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Core Functions and Capabilities of State Public Health Laboratories

A Report of the Association of Public Health Laboratories

National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect

Defining the National Agenda for Fetal Alcohol Syndrome and Other Prenatal Alcohol-Related Effects

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Core Functions and Capabilities of State Public Health Laboratories

A Report of the Association of Public Health Laboratories

Prepared by
Joyce Witt-Kushner,[1]* J. Rex Astles, Ph.D.,[1] John C. Ridderhof, Dr.P.H.,[1] Robert A. Martin, Dr.P.H.,[1]
Burton Wilcke, Jr., Ph.D.,[2,3] Frances P. Downes, Dr.P.H.,[2,4] Stanley L. Inhorn, M.D.,[2,5]
H. Peter Kelley,[2,6] Paul B. Kimsey, Ph.D.,[2,7] David E. Mills, Ph.D.,[2,8] Max Salfinger, M.D.,[2,9]
Peter A. Shult, Ph.D.,[2,10] Mahadeo P. Verma, Ph.D.,[2,11] Scott J. Becker, M.S.,[2] Doug J Drabkowski,[2]
[1]*Division of Laboratory Systems, Public Health Practice Program Office, CDC*
[2]*Association of Public Health Laboratories, Washington, DC*
[3]*Vermont Department of Health, Burlington, Vermont*
[4]*Michigan Department of Community Health, Lansing, Michigan*
[5]*State Laboratory of Hygiene, Madison, Wisconsin*
[6]*Gen-Probe, Lakeland, Florida*
[7]*California State Public Health Laboratory, Richmond, California*
[8]*New Mexico Department of Health, Albuquerque, New Mexico*
[9]*New York State Department of Health, Albany, New York*
[10]*Wisconsin State Laboratory of Hygiene, Madison, Wisconsin*
[11]*Delaware State Public Health Laboratory, Dover, Delaware*

Summary

Emerging natural and man-made threats to the health of the nation's population require development of a seamless laboratory network to address preventable health risks; this can be achieved only by defining the role of public health laboratories in public and private laboratory service delivery. Establishing defined core functions and capabilities for state public health laboratories will provide a basis for assessing and improving quality laboratory activities. Defining public health laboratory functions in support of public health programs is the beginning of the process of developing performance standards for laboratories, against which state public health laboratories, and eventually local public health and clinical laboratories, will establish and implement best laboratory practices. Public health is changing, and as a part of that change, public health laboratories must advocate for and implement improvements for public health testing and surveillance. These changes are outlined also in the Association of Public Health Laboratories consensus report (Association of Public Health Laboratories. Core functions and capabilities of state public health laboratories: a white paper for use in understanding the role and value of public health laboratories in protecting our nation's health. Washington, DC: Association of Public Health Laboratories, 2000).

Introduction

Delivery of high-quality laboratory services is essential in our health-care system both for providing the foundation for clinical decisions and as an objective means to measure and monitor biological and environmental markers. In response to an increasing concern regarding the U.S. population's vulnerability to health risks, efforts have been made to reduce preventable risks (e.g., those related to terrorist events, antimicrobial resistance, foodborne illness, and environmental threats). Accurate and timely laboratory analyses are critical to identifying, tracking, and limiting public health threats and ultimately reducing rates of preventable morbidity and mortality (*1–3*). Optimal functioning of the public health system to meet these threats is dependent on uniform and high-quality laboratory testing (*4*). Furthermore, facing public health challenges from emerging and reemerging pathogens (e.g., West Nile virus [*5*], drug-resistant communicable disease agents [*6*], and *Escherichia coli* O157:H7 [*7,8*]), requires evaluation of the functions, responsibilities, and capacities of state public health laboratories (SPHLs) (*9*). This evaluation of the role of public health laboratories includes environmental threat concerns (*10*) and appropriate application of technological advances (i.e., tandem mass spectrometry or pulsed field gel electrophoresis [*11–13*]). Certain disease prevention and control programs within CDC support and promote technical capacity in SPHLs (e.g., PulseNet for molecular typing; Laboratory Response Network for bioterrorism preparedness; Epidemiology and Laboratory Capacity program; and resources

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for tuberculosis, human immunodeficiency virus [HIV], sexually transmitted diseases, blood lead, and others).

A key precept for public health is recognizing that the majority of testing for public health is either performed in private laboratories or is dependent on private laboratories for referral and reporting. Therefore, a function of public health, and specifically of SPHLs, is to ensure the availability, quality, and reporting of laboratory testing performed in the private sector. A minimal association exists between SPHLs and private (i.e., hospital and independent) laboratories, and this limited association can lead to a lack of communication and coordination of the laboratory testing that is necessary to support public health interventions.

