2008 Protocol for Active Bacterial Core surveillance (ABCs) for the Emerging Infection Program Sites

Last Updated: January 2008

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Purpose:

1) To determine the incidence and epidemiologic characteristics of invasive disease due to *Haemophilus influenzae*, *Neisseria meningitidis*, group A streptococcus, group B streptococcus, *Streptococcus pneumoniae*, and methicillin-resistant *Staphylococcus aureus* in several large populations.

2) To determine molecular epidemiologic patterns and microbiologic characteristics of public health relevance for isolates causing the above invasive infections, such as the proportion of pneumococcal isolates that are drug-resistant among all invasive strains.

3) To provide an infrastructure for additional special studies including those aimed at identifying risk factors for disease and evaluating prevention policies.

Surveillance areas:

The total population of invasive disease surveillance is approximately 40 million. However, most areas restrict the population further for certain pathogens to ensure complete reporting and good audit data. The table below illustrates the populations under surveillance for each pathogen and area as of January 2008.

Area	***Neisseria meningitidis***	***Haemophilus influenzae***	group B *Streptococcus*	group A *Streptococcus*	***Streptococcus pneumoniae***	MRSA
CA	3,225,786 (3 county Bay area)	3,225,786 (3 county Bay area)	3,225,786 (3 county Bay area)	3,225,786 (3 county Bay area)	744,041 (San Francisco) and 170,776 (<5 year olds in Contra Costa & Alameda) ***Total*****:** 914,817	3,225,786 (3 county Bay area)
CO	2,309,124 (5 county Denver area)	2,309,124 (5 county Denver area)	36,429 (<1 years, 5 county Denver area)	2,309,124 (5 county Denver area)	2,309,124 (5 county Denver area)	2,309,124 (5 county Denver area)
CT	3,504,809	3,504,809	36,077 (<1 years, state)	3,504,809	3,504,809	3,504,809
GA	9,363,941	4,983,946 (20 county Atlanta area)	4,983,946 (all ages, 20 county Atlanta area) and 65,060 (<1 years outside 20	4,983,946 (20 county Atlanta area)	4,983,946 (20 county Atlanta area)	3,682,620 (8 county Atlanta area)

			county metro) ***Total:*** 5,049,006			
MD	5,615,727	5,615,727	5,615,727	2,612,164 (6 county Baltimore area)	2,612,164 (6 county Baltimore area)	1,418,750 (2 metro Baltimore counties)
MN	5,167,101	5,167,101	5,167,101	5,167,101	5,167,101	1,615,308 (2 metro Twin Cities counties)
NM	1,954,599	1,954,599	1,954,599	1,954,599	1,954,599	--
NY	2,131,843 (7 county Rochester area and 8 county Albany area)	2,131,843 (7 county Rochester area and 8 county Albany area)	2,131,843 (7 county Rochester area and 8 county Albany area)	2,131,843 (7 county Rochester area and 8 county Albany area)	2,131,843 (7 county Rochester area and 8 county Albany area) and 50,242 (<5 years in Erie county) ***Total:*** 2,182,085	730,807 (1 Rochester county)
OR	3,700,758	3,700,758	1,569,953 (3 county Portland area)	1,569,953 (3 county Portland area)	1,569,953 (3 county Portland area)	1,569,953 (3 county Portland area)
TN	3,005,857 (11 urban counties)	3,005,857 (11 urban counties)	3,005,857 (11 urban counties)	3,005,857 (11 urban counties)	3,005,857 (11 urban counties)	578,698 (1 Nashville county)
Total	39,979,545	35,599,550	27,792,378	30,465,182	28,204,455	18,635,855

Populations were retrieved from the National Center for Health Statistics bridged-race vintage 2006 postcensal file

Case definitions:

A case of invasive bacterial disease is defined as isolation of *H. influenzae*, *N. meningitidis*, group A *Streptococcus*, group B *Streptococcus*, or *S. pneumoniae* from a normally sterile site in a resident of one of the surveillance areas. In addition to the five core pathogens, select counties of the following surveillance areas are conducting surveillance for methicillin-resistant *Staphylococcus aureus*: California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New York, Oregon, and Tennessee.

