that of a carbon monoxide poisoning case.	PHVS_YesNoUnknown_CDC	P
Date and Time of Incident	Please provide the date and time, if known, of the carbon monoxide incident.	N/A	P
Address of Establishment Where Exposure Occurred	Street address of the location or establishment where the carbon monoxide exposure occurred.	N/A	P
City of Establishment Where Exposure Occurred	City of the location or establishment where the carbon monoxide occurred.	N/A	P
State of Establishment Where Exposure Occurred	State of the location or establishment where the carbon monoxide occurred.	PHVS_State_FIPS_5-2	P

Zip Code of Establishment Where Exposure Occurred	Zip code of the location or establishment where the carbon monoxide occurred.	N/A	P
County of Establishment Where Exposure Occurred	County of the location or establishment where the carbon monoxide occurred.	N/A	P
Event Notes	Description of incident.	N/A	P
Number of Exposed Cases	Total number of exposed persons (including case patient).	N/A	P
Average Number of Cigarettes Smoked per Day	During the past 30 days, please specify the average number of cigarettes smoked per day. There are 20 cigarettes per pack.	PHVS_NumberofCigarettesSmokedperDay_CO	P
Marijuana Smoking Status	Does the patient currently smoke marijuana?	PHVS_YesNoUnkRefused_NN D	P
Other Substance	Type of other substance used (e.g., e-cigarette tobacco, e-cigarette THC)	TBD	P
Underlying Condition(s)	Select the patient's preexisting condition(s).	PHVS_UnderlyingConditions_CO	P
Signs and Symptoms	Signs and symptoms associated with the carbon monoxide exposure or poisoning.	PHVS_SignsandSymptoms_CO	P
ICD Codes List	ICD Codes in patient's report.	PHVS_ICDCodesList_CO	P
Treatment Provided	Was patient treated for carbon monoxide exposure?	PHVS_YesNoUnknown_CDC	P
Treatment Type	Specify the treatment type.	PHVS_TreatmentType_CO	P
Treatment Location	Where did the patient receive treatment?	PHVS_TreatmentLocation_CO	P
Start Date of Treatment or Therapy	Provide the date and time of when the treatment started.	N/A	P
Occupation Related to Exposure	Is the patient's carbon monoxide exposure related to their current occupation?	PHVS_YesNoUnknown_CDC	P

Congenital Syphilis: 2 Data Elements

2 data elements were added for Congenital Syphilis. Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: Congenital syphilis (CS) occurs when a mother with syphilis passes the infection to her infant during pregnancy. When syphilis is diagnosed in a pregnant woman, CDC receives a case notification for non-congenital (adult) syphilis. If the resulting infant meets the CS case definition, CDC receives a separate CS case notification for the infant. State and local surveillance information systems allow for the linkage of these two records—mother (adult syphilis) and child (CS)—to inform disease investigation, but notifications transmitted to CDC using the STD and CS MMGs do not contain the information necessary for linking these records at the national level. As such, the clinical and sociodemographic characteristics currently reported for pregnant females (e.g., drug use, incarceration history) cannot be evaluated as risk factors for CS nor be used to identify intervention opportunities. Linking maternal and CS case notifications at the national level would involve the addition of two maternal data elements to the CS case notification. These data elements are already collected locally and are already included in the mother’s non-congenital syphilis case notification. Providing these maternal data elements on the CS case notification will allow for record-linkage at CDC and will advance the understanding of CS epidemiology & prevention.

Data Element Name	Data Element Description	Value Set Code	CDC Priority
Maternal Local Record ID	Sending system-assigned local ID of the case investigation with which the subject is associated	TBD	O
Maternal Notification Reporting Jurisdiction	National jurisdiction reporting the notification to the CDC	TBD	O

STD (not congenital): 14 Data Elements

14 data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for STD (not congenital). Names, descriptions, value set codes, and justification for the addition of these new data elements are below:

Justification: CDC recommends specific regimens to treat STDs. Patients not receiving appropriate treatment are at risk for treatment failure and/or contributing to on-going transmission; treatment with non-recommended regimens also contributes to the emergence of antimicrobial resistance. There are no national surveillance systems that systematically track treatment among persons diagnosed and reported with bacterial STDs. These data are often captured at the state/local level and the addition of these data elements will allow reporting

jurisdictions to report these to CDC associated with cases of bacterial STDs for national surveillance of treatment adherence.

Lymphogranuloma venereum (LGV) is a clinical complication of chlamydia, disseminated gonococcal infection (DGI) is a severe complication of gonorrhea, and pelvic inflammatory disease (PID) and neonatorum ophthalmia are complications of gonorrhea and chlamydia. Although these complications are rare, there are no national surveillance systems that systematically track these sequelae among persons diagnosed and reported with an STD. These data are often captured at the state/local level and the addition of this data element will allow reporting jurisdictions to report these to CDC associated with cases of bacterial STDs for national surveillance of STD-related sequelae.

Data Element Name	Data Element Description	Value Set Code	CDC Priority
Date Treatment was Prescribed	Date treatment associated with the condition was prescribed	TBD	O
Date Treatment was Administered	Date treatment associated with the condition was administered	TBD	O
Medication Administered	Name of the antibiotic administered	TBD	O
Medication Administered Dose	Dose of the antibiotic administered	TBD	O
Treatment Duration	Prescribed duration of antibiotic	TBD	O
Type of Complication	Complications associated with the illness being reported	TBD	O
Type of Complication Indicator	Indicator for associated complication	TBD	O
Treatment Dosage	Dose of the treatment associated with the condition	TBD	O
Treatment Dosage Unit	Unit of measure for the treatment associated with the condition	TBD	O

Treatment Route of Delivery	Route of delivery of treatment	TBD	O
Treatment Drug Frequency	Frequency of treatment drug	TBD	O
Treatment Drug Frequency Unit	Unit of measure for the frequency of treatment associated with the condition	TBD	O
Treatment Duration Units	Unit of measure for the duration of treatment associated with the condition	TBD	O
Drug Use Route of Delivery	Route of delivery of drug(s) used	TBD	O

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