An impediment to improving public-private coordination is the disparity of functions among SPHLs, because those functions evolved differently in each state. As of January 2002, approximately 174,000 laboratories were operating in the United States; this number included an estimated 2,000 public health laboratories, and the remainder included hospital, independent, and physician office laboratories (*14*). Laboratories are difficult to quantify or describe according to the volume and scope of work they perform. SPHLs operate autonomously, and delivery of public health testing historically has been, and will continue to be, state-based. State health systems vary in aspects that affect the delivery of quality public health testing. For example, state health systems individually determine which diseases are reportable by laboratories or clinicians (*15*). Technical standards exist for disease-specific testing, but no standard definitions exist for the broader role and functions of public health laboratories. Developing an effective laboratory system for public health testing requires definitions for standard functions of SPHLs, including a broader role in ensuring the quality of testing throughout the state.

Since the 1980s, the HIV epidemic has emphasized SHPLs' critical roles of assessing, leading, and developing health policy. Public health laboratories still consist of diverse groups and institutions (*9*). Public health laboratories are a loose network of federal, state, and local laboratories that work in undefined collaboration with private clinical laboratories (*16*). Disease outbreaks during 1992–2002 have increased the recognition of the specific testing capacities in SPHLs and reinforced the need for improving and developing communication and coordination of testing services between SPHLs and clinical laboratories (*17–20*). After the anthrax attacks during September–October 2001, agencies within the U.S. Department of Health and Human Services, including CDC, established laboratory priorities for bioterrorism preparedness. These priorities encourage leadership functions for policy development, laboratory improvement, and training and education for clinical laboratory personnel. Guidelines accompanying the FY 2002 supplemental emergency funding for bioterrorism preparedness and response and public health infrastructure improvement address the need for public-private integration of laboratory functions critical to public health. The need to develop these links is well-recognized and is the single critical benchmark for laboratories in the Guidance for Fiscal Year 2002 Supplemental Funds for Bioterrorism (*21*). That benchmark requires developing a plan to improve working relationships and communication between clinical laboratories and higher lever laboratories to ensure that core capabilities are maintained. Core capabilities concerning bioterrorism include 1) performing rule-out testing on critical bioterrorism agents; 2) safely packing and handling specimens; and 3) referring specimens and isolates to higher level laboratories for further testing.

The trend to better define the role of public health is apparent in public health policy documents (e.g., the Essential Services [*22*]). The first of the 10 essential services of public health (i.e., monitoring health status to identify and solve community health problems) is directly dependent on laboratory provision of analysis, pathogen identification, and disease monitoring. The second essential service (i.e., diagnosing and investigating health problems and health hazards in the community) is directly supported by laboratory functions (*22*). The significance of the Association of Public Health Laboratories (APHL) core functions and capabilities of SPHLs lies in the fact that laboratory testing is a common denominator for fulfillment of these and the majority of public health objectives, which are designed to be met by measurable indicators of goals. Attainment of these goals can only be accomplished through performance of consistent, high-quality laboratory testing, for which assessment requires a definition of laboratory capabilities.

Healthy People 2010, which also shapes the role of public health, addresses goals for building the public health infrastructure (*23*). Included among the goals are increasing accessibility of laboratory services and the proportion of tribal, state, and local health agencies that provide or ensure comprehensive laboratory services to support essential public health services (Objective 23-13) (*23*). The definition of critical laboratory services and its functions are described by APHL (*24*), and consensus regarding these functions of public health laboratory services is the base for assessing all laboratories. APHL's recommendations go beyond the traditional functions that are acknowledged as the responsibilities of laboratory services (i.e., specimen analysis and isolate identification, disease control and surveillance, reference and specialized testing, and food safety) to areas of leadership and strengthening laboratory infrastructure for the public health testing system (i.e., laboratory improvement and regulation, policy development,

training and education, and partnership and coordination). These recommendations for core functions enable state leaders and stakeholders (e.g., state epidemiologists, state and local health officers, and state legislators) to assess the adequacy of the public health laboratory systems, allocate resources, and encourage needed relationships between the public health system and the health-care delivery system. Further, these recommendations provide a guide for assessing and monitoring the service and value of the public health laboratories by serving as a basis for creation of policy development (*25*). From this foundation, development of laboratory performance standards and laboratory quality assurance can evolve in the United States.

Background

Development of the core functions document and this report represent the culmination of activities that reflect a 1988 Institute of Medicine (IOM) report (*25*). The IOM report stated, "public health, as a profession, as a governmental activity, and as a commitment of society is neither clearly defined, adequately supported, nor fully understood" (*25*). Since the early 1990s, a common theme of all public health reports has been that public health activities and practices were not well-defined and that the mission and infrastructure necessary to support public health was also not well-defined (*26*). In this report, we focus on one component (the state public health laboratories) of one critical piece of the public health infrastructure (laboratories) and relate the consensus view of the membership of APHL regarding the core functions and capabilities of SPHLs.

Although state public health laboratories have been in existence for longer than 100 years, no organization had yet defined necessary activities of SPHLs. However, the lack of defined activities is understandable, considering that this group of >50 laboratories was created independently by states and from the outset had different charters that gave them a heterogeneous character. Despite their diversity, in the aggregate, they represent a critical component of our nation's public health infrastructure, and public health is well-served to have a defined list of core functions and capabilities that all state public health laboratories have endorsed.

