NATIONAL DISEASE SURVEILLANCE PROGRAM - II. DISEASE SUMMARIES

OMB 0920-0004

Extension with Revisions
January 19, 2007

Point of Contact
Anne O'Connor, MS, MT(ASCP)
Centers for Disease Control and Prevention
NCID/OD/OPPE

1600 Clifton Road, NE, Mailstop C12
Atlanta, GA 30333
Telephone: (404) 639-1042
Electronic mail: AEO1@cdc.gov

Supporting Statement – National Disease Surveillance Program - II. Disease Summaries
OMB 0920-0004

The information collection, "National Disease Surveillance Program - II. Disease Summaries," is an ongoing surveillance activity at the Centers for Disease Control and Prevention (CDC). This request is for a three-year renewal of clearance with minor changes, two new forms for influenza surveillance via the internet and a *Listeria* case form are added.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Surveillance of the incidence and distribution of disease has been an important function of the U.S. Public Health Service since 1878. Through the years, PHS/CDC has formulated practical methods of disease control through field investigations.

The CDC surveillance program is based on the premise that diseases cannot be diagnosed, prevented or controlled until existing knowledge is expanded and new ideas developed and implemented. Over the years the mandate of CDC has broadened to include preventive health activities and the surveillance systems maintained have expanded. Attachment B contains descriptive summaries of each disease/condition under surveillance, an explanation of significant revisions to the forms, and the impact on burden estimates. This surveillance program is authorized under the provisions of Section 301 of the Public Health Service Act, (42 USC 241) (Attachment A).

Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologists (CSTE). Changes in the surveillance program and in reporting methods are effected in the same manner. At the beginning of this surveillance program in 1968, CSTE and CDC decided which diseases warranted surveillance. These diseases are reviewed and revised based on variations in the public's health. Surveillance forms are distributed to State and local health department staff, who voluntarily submit these reports to CDC on variable frequencies—weekly, monthly, or quarterly. CDC then calculates and publishes weekly statistics via the *Morbidity and Mortality Weekly Report* (MMWR), providing the states with timely aggregates of their submissions.

The following diseases/conditions are included in this program:

Arboviral diseases (including West Nile Viruses)
Campylobacter
Caliciviruses
Cholera and other Vibrio illnesses
Foodborne Outbreaks
Enteroviruses
Influenza Virus
Rabies
Respiratory and Enteric
Shigella
Salmonella
Waterborne Outbreaks
Listeria

2. Purpose and Use of Information Collection

State and Territorial Epidemiologists are responsible for the collection, interpretation and transmission of medical and epidemiologic information at the state level. Disease Summaries are submitted by State Health Departments to CDC where the data are tabulated, analyzed for trends, published, and distributed within the health community. By coordinating nationwide collection of epidemiological data, CDC is able to calculate annual between-state comparisons of diseases covered under this request.

These data are essential on the Local, State, and Federal levels for measuring trends in diseases, evaluating the effectiveness of current preventive strategies, and determining the need for modifying current preventive measures. For example, data collected in real time via ArboNet, allows CDC to monitor the West Nile Virus (WNV) epidemic on a weekly basis instead of the several months to one year lag time that previously existed. Because this system has expanded to include nonhuman cases such as equine, birds, and mosquito pools, CDC can provide states with a more accurate picture of the evolution of the epidemic. This in turn leads to more effective education about WNV for clinicians, public health workers, and the general public. Since dead birds usually serve as the first clue that WNV is present in an area, timely testing and reporting allows local areas to educate and warn the public through public service announcements reminding people to protect themselves against the virus while spending time outdoors.

Another example of disease monitoring to better describe and respond to outbreaks is the addition of CaliciNet, a system to collect epidemiologic information on norovirus outbreaks. Norovirus outbreaks on cruise ships receive much publicity. Reporting of gastrointestinal outbreaks is required by law on cruise ships, but only foodborne outbreaks of gastroenteritis are reportable condition on land. Yet many norovirus outbreaks are not foodborne. CDC has been testing outbreaks for noroviruses for over 10 years, most recently using RT-PCR. Increasingly state public health laboratories have been testing for noroviruses, and currently three quarters of all norovirus outbreaks are diagnosed by the states and a quarter by CDC. RT-PCR has allowed for norovirus strains to be sequenced and the development of CaliciNet, a nationwide database of norovirus sequences has allowed comparison of norovirus sequences from different outbreaks. For effective interpretation of the significance of similar sequences, however, some epidemiological information is required, and is collected by the form “Report of Outbreak of suspected viral gastroenteritis”. Data collected under CalicNet will allow CDC to link outbreaks of suspected viral gastroenteritis together and assist in the development of control measures.

3. Use of Improved Information Technology and Burden Reduction

The methodology for reporting varies depending on the occurrence, modes of transmission, infectious agents, and epidemiologic measures. The reporting of diarrheal diseases, for example, is done via an electronic reporting system, the Public Health Laboratory Information System (PHLIS). The information on individual isolates is reported from state public health laboratories to CDC electronically, in real time, as cases occur. Electronic reporting through PHLIS was implemented in 1990. Laboratory-based surveillance provides a mechanism to rapidly detect

unusual patterns in the incidence of enteric pathogens, including *Salmonella*, *Shigella*, and *Campylobacter*.

Historically, use of data collected by the foodborne disease outbreak system had been slowed because of the long time required for data entry and coding once the forms were received. In 2001, CDC introduced electronic reporting of foodborne outbreak data through the Electronic Foodborne Outbreak Reporting System (EFORS). EFORS is a web-based reporting system that collects the same information as the paper forms, and can be used by local, county, or State organizations to enter, edit and analyze data and to transmit data electronically to other State or federal offices. All reports beginning with 2001 data are entered into EFORS.

ArboNet involves 100% electronic reporting of national arbovirus surveillance data, with no forms. Fax and phone are secondary collection methods used in more urgent situations. Frequency of reporting to ArboNet by 57 state and local participating jurisdictions is highly variable. During the arbovirus transmission season (roughly May through October), some jurisdictions report daily, while others batch-report at variable intervals ranging from every few days to weekly or longer. During the "off-season", states report on an irregular basis while they clean-up their annual data. West Nile Virus is reported electronically on a single data entry screen, reducing the burden on respondents, and allowing participants rapid access to the data provided.

Influenza surveillance data (e.g. influenza-like illness and influenza viral surveillance) are reported on a weekly basis via a facsimile transmission or direct data entry over the Internet. A subset of the laboratories reporting viral information transmit data electronically via the PHLIS system (mentioned above). Reporting can be divided into sites that report only during the traditional influenza season (Oct. to May) and those sites that report year round. Forms for reporting during season and year round are identical.

The enterovirus surveillance system uses an MS Excel spreadsheet to list each detection report. The report is completed by the respondents, then emailed to the coordinator for entry into an MS Access database.

For the National Respiratory and Enteric Virus Surveillance System (NREVSS), reporting is conducted weekly using a secure CDC website. Staff report that electronic reporting allows immediate processing and analysis of national trends and allows for data correction by participating centers.

