

An outline map of New York State, showing the state's borders and the Long Island Sound to the east. The map is rendered in a light gray color.

HIV/AIDS Research Priorities for New York State for the Next Decade

Report by the New York HIV Research Centers Consortium
April 2009

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INTRODUCTION

This report provides recommendations for an HIV/AIDS research agenda for New York State. It supplements a recent NYS AIDS Advisory Council report¹ (November 2008) which urges the creation of a New York State HIV/AIDS Research Initiative that would be modeled on a successful California program. The initiative would fund NYS-based HIV/AIDS researchers to undertake research particularly relevant to the New York HIV/AIDS epidemic and would encourage the development of programs and policies that specifically address HIV/AIDS issues in the State.

The New York HIV Research Centers Consortium sponsored a conference in December 2008 to develop a research agenda for New York State. Participants included eminent basic science and social/behavioral researchers, clinicians and community-based organization representatives from over 30 institutions across New York State.

Plenary presentations were made by: Bart Aoki, PhD, Associate Director, California HIV/AIDS Research Program (CHRP), who spoke about the implementation and outcomes of CHRP; Guthrie Birkhead, MD, MPH, Deputy Commissioner, Office of Public Health, NYS Department of Health, presented an update of HIV/AIDS epidemiology and recommendations for research for New York State; and Keith Krasinski, MD, Chair of the subcommittee on the HIV/AIDS Research Initiative, NYS AIDS Advisory Council and Professor of Pediatrics and Environmental Medicine, New York University Langone School of Medicine, who provided information on the background for the report developed by the NYS AIDS Advisory Council.

Work groups were created to develop research priorities in four topic areas: Basic Research; Social, Behavioral and Prevention Research; Clinical Research; and Health Policy Research. Work group membership was selected to represent a diversity of content and disciplines within each topic area and to reflect all geographic areas of the State.

Each work group was charged with developing a list of research priorities that would focus on issues of particular relevance to New York State, draw on unique New York State research expertise or resources, be research that can best be conducted in New York State, and demonstrate the potential for economic development. The attached materials list the priorities recommended by each work group and the rationale for each research priority.

The work groups also provided justification for why these research priorities are distinctive from a national research agenda and specifically how they are relevant to New York State. Across all work groups this was addressed by noting that New York State has the highest proportion of residents living with HIV/AIDS, has a unique and diverse patient population, has the highest number of new infections, evidences significant health disparities between different populations, and has many types of programs and initiatives that can be studied to optimize outcomes. Furthermore, the many research centers in New York State provide the expertise to study the emerging complexities related to HIV infection (e.g., co-infections and aging with HIV).

1. Report available at: http://www.health.state.ny.us/diseases/aids/workgroups/aac/docs/research_tailored_for_ny.pdf

RECOMMENDED RESEARCH INITIATIVES

Basic Research Work Group

Chair: Vinayaka Prasad, PhD; Co-chair: Martin Markowitz, MD

Broad Goals: To: (i) provide better understanding of the molecular mechanisms by which HIV replicates in the cells of the immune system to aid in the development of both new drugs and an effective vaccine; and (ii) extend the accomplishments of previous basic research to meet the challenges of today. The overall goal is to elucidate the interaction of HIV and the human host and to translate this knowledge into novel methods of diagnosing and treating HIV-related conditions.

Priority Research Initiative 1:

Basic HIV research on the structural biology of HIV proteins, identification of new drug targets, mechanisms of resistance to ARTs and mechanisms of innate acquired immune response to HIV.

Rationale:

Current ARTs were developed as a result of basic investigation of the molecular biology of HIV-1. Protease inhibitors, reverse transcriptase inhibitors, fusion inhibitors have made a major impact, slowing disease progression and reducing transmission rates. Research into these areas and the development of new drugs are a high priority. Understanding the immune response to the virus will lead to novel methods of allowing the body to fight the virus and the disease. In addition, basic studies of neuropathogenesis will be essential to understanding how best to approach increasing burden of cognitive impairments in the aging NYS HIV population under rapidly changing treatment scenarios.

