

Emerging Infections Program (EIP)
Non-substantive Change Request
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Background

The National Center for National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) of the Centers for Disease Control and Prevention (CDC) is requesting approval of a non-substantive change to the approved package under OMB no. 0920-0978; expiration date 8/31/2016.

These forms are used to conduct surveillance to determine the incidence and epidemiologic characteristics of invasive disease due to *Haemophilus influenzae*, *Neisseria meningitidis*, group A *Streptococcus*, group B *Streptococcus*, and *Streptococcus pneumoniae*., specific foodborne diseases that is captured within FoodNet, and Influenza (specifically for the All Age Influenza Hospitalization Surveillance (Flu Hosp) project).

The forms for which approval for changes and additions are being sought include:

1. 2015 ABCs Case Report Form — (Attachment 1)
2. 2015 ABCs Neonatal Infection Expanded Tracking Form — (Attachment 2)
3. New Form: 2014 ABCs Non Bacteremic Pneumococcal Disease— (Attachment 3)
4. 2015 FoodNet Variable list — (Attachment 4)
5. 2014-2015 FluSurv-NET Influenza Surveillance Project Case Report Form — (Attachment 5)
6. 2014-2015 FluSurv-NET Influenza Surveillance Project Vaccination History Telephone Survey — (Attachment 6)
7. 2014-2015 FluSurv-NET Influenza Surveillance Project Vaccination History Telephone Survey (Spanish) — (Attachment 7)
8. 2014-2015 FluSurv-NET Influenza Surveillance Project Consent Form — (Attachment 8)
9. 2014-2015 FluSurv-NET Influenza Surveillance Project Consent Form (Spanish) — (Attachment 9)

The changes in this package are minor, do not change the scope of a collection, and does not greatly impact the burden. The following will detail the changes to the EIP surveillance tools including description and crosswalk of changes.

Active Bacterial Core surveillance (ABCs) - Active population-based laboratory surveillance for invasive bacterial diseases

Detailed Description of Changes

A. 2015 ABCs Case Report Form

There is no impact on burden due to the changes on this form. The changes include:

1. Question 32, Receipt of pneumococcal vaccine
 - Directions below checkboxes will be changed to ‘If between ≥ 3 months and <5 years of age and an isolate is available for serotyping, please complete the Invasive Pneumococcal Disease in Children expanded form’

B. 2015 ABCs Invasive Pneumococcal Disease in Children Case Report Form

Burden is decreasing as data elements have been removed from the data collection tool

These changes include:

1. Removed capture of manufacturer and vaccine name for Diphtheria/Tetanus/Pertussis (DTP or DTaP)
2. Removed capture of manufacturer and vaccine name for Haemophilus influenzae type B (Hib)
3. Removed rows capturing influenza immunizations
4. Added section on data sources for vaccination history, including
 - What information source was used to identify the health provider
 - How many health providers were contacted
 - What information sources were used to obtain vaccination history

C. 2015 ABCs Non-Bacteremic Case Report Form Active Bacterial Core surveillance (ABCs), a part of the Emerging Infections Program (EIP) network, is an active, laboratory, and population-based surveillance system. It is used to determine the incidence and epidemiological characteristics of invasive disease due to group A *Streptococcus* (GAS), group B *Streptococcus* (GBS), *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria meningitidis*, at 10 sites located throughout the United States. Since ABCs surveillance began in 1995, a case of invasive bacterial disease has been defined as isolation from culture of one of these pathogens from a normally sterile site in a resident of the surveillance area. Data from ABCs have been used to inform the development of vaccines, to inform the Advisory Committee on Immunization Practices (ACIP) recommendations for their use and to evaluate their effectiveness after recommendations for use are in place.

