PRIORITY:

Translating Research From Bench to Bedside to Community

Natural History and Epidemiology

Information Dissemination

AREA OF EMPHASIS

Natural History and Epidemiology

SCIENTIFIC OBJECTIVES AND STRATEGIES

OBJECTIVE–A: Transmission of HIV (Prevention, Risk Factors, and Mechanisms)

Characterize the risk factors and mechanisms of HIV transmission in domestic and international populations to guide prevention and treatment strategies.

(The scientific objectives of A, B, and C are of equal weight.)

STRATEGIES

- Utilize existing cohorts, develop new cohorts of novel subpopulations, and employ novel methods such as social network analysis, molecular epidemiology, and geographic information systems to further assess HIV transmission.
- Model how results from existing cohorts may be altered in populations with differing demographics and socioeconomic status, specifically by race, ethnicity, gender, age, sexual orientation, acquisition risk, and in-country resource capacities and availability.
- Conduct molecular epidemiology studies to identify divergent viral genotypes, drug resistance, and neutralization profiles and their temporal trends; and characterize how different HIV types (i.e., HIV-1 and HIV-2), HIV subtypes, recombinant forms, and associated risk factors influence routes and modes of HIV transmission, superinfection, natural history, response to antiretroviral therapy (ART), preexposure prophylaxis (PrEP), and emergence of antiretroviral (ARV)-resistant viruses. Conduct studies on the significance of multiple circulating subtypes and the generation of dual, multiple, and recombinant viruses in population epidemiologic dynamics and their potential implications for intervention and therapy.
- Conduct epidemiological and modeling research to improve estimates of per-contact risk of HIV transmission and to develop estimates of population-attributable risk, based on type of sexual exposure; characteristics of the infected and uninfected partners (e.g., plasma and/or anogenital tract viral load, host genetics, and coinfections); and cofactors such as drug use, psychiatric comorbidities, and antiretroviral therapy.

Strategies Related to Transmission and Its Prevention

- Evaluate sexual and blood-borne HIV transmission in relation to the following:
  - Viral factors such as viral quantity, diversity, coreceptor usage, genotype (including subtypes, recombinants, and resistance mutants), and dual virus infections in various body compartments (e.g., blood, saliva, semen, and mucosal compartments such as the female genital tract and the anorectal mucosa);
  - Host genetics and other host factors such as age, sex, race, country of origin, hormonal status, strength and breadth of immune response, comorbid chronic diseases, and coinfections;
  - Modifiable host factors such as diet and nutritional status; geographic location (urban, rural); drug, alcohol, and tobacco use and/or treatment, including substitution and other substance

use treatment modalities; mental health; circumcision status; and access to and use of health care;

- Other infections and their treatment, including *M. tuberculosis* (TB) and drug-resistant strains, multi-drug-resistant (MDR) and extensively drug-resistant (XDR) TB, *Plasmodium sp.* (malaria), sexually transmitted infections (STIs), and viral hepatitis;
- Psychological, social, cultural, geographic, and structural determinants of susceptibility to HIV acquisition among transient and migrating populations; sex workers; ethnic, sexual, and urban minorities; and other hard-to-reach populations; and
- Sexual activity, abstinence (including during the postoperative period after male circumcision), sexual networks, partner choice (e.g., serosorting), partner concurrency, partner fidelity, duration of partnership, control of STIs, hygienic practices such as douching, contraception choices, and cultural practices such as the use of traditional vaginal preparations and male circumcision.