This attempt to define the core functions of SPHLs began in approximately 1993 when APHL (then the Association of State and Territorial Public Health Laboratory Directors) developed an internal unpublished report that addressed the need to distinguish public health laboratories from other laboratories (e.g., those in clinical and hospital settings) (G. Anderson, A. DiSalvo, and W. Hausler in "Task Force Report on the Public Health Laboratory: A Critical National Resource; Report to the Association of State and Territorial Public Health Laboratory Directors," unpublished, 1993). In 1993, a perspective regarding the evolution of public health laboratories since their creation was published (*27*).

APHL continued to review the need for a more formal definition of core functions for public health laboratories, and in 1995, an internal report (R. L. Cada, S. L. Inhorn, P. Bouchard, J. M. Counts, and M. W. Kimberly in "Core Functions of Public Health Laboratories: A Report to the Association of State and Territorial Public Health Laboratory Directors by a Task Force, unpublished, 1995) was distributed to the membership. The report started the process of more clearly identifying the core functions of SPHLs and related the core functions of laboratories to assessment, quality assurance, and policy development — the core functions of public health established in the 1988 IOM report (*25*). In 1996, professionals within the laboratory section of the American Public Health Association issued an internal report on the role of public health laboratories. In 1999, health officials stated that the United States needed a national laboratory system (*17,19,20*), and the General Accounting Office stated, "public health officials have not developed a consensus definition of the minimum capabilities that state and local health departments need to conduct infectious disease surveillance" (*28*). By that time, APHL had already charged its Leadership Development Task Force with developing a definitive statement concerning the core functions of state public health laboratories. APHL's resulting strategic plan reflected the priority needs and activities of APHL and guided their mission in defining the role of SPHLs in two of their strategic goals for 1999–2001: 1) to ensure that essential laboratory services are available to support public health activities in the changing health-care environment, and 2) to advocate effectively for public health laboratories through legislation, policy development, and public information (*29*).

The work of the APHL Task Force in defining core functions and capabilities of SPHLs was performed in collaboration with and support from CDC's Public Health Practice Program Office, Division of Laboratory Systems (PHPPO/DLS). Since 1987, APHL has had a cooperative agreement with CDC through PHPPO/DLS. A component of this agreement has focused on the National Laboratory Partnership (NLP), which is a multifaceted program that allows collaboration among APHL members, professional and scientific staff, and CDC for work related to public health laboratory practice. NLP activities with CDC have supported APHL's development of this report. Representatives from PHPPO/DLS actively participated in APHL meetings and discussions that led to the consensus vote regarding the APHL position. The value of defining core functions for SPHLs lies in the support given to CDC initiatives for developing laboratory infrastruc-

ture for testing (e.g., foodborne disease investigations and vaccine-preventable diseases). PHPPO also views the core function report as a prerequisite to developing performance standards for public health laboratories. The report (*24*) was adopted in its entirety by unanimous vote as the consensus position of APHL at the 2000 APHL annual meeting. Those adopted core functions are stated in this report.

These recommendations describe the broader functions and elements that are necessary to ensure the laboratory capability to execute the core functions. The term *core function* is a role assumed by the laboratory that underlies the laboratory's ability to support public health. The term *capability* denotes a specific activity that ensures the successful implementation of an associated function. For each capability, each state public health laboratory has a capacity for performing a specified number of tests within a certain time. Laboratory capacity is a key concern in light of strengthening bioterrorism preparedness and the federal mandate to address infectious disease outbreaks, other public health threats, and emergencies (*24*).

This report is the beginning of a process to improve public health testing, which will also require the definition of core functions of public health laboratories at the local level. This will help meet the need identified in the 1988 IOM report to better define and understand one of the critical infrastructure components of public health.

SPHL Core Functions

SPHLs should accomplish the following 11 core functions as part of their organizational capacity:[†]

- disease prevention, control, and surveillance;
- integrated data management;
- reference and specialized testing;
- environmental health and protection;
- food safety;
- laboratory improvement and regulation;
- policy development;
- emergency response;
- public health-related research;
- training and education; and
- partnerships and communication.

The capabilities critical for SPHLs to be able to perform these 11 essential functions are designated in the following sections.

