

Centers for Disease Control and Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention (DHAP)

External Peer Review of DHAP Surveillance, Research, and HIV Prevention Programs

Executive Summary Findings and Recommendations



Atlanta, Georgia
November 1, 2009



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Dear Colleagues,

Starting in the fall of 2008, the Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of HIV/AIDS Prevention (DHAP) began the External Peer Review (EPR) process of DHAP's domestic HIV prevention activities. This important review covered DHAP's surveillance, research, and HIV prevention programs and included a planning phase, the selection of a panel of experts, development of questions to be addressed and exhaustive briefing materials, convening the panel of experts, and the development of the report contained herein.

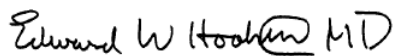
The purpose of the peer review was to obtain external review and feedback on DHAP's domestic HIV prevention programs, including research and non-research (i.e., public health practice). The specific goals of the peer review were to:

- a. Provide DHAP with objective input and guidance on its scientific and programmatic priorities and direction.
- b. Serve as a basis for CDC's next HIV Prevention Strategic Plan.
- c. Provide a platform for the development of a National HIV Prevention Plan that incorporates stakeholder perspectives and needs.

This summary contains the findings and recommendations of the EPR and materials that provide background to the reader on DHAP's programs and activities that were reviewed by the expert panel. This review required substantial effort from the panel members and the Division's Peer Review Planning Committee and particularly from the many DHAP staff members who worked hard to plan, develop, and carry out the steps leading to the External Peer Review.

We want to recognize the efforts of the panel members in providing their input and working for several months to finalize this report. This process will greatly assist CDC in meeting the scientific and programmatic needs of the HIV epidemic, which is vital to stopping the spread of HIV/AIDS in the United States.

Regards,



Edward Hook, III, MD
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Chair



Jesse Milan, Jr., JD
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I. INTRODUCTION

In the Fall of 2008, the Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP), began the External Peer Review (EPR) of DHAP's HIV Prevention Activities. This review consisted of convening a group of seventy-three (73) experts from state and local government, national partner organizations, academia, community-based organizations and risk population stakeholders from various parts of the country with experience in HIV prevention and familiarity with DHAP's intramural and extramural activities to examine DHAP's HIV prevention activities. This Peer Review would provide input to CDC on the scientific validity and quality of its activities and the appropriateness of activities to the identified need in the area of HIV/AIDS prevention.

To help guide the review process, DHAP developed a series of questions seeking input that would prove useful to CDC in determining the scientific validity of its activities and in planning for the future. Jesse Milan, JD, and Edward Hook, M.D., led the External Peer Reviewers and chaired a Steering Committee composed of the Co-Chairs of five panels who developed a series of overarching findings and recommendations. Each of the panels reviewed information provided by CDC and developed findings and recommendations in each of their areas. The panels focused upon the following:

- Planning, Prioritizing, and Monitoring
- Surveillance
- Biomedical Interventions, Diagnostics, Laboratory, and Health Services Research
- Behavioral, Social, and Structural Interventions Research
- Prevention Programs, Capacity Building, and Program Evaluation

A meeting of the EPR Reviewers and the various Panels and Steering Committee was held at the W Hotel Buckhead in Atlanta, Georgia on April 13–15, 2009. The meeting consisted of plenary presentations, panel discussions, Steering Committee discussions and a report-back session, where the Co-Chairs of the various panels reported to the entire group of EPR Reviewers and to CDC the most salient points of the discussion in their Panel.

A. ABOUT THIS SUMMARY REPORT

This Summary contains the most salient points from the Steering Committee and individual panels. A full report is available, which contains a detailed description of the process, a description of the methods used to carry out this process, and greater detail on the findings and recommendations of the various panels. The findings and recommendations included here are those of the EPR members and Steering Committee without input from CDC staff. DHAP has been presented this report and has had an opportunity to draft a detailed response.