- Further refine the timing, mechanisms, and risk factors in perinatal and postnatal transmission, including treatment of the mother, infant feeding modalities, physiology of lactation, long-term effects of perinatal interventions, maternal and infant genetic variation, and kinetics of viral resistance. These studies include:
  - Assessing the impact of maternal and infant ARV regimens of different potency and duration on mother-to-child transmission (MTCT) of HIV and on the short- and long-term health of women and their infants, and on the emergence of ARV drug resistance in the mother and in those infants who become infected despite prophylaxis;
  - Studying the safety and effectiveness of sustainable approaches to prevention of MTCT of HIV, including the provision of maternal ART, identifying successful breastfeeding weaning strategies, methods for improving the safety of formula feeding, and determining the effects of such approaches on infant morbidity and mortality;
  - Assessing the impact of maternal and infant adherence to ARV regimens on the risk of subsequent ARV resistance, clinical outcomes, and the effectiveness of ART in mothers and their children;
  - Assessing the impact of perinatal treatment and prophylaxis regimens on communitywide HIV resistance to ARVs;
  - Assessing the impact of MTCT programs on public health measures, including maternal, paternal, and infant morbidity/mortality rates; overall life expectancy; disability and/or quality-adjusted life years; and pediatric neurobehavioral development;
  - Assessing clinical outcomes, cost, and cost-effectiveness of different strategies for prevention of MTCT in the United States as well as in developing countries; and
  - Assessing the impact of not breastfeeding in high- and low-resource environments on the physical and mental health, as well as the quality of life (including stigma), of the mothers and children.

Strategies Related to Prevention and Treatment

- Conduct epidemiologic modeling studies on the aggregate impact of ART on HIV transmission, particularly in settings with endemic, high-prevalence, and emerging epidemics.
- Study the impact of widespread ART availability, adherence, and patterns of ART resistance on HIV prevalence, incidence, risk behaviors, and the transmission of resistant HIV strains.
- Conduct studies of male circumcision as a prevention tool, including:
  - Assessing the impact of adult male circumcision on an individual and community level, including assessment of HIV prevention and incidence in circumcised males and their partners, sexual behavior, and attitudes, in the domestic and international setting;

- Evaluating male circumcision delivery models with respect to safety, acceptability, cost-effectiveness, and long-term impact on HIV transmission;
- Evaluating male circumcision and its impact on HIV transmission and acquisition among men who have sex with men (MSM);
- Evaluating prevention approaches in the context of adult male circumcision, particularly those based on combinations of known methods, including reproductive health, partner reduction, condom use, and STI control; and
- Assessing the effect of male circumcision on transmission to uninfected female and male partners, considering the timing of male circumcision.

- Develop and evaluate the effectiveness of individual-, couple-, network-, and community-based interventions for HIV-infected persons and their partners to sustain behavioral change and prevent acquisition and transmission of HIV.
- Conduct studies on medication-assisted substance abuse treatment modalities and access to care (e.g., methadone maintenance, buprenorphine/naloxone, modafinil, naltrexone, antabuse, acamprosate, and stimulant abuse therapy), alone or in combination with mental health and/or behavioral interventions, as HIV prevention interventions.

OBJECTIVE–B: Disease Progression (Including Opportunistic Infections and Malignancies)

Use epidemiological research in domestic and international settings to identify influences and interactions among therapeutics, biological factors (e.g., age, host genetics, coinfections, comorbidities, HIV subtypes, and viral genetic variation), and behaviors (e.g., using the health care system, adherence, sexual activity, and alcohol and drug use) in relation to HIV progression and response to therapy, as indicated by virologic, immunologic, and clinical outcomes.

(The scientific objectives of A, B, and C are of equal weight.)