A normally sterile site is defined as a portion of the human body in which no microorganisms are found in a healthy state and include (but are not limited to) the following: blood, cerebrospinal fluid (CSF), pleural fluid, peritoneal fluid, pericardial fluid, bone, joint fluid, muscle (when covered by intact skin), and internal body site (lymph node, brain, heart, liver, spleen, vitreous fluid, kidney, pancreas, or ovary). Muscle should be considered a sterile site for group A streptococcus only.

Unless the case meets one of the special circumstances listed below, sole isolation of an organism from one of the following sites (i.e., no isolation from a normally sterile site as defined above) would <u>not</u> meet the case definition for the purpose of this surveillance: middle ear, amniotic fluid, placenta, sinus, wound, lung, gallbladder, appendix, cornea, throat, skin abscess or subcutaneous tissue abscess. (ABSCESS CURRENTLY UNDER

DISCUSSION)

Positive antigen detection, counter immunoelectrophoresis, or other non-culture based methods are not sufficient case definitions for reporting in this surveillance system.

Autopsy cases will be handled on a case-by-case basis. The ABCs coordinator should be contacted to discuss any autopsy case in which a culture was taken 12 hours or less after death. Cultures taken more than 12 hours after death will not be considered sterile site cultures for ABCs purposes.

CDC will strictly adhere to the definitions as stated above. Any cases reported in the surveillance database that do not fit these definitions will be deleted from any analysis that CDC performs.

Special circumstances:

GBS isolates associated with stillbirth: If group B *Streptococcus* is isolated from a sterile site in a stillbirth or from the placenta and/or amniotic fluid (no other sterile site for mother) and a fetal death occurs, it will be considered a maternal case for this surveillance system and a case report form should be filled out. Routine surveillance of all placentas is not required. Since detection of fetal deaths associated with placental or amniotic fluid isolates is of differing complexity in different geographic areas, the decision to systematically ascertain these cases is left to the surveillance officers. The following areas are conducting surveillance for these cases: California, Colorado, Georgia, Maryland, Minnesota, New York, and Tennessee. California, Minnesota, New Mexico and Tennessee do not audit all placenta positive cultures to determine if fetal demise occurred.

GAS and wound cultures: If group A *Streptococcus* is isolated from a wound culture and is accompanied by necrotizing fasciitis or streptococcal toxic shock syndrome (STSS) as defined by The Working Group on Severe Streptococcal Infections *(defined in JAMA 1993;269:390-91)*, it should be considered a case for this surveillance system and a case report form should be filled out. Routine surveillance of all wound cultures is not required.

Neonatal sepsis: If any bacterial pathogen (including a core ABCs pathogen) is isolated from blood or CSF of a neonate that was born in a surveillance participating hospital, it will be considered a case for this surveillance system and a Neonatal Sepsis Surveillance Form and a Neonatal Sepsis Maternal Form should be completed. Neonatal sepsis cases will be identified through the onsite cooperation of participating surveillance hospital personnel and/or laboratory audits of participating clinical labs. Common contaminants such as coagulase negative staphylococci (*Staphylococcus epidermidis)* or Candida do not need to be reported (for other examples of contaminants please refer to the Neonatal Sepsis Surveillance Form instruction sheet). Ascertainment of neonatal sepsis cases includes infants <=2 days old (> 22 weeks gestational age). In 2008, the following areas are conducting surveillance for neonatal sepsis cases: Georgia (17 area hospitals in the eight county metro area), California (3 county area), Connecticut (statewide) and Minnesota (statewide).

Early-onset and late-onset group B streptococcal disease: Sites currently complete an ABCs case report form on all cases of early and late-onset GBS disease which requires review of the infant medical record in most areas. In order to assess the extent to which continuing cases of early-onset disease reflect missed opportunities for GBS prevention and to identify risk factors for late-onset disease, sites conduct enhanced surveillance for early and late-onset GBS cases (>22 weeks gestational age) by completing a supplemental CRF with data from the maternal medical record. The following areas are conducting extended surveillance for early and late-onset GBS cases: California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon, and Tennessee.

