

Committee: Infectious Diseases

Title: Enhancing state-based surveillance for invasive pneumococcal disease

I. Statement of the Problem:

Cases of invasive pneumococcal disease among children less than 5 years old (IPD<5) and invasive, drug-resistant *Streptococcus pneumoniae* (DRSP) among all ages are currently reportable to the National Notifiable Diseases Surveillance System (NNDSS). There is considerable variation in reported data among jurisdictions, and in many sites data are incomplete. In particular, reporting of DRSP to NNDSS is suboptimal, despite continuing efforts to improve surveillance. At the national level, the data reported to NNDSS do not enable accurate assessment of invasive pneumococcal disease burden or monitoring of immunization program effects. With expected licensure of a new 13-valent pneumococcal conjugate vaccine (PCV13) in late 2009 or early 2010, surveillance should be enhanced to provide baseline and ongoing data for assessment of disease burden and immunization program effects.

II. Background and Justification:

Routine infant immunization with the 7-valent pneumococcal conjugate vaccine (PCV7) began in 2000 in the U.S. Since then, surveillance systems have reported dramatic reductions in the incidence of invasive pneumococcal disease (IPD) in children <5 years, the PCV7 target group, as well as in unvaccinated groups due to indirect vaccine effects.[1, 2]

Despite the PCV7 impact, IPD remains an important cause of illness and death with an estimated 42,000 cases and 4,500 deaths among persons of all ages in 2007.[2] About 85% of the remaining invasive infections and almost all deaths occur in adults. Among children aged <5 years, an estimated 4,600 IPD cases occurred in 2007.[2] Currently, almost all IPD cases in this age group are caused by serotypes not included in PCV7, and nearly two-thirds are caused by the 6 serotypes included in the investigational PCV13 but not in PCV7.

To track the effects of pneumococcal vaccination and other prevention efforts, CSTE has, in separate resolutions, recommended reporting of IPD<5 and of DRSP. For this reason, two event codes have been used for reporting invasive *Streptococcus pneumoniae* infection: 11717 (IPD<5) and 11720 (DRSP). To make the conditions mutually exclusive, the case definitions for these conditions had to be revised in 2006.[3] Cases in children <5 years with isolates of *S. pneumoniae* that are susceptible or for which antimicrobial susceptibilities are not available should be reported only as IPD<5 (11717). Cases in children <5 years of age for which antimicrobial susceptibilities are available and determined to be intermediate or resistant to at least one antibiotic currently approved for use of treating invasive pneumococcal infections should be reported only as DRSP (11720). The existence of separate NNDSS codes and definitions for different and overlapping subsets of the same disease may have contributed to wide variations in

reporting among jurisdictions and for variability in data completeness within jurisdictions — both of which make the national data, particularly for DRSP, difficult to interpret. Among the jurisdictions with a reporting requirement in 2007, 2 (5%) of 43 areas reported no cases of IPD<5 and 11 (26%) of 42 areas reported no cases of DRSP.

In January 2008, the Clinical and Laboratory Standards Institute published new MIC breakpoints for defining susceptibility of *S. pneumoniae* isolates to penicillin.[4] The new breakpoints are estimated to decrease the number of isolates classified as antibiotic-resistant by approximately 5%.[5] The changes in breakpoints will likely result in a surveillance artifact in DRSP reporting and further complicate interpretation of the reported data.

Meaningful monitoring of invasive pneumococcal disease requires serotyping. A method for polymerase chain reaction (PCR)-based serotyping is now available through CDC for use by state and territorial public health laboratories. The PCR method can be used for distinguishing whether the detected cases are caused by serotypes included in PCV13 or other serotypes.[6] Adopting this method will allow public health jurisdictions that systematically collect pneumococcal isolates from invasive cases to track the local impact of PCV vaccination.

Justification

Invasive pneumococcal disease incidence and mortality meet the following criteria for a nationally and **standard** notifiable condition, as specified in CSTE position statement 08-EC-02:

- All states and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws and/or regulations requiring **standard** reporting of invasive pneumococcal disease incidence and mortality to public health authorities
- CDC requests **standard** notification of invasive pneumococcal disease incidence and mortality to federal authorities
- CDC has condition-specific policies and practices concerning the agency's response to, and use of, notifications.

III. Statement of the desired action(s) to be taken:

1. CDC should create a message mapping guide that specifies the data elements for CDC notification of invasive pneumococcal disease.
2. The classification of invasive pneumococcal disease cases into separate event codes (11717 and 11720) should be discontinued, and a single code should be used for all IPD cases.
3. Notification for invasive *S. pneumoniae* disease cases among all ages should be done as follows:
 - a. All cases of invasive pneumococcal disease should be reported using a SINGLE event code.
 - b. The case definition for invasive *S. pneumoniae* disease will be: Isolation of *S. pneumoniae* from a normally sterile body site (e.g., blood, cerebrospinal fluid, or, less commonly, joint, pleural or pericardial fluid).

- c. Core surveillance data elements from all cases should be collected by all reporting jurisdictions and transmitted weekly to CDC. These data should include epidemiologically important elements such as demographics, information on underlying conditions associated with increased risk of IPD, and vaccination status.
 - d. Antibiotic susceptibility testing results (MICs, susceptibility interpretations) should be included for each case.
4. CDC will collaborate with local, state and territorial health departments to transfer the technology of PCR-based serotyping to state and territorial public health laboratories as soon as possible, with the goal of enhancing public health laboratory capacity so that the jurisdictions can better distinguish vaccine-preventable cases of IPD from those that are not caused by serotypes included in the conjugate vaccines.

IV. Goals of Surveillance:

1. To monitor the impact of immunization against pneumococcal disease
2. To track progress toward Healthy People 2010 objectives
3. To monitor drug resistance among pneumococci
4. To assist public health jurisdictions in raising awareness of vaccine recommendations.

