NATIONAL DISEASE SURVEILLANCE PROGRAM - II. DISEASE SUMMARIES

OMB 0920-0004

Revision
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Point of Contact
Amy McMillen
Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases

1600 Clifton Road, NE, Mailstop D76
Atlanta, GA 30333
Electronic mail: auh1@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 revision.

New forms have been added for influenza surveillance to better address the continuing emergence of new strains of influenza, such as 2009 influenza A (H1N1) virus. The new surveillance forms 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. Edits were made to existing forms to better collect relevant data for the 2010 influenza season.

A new form was developed to collect important information on potential human rabies cases that submit samples to the CDC rabies laboratory for diagnostic testing. This information is submitted ad hoc by physicians when submitting samples for rabies diagnosis accounting for approximately 50 submissions each year. Collection on all cases submitted for diagnosis allows for collection of information on non-rabies encephalitis cases which are periodically used in cross-sectional analysis to identify risk factors that may be associated with human rabies versus other unknown encephalitis. In addition, edits were made to animal rabies surveillance to include additional information on all animals tested for rabies by state public health, state agricultural, and university laboratories. This information is critical for determining fluctuations in rabies incidence in animal populations while controlling for testing bias. Enhanced information also includes human and animal exposures, animal rabies vaccination status, detailed animal collection locations, and rabies virus variant information which are critical in further determining the burden of animal rabies on human populations.

Edits were made to existing forms for arboviral surveillance to identify risk factors for severe illness, hospitalization, and/or death among persons with West Nile Virus (WNV) disease. These findings could be used to target WNV prevention efforts or focus future WNV immunization strategies.

Two new surveillance activities were added to address brucellosis and babesiosis.

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
Harmful Algal Bloom-related Illness
Brucellosis
Influenza Virus
Rabies
Respiratory and Enteric
Shigella
Salmonella
Waterborne Outbreaks
Listeria
Babesiosis

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, however, beginning in 2009, this system was phased out in lieu of the National Outbreak Reporting System (NORS). The current Form 52.13 (eFORS) permits the reporting of foodborne-associated illnesses; however, NORS will allow the continual reporting of foodborne-associated illnesses, in addition to the following modes of transmission: person-to-person, animal contact, and environmental contamination other than food/water.

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 August 10, 2010 Federal Register notice, Volume 75, No. 153, pages 48346-48348 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 Perry Smith, New York State Epidemiologist, pfs01@health.state.ny.us, (518) 474-1055.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Currently the Privacy Act is applicable only to information collected through the Harmful Algal Bloom-Related Illness Surveillance System (HABISS); added and approved on 12/18/2008 and 1/22/2009. Where applicable, these forms are maintained as a system of records under the Privacy Act system of records notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

Identifying information such as name, date of birth, mailing address, e-mail, and phone number of those experiencing human illness caused by environmental exposure to algal toxins in drinking and recreational waters will be collected by the state, along with the somewhat personal information regarding the health status of those symptomatic individuals. State Health Agencies need to collect identifying information for personal follow-up contact with respondents to complete the information specified in the surveillance system modules. We will not request or collect social security numbers or photographic identifiers. For aggregate data analysis at NCEH, we will use unique system identifiers assigned by the states. If a given state has not adopted this system of record-keeping, a unique identification number (ID) will be assigned for each record by the surveillance system. Furthermore, state-based personnel with access to the data will only be able to view data from their state. They will not be able to view data from other states. Finally, by year two of this project, NCEH will require the use of unique IDs in lieu of

name and address. Presently, only two Federal contractors (the Developer and the Surveillance Coordinator) have access to the identifiable HABISS data. Any future contractors or federal employees working on the surveillance system would be subject to rigorous training and CDC's rules of confidentiality. CDC access to HABISS data will always be limited to a very small number of trained employees.

Privacy Impact Assessment Information

A. In certain states, the web-based system HABISS will supplement and/or replace existing record systems at the state and local health department levels. In addition the two NCEH staff with responsibility for the system will have access to the identifiable data; therefore the Privacy Act does apply. Records will become part of Privacy Act system of records notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems."

As with other surveillance classifications (e.g. influenza, diarrheal, foodborne) under OMB 0920-0004 clearance, this surveillance system is not subject to IRB review and approval.