Invasive Pneumococcal Disease in Children: An expanded Invasive Pneumococcal Disease in Children form should be completed on all cases of *Streptococcus pneumoniae* isolated from a normally sterile site in a child 3 to 59 months of age with an isolate available for serotyping. This form is being completed by all ABCs areas that conduct surveillance for invasive pneumococcal disease. Sites should obtain vaccine history information from either the child's primary care physician or from a vaccine registry, whichever source yields the most complete information on vaccination history.

Invasive methicillin-resistant Staphylococcus aureus: If methicillin-resistant *Staphylococcus aureus* (MRSA) is isolated from a normally sterile site in a resident of a participating surveillance county, it will be considered a case for this surveillance system and a MRSA case report form should be completed (a separate ABCs case report form is not required). Each case of invasive MRSA will be

categorized as healthcare-associated or community-associated based on documentation of known risk factors in the medical records. The following areas are currently conducting surveillance for methicillin-resistant *Staphylococcus aureus*: California, Colorado, Connecticut, Georgia, Maryland, Minnesota, New York, Oregon, and Tennessee (see population table for catchment areas). Isolate collection on a subset of cases began in select surveillance areas in 2005.

Disease recurrence or persistent disease: When a pathogen is isolated from the same patient on multiple occasions a distinction between persistent or recurrent disease needs to be made to determine whether a new case report form should be completed and a new STATEID assigned. The following algorithm should be followed to distinguish between recurrent disease and persistent disease.

Recurrent disease: If *Streptococcus pneumoniae* is isolated from a normally sterile site 8 or more days after the original infection, the isolate should be collected, a new case report form should be completed, a new STATEID number assigned, recurrent disease should be marked as "yes", and the previous STATEID (PREVID) should be filled out. The previous STATEID should ALWAYS be the stateid from the FIRST episode of invasive disease due to *Streptococcus pneumoniae*. For all other pathogens, if the same pathogen is isolated from a normally sterile site 30 or more days after the original infection, the isolate should be collected, a new case report form should be completed, a new STATEID number assigned, recurrent disease should be marked as "yes", and the previous STATEID (PREVID) should be filled out. Again, the previous STATEID should ALWAYS be the stateid from the FIRST episode due to the specific pathogen. New case report forms are required for these recurrent infections since isolates will be collected for these cases, and the culture date and culture site will be different from the original infection. Special efforts to assure completeness of the underlying disease fields should be made for recurrent cases. In addition, the latter episode of infection may have fatal outcome, in distinction with earlier infections.

Persistent Disease: When methicillin-resistant *Staphylococcus aureus* is isolated from a normally sterile site from the same patient on multiple occasions within 7-30 days (inclusive), it will be considered persistent disease. A new case report form should not be filled out and a new STATEID should not be given.

Information on persistent disease will be collected for methicillin-resistant *Staphylococcus aureus* only. This information will be used to determine if treatment failures due to antimicrobial resistant organisms are occurring. Persistent disease can occur for other organisms under surveillance, for example in GBS patients with endocarditis, and GAS patients with deep tissue infections such as necrotizing fasciitis. We will not routinely collect information on persistent disease for these organisms. If you find persistent disease for *Neisseria meningitidis* or *Haemophilus influenzae*

please contact the ABCs Surveillance Coordinator.

Case ascertainment:

Case finding is active and laboratory-based. Since isolation of one of these organisms from a normally sterile site is essential to the case definition, the microbiology laboratories in acute care hospitals and reference laboratories processing sterile site specimens for residents of the surveillance area are the most efficient sites for case identification. In addition, some data of interest on cases of invasive bacterial disease is readily accessible in the microbiology laboratory (e.g., serogroup of *N. meningitidis* isolates). However, most of the data that are essential for describing the population-based epidemiology of these diseases (e.g., age, residence within the surveillance area, outcome) may not be available in many microbiology laboratories. Therefore, case identification is complemented by additional data collection for completion of a standard case report form. This data collection is done differently in each surveillance area: for example, through the cooperation of on-site hospital personnel (e.g., Infection Control Practitioners or Medical Records personnel in Connecticut, Georgia, Minnesota, New York and Tennessee), through medical record review or clinician interview by county health department personnel (e.g., Oregon and New York), or through medical record review by surveillance personnel (e.g., California, Colorado, Connecticut, Georgia, Maryland, New Mexico, and Tennessee).