II. PANEL SUMMARIES

A. STEERING COMMITTEE

Led by the External Peer Review Chairs and comprised of all the Panel Co-chairs, the Steering Committee was charged with taking a macro-level view of DHAP's efforts and approach. In response to this charge, the Steering Committee members were unanimous in their recognition of the important role of CDC in leading the nation's domestic HIV prevention efforts and DHAP's ability to work with constituents at the national, state and local levels. While these were seen as important roles, the Steering Committee saw opportunities for further growth, for improved prioritization of efforts, and for enhanced leadership on the part of CDC. The Steering Committee saw also a unique, central role for CDC in helping to guide the expected development of a federally created national plan for HIV in the United States and in bringing HIV prevention issues to our national debate on health care reform. Most importantly, the Steering Committee believed that its review would be especially useful at this juncture in CDC history with the arrival in July 2009 of the new DHAP Director.

The Steering Committee expressed a strong concern that DHAP should have been engaging in a more strategic variety of activities to better serve current needs and anticipated future trends without duplicating the efforts of other federal government agencies and nongovernmental partners. The Steering Committee expressed reservations on the process through which Division and Branch priorities were set as well as how scientific data from surveillance, behavioral and biomedical research, and program evaluation translated into program and research priorities. The Steering Committee also questioned whether current priorities were the most appropriate for the existing and future contributions of CDC to the HIV prevention needs of the United States.

Members of the Steering Committee recommended greater transparency from DHAP in priority-setting and decision-making processes and greater leadership in articulating the mix of activities needed to achieve HIV prevention goals across the United States. They urged CDC officials to resist CDC-internal and external cultural and ideological factors that may have impacted what activities and programs were carried out in the past. A stronger commitment must be made to embrace and pursue scientific validity and to document specifically how DHAP activities meet existing needs and accord with the current state of science. The organizational culture and structure of CDC were seen as barriers to more collaboration within DHAP, among Divisions within the Center, among federal and non-federal agencies, and to the speedy translation of knowledge into practice.

In regard to the current mix of activities, the Steering Committee urged greater rigor from DHAP to articulate combination approaches appropriate for various stages and concentrations of the epidemic across the United States with attention to the socio-economic conditions of affected communities and the technical capacity of local public health and community-based stakeholders to carry out needed interventions. Recognizing that external factors, funding or political considerations often affect which activities can be carried out, the Steering Committee recommended an increase in public awareness about HIV prevention sciences and other activities that heighten understanding of and demand for effective HIV prevention approaches in the United States.

In regards to future planning activities, the Steering Committee recommended that CDC accelerate the availability of data characterizing the epidemic, increase utilization of available data in planning, prioritize surveillance activities for support, and make data derived thereof more widely available in a more expeditious way to support planning nationally and at the state and local levels. The Panel also recommended that future behavioral research address system factors that fuel health disparities as a crucial barrier to optimal control of the epidemic. A similar recommendation was made on the programs to be implemented, which could address social determinants, such as poverty, education, geography, and socio-demographics, rather than just risk behavior. Biomedical research can also be more clearly defined, as current efforts, while adequate, do not take into account possible synergies with other federal agencies and other components within CDC.

B. PLANNING, PRIORITIZING AND MONITORING

The Planning Panel inquired about the data that were used for planning and were unable to discern how much of the data gathered throughout DHAP for purposes such as surveillance and program evaluation informed planning. The Panel received information on the HIV Strategic Plan and cost-benefit analyses currently carried out by DHAP staff and emphasized the need for greater transparency on how decision-making is informed by available data. The Panel recommended that DHAP take steps to increase the transparency of the decision-making process and include input from external partners.

The Planning Panel emphasized the need for a National Plan for HIV/AIDS in the United States in which DHAP and CDC would assume a leadership role for the Department of Health and Human Services (HHS), other agencies within HHS, and other federal departments to inform an outcomes-oriented approach to HIV prevention that includes measurable goals, benchmarks, and accountability mechanisms. The Panel reiterated the need for CDC to work in collaboration with other governmental and non-governmental entities in the development of the plan and provide specific models that can be used for decision-making, including comparisons of the relative effectiveness of various activities as compared to each other and in comparison to no action.