HABISS will only collect electronic records from state and local government agencies. Paper documents will neither be distributed nor collected by NCEH. HABISS operates on a secure platform, the Rapid Data Collector (RDC), which was engineered specifically for electronic survey design and data collection. Since the states need to use the data personal identifiers for follow-up purposes, it has been requested that the information be securely collected and stored for their later retrieval in HABISS. NCEH has reviewed the various options that might allow personal information to remain with the states, and not be accessible at the Federal level. After having reviewed these options, NCEH has concluded that the resources required to implement such a fundamental change are extensive and are not available at this time. However, the HABISS developer has agreed that a non-transmittable component will be a core consideration for RDC (Rapid Data Collector) 2.0, where HABISS is the flagship surveillance system.

B. A comprehensive Privacy Impact Assessment for the Rapid Data Collector system was completed in 2006. The following technical components and controls remain in place as of May 2008:

- UserID
- Password (including expiration, minimum characters, and a lock feature)
- Firewall
- Encryption
- Public Key Infrastructure

Furthermore, access to HABISS (through RDC) will be limited to users on a permission-only basis. All contractor staff working on the project will agree to safeguard the data and to not make unauthorized disclosures. Data will be safeguarded in accordance with applicable statutes including the Privacy Act. Responses in any future published reports will be presented in aggregate form and no individuals will be identified.

C. State participation in the surveillance collection is voluntary.

D. Individual consent for human case reports will be obtained by the health care professional or state epidemiologist responding to the illness report in question. HABISS is a mechanism for the states to conduct surveillance, and therefore, CDC will not collect consent directly from any individuals.

Other 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 56,136 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	31.5	20/60	567

Form	#Respondents	#Responses per Respondents	Avg.Burden	Total Burden Hours
Arboviral Diseases (including West Nile Viruses) (electronic)	57	1421	5/60	6,750
Influenza:				
-Influenza virus (fax, Oct-May) (CDC 55.31)	5	33	10/60	28
-Influenza virus (fax, year round) (CDC 55.31)	21	52	10/60	182
Influenza virus (Internet; Oct-May) (CDC 55.31)	3	33	10/60	17
Influenza virus (Internet;year round) (CDC 55.31)	35	52	10/60	303
-Influenza virus (electronic, year round) (PHLIP)	5	52	5/60	22
-Influenza virus (electronic, year round) (PHIN)	17	52	5/60	74
Influenza Annual Survey (CDC 55.31A)	86	1	15/60	22
Weekly Influenza-like Illness (Oct-May) (CDC 55.20)	540	33	15/60	4455
Weekly Influenza-like Illness (year round) (CDC 55.20)	1260	52	15/60	16,380
Daily Influenza-like illness (Oct-May)	200	231	15/60	11,550
Daily Influenza-like illness (year round)	75	365	15/60	6,844
Influenza-Associated Pediatric Death Case Report Form	57	1	30/60	29
Novel and Pandemic Influenza A Virus Infection Case Investigation Form	57	1	30/60	29
Novel and Pandemic Influenza A Virus Infection Contact Trace Back Form	57	1	30/60	29
Novel and Pandemic Influenza A Virus Infection Contact Trace Forward Form	57	1	30/60	29
Novel Human Influenza A Virus Infection Case Report Form	57	1	30/60	29
Daily Novel and Pandemic Influenza A Virus State Case Status Summary Update	57	1	15/60	14
CMRS - City health officers or vital statistics registrars (daily)	58	365	12/60	4,234
CMRS - City health officers or vital statistics registrars (weekly)	122	52	12/60	1,269
Aggregate Hospitalization and Death Reporting Activity Weekly Report Form	56	52	10/60	485
National Enterovirus Surveillance Report: (CDC 55.9) (electronic)	25	12	15/60	75

Form	#Respondents	#Responses per Respondents	Avg.Burden	Total Burden Hours
National Respiratory & Enteric Virus Surveillance System (NREVSS) (CDC 55.83A-D) (electronic)	90	52	10/60	780
Suspected Viral Gastroenteritis (Calicivirus surveillance)	20	5	5/60	8
Rabies (electronic) renamed Enhanced Animal Rabies Surveillance (CDC 55.28)	52	52	3/60	135
Rabies (paper) (CDC 55.28)	3	12	15/60	9
Possible Human Rabies Patient Info	50	1	15/60	13
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
Listeria Case Form	53	1	30/60	27
HABISS Data Entry	10	12	8	960
HABISS Monthly Reporting	10	12	30/60	60
Babesiosis Case Report Form	54	12	10/60	108
Brucellosis	56	2	20/60	37
Total				56,136

B. The estimated annual cost to respondents is $1,319,491.20. 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 56,136 and is presented in Table 2. This number includes the $40 average hourly rate for State Epidemiologists and the 1,020 burden hours for the HABISS system (1,020 x 40.00 = $40,800).

