National Notifiable Diseases Surveillance System (NNDSS)

OMB Control Number 0920-0728
Expiration Date: 04/30/2022

<u>**Program Contact**</u>

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Circumstances of Change Request for OMB 0920-0728

This is a non-substantive change request for OMB No. 0920-0728, expiration date 04/30/2022, 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
Candida auris (*C. auris*)	NNC			N		0	18
Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE)	NNC			Y		8	8
Malaria	NNC			Y		91	9

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 35 new disease-specific data elements: 18 new data element for *Candida auris* (*C. auris*), 8 new data elements for Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) and 9 new data elements for Malaria.

C. auris	
The impetus/urgency for CDC to add data elements for this condition	• To make surveillance more comprehensive and informative for public health actions • To provide more information about factors that have been associated with colonization or infection and with the identification of cases (related cases and conditions, high acuity care needs, healthcare facility exposure, travel, and specimen testing). • To monitor epidemiology • To update guidance on infection control and prevention • To link separate laboratory systems to case information

Data Element Name	Data Element Description	Value Set Code	CDC Priority[1]
Previously Counted Case	Was patient previously counted as a colonization/screening case?	PHVS_YesNoUnknown_CDC	P
Previously Reported State Case Number	If patient was previously counted as a colonization/screening case or a CP-CRE case, please provide the related case ID(s)	N/A	P
Tracheostomy Tube at Specimen Collection	Did patient have a tracheostomy tube at the time of specimen collection?	PHVS_YesNoUnknown_CDC	P
Ventilator Use at Specimen Collection	Was patient on a ventilator at the time of specimen collection?	PHVS_YesNoUnknown_CDC	P
Long-term Care Resident	Did the patient have a stay in a long-term care facility in the 90 days before specimen collection date?	PHVS_YesNoUnknown_CDC	P

[1] R=Required; P=Preferred, O=Optional

Type of Long-term Care Facility	If patient had a stay in a long-term care facility in the 90 days before specimen collection date, indicate the type of long-term care facility.	PHVS_LongTermCare FacilityType_C.auris	P
Healthcare Outside Resident State	Indicate if the patient received overnight healthcare within the United States, but outside of the patient's resident state in the year prior to the date of specimen collection.	PHVS_YesNoUnknown_CDC	P
Travel Outside USA Prior to Illness Onset within Program Specific Timeframe	Did the patient travel internationally in the past 1 year from the date of specimen collection?	PHVS_YesNoUnknown_CDC	P
International Destination(s) of Recent Travel	List the names of the country(ies) outside of the United States the patient traveled to in the year prior to the date of specimen collection, if the patient traveled outside of the United States during that time.	PHVS_Country_ISO_3166-1	P
Healthcare Outside USA	Indicate if the patient received overnight healthcare outside of the United States in the year prior to the date of specimen collection.	PHVS_YesNoUnknown_CDC	P
Country(ies) of Healthcare Outside USA	List the names of the country(ies) outside of the United States where the patient received overnight healthcare in the year prior to the date of specimen collection, if the patient received overnight healthcare outside of the United States during that time.	PHVS_Country_ISO_3166-1	P
Type of Location Where Specimen Collected	Indicate the physical location type of the patient	PHVS_SpecimenCollection	P

	when the specimen was collected	SettingType_C.auris	
County of Facility	County of facility where specimen was collected	PHVS_County_FIPS_6-4	P
State of Facility	State of facility where specimen was collected	PHVS_State_FIPS_5-2	P
Infection with Another MDRO	Does the patient have infection or colonization with another MDRO?	PHVS_YesNoUnknown_CDC	P
Co-infection Type	If patient has infection or colonization with another MDRO, indicate the MDRO.	PHVS_TypeCoInfection_C.auris	P
State Lab specimen ID	State lab specimen ID	N/A	P
WGS ID Number	NCBI SRA Accession number (SRX#) We would describe this as: The accession number generated by NCBI's Sequence Read Archive when sequence data are uploaded to NCBI. This provides both the sequence data and metadata on how the sample was sequenced.	N/A	P

CP-CRE	
The impetus/urgency for CDC to add data elements for this condition	• To make surveillance more comprehensive and informative for public health actions • To provide more information about risk factors (healthcare facility exposure, travel, and specimen testing) that have been associated with colonization or infection • To monitor and expand current epidemiology on an emerging pathogen • To update guidance on infection control and prevention • To link separate laboratory systems to case information

Data Element Name	Data Element Description	Value Set Code	CDC Priority
Travel Outside USA Prior to Illness Onset within Program Specific Timeframe	Did the patient travel internationally in the past 1 year from the date of specimen collection?	PHVS_YesNoUnknown_CDC	P
International Destination(s) of Recent Travel	This data element is used to capture the names of the country(ies) outside of the United States the patient traveled to in the year prior to the date of specimen collection, if the patient has traveled outside of the United States during that time.	PHVS_Country_ISO_3166-1	P
Healthcare Outside USA	This data element is used to capture if the patient received healthcare outside of the United States in the year prior to the date of specimen collection.	PHVS_YesNoUnknown_CDC	P
Country(ies) of Healthcare Outside USA	This data element is used to capture the names of the country(ies) outside of the United States where the patient received healthcare in the year prior to the date of specimen collection, if the patient traveled outside of the United States during that time.	PHVS_Country_ISO_3166-1	P