For the reporting of rabies, most of the respondents have converted the hard-copy form to an electronic version, and from that to an electronic spreadsheet to report cases.

Reports on *Vibrio* illnesses, including cholera, are reported to CDC using the Cholera and other *Vibrio* Illnesses Surveillance Form. Reports are faxed by state public health department officials to CDC as they are completed.

The information requested is the minimum amount required to maintain surveillance of these selected diseases.

4. Efforts to Identify Duplication and Use of Similar Information

CDC staff is in constant communication with the State and Territorial Health Officers, as well as with staff of State and Local health departments. Through this communication and their reliance on this data it has become evident that no other nationwide collection of disease-specific surveillance systems exist that monitors these diseases. Other information on the diseases included in this package is available only for limited geographic areas or collected in one-time studies. Literature searches and communication with other health professionals have revealed that the other information is not a suitable replacement for a national surveillance system. The information collected under this surveillance system is of a continuing nature and facilitates a uniform collection of data from all states and territories of the country.

5. Impact on Small Businesses and Other Small Entities

This collection of information does not involve small businesses or other small entities.

6. Consequences of Collecting Information Less Frequently

Control of diseases is dependent on rapid identification of changes in disease transmission. The frequency requested for submission of forms in this package is dependent on the particular epidemiology of the disease in question and is discussed individually for each form. Without prompt notification to CDC of disease incidence, generally on a weekly basis, epidemics and outbreaks might go undetected and a large number of cases result from failure to implement control and prevention measures.

Timely collection of information allows rapid analysis of data to detect unusual disease clusters, which is necessary to recognize foodborne outbreaks. A statistical algorithm that detects unusual clusters is applied to information collected in PHLIS.

During the arbovirus transmission season (roughly May through October), ArboNet surveillance "products" include weekly updates of national/regional/local maps on the U.S. Geological Survey (USGS) web site (www.usgs.gov), and weekly-to-monthly summary reports in CDC's flagship publication, the Morbidity and Mortality Weekly Report. Various annual reports are also produced. Internal CDC reports are generated daily to weekly during the transmission season, depending on the intensity of transmission.

Influenza surveillance data received by CDC on a weekly basis are analyzed and presented in a weekly influenza surveillance report that is distributed to public health professionals, media, and the general public. Due to the variability of influenza activity, weekly data reporting allows staff to more closely monitor influenza activity.

Monthly reports of enterovirus detections in the US via National Enterovirus Surveillance aids in establishing seasonal trends. Each year, the peak activity occurs in the summer months. However, varying types of enteroviruses in a given year may result in earlier or later peak activity.

The weekly reports collected via NREVSS are analyzed by CDC staff and the results are immediately updated on a public CDC website. Real-time data allow physicians and public health officials to make decisions based on the most up to date surveillance reports of viral activity in their area.

For rabies submission of cases is carried out on a monthly basis.

Cholera and other Vibrio illnesses information sent to CDC as cases occur allows timely coordinated national surveillance, which improves the monitoring of outbreaks and effectiveness of prevention measures.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

This collection of information is consistent with 5 CFR 1320.5 except for one aspect. Surveillance reports are requested on a periodic basis to permit rapid response to public health problems and prompt initiation of prevention and control measures. As stated in A.6., delays in reporting could result in serious public health consequences.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A copy of the December 5, 2005 Federal Register notice, Volume 70, No. 232, page 72435-72436 is enclosed (Attachment C). No public comments were received.

B. The Council of State and Territorial Epidemiologists (CSTE) is annually consulted regarding the availability of data and frequency of collection, and the revisions of any forms. The Executive Director of CSTE is: Patrick McConnon, (770) 458-3811. The Chairman of the Surveillance Policy Group, a subcommittee of the Executive Committee, is Allen Craig, Tennessee State Epidemiologist, allen.craig@state.tn.us, (615) 741-7247.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has determined that the Privacy Act is applicable to those forms in which full names are being collected (as verified in the form examples attached to this application). Where applicable, these forms are maintained as a system of records under Privacy

Act system of records notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems." However, most of the forms included in this package do not bear personal identifiable information.

Records are safeguarded appropriately. Access is limited to personnel whose official job duties require them to utilize the records. Paper forms are kept in locked file cabinets in a locked room. Computer files are password protected. State health departments reporting patient names electronically encrypt identifiers before sending them to CDC.

For the diarrheal disease case surveillance, identifiers are maintained at the state or local health department, and information is encrypted before data are transmitted to CDC. CDC does not have the capability of un-encrypting identifiers. For Cholera and other *Vibrio* surveillance, identifiers are maintained by state or local health department, and information is de-identified before sending to CDC. These systems are pass-word protected electronic databases and accessible by authorized users only. None of these surveillance systems are subject to IRB review and approval.

State and local health departments use personally identifiable information to support local disease control activities related to Foodborne Outbreaks, however, personally identifiable information related to Foodborne Outbreak surveillance is not submitted to CDC. Non-identifiable data relating to Foodborne Outbreaks is submitted to CDC via a secure system called EFORS (Electronic Foodborne Outbreak Reporting System).

Identifiable information is removed from the Listeria Case Report form before data are reported to CDC.

ArboNet involves 100% electronic reporting of national arbovirus surveillance records via CDC's Secured Data Network (SDN). Types of records include human disease cases, horse disease cases, bird infections, and mosquito infections. To report records to ArboNet, all respondents must have a CDC digital certificate issued by Verisign. No patient names or other unique personal identifiers are collected. States encode each human report with unique State Identification number of their choosing. CDC has no direct means of linking these State Identification numbers to individual persons. The geographic resolution of data collection in ArboNet is limited to the county level. i.e., if a human disease case is reported to ArboNet, the county of residence is included but not city/town or any more detailed geographic information. ArboNet records are only included for publication in CDC reports after states have confirmed that the information contained the record is in the public domain via a positive check-off system.

In the influenza surveillance system, no personal identifiers are reported to CDC and data collected is not subject to IRB approval.

The National Enterovirus surveillance system collects the age, gender and state of residence of the patient. These data are not identifiable and are not given any identifier that could be traced back to the patient. Once entered into the reporting excel spreadsheet, the sheet is emailed to the coordinator.

NREVSS data are collected through a secure website within the CDC. No identifiers are included in this surveillance system. The respondents only submit the total number of tests performed for each virus and the total number of positive results. No person-level data is collected. Once entry is complete, the data are housed on a secure SQL server, accessible only by the Office of Informatics technical developer and the NREVSS coordinator.

The majority of cases of rabies reported in the United States are in domestic or wildlife animal populations and thus personally identifiable information does not apply. Human cases reported through this system do not include any personally identifiable information, but such information may be maintained in state records. Generally only one to two cases of human rabies are reported each year and are reported as case studies in MMWR.