STRATEGIES

Strategies Related to Disease Progression and Response to ART

- Develop new interval-based or standard-of-care cohorts and maintain long-term followup of existing cohorts, including observational cohorts and clinical cohorts, to determine the changing spectrum of HIV disease; identify highly exposed uninfected persons, long-term nonprogressors, and elite suppressors; and evaluate interventions, especially in aging and minority populations, in developing countries, and in emerging epidemic zones including Eastern Europe and Asia.
- Characterize short- and long-term consequences of recent HIV infections, including host and viral genetic characteristics and differences by route of exposure, and continue to characterize the natural history of HIV disease and AIDS among those early in infection, those with minimal exposure to ART, those with virologic and/or immunologic responses to ART, and those who have experienced ART failure.
- Investigate the effect on disease progression of viral factors, including viral type/subtype, fitness, viral tropism, and innate and acquired genotypic and phenotypic resistance to ARVs.
- Characterize global patterns of innate and acquired viral resistance to ART and how these patterns are influencing the long-term effectiveness of these therapies.
- Investigate the contribution of innate host characteristics to viral measures, immune function, disease progression, and mechanisms for these effects, including host genetic factors and their modulators, sex, race, and age.
- Examine how chronic inflammatory processes and mediators such as inflammatory cytokines modify immune function, disease outcomes and survival, and response to ART, and if they differ by age group.
- Characterize the changing spectrum of clinical outcomes, causes of morbidity and mortality, and complications of ARV therapy associated with evolving therapeutic strategies, domestically and internationally.
- Assess the effect of ART treatment on the incidence, pathogenesis, and presentation of cancer in the domestic and international settings.
- Define the prevalence, incidence, predictors, potential treatments of, and consequences of cardiovascular, renal, and liver disease in HIV-infected individuals.
- Characterize the long-term effect of HIV infection on the central nervous system, including the effect of viral burden in the cerebrospinal fluid (CSF), its effect on white matter degeneration, and the role of ART in reducing the neurocognitive burden of disease and differentiating these changes from other neurocognitive diseases, such as dementia and Alzheimer's disease.

- Evaluate and characterize immune reconstitution inflammatory syndrome (IRIS), including modifiable and nonmodifiable predictors of immune recovery in diverse populations as well as best treatment practices for IRIS.

- Define the prevalence, incidence, and determinants of HIV-associated neurologic, behavioral, and psychiatric manifestations and their relation to HIV disease progression and response to ART, domestically and internationally.

- Identify, characterize, and determine the frequency, changing manifestations, and effects of HIV-related respiratory disease on morbidity, mortality, and HIV disease progression, in both untreated patients and those receiving ART. These would include recurrent bacterial pneumonia; drug-resistant, MDR-TB, and XDR-TB/HIV cases; immune reconstitution syndromes affecting the lungs, including sarcoidosis and other immune-mediated diseases; HIV-related pulmonary hypertension; accelerated emphysema; lung cancer; and coinfections.

- Investigate hemostatic disturbances in individuals with HIV infection and the role of coagulation and fibrinolytic mechanisms in risk of vascular events and other complications.

Strategies Related to Complications of Therapy

- Determine the effects of cumulative and current ART exposure to specific drugs, classes of drugs, drug combinations, and treatment strategies, overall and by age group.

- Investigate factors that are linked to the early mortality documented soon after initiation of ART in patients in developing countries.

- Characterize and investigate the role of ART-associated toxicities (including disorders in glucose, lipid, and bone metabolism, renal dysfunction, hepatotoxicity, and carcinogenesis) in specific populations, including coinfected populations (e.g., TB, MDR/XDR-TB, hepatitis C [HCV], and hepatitis B [HBV]), pregnant women, children and adolescents, the aged, populations receiving traditional medicines, resource-limited populations, minority populations, and according to nutritional status, in comparison with appropriately matched non-HIV-infected populations.

- Investigate age and gender differences in ART-associated toxicities and comorbidities in comparison with appropriately matched non-HIV-infected populations. Gender differences should also explore differences in sex steroid levels and ovarian reserve in women and how they impact metabolic, cardiovascular, bone, renal, and liver disorders.

- Investigate the role of chronic inflammation in the development of malignancies and metabolic, cardiovascular, bone, renal, and liver disorders in HIV-infected individuals and appropriate controls and how cumulative and current ART use might mediate or mitigate the effects of chronic inflammation.

- Investigate complications associated with the simultaneous use of complementary and alternative medicine interventions and ART.

Strategies Related to Comorbidities

- Intensify research on the spectrum of HIV-associated malignancies, particularly those that may develop in HIV-infected patients who have responded to ART and are expected to live longer with immune deficiency.

- Intensify research on the effects of ART and immune reconstitution on chronic infection with viruses (particularly Kaposi's sarcoma herpesvirus [KSHV/HHV-8], HCV, HBV, human papillomavirus [HPV], and Merkel cell carcinoma polyomavirus) that are associated with malignancies in HIV-infected persons.

