

78 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for 3 conditions: 75 new disease-specific data elements for *Cronobacter*, 2 new disease-specific data elements for Leptospirosis, and 1 new disease-specific data elements for Hansen's Disease. 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:

<i>Cronobacter</i>	
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> • <i>Cronobacter</i> spp. are opportunistic pathogens, and infections can be life-threatening, particularly in infants. Outbreaks of <i>Cronobacter</i> infections have been associated with neonatal intensive care units, and neonates and infants are at greatest risk for morbidity and mortality from invasive infections such as meningitis and sepsis. • Surveillance for <i>Cronobacter</i> is necessary to help estimate incidence, identify risk factors, promptly detect and trace outbreaks, and inform control and prevention measures. • The increased reporting and submission of isolates to CDC is expected to enable rapid and accurate species identification and outbreak detection. • To provide more information about risk factors (related cases and conditions, high acuity care needs, healthcare facility exposure, travel, and specimen testing) that have been associated with colonization or infection • To monitor epidemiology

Data Element Name	Data Element Description	Value Set Code	CDC Priorityⁱ
PulseNet ID	State lab ID submitted to PulseNet	N/A	1
Date Case Report Form Completed	Date case report form was completed	N/A	2
Patient Or Surrogate Able To Be Interviewed	Was patient or surrogate able to be interviewed?	PHVS_YesNoUnknown_CDC	2
Healthcare Setting Exposure Type	Type of exposure to healthcare setting	TBD	2
Clinical Syndrome	Clinical Syndrome is the type of clinical presentation the case had.	TBD	1
Obstetric Delivery Method	Type of delivery	TBD	2
Gestational Age	Gestational age (weeks)	N/A	1

Birth Weight	Birth weight (in grams)	N/A	2
Antibiotics Given to Mother	Were intrapartum antibiotics given to mother?	TBD	3
Treatment Received	Was treatment received for this condition?	TBD	2
Antimicrobial Susceptibility Testing Performed At The Laboratory	Was antimicrobial sensitivity testing done at the laboratory?	PHVS_YesNoUnknown_CDC	3
Hospitalization At Onset	Was patient hospitalized at time of illness onset?	TBD	2
Birth Multiplicity	Was infant single, multiple or unknown number of births?	TBD	3
Medication By Mouth Or Feeding Tube	Did patient receive any medication by mouth or feeding tube in the 10 days prior to illness onset?	PHVS_YesNoUnknown_CDC	2
Steroids Given	Has patient ever been treated with steroids	PHVS_YesNoUnknown_CDC	3
Gastric Acid Suppressing Medication Given	Did infant receive gastric acid suppressing medication in the 10 days prior to illness onset	PHVS_YesNoUnknown_CDC	3
Infant Feeding Method	How was infant fed 10 days prior to illness onset?	TBD	1
Specify Feeding Tube Type	If infant was fed via feeding tube, specify tube type	TBD	1
Fed Breast Milk	In the 10 days before illness began, was infant ever fed breast milk?	PHVS_YesNoUnknown_CDC	1
Breast Milk Source	If yes, what source of breast milk?	TBD	2
Exclusively Breast Fed	Was infant exclusively breast fed?	PHVS_YesNoUnknown_CDC	1
Consumed Expressed Breast Milk	Was expressed breast milk consumed (i.e., pumped and fed through bottle or tube)?	PHVS_YesNoUnknown_CDC	2
Combined Milk	If yes, was pumped milk from multiple pumping sessions ever combined and then stored for later use?	PHVS_YesNoUnknown_CDC	1
Consumed Liquid Formula	Did infant consume liquid formula in the 10 days before illness began?	PHVS_YesNoUnknown_CDC	1
Consumed Solid Food	Did infant consume any solid foods, including cereal, in the 10 days before	PHVS_YesNoUnknown_CDC	1

	illness began?		
Specify Solid Food Type	If yes, specify type of solid food	TBD	2
Specify Liquid Formula	If infant cereal was consumed, type of liquid used for preparing infant cereal	TBD	2
Formula Prepared With Water	Was water used to prepare infant formula	PHVS_YesNoUnknown_CDC	1
Formula Water Type	Type of water used for preparing infant formula		1
Formula Water Boiled	Was water boiled and cooled before adding to formula	PHVS_YesNoUnknown_CDC	1
Formula Water Mix Method	How were formula and water mixed	TBD	3
Breast Milk or Formula Additive	Was anything ever added to breast milk or formula (besides water) during the 10 days before illness	PHVS_YesNoUnknown_CDC	2
Formula Preparation Frequency	What frequency was formula prepared	TBD	3
Formula Storage Location	Where was prepared formula stored	TBD	3
Maximum Refrigerated Storage Time	Maximum storage time of prepared, refrigerated formula	TBD	1
Maximum Room Temperature Storage Time	Maximum storage time of prepared, room temperature formula	TBD	1
Formula Temperature	What temperature was formula at time of feeding	TBD	3
Formula Left In Crib	Was prepared feed ever left in a crib with infant overnight?	PHVS_YesNoUnknown_CDC	3
Formula Reused	Was a partially consumed bottle that was at room temperature for more than 2 hours ever saved and given to the infant later	PHVS_YesNoUnknown_CDC	3
Formula Lid Surface Contact	Was the lid of the formula container ever placed on the counter, in the sink, or on another surface	PHVS_YesNoUnknown_CDC	3
Formula Scoop Surface Contact	Was the formula scoop ever placed on the counter, in the sink, or on another surface	PHVS_YesNoUnknown_CDC	3

