

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

143 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for Congenital Rubella Syndrome (CRS), Salmonellosis, Shigellosis, Campylobacteriosis, Shiga toxin-producing *Escherichia coli* (STEC), Hepatitis, and Hantavirus Pulmonary Syndrome (HPS). Names, descriptions, value sets, and justification for the addition of these new data elements are below:

Congenital Rubella Syndrome (CRS): 8 Data Elements

Justification: The addition of these 8 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 CRS.

PHINU-ID	Data Element Name	Data Element Description
INV323	At the time of cessation of pregnancy, what was the age of the fetus (in weeks)?	If applicable, at the time of cessation of pregnancy, what was the age of the fetus (in weeks)?
DEM124	Birth State	State where the subject was born
MTH167	Mother's Country of Residence	What is the mother's country of residence?
TBD	Mother's pre-pregnancy serological test date.	If pre-pregnancy serological testing was performed, what was the date of mother's pre-pregnancy serological test?
TBD	Mother's pre-pregnancy serological test interpretation.	If pre-pregnancy serological testing was performed, what was the interpretation of mother's pre-pregnancy serological test?
63893-2	Pregnancy outcome	What was the outcome of the current pregnancy
VAC129	Number of doses received on or after 1 st birthday	The number of vaccine doses against this disease which the mother received on or after their first birthday
VAC142	Date of last dose prior to illness onset	Date of mother's last vaccine dose against this disease prior to illness onset

Salmonellosis: 11 Data Elements

Justification: The addition of these 11 data elements will enable the program to collect the minimum information required to determine if a case had a high risk of exposure and determine case classification.

PHINU-ID	Data Element Name	Data Element Description
TBD	Occupation/Industry/Place of Business	Is patient employed in a high risk occupation (e.g., food handler, healthcare worker, daycare worker)?
TBD	Child care attendee	Did patient have a high risk exposure related to child care facility?
TBD	Long term care facility resident	Did patient have a high risk exposure related to residence in a long term care facility?
TBD	Contact of a Salmonellosis case	Did patient have a high risk exposure related to contact with a Salmonellosis case?
TBD	Method(s) of laboratory testing	Type of laboratory testing performed
TBD	Name of test	Name of laboratory test performed
TBD	Name of test manufacturer	Name of test manufacturer
TBD	Probable case from CIDT testing	Probable case status confirmed by CIDT testing
TBD	Probable case from Epi-linkage	Probable case confirmed by Epi-linkage
TBD	Reported symptoms and signs of illness	Symptoms and signs associated with illness
TBD	WGS (Whole-Genome Sequencing) ID	The identifier used in PulseNet for the whole genome sequenced isolate that corresponds to the reported case

Shigellosis: 12 Data Elements

Justification: The addition of these 12 data elements will enable the program to collect the minimum information required to determine if a case had a high risk of exposure and determine case classification.

PHINU-ID	Data Element Name	Data Element Description
TBD	International travel in the 7 days prior to onset	Did patient travel internationally within 7 days of illness onset?
TBD	Occupation/Industry/Place of Business	Is patient employed in a high risk occupation (e.g., food handler, healthcare worker, daycare worker)?
TBD	Child care attendee	Did patient have a high risk exposure related to attendance at a child care facility?
TBD	Long term care facility resident	Did patient have a high risk exposure related to residence in a long term care facility?
TBD	Contact of a Shigellosis case	Did patient have a high risk exposure related to contact with a Shigellosis case?
TBD	Method(s) of laboratory testing	Type of laboratory testing performed
TBD	Name of test	Name of laboratory test performed
TBD	Name of test manufacturer	Name of test manufacturer
TBD	Probable case from CIDT	Probable case status confirmed by CIDT (Culture Independent Diagnostic Testing)
TBD	Probable case from Epi-linkage	Probable case confirmed by Epi-linkage
TBD	Reported symptoms and signs of illness	Symptoms and signs associated with illness

TBD	WGS (Whole-Genome Sequencing) ID	The identifier used in PulseNet for the whole genome sequenced isolate that corresponds to the reported case
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Campylobacteriosis: 11 Data Elements

Justification: The addition of these 11 data elements will allow the program to collect the minimum information required to determine if a case has a high risk of exposure and determine case classification.

PHINU-ID	Data Element Name	Data Element Description
TBD	Reported symptoms and signs of illness	Symptoms and signs associated with illness
TBD	Travel in 10 days prior to illness	Did the case have travel outside of the U.S. in the 10 days before the illness began?
TBD	Consumption of undercooked/ raw meat	Did the case eat undercooked or raw meat before the illness began?
TBD	Consumption of undercooked/ raw poultry	Did the case eat undercooked or raw poultry before the illness began?
TBD	Drinking untreated water	Did the case drink untreated water before the illness began?
TBD	Contact with untreated recreational water	Did the case have contact with untreated recreational water before the illness began?
TBD	Consumption of raw milk or unpasteurized dairy	Did the case consume raw milk or unpasteurized dairy before the illness began?
TBD	Contact with pets, farm animals with <i>Campylobacter</i> species	Did the case have contact with pets or farm animals from which <i>Campylobacter</i> species were isolated?
TBD	Contact with confirmed/probable case of Campylobacteriosis	Did the case have contact with another probable or confirmed case of Campylobacteriosis?
TBD	Consumption or exposure to implicated vehicle	Did the case consume or have exposure to a vehicle implicated in an outbreak or a location in which an implicated food vehicle was prepared or eaten?
TBD	WGS (Whole-Genome Sequencing) ID	The identifier used in PulseNet for the whole genome sequenced isolate that corresponds to the reported case

