

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

24 new data elements that were not included in the previously reviewed ICR or approved through non-substantive change requests were added for 6 conditions: Alpha-gal Syndrome, Coronavirus Disease (COVID-19), Cryptosporidiosis, Cyclosporiasis, Hepatitis 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:

<b>Alpha-gal Syndrome</b>			
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> <li>Alpha-gal syndrome (AGS) is an emerging syndrome only recently identified in 2007. Last year, a CSTE national surveillance case definition was approved to standardize reporting, however, AGS is not a nationally notifiable condition.</li> <li>The MMG that the CDC Program would like to develop would be used by states that would like to include AGS in their list of reportable conditions and to make surveillance more comprehensive and informative for public health actions.</li> <li>These data elements would help inform the burden and trends of AGS, especially regarding exposure history, clinical outcomes, severeness of disease, and laboratory test results.</li> <li>It is important to continue monitoring the epidemiology and emergence of AGS as more states report on it.</li> </ul>		
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority<sup>1</sup></b>
Date of most recent occurrence	Date of most recent reaction that prompted this report (mm/dd/yyyy)	N/A	1
Prior occurrence	Has the patient had prior reactions?	PHVS_YesNoUnknown_CDC	2
Date of first occurrence	Date of first reaction (mm/dd/yyyy)	N/A	2
Signs and Symptoms	Signs and symptoms associated with the illness being reported	TBD	1
Signs and Symptoms Indicator	Indicator for associated sign and symptom	TBD	1
Allergy to food (finding)	Has the patient ever experienced signs or symptoms of an allergic	TBD	1

<sup>1</sup> R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3

	reaction after consumption of any of the following?		
Allergy to drug (finding)	Has the patient ever experienced signs or symptoms of an allergic reaction after receiving any of the following pharmaceutical or medical products?	TBD	1
Anaphylaxis (disorder)	Has the patient ever experienced anaphylaxis due to this condition?	PHVS_YesNoUnknown_CDC	2
Tick bite	In the 12 months before first diagnosis, did the patient notice any tick bites?	PHVS_YesNoUnknown_CDC	2
Performing laboratory name	Testing laboratory	TBD	3

<b>Coronavirus Disease (COVID-19)</b>			
The impetus/urgency for CDC to add data elements for this condition		<ul style="list-style-type: none"> <li>To make surveillance more comprehensive and informative for public health actions</li> <li>To provide lineage data rapidly for surveillance monitoring and efforts.</li> </ul>	
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority<sup>1</sup></b>
Lineage	Lineage designation or sub-lineage, if available.	N/A	2

<b>Cryptosporidiosis</b>			
The impetus/urgency for CDC to add data elements for this condition		<ul style="list-style-type: none"> <li>To make surveillance more comprehensive and informative for public health actions</li> <li>To provide more information about risk factors that have been associated outbreaks</li> <li>To monitor epidemiology</li> <li>To align exposure and risk factor information with that collected on CDC's CryptoNet case investigation form</li> </ul>	
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority<sup>1</sup></b>
Travel Outside USA Prior to Illness Onset within Program Specific	Did the case patient travel internationally?	PHVS_YesNoUnknown_CDC	2

Timeframe			
Did The Case Travel Domestically Prior To Illness Onset?	Indicates whether the case traveled domestically prior to illness onset and within program specific timeframe	PHVS_YesNoUnknown_CDC	2
Specify Different Travel Exposure Window	If the travel exposure window used by the jurisdiction is different from that stated in the travel exposure questions, specify the time interval in days here. Otherwise, leave blank.	N/A	2

<b>Cyclosporiasis</b>			
The impetus/urgency for CDC to add data elements for this condition		<ul style="list-style-type: none"> <li>• During 2020 and 2021, several cyclosporiasis outbreaks likely related to leafy greens were identified, but investigations were impeded by a lack of details necessary to specify a source.</li> <li>• Packaging information will help provide more specific data to inform the identification and investigation of outbreaks related to leafy greens.</li> </ul>	
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority<sup>1</sup></b>
Fresh Lettuce Packaging	For each fresh lettuce exposure reported, indicate the type of packaging of the fresh lettuce	TBD	1

<b>Hepatitis</b>			
The impetus/urgency for CDC to add data elements for this condition		<ul style="list-style-type: none"> <li>• The data elements will contribute to enhanced surveillance efforts for those jurisdictions funded through PS21-2103 “Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments”.</li> <li>• These data elements will improve standardization of data collection for CDC surveillance.</li> <li>• These data elements will improve the overall understanding of the population and factors contributing to viral hepatitis infection.</li> <li>• The enhanced surveillance will be more comprehensive and informative for public health actions and will improve guidance on infection control and prevention.</li> </ul>	
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority<sup>1</sup></b>
Type of Outbreak	If the person is suspected of being part of an outbreak,	PHVS_CSOutbreak_HepatitisB (Per condition)	1

	please select the source of the outbreak.		
Other Reported Cases(s) Prior Years	Select the relevant conditions for which the patient met the CSTE case definition(s) in any previous reporting year. Select all that apply.	TBD	1
Test Conversion	Did the patient meet the program criteria for test conversion for the condition of interest?	PHVS_YesNoUnknown_CDC	1
Birth Sex	Sex assigned at birth	TBD (to align with USCDI standards)	1
Sexual Orientation	A person's identification of their emotional, romantic, sexual, or affectional attraction to another person	TBD (to align with USCDI standards)	1
Gender Identity	A person's internal sense of being a man, woman, both, or neither	TBD (to align with USCDI standards)	1

<b>STD (not congenital)</b>			
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> <li>These data elements will improve standardization of data collection for CDC surveillance and improve the overall understanding of the population and factors contributing to STD infections. The enhanced surveillance will be more comprehensive and informative for public health actions and will improve guidance on infection control and prevention.</li> </ul>		
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority<sup>1</sup></b>
Birth Sex	Sex assigned at birth	TBD (to align with USCDI standards)	1
Sexual Orientation	A person's identification of their emotional, romantic, sexual, or affectional attraction to another person	TBD (to align with USCDI standards)	1
Gender Identity	A person's internal sense of being a man, woman, both, or neither	TBD (to align with USCDI standards)	1