V. Methods for Surveillance

Source of data for case identification	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies)	X	
Death certificates	X	
Hospital discharge or outpatient records	X	
Extracts from electronic medical records	X	
Telephone survey		
School-based survey		
Other _____		

VI. Criteria for Reporting:

A. Narrative: A description of criteria for case ascertainment of a specific condition.

Within one week of diagnosis, report any person

1. from whom *Streptococcus pneumoniae* is isolated from a normally sterile body site; or

2. whose medical record contains a diagnosis of invasive *Streptococcus pneumoniae* disease; or
3. whose death certificate lists invasive *Streptococcus pneumoniae* disease as the cause or as a contributing cause of death.

B. Table of criteria to determine whether a case should be reported to public health authorities.

Table VI-B. Proposed Table of criteria to determine whether a case should be reported to public health authorities. Note: The following criteria are proposed for evaluation before general implementation. For purposes of currently implementing reporting the narrative description in VI-A, should be used.

Criterion	Reporting		
Isolation of <i>Streptococcus pneumoniae</i> from a normally sterile site (e.g., blood, cerebrospinal fluid, joint, pleural or pericardial fluid).	S		
Medical record contains a diagnosis of invasive <i>Streptococcus pneumoniae</i> disease		S	
Death certificate lists invasive <i>Streptococcus pneumoniae</i> disease as cause of death or significant contributing condition to death			S

Notes:

S = This criterion alone is sufficient to report a case.

C. Disease-specific data elements:

Clinical information.

Date of illness onset

Clinical syndrome (e.g., pneumonia, meningitis)

Antimicrobial susceptibilities of the pneumococcal isolate

Epidemiological risk factors

Underlying medical conditions

Pneumococcal vaccination history: vaccine types and dates

VII. A. Case Definition for Case Classification

- *Confirmed:* isolation of *Streptococcus pneumoniae* from a normally sterile body site in a person of any age.
- *Suspected:* any reported case lacking confirmation of isolation of *Streptococcus pneumoniae* from a normally sterile body site .

Table VII-B. Proposed table of criteria to determine whether a case is classified. Note: The following criteria are proposed for evaluation before general implementation. For purposes of current notification, the narrative description in VII-A, should be used.

Criterion	Confirmed	Suspected
Medical record containing a diagnosis of invasive <i>S. pneumoniae</i> disease		S
Death certificate listing invasive <i>S. pneumoniae</i> disease as the cause or a contributing cause of death		S
Other reported pneumococcal disease		S
<i>Laboratory findings</i> Isolation of <i>S. pneumoniae</i> from a normally sterile site (e.g., blood, cerebrospinal fluid, or, less commonly, joint, pleural or pericardial fluid)	S	

Notes:

S = This criterion alone is sufficient to classify a case.

N = All “N” criteria in the same column—in conjunction with at least one of the “O” criteria in each category (e.g., clinical presentation and laboratory findings) in the same column—are Necessary to identify a case for classification.

O = At least one of these “O” (Optional) criteria in each category (e.g., clinical presentation and laboratory findings) in the same column—in conjunction with all other “N” criteria in the same column—is required to classify a case.

A = This criterion must be absent (i.e., NOT present) for the case to meet the reporting criteria.

* A requisition or order for any of the “S” or “N” laboratory tests is sufficient to meet the classification criteria.

VIII. Period of Surveillance:

Surveillance is ongoing.

IX. Data sharing/release and Print criteria:

- Notification to CDC of confirmed cases of invasive pneumococcal disease (IPD) is recommended.
- Electronic reports of IPD cases among all ages in NNDSS will be summarized weekly in the MMWR Tables and yearly in the Summary of Notifiable Diseases.
- The frequency of other reports to the states and territories will be dependent on the current epidemiologic situation, antimicrobial resistance trends and status of new vaccine introduction and uptake.
- Data will be included in PAHO and WHO annual reports according to standard schedules.

- CDC will further analyze national IPD data periodically. Additional publications might include epidemiologic summaries in the MMWR or manuscripts in peer-reviewed journals.

X. References:

1. Centers for Disease Control and Prevention. Invasive pneumococcal disease in children 5 years after conjugate vaccine introduction--eight states, 1998-2005. MMWR 2008;57:144-8.
2. Centers for Disease Control and Prevention. Active Bacterial Core Surveillance Report, Emerging Infections Program Network, *Streptococcus pneumoniae*, 2007. Available via the Internet: <http://www.cdc.gov/ncidod/dbmd/abcs/survreports/spneu07.pdf>. 2008.
3. Council of State and Territorial Epidemiologists. Enhancing local, state and territorial-based surveillance for invasive pneumococcal disease in children less than five years of age. Position Statement 2006-14, 2006. Available at <http://www.cste.org/PS/2006pdfs/PSFINAL2006/06-ID-14FINAL.pdf>
4. Clinical and Laboratory Standards Institute. Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement. CLSI document M100-S18 (ISBN 1-56238-653-0). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania. 19087-1898 USA, 2008.
5. Centers for Disease Control and Prevention. Effect of New Penicillin Susceptibility Breakpoints for *Streptococcus pneumoniae*—United States, 2006-2007. MMWR 2008;57:1353-5.
6. Pai R, Moore MR, Pilishvili T, Gertz RE, Whitney CG, Beall B. Postvaccine genetic structure of *Streptococcus pneumoniae* serotype 19A from children in the United States. J Infect Dis 2005;192:1988-95.
7. Gordon L, Petkus D. (May 29, 2008). "Wyeth Receives FDA Fast Track Designation for its 13-valent Pneumococcal Conjugate Vaccine for Infants and Toddlers." Press release. Retrieved on 2008-9-29.

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