On August 13, 2014, ACIP recommended routine use of 13-valent pneumococcal conjugate vaccine (PCV13) among adults aged ≥ 65 years in series with the 23-valent pneumococcal polysaccharide vaccine (PPSV23).¹ Both vaccines have demonstrated efficacy against invasive pneumococcal disease (IPD) in placebo-controlled trials. One of the determining factors for recommending PCV13 to adults aged ≥ 65 years was its demonstrated 45% efficacy (95% confidence interval=14-65%) against vaccine-type non-bacteremic (i.e. non-invasive) pneumococcal pneumonia (NBPP) in a placebo-controlled trial conducted in the Netherlands.² Evidence is less clear as to whether PPSV23 is effective against NBPP. The incidence of NBPP

and the effectiveness of PCV13 vaccine against NBPP have a major influence on determining which vaccine or combination of vaccines would provide the greatest health benefits at the lowest costs. Given these and other considerations, ABCs Non-Bacteremic surveillance responds to the ACIP recommendations for the need to re-evaluate the pneumococcal vaccine policy for adults in 2018.

Cross walk of 2015 form changes

A. 2015 ABCs Case Report Form

| 2014 form | 2015 form |
|---|---|
| <p>32. Did the patient receive pneumococcal vaccination? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> Unknown</p> <p>If YES, please note which pneumococcal vaccine was received (Check all that apply) 1 <input type="checkbox"/> Prevnar[®], 7-valent Pneumococcal Conjugate Vaccine (PCV7) 1 <input type="checkbox"/> Prevnar-13[®], 13-valent Pneumococcal Conjugate Vaccine (PCV13) 1 <input type="checkbox"/> Pneumovax[®], 23-valent Pneumococcal Polysaccharide Vaccine (PPV23) 1 <input type="checkbox"/> Vaccine type not specified</p> <p>If between ≥3 months and <18 years of age and an isolate is available for serotyping, please complete the Invasive Pneumococcal Disease in Children expanded form.</p> | <p>32. Did the patient receive pneumococcal vaccination? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No 9 <input type="checkbox"/> Unknown</p> <p>If YES, please note which pneumococcal vaccine was received (Check all that apply) 1 <input type="checkbox"/> Prevnar[®], 7-valent Pneumococcal Conjugate Vaccine (PCV7) 1 <input type="checkbox"/> Prevnar-13[®], 13-valent Pneumococcal Conjugate Vaccine (PCV13) 1 <input type="checkbox"/> Pneumovax[®], 23-valent Pneumococcal Polysaccharide Vaccine (PPV23) 1 <input type="checkbox"/> Vaccine type not specified</p> <p>If between ≥ 2 months and <5 years of age and an isolate is available for serotyping, please complete the Invasive Pneumococcal Disease in Children expanded form.</p> |

B. 2015 ABCs Invasive Pneumococcal Disease Case Report Form

| 2014 form | 2015 form |
|--|---|
| Title: Active Bacterial Core Surveillance (ABCs) Invasive Pneumococcal Disease in Children | Title: Active Bacterial Core Surveillance (ABCs) Invasive Pneumococcal Disease in Children (aged ≥2 months to <5 years) |
| Indicate manufacturer for | Removed |

| | |
|--|---|
| Diphtheria/Tetanus/Pertussis (DTP or DTap) | |
| Indicate vaccine name for Diphtheria/Tetanus/Pertussis (DTP or DTap) | Removed |
| Indicate manufacturer for Haemophilus influenzae type B (Hib) | Removed |
| Indicate vaccine name for Haemophilus influenzae type B (Hib) | Removed |
| Indicate dates of immunization for influenza vaccine | Removed |
| Indicate manufacturer for influenza vaccine | Removed |
| Indicate vaccine name for influenza vaccine | Removed |
| | <p>Was health care provider information available from the following sources?</p> <p>Medical chart:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Did not check</p> <p>Vaccine Registry:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Did not check</p> <p>Parent/Guardian:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Did not check</p> <p><input type="checkbox"/> Refused</p> |
| | If yes to any sources, how many providers were contacted? |
| | <p>What sources were used for vaccination history?</p> <p>Medical chart:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Did not check</p> <p>Vaccine Registry:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> |

| | |
|--|--|
| | <p><input type="checkbox"/> Did not check</p> <p>Primary Care Provider:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Did not check</p> <p>Other Provider:</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Did not check</p> |
|--|--|