11. Justification for Sensitive Questions

Epidemiologic characteristics such as age, sex, and geographic location are routinely collected because of their significance in resolving public health problems. Some forms also include Race and Ethnicity data, which may be considered sensitive by some persons, but are routinely collected in HHS/CDC data collections. CDC does not collect race/ethnicity information on the following forms: foodborne outbreaks, influenza surveillance, respiratory and enterovirus surveillance, laboratory confirmed cases of rabies, waterborne disease outbreaks, and CaliciNet, because, race/ethnicity are not key risk factors for contracting these diseases. If race/ethnicity is not an integral part of epidemiologic investigation, it is not collected. Clinical laboratory data are collected and reported when that information is essential to proper identification and control of the particular health problem. Only the minimum data necessary is collected on all surveillance forms.

12. Estimates of Annualized Burden Hours and Costs

A. The total burden estimate for all forms is 21,107 hours in Table 1. Burden estimates are based on previous experience with these instruments.

Table 1 – Estimate of Annualized Burden Hours

Form	#Respondents	#Responses per Respondents	Avg.Burden	Total Burden Hours
Diarrheal Disease Surveillance:				
-*Campylobacter* (electronic)	53	52	3/60	138
-*Salmonella* (electronic)	53	52	3/60	138
-*Shigella* (electronic)	53	52	3/60	138
Foodborne Outbreak Form (CDC 52.13)	54	25	15/60	338
Arboviral Diseases (including West Nile Viruses) (electronic)	57	1421	4/60	5,400
Influenza:				

Form	#Respondents	#Responses per Respondents	Avg.Burden	Total Burden Hours
-Influenza virus (fax, Oct-May) (CDC 55.31)	8	33	10/60	44
-Influenza virus (fax, year round) (CDC 55.31)	15	52	10/60	130
*** Influenza virus (Internet; Oct-May) (CDC 55.31)	13	33	10/60	72
*** Influenza virus (Internet;year round) (CDC 55.31)	24	52	10/60	208
-Influenza virus (electronic, Oct-May) (PHLIS)	9	33	5/60	25
-Influenza virus (electronic, year round) (PHLIS)	14	52	5/60	61
Influenza Annual Survey (CDC 55.31A)	83	1	15/60	21
Influenza-like Illness (Oct-May) (CDC 55.20)	824	33	15/60	6798
Influenza-like Illness (year round) (CDC 55.20)	496	52	15/60	6448
National Enterovirus Surveillance Report: (CDC 55.9) (electronic)	25	12	15/60	75
National Respiratory & Enteric Virus Surveillance System (NREVSS) (CDC 55.83A-D) (electronic)	90	52	10/60	780
Rabies (electronic) (CDC 55.28)	50	12	8/60	80
Rabies (paper) (CDC 55.28)	3	12	15/60	9
Waterborne Diseases Outbreak Form (CDC 52.12)	57	1	20/60	19
Cholera and other *Vibrio* illnesses (CDC 52.79)	450	1	20/60	150
Outbreak Report of Suspected Viral Gastroenteritis (Calicivirus surveillance)	20	5	5/60	8
*** Listeria Case Form	53	1	30/60	27
Total				21,107

*** New form.

B. The estimated annual cost to respondents is $489,682.40. Assuming an hourly respondent average labor wage of $23.20 based on data from the Bureau of Labor Statistics web site (see http://www.bls.gov/opub/ted/2002/sept/wk3/art03.htm) for state workers. The total annual burden for this request is 21,107 and is presented in Table 2.

Table 2 – Estimated Annualized Burden Costs

Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent C
Diarrheal Disease Surveillance						
-*Campylobacter* (electronic)	53	52	3/60	138	$23.20	$3,20
-*Salmonella* (electronic)	53	52	3/60	138	$23.20	$3,20
-*Shigella* (electronic)	53	52	3/60	138	$23.20	$3,20
Foodborne Outbreak Form	54	25	15/60	338	$23.20	$7,84
Arboviral Diseases (including West Nile Virus)	57	1,421	4/60	5,400	$23.20	$125,28
Influenza						
-Influenza virus (fax, Oct-May) (CDC 55.31)	8	33	10/60	44	$23.20	$1,02
-Influenza virus (fax, year round) (CDC 55.31)	15	52	10/60	130	$23.20	$3,01
*** Influenza virus (Internet; Oct-May) (CDC 55.31)	13	33	10/60	72	$23.20	$1,67
*** Influenza virus (Internet;year round) (CDC 55.31)	24	52	10/60	208	$23.20	$4,82
-Influenza virus (electronic, Oct-May) (PHLIS)	9	33	5/60	25	$23.20	$58
-Influenza virus (electronic, year round) (PHLIS)	14	52	5/60	61	$23.20	$1,41
Influenza Annual Survey (CDC 55.31A)	83	1	15/60	21	$23.20	$48
Influenza-like Illness (Oct-May) (CDC 55.20)	824	33	15/60	6,798	$23.20	$157,71
Influenza-like Illness (year round) (CDC 55.20)	496	52	15/60	6,448	$23.20	$149,59
National Enterovirus Surveillance Report: (CDC 55.9) (electronic)	25	12	15/60	75	$23.20	$1,74
National Respiratory & Enteric Virus Surveillance System (NREVSS) (CDC 55.83A-D) (electronic)	90	52	10/60	780	$23.20	$18,09
Rabies (electronic) (CDC 55.28)	50	12	8/60	80	$23.20	$1,85
Rabies (paper) (CDC 55.28)	3	12	15/60	9	$23.20	$20
Waterborne Diseases Outbreak Form (CDC 52.12)	57	1	20/60	19	$23.20	$44
Cholera and other Vibrio Illnesses (CDC 52.79)	450	1	20/60	150	$23.20	$3,48
Outbreak Report of Suspected Viral Gastroenteritis	20	5	5/60	8	$23.20	$18
Listeria Case Form	53	1	30/60	27	$23.20	$62

Total	2,601					$489,68

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital and maintenance costs incurred by respondents.

14. Annualized Cost to the Government

Each data case report results in action taken by multiple programs in response to the required CDC mandate in maintaining preventive health activities and surveillance systems. The action taken will vary, depending on the specifics of the data reporting involving multiple staff. The cost of conducting the study to the government is estimated based on the expenses incurred in the following categories: salary, computer resources, printing, mailing, and miscellaneous, such as (telephone calls and stationary supplies). The estimated annual cost to the government is $40,000.

15. Explanation for Program Changes or Adjustments

This is a request for renewal and the current inventory is 21,107 hours. This is an increase of 8,966 hours since the last approval in 2003. Decreased in burden due to a fewer number of waterborne diseases outbreak cases. Increase of burden hours for NREVSS is a result of new respondent recruitment and has had no effect on the average amount of burden per respondent. Increase in burden due to increased foodborne outbreak reporting areas. Increase in burden due to increased sites participating in influenza surveillance during the traditional season (Oct to May) as well as year round. In addition, two new formats introduced for Internet reporting. The increase in burden hours for surveillance of cholera and other Vibrio illnesses is due to an increase in reporting areas. An increase in burden hours due to foodborne outbreak surveillance is due to an increase in reporting areas. Increase in the number of times ArboNet is accessed by states for reporting purposes, reflecting overall increase in arbovirus surveillance data collected nationwide. Calciviruses (Suspected Viral Gastroenteritis, non-foodborne noroviruses) cases result in a decrease in burden as a result of states conducting their own testing and do send data to CDC as the technology has become more widespread. Increase due to the addition of the new Listeria case report form.