Shiga toxin-producing Escherichia coli (STEC): 85 Data Elements

Justification: The addition of these 85 data elements will allow the program to address: 1) efforts to improve responsiveness to outbreak-related infections, 2) emerging or newly discovered vehicles for infection, and 3) disease-specific outcomes of public health importance. Inclusion of these variables align with recommendations by the Council for State and Territorial Epidemiologists (CSTE) and additional input from state and local public health agencies that reflect the variety of data elements routinely collected by the state public health departments during patient interviews.

PHINU-ID	Data Element Name	Data Element Description
TBD	Probable – laboratory-diagnosed	Probable case is laboratory-diagnosed
TBD	Probable – epi-linked	Probable case is epidemiologically linked
INV937	TTP	Patient had a diagnosis of TTP (Thrombotic thrombocytopenic purpura)
FDD_Q_1013	Ill contact	Patient had close contact with anyone with diarrhea or vomiting in the 7 days prior to illness onset
TBD	Gourmet cheese	Patient consumed artisanal or gourmet cheese in the 7 days before illness onset
TBD	Specify other leafy greens	Specify other leafy greens
TBD	Sprouts location	Purchase location of sprouts
TBD	Sprouts brand	Brand and variety of sprouts
TBD	Treated recreational water	Visit or swim in any treated recreational water facilities in 7 days prior to illness onset
TBD	Untreated recreational water	Visit or swim in any untreated recreational water facilities in 7 days prior to illness onset
TBD	Treated recreational water location	Location of treated recreational water facilities
TBD	Untreated recreational water location	Location of untreated recreational water facilities
TBD	Other related diagnosis	Other related diagnosis

September 13, 2017

TBD	Specify other related diagnosis	Specify other related diagnosis
TBD	Shopper card consent	Consent to retrieve purchases based on shopper card information
TBD	Ground beef at home brand	Brand and variety of ground beef consumed at home
TBD	Steak at home brand	Brand and variety of steak consumed at home
TBD	Steak at home frozen	Steak consumed at home was purchased frozen
TBD	Steak at home fresh	Steak consumed at home was purchased fresh
TBD	Bison brand	Brand and variety of bison
TBD	Wild game brand	Brand and variety of wild game
TBD	Dried meat brand	Brand and variety of dried or fermented meat
TBD	Other dried meat brand	Brand and variety of other dried or fermented meat
TBD	Pork	Patient consumed pork in 7 days prior to illness onset
TBD	Pork at home	Patient consumed pork at home in 7 days prior to illness onset
TBD	Pork at home purchase location	Purchase location of pork consumed at home
TBD	Pork at home brand	Brand and variety of pork consumed at home
TBD	Pork at home ground	Pork consumed at home was ground
TBD	Pork at home whole	Pork consumed at home was whole pig
TBD	Pork at home other form	Pork consumed at home was other form
TBD	Specify other form of pork at home	Specify other type of pork consumed at home
TBD	Pork away from home	Patient consumed pork away from home in 7 days prior to illness onset
TBD	Pork away from home location	Purchase location of pork consumed away from home
TBD	Pork away from home dish	Dish in which pork was consumed away from home
TBD	Raw milk location	Purchase location of raw milk
TBD	Raw milk brand	Brand and variety of raw milk

September 13, 2017

TBD	Raw cheese	Purchase location of cheese made from raw milk
TBD	Raw cheese brand	Brand and variety of cheese made from raw milk
TBD	Raw cheese aged	Cheese made from raw milk was aged for 60 days
TBD	Gourmet cheese location	Purchase location of artisanal or gourmet cheese
TBD	Gourmet cheese brand	Brand and variety of artisanal or gourmet cheese
TBD	Raw juice location	Purchase location of unpasteurized juice or cider
TBD	Raw juice brand	Brand and variety of unpasteurized juice or cider
TBD	Other raw dairy product	Patient consumed any other unpasteurized dairy product in 7 days prior to illness onset
TBD	Specify other raw dairy product	Specify other unpasteurized dairy product
TBD	Other raw dairy product location	Purchase location of other unpasteurized dairy product
TBD	Other raw dairy product brand	Brand and variety of other unpasteurized dairy product
TBD	Raw dough	Patient ate, tasted, or licked uncooked or unbaked dough or batter
TBD	Leafy greens	Patient consumed fresh, uncooked leafy greens in 7 days prior to illness onset
TBD	Leafy greens location	Purchase location of fresh, uncooked leafy greens
TBD	Leafy greens brand	Brand and variety of fresh, uncooked leafy greens
TBD	Loose leafy greens	Patient consumed loose fresh, uncooked leafy greens
TBD	Prepackaged leafy greens	Patient consumed prepackaged fresh, uncooked leafy greens
TBD	Cabbage	Patient consumed cabbage in 7 days prior to illness onset
TBD	Cabbage location	Purchase location of cabbage
TBD	Cabbage brand	Brand and variety of cabbage
TBD	Arugula	Patient consumed arugula in 7 days prior to illness onset
TBD	Arugula location	Purchase location of arugula
TBD	Arugula brand	Brand and variety of arugula