ABCs Change Estimates of Annualized Burden Hours from 2014 to 2015

Table A.1 Estimated Annualized Burden Hours(Highlighted forms below indicate a change in burden hours in 2015)

| Type of Respondent | Form Name | No. of respondents | No. of responses per respondent | Avg. burden per response (in hours) | 2015 Total burden (in hours) |
|---------------------------|---|---------------------------|--|--|-------------------------------------|
| State Health Department | ABCs Case Report Form | 10 | 809 | 20/60 | 2697 |
| | Invasive Methicillin-resistant <i>Staphylococcus aureus</i> ABCs Case Report Form | 10 | 609 | 20/60 | 2030 |
| | ABCs Invasive Pneumococcal Disease in Children Case Report Form | 10 | 22 | 10/60 | 37 |
| | New Form: ABCs Non-Bacteremic Pneumococcal Disease Case Report Form | 10 | 100 | 10/60 | 167 |
| | Neonatal Infection Expanded Tracking Form | 10 | 37 | 20/60 | 123 |
| | ABCs Legionellosis Case Report Form | 10 | 100 | 20/60 | 333 |

Foodborne Diseases Active Surveillance Network (FoodNet)

Minor revisions have been made to the FoodNet surveillance tool since the last change approval in 2014; however the changes did not result in a change to estimated burden hours for those forms.

Detailed Description of Changes

- Expanded the list of responses for ‘AgClinicTestType’ to reflect new tests that are now being used in clinical labs.
- Added two new variables related to culture-independent testing for STEC:
 - o DXO157
 - o DXO157TestType
- Added the following new variables to capture case exposure information to be used for attribution estimates. These variables were developed by a working group consisting of CDC and state health department sites over a two-year period. Variables were pilot-tested in 4 sites for a three-month period for *Salmonella* and *Campylobacter* cases.

- o Meat and poultry
 - CEA_Beef
 - CEA_Beef_grnd
 - CEA_Beef_out
 - CEA_Beef_unckgrnd
 - CEA_Chicken
 - CEA_Chx_grnd
 - CEA_Chx_out
 - CEA_Pork
 - CEA_Turkey
 - CEA_Turkey_grnd
 - CEA_Turkey_out
- o Fish and seafood
 - CEA_Fish
 - CEA_Fish_unck
 - CEA_Seafd
 - CEA_Seafd_unck
- o Dairy
 - CEA_Dairy
 - CEA_Milk_raw
 - CEA_Odairy_raw
 - CEA_Softcheese
 - CEA_Softcheese_raw
- o Eggs
 - CEA_Eggs
 - CEA_Eggs_out
 - CEA_Eggs_unck
- o Fruits and vegetables
 - CEA_Berries
 - CEA_Cantaloupe
 - CEA_Herbs
 - CEA_Lettuce
 - CEA_Spinach
 - CEA_Sprouts
 - CEA_Raw_cider
 - CEA_Tomatoes
 - CEA_Watermelon
- o Water
 - CEA_Ountreat_water
 - CEA_Sewer_water
 - CEA_Swim_treat
 - CEA_Swim_untreat
 - CEA_Well_water
- o Person-to-person
 - CEA_Sick_contact
- o Environmental
 - CEA_Bird
 - CEA_Cat
 - CEA_Dog
 - CEA_Farm_ranch
 - CEA_Live_poultry
 - CEA_Pig
 - CEA_Pocketpet
 - CEA_Reptile_amphib
 - CEA_Ruminants
 - CEA_Sick_pet

Influenza - All Age Influenza Hospitalization Surveillance Project

Minor revisions have been made to the FluSurv-NET Influenza Surveillance tool since the last change approval in 2014; however the changes did not result in a change to estimated burden hours for those forms.