Disease Prevention, Control, and Surveillance

- Provide accurate and precise analytical results in a timely manner for different diagnostic and analytical functions for assessment and surveillance of infectious, communicable, genetic, and chronic diseases, and environmental exposures.
- Serve as a first line of defense in rapidly recognizing and preventing the spread of communicable diseases by
  - — examining specimens for identifying disease outbreaks;
  - — isolating and identifying the causative agent;
  - — determining the source of infection;
  - — identifying carriers; and
  - — locating sources of infection in the environment.
- Serve as a center of expertise for the detection and identification of biologic agents of significance in human disease; as such, ensure access to laboratory expertise and capabilities in the disciplines of
  - — bacteriology;
  - — virology;
  - — parasitology;
  - — molecular microbiology;
  - — immunology and serology;
  - — mycobacteriology;
  - — mycology; and
  - — hematology and immunohemotology.
- Provide specialized tests for low-incidence, high-risk diseases (e.g., tuberculosis, rabies, botulism, and plague); detect epidemiologic shifts; and detect newly emerging pathogens, including but not limited to
  - — testing specimens from suspect cases of tuberculosis to identify *Mycobacterium tuberculosis* infections and determine effective antibiotic treatment;
  - — testing influenza specimens as directed by national and international surveillance efforts to identify viral strains and control influenza;
  - — testing animal specimens from suspected rabies carriers to detect the virus and ensure that prevention measures appropriately protect humans and domestic animals from exposure; and
  - — assisting public and private health-care providers in investigating and controlling communicable or environmental diseases.
- Provide population surveillance, or screening, for conditions of interest to the public health community, including screening for inherited neonatal metabolic disorders, environmental toxins, immune status, risk factors, chronic blood diseases, blood lead, and antibiotic resistance.
- Perform tests to meet specific program needs of public health agencies.

Integrated Data Management

- Serve as the focal point for accumulating, blending, and disseminating scientific information in support of public health programs, including

[†] Not listed in order of priority or significance.

— capturing laboratory data essential for public health analysis and decision-making;
— ensuring the ability to maintain and communicate laboratory data by using standardized data formats;
— ensuring rapid dissemination of laboratory information to assist in identification, understanding, and controlling disease outbreaks;
— providing primary data necessary to provide information for and implement policy and planning; and
— providing a statewide disease reporting network, with centralized facilities for receipt, storage, retrieval, and analysis of data.

- Participate as a key link in national database systems to collect, monitor, and analyze laboratory data, including as the primary data link with CDC for surveillance of diseases of national and global concern.
- Serve the data needs of state epidemiologists, other laboratories, and practitioners in identifying trends and sentinel events that indicate emerging health problems.

Reference and Specialized Testing

- Serve as the state's primary reference microbiology laboratory to
  — test for, and aid in the diagnosis of, unusual pathogens;
  — confirm atypical laboratory test results;
  — verify results of other laboratory tests;
  — provide oversight for quality assurance;
  — test epidemiologically significant specimens with potential public health implications;
  — provide reference diagnostic testing to private sector laboratories that might not have the capability to fully identify disease agents of public health significance;
  — test for diseases of public health consequence that are too rare or unusual for other laboratories to maintain capacity for testing, including human genetic markers of disease; and
  — provide toxicology testing, including drug, alcohol, poison, and trace metal analyses.

Environmental Health and Protection

- Conduct scientific analyses of environmental samples (air, water, and soil) to identify and monitor potential threats to human health and ensure compliance with environmental regulations.
- Analyze environmental and biological specimens and detect, identify, and quantify toxic contaminants (e.g., lead, pesticide residues, heavy metals, and volatile organic compounds).
- Provide or ensure laboratory services that support assurance of clean air in the state, by testing for particulates, radon, and toxic compounds.
- Provide environmental chemistry testing, which includes inorganic (e.g., nonmetals, metals, and nonmetal contaminants) and organic compounds (e.g., semivolatiles, volatiles, pesticides, and herbicides).
- Provide or ensure laboratory services that support assurance of clean water in the state, by analyzing water for synthetic organic chemicals, pesticides, inorganic chemicals, microorganisms, and radionuclides.
- Provide or ensure analysis of environmental samples (e.g., soil, dust, drinking water, and paint chips) to quantify potential sources of exposure to hazardous substances.
- Conduct scientific laboratory analyses of environmental samples to determine the relationship between environmental hazards and human health.
- Measure toxicants to determine conclusively the extent of a community's exposure to environmental hazards.
- Provide industrial hygiene/occupational health testing to assist in efforts to protect indoor air quality and workers' health, including routine analysis of asbestos, acids, amines, solvents, silica, metals (including lead), gases, pesticides, radon, spores, fungi, and other analytes.

Food Safety

- Test specimens from persons, food, and beverages implicated in foodborne illness outbreaks to identify causes and sources. Testing might include assays to detect organisms (e.g., *Escherichia coli* O157:H7, staphylococcus, bacillus, salmonella, shigella, vibrio, listeria, and clostridium).
- Analyze food specimens to detect, identify, and quantify toxic contaminants (e.g., pesticide residues, heavy metals, and volatile organic compounds).
- Provide, or ensure, radiation-control studies to monitor radioactive contamination of water, milk, shellfish, and other foods.

Laboratory Improvement and Regulation

- Coordinate and promote quality assurance programs for private clinical and environmental laboratories through training, consultation, certification, and proficiency testing.
- Serve as the standard of excellence for local and private laboratory performance.
- Exercise leadership and authority as the agency responsible for laboratory regulation and training in the clinical and environmental areas.