Table 3 – Change in Burden

Form	**Currently Requested Burden**	**Previous Burden**	**Change in burden hours**
Diarrheal Disease Surveillance:			
-*Campylobacter* (electronic) (PHLIS)	138	138	0
-*Salmonella* (electronic) (PHLIS)	138	138	0
-*Shigella* (electronic) (PHLIS)	138	138	0
Foodborne Outbreak Form	338	325	+13

Form	Currently Requested Burden	Previous Burden	Change in burden hours
Arboviral Diseases (including West Nile Viruses) (electronic)	5,400	3,099	+2301
Influenza:			
-Influenza virus (fax, Oct-May) (CDC 55.31)	44	242	-198
-Influenza virus (fax, year round) (CDC 55.31)	130	104	+26
***- Influenza virus (Internet, Oct-May) (CDC 55.31)	72	0	+72
***- Influenza virus (Internet, year round) (CDC 55.31)	208	0	+208
-Influenza virus (electronic, Oct-May) (PHLIS)	25	39	-14
-Influenza virus (electronic, year round) (PHLIS)	61	43	+18
Influenza Annual Survey (CDC 55.31A)	21	20	+1
Influenza-like Illness (Oct-May) (CDC 55.20)	6,798	5,115	+1683
Influenza-like Illness (year round) (CDC 55.20)	6,448	1,690	+4758
National Enterovirus Surveillance Report: - (CDC 55.9) (electronic)	75	75	0
National Respiratory & Enteric Virus Surveillance System (NREVSS) (CDC 55.83 A-D)	780	771	+9
Rabies (electronic) (CDC.55.28)	80	80	0
Rabies (paper) (CDC 55.28)	9	9	0
Waterborne Diseases Outbreak Form (CDC 52.12)	57	40	17
Cholera and other *Vibrio* illnesses	150	100	+50
Outbreak Report of Suspected Viral Gastroenteritis	8	13	-5
*** Listeria Case Form	27	0	+27

*** = New Form

16. Plan for Tabulation and Publication and Project Time Schedule

Data collected as part of the CDC surveillance activities are published frequently in the *MMWR* and in the Surveillance Summaries published periodically as part of the *MMWR*. In addition, the data are included in the *MMWR* Annual Summary, in individual surveillance reports prepared on individual diseases under surveillance, and in journals related to individual diseases.

Data on diarrheal disease case surveillance (for *Salmonella* and *Shigella*) are published as an annual summary and posted on the CDC website. The many reports that CDC generates from ArboNet are considered adequate feedback to participants.

Data collected through the influenza surveillance system are compiled and analyzed on a weekly basis and published in the weekly influenza surveillance report that is distributed to public health professionals, the media, as well as the general public (report is available online). Once laboratory and influenza-like illness data have been cleaned, datasets for each season are also made available via the Influenza website.

Approximately every two years, a summary of enteroviral activity is reported in the MMWR. In years with a large burden of disease or with outbreaks of public interest, additional reports are published. In the future, there are plans to publish on CDC's public website tabular data of national activity for the current year, as well as historic data by state.

Graphs are updated weekly on the CDC's public website for NREVSS. In addition, MMWR reports of viral activity are published each year for RSV, and occasionally for other viruses included in the surveillance system. Reports are also periodically published in peer-reviewed journals.

Rabies surveillance data is tabulated and reported annually in the December issue of the Journal of the American Veterinary Medical Association in order to reach practicing veterinarians.

Data on *Vibrio* illnesses from the Cholera and Other *Vibrio* Illnesses Surveillance System (COVIS) are published as an annual letter to members of the Council of State and Territorial Epidemiologists (CSTE) and posted on the CDC website.

Data on Calicinet (suspected Viral Gastroenteritis) have been published in the Journal of Infectious Diseases in 2006.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Many of the disease summary forms included in this request have required only minor modifications since first approved. Because of their long period of use, paper forms still in use are printed in large quantities. It is requested that permission be granted to exclude the expiration date from all disease summary forms included in this request.

18. Exceptions to Certification for Paperwork Reduction Act Submission

As stated in A.17 above, many of these reports are rarely revised and are in stock at the time of the routine expiration date. Because of this also, the public burden statement has not been revised on most of the forms. The most current statement will be added to each form upon OMB approval of the current package and reprinting of the forms.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

   No sample selection is involved in this surveillance study. The surveillance report forms and instructions are distributed to all States and Territories of the United States. State and local health department staff submits these reports to CDC on variable frequencies ---- weekly, monthly, or quarterly. In certain circumstances, such as outbreak situations, reports are first made by telephone, and then followed by a written report. CDC then calculates and publishes weekly statistics via the *Morbidity and Mortality Weekly Report* (MMWR), providing the states with timely aggregates of their submissions.

2. Procedures for Collection of Information

   Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologist (CSTE). Changes in the surveillance program and in reporting methods are affected in the same manner. At the beginning of this surveillance program CSTE and CDC decided which diseases warranted surveillance. These diseases are reviewed and revised based on variations in the public's health.

3. Methods to Maximize Response Rates and Deal with Non-response

   There is not a method to deal with non-response as the state public health laboratories submit the disease surveillance forms as a part of their job to perform a public health service. Therefore, the response rate is expected to be 100%.

4. Test of Procedures or Methods to be Undertaken
   This a revision of a previously approved data collection, only minor changes to the data collection instruments have been made. No other test of procedures has been performed.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Patrick McConnon
Council of State and Territorial Epidemiologists (CSTE)
Executive Director
(770) 458-3811

ATTACHMENTS

Attachment A - Section 301 of the Public Health Service Act (42 USC 241).
Attachment B - Data Collection Forms and Summaries of Forms
Attachment C – 60 Day Federal Register Notice

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

DIARRHEAL DISEASE SURVEILLANCE

The three most common bacterial causes of diarrhea in the United States are *Salmonella, Campylobacter*, and *Shigella*. The Council of State and Territorial Epidemiologists has endorsed the need for CDC to maintain surveillance for all three infections. The data are essential to measure trends, recognize multi-state or international outbreaks, and evaluate effectiveness of prevention efforts.

The surveillance system involves entry of data into an electronic reporting system which was implemented in 1990, the Public Health Laboratory Information System (PHLIS) by State Health Departments. PHLIS is a PC-based reporting system for local, county, or State organizations to enter, edit and analyze data and to transmit data electronically to other State or federal offices. PHLIS was developed by CDC, and is potentially capable of handling any data types (epidemiologic, laboratory, hospital, special studies, etc.). The laboratories are asked to enter information on human and nonhuman isolates. Data requested include: species/serotype, patient's name (which are encrypted prior to coming to CDC, see justification below), age, sex, county of residence, residence type at onset, and specimen from which isolate was obtained (stool, blood, other). Cooperating State Health Departments report to CDC, by phone if there is something felt to be urgent. Currently, information concerning isolates is electronically reported each week through PHLIS from all 50 states and selected territories. Patient name or other identifiers are maintained at the state health department and are stripped electronically before information is transmitted to CDC. The switch to electronic entry and reporting also improved the function of the systems in other ways, reducing time needed for data entry and transmission and analysis, and giving the participants more ready access to the data.