- Establish standards in different regions of the developing world affected by the HIV epidemic for lymphocyte subsets, activation markers, and hematologic and clinical chemistries, and determine the influence of endemic diseases (such as malaria, TB, hepatic viruses, and helminthic infections) on such standard values.

- Investigate TB-HIV interactions, including the effects of dual infection on the infectiousness and progression of both TB and HIV, and the effect of various treatment strategies on disease control and TB drug-resistant strains.
  - Investigate new approaches to successful diagnosis and linkage to care of both HIV and TB in high-prevalence settings.
  - Investigate the MDR/XDR-TB epidemic, evaluating risk factors for MDR/XDR-TB prevalence, incidence, therapeutic options, and clinical outcomes among HIV-infected patients.
  - Investigate the prevalence of disseminated (miliary) disease, including cerebral TB, its impact on everyday function, disease progression, and therapeutic options among HIV-infected patients.
  - Develop novel TB diagnostics for use with HIV-infected patients in order to rapidly identify MDR/XDR-TB in HIV/TB-coinfected populations.
  - Assess outcomes related to methods of integrating TB and HIV care on survival, quality of care, cost, and cost-effectiveness of care.
  - Investigate the impact of treating latent TB on the epidemiology of HIV/TB coinfection in endemic countries to determine whether it is feasible, effective, and cost-effective.
- Evaluate the impact of treatment of alcohol use and abuse, illicit drug use, and mental health disorders on the effectiveness and consequences of ART, HIV disease progression, development of comorbidities, and mortality.
- Support research efforts to link existing databases on cancer, TB, transplant, etc., and death registries to enhance understanding of HIV/AIDS outcomes in standard-of-care cohorts.
- Assess the interaction of HIV infection and ART on other infections and their treatments.
- Investigate the most appropriate triage of multiple comorbidities and the order in which comorbid conditions should be treated in HIV-infected patients.
- Study the emergence and reemergence of infectious diseases and the clinical and epidemiological characteristics of antimicrobial-resistant infections in HIV-infected populations (e.g., MDR-TB, sulfa-resistant malaria, antibiotic-resistant pneumococcal pneumonia, cotrimoxazole-resistant *Pneumocystis jiroveci* pneumonia, methicillin-resistant *Staphylococcus aureus* [MRSA] infections, and lamivudine-resistant HBV infections).
- Estimate the prevalence of specific HPV types associated with cervical cancer and high-grade dysplasia in HIV-infected women, and evaluate the effectiveness of HPV vaccines among HIV-infected individuals from geographically diverse regions.
- Assess the interaction of ARVs on HPV persistence and regression of cervical lesions to understand the dynamics of the two viruses with a goal of optimizing care for HIV-infected women, especially in resource-limited settings.
- Assess the effect of primary care screening and interventions (e.g., statin use, hypertension management, smoking cessation, depression treatment, and cancer screening and treatment) on HIV disease outcomes and survival. Use these assessments to guide recommendations for adaption and prioritization of primary care guidelines for those with HIV infection.

Strategies Related to MTCT and Pediatric HIV Infection

- Assess the implications and outcomes, including uptake, of different strategies of prevention of MTCT on transmission and costs of care in HIV-infected mothers and their infants.
- Evaluate the differences in adherence, treatment response, and HIV outcomes between adolescents, adults, and perinatally infected children; in behaviorally acquired versus perinatally infected adolescents; and in adolescents treated in pediatric versus adult HIV treatment centers.
- Investigate the long-term outcome of complications due to HIV and ART use in HIV-infected pediatric populations as these children reach adolescence and adulthood.

- Study the effect of the health status of HIV-infected mothers and of ART during pregnancy, lactation, and early child life on survival and quality of life of their HIV-infected and -uninfected children and on maternal outcomes.

- Study HIV-infected and -uninfected children and adolescents to determine factors related to impaired growth and neurodevelopment; cognitive, behavioral, and psychomotor development; impact of other childhood infectious diseases and nutritional status; and safety and efficacy of immunizations, and how these may be affected by biomedical and behavioral interventions.

