CDC/National Center for Immunization and Respiratory Diseases/Influenza Division

Information Collection Request for:

All Age Influenza Hospitalization Surveillance Project
(All Flu Hosp)

Part B

Laurie Kamimoto, Principal Investigator
Telephone: (404) 639-4653
E-mail: lek0@cdc.gov
Fax: (404) 639- 3688

Lyn Finelli, Collaborator
Telephone: (404) 639-2554
E-mail: lyf8@cdc.gov

Joyce Gyamfi, Project Manager
Telephone: (404) 639-2476
E-mail: gcx3@cdc.gov
Fax: (404) 639-3970

March 27, 2008

All Age Influenza Hospitalization Surveillance Project

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

No sampling scheme is needed for the pediatric hospitalization project, or the first phase of the adult flu hosp project. A standardized case report form will be completed on all persons that meet the case definition. However, for the adult influenza hospitalization study, states may consider sampling across the catchment area or further stratified by age group and/or hospital, if the number of cases exceeds the site's capacity for follow-up in a timely manner.

A sampling strategy will be worked out for the second phase of the adult flu project (discharge audit) for each site that is both manageable and representative of a baseline population. The discharge audit will be conducted retrospectively following the 2007-2008 flu seasons. Of the total number of cases from a discharge database that were ≥18 years of age at the time of hospital admission (October 1, 2007-April 30, 2008), reside in a catchment area county, had an ICD9 code of interest and did not match to a prospectively identified surveillance case, a sampling strategy should be employed such that ideally no more than 300 medical records will be reviewed by any one site. Cases from which sampling will occur should be stratified by hospital and age group (18-49, 50-64 and ≥ 65 years)

Any hospital with ≤ 10 cases should plan to review all of case medical records identified that were hospitalized at this hospital for evidence that the case met the surveillance case definition. Hospitals with >10 cases should then employ an age-stratified sampling scheme. Since the elderly make up a disproportionate amount of the adult hospitalized cases, younger ages should be "oversampled." At a minimum 15% of person 18-49 years, 10% of persons 50-64 years and 5% of persons ≥ 65 years should be sampled. It may be necessary to increase the proportion sampled such that the total number of medical records to be reviewed is between 200 and 300. No **fewer** than 200 records should be reviewed by any single site. (See Attachment 17 for Example of Sampling Strategy),

Current Procedural Terminology (CPT) is used for billing and reimbursement purposes. Of the total number of cases from a discharge database that were ≥18 years of age at the time of hospital admission (October 1, 2006-April 30, 2007), reside in a catchment area county, had CPT codes of interest and did not match to a prospectively identified surveillance case, a sampling strategy based on hospital and patient age should be employed such that ideally no more than 300 medical records will be reviewed by any one site. Any hospital with ≤ 10 cases should have all case medical records reviewed for evidence that the case met the Adult Flu Hosp surveillance case definition. Hospitals with >10 cases should employ an age-stratified sampling scheme. Since elderly make up a disproportionate number of the adult hospitalized cases, younger ages should be "oversampled." At a minimum 10% of person 18-49 years, 7.5% of persons 50-64 years and 5% of persons ≥ 65 years should be sampled. It may be necessary to increase the proportion sampled such that the total number of medical records to be reviewed is between 200 and 300. No **fewer** than 200 records should be reviewed by any single site. (See Attachment 17 for Example of Sampling Strategy using ICD9s. A similar strategy should be employed for CPTs.)

10 EIP sites will participate in the pediatric and adult influenza hospitalization project, representing 12 metropolitan areas and approximately 7% of the US population. All hospitals that accept adult and/or pediatric admissions in the catchment areas under surveillance should be included for active public health surveillance so accurate population-based rates can be calculated.

Age-specific rates of laboratory-confirmed influenza-associated hospitalizations and influenza-associated severe complications will be calculated using population denominators from the most recent census data available for pediatric and adult populations. For the Adult Flu Hosp Project, at a minimum influenza hospitalization rates will be estimated for the following age groups: 18–49, 50–64, and ≥ 65 years. For the pediatric project, rates will be estimated for the following age groups: < 6 months, 6-23 months, 2-4 years, and 5- 17 years. Rates will also be calculated separately for children with underlying medical conditions as outlined in ACIP recommendations for influenza vaccination.

Interim analyses of aggregate data will be conducted to estimate hospitalization rates and monitor factors associated with serious influenza-associated complications in pediatric populations. Final analysis will include a summary of the epidemiologic characteristics of hospitalized cases using standard descriptive statistics. Where appropriate, univariate and multivariate analyses will be conducted to evaluate factors associated with serious influenza-associated complications.

All analyses will be conducted using SAS. Aggregate results will be shared with relevant CDC programs, including the ACIP, and opportunities for publication will be sought.

2. Procedures for the Collection of Information (#17-26, #36-44)

See project flowcharts (attachments 18, 19, and 20).

Active public health surveillance for laboratory-confirmed influenza hospitalization cases in all age groups will be conducted in selected catchment areas in 10 states. Case finding is by prospective search of hospital laboratory, admissions, infection control practitioner databases/logs, or review of reportable conditions databases. Prospective cases will be identified through active contact with hospital laboratories, admissions departments, and infection control practitioners, or through review of reportable condition databases. Methods may vary slightly among surveillance areas or among hospitals within an area depending on the availability of laboratory and admissions databases. For hospitals with computerized viral laboratory data, computerized listings of all influenza positive cases in all age groups should be obtained on a weekly basis throughout the influenza season. In an effort to minimize burden for hospitals without computerized laboratory data, surveillance personnel will contact designated laboratory contacts in each health care facility every two weeks (at a minimum) to identify potential new cases. Influenza admissions also may be tracked by infection control professionals or other hospital staff serving hospital wards where influenza cases might be admitted. For hospitals in states where hospitalized influenza cases are a reportable condition, infection control practitioners review laboratory results and admission logs. For all potential cases identified, medical charts will be reviewed by surveillance officers

appointed by the state health department to determine whether case definition inclusion criteria are met.