September 13, 2017

TBD	Kale	Patient consumed kale in 7 days prior to illness onset
TBD	Kale location	Purchase location of kale
TBD	Kale brand	Brand and variety of kale
TBD	Premade salad	Patient consumed pre-made, single-serving salads in 7 days prior to illness onset
TBD	Premade salad location	Purchase location of pre-made, single-serving salads
TBD	Premade salad brand	Brand and variety of pre-made, single-serving salads
TBD	Other prepackaged leafy greens	Patient consumed other pre-packaged leafy greens or salad kits
TBD	Other prepackaged leafy greens location	Purchase location of other pre-packaged leafy greens or salad kits
TBD	Other prepackaged leafy greens brand	Brand and variety of other pre-packaged leafy greens or salad kits
TBD	Other leafy greens location	Purchase location of other leafy greens
TBD	Other leafy greens brand	Brand and variety of other leafy greens
TBD	Herbs	Patient consumed fresh herbs in 7 days prior to illness onset
TBD	Specify herbs	Specify fresh herbs
TBD	Herbs location	Purchase location of fresh herbs
TBD	Herbs brand	Brand and variety of fresh herbs
TBD	Specify petting zoo	Specify petting zoo
TBD	Specify type of livestock	Specify type of livestock
TBD	Specify fair	Specify fair or event with animals
TBD	Pet	Patient has a pet of their own
TBD	Specify pet	Specify pet
TBD	Specify institution	Specify institution
TBD	Treated recreational water type	Types of treated recreational water facilities
TBD	Untreated recreational water type	Types of untreated recreational water facilities

September 13, 2017

TBD	Occupation	Patient's occupation
TBD	Food allergy	Does the patient have a food allergy?
TBD	Special diet	Is the patient on a special diet?

Hepatitis: 12 Data Elements

Justification: The addition of these 12 data elements will allow the program to collect the minimum information required to meet CSTE reporting requirements for the case definitions of Perinatal Hepatitis. The concepts determine possible maternal infection with hepatitis, maternal treatment for hepatitis that may mitigate infant hepatitis exposure, additional risks to infant, determine outbreak clusters, infant health at time of birth, and to evaluate effectiveness of maternal therapy for Hepatitis prior to infant delivery and determining proper administration of immunoglobulin.

PHINU-ID	Data Element Name	Data Element Description
TBD	Maternal HBeAg result, date	Maternal HBeAg result, date
TBD	Maternal HBV DNA (or genotype), result, date	Maternal HBV DNA (or genotype), result, date
TBD	Maternal Alanine aminotransferase (ALT)	Maternal Alanine aminotransferase (ALT)
TBD	Maternal antiviral therapy, if any	Maternal antiviral therapy, if any
TBD	Maternal Coinfection with human immunodeficiency virus or hepatitis C virus	Maternal Coinfection with human immunodeficiency virus or hepatitis C virus
TBD	Maternal State/Territory of residence at time of infant's diagnosis	Maternal State/Territory of residence at time of infant's diagnosis
TBD	Infant Birthweight	Infant Birthweight
TBD	Infant Time of birth (military time)	Infant Time of birth (military time)
TBD	Infant State/Territory of birth	Infant State/Territory of birth

September 13, 2017

TBD	HCV RNA (NAAT) test results	HCV RNA (NAAT) test results and timing of test performance
TBD	HCV genotype test results	HCV genotype test results and timing of test performance
TBD	HCV antigen test results	HCV antigen test results and timing of test performance

Hantavirus Pulmonary Syndrome (HPS): 4 Data Elements

Justification: The data elements included in this change request allow the program to information on: whether a pet exposure has occurred, whether blood was noted in a patient’s urine, and whether protein was noted in a patient’s urine. If the site of exposure was the residence, the addition of the street address data element allows CDC to geo-tag the location and represent it on a map. This adds an enhanced degree of detail not captured with zip codes along. Including these data elements will allow CDC to improve data quality, better understand the epidemiological contexts for exposure, and better delineate symptomology for HPS.

PHINU-ID	Data Element Name	Data Element Description
TBD	Proteinuria	Was Proteinuria detected?
TBD	Hematuria	Was Hematuria detected?
TBD	Exposure occurred from pet rodent	Did exposure occur from a pet rodent?
DEM225	Street address	What is the patient’s street address?