To assure complete, timely reporting and collection of isolates (before they are discarded by the laboratories), contact with microbiology laboratories must be frequent. In hospitals without computerized microbiology data, surveillance personnel should contact the designated microbiology laboratory contacts regularly to identify new cases and request isolate submission. Where microbiology data are computerized, electronic listings of all isolates of the pathogens of interest from normally sterile sites [i.e., blood, cerebrospinal fluid, pleural fluid, peritoneal fluid, pericardial fluid, bone, joint fluid, muscle (GAS only)), or internal body site (lymph node, brain, heart, liver, spleen, vitreous fluid, kidney, pancreas, or ovary)] should be obtained on a monthly basis. If enrollment into special studies falls below 90% due to slow reporting or isolate collection falls below 85% of surveillance cases, regular calls (e.g., every two weeks) to microbiology labs should be instituted to ensure that delayed reporting of cases does not have an adverse effect on enrollment rates into special studies or isolate collection rates.

Each area must determine what methods will be used for collection of data that are unavailable in the clinical microbiology laboratory. It is essential that the method(s) selected are detailed in writing and shared with CDC and the other surveillance areas, to permit assessment of the comparability of data collection. In addition, problems with proposed methods for data collection should be identified promptly and new methods substituted and changes documented when appropriate. In addition to formal audits of the surveillance systems (see below), surveillance areas should regularly assess the completeness of information collected for each case. If any core variables (e.g. outcome) are frequently incomplete, the data collection method should be revised to correct the problem. CDC should be notified regarding changes in data collection methods as these occur.

Underlying Conditions

Ideally, underlying medical conditions should be determined for each case identified for surveillance purposes. Underlying conditions should individually be marked on the case report form file as "yes" if indicated by the physician or chart. If a history is available and no underlying conditions are indicated, "none" should be marked on the case report form and the underlying conditions skipped. If a history is not available (when the surveillance officer and/or ICP is unable to locate a medical record or the physician contacted does not know the patient's history), "unknown" should be marked on the case report form and the underlying conditions skipped.

For 2008, all ABCs surveillance areas are recording underlying conditions for persons with invasive infections due to *Haemophilus influenzae*, *Neisseria meningitidis*, group A *Streptococcus*, group B *Streptococcus*, *Streptococcus pneumoniae,* and methicillin-resistant *Staphylococcus aureus.*

Surveillance Evaluation (Laboratory Audit and Evaluation of Electronic Laboratory Data Systems)

To ensure that all cases of diseases under surveillance are being reported to the ABCs system, routine audits of the reporting laboratories will be performed. If a laboratory is <u>not</u> able to routinely report all sterile site culture results via an electronic computer printout, an audit of the reporting laboratory will be required twice a year (every January and July for the previous 6 month period). During the audit, the primary data source at every reporting site (usually a laboratory log book or electronic list) which lists all isolates from normally sterile sites should be reviewed for organisms under surveillance, and compared to the list of cases that were reported through routine surveillance to the surveillance officer. A case report form should be completed on all newly identified cases which had not been entered into the surveillance data base previously. This procedure may require visiting each reporting site, or obtaining an electronic list of all laboratory data. Isolates of cases identified by audit should be obtained if available, but in most instances, since the audit is infrequent, these isolates will have been discarded.

For those laboratories that are able to routinely report all sterile site culture results via computer printouts there is no need to perform an audit (i.e., review of laboratory log book or electronic list twice a year) as we assume 100% sensitivity. However, because we are relying on complex, automated computer systems to capture all cases of ABCs pathogens from sterile sites, surveillance personnel should routinely evaluate data generated from laboratory computer systems to ensure that all eligible surveillance cases are being captured on routine electronic printouts. The methods for evaluating the accuracy of data obtained from laboratory computer systems will likely vary from site to site and sometimes between hospitals within a site. As a result, the methods for evaluating electronic printouts from laboratory computer systems will be left to the discretion of each individual ABCs site.

Complete case report forms on both "audit" cases and any other outstanding cases should

be entered into the computer database by March 1 and September 1 for the audited six-month period. If complete case report forms cannot be entered into the database by these deadlines, basic demographic information such as age, sex, species, race and county of residence should be entered into the database for these incomplete cases.