Detailed Description of Changes

A. 2014-15 FluSurv-NET Influenza Surveillance Project_Case Report Form

- A question was added to capture the type of address provided for the patient.
- Additional questions were added to capture additional patient provider contact information.
- To better capture information on where the patient resided at the time of, additional residence type options for question C13 were added.
- Questions regarding Influenza testing results were updated to include new influenza testing types and corresponding result options.

- To better capture information regarding signs/symptoms at the time of admission, question E2 was rephrased to list signs/symptoms as they appear in medical chart – but original intent of question was preserved.
- The options for specifying location of consolidation was removed from questionnaire.
- The section on vaccination status has now an option to record type of vaccination (injected or nasal spray) for children <9 years of age.

B. 2014-2015 FluSurv-NET Influenza Surveillance Project_Vaccination History Telephone Survey (Changes Account for the English and Spanish Version)

- Addition of a question to capture the type of vaccination (injected or nasal spray) received by patients <9 years of age.

C. 2014-2015 FluSurv-NET Influenza Surveillance Project_Consent Form (Changes Account for the English and Spanish Version)

- Location of reference material for continuation of interview was updated to reflect current location.

Cross walk of 2015 form changes

A. 2014-15 FluSurv-NET Influenza Surveillance Project_Case Report Form

| <u>Question on 2013-14 Form</u> | <u>Question on 2014-15 Form</u> |
|--|--|
| N/A | A10. Address Type: _____ |
| N/A | A16. Primary Provider (PCP) Name 2: _____ |
| N/A | A17. Primary Provider (PCP) Phone 2: _____ |
| N/A | A18. Primary Provider (PCP) Fax2: _____ |
| E13. Where did patient reside at the time of hospitalization? <input type="checkbox"/> Private residence <input type="checkbox"/> Rehabilitation facility <input type="checkbox"/> Group home/Retirement home <input type="checkbox"/> Assisted living/Residential care <input type="checkbox"/> Homeless/Shelter <input type="checkbox"/> Nursing home <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify: _____ | E13. Where did patient reside at the time of hospitalization? <input type="checkbox"/> Private residence <input type="checkbox"/> Alcohol/Drug Abuse Treatment <input type="checkbox"/> Group home/Retirement home <input type="checkbox"/> Homeless/Shelter <input type="checkbox"/> Hospitalized at birth <input type="checkbox"/> Jail/Prison <input type="checkbox"/> LTACH/Transitional Care (TCU) <input type="checkbox"/> Mental Hospital <input type="checkbox"/> Nursing home <input type="checkbox"/> Rehabilitation facility <input type="checkbox"/> Hospice <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify: _____ |
| D1-4. Test 1-4: <input type="checkbox"/> Rapid <input type="checkbox"/> RT-PCR <input type="checkbox"/> Viral Culture <input type="checkbox"/> Serology <input type="checkbox"/> Fluorescent Antibody <input type="checkbox"/> Method Unknown/Note Only | D1-4. Test 1-4: <input type="checkbox"/> Rapid <input type="checkbox"/> Molecular Assay <input type="checkbox"/> Viral Culture <input type="checkbox"/> Serology <input type="checkbox"/> Fluorescent Antibody <input type="checkbox"/> Method Unknown/Note Only |
| D1a-4a. Result: <input type="checkbox"/> Flu A (not subtyped) <input type="checkbox"/> Flu B <input type="checkbox"/> Flu A & B <input type="checkbox"/> Flu A/B (Not Distinguished) <input type="checkbox"/> 2009 H1N1 | D1a-4a. Result: <input type="checkbox"/> Flu A (no subtype) <input type="checkbox"/> Flu B(no genotype) <input type="checkbox"/> Flu A & B <input type="checkbox"/> Flu A/B (Not Distinguished) <input type="checkbox"/> 2009 H1N1 |