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 Costs
Diarrheal Disease Surveillance						
-*Campylobacter* (electronic)	53	52	3/60	138	$23.20	$3,201.60
-*Salmonella* (electronic)	53	52	3/60	138	$23.20	$3,201.60
-*Shigella* (electronic)	53	52	3/60	138	$23.20	$3,201.60

Foodborne Outbreak Form	54	31.5	20/60	567	$23.20	$13,154.40
Arboviral Diseases (including West Nile Virus)	57	1,421	5/60	6,750	$23.20	$156,600.00
Influenza						
-Influenza virus (fax, Oct-May)	5	33	10/60	28	$23.20	$649.60
-Influenza virus (fax, year rd)	21	52	10/60	182	$23.20	$4222.40
Influenza virus (Int Oct-May)	3	33	10/60	17	$23.20	$394.40
Influenza virus (Int; year round)	35	52	10/60	303	$23.20	$7029.60
-Influenza virus (elec PHLIP)	5	52	5/60	22	$23.20	$510.40
-Influenza virus (elec PHIN-MS)	17	52	5/60	74	$23.20	$1,716.80
Influenza Ann Sv (CDC 55.31A)	86	1	15/60	22	$23.20	$510.40
Weekly Influenza-like Illness (Oct-May) (CDC 55.20)	540	33	15/60	4455	$23.20	$103,356
Weekly Influenza-like Illness (year round) (CDC 55.20)	1260	52	15/60	16,380	$23.20	$380,016
Daily Influenza-like Illness (Oct-May)	200	231	15/60	11,550	$23.20	$267,960
Daily Influenza-like Illness (yr round)	75	365	15/60	6,844	$23.20	$158,780.80
Influenza Pediatric Death	57	1	30/60	29	$23.20	$672.80
Nov & Pan Influz A Case Investigation	57	1	30/60	29	$23.20	$672.80
Nov & Pan Influz A Trace Bk	57	1	30/60	29	$23.20	$672.80
Nov & Pan Influz A Trace Fwd	57	1	30/60	29	$23.20	$672.80
Nov Influz A Case Rep	57	1	30/60	29	$23.20	$672.80
Daily Nov & Pan Influz A State Status Summary Update	57	1	15/60	14	$23.20	$324.80
City Hlth Off Vital Stats (daily)	58	365	12/60	4,234	$23.20	$98,228.80
City Hlth Off Vital Stats (wkly)	122	52	12/60	1,269	$23.20	$29,440.80
Aggregate hosp & Death Activity Weekly Report	56	52	10/60	485	$23.20	$11,252
Natnl Entero Surv (CDC 55.9) e	25	12	15/60	75	$23.20	$1,740.00
Natnl Res & Ent Surv(NREVSS) (CDC 55.83A-D) (electronic)	90	52	10/60	780	$23.20	$18,096.00
Susp Viral Gastro (Calicivirus)	20	5	5/60	8	$23.20	$185.60
Rabies (electronic) (CDC 55.28)	52	52	3/60	135	$23.20	$3,132.00
Rabies (paper) (CDC 55.28)	3	12	15/60	9	$23.20	$208.80
Possible Human Rabies Patient	50	1	15/60	13	$23.20	$301.60
Watrbrn Dis Outbrk(CDC52.12)	57	1	20/60	19	$23.20	$440.80
Cholera/other Vib (CDC 52.79)	450	1	20/60	150	$23.20	$3,480.00
Listeria Case Form	53	1	30/60	27	$23.20	$626.40
HABISS Data Entry	10	12	8	960	$40.00	$38,400
HABISS Monthly Reporting	10	12	30/60	60	$40.00	$2,400
Babesiosis Case Report Form	54	12	10/60	108	$23.20	$2,505.60
Brucellosis	56	2	20/60	37	$23.20	$858.40
Total						$1,319,491.20

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 a revision.

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 - Disease Summaries
Attachment C – 60 Day Federal Register Notice