Form name	No. of respondents	No. of responses/respondent	Hrs/response	Total burden in hrs.
Campylobacter (Electronic) (PHLIS)	53	52	3/60	138
Salmonella (Electronic) (PHLIS)	53	52	3/60	138
Shigella (Electronic) (PHLIS)	53	52	3/60	138

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

MONTHLY REPORT OF LABORATORY CONFIRMED CASES OF RABIES (CDC 55.28)

Because of the severity of the disease, prevention of rabies is essential. The acute encephalomyelitis is usually fatal. Most exposures are caused by the bite of an infected animal. Changes in patterns of animal rabies are detected by monthly reporting. An accurate assessment of the occurrence of rabies is essential for determining if post exposure prophylaxis is necessary. Surveillance of the raccoon rabies epizootic in the mid-Atlantic states has led to efforts to develop control measures for rabies in wildlife. The number of cases of rabies in domesticated cats has exceeded the number of cases in dogs each year since 1981, except 1987. This observation has led to greater efforts to develop more stringent vaccination requirements for cats. During the period from 1990 through 1998, 20 of 22 human rabies deaths caused by infections acquired within the United States were the result of variants of the rabies virus known to be associated with rabid bats. Resulting increased awareness of risk associated with bat bites and enhanced reporting of taxonomic descriptions of the species of bats involved with human exposures to better understand the natural history of rabies in bats have resulted in increases in rabies surveillance activity. Human rabies cases are reported with the same form, with human filled in the other species category. With only 2-3 cases a year, these are usually presented individually as case reports in *MMWR.*

Information collected in this surveillance system is published annually in the *MMWR* and tabulated in the *MMWR Annual Summary*.

Since the 1989 report and in all subsequent reports, CDC first publishes in the *Journal of the American Veterinary Medicine Association* to reach practicing veterinarians.

Form name	No. of respondents	No. of responses/respondent	Hrs/response	Total burden in hrs.
Rabies (Paper)	3	12	15/60	9
Rabies (Electronic)	50	12	8/60	80

Changes to form include:
Title and Address for reports clearance officer have been updated. CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, GA 30333; ATTN: PRA (0920-0004)

Form Description for the Information Collection "National Disease Surveillance Program - II.

Disease Summaries," OMB No. 0920-0004

NATIONAL RESPIRATORY AND ENTERIC VIRUS SURVEILLANCE SYSTEM (NREVSS) - Forms 55.83A-D

Respiratory viruses reported using this form include RSV, PIV, Res. Adenovirus and influenza, and Enteric viruses include Rotatvirus and Adenoviruses 40 and 41. Respiratory syncytial virus (RSV) is the most important viral respiratory tract pathogen of infants and young children, and may cause serious disease in immunocompromised patients and the elderly. Annual epidemics are associated with increased rates of pneumonia and bronchiolitis hospitalization among infants and young children. The human parainfluenza viruses (HPIV) are also important respiratory pathogens in children, and epidemics are associated with increases in physician visits for bronchiolitis, croup, and pneumonia. RSV, HPIV, and adenoviruses are important causes of nosocomial pneumonia and other lower respiratory tract illness. Rotavirus is the most common cause of severe diarrhea in children in the United States, with an estimated 3 million cases and 70,000 hospitalizations per year.

Since January 1989, selected clinical and public health laboratories have reported to CDC the number of specimens tested and number of specimens positive for RSV, HPIV, adenovirus, and rotavirus. The purpose of this surveillance system is to track temporal and geographic trends for these viruses and to make the findings available to public health care professionals and health-care providers in a timely fashion. The primary objective of the system is to identify epidemics geographically, and not to enumerate cases.

In July 1990 the reporting was changed from monthly to weekly reporting with a computerized telephone polling system and results were collected by diagnostic testing method (antigen detection testing, virus isolation, electron microscopy and PCR added in 2004). In 2002, the system was changed again to transfer all data entry to the online system. Weekly electronic reporting allows immediate processing and analysis of national trends and allows for data correction by participating centers. Influenza data collection was added July 1997 to increase reporting to influenza surveillance systems, and allows the reporting of influenza during non-influenza surveillance season.

Annual summaries and alerts are published periodically in the *MMWR* and in medical journals. NREVSS data have been used to better define the epidemiology of RSV, HPIV, and rotavirus. Compiled data are made available over the Internet for infection control practitioners and other health care providers to use in planning and implementing effective control measures, and for researchers to assess in the effectiveness of new vaccines.
(URL: http://www.cdc.gov/ncidod/dvrd/revb/nrevss/index.htm).

Changes to the form include:

- The forms are numbered 55.83A-D at the bottom of each form. (That needed no correction.)

- The CDC Project Clearance Officer address has been changed from MS D-24 to MS D-74.

- The addresses for the Influenza Branch and Respiratory & Enteric Viruses Branch have been updated (bottom of pages 2-4 on each worksheet) as follows.

    - For Influenza, the new contact info is underlined: Epidemiology & Surveillance Branch (Proposed), Influenza Division (Proposed), Building 1, Room B-49A, MS A-32. The phone and fax info haven't changed, but the e-mail address is changed from kws3@cdc.gov to aof9@cdc.gov.

    - For Viral Diseases, the new contact information is underlined: Epidemiology Branch (proposed), Division of Viral Diseases (proposed), and the rest of the information (address, mailstop, phone, fax & e-mail) are unchanged.

Form name	No. of respondents	No. of responses/respondent	Hrs/response	Total burden in hrs.
NREVSS	90	52	10/60	780

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

NATIONAL ENTEROVIRUS SURVEILLANCE SYSTEM (CDC 55.9)

Since 1964, state health departments have reported to CDC all enteroviruses isolated in their laboratories, regardless of clinical syndrome. This project, known as the Enterovirus Surveillance Program, was initially undertaken through the auspices of the Joint Committee of the Conference of State and Territorial Public Health Laboratory Directors. Reports are generally sent directly from the laboratory to CDC. Information solicited on the previously approved reported form (CDC 55.9) included demographic data (age, sex, state, year); clinical data (date of onset, syndrome, outcome); and laboratory data (enterovirus type isolated, anatomic source(s) if isolation) on all cases with one or more enterovirus isolated.

The present reporting form has been developed in Microsoft Excel to reduce the reporting burden. Clinical data is not requested, because in most cases this information is not available to the reporting laboratories, and the date of specimen collection is requested in lieu of onset date.

The purpose to undertaking national enteroviral surveillance was to monitor trends in the circulation of these viral agents, many of which are associated with severe clinical illness. Through analysis of the national database, one may approach more immediate problems of outbreak recognition and etiologic diagnosis. Ultimately, these data may provide insight leading to better control and prevention practices. Results of these reports are published periodically in the *MMWR* and peer-reviewed journals.