- Develop and oversee statewide quality assurance and laboratory improvement programs to ensure the reliability of laboratory data used for communicable disease control and environmental monitoring.
- Oversee the licensure, certification, and accreditation of laboratories to ensure that medical, environmental, food safety, and alcohol testing laboratories fulfill state and federal mandates.
- Provide analytical support of federal, state, county, and local regulations and laws.

Policy Development

- Provide scientific and managerial leadership in developing state and federal public health policy and in developing, promoting, and integrating public health laboratory science into practice.
- Participate in developing standards for all health-related laboratories, including food, environmental, clinical, and research standards.

Emergency Response

- Provide laboratory support as part of state and national disaster preparedness plans for environmental or health emergencies, including
  - — rapidly identifying and investigating analyses of biological, chemical, and radiological agents, regardless of the source of exposure (i.e., unintentional, terrorist, or natural disaster);
  - — ensuring the capacity to quickly and accurately handle a substantial volume of tests during an emergency situation; and
  - — providing a rapid response system for hazardous contaminants in waste spills; air, water, and soil; and in foodborne disease outbreaks.

Public Health-Related Research

- Evaluate and implement new technologies and analytical methodologies to ensure that laboratories provide state-of-the-art, cost-effective, and timely analytical and diagnostic services and support to the public health and health-care communities in the state, including
  - — identifying the need for new laboratory methodologies for disease detection and prevention;
  - — conducting research to improve laboratory tests for more effective disease surveillance; and
  - — conducting research to develop rapid methods for laboratory diagnosis.
- Collaborate with academic and private sector researchers and other government agencies to adapt emerging technologies to public health laboratory techniques and information systems.
- Conduct applied studies into new and improved analytical methods and services that are necessary to meet changing public health surveillance and environmental regulatory requirements.
- Provide advice to the private sector regarding newly marketed tests.

Training and Education

- Sponsor training opportunities to improve scientific and technical skills of public health laboratory staff.
- Provide, or facilitate, training courses and workshops for laboratory staff in private and public sectors to continually upgrade the knowledge and skills essential for providing quality services in medical, environmental, and public health laboratories.
- Provide short- and long-term training opportunities to prepare scientists for careers in public health laboratory practice.
- Provide continuing education in management and leadership development for those in administrative positions.
- Participate in training of international scientists.

Partnerships and Communication

- Develop and strengthen statewide partnerships among state, county, and city public health leaders, managed care organizations, academia, and private industry to advance understanding of the critical role played by public health laboratories in supporting the core functions of public health.
- Emphasize the role and value of the public health laboratory to state public health programs.
- Participate in state strategic policy planning and development processes.
- Maintain strong communication networks among
  - — health officers/commissioners;
  - — county and city health officials;
  - — state epidemiologists;
  - — directors of sexually transmitted disease, tuberculosis control, chronic disease prevention, maternal and child health, and environmental programs;
  - — legislators;
  - — state health budget personnel;
  - — other laboratory management staff; and
  - — other state leaders.

Conclusion

Before development of the APHL Core Functions and Capabilities of State Public Health Laboratories (*24*), a concise and thorough definition of public health laboratory functions in support of public health programs did not exist. Typically, public health laboratories had been recognized only for the service they provided in analyzing specimens, both human and environmental, and for identification and confirmation of microorganisms. Funding was available for these visible functions of the laboratory, but recognition and noncategorical funding was not available for functions related to infrastructure, including training and workforce development; communication among laboratories, medical colleagues, and the public; and leadership for laboratory personnel. Certain external activities directly related to the analysis function have not been recognized (e.g., transport of isolates and specimens to referral laboratories — the cost and logistics have been left to the individual laboratories, both public and private, to work out on their own [state-supported laboratory transport systems exist in only a limited number of states]).

The APHL core functions and this report are advancements in understanding the unique roles and activities provided by public health laboratories in the United States. Other national public health activities — including bioterrorism preparedness — will benefit from recognition of these roles and functions. The timing of efforts that are the logical outgrowth of the core functions is critical during this period of strengthening public health infrastructure and preparedness for bioterrorist events and other public health emergencies. The definition of laboratory core functions will provide a basis for assessment and improvement of laboratory activities, followed by policy development and quality assurance.

The National Laboratory System, a cooperative initiative of CDC and APHL, is dependent on and supportive of the laboratory core functions, including those external functions that integrate with clinical laboratories. The National Laboratory System is a strategic priority for APHL and includes the objectives of assessing and monitoring private and public laboratory capacities, increasing coordination and communication among laboratories, and building partnerships between public and private laboratories, workforce development through training and education, and promotion of laboratory standards. As federal guidelines have emphasized the need for effective working relationships and communication between clinical laboratories and higher-level laboratories, pilot projects in four states have demonstrated the benefits of systematic integration of laboratories, with attention toward upgrading laboratory function.