Priority Research Initiative 2:

Use of systems biology approach to investigate differences among racially distinct groups in terms of HIV replication and susceptibility to HIV infection.

Rationale:

Genomic technologies have made it possible to monitor global changes in cellular gene expression (gene expression profiling), document intracellular networks of protein-protein interactions (protein interactomes) and record changes to the machinery that contains the genetic information in cells such as DNA methylation, histone modification and other chromatin changes that impact gene expression (epigenetics). Analyses of these complex systems will facilitate understanding the host factors that control the virus and will lead to improved treatment, tailored to the ethnic background of the patient.

Priority Research Initiative 3:

Integrative studies for conditions related to aging (e.g., heart disease, liver disease, neurocognitive disorders), impact of recreational drug use, studies of co-morbidities (such as hepatitis C virus [HCV] and tuberculosis).

Rationale:

National trends tend not to consider local phenomena to fund research. While national funding policies are driven by categorization of specific topics to different compartments, NYS needs to take an integrated approach to solve the problems that are rampant in New York State.

Priority Research Initiative 4:

Epidemiology to identify different subtypes of HIV including phylogenetic analyses of transmitted viruses; evaluating non-B subtypes, monitoring resistance and exploring genetic susceptibility to disease among the diverse populations in the State.

Rationale:

Federal agencies monitor the appearance of new forms and perform surveillance at national and regional levels but do not evaluate state-level trends.

Social, Behavioral and Prevention Research Work Group

Chair: Marya Gwadz, PhD; Co-chair: Beryl Koblin, PhD

Broad Goal: To advance behavioral, social, and prevention research and bolster HIV prevention and secondary prevention, and treatment of and successful adaptation to HIV infection. Many of the aims emphasize the need to access and engage highly vulnerable populations. The aims target under-studied areas and emphasize innovative approaches to these pressing problems. They are intended to build on what is already working in New York State, address what is not working, and to supplement and complement Federal funding streams.

Priority Research Initiative 1:

Cross-disciplinary studies involving basic science, treatment, behavioral, social and community disciplines for all aspects of HIV research.

Rationale:

Interdisciplinary collaboration is essential for all phases of HIV research. For example, the results of clinical trials of new treatments or prevention technologies may not be fully understood because of incomplete data on community or group readiness, adherence, or other aspects of the treatment or product. Interdisciplinary collaborations can address the critical problem of the under-representation of vulnerable populations (women, people of color) in biomedical research and clinical trials. Enhancing collaborations are a component of ameliorating health disparities.

Priority Research Initiative 2:

Research to better understand and utilize existing systems and structures (e.g., education, health care, virtual networks) to optimize prevention, intervention and care.

Rationale:

New technologies are constantly emerging and can be harnessed for HIV/AIDS prevention and treatment. Many systems of care are not integrated with each other, such as systems to identify and treat STIs and HIV. Risk groups (e.g., MSM, NIDU, IDU, heterosexuals, etc.) are networked with each other and a better understanding of these networks could enhance HIV prevention efforts.

Priority Research Initiative 3:

Observational and intervention research to optimize HIV testing and its positive impact.

Rationale:

There are a large number of gaps in NYS regarding HIV testing and after-care. These include:

- Delay between positive HIV test results and treatment for a substantial proportion of the population.
- Insufficient linkage and support for behavior change/maintenance after testing (if negative).
- Urgent need to bring under-served groups into routine care. HIV testing may not be a priority for these groups and therefore must be considered in the social context of their lives.

As HIV testing practices and technologies and the larger context change, there is a need to modernize the way testing is done. It may be necessary to adapt HIV counseling strategies to settings or populations. There is a large category for whom risk category is unknown. This gap must be closed. Most interventions are mono-level. Multi-level interventions are needed for complex problems such as those associated with HIV.

Priority Research Initiative 4:

Improve impact of evidence-based interventions (EBIs), improve evaluation of EBIs and build capacity for organizations that conduct EBIs.