Changes to the form include:

- The spreadsheet is CDC Form 55.9, revised ~October 2004, and the spreadsheet has been revised with the form number and revision date.
- The CDC Project Clearance Officer address had been changed from MS D-24 to MS D-74.
- A contact address has been added to the spreadsheet, as follows:
    - Contact: Epidemiology Branch (proposed), Division of Viral Diseases (proposed), Building 3, Room 111, MS A-34, Phone: 404-639-3596, Fax: 404-639-1307, e-mail: nrevss@cdc.gov

Form Name	# Participating Sites	# Reports per Site per year	Hrs/response	Response Burden
National Enterovirus Surveillance Form	25	12	15/60	75

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

INVESTIGATION OF A FOODBORNE OUTBREAK (CDC 52.13)

This report provides for the systematic entry of basic data from an epidemiologic investigation of an acute foodborne disease outbreak of any etiology, including bacterial, parasitic, viral or chemical causes. Foodborne illnesses are due to a multitude of pathogens, toxins, and chemicals that may contaminate food. Outbreaks occur in a variety of population groups such as schools, camps, general dining halls, institutions of various types, as well as in the general community. This report form also serves as a training device and a guide to health departments that routinely investigate foodborne outbreaks. State and local health departments send completed reports on outbreaks they have investigated to CDC to be tabulated and analyzed and summarized. Data are published periodically in the *MMWR* and the *Foodborne Disease Surveillance Report*. Historically, use of data collected by this system had been slowed because of the long time required for data entry and coding once the forms are received. In 2001, CDC introduced electronic reporting of foodborne outbreak data through the Electronic Foodborne Outbreak Reporting System (EFORS). EFORS is a web-based reporting system that collects the same information as the paper forms, and can be used by local, county, or State organizations to enter, edit and analyze data and to transmit data electronically to other State or federal offices. All reports beginning with 2001 data are entered into EFORS. Instructions for completing the form and posted on the internet. The form includes the OMB approval number and the burden advisement.

Changes to the form include:

1. Addition of question1, page 1: Report type
2. Addition of question 10, page 2: Isolate Subtype
3. Addition of question 18, page 3: Trace back and source
4. Addition of question 19, page 4: Recall
5. Addition of question 20, page 4: Available reports
6. Addition of part 3, page 4: School questions 1-6
7. Addition of part 4, page 5: Ground beef questions 1-3
8. Addition of part 5, page 5: Mode of transmission question 1
9. Addition of part 6, page 5: Additional egg questions 1-2
10. Change in address in OMB footer
11. Increase in estimated burden to complete this form from 15 to 20 minutes per response, or 325 to 338 hours total

Form name	No. of respondents	No. of responses/respondent	Hrs/response	Total burden in hrs.
Foodborne Outbreak Investigation	54	25	15/60	338

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

WATERBORNE DISEASES OUTBREAK REPORT FORM (CDC 52.12)

The Waterborne Disease Outbreak Surveillance System is a collaboration between CDC, the Council of State and Territorial Epidemiologists, and the Environmental Protection Agency (EPA). This system is the only surveillance system for tracking and analyzing waterborne disease outbreaks in the United States and it has compiled data on over 1300 outbreaks since 1971. The data are used routinely to inform CDC recommendations and the system supplies critical data for EPA decision-making regarding existing and new regulations related to drinking water safety.

This form is used to summarize the data collected in investigations of waterborne disease outbreaks caused by drinking water or recreational water. The form captures the etiologic agents responsible for the outbreaks and identifies the water system deficiencies associated with outbreaks in order to improve prevention efforts. Data collected include: type of exposure, location of outbreak, date of outbreak, number of persons exposed and ill, symptoms, incubation period, duration of illness, etiologic agent, epidemiologic results such as attack rates, laboratory results of human specimens and water samples, characteristics of the water system and its deficiencies, and factors contributing to the contamination of the water. The form ensures the systematic collection of data by state and local health departments, which routinely investigate these outbreaks. No personally identifiable data are collected on this form. The data collected on this form are maintained in a database which resides on a CDC server and access is restricted.

Data on reported waterborne outbreaks are analyzed and published every two years in the Morbidity and Mortality Weekly Report Surveillance Summaries (MMWR-SS). These Surveillance Summaries are the most comprehensive account of waterborne disease outbreaks in the United States and have been cited in scientific publications more than 450 times over the past 15 years.

This form is paper-based; however, CDC is currently working towards merging this reporting system with the existing Electronic Foodborne Outbreak Reporting System (EFORS) to simplify data collection and entry for state partners.

Form name	No. of respondents	No. of responses/respondent	Hrs/response	Total burden in hrs.
Waterborne diseases outbreak investigation	57	1	20/60	19

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

OVERVIEW OF CDC INFLUENZA SURVEILLANCE
Increase in burden due to increase in cases. Two new formats introduced for Internet reporting.

This group contains descriptions of the following four forms:
WHO Collaborating Center for Influenza Surveillance, Influenza Virus Surveillance: CDC 55.31 (facsimile/internet), US WHO Influenza Collaboration Laboratories Address Update CDC 55.31A (annual survey)
U.S. Influenza Sentinel Provider Surveillance: CDC 55.20E (work folder), Sentinel Provider Reports of Influenza-Like Illness (ILI) CDC 55.20 (facsimile)

The Centers for Disease Control and Prevention has responsibility for surveillance of influenza with the goal of determining the impact of the disease on the U.S. population and developing improved control measures. It has been estimated that influenza is responsible for approximately 36,000 deaths and more than 200,000 hospitalizations during an average influenza season. The continuing emergence of new strains of influenza necessitates annual virologic and epidemiologic surveillance.

Surveillance data are used to determine vaccine composition for the following year. Influenza virus type A (H3N2), A (H1N1), and B circulate worldwide, but with differing intensities each year. Influenza virus type A (H3N2) infections have been associated with reports of outbreaks among all age groups. Influenza A (H1N1) infections have been recognized predominately among children and young adults and are associated with school outbreaks. Influenza type B virus has caused outbreaks of influenza in schools as well as other institutions, such as nursing homes. Surveillance permits rapid detection of influenza virus circulation and the degree to which vaccine virus strains match circulating wild type virus strains. It provides data used in determining influenza-associated morbidity, mortality, and economic loss. Furthermore, it may assist in the control of the disease by affording the opportunity for rapid preventive action, for example, by chemoprophylaxis of high-risk persons who have not received vaccine.

In addition to monitoring annual influenza epidemics, this system is in place to detect viruses with pandemic potential and track the course of the next influenza pandemic.

Influenza Virus Surveillance (Form CDC 55.31)

Form CDC 55.31 is a single fax form used to collect summary influenza virus data from collaborating laboratories around the country. The web interface for labs that choose to report their data over the Internet is identical to the paper fax form. For laboratories that utilize the electronic method of reporting data, there is no reporting form since a connection is established between the laboratory and a CDC server.

