

National Notifiable Diseases Surveillance System (NNDSS)

OMB Control Number 0920-0728

Expiration Date: 03/31/2024

Program Contact

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Submission Date: October 27, 2021

Circumstances of Change Request for OMB 0920-0728

This is a non-substantive change request for OMB No. 0920-0728, expiration date 03/31/2024, for the reporting of Nationally Notifiable Diseases. Information on proposed disease-specific data elements to be added through this non-substantive change request is enumerated in the table below:

Disease Name in NNDSS Collection	Nationally Notifiable (NNC) OR Under Standardized Surveillance (CSS)	Current Case Notification (Y/N)	Proposed Case Notification (Y/N)	Current Disease-specific Data Elements (Y/N)	Proposed Disease-specific Data Elements (Y/N)	Number of Existing Data Elements in NNDSS	Proposed Number of new NNDSS Data Elements
Babesiosis	NNC			Y		73	1
Hepatitis	NNC			Y		179	5
Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19)	CSS			Y		44	10

The National Notifiable Diseases Surveillance System (NNDSS) is the nation’s public health surveillance system that enables all levels of public health (local, state, territorial, federal and international) to monitor the occurrence and spread of the diseases and conditions that CDC and the Council of State and Territorial Epidemiologists (CSTE) officially designate as “nationally notifiable” or as under “standardized surveillance.” The NNDSS program creates the infrastructure for the surveillance system and facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions: public health departments in every U.S. state, New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau). The NNDSS also facilitates relevant data management, analysis, interpretation and dissemination of the information. The data are used to monitor the occurrence of notifiable conditions and to plan and conduct prevention and control programs at the state, territorial, local and national levels.

This request is for the addition of 17 new data elements: 1 new core data element for all conditions, and 16 new disease-specific data elements. The 16 new disease-specific data elements include: 1 new disease-specific data elements for Babesiosis, 5 new disease-specific data elements for Hepatitis and 10 new disease-specific data elements for Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19).

Core: 1 Data Element			
The impetus/urgency for CDC to add data element for all conditions		<ul style="list-style-type: none"> To make surveillance more comprehensive and informative for public health actions To monitor epidemiology To update guidance on infection control and prevention 	
Data Element Name	Data Element Description	Value Set Code	CDC Priorityⁱ
Birth Sex	What was patient's sex at birth?	N/A	1

Babesiosis: 1 Data Element			
The impetus/urgency for CDC to add data elements for this condition		<ul style="list-style-type: none"> The data element included in this request will allow jurisdictions to submit the local record ID of a mother's case within a congenital case. Link reported congenital babesiosis cases to the mother's reported babesiosis case to gain a better understanding and more complete picture of risk factors. Assist in improving CDC's epidemiologic understanding of the rare condition of congenital babesiosis and disease trends over time. 	
Data Element Name	Data Element Description	Value Set Code	CDC Priority¹ (New)
Mother's Local Record ID	Provide the local record ID used for reporting mother's case (DE Identifier "N/A: OBR-3" in the Generic portion of the message). This will be used for linking the reported congenital case to the mother's reported case.	N/A	3

Hepatitis: 5 Data Elements	
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> The data elements included in this change request will contribute to enhanced surveillance efforts for those jurisdictions funded through PS21-2103 "Integrated Viral Hepatitis Surveillance and

¹ R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3

	<p>Prevention Funding for Health Departments”.</p> <ul style="list-style-type: none"> • Improve the overall understanding of the population and factors contributing to viral hepatitis infection. • Enhanced surveillance will be more comprehensive and informative for public health actions and will improve guidance on infection control and prevention. 		
Data Element Name	Data Element Description	Value Set Code	CDC Priority ² (New)
Transplant Date	Date(s) of organ transplant(s).	NA	2
Subject of Lab Test Performed	Indication to specify whether the Lab Test Performed was for the mother or infant.	PHVS_MotherInfantIndicator_NND	1
Previously Infected Individual	Did the subject meet the case definition for a previous case investigation of this disease or condition?	Yes No Unknown (YNU)	2
Previous State Case Number	If the subject previously met the case definition for the disease or illness, what was the previously submitted sending system-assigned local ID (case ID) of the case investigation with which the subject is associated?	N/A	2
Other Reported Case(s)	Select all of the newly reported case(s) of the hepatitis confirmed within the current reporting year other than the primary condition reported for this case notification.	PHVS_NotifiableConditions_Hepatitis	2

Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19): 10 Data Elements	
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> • To allow the CDC COVID-19 response to conduct enhanced domestic surveillance of multisystem inflammatory syndrome in children (MIS-C), a condition which was first identified in April 2020 and was reported out of the UK. This rare but severe condition is temporally related to previous SARS-CoV-2 infection. Due to the urgency in collecting information on these cases to learn more about this condition, a national surveillance system was rapidly developed