Strategies Related to Aging

- Investigate the relationship between HIV infection and the spectrum of physical and mental health outcomes that increase with aging (e.g., cancer, renal disease, cardio- and cerebrovascular disease, diabetes, hypertension, arthritis, anemia, and dyslipidemia), as they affect disease outcomes and survival.

- Study the incidence and determinants of physical and cognitive decline in aging HIV-infected individuals and the effect of frailty and functional impairment on HIV, ARV use, and self-care behaviors.

- Study the effects, such as immunologic and virologic response to treatment, and adverse effects of HIV and ART in aging populations that have coexisting morbidities and who receive numerous medications.

- Evaluate immunologic and virologic measures of HIV disease progression, ART-related toxicities, and mortality in older versus younger adults receiving ART to refine treatment guidelines for older HIV-infected patients.

- Develop guidelines for treating comorbid and chronic conditions in aging HIV-infected patients.

Strategies Related to Adherence, Access to Care, and Quality of Life

- Develop and evaluate novel methods, such as behavioral reports and biological markers of use, for accurately measuring adherence to therapy and efficacy of preventive therapies.

- Study determinants of adherence to ART and adverse events of ART in all age and risk groups, as well as in times of transition such as pregnancy and growth from child to adolescent to adult, to inform interventions to improve adherence.

- Study the impact of access to care, ART, microbicides, and vaccines on risk behaviors and HIV acquisition among at-risk populations, including minorities, MSM, adolescents, and young adults.

- Investigate how different patterns of access, adherence, and exposure to ART in treatment-experienced and -inexperienced populations contribute to ARV resistance and disease progression.

- Elucidate the effects of HIV infection on pain and sleep disturbances, including prevalence, possible immunological and endocrine mechanisms, associations with HIV outcomes, possible changes with ART, and influence on quality of life and physical and mental health.

- Develop studies on the impact of routine, voluntary HIV testing, point-of-care rapid testing, home-based testing, and Internet-based test notification, and their roles in different prevalence settings in increasing access to care and improving HIV-related outcomes.

- Examine predictors of successful retention of HIV-infected patients in care, from the time of HIV testing through the time of ART provision and patient followup.

OBJECTIVE–C: Methodologies

Develop and evaluate methods and resources for HIV/AIDS epidemiological and clinical studies that use culturally appropriate approaches; incorporate new laboratory, sampling, and statistical methods with information systems; and better integrate research findings into clinical practice and regional, national, and international policy.

(The scientific objectives of A, B, and C are of equal weight.)

STRATEGIES

- Evaluate and promote the use of multiple study designs that incorporate appropriate ethical, cultural, and policy context for studies of HIV disease and AIDS in diverse domestic and international populations.
- Continue to support local, regional, and international collaborations to integrate and harmonize existing data for scientific investigations.
- Capture data from large U.S. and international HIV screening programs, such as blood donor screening programs, to monitor incidence and temporal trends, viral genotypes, drug resistance, and neutralization profiles.
- Ensure that the population composition of domestic epidemiological studies accurately represents populations at risk for and affected by HIV/AIDS, such as older Americans, adolescents and young adults, MSM, racial and ethnic populations, and persons affected by other comorbidities.
- Encourage more HIV prevention research studies in marginalized and vulnerable populations in the United States (e.g., immigrants, migrant workers).
- Involve representatives of the community and study participants in all phases of research planning, design, management, approval, and reporting, when possible and appropriate, and promote and support academic/community-based research collaborations.
- Implement research training and career development opportunities for medical and health professionals from communities disproportionately affected by the epidemic, both in developing countries and domestically. Training should include research ethics, study design, informatics, biostatistics and modeling, data management and analysis, manuscript preparation and publication, grant writing, and translational research to promptly bring basic science results to clinical care and clinical results to health policy and implementation.
- Promote study designs that provide the highest degree of human subject protection and benefit possible, according to U.S. Government requirements.
- Promote study designs that include plans for dissemination of findings to community representatives, study participants, health care practitioners, payors, and policymakers.