Equipment Disassembled	Were bottles, nipples, and rings always completely disassembled before cleaning	PHVS_YesNoUnknown_CDC	2
Bottle Cleaned	Were bottles cleaned after each use	PHVS_YesNoUnknown_CDC	2
Bottle Cleaning Method	How were bottles cleaned	TBD	3
Bottle Scrub Method	Were bottles scrubbed using	TBD	2
Bottle Cleaned With Soap	Was soap used when cleaning bottles	PHVS_YesNoUnknown_CDC	2
Bottle Drying Method	How were bottle parts dried	TBD	2
Equipment Sanitized	Were bottles, nipples, and/or rings sanitized	PHVS_YesNoUnknown_CDC	2
Equipment Sanitized Frequency	If yes, how often were they sanitized	TBD	2
Equipment Sanitized Method	How were parts sanitized	TBD	3
Pump Type	What type of pump was used	TBD	3
Pump Disassembled	Were flanges, valves, membranes, and connector tubing always completely disassembled before cleaning	PHVS_YesNoUnknown_CDC	2
Pump Cleaned	Was the pump kit, not including tubing, cleaned after each use	PHVS_YesNoUnknown_CDC	2
Pump Cleaning Frequency	If no, how many times was it used before being cleaned	TBD	2
Pump Rinsed	Was kit rinsed between uses	PHVS_YesNoUnknown_CDC	2
Pump Storage Location	Where was unwashed kit stored between uses	TBD	3
Pump Cleaning Method	How were pump and parts cleaned	TBD	2
Pump Scrubbing Method	Were pump and parts scrubbed using	PHVS_YesNoUnknown_CDC	2
Pump Cleaned With Soap	Was soap always used when washing pump kit and parts	PHVS_YesNoUnknown_CDC	2
Pump Drying Method	How were pump parts dried	TBD	3
Pump Sanitized	Was pump kit ever sanitized	PHVS_YesNoUnknown_CDC	3

Pump Sanitized Frequency	If yes, how often were they sanitized	TBD	3
Pump Sanitized Method	How were parts sanitized	TBD	3
Pump Reassembled When Damp	Was clean pump kit ever reassembled while still damp	PHVS_YesNoUnknown_CDC	3
Product Name	Complete product name (including brand, type, and variety)	TBD	1
Product Manufacturer	Product manufacturer	TBD	1
Product Type	Type of product	TBD	1
Product Size	Size of container	TBD	2
Lot Number	Lot number(s), if known	N/A	1
Use By Date	Use by Date	N/A	1
Date First Consumed	Date first consumed	N/A	1
Date Last Consumed	Date last consumed	N/A	1
Dates Consumed Unknown	Dates Consumed Unknown	TBD	1
Antibiotics With Intermediate Resistance	If yes, antibiotics with intermediate resistance:	N/A	3
Antibiotics With Complete Resistance	If yes, antibiotics with complete resistance:	N/A	2

<i>Leptospirosis</i>	
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> • To provide more information about risk factors (related cases and conditions, high acuity care needs, healthcare facility exposure, travel, and specimen testing) that have been associated with colonization or infection • To update guidance on infection control and prevention

Data Element Name	Data Element Description	Value Set Code	CDC Priorityⁱ
Congregant Living Setting	In the 30 days prior to illness onset, did the subject	TBD	3

	ever reside in any of these congregate living settings:		
Homelessness	In the 30 days prior to illness onset, did the subject ever sleep in:	TBD	2

Hansen's Disease	
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> • To monitor the frequency of complications developed due to Hansen's Disease. • To provide more information on types of disabilities developed due to Hansen's Disease. • To monitor epidemiology of Hansen's Disease.

Data Element Name	Data Element Description	Value Set Code	CDC Priorityⁱ
Sequelae of Hansen's Disease	Hansen's Disease complications leading to disabilities such as any sensory abnormalities or deformities of the hands, eyes, or feet.	TBD	2

ⁱR=Required, 1=Priority 1, 2=Priority 2, 3=Priority 3