Rationale:

There is a need to identify active components of an intervention in order to streamline them, improve the process of translating EBIs in community-based organizations, improve evaluation and tools to evaluate efficacy, understand how EBIs fit with characteristics of organizations and how this affects efficacy. EBIs typically are generated from the research community and move to the clinical setting; better mechanisms to identify EBIs from the community are also needed.

Priority Research Initiative 5:

Secondary prevention research to improve intervention efficacy for positives and further our understanding of differences in HIV transmission rates in NYS as compared with other states.

Rationale:

There are a number of gaps including how to boost intervention efficacy for positives. Data suggest that the rate of transmission is lower in NYS than other states. This must be explored and better understood.

Priority Research Initiative 6:

Innovative epidemiological research to understand the role of co-factors, such as social networks, sexually transmitted infections (STIs) and mental health in HIV transmission.

Rationale:

The role of various co-factors in HIV transmission and variations in transmission rates among known positives are not well understood.

Other Suggestion:

Train investigators, in particular those from under-represented groups, to ameliorate health disparities and provide important perspectives on cultural proficiency and expertise. Increasing the numbers of investigators from under-represented groups is a component of ameliorating health disparities. Such investigators also provide important perspectives on cultural proficiency and cultural expertise and enhance the science.

Clinical Research Work Group

Chair: Roy Gulick, MD, Co-chair: Mary Klotman, MD

Broad Goal: To facilitate and encourage clinical research investigations to inform and improve the management, care, and general health of the diverse group of HIV-infected patients living in New York State, including those at all stages of HIV infection (from acute infection to late-stage disease).

Priority Research Initiative 1:

Acute HIV infection and drug resistance issues regarding assessment, presentation and optimal treatment of acute HIV infection.

Rationale:

Ongoing questions about assessment, presentation, and optimal treatment of acute HIV infection, particularly in patients other than white males. Knowledge of drug resistance patterns is critical to optimizing choices of antiretroviral treatment within the state.

Priority Research Initiative 2:

Aging of the HIV-infected population which requires treating HIV along with medical issues related to aging.

Rationale:

Average age of an HIV-infected person in New York currently is 45 years old. As HIV-infected individuals live longer, medical issues of aging become important. These include concomitant illnesses such as diabetes, hypertension, coronary artery disease, liver and renal disease; consequences of chronic immune system activation, and their influence on individual medication management such as changing pharmacokinetics.

Priority Research Initiative 3:

HCV/HIV co-infection requires collaboration between HIV and HCV researchers and clinicians to optimize assessment and treatment for both infections.

Rationale:

Viral co-infection is important to understand to optimize assessment and treatment of both infections. Collaboration between HCV and HIV treaters and programs is essential. A number of investigational HCV drugs currently are in development.

Priority Research Initiative 4:

Heterosexual transmission of HIV questions regarding pathophysiology and pathogenesis, hormonal influences in women and the effects of STIs.

Rationale:

Unanswered scientific questions concerning: pathophysiology and pathogenesis of heterosexual HIV transmission; hormonal influences in women; effects of sexually transmitted infections (STIs).

Priority Research Initiative 5:

Late-stage HIV disease and how to optimally manage inpatient hospitalizations and treat co-morbidities that occur in late-stage HIV disease.

Rationale:

Unanswered scientific questions about people presenting with late-stage HIV disease; current reasons and optimal management for inpatient hospitalizations of HIV-infected patients. Early mortality in 2008 not well understood. Significant co-morbidities occur in late-stage HIV disease: renal disease, liver disease, cardiovascular disease, mental health diseases.

Priority Research Initiative 6:

Life-style issues for HIV-infected patients which may include better treatments for smoking cessation, understanding the interaction of recreational drugs and HIV therapies and the benefits of nutrition and exercise.

Rationale:

Better treatments for smoking cessation are needed. Interactions of recreational drugs and HIV therapies are not well understood. Benefits of nutrition/diet and exercise are not well described in HIV-infected patients.