Data management and transmission to CDC

Case report forms, isolate forms and any additional special study forms (e.g., neonatal sepsis, early- and late-onset GBS extended form and invasive pneumococcal disease in children extended form) will be entered and maintained at each surveillance area. CDC has provided an Access database to all interested surveillance areas for data entry. Surveillance areas have agreed on common core variables and on standardized coding of responses to these variables. Each EIP site may choose to collect additional data of local interest. The computerized databases, with personal identifiers removed, will be transmitted to CDC by the fifth of every month. Password-protected databases should be posted to the appropriate site-specific folder on the CDC ftp site: ftp://sftp.cdc.gov and an email notification should be sent to:

Carolyn Wright: cfw3@cdc.gov

Unless otherwise indicated, all questionnaires/forms from special studies should be sent to:

Emily Weston, MPH

Centers for Disease Control and Prevention
RDB, DBD, NCIRD
1600 Clifton Road
Mailstop C-23
Atlanta, GA 30333

Surveillance Feedback

CDC will provide each surveillance area with several forms of feedback including data integrity checks (case report form, early- and late-onset GBS extended form, neonatal sepsis forms, and isolate edits, sent quarterly), summary tables, conference call minutes, and laboratory results. Specifically, data from multiple sites will be concatenated approximately 3 weeks after receipt at CDC. CDC will send an electronic packet via e-mail containing summary tables, laboratory results, and other relevant surveillance materials to the sites on a monthly basis. On the second Wednesday of every month, CDC will conduct a conference call with site surveillance officers to discuss ABCs-related issues. Lastly, CDC will organize two annual meetings: the ABCs Steering Committee meeting with attendance by the ABCs PIs and one surveillance officer from each site, and the ABCs Surveillance Officers meeting with attendance by at least two surveillance officers from each site.

Feedback from sites to local hospitals, laboratories, and other constituents is at the discretion of each site. CDC requests copies of each site's newsletters or other materials provided to local hospitals regarding the surveillance program. One copy of each local feedback newsletter/packet should be sent to the ABCs Surveillance Coordinator.

Vital statistics projects:

On an annual basis, sites are required to utilize vital statistics records to enhance the quality of ABCs data and to obtain live birth data that will be used as denominators for special ABCs populations. CDC requests that sites perform vital statistics activities between October and December of each calendar year. Additional information on the vital statistics projects can be found in the project-specific protocols.

Live birth denominator collection: Live birth data will be used as denominators for the purpose of estimating disease incidence for neonatal pathogens that are collected as part of ABCs, and for denominators that pertain to special studies using the ABCs platform. Sites will be required to provide CDC with the following two datasets on an annual basis:

1. Live births to surveillance area residents stratified by county of maternal residence, location of birth, hospital ID, maternal race, paternal race, maternal ethnicity, paternal ethnicity, and term/pre-term status

2. Live births that occur in surveillance area counties, stratified by county of maternal residence, location of birth, hospital ID, maternal race, paternal race, maternal ethnicity, paternal ethnicity, and term/pre-term status

Race-Ethnicity Project: As a way of enhancing ABCs ability to track racial and ethnic disparities for infections in infants and young children, ABCs personnel will utilize state birth certificate records to collect maternal and paternal race and ethnicity for ABCs cases < 5* years of age for which race and/or ethnicity values are missing. On an annual basis, CDC will provide each site with a data set of ABCs cases < 5* years of age which are missing race and/or ethnicity and request that each site obtain maternal and paternal race and ethnicity from vital records for these cases. (*Note: match was revised from <2 years to <5 years of age beginning with 2006 data match)

Deaths Project: In order to assess and revise ascertainment of outcome among all ABCs cases, each site will compare all ABCs cases with unknown outcome* to their in-state death registry on an annual basis using personal identifiers. STATEID, updated outcome (UPDEATH), and date of death will be collected for each valid match of death registry to ABCs case report. (*Note: match was revised from all cases to cases with unknown outcome only beginning with 2006 match).