State, county, city, or university laboratories that collaborate with the World Health Organization (WHO) Influenza Surveillance Program report numbers of throat or nasopharyngeal swab specimens submitted for influenza diagnosis and the number positive for influenza. All laboratories report these data weekly from October through mid-May and a subset of these laboratories are reporting these data all year. These reports are used to assess and report the distribution of influenza virus strains throughout the United States.

Weekly data are transmitted to CDC by facsimile (23 laboratories), over the Internet (37 laboratories), or electronically using the Public Health Information System (PHLIS) (23 laboratories). Transmission of data via PHLIS, an electronic system that can be corrected and updated with the latest, most accurate influenza isolate information, improves the timeliness and quality of the data. Most of the 23 state laboratories using PHLIS have elected to develop an interface between their laboratory computer and PHLIS to transmit their data. In these instances, their previous weekly burden of summarizing this information and transmitting it by facsimile or Internet has been reduced. No patient identifiers are received at CDC.

Changes to the form 55.31 include:

- Correction of the OMB approval number
- Update of address to CDC, Project Clearance Officer, 1600 Clifton Road, MSD-74, Atlanta, GA 30333, ATTN: PRA (0920-0004)

Form Name	No. of Respondents	No. of Responses per Respondent	Hrs/response	Total Burden in hrs.
Influenza Virus (fax, Oct-May) (CDC 55.31)	8	33	10/60	44 hours
Influenza Virus (fax, year round) (CDC 55.31)	15	52	10/60	130 hours
Influenza Virus (Internet, Oct-May) (CDC 55.31) ***	13	33	10/60	72 hours
Influenza Virus (Internet, year round) (CDC	24	52	10/60	208 hours

55.31) ***				
Influenza Virus (Electronic, Oct-May) (PHLIS)	9	33	5/60	25 hours
Influenza Virus, (electronic, year round) (PHLIS)	14	52	5/60	61 hours

*** New format this submission

Influenza Virus Surveillance Survey (Form CDC 55.31A)

Once a year a survey is sent to each participating laboratory to obtain information used in analyzing and interpreting data obtained from year-to-year.

Form Name	No. of Respondents	No. of Responses per Respondent	Hrs/response	Total Burden in hrs.
Influenza Annual Survey (CDC 55.31A)	83	1	15/60	21 hours

Sentinel Provider Weekly Surveillance for Influenza-like Illness (CDC 55.20)

Form CDC 55.31 is a single fax form used to collect summary influenza-like illness data from participating sentinel providers. Providers have the option of faxing this data in via a toll-free fax number or reporting data over the Internet. The web interface is identical to the fax form.

The workfolder (CDC 55.20E) is used by the provider to track their own data submitted throughout the season.

Because state health department morbidity estimates are imprecise and generally untimely, a system was developed in 1982 to collect influenza-like illness data directly from practicing family physicians who voluntarily participated without remuneration. Prior to 1997, CDC and state health departments maintained separate influenza sentinel provider surveillance systems. In 1997, CDC collaborated with state health departments to reduce duplication of efforts and allow resources to be focused on expanding the number of providers reporting in order to improve the geographic representation and completeness of the data. Over the years, the system has continued to evolve and expand. For the 2005-06 season, approximately 1,320 regularly reporting health care providers in all 50 states will participate.

Participating providers report the following data each week from October through mid-May: influenza-like illnesses by age group, and the total number of patients seen for any reason. These data are shared by CDC and state health departments. A subset of providers has volunteered to report these data year round. Year-round influenza surveillance data will provide a baseline level of influenza activity during the summer months and will also have the potential to become an important component of early detection for an influenza pandemic, or other unusual occurrences of influenza-like illness.

The primary method of reporting is Internet (83%) using form 55.20E as a work folder. A few providers still prefer to transmit their data via facsimile (17%) (CDC55.20). Due to the discontinuation of the touch tone phone system for data transmission, the facsimile form is now part of the work folder.

Changes to the form 55.2 include:

- Correction of the OMB approval number
- Update of address to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0004)

Form Name	No. of Respondents	No. Responses per respondent	Hrs/response	Total Burden in hrs.
Influenza-like Illness (Oct-May) (CDC 55.20)	824	33	15/60	6,798 hours
Influenza-like	496	52	15/60	6,448 hours

Illness (year round) (CDC 55.20)				

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

Arboviral Diseases (including West Nile Virus) (100% electronic collection)

Prior to the first detection of West Nile virus (WNV) in the United States in September 1999, arboviral diseases - along with other nationally notifiable diseases - were electronically reported to the CDC through the National Electronic Telecommunications System for Surveillance (NETSS), whose publication of disease activity lags from several months to a year behind the date of disease reporting. No endemic arboviruses are currently reported through NETSS. At one time, reporting to NETSS was via the Human Arboviral Encephalitis Surveillance system on CDC form 55.3, which is now obsolete.

The public health concern over the anticipated geographic spread of WNV within in the United States led CDC in 2001 to begin accepting reports of WNV via ArboNET, an enhanced, web-based electronic reporting system for closely monitoring national WNV activity in humans, non-human mammals, birds and mosquitoes. The inclusion of other nationally notifiable arboviruses into ArboNET occurred in 2003**.** If needed, CDC ArboNET staff can also receive arboviral activity reports by telephone, fax, or e-mail. This unique, multi-faceted surveillance system has proven essential for the early detection of arboviral disease activity and for monitoring the spread of epidemic transmission of WNV. The arboviral transmission season begins in early summer with peak activity generally occurring in August-September when vector mosquito populations are at their peak. Information on nationwide transmission is disseminated weekly on electronic bulletin boards during the transmission season. In addition, periodic reports and an annual summary are published in the *MMWR*. Access to ArboNET requires a Digital Certificate to assure restricted access to sensitive data.

Form name	No. of respondents	Average no. of responses/respondent	Hrs/response	Total burden in hrs.
Arboviral Diseases (including West Nile Viruses)	57	1421	4/60	5,400

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

Cholera and other *Vibrio* Illness Surveillance Report (CDC 52.79)

In 1988, Gulf Coast State Health Departments agreed to voluntarily report laboratory confirmed *Vibrio* illnesses to CDC. *Vibrio* species are naturally occurring marine bacteria and an important cause of seafood-borne and wound associated illnesses. Certain *Vibrio* species (e.g., *V. cholera, V. parahemolyticus*) cause dehydrating diarrheal illnesses. In addition to endemic cholera in the United States, illnesses caused by epidemic strains of cholera are reported among travelers returning from southern Asia and Latin America.

Other *Vibrio* species (e.g., *V. vulnificus*) result in septicemia and even death in individuals with underlying diseases such as liver disease or congestive heart failure. Since the 1970's, CDC has identified *V. vulnificus* as an emerging foodborne pathogen.

Beginning with data collected in 1999, an annual summary of results has been provided to CSTE and distributed to all state epidemiologists and directors of state public health laboratories. The data provide important information on the public health impact of vibriosis in the Gulf Coast States.