Priority Research Initiative 7:

Perinatal HIV infection survivors are not well described in medical literature in terms of psychosocial and biomedical outcomes.

Rationale:

Survivors of perinatal HIV infection are not well described in medical literature.

Priority Research Initiative 8:

“Personalized” HIV medicine issues regarding whether one can use genetics, HIV tropism, pharmacokinetics to predict HIV drug responses and toxicities and provide individualized treatment. How complementary therapies interact with HIV medications.

Rationale:

Can one use genetics, HIV tropism, pharmacokinetics, etc. to predict HIV drug responses and toxicities and provide more individualized treatment? It is not well understood how traditional or complementary therapies interact with HIV medications.

Health Policy Research Work Group

Chair: Robert Bank; Co-chair: Ginny Shubert, JD

Broad Goal: To determine the most efficient and cost-effective policies that will substantially reduce infections, increase access to and maintenance in primary and supportive care, and reduce health disparities.

Priority Research Initiative 1:

Determining individual, structural and contextual factors, service systems and policies associated with delayed HIV testing and entry into care.

Rationale:

Clinical and public health significance to delayed entry into care (e.g. life-years lost, continued HIV transmission, health and social costs).

Priority Research Initiative 2:

Exploring the non-medical determinants of discontinuous care.

Rationale:

Currently only the medical model is being explored, and it is not producing outcomes.

Priority Research Initiative 3:

Determining the most effective models of care so as to reform health care access and delivery.

Rationale:

The need to reform health care access and delivery - generally, and Medicaid in particular – and the need to refine or adjust the health workforce to manage comprehensive primary care and more complex medical issues as the HIV population ages.

Priority Research Initiative 4:

Impact of transitioning to different medical insurance coverage (e.g., from fee for service to Medicaid managed care).

Rationale:

As Medicaid managed care is mandated for persons with HIV, there is an immediate need for research to enable policy makers to identify implementation problems and solve them. Other vulnerable populations have found the shift to Medicaid managed care problematic.

Priority Research Initiative 5:

Identify frequent users of multiple systems (e.g., corrections, shelters, mental health care) and develop system treatment approaches to reduce cost and improve outcomes

Rationale:

There is inadequate coordination of services among key providers and systems of care that serve persons living with or at high risk of HIV (e.g., corrections, shelter and mental health care) with adverse consequences for individuals and service systems, and less effective use of public expenditures.

Priority Research Initiative 6:

Impact of non-medical public health interventions such as housing on HIV prevention, health care access and cost.

Rationale:

Research has shown strong and consistent correlations between housing stability and HIV risk behaviors, health care access and health outcomes among PLWHA.

Priority Research Initiative 7:

Determine what community level intervention in education, employment and housing is needed within neighborhoods that experience disproportionate health disparities and assess whether it will reduce HIV transmission.

Rationale:

There is an opportunity for community level intervention in highly impacted neighborhoods to reduce disparities.

Priority Research Initiative 8:

How to get low threshold buprenorphine to opiate users throughout NYS.

Rationale:

We have more heroin users than anywhere else and drug users are late to test, drop out of care and are high sexual risk-takers.

Other Suggestion:

The group strongly encourages the inclusion of a rapid policy research process that would enable the research infrastructure to be responsive to and inform health and social service policy-making in the State.

Basic Science Research Work Group

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APPENDIX



SETTING AN HIV/AIDS RESEARCH AGENDA FOR NEW YORK STATE
New York HIV Research Centers Consortium Scientific Conference
Wednesday, December 3, 2008, 8:30 am - 3:00 pm
71 West 23rd Street, 19th Floor Conference Center, New York, NY