Another key continuation of the definition of laboratory core functions is the need to develop performance standards. Performance standards are critical for public health in providing potential benefits of improved accountability; better resource deployment; enhanced capacity building for community, state, and national public health systems; widespread use of best practices; and increased focus on mission and goals (*30*). The same premise is true for benefits of performance standards for laboratories. Work is in progress to create performance standards for the nation's laboratories through collaborative efforts of APHL and CDC.

The outcome from the definitions within the APHL 2000 Consensus White Paper on the Core Functions and Capabilities of State Public Health Laboratories will extend through the following needed initiatives:

- performance standards for state public health laboratories;
- a coordination of laboratory efforts through a national system, which will strengthen public health laboratories and establish connections with local public health and private laboratories;
- definition of core functions and performance standards for local public health laboratories; and
- performance standards.

Collectively, these efforts will enable all laboratories in the United States to actively support and participate in major public health activities that keep the population healthy and free of disease and unhealthy environmental exposures.

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Defining the National Agenda for Fetal Alcohol Syndrome and Other Prenatal Alcohol-Related Effects

Prepared by
Mary Kate Weber, M.P.H.[1]
R. Louise Floyd, D.S.N.[1]
Edward P. Riley, Ph.D.[2]
Dixie E. Snider, Jr., M.D.[3]
[1]*Division of Birth Defects and Developmental Disabilities*
National Center on Birth Defects and Developmental Disabilities
[2]*San Diego State University*
San Diego, California
[3]*Office of the Director*
Centers for Disease Control and Prevention

Summary

Prenatal alcohol exposure can lead to serious birth defects and developmental disabilities. A need exists to develop effective strategies for both children with fetal alcohol syndrome (FAS) or other prenatal alcohol-related effects and for women at high risk for having an alcohol-exposed pregnancy. Since the syndrome was identified approximately 30 years ago, advancements have been made in FAS diagnostics, surveillance, prevention, and intervention, but a substantial amount of work remains. Collaborations among partners in federal, state, and local agencies, academia, clinical professions, school systems, and families are critical to developing and implementing successful efforts related to FAS and fetal alcohol effect (FAE). In 1999, Congress directed the Secretary of the U.S. Department of Health and Human Services to convene the National Task Force on FAS and FAE (the Task Force). CDC's National Center on Birth Defects and Developmental Disabilities, Fetal Alcohol Syndrome Prevention Team, coordinates the Task Force and manages its operation. Since the Task Force was chartered in 2000, Task Force members, with input from multiple partners, have convened to deliberate and determine the Task Force mission, goals, and priority concerns to be addressed. This report describes the structure, function, mission, and goals of the Task Force and provides their first recommendations. An explanation of how the Task Force recommendations were generated and the Task Force's next steps are also reported.

Background

Prenatal alcohol use is one of the leading preventable causes of birth defects and developmental disabilities. According to the 1999 Behavioral Risk Factor Surveillance System, 12.8% of women reported drinking alcohol during pregnancy (*1*). Children exposed to alcohol during fetal development can suffer multiple disorders that range from subtle changes in I.Q. to profound mental retardation. They can also suffer growth retardation and be born with birth defects of major organ systems. One of the most severe outcomes is fetal alcohol syndrome (FAS), which includes central nervous system disorders, growth retardation, and facial malformations. CDC studies have documented FAS prevalence rates ranging from 0.2 to 1.5/1,000 live births (*2–4*).

The material in this report originated in the National Center on Birth Defects and Developmental Disabilities, José F. Cordero, M.D., Director, and the Division of Birth Defects and Developmental Disabilities, Joseph Mulinare, M.D., M.S.P.H., Acting Director.

FAS was first described in scientific literature in the United States approximately 30 years ago (*5*). Since that time, advancements have been made in FAS diagnostics, surveillance, prevention, and interventions. Disorders related to prenatal alcohol exposure have generated substantial interest and activity among CDC's partners (e.g., federal, state, and local agencies; school systems; academicians and clinicians; advocates; and families) and affected persons. However, additional work still needs to be done to prevent prenatal alcohol-related disorders and effectively intervene with children and families affected by them. Problems that still need to be addressed include 1) raising public awareness regarding the dangers of alcohol use during pregnancy and the adverse outcomes associated with prenatal alcohol exposure (i.e., FAS and other alcohol-related effects); 2) educating and training health and social service professionals concerning how to identify and intervene with women at risk for alcohol-exposed pregnancies; 3) developing effective intervention programs for children affected by prenatal alcohol exposure; 4) promoting and supporting basic research to identify the etiology and mecha-

nisms involved in FAS; and 5) improving the quality of life of affected persons and families.