| | |
|---|---|
| <input type="checkbox"/> H1, Seasonal <input type="checkbox"/> H1, Unspecified <input type="checkbox"/> H3 <input type="checkbox"/> Flu A, Unsubtypable <input type="checkbox"/> Negative <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify: _____ | <input type="checkbox"/> H1, Unspecified <input type="checkbox"/> H3 <input type="checkbox"/> Flu A, Unsubtypable <input type="checkbox"/> Flu B, Yamagata <input type="checkbox"/> Flu B, Victoria <input type="checkbox"/> Negative <input type="checkbox"/> Unknown Type <input type="checkbox"/> Other, specify: _____ |
| E2. Acute conditions at admission (Check all that apply): <input type="checkbox"/> Acute respiratory illness <input type="checkbox"/> Asthma and/or COPD exacerbation <input type="checkbox"/> Fever <input type="checkbox"/> Pneumonia <input type="checkbox"/> Other respiratory or cardiac conditions <input type="checkbox"/> Other, neither respiratory nor cardiac conditions <input type="checkbox"/> Unknown | E2. Acute signs/symptoms at admission [within 2 weeks prior to positive flu test]: <input type="checkbox"/> Altered mental status/confusion <input type="checkbox"/> Chest pain <input type="checkbox"/> Congested/runny nose <input type="checkbox"/> Conjunctivitis/pink eye <input type="checkbox"/> Cough <input type="checkbox"/> Diarrhea <input type="checkbox"/> Fever/chills <input type="checkbox"/> Headache <input type="checkbox"/> Myalgia/muscle aches <input type="checkbox"/> Nausea/vomiting <input type="checkbox"/> Rash <input type="checkbox"/> Seizures <input type="checkbox"/> Shortness of breath/resp distress <input type="checkbox"/> Sore throat <input type="checkbox"/> Wheezing <input type="checkbox"/> Other, non-respiratory |
| E3. Date of onset of acute respiratory symptoms: ____/____/____ <input type="checkbox"/> Unknown | E3. Date of onset of acute respiratory symptoms [within 2 weeks prior to positive flu test]: ____/____/____ <input type="checkbox"/> Unknown |
| E3a. If no respiratory symptoms, date of onset of acute illness resulting in hospitalization: ____/____/____ <input type="checkbox"/> Unknown | E4. Date of onset of acute condition resulting in current hospitalization: ____/____/____ <input type="checkbox"/> Unknown |
| E9i. Immunocompromised Condition <input type="checkbox"/> Yes <input type="checkbox"/> No/Unknown <input type="checkbox"/> AIDS or CD4 count < 200 <input type="checkbox"/> Cancer diagnosis in last 12 months <input type="checkbox"/> Complement deficiency <input type="checkbox"/> HIV Infection <input type="checkbox"/> Immunoglobulin deficiency <input type="checkbox"/> Immunosuppressive therapy <input type="checkbox"/> Organ transplant <input type="checkbox"/> Stem cell transplant (e.g., bone marrow transplant) <input type="checkbox"/> Steroid therapy (taken within 2 weeks of admission) <input type="checkbox"/> Other, specify _____ | E10i. Immunocompromised Condition <input type="checkbox"/> Yes <input type="checkbox"/> No/Unknown <input type="checkbox"/> AIDS or CD4 count < 200 <input type="checkbox"/> Cancer: current/in treatment or diagnosed in last 12 months <input type="checkbox"/> Complement deficiency <input type="checkbox"/> HIV Infection <input type="checkbox"/> Immunoglobulin deficiency <input type="checkbox"/> Immunosuppressive therapy <input type="checkbox"/> Organ transplant <input type="checkbox"/> Stem cell transplant (e.g., bone marrow transplant) <input type="checkbox"/> Steroid therapy (taken within 2 weeks of admission) <input type="checkbox"/> Other, specify _____ |
| E9k. Other <input type="checkbox"/> Yes <input type="checkbox"/> No/Unknown <input type="checkbox"/> Liver disease (e.g., cirrhosis, chronic hepatitis, hepatitis C) <input type="checkbox"/> Morbidly obese (ADULTS ONLY) <input type="checkbox"/> Obese <input type="checkbox"/> Pregnant <input type="checkbox"/> If pregnant, specify gestational age in weeks: _____ <input type="checkbox"/> Unknown gestational age <input type="checkbox"/> Post-partum (two weeks or less) <input type="checkbox"/> Other, specify _____ | E10k. Other <input type="checkbox"/> Yes <input type="checkbox"/> No/Unknown <input type="checkbox"/> Intravenous drug use <input type="checkbox"/> Liver disease (e.g., cirrhosis, chronic hepatitis, hepatitis C) <input type="checkbox"/> Systemic lupus erythematosus/SLE/Lupus <input type="checkbox"/> Morbidly obese (ADULTS ONLY) <input type="checkbox"/> Obese <input type="checkbox"/> Pregnant <input type="checkbox"/> If pregnant, specify gestational age in weeks: _____ <input type="checkbox"/> Unknown gestational age <input type="checkbox"/> Post-partum (two weeks or less) <input type="checkbox"/> Other, specify _____ |
| H1f. Human metapneumovirus <input type="checkbox"/> Yes, positive <input type="checkbox"/> Yes, negative <input type="checkbox"/> Not tested/Unknown Date: ____/____/____ | H1f. Parainfluenza 4 <input type="checkbox"/> Yes, positive <input type="checkbox"/> Yes, negative <input type="checkbox"/> Not tested/Unknown Date: ____/____/____ |
| H1g. Rhinovirus | H1g. Human metapneumovirus |