The Panel stressed the need for CDC to report data on epidemic burden, population impact, programs implemented, program outcomes, and other relevant information in an annual report to be disseminated to the public. This annual report should make available to all interested parties information on the effectiveness of CDC's activities in fighting HIV transmission. In the assessment of the Planning Panel, one of DHAP's central priorities must be to increase public understanding of and support for primary HIV prevention activities in order to sustain and grow access to needed HIV prevention services in the United States and achieve needed reductions in HIV incidence and health disparities.

C. SURVEILLANCE

The Panel emphasized the critical role of the core HIV surveillance system, the keystone to HIV prevention and essential to HIV care and treatment programs. The capacity of and demands on the surveillance system have increased markedly over the past decade with the number of individuals living with HIV growing each year; confidential name-based HIV reporting just now implemented; the increasingly complex technology and requirements for electronic reporting, matching, and new data management systems; and expectations and opportunities for surveillance to support programs more actively. The core HIV surveillance system has never been evaluated against the established

performance standards. This evaluation, expected to be conducted in 2010, will likely illuminate strengths and deficits in the system's ability to characterize the epidemic and support prevention and care programs. The Panelists recognized the unprecedented monitoring and prevention opportunities inherent in comprehensive laboratory reporting and encouraged CDC to support the jurisdictions' capacity to implement such reporting systems. The panel noted CDC's recent efforts to incorporate "supplemental" surveillance activities into Core surveillance processes; integration of such activities promotes more efficient use of resources and greater standardization of data. The panel viewed HIV surveillance as an integral component of CDC's overall prevention portfolio and recommended that CDC reassess the role of surveillance and the adequacy of funding dedicated to this critical system.

Other overarching observations:

- The ability to conduct timely and meaningful data analysis to inform local program activities is challenged on many fronts across CDC's HIV surveillance initiatives: some initiatives are not funded to support dedicated staff effort to ensure analysis and effective application of surveillance data to program; some surveillance activities may not be sufficiently robust to inform program locally (i.e., current HIV incidence surveillance system); additional guidance is needed about appropriate use of local data (i.e., core as well as incidence and resistance data); related initiatives have separate data management systems causing redundant effort and variable data quality; new data management systems are more complicated and require more advanced programming and analysis skills than in the past; many CDC personnel assigned to provide support to local jurisdictions are not sufficiently familiar with projects or best practices to provide meaningful assistance; CDC data analysis and information technology resources are strained.
- Advances in testing technologies necessitate ongoing review of their impact on surveillance activities such as: the case definition and case ascertainment processes, the ability to implement the current HIV incidence surveillance system and the validity of the current estimation methodology, opportunities to integrate incidence surveillance into routine surveillance if the time of infection can be ascertained reliably at individual level, the increasingly critical link between surveillance and prevention action to interrupt transmission that surveillance of acute and incident infections may afford.
- Lower morbidity jurisdictions are historically not represented in supplemental surveillance activities, and many report challenges with the increasingly complex data management and analysis needs.
- Closer collaboration is needed between program and surveillance to ensure most effective application of surveillance data to guide program; the use of GIS mapping to correlate HIV infection with other socio-economic and geographic characteristics may be an additional tool to develop.
- Greater integration and collaboration with the surveillance and program activities of related conditions, such as sexually transmitted diseases, tuberculosis, and hepatitis C is needed.
- Allocation of funding across the jurisdictions to conduct HIV surveillance activities does not appear equitable. The method for determining funding levels for surveillance activities should be assessed and made transparent.

The Surveillance Panel reviewed components of DHAP's HIV case surveillance, HIV incidence surveillance, drug resistance surveillance, behavioral surveillance, and clinical surveillance programs. The participants noted strengths, weaknesses, and the unique contributions of each program in detail in the Surveillance Panel Summary section of this report.

D. BIOMEDICAL INTERVENTIONS, DIAGNOSTICS, LABORATORY, AND HEALTH SERVICES RESEARCH

The Panel reviewed information on current research and questioned how decisions are made within DHAP regarding the direction of research. The Panel discussed at length the role of the Laboratory, Epidemiology, and Behavioral and Clinical Surveillance Branches in conducting research that can result in useful data for program implementation.