The collection of information does not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. The paper form is necessary because public health nurses at the local level often perform initial data collection. Data collection is focused on relevant clinical and epidemiologic features of *Vibrio* illnesses. Use of the form is more efficient than the review of medical records to capture this information.

The following are changes to the form:
1. First three letters of last (formerly first) name: Isolates of *Vibrio cholerae* and *Vibrio parahaemolyticus* are requested to be sent to CDC for further characterization, e.g., serotype. We would like to link Cholera and other *Vibrios* Illnesses Surveillance (COVIS) data with a database of *Vibrio* isolates that are maintained by our laboratory, in order to link epidemiologic information with the laboratory test results. The laboratory database is kept as Microsoft Excel file with no personal identifiers, except the first three letters of the patient's last name. Information is only accessible by authorized users.

2. We've added a field for state epi number so that now there are two state numbers (an epi # and a lab #). Local and state health departments usually assign numbers to cases that differ from their lab. This helps them keep track of which cases they've reported to us.

3. Ethnicity variable added (Hispanic or non-Hispanic): we added this because it is now standard to ask.

4. Race variable options changed to conform with OMB standards: Asian and Native Hawaiian/Other Pacific Islander are now two separate options and Hispanic was removed as a race as it is now asked in the ethnicity variable.

5. Added the fax number to the form in addition to the address. Nearly half of the reports get sent to us by fax, which is why it would be helpful to add it to the contact information.

The OMB header and burden footer will be corrected. The new OMB number (0920-0004) will be added. 0920-03222 is the OMB clearance number for the previous version of CDC form 52.79, which expired in February 2006. The form was revised with the changes mentioned previously. We request reinstatement under 0920-0004. Cholera is toxigenic *Vibrio cholerae*. It has been a nationally notifiable disease for many years. It's inclusion in the COVIS surveillance system has been since 1988. The modes of transmission, clinical syndromes are similar to that of other *Vibrios*, and the need for surveillance information is equally essential.

The prevalence of preexisting conditions, including alcoholism, immunosuppressive disorder, diabetes, and liver disease is higher among those with severe *Vibrio* infections, and they may serve as a predictor for fatal outcome. This collection of information is necessary to further characterize their role as risk factors for infection and severe disease. Personal identifiers are maintained by state or local health department, and information is de-identified before sending to CDC. The database is a secure SQL database that is pass-word protected and accessible by authorized users only.

Respondents	No. of respondents	No. of responses/respondent	Hrs/response	Total Burden in hrs.
Local Health Department staff	270	1	20/60	90
Health care facility staff	135	1	20/60	45
Physicians	45	1	20/60	15
Total				150

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

Outbreak Report of Suspected Viral Gastroenteritis

(Outbreaks of viral gastroenteritis are usually caused by norovirus or sapovirus which collectively are referred to as caliciviruses)

Noroviruses are estimated to cause 23 million cases (33%) of all cases of gastroenteritis annually. Norovirus disease occurs as sporadic disease or as outbreaks of diarrhea and vomiting, in all age groups.

Noroviruses can be transmitted via contaminated food, contaminated water or directly from person to person. Many outbreaks involve several modes of transmission such as initial foodborne followed by person to person. In many cases the source of infection is unknown. The diverse modes of transmission are reflected in the diverse settings in which outbreaks occur such as restaurants, nursing homes, hospitals and schools. Historically however, diagnosis of noroviruses has been very difficult. Recent development of RT-PCR techniques has revolutionized the detection and characterization of norovirus strains, and testing for norovirus in outbreaks of gastroenteritis is gradually becoming more frequent.

CDC has been testing outbreaks for noroviruses for over 10 years, most recently using RT-PCR. Increasingly state public health laboratories have been testing for noroviruses and currently three quarters of all norovirus outbreaks are diagnosed by the states and a quarter by CDC. RT-PCR has allowed for norovirus strains to be sequenced and the development of CaliciNet, a nationwide database of norovirus sequences has allowed comparison of norovirus sequences from different outbreaks.

For effective interpretation of the significance of similar sequences, however, some epidemiological information is required. Currently, epidemiological information on norovirus outbreaks that are linked to food contamination is reported to the foodborne branch electronically via EFORS. However, there is no collection of epidemiological data of non-foodborne outbreaks of norovirus.

We wish to renew the approval for our 2 page form to gather epidemiological information on non-foodborne norovirus outbreaks tested at CDC. Data collected will include suspected source, setting, number exposed, and number of cases. This will allow CDC to link outbreaks together and assist in the development of control measures. This information will eventually be collected through a web-based reporting system which is being developed. The information will be accessible to states investigating outbreaks, initially by contact with the viral gastroenteritis section at CDC, and in the future via the Internet.

The burden has been reduced since more states do their own testing and do not send to CDC as the technology has become more widespread.

OMB number and updated address will be added to the form. In addition, the burden advisory statement have been added on the document.

Information below based on 20 states not testing for noroviruses and an average of 5 outbreaks per year requiring testing.

Form name	No. of respondents	No. of responses/respondent	Hrs/response	Total burden in hrs.
Outbreak Report of Suspected Viral Gastroenteritis	20	5	5/60	8

Form Description for the Information Collection "National Disease Surveillance Program - II. Disease Summaries," OMB No. 0920-0004

LISTERIA CASE FORM

Listeria monocytogenes is a facultative intracellular pathogen that causes serious illness among newborns, elder, and immunocompromised persons. It is usually acquired through ingestion of contaminated food, and it is a leading cause of death due to foodborne diseases in the United States. In 1999, the Council of State and Territorial Epidemiologists (CSTE) adopted a position statement making listeriosis a nationally notifiable disease. The Listeria Case Form, a standardized case questionnaire which contains detailed questions on the consumption of high-risk foods, was developed by CSTE and CDC. Prompt interviewing of case patients using this form has lead to improvements in detecting and investigating listeriosis outbreaks, and the reduction of resources required to investigate listeriosis outbreaks. Data obtained from this form has lead to the timely identification and recall of contaminated foods.

The collection of information does not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. The paper form is necessary because public health nurses at the local level often perform initial data collection. Data collection is focused on relevant clinical and epidemiologic features of listeriosis collecting through medical chart review and patient interview.

Personal identifiers collected by state or local public health officials; this information is removed from the form and maintained at the state health department before submission to CDC. Data are reported to CDC monthly.

Changes to the form include:

1. Change of address to: (with corrected zip code)
   Enteric Diseases Epidemiology Branch
   Centers for Disease Control and Prevention
   Mailstop A-38
   Atlanta GA 30333
   Fax: (404) 639-220
2. Instructions regarding de-identification of data prior to transmission to CDC will be clarified as follows:
   Delete: "detach here to remove personal identifiers if necessary"
   Add/Substitute: "Detach here – personal identifiers are not submitted to CDC"

Form name	No. of respondents	No. of responses/respondent	Hrs/response	Total burden in hrs.
Listeria Case Form	53	1	30/60	27

ATTACHMENT A

ATTACHMENT B

ATTACHMENT C