AGENDA

- 8:30 ***Convene and Welcome/Breakfast***
 Sherry Deren, PhD, Jack A. DeHovitz, MD, MPH & Anke A. Ehrhardt, PhD
 New York HIV Research Centers Consortium Steering Committee
- 9:00 - 10:00 ***Plenary Speakers***
 Bart Aoki, PhD, California HIV/AIDS Research Program
 Guthrie Birkhead, MD, MPH, New York State Department of Health
- 10:00 - 10:15 ***Overview of Work Group Mandates***
 Sherry Deren, PhD and Jack A. DeHovitz, MD, MPH
- 10:15 - 10:30 **Break**
- 10:30 - 12:30 ***Individual Work Group Meetings***
 Work Group I: Basic Science Research
 Work Group II: Social, Behavioral and Prevention Research
 Work Group III: Clinical Research
 Work Group IV: Health Policy Research
 Work Group V: Developing Strategies for Funding the NYS HIV/AIDS
 Research Agenda
- 12:30 - 1:00 ***Work Group Report Preparation***
- 1:00 - 2:30 ***Working Lunch***
 Presentations (1:00 - 1:30):
 Laura Morrison, Chief of Staff for Tom Duane, NYS Senate
 Keith Krasinski, MD, Chair of the subcommittee on the HIV/AIDS
 Research Initiative, NYS AIDS Advisory Council & NYU Langone
 School of Medicine
 Work Group Reports (1:30 - 2:30)
- 2:30 - 3:00 ***Concluding Remarks and Next Steps***
 Sherry Deren, PhD, Jack A. DeHovitz, MD, MPH & Anke A. Ehrhardt, PhD

**NEW YORK HIV RESEARCH CENTERS CONSORTIUM
MISSION STATEMENT**

The New York HIV Research Centers Consortium is a collaborative project of HIV research centers in the greater New York area. The mission of the Consortium is to enhance scientific knowledge of the HIV/AIDS epidemic and related issues by facilitating inter-institutional, multidisciplinary collaborations by scientists affiliated with HIV research centers in the New York region. There are currently 28 member Centers in the Consortium.

The aims of the Consortium are:

1. To promote inter-institutional exchange of information about our work
2. To foster inter-institutional, multidisciplinary collaboration
3. To enhance the dissemination of knowledge to public policy makers, researchers, and HIV-affected communities
4. To promote the application of knowledge obtained to the New York area and to other domestic and international populations

For information on the Consortium, please contact a member of the Steering Committee:

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NEW YORK HIV RESEARCH CENTERS CONSORTIUM (APRIL 2009)

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AIDS Policy Research Group, Rutgers the State University of New Jersey

Albany Medical College, Division of HIV Medicine

Baron Edmond de Rothschild Chemical Dependency Institute (CDI), Beth Israel Medical Center

Center for AIDS Research (CFAR), Albert Einstein College of Medicine/Montefiore Medical Center

Center for AIDS Research (CFAR), New York University School of Medicine

Center for AIDS Research and Treatment (CART), North Shore University Hospital

Center for Community and Urban Health, Hunter College of the City University of New York

Center for Comprehensive Care (CCC), St. Luke's-Roosevelt Medical Center

Center for Drug Use and HIV Research (CDUHR), New York University College of Nursing

Center for Health, Identity, Behavior & Prevention Studies (CHIBPS), Department of Applied Psychology, New York University

Center for Health, Intervention & Prevention (CHIP), University of Connecticut

Center for HIV/AIDS Educational Studies and Training (CHEST), Hunter College of the City University of New York

Center for Infectious Disease Epidemiologic Research (CIDER), Columbia University Mailman School of Public Health

Center for Interdisciplinary Research on AIDS (CIRA), Yale University School of Medicine

Center for Urban Epidemiologic Studies (CUES), New York Academy of Medicine

Designated AIDS Center, SUNY Upstate Medical University, Syracuse

Harlem Health Promotion Center, Columbia University Mailman School of Public Health

HIV Center for Clinical and Behavioral Studies, NYS Psychiatric Institute & Columbia University

HIV Center for Women and Children, SUNY Downstate Medical Center

HIV Clinical Trials Unit, Weill Medical College of Cornell University

HIV Treatment Development Center, SUNY Stony Brook Medical Center

Infectious Diseases and HIV Medicine, University at Buffalo, SUNY

Mount Sinai Medical Center, AIDS Psychiatry Research Group

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