Gene Identifier	Gene identifier	PHVS_GeneName_CP-CRE	P
Previously Counted Case	Was patient previously counted as a colonization/screening case?	PHVS_YesNoUnknown_CDC	P
Previously Reported State Case Number	If patient was previously counted as colonization/screening case please provide related case ID(s)	N/A	P
WGS ID Number	NCBI SRA Accession number (SRX#) We would describe this as: The accession number generated by NCBI's Sequence Read Archive when sequence data are uploaded to NCBI. This provides both the sequence data and metadata on how the sample was sequenced.	N/A	P

Malaria			
The impetus/urgency for CDC to add data elements for this condition	• To make surveillance more comprehensive and informative for public health actions • To assess treatment timeliness and appropriateness of care • To better monitor for adverse events related to antimalarial medications		
Data Element Name	**Data Element Description**	**Value Set Code**	**CDC Priority**
Admitted as Inpatient	Was subject admitted to the hospital for greater than 24 hours as an inpatient?	PHVS_YesNoUnknown_CDC	P
Date Treatment or Therapy Started	Date the treatment was initiated	N/A	P
Date Treatment or Therapy Stopped	Date treatment stopped	N/A	P
Treatment Duration	Number of days the patient was prescribed antimalarial treatment	N/A	P
Medication Administered Relative to Treatment	Indicate if the patient took the medication 2 weeks before treatment or within the 4 weeks after starting treatment.	PHVS_MedicationAdministered RelativeTreatment_Malaria	P
Medication Administered	Please list all prescription and over the counter medicines the patient had taken during the 2 weeks before and during the 4 weeks after starting treatment for malaria. If information for both pre- and post-treatment are available, please complete below questions for each time frame.	N/A	P
Medication Start Date	Medication Start Date	N/A	P
Medication Stop Date	Medication Stop Date	N/A	P
Medication Duration	Number of days that patient took the medication referenced	N/A	P

Burden

Burden to add 35 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 4 hours is incurred for respondents to add 35 data elements to their surveillance system and modify their electronic case notification message to accommodate those 35 additional data elements. This one-time burden of 4 hours is noted in the following table:

One-Time Burden to Add 35 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 35 Data Elements	
States	50	1	4	
Territories	5	1	4	
Freely Associated States	3	1	4	
Cities	2	1	4	
Total				

The total annualized one-time burden is 60 hours (50 hours for states, 5 hours for territories, 3 hours for freely associated states and 2 hours for cities) as noted in the table below.

Annualized One-Time Burden to Add 35 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 35 Data Elements	Total Annualized One-Time Burden (in hours)
States	50	1	1	50
Territories	5	1	1	5

Freely Associated States	3	1	1	3
Cities	2	1	1	2
Total				60

60 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	21	1,050
States	One-time SO/GI Survey	12	1	5/60	1
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 Diseases and Data Elements	5	1	10	50
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	7	21

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	21	42
Total					19,398

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	$44.59	$38,660
States	Weekly (Non-automated)	10	52	2	1,040	$36.65	$38,116
States	Weekly (NMI Implementation)	50	52	4	10,400	$44.59	$463,736
States	Annual	50	1	75	3,750	$36.65	$137,438
States	One-time Addition of Diseases and Data Elements	50	1	21	1,050	$44.59	$46,820
States	One-time SO/GI Survey	12	1	5/60	1	$36.65	$37
Territories	Weekly (Automated)	5	52	20/60	87	$44.59	$3,879
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93	$36.65	$3,408
Territories	Weekly (NMI Implementation)	5	52	4	1,040	$44.59	$46,374
Territories	Annual	5	1	5	25	$36.65	$916
Territories	One-time Addition of Diseases and Data Elements	5	1	10	50	$44.59	$2,230
Freely Associated States	Weekly (Automated)	3	52	20/60	52	$44.59	$2,319

Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56	$36.65	$2,052
Freely Associated States	Annual	3	1	5	15	$36.65	$550
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	7	21	$44.59	$936
Cities	Weekly (Automated)	2	52	20/60	35	$44.59	$1,561
Cities	Weekly (Non-automated)	2	52	2	208	$36.65	$7,623
Cities	Weekly (NMI Implementation)	2	52	4	416	$44.59	$18,549
Cities	Annual	2	1	75	150	$36.65	$5,498
Cities	One-time Addition of Diseases and Data Elements	2	1	21	42	$44.59	$1,873
Total							**$822,575**