Strategies Related to Natural History/Pathogenesis

- Develop epidemiologic, laboratory-based, and simulation modeling methods in conjunction with prospective cohort studies, domestically and internationally, to monitor response to ART and the incidence of complications related to chronic use of ART, including:
  - Develop and test methods to produce accurate, reproducible, and inexpensive virologic, immunologic, bacteriologic, pharmacologic, neurobehavioral, and genetic assays suitable for large-scale epidemiological research and surveillance in developing nations. Emphasis should be on simple and reliable staging of disease progression for the initiation and monitoring of ART and opportunistic infection (OI) prophylaxis; hepatitis testing; HIV resistance testing; and

noninvasive, rapid, and inexpensive diagnostic assays for sexually transmitted diseases (STDs), other coinfections including malaria, TB and XDR-TB, and malignancies.

- Develop, maintain, and effectively cultivate ongoing and newly developed cohort studies, domestic or international specimen repositories, and databases for interdisciplinary HIV-related studies. Collaborative studies between cohorts and nested studies that utilize these resources should be particularly encouraged.

- Identify and/or develop uniform assessment tools to measure host and environmental characteristics, including substance abuse and mental health, which may affect immediate and longer-term HIV-related health outcomes. Assessment tools should be both culturally appropriate and scientifically valid.

- Develop assays to identify recent HIV infection, especially methods appropriate for international populations and measures integrated into point-of-care testing.

- Develop assays to distinguish between serological changes induced by HIV vaccine candidates and those induced by HIV infection in countries where NAT (nucleic acid test) testing is not readily available.

Strategies Related to Research on Design and Analysis of Epidemiologic Data

- Develop new epidemiological designs and statistical methods, including development of informatics tools and simulation, to better characterize transmission dynamics and monitor long-term trends in disease progression and development of toxicities in the setting of potent ART.

- Continue to develop and improve upon quantitative methods for making effective and appropriate use of data from large observational, cross-sectional, and cohort studies, such as:

  - Assessing costs of care for HIV disease management and treatment of comorbidities, both domestically and internationally;

  - Methods for inferring causal effects of nonrandomized exposures (e.g., treatment and policy changes);

  - Methods for estimating incidence rates in cross-sectional samples;

  - Methods for sampling hidden populations (e.g., venue-based, Internet-based, snowball, mixed method, respondent-driven, and time-location sampling);

  - Models and inferential methods for characterizing multiple/comorbid disease processes and events;

  - Methods for linking cohort data to health care utilization and cost data to address health policy questions;

  - Methods for simultaneously addressing more than one hypothesis or intervention, including the use of factorial randomized trials and quasi-experimental designs; and

  - Methods for collecting and analyzing spatio-temporal data, especially as they relate to transmission and spread of HIV infection.

- Encourage research on innovative design and analysis through interdisciplinary collaboration between methodologists from different fields, such as biostatistics, econometrics, epidemiology, computer science, biomathematics, decision sciences, operations research, health services research, and demography.

- Promote collaborative studies using genetic epidemiology methods (e.g., genome-wide association studies [GWAS]) applied to large, diverse populations to elucidate mechanisms of HIV infection, disease progression, and complications.

Strategies Related to Interventions

- Study and evaluate the various operational strategies that can be employed to "bring to scale" and to evaluate countrywide ART programs and successful preventive or therapeutic interventions, such as male circumcision, including the use of

operations research and integrated observational databases to evaluate treatment effectiveness and cost-effectiveness at the individual, community, and population levels.