Introduction

In 1998, the U.S. Congress recognized the significance of a coordinated effort to address the concerns related to FAS and fetal alcohol effect (FAE). The Secretary of the U.S. Department of Health and Human Services (DHHS) was directed through the Public Health Service Act, Section 399G (42 U.S.C. Section 280f, as added by Public Law 105-392) to establish a National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect (the Task Force) that would 1) foster coordination among all governmental agencies, academic bodies, and community groups that conduct or support FAS and FAE research, programs, and surveillance; and 2) otherwise meet the needs of populations impacted by FAS and FAE. On May 17, 2000, in accordance with Public Law 92-463, the Task Force was chartered. Authority to establish the Task Force was delegated to CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD). NCBDDD's Fetal Alcohol Syndrome Prevention Team was assigned primary responsibility for establishing the Task Force and managing its operations. The Task Force function, as outlined in its charter (*6*), is to

- advise persons involved in federal, state, and local programs and research activities of FAS and FAE regarding such topics as FAS awareness and education for relevant service providers and the general public (including school-aged children and women at risk), medical diagnosis for FAS and FAE, prevention and intervention strategies for women at risk, and essential services for affected persons and their families;
- coordinate its efforts with the DHHS Interagency Coordinating Committee on Fetal Alcohol Syndrome (ICCFAS); and
- report, on a biennial basis, to the DHHS Secretary and relevant committees of Congress on the current and planned activities of the participating agencies.

The Task Force includes 12 members and the chair. Members are selected by the DHHS Secretary, or designee, from authorities knowledgeable in FAS and FAE, including members of the academic community; clinicians; representatives from federal, state, and local government agencies and offices; parents or legal guardians of persons with FAS and FAE; and representatives from advocacy and research organizations. ICCFAS, coordinated through the National Institute of Alcoholism and Alcohol Abuse (NIAAA), is a committee of representatives from federal agencies working on FAS-related activities. The chair of the ICCFAS is a standing member of the FAS/FAE Task Force. Partners regularly attend the Task Force meetings and play a vital role in the process.

Task Force Methods

After committee appointments were confirmed, the Task Force convened to identify priority concerns. In December 2000, during the Task Force's inaugural meeting, working groups were formed to begin addressing key priorities. In keeping with recommendations from the Institute of Medicine Committee on FAS, the Task Force used the term alcohol-related neurodevelopmental disorder (ARND) to denote cases with evidence of central nervous system neurodevelopmental abnormalities that have been linked in clinical or animal research to prenatal alcohol exposure, but that do not meet the diagnostic criteria for FAS (*7*). ARND prevalence is believed to be approximately three times greater than FAS (*8*). The Task Force engaged in a strategic planning process to clarify its role by creating a mission statement and goals. The Task Force's mission is to prevent FAS and ARND and to promote effective, lifelong interventions for those affected. Task Force goals are to 1) advise and foster coordination among all state, local, and federal agencies; tribal councils; and other private entities regarding FAS and ARND concerns; 2) promote communication and education regarding the adverse conditions associated with prenatal alcohol use; 3) identify research needed to develop effective strategies for preventing and treating FAS and ARND; 4) assess what services are available and identify gaps in needed services for women at risk and persons affected by prenatal alcohol exposure; and 5) ensure that appropriate diagnostic and treatment services are made available to women at risk for an alcohol-exposed pregnancy and to children and adults with FAS and ARND. By using its mission statement and goals as a foundation, the Task Force developed recommendations regarding the most critical concerns.

Task Force Recommendations

Through a consensual group process, occurring first in working groups and then with the full committee, the Task Force generated its first recommendations. Certain Task Force members are scientists knowledgeable in FAS and ARND whose ideas are based on the best evidence to date; however, the following recommendations also incorporate the insights of members who care for or provide services to affected children or provide substance abuse services to women at risk for an alcohol-exposed pregnancy. The initial working groups were combined into two major groups, the Research Working Group and the Services and Public Awareness Working Group.

The purpose of the Research Working Group was to evaluate existing FAS and ARND research and make recommendations concerning needed actions to remedy deficiencies in high-priority areas. This group generated recommendations 1–6. The Services and Public Awareness Working group identified concerns that need to be explored to ensure the availability of high-quality, effective services for women at risk for an alcohol-exposed pregnancy and for persons with FAS or ARND, and to achieve an increased level of visibility and public awareness regarding concerns of prenatal alcohol use, FAS, and ARND. This group generated recommendations 7–15.

Task Force recommendations are as follows:

1. Develop a clinical case definition for diagnosing FAS, including a neurocognitive phenotype, and begin work on establishing a clinical case definition for ARND.
2. Develop a uniform surveillance case definition for FAS and begin formative work on a uniform surveillance case definition for ARND.
3. Develop a white paper to review and summarize relevant epidemiologic research addressing the scope of the problem, prevalence, risk factors, impediments to diagnosis, and number of women at risk for an alcohol-exposed pregnancy.
4. Develop a white paper to review the evidence for effective prevention and treatment strategies for women at risk for or engaging in prenatal alcohol use. The report should describe women at risk, identify barriers to implementing effective strategies, and proscribe against implementation of untested models or models that are not evidence-based.
5. Develop a health services research agenda focusing on families of persons with FAS and ARND that address such concerns as why certain families do well and stay together, the impact of FAS and ARND on families relative to other birth defects, and how the legal system deals with FAS and ARND.
6. Develop a science research agenda, including translational research that brings basic research findings to the clinical domain (e.g., neuroimaging), and address concerns of maternal and fetal susceptibility to FAS and ARND.
7. Complete a profile of state, tribal, and private entities with existing services for persons with FAS and ARND and women at risk for an alcohol-exposed pregnancy; the profile should include eligibility criteria and ongoing educational efforts for professionals regarding FAS and ARND.
8. Develop an agenda that will lead to a national standard of care for persons with FAS and ARND during their life span, including best practices and plans for dissemination of standards to relevant health-care professionals.
9. Endorse a national coordinated media campaign and request that ICCFAS recommend how to coordinate this effort among all federal agencies.
10. Endorse the U.S. Surgeon General's Advisory statement regarding drinking during pregnancy, and urge that the statement be reissued as part of the coordinated national media campaign.
11. Contact the Office of National Drug Control Policy to recommend inclusion of information regarding FAS and ARND in their resource materials.
12. Develop a checklist of essential state services needed to prevent FAS and ARND, to treat persons with FAS and ARND and their families, and to better identify women at risk for having an alcohol-exposed pregnancy.
13. Develop and disseminate a plan for systemwide education regarding prenatal alcohol-related disabilities to be offered to professionals in health services, judicial services, education, child welfare, vocational rehabilitation, juvenile justice, maternal child health clinics, and disabilities services and prevention.
14. Develop and disseminate a kindergarten–grade 12 curriculum to address FAS, ARND, and prenatal alcohol use.
15. Investigate incorporating information related to prevention and treatment of FAS and ARND into the credentialing requirements for teachers, juvenile justice workers, lawmakers, and health-care professionals (e.g., include FAS-related questions on state board exams).

Next Steps

As a first step, the Task Force has been working closely with CDC and other federal agencies to address these recommendations in a comprehensive and coordinated fashion. Because work in areas related to the recommendations is already under way, and expertise exists across federal agencies, collaboration between the FAS/FAE Task Force and ICCFAS is essential. Next steps include identifying which agency will take the lead on each recommendation and collaborating with partners within and outside of the federal system to devise an implementation plan for these recommendations.

Certain initiatives already under way focus on the Task Force recommendations. In 2002, CDC received a Congressional mandate to develop guidelines to diagnose FAS and other conditions resulting from prenatal alcohol exposure, incorporate these guidelines into the curricula of medical and allied health students and practitioners, and disseminate curricula to and provide training for the target audiences regarding these guide-

lines. CDC will coordinate this activity with the Task Force to develop diagnostic and surveillance guidelines for FAS. These efforts address Task Force recommendations 1 and 2. In addition, CDC recently solicited proposals to fund four regional training centers for the education and training of medical and allied health students and professionals concerning FAS and other prenatal alcohol-related disorders. These centers will develop, conduct, and analyze population-based surveys of medical and allied health students and practitioners to understand their knowledge, attitudes, and beliefs regarding the diagnosis, treatment, and prevention of FAS and other prenatal alcohol-related disorders. The surveys will also assess respondents' previous training experiences, practices, and educational needs, and barriers to diagnosis and treatment. On the basis of these findings and a review of existing curricula, the centers will develop, implement, and evaluate educational curricula for medical and allied health students and practitioners that incorporate diagnostic guidelines for FAS and other prenatal alcohol-related disorders. This effort addresses the education-related recommendations, specifically recommendations 13 and 15.

The FAS Center for Excellence, administered by the Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, was recently established under section 519D of the Children's Health Act of 2000. The FAS Center for Excellence has conducted a series of town hall meetings across the United States to gather information regarding the concerns of FAS- and ARND-affected families and communities. These findings will provide further information for implementing the recommendations, including the recommendations related to public awareness of FAS and ARND prevention and the availability of services. In addition, the FAS Center for Excellence has initiated an environmental scan aimed at highlighting model programs for FAS prevention and treatment and identifying gaps in existing service delivery systems. These activities address recommendations 5, 7, and 8. NIAAA sets the basic sciences research agenda for FAS and other prenatal alcohol-related outcomes and supports its implementation through the National Institutes of Health grant process (recommendation 6). NIAAA also convenes and chairs the ICCFAS and, thus, has lead responsibility for ensuring coordination of efforts among federal agencies in addressing FAS and ARND (recommendations 9 and 10).

Ongoing challenges for the Task Force include developing strategies to enhance implementation of the recommendations in this report as well as others that will be released throughout the term of this chartered committee. Task Force meetings are held approximately twice a year and are open to the public. Meeting notices are published in the *Federal Register*. Further information regarding the Task Force and minutes of previous meetings can be accessed at http://www.cdc.gov/ncbddd/fas/taskforce.htm.

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