| | |
|--|--|
| <input type="checkbox"/> Yes, positive <input type="checkbox"/> Yes, negative <input type="checkbox"/> Not tested/Unknown Date: ____/____/____ | <input type="checkbox"/> Yes, positive <input type="checkbox"/> Yes, negative <input type="checkbox"/> Not tested/Unknown Date: ____/____/____ |
| H1h. Other, specify: _____ <input type="checkbox"/> Yes, positive <input type="checkbox"/> Yes, negative <input type="checkbox"/> Not tested/Unknown Date: ____/____/____ | H1h. Rhinovirus/Enterovirus <input type="checkbox"/> Yes, positive <input type="checkbox"/> Yes, negative <input type="checkbox"/> Not tested/Unknown Date: ____/____/____ |
| N/A | H1i. Coronavirus (type): _____ <input type="checkbox"/> Yes, positive <input type="checkbox"/> Yes, negative <input type="checkbox"/> Not tested/Unknown Date: ____/____/____ |
| J2c. Please specify location for bronchopneumonia/pneumonia/consolidation/lobar infiltrate/air space density/opacity: <input type="checkbox"/> Single lobar <input type="checkbox"/> Multiple lobar (unilateral) <input type="checkbox"/> Multiple lobar (bilateral) <input type="checkbox"/> Unknown | Removed |
| K2a. If discharged alive, please indicate to where: <input type="checkbox"/> Home <input type="checkbox"/> Other hospital <input type="checkbox"/> Hospice/Home hospice <input type="checkbox"/> Homeless/Shelter <input type="checkbox"/> Rehabilitation Facility <input type="checkbox"/> Group home/Retirement home <input type="checkbox"/> Assisted living/Residential Care <input type="checkbox"/> Home with Services <input type="checkbox"/> Nursing home <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify: _____ | K2a. If discharged alive, please indicate to where: <input type="checkbox"/> Private residence <input type="checkbox"/> Alcohol/Drug Abuse Treatment <input type="checkbox"/> Assisted living/Residential Care <input type="checkbox"/> Group home/Retirement home <input type="checkbox"/> Home with Services <input type="checkbox"/> Homeless/Shelter <input type="checkbox"/> Jail/Prison <input type="checkbox"/> LTACH/Transitional Care (TCU) <input type="checkbox"/> Mental Hospital <input type="checkbox"/> Nursing home <input type="checkbox"/> Rehabilitation Facility <input type="checkbox"/> Hospice <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify: _____ |
| M1. Did patient receive the influenza vaccine for the current influenza season? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | Removed |
| M2-M6. [vaccination history source] <input type="checkbox"/> Yes <input type="checkbox"/> Yes, specific date unknown <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Checked | M1-M4. [vaccination history source] <input type="checkbox"/> Yes, full date known <input type="checkbox"/> Yes, specific date unknown <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Checked |
| N/A | M1b-M4b. If patient < 9 yrs, specify vaccine type: Injected Vaccine Nasal Spray/FluMist Combination of both Unknown type |