- Study and evaluate prevention packages that combine multiple strategies into one intervention, especially those that combine behavioral, biological, and structural interventions.
- Develop studies to compare the effectiveness and efficacy of various HIV prevention strategies (e.g., opt-out testing, secondary prevention) between populations with generalized versus concentrated epidemics.
- Determine the outcome of different approaches to routine, voluntary, and rapid HIV testing in different settings, and among different racial/ethnic populations.
- Assess the optimal algorithms for HIV diagnosis in patients, including strategies for identification of acute infection.
- Assess the effectiveness and outcomes of clinical and/or laboratory monitoring for the initiation, monitoring, and switching of ART, particularly in resource-limited settings, including laboratory monitoring with new methods that are technologically appropriate and affordable in various international settings.
- Develop appropriate clinical and laboratory definitions of short- and longer-term ARV failure, and develop mechanisms for monitoring and assessing drug resistance evolution in HIV types, subtypes, and variants in domestic as well as international settings.
- Develop, evaluate, and promote new, improved, and cost-effective methods and strategies to prevent HIV transmission via blood transfusion, as well as other medical interventions and iatrogenic exposures in developing countries, including instrument sterilization.
- Assess the impact and cost-effectiveness of different strategies for HIV testing and counseling and linkage to/maintenance of care for different populations, including adolescents, seniors, racial and ethnic populations, and populations in diverse international settings.
- Develop strategies to validate the use of surrogate markers for HIV acquisition and/or transmission risk, including use of behavioral measures and biomedical markers.
- Develop and refine simulation and modeling strategies to assess the costs and impacts of a variety of interventions on HIV transmission, cofactors of HIV infection, and communitywide morbidity and mortality.

Strategies Related to Policy

- Design and implement evaluations of large-scale HIV testing and treatment programs, with attention to clinical outcomes, HIV incidence rates, long-term dynamics of the HIV epidemic, and comparative costs for the programs relative to present-day strategies.
- Evaluate the long-term clinical and nonclinical impact, cost, and health care utilization ramifications of different strategies for care, including treatment of HIV-associated conditions, ART, complications of ART, and other comorbidities.
- Assess the impact and acceptability of routine, voluntary HIV testing programs and new models for point-of-care testing and results notification, including issues such as stigma and confidentiality.
- Support HIV policy research, including studies of laws and economics, necessary for translating epidemiological and clinical studies into policy to improve health and to make cost-effective clinical and policy decisions.
- Assess the impact of strategies for managing HIV coinfections in international settings using modeling and other integrative methodologies.

AREA OF EMPHASIS

Information Dissemination

SCIENTIFIC OBJECTIVES AND STRATEGIES

OBJECTIVE–A: Disseminate Information to All Constituencies

Support the effective dissemination, communication, and utilization of HIV and AIDS information to all constituent communities of the NIH, domestically and internationally.

STRATEGIES

- Rapidly disseminate new research findings, including information on the potential implications for prevention, care, and treatment of HIV-infected individuals, using existing and innovative methods.
- Promote study designs that include plans for dissemination of appropriate and relevant findings to study participants, health care practitioners, community representatives, policymakers, and the public.
- Facilitate the development of HIV prevention and treatment guidelines based on the latest clinical research findings.
- Utilize computer and other information dissemination technology (including the Internet) to disseminate up-to-date HIV and AIDS information; information about HIV therapeutic, vaccine, microbicide, and other prevention trials; and information about HIV training programs.
- Expand access to and education about current state-of-the-art treatment and patient management guidelines, including information on clinical trials, using multiple technologies such as online access and voice access *(AIDSinfo)*.
- Widely disseminate information concerning specimen repositories, including existing repositories, specimens available, and relevant information concerning cohorts, contact information, and the process for obtaining access to samples.
- Widely disseminate experimental findings regarding AIDS-related studies using nonhuman primates (NHPs) as well as the availability of animals for AIDS-related studies.
- Collect, archive, and promote use of existing data from NIH-supported basic and applied research for secondary data analysis, including rapid development of public use data sets that can be used for secondary data analysis in NIH-supported studies, especially baseline survey and HIV/STD (sexually transmitted disease) incidence data.
- Improve current techniques and develop and evaluate new techniques for the two-way communication of information to scientific and lay audiences, particularly to hard-to-reach populations, including information about clinical trials.
- Improve outreach and support access to AIDS information resources (including computers) by community groups, health care providers, and community-based AIDS service organizations, including those serving racial and ethnic populations.
- Work with community-based organizations (CBOs), nongovernment organizations (NGOs), and local agencies to develop and promote effective methods of information dissemination on treatment, prevention, and research in target populations to increase awareness and reduce stigma.