² R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3

	<p>and deployed under the COVID-19 public health emergency declaration.</p> <ul style="list-style-type: none"> • 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 enable CDC to assess whether reported cases align with our case definition. Without these elements, it would not be possible to identify incident cases of MIS-C. • Obesity has been associated with adverse outcomes associated with COVID-19; therefore, collecting data elements related to this comorbidity enables investigation of potential links between obesity and MIS-C. • To assist with determination of timeline from acute SARS-CoV-2 infection to MIS-C to better determine the course of illness. • Data elements reflect potential risk factors for MIS-C. It is important to identify which children with SARS-CoV-2 infection are at risk for MIS-C and which children with MIS-C have specific risk factors leading to severe illness. • Data elements covering clinical complications, outcomes, and treatments will optimize diagnostic and treatment practices for MIS-C. • Data elements regarding COVID-19 vaccination are critical to understanding the relationship, if any, between development of MIS-C and receipt of COVID-19 vaccination. • Data elements will allow for better characterization of MIS-C, potentially leading to an update of the case definition. • All health departments have set up their reporting databases to align with the case report form for streamlined reporting and standardization of reporting.
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Data Element Name	Data Element Description	Value Set Code	CDC Priority³ (New)
MIS Inclusion	Did the patient meet all inclusion criteria associated with MIS illness case definition	PHVS_YesNoUnknown_CDC	1
MIS Inclusion Criteria	Inclusion criteria associated with the illness being reported	MIS Inclusion (MIS)	1
MIS Inclusion Criteria indicator	Indicator for associated inclusion criteria	PHVS_YesNoUnknown_CDC	1
Patient outcome date	Date of hospital discharge or death	N/A	1
Medical history	Does the patient have a history of the following illnesses prior to developing MIS-C symptoms?	Patient history (MIS)	1
Medical history indicator	Indicator for associated	Patient history (MIS)	1

³ R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3

	medical history diagnosis		
Date of medical history	Date of past medical history diagnosis	N/A	1
Imaging Study	Listing of imaging studies the subject received for this illness	Imaging Studies	1
Imaging Study indicator	Provide a response for normal or abnormal results for each imaging study received	Normal, Abnormal, Not Done	1
Left ventricular ejection fraction (LVEF) level	Specify left ventricular ejection fraction (LVEF)	1: ≥55%, 2: 50-54% 3: <50%	1

Burden

The burden to add 17 data elements to NNDSS is applicable to all 50 states, 5 territories, 3 freely associated states, and 2 cities. Although not all territories and freely associated states use electronic, automated transmission for their case notifications, it is expected that they will adopt electronic, automated transmission in the next three years. This burden includes the one-time burden incurred by the respondents to add the data elements to their surveillance system and modify their case notification message. A one-time average burden of 2 hours is incurred for respondents to add 17 data elements to their surveillance system and modify their electronic case notification message to accommodate those 17 additional data elements. This one-time burden of 2 hours is noted in the following table:

One-Time Burden to Add 17 Data Elements to NNDSS

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours): One-time Addition of 17 Data Elements
States	50	1	2
Territories	5	1	2
Freely Associated States	3	1	2
Cities	2	1	2

The total annualized one-time burden is 39 hours (33 hours for states, 3 hours for territories, 2 hours for freely associated states and 1 hour for cities) as noted in the table below.

Annualized One-Time Burden to Add 17 Data Elements to NNDSS

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours): Annualized One-time Addition of 17 Data Elements	Total Annualized One-Time Burden (in hours)
States	50	1	40/60	33
Territories	5	1	40/60	3
Freely Associated States	3	1	40/60	2
Cities	2	1	40/60	1
Total				39

39 hours were added to the existing burden hours in Table A.12A and Table A.12B below.

A.12A. Estimates of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
States	Weekly (Automated)	50	52	20/60	867
States	Weekly (Non-automated)	10	52	2	1,040
States	Weekly (NMI Implementation)	50	52	4	10,400
States	Annual	50	1	75	3,750
States	One-time Addition of Diseases and Data Elements	50	1	40/60	800
Territories	Weekly (Automated)	5	52	20/60	87
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93
Territories	Weekly (NMI Implementation)	5	52	4	1,040
Territories	Annual	5	1	5	25
Territories	One-time Addition of	5	1	40/60	80

	Diseases and Data Elements				
Freely Associated States	Weekly (Automated)	3	52	20/60	52
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	40/60	48
Cities	Weekly (Automated)	2	52	20/60	35
Cities	Weekly (Non-automated)	2	52	2	208
Cities	Weekly (NMI Implementation)	2	52	4	416
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements	2	1	40/60	32
Total					19,194

A.12B. Estimates of Annualized Cost Burden

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Respondent Cost
States	Weekly (Automated)	50	52	20/60	867	\$46.23	\$40,081
States	Weekly (Non-automated)	10	52	2	1,040	\$37.64	\$39,146
States	Weekly (NMI Implementation)	50	52	4	10,400	\$46.23	\$480,792
States	Annual	50	1	75	3,750	\$37.64	\$141,150
States	One-time Addition of Diseases and Data Elements	50	1	40/60	800	\$46.23	\$36,984
Territories	Weekly (Automated)	5	52	20/60	87	\$46.23	\$4,022
Territories	Weekly, Quarterly (Non-	5	56	20/60	93	\$37.64	\$3,501

	automated)						
Territories	Weekly (NMI Implementation)	5	52	4	1,040	\$46.23	\$48,079
Territories	Annual	5	1	5	25	\$37.64	\$941
Territories	One-time Addition of Diseases and Data Elements	5	1	40/60	80	\$46.23	\$3,694
Freely Associated States	Weekly (Automated)	3	52	20/60	52	\$46.23	\$2,404
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56	\$37.64	\$2,108
Freely Associated States	Annual	3	1	5	15	\$37.64	\$565
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	40/60	48	\$46.23	\$2,219
Cities	Weekly (Automated)	2	52	20/60	35	\$46.23	\$1,618
Cities	Weekly (Non-automated)	2	52	2	208	\$37.64	\$7,829
Cities	Weekly (NMI Implementation)	2	52	4	416	\$46.23	\$19,232
Cities	Annual	2	1	75	150	\$37.64	\$5,646
Cities	One-time Addition of Diseases and Data Elements	2	1	40/60	32	\$46.23	\$1,479
Total							\$841,490

ⁱ R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3, TBD=To be determined