B. 2014-2015 FluSurv-NET Influenza Surveillance Project_Vaccination History Telephone Survey

| <u>Question on 2013-14 Survey</u> | <u>Question on 2014-15 Survey</u> |
|-----------------------------------|---|
| N/A | 1b) What type of flu vaccine did [you / child's name] receive? <input type="checkbox"/> Injected Vaccine <input type="checkbox"/> Nasal Spray/FluMist |

| | |
|--|---|
| | <input type="checkbox"/> Combination of both <input type="checkbox"/> Unknown type |
|--|---|

C. 2014-2015 FluSurv-NET Influenza Surveillance Project_Consent Form

| Question on 2013-14 Consent Form | Question on 2014-15 Consent Form |
|---|--|
| <p>Hello. My name is _____ from the ____ [state] Department of Public Health. May I speak to _____ [patient’s name /parent of [child’s name]] . We are working with the Centers for Disease Control and Prevention and other health departments to learn more about influenza disease or the flu. To do this, we are talking to people who have been in the hospital with the flu. We want to look at things that may affect their illness and whether they were vaccinated against the flu.</p> <p>Because you/your child [or NAME if speaking with proxy] were in the hospital for the flu beginning on _____ [day admitted], I would like to ask you a few questions about whether you/your child [or NAME if speaking with proxy] received the flu vaccine this season. This will take about five minutes. Your participation is voluntary and if you choose to refuse it will not affect any medical care or benefits you receive. All of your responses will be kept confidential as much as the law allows. You may refuse to answer any questions and may stop at any time. This information will help [State/Local Health Department] and CDC better describe influenza-associated hospitalizations. Additionally, this information may help us improve vaccination recommendations for flu and better protect the public’s health. There is no other benefit to you for answering these questions. There is also no risk to you. If you have any questions about the study, you may call _____ [state contact] at the Department of Public Health at XXX-XXX-XXXX. Do you have any questions before I begin? May I continue with this interview? <input type="checkbox"/> Yes <input type="checkbox"/> No If YES, go to Appendix F. If NO: Thank you for your time. Have a good day</p> | <p>Hello. My name is _____ from the ____ [state] Department of Public Health. May I speak to _____ [patient’s name /parent of [child’s name]] . We are working with the Centers for Disease Control and Prevention and other health departments to learn more about influenza disease or the flu. To do this, we are talking to people who have been in the hospital with the flu. We want to look at things that may affect their illness and whether they were vaccinated against the flu.</p> <p>Because you/your child [or NAME if speaking with proxy] were in the hospital for the flu beginning on _____ [day admitted], I would like to ask you a few questions about whether you/your child [or NAME if speaking with proxy] received the flu vaccine this season. This will take about five minutes. Your participation is voluntary and if you choose to refuse it will not affect any medical care or benefits you receive. All of your responses will be kept confidential as much as the law allows. You may refuse to answer any questions and may stop at any time. This information will help [State/Local Health Department] and CDC better describe influenza-associated hospitalizations. Additionally, this information may help us improve vaccination recommendations for flu and better protect the public’s health. There is no other benefit to you for answering these questions. There is also no risk to you. If you have any questions about the study, you may call _____ [state contact] at the Department of Public Health at XXX-XXX-XXXX. Do you have any questions before I begin? May I continue with this interview? <input type="checkbox"/> Yes <input type="checkbox"/> No If YES, go to Appendix 7. If NO: Thank you for your time. Have a good day.</p> |