- Support dissemination of information, including to constituent communities, in culturally and linguistically appropriate ways.
- Develop and disseminate educational information to enhance understanding of HIV and basic and clinical research processes by health care providers, community-based AIDS service organizations, social service organizations, policymakers, and persons with HIV and AIDS.
- Develop and disseminate information resources about HIV prevention, microbicide, vaccine, and treatment clinical trials to increase awareness about research in these areas and the importance of supporting and participating in clinical studies.
- Evaluate the effectiveness of communication efforts by appropriate means, including obtaining feedback from target audience members through such methods as usability testing of paper and computer interfaces (see *www.usability.gov)* and information dissemination intermediaries, such as journalists and health educators.
- Promote wide dissemination of the annual *Trans-NIH Plan for HIV-Related Research* and other HIV-related reports as they become available.
- Promote and enhance the exchange of scientific information and communication between public and private research enterprises, such as enhancing communication with the pharmaceutical industry concerning research on the development of therapeutics, vaccines, and microbicides, and working with industrial scientists to make information concerning basic science and HIV protein structures available to the general scientific community.
- Communicate and exchange information internationally on topics such as prevention and treatment, patient management guidelines, and research results that improve the care of HIV-infected individuals, including those in developing countries.
- Support the exchange of basic and applied research information at community, regional, national, and international conferences and workshops.
- Support the cross-collaborations of HIV and AIDS information providers to develop more integrated and comprehensive information dissemination approaches.
- Provide online access to presentation materials, including full text of abstracts and other information (e.g., slides, graphics, plenary presentations) from scientific meetings.

OBJECTIVE–B: Develop New Communications Strategies

Support research to identify existing gaps in communication approaches, identify and evaluate existing strategies, and develop and test new and innovative communication strategies that will improve access to and use of state-of-the-art HIV information by all relevant target audiences, domestically and internationally.

STRATEGIES

- Assess the information needs and resources used by various audiences, including biomedical and behavioral research communities, health care providers, service providers, persons living with HIV and their advocates, at-risk populations, scientific and lay media, and the general public.
- Identify obstacles to information dissemination and develop, test, and evaluate possible ways to overcome these obstacles.
- Develop, test, and evaluate innovative strategies for effectively reaching specific audiences (e.g., racial and ethnic populations, adolescents, drug users, other hard-to-reach populations, and health care providers) with relevant HIV information.
- Investigate how and under what circumstances different communication and dissemination strategies influence the adoption of scientifically based HIV behavior-change interventions and clinical practices in specific audiences.
- Promote use of new technologies and evaluate their effectiveness for disseminating basic and clinical research findings.
- Work to reduce communication gaps between academic researchers and treatment providers so that research results are more effectively disseminated to providers and that research agendas reflect the needs of practicing clinicians.

OBJECTIVE–C: Coordination and Collaboration Efforts

Develop, implement, and evaluate methods of coordination and collaboration on HIV/AIDS communications activities among NIH Institutes and Centers (ICs) and with other Federal and non-Federal groups, and international partners.

STRATEGIES

- Promote and foster information dissemination regarding research and programmatic efforts across the ICs, among U.S. Government agencies, and with international partners.
- Promote collaboration among all ICs in providing information about their HIV/AIDS clinical trials to *AIDSinfo* and *ClinicalTrials.gov*.
- Expand the development of HIV/AIDS resources on the Internet to facilitate national and international research collaboration and data sharing.
- Build and enhance partnerships among CBOs/NGOs and basic, clinical, and behavioral researchers to encourage exchange of information and experience.
- Continue collaborations with the Joint United Nations Programme on HIV/AIDS, the Pan American Health Organization, and other international AIDS agencies or societies on information/communications efforts, including information about international clinical trials.
- Collaborate with public and health sciences libraries, health care providers, AIDS Education and Training Centers, and community-based HIV/AIDS service organizations to facilitate access to needed information and disseminate NIH HIV-related reports.
- Expand collaboration to include academic, medical, and other communities, as appropriate, in the dissemination of NIH HIV-related reports.
- Expand the development and sharing of HIV/AIDS resources on the Internet to facilitate national and international research collaboration and data sharing.