Isolate collection:

Information should be entered into the isolate database for all identified ABCs cases. This includes cases with isolates being sent to CDC/Texas, cases with isolates being stored at the sites, as well as cases for which no isolate is available. For cases with no available isolate, a reason should be indicated as to why an isolate was not collected. Isolates should be batched for sending to CDC/Texas reference lab. Please refer to the ABCs isolate protocol for additional information on the collection and shipping of ABCs isolates.

Neisseria meningitidis:	All isolates should be serogrouped and subsequently sent to CDC for further testing. If serogrouping cannot be performed at the site, it will be performed at CDC. These isolates could potentially be used for research purposes.
Haemophilus influenzae:	All isolates should be serotyped and subsequently sent to CDC for further testing. If serotyping cannot be performed at the site, it will be performed at CDC. These isolates could potentially be used for research purposes.
group A *Streptococcus*:	All invasive group A streptococcal isolates should be sent to CDC for T- and *emm*-typing. Susceptibility testing will be performed on a subset of isolates.
group B *Streptococcus*:	All invasive group B streptococcal isolates should be sent to CDC for serotyping and susceptibility testing (optional for sites). *Streptococcus pneumoniae:* All invasive isolates from *Streptococcus pneumoniae* will be sent directly to the contract lab in Texas or to CDC (GA only) for additional antimicrobial susceptibility testing (all sites except MN send isolates). These isolates will be sent from Texas to CDC for serotyping. Subtyping of *S. pneumoniae* isolates using advanced methods will also be performed on a sample of isolates with the collaboration of several investigators.
Methicillin-resistant *Staphylococcus aureus*	Isolates from select sites are sent to CDC, where, at a minimum, the following microbiologic assessments are conducted: confirmation of isolate purity, identification, antimicrobial susceptibility testing, pulsed-field electrophoresis and analysis, toxin testing, and gene typing. The specific microbiologic assessments performed at each site laboratory may vary; however, none are required.

All streptococcal (*Streptococcus pneumoniae*; group A *Streptococcus*; group B *Streptococcus*) isolates from participating ABCs areas are being archived at the CDC and ATSDR Specimen Packaging, Inventory, and Repository (CASPIR). In addition to

maintaining aliquots for internal use, CASPIR will also maintain aliquots that will be available for release to outside researchers. Limited information will accompany each anonymized isolate and will include demographic and clinical information along with microbiological data (i.e., serogroup, serotype and *emm* typing, antimicrobial resistance patterns). For more information see: http://www.cdc.gov/abcs/isolatebank/

The following table illustrates where the isolate is being stored and/or tested and the year that testing began in each area by bacterial pathogen. If no end year is indicated, the collection is ongoing.

Area	*Neisseria meningitidis*	*Haemophilus influenzae*	group B *Streptococcus*	group A *Streptococcus*	*Streptococcus pneumoniae*	MRSA
CA	CDC 1989	CDC 1989	--	CDC June 1994	Texas 1995 (SF General isolates to CDC, 1997-2000)	CDC 2005
CO	CDC 2000	CDC 2000	CDC 2000 (<1 yr olds only beginning 2007)	CDC 2000	Texas 2000	CDC 2005; State 2005 (PFGE)
CT	CDC 1995	CDC 1995	--	CDC 1995 - 2004	Texas 1995	CDC 2005; State 2005 (PFGE)
GA	CDC 1989	CDC 1989	CDC 1994-1995 State 1996-1997 CDC 1998	CDC June 1994	CDC 1994	CDC 2005; State 2006 (PFGE, SCCmec, PVL (not full toxins))
MD	CDC 1992	CDC 1992	State 1991-1995 CDC March 2003	CDC 1997	Texas 1995	--
MN	CDC 1995	CDC 1995	U of MN 1995 CDC 2001 (>1 yr old)	CDC 1995	State 1995	CDC 2005; State 2005 (PFGE)
NM	CDC 2004	CDC 2004	CDC 2004	CDC 2004	Texas 2004	--
NY	CDC 1997	CDC 1997	CDC 1997 CDC 2006 (0-89 days only)	CDC 1997	Texas 1997	CDC 2005
OR	CDC 1996	CDC 1996	CDC 1996	CDC 1995	Texas 1995	CDC 2005; State 2005 (PFGE)
TN	CDC 1989	CDC 1989	--	CDC 1999	Texas 1995	CDC 2005