Medical chart review and data abstraction using the project's case report form will be conducted upon verification of an influenza positive lab result to collect more detailed clinical and epidemiologic information. For all persons meeting the case definition and inclusion criteria, a standardized case report form will be completed using data obtained from the laboratory and medical chart review (Attachments 3, 4, and 5). To obtain influenza vaccine history, sites will either: 1) review medical chart, or 2) contact patients, their proxies or long term care facilities, from where a case resided prior to hospitalization, and/or primary care providers by fax to obtain that information. When influenza vaccination history is absent from the medical records, all sites will conduct either a telephone interview of the case or proxy or medical provider to obtain influenza vaccination history.

To adequately evaluate the vaccination status of all individuals hospitalized for influenza, a phone interview of patient or proxy has been included to collect influenza vaccination history, and pneumococcal conjugate vaccine for children born in or after 1998, in an unbiased manner if that information is not available in the medical record, or if the primary care provider is unknown (Attachments 13 & 14). (If influenza vaccination information is available but no information on pneumococcal conjugate vaccine can be found, the patient's primary care provider will be contacted to obtain pneumococcal vaccine information *only for children born in or after 1998*).

To address any limitation in completeness of case identification, a retrospective discharge audit will be conducted by each participating site following the 2006-07 season. Based on a range of discharge diagnoses, ICD9 480–487 (pneumonias and influenza), persons aged ≥ 18 years who are residents of a geographically-defined area and who have were admitted to hospitals during October 1, 2007 through April 30, 2008, will have their medical chart examined to identify whether they had an influenza positive test result at the beginning of their hospitalization and were missed by usual case ascertainment methods. The discharge audit will be conducted retrospectively following the 2007-2008 flu seasons. The completeness evaluation is a matching (or linking) study, followed by chart abstraction of missed cases (core project). (Attachments 5-9).

3. Methods to Maximize Response Rates and Deal with Nonresponse (#62-73)

There is not a method to deal with non-response as the state public health laboratories and partnering academic institutions 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%. However, some responses will require the surveillance officer to contact patients to obtain vaccination status information. Approximately 10% and 15% of pediatric and adult cases, respectively, will have an incomplete vaccination history because the patient or proxy refused to be interviewed.

Contact information will only be required in some circumstances when the influenza and pneumococcal conjugate vaccination history are not noted in the medical record, hospital database or state vaccination registry. For children, if influenza vaccination information is available but no information on pneumococcal conjugate vaccine can be found, the patient's primary care provider will be contacted to obtain

pneumococcal vaccine information *only for children born in or after 1998*. If pneumococcal status is not documented in an adult's chart, no effort will be made to obtain the status unless information related to influenza vaccination status is needed.

If the medical chart does not contain the name of the patient's primary care provider, it will be necessary to contact the patient or proxy. Attempts will be made to contact a patient up to 3 times to obtain this information. If a patient is reached and provides vaccination history themselves, they should also be asked for the provider's information so that additional information can be obtained.

Participating sites will interview patient or proxy by phone. Sites will use the following methods to try to locate patients' families: 1) medical charts, 2) laboratory records, or 3) directory assistance ("411"), and 5) internet phone/address searches (including name and address/reverse directories). Sites will try to identify the family member who is most familiar with the patient's medical history during the phone interview.

Once a correct phone number is identified, sites will make multiple attempts to reach the family member. To minimize non-response because of unusual work or life schedules, these attempts should include calling during different daytime periods during the week and weekend. Sites will stop trying to call a patient or proxy if they cannot locate a correct phone number after using the search methods listed above or if successful contact is not made after multiple attempts at what appears to be a correct number.

A primary limitation of this activity is that case ascertainment may not be complete. To identify all laboratory-confirmed cases, all laboratories would need to be audited, not just hospital laboratories; however, because the majority of influenza positive cases will not require hospitalization, the workload in determining which of the positive cases required hospitalization would be impractical.

Another limitation of performing surveillance for laboratory-confirmed influenza is that not all patients with influenza will receive influenza diagnostic testing and not all those that are tested will be positive, even if they have influenza, due to the timing of viral shedding and specimen collection. However, because the clinical presentation of influenza is similar to that of many other illnesses, we have limited our case definition to individuals with laboratory-confirmed evidence of influenza. Based on the findings of the discharge audit, the case definition may need to be modified to ensure that accurate rates of influenza associated hospitalizations are being captured.

4. Test of Procedures or Methods to be Undertaken

The data being collected represents standard clinical and demographic information. No tests of procedures or questions were preformed.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data (#52-55, #78)

Laurie Kamimoto and Lyn Finelli, Influenza Division, National Center for Immunization and Respiratory Diseases (NCIRD), CDC; principal investigator and collaborator, respectively

Joyce Gyamfi, Influenza Division, NCIRD, CDC; project manager
Other staff in the Influenza Division are consulted as needed.

Each EIP site analyses and reports their data, as needed.