The Panel observed that the prioritization process for funded research activities was not always based upon, nor linked to, broader division priorities. The Panel discussed what and how data was used to support the research agenda and how data from surveillance and program implementation was utilized to inform the direction of research. They recommended the creation of an internal scientific review panel to prioritize and align the decision-making process regarding the direction of research with the programmatic needs of DHAP. This panel would also oversee a thorough regularly scheduled ongoing review of research activities to ensure their applicability to current needs. In addition, it was recommended that DHAP convene an external panel of scientific experts at defined intervals to assess the effectiveness and appropriateness of the current scientific portfolio in relation to the HIV epidemic.

The Panel questioned whether the research being conducted, in developing assays and Pre-Exposure Prophylaxis (PrEP) was coordinated with other governmental and non-governmental organizations, such as pharmaceuticals, and whether this type of research was the appropriate role for CDC.

The Panel emphasized the need for greater collaboration and coordination within DHAP; with other CDC entities, including the Global AIDS Program (GAP); with industry; and with other federal agencies, especially the National Institutes of Health and the President's Emergency Plan for AIDS Relief (PEPFAR).

The Panel acknowledged that the clear strength of the CDC scientific portfolio was in its translational work implementing science into public health practice. Yet, the Panel recognized the unique contribution of CDC research that did not fit into this translational category, including primate studies, health services research, natural history studies, and cost-effectiveness studies. The Panel recommended that in several of these areas, research could be enhanced and should be pursued.

E. BEHAVIORAL, SOCIAL, AND STRUCTURAL INTERVENTIONS RESEARCH

The Panel reviewed the research being carried out in the development of behavioral interventions and concluded that the past emphasis on demographics-based research has not resulted in interventions that address the individual level of risk and may have been counter productive in emphasizing race and ethnicity as factors that contribute to risk. The Panel emphasized in unequivocal terms the need to shift the focus of research to individual levels of risk. Among the

issues that can be considered in developing research methodologies are the following: practices, social factors, and behaviors that fuel HIV epidemics across populations and settings.

The Panel also emphasized that DHAP should engage in formative (Phase 1) research, which is an area where it has a good record and has collaborative relationships with practitioners, and operational (Phase 4) research, which studies the real world implementation of interventions derived from research. As the funder of prevention programs, DHAP and its partners would be better served in those areas of population and need definition and program implementation.

The Panel also questioned the effectiveness of the process to translate research into practice and evaluation data back to inform the research formulation process. Whereas there are extensive opportunities for collaboration and information sharing, the Panel believed that these were not sufficiently explored and carried out.

F. PREVENTION PROGRAMS, CAPACITY BUILDING, AND PROGRAM EVALUATION

The Program Panel emphasized that future prevention programs should address social determinants that have impact on risk behavior (poverty, racism, homophobia, incarceration, homelessness, substance abuse, immigration, and power inequities, among others).

The Panel also emphasized that gay, bisexual, and other men who have sex with men (MSM) should be given more attention in the development and implementation of prevention programs given their historic and current epidemic burden. The panel emphasized the importance of differentiating HIV prevention approaches for men who self identify as gay and bisexual and those who do not. Special emphasis should be given to transgender populations.

The Panel questioned the current structure of DHAP and whether it is responsive to the prevention needs of the populations at risk and whether a more streamlined structure would better serve those needs. The Panel indicated that it was not clear how and whether data from surveillance and epidemiology and program evaluation were used for the development of more effective programs.

The Panel recommended enhancing approaches to HIV prevention by including the funding of needle exchange programs, the reinforcement of abstinence and of consistent and correct condom use, and the use of social marketing strategies for the dissemination of information on HIV prevention.

Finally the Panel recommended a redefinition of the essential elements of a Comprehensive HIV Prevention Program, which are defined in the Supplemental Guidance for HIV Prevention Community Planning, to incorporate activities currently carried out by non-governmental organizations at the national and community-based level.

G. EXTERNAL PEER REVIEW PANEL MEMBERS

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